DRUG LABELS AND REPRODUCTIVE HEALTH:

HOW VALUES AND GENDER NORMS SHAPE REGULATORY SCIENCE AT THE FDA

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I dedicate my labor

to my partner Taeyin,

for awakening me, bringing me joy, and grounding my life,

to my parents Nancy and Jon,

for their open-mindedness and unconditional support,

and to my mother-in-law Yoo a,

for nourishing me throughout the journey.

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Preface

> So there's a puzzle: what are women held to be guilty of doing or being?
>
> Withholding and failing to give, I think; being cold, callous, and heartless; neglecting their natural duty to provide a safe haven and nurture, by evicting a vulnerable being from their rightful home, their birthright. Hence women who seek abortions, even to save their own lives, are a blank canvas on which to project a set of grievances borne of unmet felt needs in turn borne of a sense of entitlement.
>
> -Kate Manne, feminist philosopher
> *Down Girl: The Logic of Misogyny* (2018, p. 99)

> Abortion is the only personal decision that is subjected to this level of governmental oversight. More states require waiting periods before obtaining an abortion than buying a gun or getting married. … The presumption undergirding abortion decision making is that women who have had sex and are accidentally or unintentionally pregnant can't be trusted to comprehend the consequential weight of their actions. The law requires them, like bad little girls, to "prove" to authorities that they have thought carefully about what they're about to do.
>
> -Dr. Willie Parker, abortion provider
> *Life's Work: A Moral Argument for Choice* (2017, p. 141)

This dissertation is about science and its social functioning, particularly how medical knowledge functions to control women and their bodies. Feminists—including academics, activists, and healthcare professionals—are highly attentive to these social dynamics and their contribution to structural forces of domination. This relation between knowledge and practice is what Kate Manne (2018) illustrates when she shows how acts of misogyny are grounded in the sexist ideology of male entitlement. It is what Dr. Willie Parker (2017), an abortion provider, challenges when he criticizes paternalistic laws that are based on diminutive views of women for restricting abortion access. And it is what I explore when I analyze how drug labels are shaped by sexist gender norms and then used to keep women down, particularly poor women and women of color.

As with any scholarly work focused on values, there is always a question about the values of the author. Writing this dissertation has transformed me professionally and personally, and I

would be remiss to neglect a more personal introduction to this work. I entered this project as a young Catholic man, raised in "pro-life" culture and interested in the ethics and science of reproductive health. I have since left the Catholic church and become a committed feminist and activist for reproductive justice. I have learned that while the events I cover might not appear to be about men like myself, they are intimately related to what it means to be a man like myself. The values with which I finalize this work are partially the result of the process of writing and researching this dissertation.

The project started as a grant proposal to the National Science Foundation (NSF). My graduate studies at IU began in the fall of 2014. I had just graduated from the University of Notre Dame and had spent much of the previous year researching environmental justice with Professor Kristin Shrader-Frechette. My final project involved ethical and scientific issues in the cleanup of a Superfund in rural Illinois. The former smelter site was exposing a disproportionately poor, Latinx community to high levels of lead and other toxic heavy metals. I had continued to work with Prof. Shrader-Frechette through the summer, and if you had asked me during the first week of classes what I expected to research in graduate school, I would have said environmental health, racism, and policy. But, once I gained a little distance from Notre Dame, I found that another form of injustice in regulatory science demanded my attention.

In late 2013, Notre Dame joined several other (mostly Catholic) institutions in suing the federal government for the "contraceptive mandate" (Tschann and Soon 2015). As part of the Affordable Care Act ("Obamacare"), employers were required to cover all FDA-approved contraceptives to their employees (at least those with uteruses). As I had learned in my Jesuit high school, Catholic social teaching disallows all *hormonal* forms of birth control, based on rules that require sexual relations to be "procreative," i.e., "capable of generating new life" (Pope

Paul VI 1968, sec. 12). It also prohibits abortion, i.e., any form of interference after fertilization, which includes some intrauterine devices (IUDs) and potentially some forms of emergency contraception (Pope Benedict XVI 2008, sec. 23). Around the beginning of grad school, I read a *New York Times* article from Pam Belluck suggesting that some emergency contraceptives do not in fact work after fertilization and that the European label had been changed to reflect this fact (Belluck 2012). I quickly grew interested in the dynamics between the scientific, ethical and religious aspects of the controversy.

As I began to research the mechanism of emergency contraception in Bloomington, I quickly realized how politicized the science was. While my first NSF proposal failed, I was captivated, and so I continued to work with the case. The following year, I received the Graduate Research Fellowship, and luckily, my program suggested I take history seriously—particularly Professor Jutta Schickore—for I soon discovered Heather Prescott's (2011) account of the morning-after pill. There I learned that the influence of ethics and politics on the science went back to the very beginnings of the technology in the 1960s. Through Patricia Miller's (2015) *Good Catholics*, I learned more about the internal politics of abortion among Catholics, and I was repulsed by the role of the Catholic bishops in the US as a free-standing lobby, which focused the vast majority of its attention for social issues and funds (from Sunday mass offerings) on restricting women's abortion and contraception access. Miller introduced me to Catholics for a Free Choice, the pro-choice group of religious individuals that has resisted the bishops' hegemony in the US and championed women's reproductive rights. I had already come to see the vital role that birth control plays in women's liberation, but it was not until I encountered this group that I really understood the importance of abortion rights and access for social justice.

Increasingly, the male-dominated Catholic church felt ostracizing, and my partner Taeyin and I decided to leave in 2015. At Notre Dame, Taeyin had awakened me to feminism. I had begun to study feminist philosophy of science through Prof. Shrader-Frechette, and I was thoroughly enthused by Helen Longino's (1990) work, which became my philosophical handbook. Yet, it was not until working with Professor Lisa Lloyd that I realized the power of a feminist approach for working through the complexities of a scientific controversy. As we shifted through the case of the morning-after pill, I became increasingly critical of how sexist values and gender norms disappeared women for other concerns like the embryo, zygote, or fetus, and how this bias contributed to larger injustices. I realized that merely describing the influence of values on science was not enough, particularly when the social consequences were so dire. I was particularly inspired by Black feminists like Loretta Ross (2006) to think more deeply about how reproductive rights include not only the right to abortion, but also the right to have a child and raise children in a healthy, safe environment, and how *reproductive injustice* disproportionately affects the most marginalized groups of people.

I have also found it difficult to write about reproductive justice without also engaging in it. Male privilege would permit me to neglect these social issues, but this would only contribute to further injustice. Accordingly, I realized how necessary it was to get involved with organizations like Pro-Choice South Bend (Indiana) and All-Options Pregnancy Resource Center (Bloomington, Indiana) and to attend activist-academic conferences like the New View Campaign's 2016 Capstone Conference (Bloomington, Indiana) and Sister Song's 2017 Let's Talk About Sex Conference (New Orleans, Louisiana). I see these efforts as integral parts of this larger project, including my publications in more popular venues like *Lady Science* (ChoGlueck

2019). I also hope to use my expertise and male privilege to improve policy making in the future to prevent reproductive injustices like those discussed and critiqued in this work.

While this feminist stance was not exactly what I began with, it is where the process has led so far. I remain religious (in the more progressive Episcopal Church), but I also strive to be a reproductive justice advocate. I hope that readers can witness the transformative power of this work and that some of that power is contagious.

South Bend, Indiana

April 2019

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Christopher James ChoGlueck

Drug Labels and Reproductive Health:

How Values and Gender Norms Shape Regulatory Science at the FDA

The US Food and Drug Administration (FDA) is fraught with controversies over the role of values and politics in regulatory science, especially with drugs in the realm of reproductive health. Philosophers and science studies scholars have investigated the ways in which social context shapes medical knowledge through value judgments, and feminist scholars and activists have criticized sexism and injustice in reproductive medicine. Nonetheless, there has been no systematic study of values and gender norms in FDA drug regulation.

I focus on three questions about values in regulatory science. First, how have societal values and gender norms shaped the way that the FDA regulates drugs in the realm of reproductive health, specifically with drug labels? Second, what are the ethical, epistemic, and social consequences of these influences on regulation for women and other marginalized groups? Third, which societal values and gender norms ought to influence drug regulation about reproductive health, and how ought this happen? Integrating philosophical analysis with historical archival research and in-depth interviews, I conduct three case studies of drug labeling about reproductive health: (1) the "drug fact" about the mechanism of the morning-after pill; (2) the package inserts for patients about the health risks of oral contraceptives; and (3) the special physician labels made for prescribing drugs to pregnant women.

I identify three challenges for the FDA and suggest ways to reduce the influence of sexist values and facilitate feminist alternatives. First, across these cases, I have found that there are many ways in which other concerns in reproductive medicine (such as zygotic life, fetal health, and population control) have devalued women's health. Second, both knowledge and ignorance

about their reproductive health have contributed to women's oppression, especially poor women and women of color. Finally, by avoiding the epistemic dimensions of ethics, powerful, mostly male parties in medicine (such as doctors, pharmaceutical companies, and religious institutions) have misused "informed consent," "religious freedom," and "paternalism" for unethical purposes. For improvement, I suggest extracting sexist values and gender norms from regulatory science that cause epistemic injustices, and I point to success stories for reforming sexism with feminism at the FDA.

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Introduction.

Drug Labels and Reproductive Health at the FDA:

A Saga of Values and Gender Norms in Regulatory Science

1. Introduction

"This is a sad day for American women and for the FDA," lamented the editors of the *New England Journal of Medicine* (A. J. Wood et al. 2005, p. 1199). On September 22, 2005, after over two years of negotiations with the pharmaceutical company, the US Food and Drug Administration (FDA) indefinitely delayed the decision to switch the morning-after pill Plan B from prescription-only to over-the-counter status. Given the politics surrounding the decision over the emergency contraceptive, these editors questioned the FDA's *scientific* integrity: "The recent actions of the FDA leadership have made a mockery of the process of evaluating scientific evidence, disillusioned many of the participating scientists both inside and outside the agency, squandered the public trust, and tarnished the agency's image. American women and the dedicated professionals at the FDA deserve better. Will we ever again be able to believe in the FDA's independence?"

Later that year, the US Government Accountability Office found the FDA's delay of the Plan B switch "unusual," particularly because its top-down nature and the novel concern for the sexual health and cognitive abilities of "younger adolescents," specifically 11- and 12-year-old girls (GAO 2005). Less than one month before the indecision, Susan Wood resigned from her FDA post as assistant commissioner for women's health and director of the Office of Women's Health. She opened her public resignation letter with a quote from Thomas Henry Huxley: "Science commits suicide when it adopts a creed" (S. F. Wood 2005, p. 1650). Unless "science is

the driving force in the agency," Wood did not believe she could promote the mission of her office to champion women's health (S. F. Wood 2005, p. 1651).

This is not an isolated case. The history of FDA regulation is fraught with controversies over the role of values and politics in science, particularly in the realm of reproductive health. Moreover, as Wood (2005, p. 1650) herself noted, "Women's health issues have been deeply entwined with the history of the agency." For instance, in 1962 following the "thalidomide tragedy," involving birth defects associated with a sedative taken early in pregnancy, Congress expanded the FDA's powers over pre-market trials of effectiveness (Carpenter 2010). To protect developing fetuses (and pregnant women) from harmful exposure, the FDA formally excluded "women of childbearing potential" from clinical trials beginning in 1977, only to be overturned in 1993 to increase women's representation (Epstein 2007; Merkatz and Junod 1994). In addition, the first drug label made specifically for patients was for oral contraceptives—in the face of growing medical consensus over their blood clotting risk as well as political efforts to curb "the population problem" (Watkins 1998). The saga continues with more recent cases like emergency contraception, which the FDA only made fully accessible without a prescription to women of all ages in 2013 by a court order (Dooren 2013).

In these cases of regulatory science, ethics and epistemology become entangled over reproductive health. There are many ways in which social context shapes medical knowledge. These effects include the role of values in medicine and regulatory science (Cranor 1993; Douglas 2009; Elliott 2011; Longino 1990; Shrader-Frechette 1991) and the influence of science advisors, advocacy groups, and industry on policy making involving science (Carpenter 2010; Epstein 2007; Fernández Pinto 2017; Hamilton 2009; Holman and Elliott 2018; Jasanoff 1990; Michaels 2008; Oreskes and Conway 2011). Furthermore, critical feminist scholars and activists

have disparaged the rampant sexism and injustices in medicine, public policy, and drug regulation, involving oppressive stereotypes about sex, gender, race, and class (Armstrong 2003; Duden 1993; Freeman 2015; Kukla 2010; Lyerly et al. 2009; Roberts 1997; Ross 2006; Ross et al. 2017; Rothman 1989; Tiefer 2010; Tuana 2006).

Despite the confluence of ethical and epistemic issues surrounding sex, reproduction, and maternity, there has been no systematic study of values and gender norms in regulatory science at the FDA. *How, for instance, have societal values and gender norms shaped the way that the FDA regulates drugs in the realm of reproductive health? What are the ethical, epistemic, and social consequences of these influences on regulation for women's healthcare? Moreover, which societal values and gender norms ought to influence drug regulation about reproductive health, and how ought this happen?* These are questions for a socially relevant philosophy of science (Fehr and Plaisance 2010). They have intellectual significance for medical ethics, epistemology, and history; and they matter for society more broadly because of their impact on drug regulation, reproductive health, and reproductive justice.

In this introduction, I discuss the background, scope, methodology, and structure of this dissertation. My first aim is to clarify which values have shaped knowledge about drugs and reproduction and how those influences have impacted women's healthcare. My second goal is to evaluate these influences by exploring feminists' attempts at reform and by providing tools for criticism and improvement. Accordingly, I conducted three case studies of drug labeling about reproductive health, the morning-after pill (emergency contraception), the Pill (regular oral contraceptives), and other prescriptions used during pregnancy and breastfeeding. My methodology integrates historical research and in-depth interviews with philosophical analysis from a feminist approach. I identify three challenges for the FDA in regulatory science: the

devaluing of women's health in reproductive medicine for countervailing concerns, the oppression of women and other marginalized groups through both knowledge and ignorance about their health, and the misuse of ethical concepts for unethical purposes by powerful parties. For improvement, I suggest extracting sexist values and gender norms from regulatory science that cause epistemic injustices, and I point to success stories for reforming sexism with feminism at the FDA.

2. Drug Labels, Values in Regulatory Science, and Injustice in Reproductive Health

Drug labels provide a useful focus to better understand the dynamics between ethics and epistemology in regulatory science and reproductive health. There are many opportunities for societal values and gender norms to influence how regulators, their advisers, and pharmaceutical companies write drug labels and how doctors, patients, and others in healthcare use them. Drug regulation is an area of science and policy that has drawn attention from scholars, activists, and policy makers interested in medical ethics and epistemology. Furthermore, the ethical debates and political struggles specific to reproductive health—about women's rights, "fetal rights," family planning, population control, eugenics, birth defects, motherhood, abortion, and "religious freedom"—can shape knowledge production and regulation in ways that can promote or ignore women's wellbeing, particularly for marginalized groups of women. Scholars and activists in bioethics, feminist theory, and critical race theory have explored the resulting injustices in reproductive medicine and policy. This section provides an introduction into the history of drug regulation, specifically drug labeling, the role of values in regulatory science, and the sexism and injustice in reproductive health.

2.1. A brief history of drug regulation and labeling at the FDA

Throughout FDA history, sex, gender, and reproduction have been consistent concerns in drug regulation and for drug labeling more specifically.[1] As Daniel Carpenter notes in his history of the agency, these foci were manifestations of a larger pattern:

> Along with the patient package insert [for the Pill], these [pregnancy] sections and their contents reflected the degree to which *American women* as the 'ultimate consumers' of prescription drugs had come to define the concepts and assumptions of post-market regulation. Yet under continuing concerns about teratogenicity in the shadow of thalidomide, the rules also reflected a reigning conception of *women as mothers, potential or actual.* (Carpenter 2010, p. 614, my emphasis)

But what is the function of labeling in drug regulation, and how did regulation and labels come to focus on gender norms and reproductive health?

Drug labeling was the first site of pharmaceutical regulation by the US federal government. Beginning with the Post Office in the late-19th century, the Postmaster General began rejecting packages from untrustworthy doctors ("quacks") to combat "misbranded" drugs (J. H. Young 1967, p. 66). The Pure Food and Drug Act of 1906 then enlisted the scientific expertise of the Bureau of Chemistry in the battle against "quackery," banning fraudulent labels that were "false or misleading in any particular" (J. H. Young 1967, p. 4). This legislation identified the domain of federal pharmaceutical regulation as primarily *epistemic*: its control was over the status of claims made about propriety drugs (marketed to patients directly for self-medication). For instance, the first seizure and destruction occurred on account of the bold, deceptive label of William Radam's Microbe Killer: "Cures all diseases." This duplicitous label cost the manufacturer 539 boxes and 322 cartons of product, which a US marshal, a drug inspector, and a fireman opened, smashed, and burned in 1913 (see J. H. Young 1967, p. 62).

[1] For my historical and political account of the FDA, I rely primarily on Daniel Carpenter's (2010) *Reputation and Power* and to a lesser extent James Harvey Young's (1992) *The Medical Messiahs*.

Initially, the Food, Drug, and Insecticide Administration (est. 1927, later renamed the Food and Drug Administration) had only negative powers that were *directive*: to stop or constrain the marketing of goods based on the claims made in the labeling. In 1938, following a series of deaths from newer, more potent pharmaceutical agents, Congress gave the agency more positive powers of *gatekeeping* (controlling access to the market) and *conceptual control* (setting the terms, concepts, and standards of communication and thus research and thought) (Carpenter 2010, pp. 74, 15–17). In particular, the law now required stronger, compulsory labeling requirements and pre-market review for new drugs to ensure their "safety in use." Yet, during the 1940s and '50s, the agency found that regulating *safety* was inseparable from evaluating their therapeutic effect. These more potent drugs had some safe uses but also dangerous ones, and the agency relied on the labeling to distinguish safe from unsafe according to intended use and dosage (Carpenter 2010, p. 154). Considerations of effectiveness were outside the agency's *official* purview until 1962, when the agency leveraged its reputation to codify (in the Kefauver-Harris Drug Amendments) its previously uncoordinated regulation of drug *efficacy*, standardizing the use of clinical trials for both safety and effectiveness. It did so in the wake of the "thalidomide tragedy" in order to prevent birth defects at the scale seen in West Germany (Carpenter 2010, pp. 260–69). This legacy of thalidomide established the agency as the protector of fetuses (and pregnant women) from teratogenic drugs.

While drug regulators have expanded and shifted their focus to pre-market testing, "[m]uch of the early practice of drug review became an exercise in regulating the label" (Carpenter 2010, p. 114). Even once the agency began to regulate safety after 1938, it often rejected or delayed new drugs based on unevidenced or unsettled claims in labeling. Furthermore, as the FDA began to consider more potent agents around this time, it relied on the

label to determine their "relative safety" by distinguishing safe uses and doses from dangerous ones (Carpenter 2010, p. 154). In addition to motivating recalls, labeling became an indirect means of the post-approval regulation of the pharmaceutical industry, which grew rapidly at this time. In the 1950s and '60s, the FDA began to more formally regulate promotional material as "labeling" during the approval process (Carpenter 2010, pp. 166–70). Particularly in post-market regulation, these label-based powers remain one of primary forms of FDA drug regulation, in part because they are the main source of information about drugs for prescribers and consumers. In 1961, the FDA adopted a new policy of requiring a physician's insert in all prescriptions, which included full instructions for use, dosage, and side effects (Carpenter 2010, p. 237).

During the mid-20th century, the moral understanding of the *social function of labeling* shifted away from the Progressive-Era notion of misbranding as a vicious "adulteration" that harmed unwitting citizens (Carpenter 2010, p. 165). Fueled by the consumer movement, the more contemporary understanding focused on the virtues of honesty and responsibility in "truthful labeling" as a means of enhancing the interests and welfare of consumers and their "right to known" (Carpenter 2010, p. 341). In 1979, the FDA reinterpreted the 1938 law (that requires drugs be labeled with "adequate directions for use") as directions that "a layman can use" during their move to uniform labeling.

While using the language of "layman," the agency had come to see "American women as the 'ultimate consumers' of prescription drugs," particularly in labeling (Carpenter 2010, p. 614). For instance, the first wide-spread use of patient inserts made specifically for patients was with oral contraception in 1970 because of the risks of blood clots. The agency then required other package inserts to be made specifically for patients with anti-diabetic drugs ('72), tranquilizers during pregnancy ('76), and aspirin ('80s) (Carpenter 2010, p. 612). Then, largely in response to

the "thalidomide tragedy," the FDA created a special system of labeling categories for conveying the risks to fetuses from maternal prescription use during pregnancy (Kelsey 1982). In the Uniform Labeling Requirements of 1979 for prescription drugs, three of the eight of the "Precautions" (namely, Pregnancy, Labor and delivery, and Nursing mothers) focused on aspects of maternal health (Federal Register 1979). These influences of gender norms on drug labeling suggest that ethics, politics, and culture influence how regulators, advisers, and pharmaceutical companies write labels and how doctors, patients, and others in healthcare use them. What have scholars had to say about values in regulatory science?

2.2. Values in regulatory science

Drug labels lie at the intersection of ethics and epistemology in regulatory science. For instance, Barbara Osimani (2007b, 2007a) analyzed drug package leaflets in the Germany context as a basis for informed consent. Unlike in the US, the package leaflets in Germany have *legally* binding force for drug consumers. Osimani argues that the leaflet has a dual legal function for German consumers: (1) warning and preventing risk and (2) disclosing the "residual risk" for patients after regulation and prescription. These functions correspond to different *ethical* principles grounding informed consent: whereas the first aims at the right to safety, the second targets the right to self-determination. Osimani contends that the package leaflets justify the contributory liability of consumers for their non-compliance regarding safety. However, she maintains that the leaflet does not completely offload the responsibility of pharmaceutical firms or doctors for the residual risk.

Like other areas of science, regulatory science can require value judgments involving ethics, politics, and culture because of the various uncertainties that pervade empirical inquiry

and the social stakes of knowledge production (ChoGlueck 2018; Cranor 1993; Douglas 2009; Elliott 2011; Shrader-Frechette 1991). Yet, unlike academic research that is aimed more at originality and theoretical significance, regulatory science is conducted by government, industry, and its advisers for policy making (Jasanoff 1990). In this "fifth branch" of government, *democratic* reformers (typically public interest groups) push for democratization via actively including more values, while t*echnocratic* reformers (typically special interest groups) champion more scientific expertise and oversight. In Science and Technology Studies (STS), Sheila Jasanoff has proposed a *negotiated* model of regulatory science between the democratic and technocratic reformers. She contends that science ought to provide a "serviceable truth" and that scientists can still offer their expertise to be harnessed for public interests (Jasanoff 1990, p. 250). These measures enable advisers and regulators to utilize the power of science without sacrificing credibility, flexibility, or expertise.

Focusing more on drug regulation, Carpenter (2010) provides another account of regulatory power at the FDA. Like Jasanoff, he argues that the source of FDA power is *not* solely in the public interest for consumer welfare or the interest of the regulated industry via "capture." Instead, Carpenter points to the *reputation* of the agency, such as the social motivations from status and legitimacy that FDA faces from its various audiences. For instance, the FDA and the media painted the thalidomide story as an averted "tragedy" and thus a bureaucratic triumph. This reenergized reform efforts in the early 1960s, allowing the agency to fuse together its reputation as a *policer* of industry, a *gatekeeper* for medicine, and a *protector* of consumers. Carpenter argues that this multifaceted reputation continues to afford the FDA the ability to control the marketing of, access to, and research on pharmaceutical drugs.

These primarily *descriptive* accounts from Jasanoff and Carpenter provide important insights into how regulatory science works. However, from a philosophical perspective, they are too weak to provide the thicker *normative* force needed to answer particularly challenging questions about values in regulatory science: Which values ought to shape drug regulation, and how? Who ought to be involved in these decisions? Which conceptions of ethics and justice ought to shape regulation?

Like other philosophers of science, those working with regulation and policy have largely come to reject older ideals of science that assumed *value-freedom*. Today, there are many efforts to identify how societal values influence science and to develop alternative ideals useful for advisers and regulators (Biddle 2013; Douglas 2015; Hicks 2014). Their work builds on feminist philosophy of science from Helen Longino (1990), Sandra Harding (1991), and Elisabeth Lloyd (1995), who criticized older accounts of scientific rationality and objectivity that proscribed ethical and political values. In their place, these philosophers developed alternative accounts of scientific objectivity that allowed for societal values. Because they were social in their very constitution, these alternative accounts even encouraged certain ethical and political considerations within science. Longino's *contextual empiricism,* for instance, promotes an integrated study of scientific processes, their societal significance, and the relation between the two:

> "Letting the data suggest" is a recipe for replicating the mainstream values and ideology that feminists and radical scientists reject. The contextualist approach indicates that it is counterproductive to try to split oneself into different selves, doing different takes—a scientists here, a political actor there, perhaps an aesthete over there. Scientific inquiry is not detached in the requisite manner from the social, political, and cultural contexts that support it. (Longino 1990, pp. 218–19)

The *critical* task for contextual empiricists is to attend first to patterns of scientific reasoning and then to the interests and social stakes they serve. Longino's *normative* account of objectivity

directs us to the epistemic benefits of diversity and criticism in scientific communities, explaining how value-laden research like feminist science could improve empirical inquiry.

Adapting Longino's insights to regulatory science, Kristin Shrader-Frechette (1993) has shown how various methods for integrating science into environmental policy (such as relying upon expert judgment or privileging type-I or type-II errors) involve both ethical and technical considerations. She has proposed several reforms for agencies conducting risk assessments, both in terms of research methodology and policy-making procedures. Likewise, Carl Cranor (1993) analyzed the uncertainties of carcinogenic risk assessment and the value judgments necessary for assessing the risks of toxic substances. He argues that the typical "cautious scientific attitude" is inappropriate in the legal context and that the quest for certainty can have harmful consequences by underregulating carcinogens and undercompensating plaintiffs.

More recently, Heather Douglas (2009) focuses on the political influence and moral responsibility of scientists serving as science advisors, particularly at the US Environmental Protection Agency (EPA). Expanding on the classic work of Richard Rudner (1953), she contends that hypothesis choice requires scientists to make value judgments when there are ethical consequences for choosing a standard of evidence. While rejecting a "direct" influence of values on hypothesis choice (where values support/reject a hypothesis), she supports an "indirect" role of values (where they merely determine the standard of evidence needed for hypothesis testing). Rather than trying to eliminate values from science in vain, Douglas prescribes transparency, accountability, and democratization of the value judgments that scientists need to make as advisers to regulatory agencies.

In his in-depth study on low-dose exposure to pollution, Kevin Elliott (2011) analyzes the methodological and interpretive choices in environmental research. He demonstrates how

special-interest groups marshal scientific experts with conflicts of interest to support their agenda. Elliott also provides several reforms for preserving the integrity of science from financial perversions; for improving group deliberations involving advisers, experts, and publics; and for making judgments more transparent.

Philosophers have also investigated the ways that social context shape medical knowledge in *pharmaceutical* regulation, with special attention to commercial and industrial forces (Biddle 2007; Holman 2015; Holman and Bruner 2017; Holman and Elliott 2018; Jukola 2015; Osimani 2007a; Stegenga 2016). For instance, Bennet Holman (2015) contends that commercial pressures are responsible for much of our regulatory epistemology, such as the elaborate and costly system of randomized control trials (RCTs). He conceptualizes the back-and-forth between the FDA and the pharmaceutical industry as an *asymmetric arms race*, in which parties with different goals (truth and profit, respectively) develop measures and countermeasures in response to the tactics of the other. More recently, he has shown with Sally Geislar (2018) how industry has co-opted FDA public forums of patient input for "corporate ventriloquism." Holman and Geislar suggest that the FDA assess its strategies of circumventing the industry for reliability and robustness to take-over, and they emphasize the need for developing a different incentive structure that aligns with public interests. There is an important role for external criticism in biomedicine for criticizing commercial bias (Jukola 2015). Nonetheless, the potential remains bleak for patients to provide such perspectives without being co-opted by industry for private interests (Tempini and Teira 2019).

As these scholars have shown, values pervade regulatory science in several ways pertinent to drug regulation and labeling. First, the policy relevance of regulatory science renders many methodological value judgments into ethical and political choices. For instance, scientists

and industries conduct safety assessments to enable later risk management and regulatory decisions, so the choice of a standard of evidence effectively becomes a threshold for government action. While philosophers of regulatory science have addressed the role of societal values resulting from *commercial* pressure, they have placed less emphasis on other values, such as those related to sex, gender, and reproduction.

Second, these scholars have shown that there are many possible value judgments to make, but it is not clear how scientists should make them. Certainly, social responsibility for public interests is necessary, particularly given the public funding of research and regulation (Kourany 2010), but this requirement remains insufficient. The specific values required for this normative task at the FDA need more specification, especially when value conflicts go beyond the simple duality of private versus public interest.

Third, given the conflicts of interest and antagonism between the parties involved, it is even less clear who should (or could) make these choices. As STS scholars have shown, social and cultural factors such as credibility, expertise, and reputation are epistemically relevant but highly unstable in regulatory science. While science advisers, pharmaceutical companies, politicians, and policy makers at regulatory agencies are already heavily involved in the process, the possibilities for involving consumers and other stakeholders are less clear—especially given the influence of industry on public opinion and input. Thus, it is important to investigate the influence of power relations and institutional forces on regulatory science. As we shall see, these descriptive and normative issues become magnified in the realm of reproductive medicine.

2.3. Sexism and injustice in reproductive health

As we turn from regulatory science to reproductive health, many issues remain the same, but the operative values shift. More specifically, *commercial* pressure takes a backseat to *patriarchal* forces and other forms of oppression—although one should note that industry is an influential backseat driver! For instance, looking specifically at pharmaceutical development for women's health, feminist activist-scholars have sought to provide a "New View" of women's sexuality. Historically, women's reproduction and sexuality have been increasingly medicalized by pharmaceutical means, including hormonal treatments for birth control, menstruation, and menopause (see Cacchioni 2015a). More recently, Lenore Tiefer (2006) has led a social movement protesting the creation of the diagnosis "female sexual dysfunction." They contend this diagnosis is a case of *disease mongering*: an opportunity for commercial exploitation by the pharmaceutical industry. When a pharmaceutical company applied to the FDA to treat this "disease" with the ineffective flibanserin (Addyi), Tiefer's movement directed their efforts to the public forum for patient testimony. However, industry secured approval by coopting the forum for "corporate ventriloquism" (see also Cacchioni 2015b; Holman and Geislar 2018; Segal 2018).

Feminist scholars and activists have long recognized and disparaged the sexism and paternalism rife throughout medicine. The women's health movement during the late 1960s and '70s encouraged women to "take control of their bodies" and "seize the means of reproduction" (Murphy 2012). Radical feminists realized that the oppression women experienced in medicine relied in part on the lack of medical knowledge about them and their bodies. Thus, one of the movement's defining features was its strategy of resisting oppression by collecting and spreading

medical knowledge about female bodies, including but not limited to information about reproductive health (Baird et al. 2009; Kline 2010; Tuana 2006).

A classic example of this strategy is *Our Bodies, Ourselves*, from the Boston Women's Health Book Collective. The collective took aim at androcentrism in male-dominated medical education and heterosexism in research on women's sexuality. In contrast to the medical frameworks at the time, this book cultivated its readers as feminist subjects, activated their attention to their own bodies and experiences, and criticized dominant medical discourses (K. Davis 2007). For this reason, Nancy Tuana describes the women's health movement as epistemological in its strategy:

> The women's health movement, while a diverse movement, aimed to take our bodies back from the institutions of medicine and reframe our knowledge and experiences of our bodies in ways not configured by sexism and androcentrism. In this sense, *the women's health movement was an epistemological resistance movement geared at undermining the production of ignorance* about women's health and women's bodies in order to critique and extricate women from oppressive systems often based on this ignorance, as well as *creating liberatory knowledges.* (Tuana 2006, p. 2, my emphasis)

As feminism developed within the academy, scholars began to build these oppositional epistemologies that criticized sex/gender biases in science (Richardson 2010; Subramaniam 2009). Feminist science studies grew in the 1970s, with scathing critiques of biology on sexual differences and supplemental histories of American and European women in science. Their scholarship transformed the sciences, especially medicine, biology, and the human sciences (Schiebinger 2001). In subsequent decades following the success of these impacts, feminist philosophers rethought empiricism, objectivity, and reality to make sense of the epistemic improvements initiated by feminist values and women's standpoints (Wylie 2012). One key contribution from feminist philosophers of science has been their detailed case studies of

sex/gender bias, especially biological determinism and androcentrism in biology (Fausto-Sterling 2000; Lloyd 2005; Longino 1983).

Feminist scientists, historians, and philosophers have criticized the sexism throughout *medicine and public health*. Ethicists like Susan Sherwin (1992) and scientists like Marianne Whatley (1988) denounced the traditional model of doctor-patient relations as hopelessly paternalistic, with gendered views of passive "patients" that seek compliance to a predetermined "correct" behavior. In medical research, scientists have often taken the male body as the norm, utilizing subjects with female bodies primarily for special cases such as pregnancy, menstruation, and menopause. Following the women's health movement, policy makers at the National Institutes of Health (NIH) and FDA attempted to reform these androcentric policies to include women and measure differences by gender and sex (Bueter 2015; Epstein 2007; Merkatz et al. 1993).

In reproductive medicine specifically, sexist gender norms about motherhood are the root of the problem. According to Barbara Duden (1993), while pregnancies in the past began with women's experience of quickening, today they are technologically certified by medical experts when women are informed by ultrasounds, pregnancy test, or a report in the mail. Duden argues that these developments have resulted in the "epoch of fetal dominance" in gynecology, where the "public fetus" has become a sacred idol, venerated in politics, courts, and the media (see also Rothman 1989). More recently, Laura Freeman (2015) criticizes certain technological practices, such as privileging fetal-heart monitors over women's own sense of contractions, for unjustly reducing the credibility of pregnant women and increasing their alienation and powerlessness within medicine.

Similarly, Iris Marion Young (1984) charges that the self-understanding of pregnant women and their bodily experience have been conditioned to take this abstract idea as a personal reality and responsibility. In the law, the perception of a *maternal-fetal conflict* often leaves pregnant women as mere "maternal environments" or "fetal containers" for the "precious cargo" within (Lupton 2012; Purdy 1990; Rothman 1989). According to the feminist Obstetrics and Gynecology Risk Research Group, sexist values like *fetal-centrism* and *natalism* skew our reasoning about risk during pregnancy. For instance, they mislead doctors to ignore the risks of failing to intervene for pregnant women's non-obstetrical needs, such as not ordering diagnostic tests for a maternal disease state. While pregnant women have their own health needs, prior to their role as a mother, fetal-centrism elides the women's wellbeing and the risks to her health. Gender norms about "good mothers" also encourage women and their doctors in "the pursuit of absolute zero risk to the fetus," which is neither possible nor desirable from a feminist perspective because of how it devalues women's health and agency (Lyerly et al. 2007, 2009).

Feminist scholars have also shown how sexist value shape *public health* about reproduction. For instance, while there is strong evidence that heavy drinking causes fetal harm, only 5% of alcoholic women give birth to babies with fetal-alcohol syndrome; nevertheless, warnings from the US Surgeon General and Congress-mandated labels maintain that *all* pregnant women bear responsibility to abstain from alcohol during pregnancy to avoid fetal impacts (Armstrong 2003). Similarly, reproductive risk warnings (such as those required by California Proposition 65) allow businesses to provide written precautions rather than testing for and removing chemicals harmful for pregnant women and fetuses. They often take the latter option of informing, choosing to provide no information of the chemicals and pinning risk management on pregnant consumers. Rebecca Kukla (2010) has argued persuasively against this strategy on

ethical grounds: it takes reproductive risks to be more important than other risks; it unfairly places the responsibility for the risk on pregnant consumer (not businesses or the state); the warnings are useless for decision making; and they only serve to exclude women from public spaces. Even before pregnancy, recent campaigns for *preconception health* at the US Center for Disease Control build an ethic of "anticipatory motherhood," which "revolves around fetuses that are assumed to be conceived in the future" (Waggoner 2015, p. 945).

In addition to these critiques of sexism, activists and scholars in critical race theory and Black feminism have analyzed other forms of oppression in reproductive medicine involving *race* and *class* (A. Y. Davis 1983; Roberts 1997). For instance, there are significant maternal *health disparities* between white women and women of color. Black women face two to three times the risk of dying from pregnancy than do white women (Tucker et al. 2007). Women of color are also more likely to become seriously ill during pregnancy (Creanga et al. 2014). The barriers to *healthcare access* are also different for women of color. Laws criminalizing feticide and prohibiting sex-selective abortion encourage racial profiling by doctors that target Asian-American women (Kapoor 2018). Nevertheless, these xenophobic laws are premised on misinformation. For instance, while sex-selective practices are common in areas of China and India (e.g., Jiang et al. 2012), male-biased sex ratios are higher in some European and Caucasian countries like Liechtenstein and Armenia; furthermore, these statistics from Asian countries are overblown to justify racial discrimination and to criminalize abortion in the US (National Asian Pacific American Women's Forum et al. 2014).

Advocates of poor women and women of color have elucidated and protested the unique forms of sexism they experience. Eugenicists and white supremacists have used negative depictions of Black women, such as the "welfare queen," to justify their racial inferiority and

state control over their reproduction. Constraints on Black women's reproductive decisions have been a central facet of gender and racial oppression in the US, beginning with slavery, extending through the era of eugenics, and continuing more recently in debates over forced sterilization, welfare reform, and criminal justice reform (Roberts 1997; Washington 2008). During the late 1960s and early-70s, while primarily white middle-class women fought for the right to contraception and abortion, poor women and women of color pushed for reforms to the welfare system that punitively required contraceptives of its recipients and did not cover abortion costs (Nelson 2003; Ross and Solinger 2017). While both sets of activists teamed up to oppose abortion restrictions at public hospitals and FDA regulation of the Pill, welfare-rights advocates (mostly Black, mostly women) pointed to broader issues impacting reproductive liberty, such as urban poverty, racial inequality, and the welfare system (Murphy 2012; Valk 2010; R. Y. Williams 2005).

Engaged with this activist tradition, Black feminists have developed the framework of *reproductive justice*. Pioneered by Loretta Ross (2006), Dorothy Roberts (1997), and others, the framework of reproductive justice affirms the *positive* rights of all people to have a child, to not have a child, and to raise children in safe, health environments. They contrast this with the more *negative* and individualistic notion of reproductive freedom (i.e., pro-choice), which privileges those with means to realize the rights to abortion and contraception recognized by government and ignores the structural impairments of freedom experience by poor women and women of color to exercise their right to choose (Ross et al. 2017).

As these feminist scholars, activists, and policy makers have shown, sexism and injustice pervade reproductive health in several relevant ways. First, androcentrism has been widespread in biological and medical research, leading to relative ignorance about women's health and

female bodies in comparison to men's health and male bodies. Furthermore, sexist values and paternalistic practices are common in medicine. Yet, in what ways has sexism functioned in regulatory science specifically?

Second, apart from androcentrism, there are a variety of societal values and gender norms operative in reproductive health. For instance, fetal-centrism continues to displace concern for women's maternal health. This form of sexism is strengthened by gender norms about "good mothers," and the pursuit of "absolute zero risk to the fetus" even extends into preconception health. Additionally, because poor mothers and mothers of color are stereotyped as perennially "bad mothers," these existing biases and unfair practices intersect with other forms of oppression like racism and classism (Collins and Bilge 2016). Accordingly, it is important to look at both the promotion and restriction of fertility as different forms of social control that affect women in their diversity. Nonetheless, the operative values and gender norms at the FDA involving reproductive health are unclear.

Third, women's health advocates have made significant strides in correcting these problems, but it would be too hasty to conclude that "the war is won" for feminism. Regulatory guidelines for medical research have made clinical trials more inclusive and less androcentric, and agencies like FDA have established offices dedicated to the health of women and people of color (Epstein 2007). Yet, the institutionalization of the women's health movement has created uncomfortable entanglements of feminist health organizations with opportunistic philanthropists and pharmaceutical companies looking to capitalize on women's health (Murphy 2012). It remains to be seen how this organizational shift in the women's health movement has affected its ability to criticize sexism and injustice in regulatory science.

Despite the confluence of ethics and epistemology at the intersection of drug regulation and reproductive health, this area has not been a focus of either philosophical analyses of values in science or feminist critiques of injustice in medicine. Particularly because of the social importance of promoting women's health and reproductive justice in drug regulation, this dissertation aims to fill these gaps.

3. Scope: Audience and Research Questions

This dissertation has two overarching aims. My first aim is to clarify which values and norms have shaped knowledge about drugs and reproduction and how those influences have impacted women's healthcare. My second goal is to evaluate these influences by exploring feminists' attempts at reform and by providing tools for criticism and improvement. At its core, this dissertation is a project in *socially relevant philosophy of science*. As articulated by Carla Fehr and Kathryn Plaisance (2010), this mode of philosophy focuses on scientific issues integral to public welfare, engages with stakeholders, and seeks to maximize social impact. The benefits of such projects are manifold, extending throughout philosophy, other humanities, the sciences, and society.

Accordingly, as an interdisciplinary endeavor, there are several audiences for this dissertation—though not necessarily in the form presented here—in roughly the following order. Beginning with academics: First, I am speaking to *philosophers of science*, particularly those who are interested in the topics of values in science, science and gender, and history and philosophy of science (HPS). My second audience is *philosophers of medicine* who specialize in medical epistemology, pharmaceutical regulation, and evidence-based policy. Third, I want to engage *feminist scholars* including women's and gender studies focused on medicine,

reproductive health, and reproductive justice. Fourth, my work touches on issues in *bioethics and health law*, particularly on informed consent, conscientious objection, and religious freedom. Fifth, my work is relevant to *historians of medicine* writing on contraceptives, pregnancy, women's health, pharmaceuticals, and the FDA. Finally, I hope to connect with *STS scholars* working on political and social issues in regulatory science.

Turning to non-academics, I also want to engage policy makers at the FDA and their scientific advisers (including doctors and scientists). Part of the rationale for conducting interviews with FDA staff is to build relationships that will lead to collaborations of mutual benefit. Based on the attendance at my talks at conferences and public forums, I also believe that many consumers of pharmaceuticals involving reproductive health, especially the patients of obstetrics and gynecology, will find my research interesting and thought provoking.

Moving to my *research questions*, recall the existing work on the intersection of ethics and epistemology in drug regulation and reproductive health. In philosophical research on values in regulatory science, there has been less focus on the role of ethical and political values other than commercial forces, such as those related to sex, gender, and reproduction. Furthermore, various normative questions remain open about managing values in regulatory science. Furthermore, in the discussion among feminists about sexism and injustice in *reproductive* health, there has been no systematic treatment of the issues specific to drug regulation. Accordingly, this dissertation proposes to answer three questions, the first and second *critical* and the third *normative*.

(1) How have societal values and gender norms shaped the way that the FDA regulates drugs in the realm of reproductive health, specifically with drug labels?

(2) What are the ethical, epistemic, and social consequences of these influences on regulation for women's healthcare?

(3) Which societal values and gender norms *ought* to influence drug regulation about reproductive health, and *how* ought this happen?

My critical questions draw on both sets of literature by investigating the connection between ethics and epistemology in one form of producing knowledge (namely, drug labeling). The first question also requires identifying and clarifying *which* societal values and gender norms are operative. I pay special attention to methodological value judgments, the role of science advisers and regulators, the enforcement of gender norms, commercial and social forces in medicine, and societal stakes in reproductive politics. Then, my second question turns to how that knowledge is used by attending to the impacts of these decisions and processes. I analyze and evaluate their contribution to medical harms, ethical wrongs, legal consequences, systematic ignorance, and the oppression and liberation of marginalized groups, particularly under patriarchy. Finally, I discuss the normative dimensions of values in regulatory science and reproductive health, drawing on feminism for my critical conceptions of agency, justice, and gender. Because these are not traditional questions in philosophy of science, they require non-traditional methods, which I elaborate next, engaging different areas in philosophy, the humanities, and social sciences.

4. Methodology: An Empirical and Feminist Approach

Overall, I describe my methodology as an *empirical, feminist* philosophy of science. Regarding my empirical approach, I use case studies that draw on historical and sociological methods to guide my inquiry, engage participants, and evidence my claims. To gather primary sources, I conducted archival research and in-depth open-ended interviews. I also use historical and

sociological methods of analysis, such as developing narratives, assessing existing historiographies, and qualitative data analysis. I leave more detailed discussion of these methods for individual chapters, but I will discuss my overarching methodology here.

Case studies are particularly useful for philosophy of science when a case is understood as a *historical episode* of something more abstract, that is, "a concrete instantiation of the general concepts (the characters, the setting, the type of events to be expected, etc.), and each episode also contributes to the articulation of the general concepts" (Chang 2011, p. 111). Accordingly, as Hasok Chang suggests, by integrating HPS, philosophers can generate abstract ideas, demonstrate their cogency, and evidence their broad applicability. With my series of historical case studies, I explore abstract issues in epistemology and ethics like biomedical mechanisms, value-laden knowledge, epistemic injustice, patriarchy, informed consent, and ignorance. Grounded in a historical understanding, I can deliberate whether existing philosophical accounts are scientifically applicable and socially appropriate and, if not, develop more attuned alternatives.

Interdisciplinary research such as HPS is a superior means for identifying and solving real-world problems (rather than more disciplinary ones). Henik Thorén contends that interdisciplinarity is essentially an enterprise of "problem transfer," particularly given the penchant of philosophy for normativity:

> On the assumption that philosophy of science is a normative project and that such a project is cut-off from facts about science by the is/ought dichotomy this connection becomes admittedly limited. But at least one tie always remains, namely that *philosophy of science needs science as a source of problems*. These problems are not necessarily problems that scientists think they have, or are interested in, but nonetheless arise out of their practices. (Thorén 2015, p. 156, my emphasis)

Likewise, in this project, I use empirical methods to identify challenges *in* regulatory science and to determine which issues deserve focus. For instance, one of the primary benefits of my initial

interviews on the morning-after pill was Susan Wood's suggestion that I investigate the pregnancy label revision (part III).

And yet, some processes of interest in regulatory science are not accessible via historic archives, particularly those without a paper trail. Whereas academics publish their views, regulatory agencies operate within the "oral culture of Washington," so many key interactions and negotiations are unrecorded (Smith 1992, p. 205). This form of decision-making renders many reports reflective of the final negotiation but uninformative of the "black box" of internal deliberation, even with the increased transparency of government, e.g., the Freedom of Information Act (FOIA). Furthermore, the FOIA system is notoriously difficult to use—particularly during the longest government shutdown in US history (see Zaveri et al. 2019).

Accordingly, in addition to integrating philosophy with history, I have also drawn on sociology for empirical methods. Several philosophers of science have found that *qualitative methods* of collection and analysis are useful for investigating scientists in real-world contexts of practice (e.g., Osbeck and Nersessian 2015). In-depth interviews that are also grounded in history are particularly helpful for understanding "the nature of scientific knowledge" in so far as it is "the tangled web of individual and group dynamics that define its growth" (Keller 1983, p. xii). Evelyn Fox Keller, for instance, used interviews with biologist Barbara McClintock to understand not only her scientific contribution but also her tenuous place within the scientific community. Likewise, I have utilized qualitative interviews and analysis to better understand the internal dynamics of regulatory science behind the process of drug labeling.

In addition to my empirical methodology, I take a *feminist* approach toward this project for my critical and normative framework. Feminist empiricism is an approach within feminist philosophy of science that takes both empirical success and cognitive values to be necessary for

justifying claims. Furthermore, it holds the aims of science relative to social context, admitting a diversity of societal values particularly feminism and egalitarianism (Crasnow 2013; Intemann 2010). Following Longino, I take an approach to be feminist when it is critical toward *elucidating gender and its effects* and normative toward *ending oppression*:

> What makes feminists feminist is the desire to dismantle (eliminate, end) the oppression and subordination of women. This requires identification of the mechanisms and institutions of gender. The cognitive goal of feminist researchers therefore, is to reveal the operations of gender by making visible both the activities of those gendered female and the processes whereby they are made invisible, and by identifying the symbolic and institutional mechanisms whereby female gendered agents are subordinated. (Longino 2008, p. 77)

My research questions correspond with these qualities: questions 1 and 2 critically illuminate gender and expose injustice while question 3 aims to eliminate sexist values. Because not all injustice is the same, I understanding oppressions broadly and intersectionally, accounting for the dynamics between sex, gender, race, and class (Collins and Bilge 2016; A. Y. Davis 1983).

It will become more apparent in the chapters how a feminist approach accomplishes these critical and normative goals. First, it promotes certain political and pragmatic foci as the subject of philosophical examination, such as how mechanistic knowledge functions as a political tool and how ethical ideals are misused in practice. Furthermore, feminism supplies a normative framework for analyzing and evaluating how knowledge is produced and used, such as how women are systematically kept ignorant and how knowledge can shape women toward oppressive gender norms.

5. Overview of Cases and Chapters

I have chosen three case studies as historical episodes of drug labeling about reproductive health. Each study focuses on a drug label or a system of labeling. Part I focuses on the drug label about

the mechanism of the morning-after pill (emergency contraception). Part II involves the package inserts for patients about the health risks of the Pill (regular oral contraceptives). Part III examines the special labeling system for physicians to counsel women about taking prescriptions while pregnant and breastfeeding. Before elaborating on the cases, I will first explain why I chose this set.

Together, they provide a broad sample of ethical issues involving abortion rights, contraceptive access, and population health. Thus, we see how societal values involving medical paternalism and informed consent manifest at distinct stages in human reproduction, including prior to ovulation, around fertilization, and during gestation. This spread also allows us to see how gender norms about women and motherhood change by context, such as preventing pregnancy versus preventing fetal exposure. It also illustrates how gender norms intersect with racialized and class-based stereotypes, such as the maternal responsibility of marginalized groups of women to reduce population growth (and stay off welfare). Accordingly, following the insights of the reproductive justice movement, this sampling touches on the variety of injustices faced by women who occupy different social positions.

This collection includes a spread of drug labels, from the "drug facts" on over-the-counter medications to the patient leaflets and physician inserts for prescription drugs. It also looks at both specific labels and systems of labeling. The set of cases thus covers different social dynamics among different dyads and groupings within medicine and health policy in the US, including doctor-patient, pharmacist-patient, patient-insurer-employer, doctors-regulators, consumer-producer-regulator, citizens-courts, advisers-regulators, activists-policymakers, and regulator-regulator within the FDA. This breadth captures the diverse ways that values constitute regulatory science and how scientific knowledge is used throughout healthcare.

Furthermore, these cases are relevant to policy makers and society for various reasons. Two cases (the Pill and the morning-after pill) are recognized public controversies, having shaped the history of the FDA and our cultural memory about drugs (see Carpenter 2010). The third case (pregnancy labels) has attracted less public attention, but it has created significant internal dispute as a potential controversy, in part because of its relation to the monumental "thalidomide tragedy."

Nevertheless, my inclusion and ordering of the cases is biographical and somewhat happenstance, and the reader will likely notice a development of thought moving through them. I began with the morning-after pill, which shaped my choices to look at other anti-fertility treatments and then move to maternal health and labels promoting fertility. Chronologically, I begin all three cases in the 1960s. Because of practical constraints and more historical interest in case 2, I have chosen to follow only cases 1 and 3 to the present. Geographically, I have narrowed all three cases to the US primarily because of my focus on the FDA. However, case 1 takes us throughout the Americas and involves some comparisons with Europe. I will now describe the cases and briefly summarize the associated chapters.

5.1. Part I. Labeling contraception as abortion: The morning-after pill's "drug fact"

In my first case (Part I), I explore the long and controversial history of *the morning-after pill*, also known as emergency or post-coital contraception. The morning-after pill was developed in the 1960s as an alternative to regular hormonal contraception because the latter had significant side effects on women's health. This "day-after" treatment was utilized by population-control advocates and later women's health advocates to achieve their political goals, both aimed at increasing its accessibility (Prescott 2011). Yet, unlike the Pill, the morning-after pill raised the

specter of abortion because it could act after ovulation, potentially even after fertilization and implantation. As the "pro-life" movement grew during the '70s and '80s, led by Roman Catholics, it increasingly targeted the morning-after pill as an "abortifacient contraceptive," which had become standard treatment at university clinics and in emergency rooms to prevent pregnancy after rape (Miller 2015; D. K. Williams 2016; Wynn and Foster 2012).

Much of the controversy that has ensued over this treatment involves its *mechanism of action*, particularly following the approval of Plan B (a progestin-only formulation) at the FDA in 1999. Anti-abortionists have been particularly concerned about Plan B's potential to act indiscriminately on zygotes (i.e., after fertilization), which they considered the unethical termination of human life. After it was finally approved, following the controversy involving Wood's resignation, Plan B was labeled that it "may also prevent…attachment of a fertilized egg to the uterus (implantation)" (FDA 2006). Chapters 1-3 in part I focus on the mechanism of the morning-after pill and interplay between its advocates and critics, particularly women's health advocates and anti-abortionists. The chapters explain the creation of this drug label, its historical precedent, and its eventual consequences at hospitals, pharmacies, and courts, primarily in the US, but also in Chile and France.

Chapter 1 uses these debates to gain insight into the deeper reasons for the production and use of *mechanistic knowledge* throughout biomedical research, clinical practice, and governmental regulation.[2] I survey the history of knowledge concerning the morning-after pill's mechanism over the past half-century, beginning with its initial research and development, its use in hospital clinics especially by Catholics, and governmental regulations about increasing access. I argue that existing accounts of mechanism narrowly focus on more proximate issues

[2] Chapter 1 is published in *Synthese* (ChoGlueck 2019a).

related to therapeutic effectiveness and neglect many of the key challenges facing practitioners and policy makers, particularly involving values and context. To practice *socially relevant philosophy of science*, I argue that we need to account for mechanistic knowledge beyond mere effectiveness. This chapter uses the history of the morning-after pill to show how mechanistic knowledge can also provide moral guidance, aid ethical categorization in the clinic, and function as a political instrument.

In *chapter 2*, I explore how and why scientific facts are *value-laden*, using the debates at the FDA during the early 2000s surrounding the morning-after pill's "drug fact" that it "may prevent implantation." I draw on feminist criticisms of fetal-centrism in medicine to understand the value system of *zygote-centrism*, a sexist ideology that focuses the attention of scientists and healthcare professionals away from women and toward fertilized embryos (zygotes). I argue that this drug label is value-laden in two senses. First, because value judgments played a variety of roles in making the claim factually certain, there was a deep entanglement of fact and value. Second, because of the social currency of this "drug fact" for protecting would-be providers' refusals, it has empowered anti-abortionists to impose their values and limit women's access. In addition to providing a novel account of value-ladenness, this chapter also challenges the plausibility of science advisers' using "hedged hypotheses" to remain value-free (contra Betz 2013).

Building on my analysis of value-ladenness in chapter 2, *chapter 3* explores which values and whose values are legitimate within women's reproductive health, using the case of anti-abortionist doctors who refuse to provide the morning-after pill. Feminist philosophers of science have proposed a variety of arguments against sexist values in science. Providing a novel alternative, I contend that our knowledge and epistemic practices should not commit *epistemic*

injustices. This analysis demonstrates how sexist values and gender norms can hinder the epistemic autonomy of individual knowers and contribute to patriarchal oppression. Anti-abortionist providers created Plan B's drug label and then used it to justify their refusals to supply or finance the medicine. This value-laden knowledge enabled them to shape potential users toward patriarchal ends by warning "good mothers" about their duties to zygotes and punishing "bad mothers" with refusal. Therefore, I argue that the sexist values of anti-abortionists that prioritize zygotic health are illegitimate in this context because they cause epistemic injustices and perpetuate epistemic oppression. My approach advises against new initiatives that protect the "religious freedom" of healthcare providers because these structures will contribute to further epistemic injustices.

5.2. Part II. Informing patients about risks: Package inserts for oral contraceptives

Before emergency contraception took the limelight, regular oral contraception was at center stage. The first pharmaceutical contraceptive was Enovid, initially approved in 1957 for gynecological disorders and then in 1960 for birth control. Feminist aims to enable women's self-determination and eugenic desires for a technological solution to the "population problem" motivated the search for hormonal birth control. Because the Pill was one of the earliest pharmaceuticals designed for use in otherwise healthy people, it was difficult to weigh the risks when the benefit was not curing a disease. This difficulty came to the fore as reports of blood clots began in 1961 and continued to accumulate. While the British government halted prescriptions for the riskier dosages in late-'69, the FDA maintained that the Pill was still "safe within the intent of the legislation," and thus it remained on the market in the US until the late-'80s (Marks 2001; Marsh and Ronner 2008; Watkins 1998).

Rather than market removal (as in the UK), the strategy used by the FDA to communicate this risk and inform women was both novel and highly controversial. Women's health advocates like Barbara Seaman (1969) were calling for *full disclosure* of the risks, which she argued were unacceptable because of safer, equally effective alternatives. Her advocacy resulted in two months of senate hearings (the Nelson Hearings in 1970), during which many expert witnesses justified some withholding of the risks given the sex/gender of the users and the Pill's role in population control. Afterwards, the commissioner of the FDA announced plans for a patient information sheet that would inform users directly for the first time and provide full disclosure. Yet, by the time of implementation, the agency shortened and simplified the insert significantly to facilitate patients' understanding and encourage them to consult with their doctors. Part II looks more deeply at the Nelson Hearings and the FDA's first patient insert, consisting of an overture on the gendering of expertise and a chapter about informed consent.

In the *overture* to Part II, I investigate the women who participated in the hearings and how their *expertise* was gendered.[3] While some historians have briefly discussed the role of women at the Nelson Hearings (Tone 2002; Watkins 1998), they have not shown how the import of their contributions were limited by problematic gender norms about expertise. Although women contributed as experts and as protesters, sexist gender norms about expertise shaped who was seen as credible and who was thought to have merely disturbed the proceedings. Women participants occupied various positions, some as doctors and scientists, whose judgment reinforced the status quo in male-dominated medicine, and others as lay experts, whose contributions were dismissed as being hostile or uneducated. In the background were widely shared racialized convictions about the Pill as a tool for population control.

[3] *Lady Science* has published this essay (ChoGlueck 2019b).

With the stage set by this preface, *Chapter 4* examines the epistemic-ethical dimensions of *informed consent* through this first major case of the FDA attempting to inform patients directly. I provide a historically engaged analysis of the ethics of informing patients, drawing on arguments and critiques from historical actors, including politicians, doctors, and activists. Using the case of the Pill, I illustrate how powerful, mostly male parties misused ideals of informed consent *to keep women ignorant* about their reproductive health for population control and financial gain. For instance, doctors argued against full disclosure because they thought it would "upset" or "frighten" women, leading to emotional rather than rational reactions and a rise in population from "unfit" groups. Existing accounts of informed consent ignore these epistemic-ethical aspects. I argue that bioethics should focus less on these ideals in the abstract and more on how they are used in practice, exemplified by gender politics in regulatory science. I provide a more socially attuned account of informed consent, which attends to the power relations of informing and the politics of information. Accordingly, achieving informed consent requires ameliorating social injustice through medical information like drug labels.

5.3. Part III. Revising physician labels: Information on the risk of drugs during pregnancy

Moving from means of infertility to those of fertility, the final section focuses on the use of drugs in pregnancy and lactation. Following the "thalidomide tragedy" in 1961, the FDA's power was expanded significantly to oversee pre-market trials, officially regulate efficacy along with safety, and require subjects' informed consent in trials (Carpenter 2010; Stephens and Brynner 2001). Furthermore, the FDA took several measures to protect "the unborn" from exposure in utero (Kelsey 1982). In particular, the FDA excluded "women of childbearing potential" from the early stages of clinical trials when the drug is first given to humans and the dose is set. Thus,

based on this concern for fetal impacts and the possibility of birth defects, most pharmaceutical research in the 1980s was based on male tolerance and physiology (Merkatz and Junod 1994). While women's health advocates have reformed the FDA (and NIH) to better include women and measure differences by sex/gender, many gaps remain, particularly about pregnant women's use of drugs (Epstein 2007; Merkatz et al. 1993).

Also in the wake of thalidomide, the FDA introduced a special section in the physician label for the use of prescriptions in pregnancy, with a unique system for communicating the *teratogenic* potential (risk of birth defects) according to five categories (Federal Register 1979; Kelsey 1982). Although it has been one of the most consulted sections of the physician label, the category system was harshly criticized, particularly by teratologists, as misinformative and misperceived by doctors and patients (e.g., Friedman 1993; Scialli 1992). Following the successes with improving women's health, the FDA sought to revise these pregnancy labels in order to provide pregnant women more information, particularly supported by the Office of Women's Health. While they were able to finalize the revision in 2014, these reformists received significant pushback internally about concerns of creating "another thalidomide" and unleashing "a sea of teratogens." Furthermore, even with a revised system, significant gaps in knowledge would remain; therefore, the agency began a variety of initiatives to encourage more research of maternal health and fetal impacts, such as making guidance documents for industry about ethics in maternal-fetal research and collecting pregnancy registries into one standardized location.

Chapter 5 focuses on the removal and replacement of this category system about the risks of taking drugs during pregnancy, which has not yet received any scholarly treatment. I document and investigate these efforts by the FDA to aid physicians in counseling pregnant and nursing women, especially the challenges faced and overcome by regulators. I conducted four in-

depth interviews with current and former staff, and I analyzed official reports, public comments, and advisory meetings. I focus on older policies focused on fetal health and newer, feminist initiatives aimed at also including women's health into maternal health regulations.

This chapter demonstrates how ethical values become embedded in regulatory science through past successes and failures and how that history shapes subsequent reforms, both promoting and limiting knowledge production. I argue that the revision of the pregnancy label was an improvement upon the earlier version which prioritized fetal health and, therefore, it should be understood as a *feminist success story*. For one, the revision transformed the objectivity of the information presented to doctors and their patients to be more transparent and useful than the previous category system. Second, the revised label promotes a broader range of women's values and interests, including fetal health and women's health, supporting pregnant women in exercising a broader range of reproductive rights than before. Third, the revised labels promote pregnant women's voluntary participation in the process of science through post-market pregnancy registries. By engaging with regulators involved in making these changes, this analysis helps us to understand progress in regulatory science as an epistemic-ethical reform, specifically as a means of challenging sexist values with feminist criticism and alternatives.

6. Conclusions

Across these episodes of labeling drugs about reproduction, we find the entanglement of ethics and epistemology: values shape regulatory science in ways that often complicate the process of knowledge production, sometimes for better and sometimes for worse. These entanglements created three challenges in regulatory science in the realm of reproductive health. First, across these cases, there are many ways in which women's health has been unfairly devalued for other

concerns in reproductive medicine, such as zygotic life, fetal health, and population control. Second, both knowledge and ignorance about their reproductive health have oppressed women, especially poor women and women of color. Finally, powerful, mostly male parties in medicine including doctors, pharmaceutical companies, and religious institutions have misused ethical concepts and practices, such as informed consent, religious freedom, and medical paternalism, for unethical purposes. I offer these challenges in regulatory science to provide new directions for socially relevant philosophy on drug regulation, values in medicine, and feminist science studies.

Not all these entanglements compromise regulatory science, and I suggest ways to reduce the influence of sexist values and facilitate feminist alternatives. For one, I provide a novel account of why sexist values and gender norms are illegitimate in regulatory science, specifically for reproductive health, involving epistemic injustice. In addition, I discuss who should be involved in decision making at the intersection of ethics and epistemology. While imagining some solutions, I also consider actual attempts at improvement, particularly the ability of the feminist health advocates at the FDA to criticize sexism and injustice in regulatory science.

While many of the episodes that follow this introductory chapter are depressing and upsetting, I encourage the reader to continue: my analysis does get more positive and hopeful by the end. It is only by recognizing the extent of the damage incurred that we can strategize judiciously about which solutions are possible, workable, and ethical.

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Part I.

Labeling Contraception as Abortion:

The Morning-After Pill's "Drug Fact"

Chapter 1.

Broadening the Scope of Our Understanding of Mechanisms:

Lessons from the History of the Morning-After Pill

Abstract: Philosophers of science and medicine now aspire to provide useful, socially relevant accounts of mechanism. Existing accounts have forged the path by attending to mechanisms in historical context, scientific practice, the special sciences, and policy. Yet, their primary focus has been on more proximate issues related to therapeutic effectiveness. To take the next step toward social relevance, we must investigate the challenges facing researchers, clinicians, and policy makers involving values and social context. Accordingly, we learn valuable lessons about the connections between mechanistic processes and more fundamental reasons for (or against) medical interventions, particularly moral, ethical, religious, and political concerns about health, agency, and power. This chapter uses debates over the controversial morning-after pill (emergency contraception) to gain insight into the deeper reasons for the production and use of mechanistic knowledge throughout biomedical research, clinical practice, and governmental

regulation. To practice socially relevant philosophy of science, I argue that we need to account for mechanistic knowledge beyond immediate effectiveness, such as how it can also provide moral guidance, aid ethical categorization in the clinic, and function as a political instrument. Such insights have implications for medical epistemology, including the value-laden dimensions of mechanistic reasoning and the "epistemic friction" of values. Furthermore, there are broader impacts for teaching research ethics and understanding the role of science advisors as political advocates.

1. Introduction

Thinking about mechanisms—that is, how something works, acts, or causes an effect—pervades scientific reasoning and policy making. Accordingly, philosophers of science have sought to provide accounts of mechanism that are useful for both researchers and policy makers. For instance, Carl Craver and Lindley Darden (2013, p. xviii) intend to "write a practically useful book for those engaged in discovery" by offering to contemporary researchers a framework of mechanism and strategies from the history of science. More geared toward policy makers, Federica Russo and Jon Williamson offer an alternative account of mechanisms to critique the evidence hierarchies that guide public-health policy, such as measuring environmental exposure and reducing obesity (Russo 2012; Russo and Williamson 2012). For an even broader audience, Nancy Cartwright and Jeremy Hardie (2012, p. 5) provide a guidebook for Evidence-Based Policy involving mechanistic reasoning, intended to be accessible to experts and laypeople involved in policy making including "classroom teachers thinking about homework, city councils deciding whether to build a leisure center, or government ministers contemplating drug policies." Clearly, these philosophers of science and medicine hope to provide practical and applicable

accounts of mechanism.

Existing accounts have forged the path to scientific and social relevance. They have looked at mechanistic reasoning in its historical context and in practice (e.g., Machamer et al. 2000; Darden 2006; Craver & Darden 2013), and they have expanded to include various special sciences and public policy (e.g., Illari & Williamson 2012; Russo 2012; Clarke et al. 2014).[4] First and foremost, philosophers of mechanism have sought to elucidate the reasoning by which scientists employ to connect a phenomenon with its causes, organization, processes, and parts (for reviews, see Craver and Tabery 2017; Glennan 2016; Illari and Williamson 2012).[5] In biomedicine and health policy, they have shown in a variety of ways how mechanistic knowledge and reasoning involves the *effectiveness* of a treatment (i.e., its ability to produce an effect). They have found three possible roles for mechanisms in medicine that map onto the contexts of discovery, justification, and application, which I call the *heuristic*, *evidential*, and *instrumental* functions.[6] First, the search for mechanisms of effective treatments has guided the methodology of how such knowledge is sought heuristically (Darden 2006; Craver and Darden 2013; Solomon 2015). Once found, mechanisms help clinicians to evidence claims about effectiveness epistemically (Russo and Williamson 2011; Howick 2011). Then, in policy making and society more generally, mechanistic reasoning provides an instrumental aid for making

[4] I thank an anonymous reviewer for suggesting that socially relevant philosophy is the next step in the philosophy of mechanisms after the turns to history, practice, and the special sciences.
[5] Overlooking some of the differences between their accounts, the specifics range from organized entities and activities that operate regularly and cyclically (Machamer et al. 2000) and complex systems whose parts interact directly and invariantly to make a difference between variables (Glennan 2002) to a structure performing a function by virtue of its organized parts (Bechtel and Abrahamsen 2005). However, for my purpose of understanding the production and use of mechanistic knowledge, these nuanced distinctions are immaterial.
[6] There has been extensive philosophical debate over the sharpness of these context-based distinctions and their epistemic import (see Schickore and Steinle 2006). Nevertheless, if understood as loosely overlapping phases operating throughout inquiry, they provide a useful structure for framing my analysis.

effective interventions and applications (Cartwright and Hardie 2012; Russo 2012).[7]

Now, if we want to practice *socially relevant philosophy of science*, we must attend to the issues that are important to researchers, clinicians, and policy makers, particularly those involving human values and social context (Fehr and Plaisance 2010; Weaver 2017). While these philosophical accounts of mechanism have provided insightful analyses into more proximate issues related to therapeutic effectiveness, the time has come to explore the deeper challenges facing researchers, clinicians, and policy makers. These issues involve value questions about morality, ethics, and religion and the politics associated with the production and use of knowledge about mechanisms. Philosophers have argued forcefully for the importance of accounting for how context and values shape scientific research and science policy (Douglas 2009; Elliott 2011; Kitcher 2011; Longino 1990). For instance, the questions scientists ask—and the projects that get funded—are limited to those which they take to be *significant*, requiring value judgments about priority, framing, and use into the production of knowledge. Furthermore, managing different empirical uncertainties such as underdetermination and inductive risk also requires value judgments, often relying on contextual values with societal stakes (ChoGlueck 2018). To achieve social relevance, philosophers of mechanism should take this next step to broaden their accounts by including the interplay between science, medicine, and society.

Using an in-depth case study of the mechanism of the morning-after pill (emergency contraception), this chapter argues that, antecedent to producing effective treatments, mechanistic knowledge relates to broader beliefs about health, agency, and power involving human values. Here, researchers and policy makers produce and use mechanistic knowledge to

[7] Since I aim to expand and then reframe the discussion, I will not evaluate these existing arguments, although I will note criticisms (see footnotes 8, 10, 11, and 12).

determine what forms of effectiveness and what treatments are desirable in the first place. For one, we shall see how during initial development mechanistic knowledge can provide researchers with moral guidance regarding how to follow religious and ethical codes and to achieve political goals. Second, mechanistic reasoning can also help physicians in clinics categorize treatments over ethically loaded terrain. Third, it can equip researchers and healthcare professionals with the useful sort of scientific information needed for political advocacy. Rather than a simple epistemic means to effective intervention—the focus of existing philosophical accounts—knowing and understanding mechanisms is a crucial aspect of many ethical, political, and social controversies. Accordingly, this chapter argues that the time is ripe for philosophers to expand and reframe the discussion of mechanisms in medicine to attend to these humanistic and cultural aspects of mechanistic reasoning.

While this chapter's immediate aim is descriptive, ultimately it enables a more critical project: understanding how mechanistic knowledge is used in biomedicine and health policy in order to improve it. For one, my analysis showcases value-laden dimensions of mechanistic reasoning and how they vary across context. In particular, we see how values create "epistemic friction." Values in early research and development shape the expertise and knowledge available (and absent). Values in clinics and hospitals promote the development of new classificatory schemes for novel, contentious treatments. The values of public advocacy groups prompt scientists to produce and promulgate specific forms of information for patients, governmental agencies, and courts.

Moreover, controversies over the mechanisms of contraceptives have enormous societal significance. The World Health Organization lists these "emergency contraceptives"—taken after sexual intercourse to reduce the chance of unwanted pregnancy—as a core essential

medicine (WHO 2017, p. 40, 18.3.1). Virtually all women in the US have used contraception at one point in their lives (Daniels, Mosher, et al. 2013), and over last decade, 11% (5.8 million) of US women of reproductive age had used emergency contraception specifically (Daniels, Jones, et al. 2013). One key obstacle to women's access to this important drug, as we shall see, has been concerns about its mechanism related to ethical and religious objections to abortion, particularly from Roman Catholics, entangling medical epistemology with reproductive ethics and gender politics.

An integrated methodology in history and philosophy of science (HPS) grounds this chapter's aim at socially engaged philosophy. To articulate the challenges that researchers, doctors, and science advisors faced when producing and using knowledge about this mechanism, my analysis moves iteratively from the more abstract discussion of philosophers to the concrete details of history and back again (for a similar approach, see H. Chang 2011). As an HPS project, this chapter seeks to provide lessons for philosophers about different aspects of mechanistic knowledge by working through three episodes in the history of the morning-after pill. Rather than merely reporting a case study based on historians' secondary accounts and then generalizing from it, I have conducted historical research from primary and secondary sources, which I use to make my own historical account and then engage critically with the relevant philosophical literature. I have utilized new primary sources, such as commentaries from Catholic physicians' journals and related Catholic hospital directives, Planned Parenthood conference proceedings, and peer-reviewed articles on emergency contraception. I have also drawn upon a wide variety of secondary sources, including Heather Prescott's ground-breaking (2011) monograph on the history of the morning-after pill, Angel Foster and Lisa Wynn's (2012) collected volume on the International Consortium for Emergency Contraception, Patricia Miller's (2015) history of

debates over abortion among American Catholics, and Daniel Williams's (2016) pre-history of the Pro-Life Movement. Nevertheless, unlike these other histories involving emergency contraception, particularly Prescott's (2011), my narrative highlights the long-standing concern with the pill's mechanism from both women's health advocates and anti-abortionists throughout the past fifty years. In particular, I trace the shifting functions afforded to mechanistic knowledge by people with different values and in different contexts. For geographical comparison, my account moves throughout North and South America, where most of the research was conducted and where several of the most contentious political battles took place.

Each section discusses the way philosophers have construed mechanistic knowledge or reasoning, followed by my own narrative and analysis of a different or broader function. This HPS iteration between history and philosophy takes us through several milestones in the saga of the morning-after pill, including its initial development, its subsequent clinical use, and its later governmental regulation. The chronology begins in the 1960s, during the spread of the first hormonal contraceptives, when research on the alternative "day-after" pills began in the US. Section 2 delves into how reasoning about *post-coital* mechanisms during this early development engaged researchers morally, either toward or against intervention—particularly Catholic doctors in the face of prohibitions on contraception and abortion from the Vatican. The next milestone is the spread of the first morning-after pill to clinics and hospitals throughout the world in the late 1960s and early '70s (before the discovery of the health risks of estrogen). Section 3 contrasts the different schemes employed by clinicians and hospital administrators for categorizing the new (off label) treatment as a contraceptive or abortifacient. The final milestone is the governmental regulation of safer progestin-based emergency contraceptives in the late 1990s and early 2000s, including legislative battles and court cases over women's access to this drug.

Section 4 covers two of these recent struggles in the US and Chile, where scientists used mechanistic information as a political instrument either for women's agency in healthcare or for provider's rights to refuse offering these pills.

Reflecting on these insights, Section 5 argues that mechanistic knowledge is produced and used not only for understanding or utilizing effectiveness but more generally for promoting health; this broader understanding involves human life, norms, and values. There, I discuss how these lessons apply more broadly to other cases of mechanistic knowledge because of the relations of treatment mechanisms to cultural norms, ethical values, and economic currency. Section 6 discusses the implications of expanding beyond our current understanding of mechanisms for philosophy and society, spanning from the relations between values and mechanistic knowledge to the teaching of research ethics and the role of science advisers.

2. Moral Guidance for/against Intervention after Coitus

We begin with the search for mechanisms during early research and development. In the so-called context of discovery, philosophers have shown how mechanistic reasoning is significant for its *heuristic* function (Craver and Darden 2013; Darden 2006; Solomon 2015). Typically, drugs and other treatments must be researched and developed before they can be tested in human trials, evaluated by governments, and prescribed by physicians. Often this search in the field of "translational medicine" is framed around pathological and physiological mechanisms, which guide researchers by structuring their discovery toward fruitful outputs (Solomon 2015). Rather than thinking of discovery as a boundless endeavor without rules, Darden (2006) argues that mechanisms provide a *logic of discovery*. Therefore, if the goal is to discover mechanisms, there are many advisable strategies based on the history of science (see also Thagard 2011). She

discusses these strategies at length, such as for the construction of hypotheses, evaluation of their plausibility, and revision according to new developments. For Darden, and others like Craver and Miriam Solomon, the significance of mechanisms during early research is first as the epistemic goal of inquiry and second as a heuristic that provides the means for achieving that goal (Craver and Darden 2013; Solomon 2015; see also La Caze 2011).[8]

In this section, I contend that mechanistic reasoning provides more than a heuristic for discovery by affording *moral guidance* over when and whether to intervene. To intervene, or not to intervene, that was the question—but it was a moral question for individual researchers to discern. For the morning-after pill, thinking about the mechanism did guide initial development as well as later refinements toward more safe and effective formulations (e.g., Glasier et al. 1992; Morris, Van Wagenen, Hurteau, et al. 1967). However, it would be misleading to say that simply guiding detached discovery was the chief reason for scientists' mechanistic interests. Instead, their main interest in this mechanism was over its relation to the ethics of reproduction and the politics of women's health. Mechanistic reasoning provided researchers with *a distinctly moral form of guidance* regarding their ethical codes, religious beliefs, and political goals. Developers of the pill were proponents of contraception regardless of when it worked, typically for eugenics and population control.[9] Detractors spurned late-acting pills as equivalent to abortion, which they condemned mostly for religious reasons (as Roman Catholics). As we shall see, reasoning about the mechanism of this drug-in-development crucially influenced research personnel, shaping the expertise and knowledge available or absent during early development.

[8] In contrast, Jeremey Howick (2011) argues that mechanistic reasoning is not a reliable heuristic because of its high cost-to-benefit ratio.

[9] Unlike the developers themselves, some of their collaborators and patrons were feminists committed to women's liberation, such as Margret Sanger and Katharine Dexter McCormick. Nevertheless, they were all motivated to some degree by eugenics and the need for population control (see Marks 2001; Marsh and Ronner 2008).

For these advocates and critics of this pill, their prior collaboration during the 1950s framed their relationship and their interest in contraception. Biologist Min Chueh Chang (b.1908—d.1991) and physician John Rock (b.1890—d.1984) worked together to develop what became "The Pill" with the support and direction of the Worcester Foundation for Experimental Biology (WFEB) in Shrewsbury, Massachusetts. Chang was an experimental biologist trained at Cambridge, who began working at WFEB in 1945 on fertilization under the direction of co-founder Gregory Pincus (b.1903—d.1967). Along with intellectual curiosity about the process of fertilization, personal eugenic concerns about unchecked population growth motivated the contraceptive research of Chang and Pincus (M. C. Chang 1968; Greep 1995).

Rock was also affiliated with Worchester, having conducted the Pill's preliminary human tests at his Massachusetts clinic and co-directed the later trials in Puerto Rico. For improving marital relations overburdened by children, this Catholic physician founded the first free birth-control clinic in Massachusetts in the late-1930s (Marsh and Ronner 2008, p. 147). Rock and Chang's collaboration with others, including feminist-eugenicist social reformers Margret Sanger and Katharine Dexter McCormick, paved the way for the first hormonal contraceptive Enovid, approved in 1960 (see Marks 2001; Tone 2001; Marsh and Ronner 2008).

Rock's support of hormonal contraception put him at odds with most other Catholic physicians of the day (see Williams 2016). Moreover, he deviated from Catholic teaching in his support of artificial contraception *because* of his understanding of its mechanism. In 1963 he published a widely popular book, titled *The Time Has Come: A Catholic Doctor's Proposals to End the Battle over Birth Control*. There, he argued that progesterone merely prevents ovulation to extend the natural "safe period" of infertility. Catholic social teaching allowed couples to use the natural method of infertile periods for family planning. Thus, Rock argued that a "pill-

established safe period" should have the same moral and theological implications (Rock 1963, pp. 168–69).

Nonetheless, apart from contraception, the Catholic social teaching that abortion is a mortal sin begins at *fertilization* when egg and sperm fuse. This stance relies in part on the ontological and ethical beliefs that, once a life has a human soul, it is a full human person and that ensoulment happens at fertilization, hence the "conception" of the person (see Miller 2015, pp. 60-63; Williams 2016, p. 12). This ontological issue of where a woman's body ends and another person's begins has ethical implications for bodily autonomy and its limits. Under Catholic teaching, ending the life of a zygote (fertilized egg) or more developed fetus constitutes the immoral killing of an innocent person and thus was prohibited at Catholic hospitals (NCCB 1971). Thus, entwined with the moral status of the zygote are the ethics and politics of motherhood, particularly the rights and responsibilities of women after fertilization, such as in the case of preventing pregnancy for rape survivors (Luker 1984; compare, e.g., Lynch 1977; McCarthy 1977).

Rock believed in the moral legitimacy of abortion for the mother's health and even conducted experiments on zygotes and embryos. Nonetheless, he remained uneasy about elective abortion and was undecided about the precise timing of ensoulment (see Marsh and Ronner 2008, pp. 57, 241, 351 n.7). Most relevant to our story, Rock (1965) used *mechanistic reasoning* to appease other Catholic doctors who were more concerned about the risk of abortion (meaning termination after fertilization). The main action of progestins, he claimed, was to inhibit the release of an egg from the ovaries. While they do alter cervical mucous and limit endometrial glands, "there can be no question of an abortion if there is nothing to abort" (Rock 1965, p. 402).

While Rock was using mechanistic knowledge to defend this anovulatory pill, Chang

sought more effective interventions with less of the side effects that were attracting medical and public concern (Watkins 1998). In 1959, he induced ovulation in rats and rabbits and then treated them *after insemination* with an antifertility agent (M. C. Chang 1959). Chang explained the observed "anti-zygotic activity" in terms of the compound's effect on the transport of fertilized eggs through the Fallopian tubes. During the mid-60s, his research team found the estrogen ethinyl estradiol (EE) to be the most effective in such interference in rabbits and hamsters (M. C. Chang 1964; M. C. Chang and Yanagimachi 1965; M. C. Chang and Harper 1966). To make birth control better and solve the "so-called population explosion," Chang thought, would require effective "day-after" solutions: "It is always better to reach a specific target than the whole system" (quoted in Lader 1966, p. 58). He targeted the embryo in transport rather than the higher nervous centers because the cognitive side effects (e.g., nausea, headaches, depression) "might be disadvantageous" for women's health (M. C. Chang 1967, p. 387).

But Rock disagreed that reaching this "specific target" of egg transport is "always better." In a 1966 interview for the *New York Times* on Chang's progress, he diverged with his old teammates and indicted their new approach: "I feel this pill is an abortifacient" (Lader 1966, p. 55). Despite having no objections to his own *in vitro* fertilization (IVF) experiments two decades earlier (Marsh and Ronner 2008, pp. 103–4), Rock would not support this post-coital pill, at least publicly. WFEB director Pincus responded that the new pill could *not* be abortifacient. Unlike the Catholic Church, the nascent American College of Obstetrics and Gynecology (ACOG) defined 'pregnancy' as beginning with implantation (see Section 3). Unlike in their previous collaboration, Rock's resistance limited WFEB's access to human subjects, so Chang stuck to his regular method of animal experiments in the lab. After Pincus's death in 1967, Chang left this anti-fertility work to focus more on facilitating pregnancy with IVF (M. C. Chang 1968; see

Greep 1995).

Two Yale professors at the university's School of Medicine, however, did have access to human and non-human primates. Biologist Gertrude van Wagenen (b.1893—d.1978) was studying rhesus monkeys in one of the earliest captive colonies, which she began in 1935 (Fridman 2002; Rossiter 1982). She discovered that administering high doses of estrogen led to infertility. Van Wagenen brought this to the attention of her colony's clinical adviser, the gynecologist John Morris (b.1914—d.1993), who was interested in population control. Together they found that ovulation and implantation were absent after dosing monkeys with estrogens like EE and diethylstilbestrol (DES) (Kohorn 2009).

To inhibit implantation, the Yale group subsequently tested over 15 anti-fertility compounds in rats, rabbits, monkeys, and then humans, eventually settling on DES (Morris and Van Wagenen 1966; Morris, Van Wagenen, Hurteau, et al. 1967; Morris, Van Wagenen, McCann, et al. 1967). This synthetic estrogen already had approval of the US Food and Drug Administration (FDA) in 1941 for alleviating menopause symptoms, and it would remain on the market until 1971 when its carcinogenicity in humans was established (Langston 2010). In the meantime, the technology begun by Chang and continued by van Wagenen and Morris subsequently spread throughout student health centers and hospitals in the US (Prescott 2011).

In sum, during this initial period of research in the 1960s, mechanistic reasoning functioned as guidance for individual researchers' moral decision making. The ethical and political relevance of the mechanism of the post-coital pill influenced who engaged in the research, why, and how they did it. Scientists with the goal of developing better population control such as Chang, Morris, and van Wagenen sought safer and more effective means of hormonal contraception. They figured that the Pill indiscriminately restructured women's

menstrual functioning, likely causing unnecessary side effects and possibly comprising the effectiveness of population control because of discontinuation. Thus, they reasoned mechanistically to intervene *more strategically and precisely* on processes besides ovulation via post-coital administration. Contrasted with earlier combined-oral contraceptives that were taken regularly and suppressed ovulation, these new post-coital methods were intentionally designed to act later (on egg transport, fertilization, or implantation). Better to intervene later and more precisely, they thought, than to undermine the effectiveness of family planning and population control.

However, Chang's relatively safer formulation using EE was neglected by the Yale group, in part because of Rock's reticence over how the pill worked. His religious and ethical beliefs gave the mechanism special *moral valence*, such that interventions after ovulation were off-limits. Rock was willing to deviate from other Catholic physicians on the Pill because its action was on ovulation alone; nonetheless, he was uneasy with Chang's newer techniques, so he left the team. Accordingly, his expertise in running human trials abroad for the pharmaceutical company was no longer available. After Morris and van Wagenen took up the helm, they found both DES and EE to be effective, but they publicly promoted the use of DES (Scientific American 1966, p. 56). Despite their efforts to test for health harms, soon the safety of their procedure came under fire as the risks of DES surfaced (Hatcher and Conrad 1971; see Langston 2010). It is plausible that Rock's presence might have led to more testing in humans with EE, which is still used in lower doses for combined oral contraception. Regardless of the specific effect, Rock's moral qualms undercut his former team's ability to respond empirically to the Yale group.

Thus, this moral guidance builds on the more *detached* heuristic function of simply

providing a strategy for discovery/development (from Craver and Darden 2013; Darden 2006; Solomon 2015); it too has *epistemic consequences* regarding expertise and methodology. Reasoning about post-coital mechanisms took on ethical, political, and religious significance, differently engaging the expertise of Chang (and eventually van Wagenen and Morris) toward intervention while disengaging Rock. Accordingly, it pointed their techniques toward more precise interventions over more general ones, while also altering their methods of treatment and access to research subjects. Reasoning about mechanisms provided a distinctly moral form of guidance, directly relevant to the research personnel's values about why effective post-coital contraception was desirable (for the goal of population control) or not (as an abortifacient means).

3. A Scheme for Ethical Categorization: Abortion, Contraception, Both, or Neither?

Moving from discovery to justification, we turn to the role of mechanisms in the clinical context. Many philosophers of medicine have discussed the *evidential* function of mechanisms in clinical practice, i.e., for justifying claims of therapeutic effectiveness for populations of patients (Clarke et al. 2014; Dragulinescu 2017; Howick 2011; Illari 2011, 2017; La Caze 2011; Russo and Williamson 2007, 2011, 2012; Thagard 1999). Philosophers often emphasize this evidential role for mechanistic knowledge in their critiques of evidence hierarchies. For instance, many advocates of Evidence-Based Medicine rank randomized clinical trials (RCTs) and systemic reviews of them at the top of the hierarchy of evidence and mechanistic studies at the bottom or off the chart (e.g., GRADE Working Group 2004; Guyatt et al. 2015).[10] Cartwright and others

[10] However, one should note that it not a hierarchy of *evidence* per se but of *methodologies* (Bluhm 2005). For a review of critiques of Evidence-Based Medicine, and an analysis of its proper place in medical epistemology, see Solomon (2011, 2015).

contend that while RCTs can establish a causal connection between two factors given the satisfaction of study assumptions, mechanisms can provide some evidence of confounding and non-causal correlations (Cartwright and Hardie 2012; Howick 2011; Illari 2017). Going further, Russo and Williamson argue that both mechanisms and RCT statistics are "normally required" for causal inference, although neither is necessary nor sufficient (Russo and Williamson 2012, p. 250).[11]

I argue that, beyond the evidentiary role of mechanisms in the clinic, they can further assist clinicians in developing categories (or schemes) over ethically tumultuous terrain. Granted, the effectiveness of the morning-after pill depends on when it is taken during a woman's menstrual cycle, so clinicians have long emphasized the mechanism's importance for determining the period of effectiveness (e.g., Kesserü et al. 1974) and counseling individual patients (e.g., Grou and Rodrigues 1994). Yet, that is only part of the story: mechanistic knowledge took on a different clinical function within obstetrics and gynecology (OB/GYN) over categorizing the treatment, in part because of its technical novelty and its political currency as a tool of contested ethical quality during the era of legal reform around contraception and abortion. The liminal status of this new technology prompted clinicians to revisit the old definitions of 'contraception,' 'pregnancy,' and 'abortion' and to grapple with the uncertainty of the mechanism. In newfound clinical contexts, supportive scientists and medical professionals sought to separate the categories of post-coital contraceptive and abortifacient, while contraception critics and anti-abortionists, particularly Catholics, rejected this categorical scheme

[11] This evidential function in the strong form advocated by Russo and Williams is more contested than the heuristic one. Medical researchers (e.g., Guyatt et al. 2015) and institutions (e.g., the Cochrane Collaboration) oppose it implicitly by omission from their hierarchies of evidence. Several philosophers argue against the evidential function of mechanism explicitly (Andersen 2012; Bluhm 2013; Broadbent 2011; Dragulinescu 2012; Solomon 2015), while others argue that the possible evidential import of mechanistic evidence can be outweighed by commercial forces (Holman 2017).

as ethically suspect. As we shall see, these divergent clinical categorizations reflected deeper divergences over how to control or promote women's health, and they had substantial effects on women's treatment options in hospitals.

When Morris and van Wagenen's procedure spread to clinics in 1966, it ushered in new concerns about categorization. Relaying this progress, *Time Magazine* described the pill as "not literally a contraceptive, since it does not work by preventing ovulation" like the other hormonal methods available at the time (Time 1966). So, what is this new pill? Its ambiguous status took on legal significance in the context of contraception and abortion reform. In 1965, the US Supreme Court overturned state prohibitions of contraception as unconstitutional in the landmark case *Griswold v. Connecticut*. Other US state laws continued to prohibit substances intended to abort or miscarry; nonetheless, popular support for the legalization of abortion was swelling (CDD 1967). By the late 1960s, groups ranging from the American Medical Association to the American Baptist Convention supported legal access to abortion. The only organized opposition to legalization for abortion and contraception came from Roman Catholics, especially clergymen and physicians (see Burns 2005; Luker 1984; Williams 2016).

Scientists and family-planning professionals were acutely aware of this classification problem, which came to the fore in Santiago, Chile, during the 1967 conference of the International Planned Parenthood Federation (IPPF). The IPPF invited representatives from WFEB and Yale to the Global South to present their new results, which commentators agreed were very promising (Jackson 1967, p. 485; Parkes 1967, p. 505; Sjövall 1967, pp. 510–11). During the conference's closing session, after reports from Chang, Morris, and van Wagenen, Thorsten Sjövall (b.1913—d.1998; Vice President of IPPF Europe and Near East Region) reflected on how the drug's ambiguous classification related to these progress reports' ethical

significance (Sjövall 1967, p. 510). Rather than focusing on "the legally and ethically accepted definitions for the beginning of life" he suggested that ethical evaluations ought to prioritize "the subjective experience of the woman" (Sjövall 1967, p. 511). By shifting the focus from physiology to psychology, he reasoned that the post-coital pill might better be defined as a 'contraceptive' rather than an 'abortifacient' because women experience it working more like the former than the latter.

To settle ambiguities such as these, OB/GYNs began to standardize terms. The ACOG (established 1951) released its first volume of terminology in 1972. Morris—one of the researchers from Yale—was a major contributor and consultant to the effort. The volume's definition of 'conception' aligned with the morning-after pill's developers: "Conception is the implantation of the blastocyst. It is not synonymous with fertilization. SYNONYM: *Implantation*" (Hughes 1972, p. 299). 'Pregnancy,' defined as "the state of a female after conception and until termination of the gestation," thus excluded the days before implantation (Hughes 1972, p. 327). And 'abortion,' listed as one of the "complications of pregnancy," also excluded inhibitory action prior to implantation (Hughes 1972, p. 414). This terminology provided an alternative ontological and ethical position to the growing "Right-to-Life" movement, spearheaded by Catholics, who defined 'the conception of life' and 'personhood' as beginning at fertilization and thus defended the rights of zygotes (Williams 2016).

Thus, Catholic OB/GYNs would now be using non-standard terms when calling the post-coital pill an 'abortifacient,' such as Rock had six years earlier. The secular OB/GYN discipline and the Catholic Church had developed competing categorical schemes, with 'pregnancy' beginning at implantation and fertilization, respectively. But what about this new pill? Chang and Pincus considered their pill simply a post-coital form of 'contraception' because it interfered

with egg transport (Lader 1966, p. 55). The Yale group classified it differently, following the sentiments of Sjövall: what mattered was not only the physiological mechanism but also the ethical and cultural significance of "how it works." In 1973, Morris and van Wagenen proposed using the special category of 'interception' for preventing implantation (1973, p. 101). Two researchers had coined 'interception' a couple years prior because unlike 'abortifacient' it lacked undesirable psychological and ethical connotations based on "social background and moral taboos" (Naqvi and Warren 1971, p. 732). The Yale team thought that estrogen administered after intercourse did not interfere with ovulation or fertilization or after implantation but only with the process of implantation. Their treatment was not quite contraceptive (*pace* Chang and Pincus) nor abortifacient (*pace* Rock), but rather something novel operating in between. Thus, the ethical stakes of this innovative treatment shaped the development of clinical classifications and even promoted the development of a new concept.

Despite the legalization of abortion in various states and then at the federal level in 1973, the ACOG it could not simply define away the new social movement of "Right-to-Life" opposition to abortion. In their *Ethical and Religious Directives for Catholic Hospitals*, the US bishops prohibited physicians from providing and even discussing contraception and abortion. The 1971 edition of the *Directives* prohibited post-coital contraception, stating that preventing implantation via endometrial curettage (scraping the uterine wall) "is morally equivalent to abortion," even for treating women who had survived rape (NCCB 1971, dirs. 19 & 24).

As curettage gave way to hormones as the standard treatment after rape for preventing pregnancy, Catholics also debated the new treatment's ethical and clinical legitimacy, in part because of the uncertainty surrounding its mechanism. In 1977, *The Linacre Quarterly*—the official journal of the US-based National Federation of Catholic Physicians' Guilds—printed a

point/counterpoint for and against DES as post-coital treatment of rape survivors. Catholic priest and theology professor Donald McCarthy defended the ethical permissibility of the drug, citing Morris and van Wagenen (1966) that it could act merely as an anovulant if given before ovulation. He contended that post-coital contraception would be justifiable after rape as a woman's self-defense "to counter the violence of the rape aggressor" (McCarthy 1977, p. 213). Thus, McCarthy was willing to allow the use of a hormonal treatment in the situation of rape—but only if working before fertilization to prevent pregnancy.

In his counterpoint, William Lynch (President-elect of the National Federation of Catholic Physicians' Guilds) objected, faulting McCarty for ignoring more recent work on the "interceptive" capacity of DES (i.e., Morris and Van Wagenen 1973). But unlike van Wagenen and Morris, this physician equated the new post-coital agent with abortion: "Interception by any other name is abortion" (Lynch 1977, p. 228). In response, McCarthy held his ground by objecting to Lynch's standard for certainty: "As with all contraceptive drugs, it is difficult *to prove absolutely* that ovulation has been blocked in each individual cycle despite their known contraceptive effects" (McCarthy 1978, my emphasis). Like Rock previously, these Catholics valued knowledge about the mechanism for its ethical, ontological, and religious relevance to abortion and reproductive health. In contrast with Rock's disinclination to *research*, their values motivated a disinclination to *use and prescribe* the now-available pill if it acted (or might act) in a certain way. Even for Catholics who prioritized women's interests, such as McCarthy, the mechanism of treatment could preclude its ethicality when fertilization had occurred. Furthermore, the uncertainty of its mechanism took on heightened significance where the bishops' *Directives* left little room for any form of contraception and banned treatments categorized as 'abortifacient.'

Following McCarthy, the subsequent edition of the Bishop's *Directives* allowed for hormonal treatment in hospitals but only to delay ovulation, thus necessitating a pregnancy test and testimony from the woman about her cycle (NCCB 1995, dir. 36). While seemingly tolerant and possibly even favorable of contraception, the abortion-rights group Catholics for a Free Choice (CFFC) conducted an undercover survey and found otherwise: this rule resulted in more than 4 out of 5 Catholic hospitals never providing post-coital pills to women and less than 1 out of 4 offering referrals elsewhere (Bucar 1999). At that time, Catholic hospitals were more likely than non-affiliated hospitals to prohibit discussion, prescription, and dispensation of this treatment to rape survivors, despite its status as the medical standard of care (Smugar et al. 2000). CFFC distributed its results to over 30 media outlets to shame the Catholic hierarchy and motivate reform (Miller 2015, pp. 174–89).

In sum, the novelty of the technology and the legal stakes of contraception and abortion encouraged physicians to develop new classificatory schemes. Their ethical and religious values mediated how they used their knowledge of the treatment's mechanism to define what it was and to distance it from what it was not. To avoid the connotations of 'abortion,' pro-contraception scientists and physicians sought to distance the post-coital pill as merely a 'contraceptive' or 'interceptive.' Anti-abortion Catholics rejected the ACOG's definitions as ethically suspect, but Catholic advocates of women's rights defended the morning-after pill either for limited use (McCarthy) or as a necessary component of women's health care (CFFC). Related to their different ontological commitments, these different schemes highlight divergent conceptions of women's reproductive health, either prioritizing women's agency or circumscribing it to her procreative ability. Furthermore, the disagreement within each group resulted from their different values and the empirical uncertainties of the drug's mechanism.

Reflecting on this historical episode, we see how the clinical function of the mechanism went beyond justifying claims about effectiveness or even counselling patients accordingly—the *evidential* functions discussed extensively by existing philosophical accounts (Clarke et al. 2014; Dragulinescu 2017; Howick 2011; Illari 2011, 2017; La Caze 2011; Russo and Williamson 2007, 2011, 2012; Thagard 1999). Instead, understanding the mechanism and the uncertainties surrounding it factored into debates over treatment categorization and prompted the expansion of old categories like 'contraception' and the development of new concepts like 'interception.' Classifying the morning-after pill was not simply a dispassionate or abstract enterprise but a thoroughly ethical one with concrete stakes involving early stages of human life, treatment for rape survivors, and women's rights. It pitted Catholic OB/GYNs against non-Catholics, but it also elucidated conflict within each group because of different values and uncertainties. As we shall see, struggles surrounding the mechanism and patients' access only increased as the drug became more widely available outside the oversight of physicians.

4. A Political Instrument for/against Access and Agency

Finally, we move from justification in the clinic to application in the wider realm of government and healthcare policy. When going beyond the lab and the clinic, philosophers of science have acknowledged that mechanistic knowledge has the practical potential to enable *control*—both of biology (Craver and Darden 2013) and society (Cartwright and Hardie 2012; Russo 2012; Russo and Williamson 2012). Mechanistic knowledge has allowed humans to intervene on causal processes with treatments targeting the various links of the causal chain, e.g., attempts to cure or manage cystic fibrosis via therapy of genes, transcription factors, protein synthesis, or immune response. Craver and Darden call this the "*pragmatic value* of knowing how something works"

(2013, pp. 186–95, my emphasis; see also Au 2016). Russo (2012) argues that evidence of mechanisms also provides policy makers relevant information about the available causal pathways for intervention so that they act on factors that are both causal and manipulable, rather than spurious and inaccessible (see also Russo and Williamson 2012; Marchionni and Reijula 2018). Cartwright and Hardie (2012) argue that while RCTs can decisively "clinch" conclusions about treatment effectiveness at a trial, they do not provide answers to information about process, which is necessary for successfully predicting whether/how a treatment will work elsewhere. Thus, to make reliable predictions about policy-effectiveness, they suggest policy makers reason mechanistically about the steps required and processes responsible for such effectiveness (see also Cartwright and Stegenga 2011). For instance, writing the steps from start to finish can help policy makers identify relevant support factors, and diagramming processes fleshes out implicit assumptions and potential negative feedbacks.[12]

Nevertheless, as well shall see, the control afforded by mechanistic information goes beyond making effective interventions and policy predictions. These proposals intimate the social power of mechanisms, yet we can go further: this section describes how mechanistic information can factor into economic and legal skirmishes as *an instrument of social power* itself. In the arena of governmental regulation, both advocates and critics of the morning-after pill used mechanistic knowledge instrumentally to increase or limit women's access to this treatment. Anti-abortion science advisers in the US advocated for labeling the morning-after pill Plan B as having a possible postfertilization mechanism, and others later used this label to limit women's insurance coverage. Contemporaneously, envisaging similar barriers in the majority-

[12] Nonetheless, some philosophers have condemned such attempts to generalize or extrapolate from mechanistic knowledge as dubious because of the instability of mechanisms across populations (Howick 2011; see also La Caze 2011).

Catholic country of Chile, pro-contraception scientists designed experiments to pinpoint the mechanism, reduce uncertainty, and promote access to the drug. Beyond utilizing or predicting effectiveness, these scientists and physicians throughout the Americas leveraged mechanistic information for or against women's agency in medicine. To contrast the strategies of anti-abortionists and women's health advocates, this section begins with the US case and then moves to Chile.

Following the discovery of the carcinogenic risks of DES in the early-70s (Hatcher and Conrad 1971), researchers around the world developed alternatives to estrogen, including a progestin-only formulation using levonorgestrel. Women's health advocates led by Sharon Camp sought to increase access to this new formulation, founding the International Consortium for Emergency Contraception (ICEC) in 1995. However, concerns about the allegedly abortifacient mechanism had a market-chilling effect, creating problems for the ICEC in Australia, Burma, Chile, Great Britain, Mexico, the US, and elsewhere (Foster and Wynn 2012; Prescott 2011).

As part of ICEC's campaign to streamline approval abroad, Camp submitted an application for "Plan B" to the FDA, which was approved in 1999. However, women's health advocates were unsatisfied with access limited to prescription holders and adults (18+)—restrictions they considered "special paternalistic scrutiny" without scientific or legal justification (Ellertson et al. 1998, p. 229). Thus, to expand women's access to this "back-up birth control" (hence, Plan B), Camp applied for non-prescription sale over-the-counter. At the 2003 science advisory meeting, the pharmaceutical sponsor argued that the active ingredient *levonorgestrel* does not act after fertilization, rendering the drug "an oral contraceptive, not an abortion pill" (FDA 2003, p. 31).

Committee member Joseph Stanford balked at this anovulatory characterization. A

professor of family and preventive medicine at the University of Utah, Stanford was a Catholic-influenced Mormon physician who believed human life (and personhood) begins at fertilization (Larimore et al. 2004; Stanford 2011). He claimed that postfertilization action was possible because of the capacity of the drug to act five to six days after treatment. Therefore, it was ethically necessary to communicate this possibility to patients for their informed consent (FDA 2003, p. 271; Larimore and Stanford 2000; Kahlenborn et al. 2002). Despite alternative interpretations of the research, five committee members supported a label on the outside carton to inform patients "at the point of purchase" (FDA 2003, pp. 319, 398–411; see chapter 2 for a more in-depth analysis of the meeting).

The committee approved over-the-counter sale (4-NO against 23-YES), but the FDA retained Plan B's prescription-only status for almost three years because of conservative and religious opposition, including anti-abortion resistance (Wynn and Trussell 2006; Prescott 2011). In response to the objections of Stanford and two other advisers (2004), the pharmaceutical company included the mechanism in boldface on the final 2006 label as a "Drug Fact": "this drug works mainly by preventing ovulation (egg release). It *may also prevent* fertilization of a released egg (joining of sperm and egg) or *attachment of a fertilized egg to the uterus (implantation)*. See consumer information leaflet." (FDA 2006, my emphasis). This unique drug label is the only instance describing a mechanism on the carton, and it was later added to the FDA website alongside the mechanisms of other forms of birth control (FDA 2013).

The FDA's official information about the mechanism had substantial effects on women's insurance coverage through the *Burwell v. Hobby Lobby Stores, Inc.* (2014) case. The craft store Hobby Lobby and the Christian bookstore Mardel claimed that governmentally required services such as Plan B were abortifacient and thus sued the government for violating their "religious

freedoms." The plaintiffs relied on FDA information about how Plan B works, and the court allowed them to refuse coverage for their employees as part of their religious rights (Supreme Court of the United States 2013, n. 6, 2014, n. 7). Thus, while the science advisors like Stanford had justified this label to support the agency of *patients* and satisfy their "right to know" (FDA 2003, pp. 405–8), it had a different effect in court. The authoritative information gave anti-abortionists a political instrument with legal currency to support the agency of would-be *providers* to refuse women the drug (for more on the social functions of this label, see chapters 2 and 3).

In contrast to this case in North America, around the same time in South America, we see how women's health advocates utilized mechanistic knowledge as a political instrument *for* women's access and agency rather than against it. In Chile, the advocates of women's health foresaw the potential for information about the mechanism of emergency contraception to limit women's access (Schiappacasse and Díaz 2012). Because of the religious opposition to researching fertility control at the Pontificia Universidad Católica de Chile, physicians Horacio Croxatto (b. 1936) and Soledad Díaz established the Instituto Chileno de Medicina Reproductiva (ICMER) in 1985 in Santiago. They aimed to satisfy "the growing need for effective means to allow people to replace 'all the children God wants to give me' for 'all the children I responsibly want and can have'" (translated from Croxatto 2005).

A decade after leaving the Pontificia Universidad, Díaz discovered that the acceptability of emergency contraception in Chile hinged on reversing the negative perception of its being "microaborto" (a "micro-abortion" acting after fertilization) from Catholics and conservatives (Díaz et al. 2003a, 2003b). In 2001, immediately following approval of the first dedicated morning-after pill in Chile, the Corte Suprema banned their manufacture and provisioning. This

decision was based on the Chilean constitution's explicit protection of "la vida del que está por nacer" (the life of the unborn) (Schiappacasse and Díaz 2012).

The literature available at that time on the mechanism of progestin-only emergency contraception was rather convoluted, especially regarding postfertilization. Many studies evidenced the ability of post-coital levonorgestrel to delay or suppress *ovulation* (e.g., Spona et al. 1975; Garmendia et al. 1976; Landgren et al. 1989; Durand et al. 2001; Hapangama et al. 2001; Marions et al. 2002). However, its effect on *fertilization* was not as well studied or evidenced (limited to Kesserü et al. 1974, 1975), and its effects on *implantation* were difficult to replicate consistently (for positive findings, see Landgren et al. 1989; Moggia et al. 1974; Shirley et al. 1995; Ugocsai et al. 1984; for negative findings, see Durand et al. 2001; Marions et al. 2002). This mixed state of the evidence enabled several scientific reviewers (including Stanford in the US) to claim that post-coital progestin *might* act after fertilization and that patients and providers deserve to know such (Kahlenborn et al. 2002; Larimore and Stanford 2000; Wilks 2000).

Croxatto disagreed with these interpretations of the evidence, pointing instead to the earlier mechanisms of inhibiting ovulation and sperm migration (Croxatto et al. 2001). Previous studies had relied on indirect measures of embryological development, such as trial statistics, endometrial receptivity, and hormones levels. In contrast, using different timings of levonorgestrel administration, ICMER researchers made more direct measurements of development, including the number of eggs ovulated, fertilized, and implanted in rats (Müller et al. 2003); follicle size and pregnancy in *Cebus* monkeys (Ortiz et al. 2004); and follicle size in humans (Croxatto et al. 2004). In all three studies, they found this progestin inhibited or suppressed only ovulation—not fertilization or implantation. After the 2004 double-blind trial in

humans, Croxatto considered the results definitely supportive of pre-fertilization mechanisms (Population Council 2005).

Nonetheless, ICMER's work was insufficient to convince beyond a reasonable doubt the Tribunal Constitutional in 2008 that this drug could not work after fertilization; therefore, the court effectively banned public provisioning of emergency contraception because of the mechanism (Schiappacasse and Díaz 2012). While unsuccessful in Chile, ICMER's work promoted further study that confirmed their findings (e.g., Lalitkumar et al. 2007). The empirical uncertainty of this pill's mechanism seems to have lessened over time, particularly as some anti-abortionists have come to reject a postfertilization effect (e.g., Austriaco 2007). However, the controversy remains unresolved in much of North and South America, with a powerful minority of anti-abortionists continuing to assert the possibility of a postfertilization effect based on different standards of evidence (e.g., Kahlenborn et al. 2015).[13]

The situation is different in Europe. Based on these empirical developments, the ICEC issued joint report with the International Federation of Obstetrics and Gynecology that concluded levonorgestrel works by inhibiting ovulation and maybe fertilization but "cannot prevent implantation of a fertilized egg. Language on implantation should not be included in [levonorgestrel emergency contraceptive pills] product labeling" (FIGO and ICEC 2011). Accordingly, the French manufacturer of the levonorgestrel-only pill NorLevo removed reference to implantation in its information leaflets for doctors and patients (HAS 2015). Part of the reason for this discrepancy between Europe and elsewhere is the relatively lesser political clout of anti-abortionists and the Catholic Church in much of the continent. The supporters of the

[13] While beyond the scope of this chapter, I think that such standards are empirically unsatisfiable and thus deceptive. Chapter 2 explicates these value judgments, and chapter 3 criticizes them.

morning-after pill in Chile also sought to quell political opposition by producing mechanistic knowledge *for* women's access and agency. Croxatto and Díaz granted the importance of patients' values but were not willing to obstruct access without what they took to be strong evidence against postfertilization action.

In these governmental arenas, the role of mechanistic knowledge was pragmatic but beyond the specific sense offered by philosophers of predicting or intervening effectively through treatment and policy (Cartwright and Hardie 2012; Cartwright and Stegenga 2011; Craver and Darden 2013; Darden 2006; Marchionni and Reijula 2018; Russo 2012; Russo and Williamson 2012). Instead, scientists leveraged knowledge about the mechanism in regulatory battles as *epistemic means for their political goals*. They saw the legal and political utility of information about mechanisms, either for or against access, and as science advisers or researchers they produced and promulgated those forms of information for governmental bodies. The US opposition used its mechanistic knowledge to create warning labels about postfertilization possibilities. Corporations later used this information to challenge their legal obligation to provide such pills in order to protect their "religious freedom" and the zygotic life they considered to have legal and human rights. In turn, the information disabled women as patients and consumers by restricting their coverage and access. In contrast, Chilean advocates challenged these claims with a carefully designed set of experiments, which ultimately influenced the labeling in Europe. In both episodes, values mediated how scientists used their knowledge of the mechanism: either to protect the agency and economic interests of would-be providers or to increase women's access and agency. Mechanistic information provided scientists a political instrument for achieving their political goals, again showcasing how knowledge about mechanisms is used for more than immediate therapeutic effectiveness.

5. A Broader Scope for Understanding Mechanisms

Having moved back and forth between the abstractions of philosophy and the particulars of history, this chapter analyzed the production and use of mechanistic knowledge through several episodes in labs, clinics, and beyond. This section reflects on this HPS iteration and the challenges it raises for existing philosophical accounts. As we've seen throughout, the philosophical conversation on mechanisms is ready to be expanded. To recapitulate: rather than merely providing a heuristic for discovery, reasoning about mechanisms offers moral guidance when considering intervening on a process related to ethics or politics (Section 2). Aside from its possible evidential import for justifying effectiveness, knowledge about mechanisms informs clinicians in their categorization of treatments by relating medical definitions to their ethical connotations and political stakes (Section 3). Finally, instead of functioning as a tool only for making effective applications and policy, mechanistic information can also factor into political struggles as an economic and legal tool for achieving certain goals and undermining others (Section 4).

Because philosophers wish to provide practical and applicable accounts of mechanism, the time has come to broaden our scope to attend to the variety of challenges faced by scientific practitioners, physicians, and policy makers. While the three proposals of philosophers (heuristic for discovery, evidence of effectiveness, and instrument for effective control) provide important insights into scientific practice, they constitute a limited set of the possible reasons that researchers, clinicians, and institutions take mechanisms to be important. The limitation itself points to a deeper issue about our philosophical scope. The existing accounts of mechanisms focus the imminent and proximate issue of a drug's *effectiveness*: either creating, understanding,

or utilizing treatments that produce a desired effect. Mechanistic reasoning does often shape scientific practice toward effective treatments; however, we have seen how scientific and social interests in mechanistic knowledge do not always arise from desires to develop effective drugs, justify claims about their effectiveness, or plan effective interventions. *The next step in the philosophy of mechanisms is to articulate the broader function of mechanistic knowledge and reasoning*. Typified by these episodes in the history of the morning-after pill, a more holistic and contextual understanding should attend to human values and the social aspects of biomedicine and health policy.

Across these historical episodes, we have seen how mechanistic reasoning relates not only to whether a treatment produces an effect that is desired, but *whether, when, and why that effect and that treatment are desirable in the first place*. In so far as knowledge of a drug's mechanism relates only to therapeutic effectiveness, one must take for granted the desirability of the effect and thus the desirability of having an effective treatment. That is, if it remains uncontested that an effective treatment is wanted or needed *regardless of the physiological mechanism*, then the existing functions proffered by philosophers might suffice. A simple example might be cancer, which easily evinces widespread public contempt and has even provoked the so-called "War on Cancer." If all is fair in love and war, then the means by which we battle cancer matter little apart from their potential for victory (i.e., effectiveness). For simplified cases of uncontested targets, it is possible that scientists could strive to make the treatment happen, thinking about mechanisms without moral reflection or political implications.

However, when the treatment itself is contested as a legitimate form of medicine or politicized otherwise, then we need to go beyond effectiveness to understand the holistic and contextual significance of mechanistic reasoning. The "War on Cancer" is a telling example:

industry and anti-regulation advocates designed this wartime rhetoric to motivate streamlined approval for cancer treatment and to distract from preventative policies that would reduce industry profit (Coleman 2013; Davis 2007). Furthermore, we need to think more broadly and critically about what 'effectiveness' even means. The case of the morning-after pill supports these imperatives. Emergency contraception is desired by many for improving women's health and increasing self-determination, in part because their ontological and ethical beliefs about women's bodies encourage effectiveness after fertilization. However, this very form of treatment is contested by others for its temporal proximity to abortion and its physiological potential to act indiscriminately after an ontological change that they deem ethically significant (namely, fertilization). Since knowledge about mechanisms is important for defining technologies as 'contraceptive,' 'abortifacient,' or otherwise, biological mechanisms are integrally connected with value-laden ontological and ethical beliefs. When intervening on causal processes carries such societal stakes, we should expect mechanistic knowledge and reasoning to connect with these other aspects of human life involving norms and values.

We are now well posed to reorient the philosophical discussion about the production and use of mechanistic knowledge. Certainly, as philosophers have been arguing, "mechanisms matter!" Yet, as we've seen throughout these episodes with the morning-after pill, interest in the mechanism of action *ultimately* derives from how knowledge about it allows us to understand, promote, or control health for individual patients and society. *Thinking mechanistically involves the potential to reorder human individuals and societies toward normal and normative states*, *with all the social norms, ethical values, and political stakes such interventions entail.* In the case of women's reproductive health, medicine is clearly a thoroughly ethical and political enterprise (Wynn and Trussell 2006). Many view contraception and abortion as constitutive of

women's health, but access to these treatments remains under constant threat throughout the world (Foster and Wynn 2012). In the US, the courts have reduced federal requirements for insurance coverage of contraceptives while state legislatures continue to chip away at the number of abortion facilities and providers with overly burdensome regulations (Guttmacher Institute 2018). This study suggests philosophers ought to consider the broader functions of mechanisms for scientists, patients, providers, policy makers, and society—particularly if we want to do more *socially relevant* philosophy of science (Fehr and Plaisance 2010; Weaver 2017).

Now, one might wonder about the extent to which this need for a broader scope can be generalized beyond or abstracted from my case study and the context of women's reproductive health. *When must we go beyond effectiveness to understand the production and use of mechanistic knowledge? How frequently does mechanistic reasoning involve these humanistic and cultural issues?* Rather than generalizing from a single case, I have sought instead to bring new perspectives to our understanding of mechanisms that are cogent and broadly applicable (see H. Chang 2011). Thus, I aim to go beyond my case study and the context of women's reproductive health to mechanisms in science and medicine more broadly. To show that my argument is about specifically *mechanistic* knowledge (and the associated philosophy of mechanisms) rather than any politically or ethically relevant knowledge in science, I need make the case for its applicability within that class of knowledge.[14] I will make this case using three issues that span across biomedicine and health policy, beginning with early-life and near-death interventions and ending with pharmaceutical development. These examples encompass embryology, cardiology, neurology, pharmacology, and translational medicine.

First, the production and use of mechanistic knowledge in human-embryo research (e.g.,

[14] I thank David Teira and Ashley Graham Kennedy for suggesting this objection and possible responses.

IVF, embryonic stem cells, and cloning) shares many features with the morning-after pill, illustrating the prevalence of such issues throughout embryology and reproductive health. For instance, during the 1980s and '90s, mechanistic reasoning about the timing of conception provided similar moral guidance for/against intervention during the spread of IVF clinics. Subsequent ethical oversight of such practices prompted the creation of the new category of 'preembryo' (or, not quite an embryo) referring to the first 14 days after fertilization, with mechanistic knowledge again aiding categorization for clinics over ethical terrain. The National Institutes of Health's "14-day rule" limits research on human embryos beyond the point of gastrulation, following resistance from advocates of embryos' human rights. The rationale behind the rule was "pluralistic" and mechanistic: this biologically significant point of transition served as a compromise between those with different values regarding prenatal life (see Hurlbut 2017).

Like early-life interventions, the desirability of near-death treatments also turns on issues surrounding the parts of the process. The controversies over *brain death* illustrate how mechanistic reasoning outside embryology and reproductive health relates to ethical and cultural values other than when life begins. In the late 1960s, doctors faced new ethical concerns about organ transplants and life support. An ad hoc committee at Harvard Medical School influentially argued that the medical definition of 'death' ought to be the cessation of neural activity (hence, 'brain death') resulting in an irreversible coma, rather than the traditional definition based on the cessation of cardiovascular activity. The committee justified this novel criterion for death based on the decreased suffering of family members and those seeking organs as well as the need for a new criterion for terminating life-sustaining treatment (Rothman 2003). While widely accepted in the US and elsewhere, not everywhere followed so quickly, particularly in Japan and Israel. In

traditional Japanese culture, death was observed as a communal process. Thus, rather than a single moment in an individual's life, a person's death was a recognition of this change by their community that extended in time. Public resistance to assimilating the Western concept of brain death was based in part to these divergent values and norms related to personhood and death (Hoshino 1993; Nudeshima 1991). In Israel, as a comparison, there were controversies over interpreting authoritative Jewish texts regarding the definite signs of life, such as breath, heartbeat, and procreation. One crucial consideration was whether 'death' involved loss of blood flow to the head, rendering it a biological process like decapitation, which was widely viewed as a sign of certain death (Gross et al. 2018). Across these contexts, we see how mechanistic reasoning about the process of death involved ethical issues, like the termination of life-sustaining treatment, and cultural norms, like the recognition of death by one's community.

Outside issues common in bioethics, the design and structure of biomedical research illustrate how pharmaceutical companies use mechanistic knowledge for financial gain. Consider the design of *surrogate endpoints*, which researchers use to evaluate the effectiveness of drugs in the place of more patient-relevant outcomes like morbidity and mortality. The possible therapeutic significance of mechanisms for evidencing effectiveness via surrogate endpoints can be outweighed by commercial pressures. Why? Systemic problems with industry funding can overwhelm our knowledge base without corrupting the reasoning of individuals (Holman and Bruner 2017). For instance, during the 1980s, anti-arrhythmic drugs became popular treatments for patients who had suffered heart attacks. The trials evidencing their effectiveness, however, were based on the endpoint of suppressing arrhythmias rather than reducing deaths. While nearly all arrhythmias were harmless, a substantial portion of heart attacks were precipitated by them, which researchers and physicians took as evidence of their key role in the process. (They

reasoned mechanistically that when the ventricle contracts arrhythmically with an extra beat before it has time to refill, it could at times damage the lungs, brain, and kidneys and ultimately lead to the mortality risk observed.) However, Bennett Holman (2017) has argued that the surrogate endpoint gained credence not simply on the ground of mechanistic reasoning: more instrumentally, the drug industry shaped the medical discussion by manufacturing expert consensus over it for FDA approval. By supporting researchers with pro-industry results, the drug sponsor amplified the impact of commercially favorable articles to promote this lucrative mechanistic knowledge. While there was a body of evidence supporting the arrhythmias-suppression mechanism, this evidence itself was the result of sustained pressure from industry to justify the use of these drugs. Therefore, the very category of 'effectiveness' has economic value that influences how mechanistic knowledge is produced and used.

This case of the commercialization of mechanistic knowledge might seem ethically or epistemically vicious. Nonetheless, such uses (or abuses) of mechanistic reasoning are common in "translational medicine," which aims to expediate the time "from bench to beside" (Solomon 2015). Drug companies have partnered with universities to secure governmental funding of "basic research" on mechanisms and to externalize the costly risks of early development—all while still securing knowledge with commercial potential for new markets down the road (Robinson 2018). Because of the entanglement of commercial and medical interests, biomedical researchers and their industry benefactors can utilize mechanistic reasoning to make dubious claims about therapeutically irrelevant effectiveness for financial gain. Commercial pressures also disincentivize less lucrative forms of mechanistic reasoning. In the case of bacterial resistance to antibiotics, Ashley Graham Kennedy (2018) argues that developers could utilize the mechanisms of evolution to re-sensitizing bacteria that have acquired antibiotic resistance and

recycle old drugs. However, industry appears to be ignoring this mechanistic knowledge because of the financial incentives for creating new drugs and markets.

In sum, the cultural norms, ethical values, and economic currency associated with 'life,' 'death,' and 'effectiveness' shape mechanistic reasoning in the design and use of pharmaceuticals and other treatments. This variety of examples suggests that well beyond the morning-after pill and outside women's reproductive health, it is common for the desirability of drugs to hinge on their mechanisms.

6. Conclusion: Socially Relevant Medical Epistemology

This analysis provides a constructive expansion on the existing work from philosophers, who have already done much to explain the epistemic and methodological significance of mechanisms in science. Philosophers have illustrated the many ways that societal values actually and inevitably shape scientific research and science policy, for better and for worse (ChoGlueck 2018; Douglas 2009; Elliott 2011; Kitcher 2011; Longino 1990; Weaver 2017). Likewise, this chapter attempts to broaden the existing scope of philosophies of mechanism by providing a richer description of how mechanistic knowledge functions in biomedicine and health policy. Accounting for social forces improves our understanding of the value-laden dimensions of scientific reasoning and how they vary across context, specifically for mechanisms (see Holman 2017; Kennedy 2018; Robinson 2018). This descriptive project aims ultimately at the more normative and critical one of improving how contextual values function in biomedicine and health policy. While direct guidance is beyond purview of this chapter, it does have several implications regarding the philosophy of science and values, research ethics, science pedagogy, and science advising, which I will discuss briefly.

Values have distinct implications for medical epistemology about mechanisms. In several ways, we have seen how values generate "epistemic friction" by influencing what scientists and physicians know about mechanisms, how they produce that knowledge, and how they use it.[15] For instance, concerns about the morning-after pill's mechanism altered the expertise and knowledge either available or absent during early development. Personal moral values (and differences between them) have direct consequences on the methods available to a lab for how it could intervene, such as the absence of Rock's background with human trials and the availability of Chang's proficiency with non-human animals. Furthermore, scientists can be inclined to intervene more specifically and at one point rather than another because of the moral valence of one part of a causal process, such as fertilization for its desired contraceptive capacity or its feared abortifacient potential.

The implications of values in clinics were different but no less definite. The ethical and religious beliefs of clinicians and healthcare institutions promoted the development of new concepts and categories. These values not only limited knowledge production but more pro-actively molded it toward certain norms of health, such as with liminal, ethically ambiguous concepts like 'interception.' Moreover, as treatments spread and the number of users and providers increases, there is a richer diversity of value judgments over how to handle uncertainties. This can lead to disagreement among those with similar beliefs, as we saw with women's health advocates, anti-abortionists, and Catholics.

Values in governmental contexts have different effects. Political battles create feedback effects on the production of knowledge about mechanisms, and mechanistic interests prompt

[15] I thank Robyn Bluhm, David Teira, and an anonymous reviewer for pressing me to expound on these epistemic implications of value-ladenness.

scientists and physicians to act as advocates by promulgating specific forms of information for governmental bodies and producing new sorts of knowledge. Researchers' values are embodied in their standards of evidence, but their standards must pass legal muster to accomplish their desired political goals. Compare Stanford's anti-abortion advocacy as an adviser in the FDA with Croxatto and Díaz's pro-contraceptive advocacy as researchers in a mostly Catholic context. The former found the available evidence enough to support his position against the pill, and he could justify his standard of evidence based on the generally accepted right of patients to know. The latter, in contrast, were unsatisfied with the evidence and thus produced new knowledge with more exacting methods to pinpoint the mechanism step-by-step. Yet, their standard of evidence was insufficient in Chile given the legal protections for the rights of the unborn.

Beyond its intellectual contributions, my analysis also has broader implications for society at large. While contraception and abortion are common topics for bioethicists, they have not attracted the attention of philosophers of science and medicine, potentially seen as primarily ethical issues without epistemic relevance. Such an assumption would be wrong, but it would also be androcentric by overlooking women's widespread use of contraception and its necessity as an essential medicine (Daniels, Jones, et al. 2013; Daniels, Mosher, et al. 2013; WHO 2017). Furthermore, it would render our philosophy socially irrelevant and impotent for making meaningful attempts to understand and improve medicine. As Holman (2017) argues, a "friction-free epistemology" that abstracts from sociological forces is not very helpful for capturing the real-world pressures that are constitutive of medicine.

In contrast, this sort of study can inform critical efforts in research ethics and science pedagogy. For instance, in labs with ethically and politically sensitive objects of inquiry, these real-world examples enable students and practitioners to see how mechanistic reasoning relates

to questions beyond immediate effectiveness for reaching some given endpoint. Creative approaches to ethics education are crucial for developing scientists' epistemic and moral responsibilities beyond their personal values and individual responsibility (Douglas 2014; Rolin 2017). This analysis guides us through rethinking the criterion of effectiveness as not necessarily desirable and probing the connections between ontology, ethics, politics, and epistemology. These historical episodes can help researchers and students contrast alternative values and point to previous ways of handling difficult issues. Accordingly, they can learn how to connect the different layers of mechanistic reasoning, including normative dimensions, and consider the possible epistemic and practical consequences downstream.

In addition, this analysis illustrates the epistemic means by which science advisers can attempt to influence governmental agencies and the courts, particularly how they can succeed and fail as advocates. While philosophers of science have sought to provide practicable guidance for science advisors (e.g., Douglas 2009; Steele 2012), their suggestions of avoiding wishful thinking and implementing rational decision theory do not address some of the political realities of the contentious advisory process. For one, science advisors wield significant political power in policy making, akin to a "fifth branch" of government (Jasanoff 1990). At the time of the FDA labeling, anti-abortion advisers expressed concerns for *the rights of women* as consumers who were opposed to abortion. Yet, their label's larger achievement for anti-abortionists was in advocacy for *the rights of employers* to refuse insurance coverage based on "religious freedom." Second, this analysis illustrates the need for the courts to reconsider the seeming value-freedom of information. "Drug Facts" produced by the FDA can be value-laden with special interests, such as how anti-abortion advisers advocated for a warning label to protect zygotic life. Because of how its authoritativeness overshadowed its political function, this mechanistic knowledge

effectively restricted women's healthcare options and agency. In the next two chapters, I focus on these worrisome consequences of the FDA's information.

If we want to practice socially relevant philosophy of science, the time has come to connect medical epistemology with the cultural and value-laden aspects of biomedical research and clinical practice as well as the politics of health (Fehr and Plaisance 2010). Such links are important for understanding drug development, where industry wields significant power, and particularly for reproductive health, where conflicting values and gender politics limit women's access and agency. As scientists develop new means of contraception and abortion, these technologies will continue to be evaluated according to these shifting social stakes that hinge in part on the mechanism of action. Epistemology in context and in practice is full of contentions, but so is medicine. By accounting for the specific challenges that arise with mechanistic reasoning, we can take another step toward tackling them.

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Chapter 2.

"Drug Facts" and Values:

Uncertain but Powerful Knowledge about Emergency Contraception

Abstract: How and why are facts value-laden? This chapter answers these questions by investigating the debates at the US Food and Drug Administration (FDA) during the early 2000s surrounding Plan B's "drug fact" that this morning-after pill "may prevent implantation." Drawing on feminist criticisms of fetal-centrism in medicine, I focus on zygote-centrism, one operative set of values about women's reproductive health. Zygote-centrism biased researchers away from the health of women and toward their reproductive capacity and its products, specifically the life of zygotes. I then conduct a survey of value judgments at different levels of uncertainty, followed by a contextual analysis of the social utility and currency of "drug facts" comparing the US with France. I conclude that this "drug fact" is value-laden both constitutively and socially. First, because value judgments played a variety of roles in making the claim factually certain, there was a deep entanglement of fact and value. Second, because of the social currency of this "drug fact" for protecting would-be providers' refusals, it has empowered anti-abortionists to impose their values on women and limit their drug access. The social significance of recognizing these two senses includes undermining the use of hedged hypotheses as a value-free solution for scientific advisers.

1. Introduction

In biomedicine, healthcare, and regulatory science, feminist advocates of women's health often struggle with proponents of fetal health, and this conflict has significant effects on medical

knowledge and practice (Armstrong 2003; Kukla 2010; Waggoner 2015). For instance, in 2006, the US Food and Drug Administration (FDA) approved a new label for the emergency contraceptive Plan B, which included the "drug fact" that this morning-after pill "may also prevent implantation." As we saw in chapter 1, FDA advisers who opposed abortion expressed concerns that if this contraceptive acted after fertilization it would be abortifacient; therefore, the FDA and pharmaceutical company included this claim on the drug packaging after (FDA 2003, 2006; see ChoGlueck 2019). The FDA's authoritative statement about Plan B became the scientific premise of a landmark Supreme Court decision less than a decade later, but around the same time the French manufacturer removed a similar statement about implantation from its patient package inserts (HAS 2015).[16] How can we better understand this seemingly uncertain but powerful "drug fact" about the mechanism of emergency contraception?

Philosophers of science have come to use the concept of *value-ladenness* to describe the different ways that values—including cognitive, scientific, contextual, and ethical ones—are "encoded" into background assumptions and standards of evidence, which scientists use to reason between theories and data (Douglas 2009, p. 18; Longino 1990, p. 216). These accounts of values in science agree that scientific knowledge production has societal stakes, which inevitably influence the demand and uptake of knowledge (ChoGlueck 2018). But if science is saturated with value judgments, creating a whole "tapestry of values" (Elliott 2017), how are the different threads weaved together? Moreover, what is the relation of these values in science with the social value of knowledge in society?

Toward providing a more comprehensive account of how and why values pervade

[16] *Burwell v. Hobby Lobby Stores*, 573, U.S., 1, 9 (2014). See footnote 7. https://www.supremecourt.gov/opinions/13pdf/13-354_olp1.pdf.

science, this chapter synthesizes disparate accounts of value judgments. Furthermore, I connect the operation of values in constituting scientific knowledge with the social function of knowledge as useful for certain political and economic goals. Thus, I argue that knowledge can be value-laden in two connected senses: a *constitutive* sense, in which values played a role in managing different uncertainties about a claim's status as fact, and a *social* sense, in which the claim's uneven social currency differentially enabled certain groups to achieve their political goals at the expense of others' aims.

To develop this account, I turn to the controversy over the FDA's "drug fact" about Plan B's allegedly abortifacient mechanism. I draw on feminist criticisms of medicine in section 2 to situate this case within a broader context of fetal-centrism. Section 3 then examines *zygote-centrism*, a related set of value operating in this episode that were likewise criticized by feminists and women's health advocates. This analysis draws on the meeting minutes from the FDA's science advisory committees (FDA 2003), which resulted in the 2006 label, as well as pertinent medical literature, such as review articles, bioethics articles, and opinion pieces. Section 4 surveys value judgments about Plan B's mechanism at various levels of scientific uncertainty, and section 5 compares the social implications of the US government's decision with simultaneous developments in France.

My case study makes three contributions to philosophy of science and medicine. First, while feminist philosophers have criticized obstetrics and public health for their fetal-centrism regarding reproductive risks during pregnancy (e.g., Kukla et al. 2009; Lyerly et al. 2009), less critique has been levied toward zygote-centrism within gynecology around conception. Second, previous philosophical analyses of commercial values in regulatory science pit economic interests against public-health concerns (e.g., Cranor 1993; Elliott 2011; Shrader-Frechette

1991). I consider the entanglement of economic and health interests in reproductive healthcare (see Murphy 2012). Third, unlike others forms of sexism that have received feminist attention like androcentrism (see Lloyd 2005; Longino 1990), zygote-centrism is less directly male-focused than reproduction-focused. Instead, it is pro-natalist and has strong connections to the protocols of Catholic institutions in the US such as hospitals (Miller 2015).

This study also has social significance because it challenges the plausibility of science advisers' using "hedged hypotheses" to remain value-free (Betz 2013). In addition, by exposing how constitutive and social value-ladenness allows for social control, this chapter can inform efforts to better diagnose and ameliorate reproductive injustice in women's health. My critical analysis of zygote-centric values in this chapter illustrates how sexist values can be *imposed through value-laden facts* on women for oppressive purposes. Building on my examination of mechanistic knowledge as a tool for social power in chapter 1, this chapter enables the normative analysis in chapter 3. There, I argue that these values are a sexist ideology and that the label contributed to patriarchal oppression. But before we can evaluate the influences of these values, we must first understand their nature and place in society.

2. Values in Medicine: Centering Fetuses, Decentering Women

This section discusses the fetal-centrism widespread in medicine to better contextualize the values operative in the morning-after pill episode. In the United States and elsewhere, there are many laws and regulations that treat pregnant women like mere "fetal containers" or "maternal environments" for the "precious cargo" within (Duden 1993; Lupton 2012; Rothman 1989). The "fetal container" model of pregnancy is based on a perceived conflict between pregnant women and developing fetuses when women are seen as negligent or deviant (Annas 1986; Macklin

1990; Purdy 1990). This belief is codified in laws that coerce pregnant women into procedures without their consent to protect fetal health and criminalize their resistance as "fetal neglect." These laws pit pregnant women against their fetuses because of gender norms about "bad mothers," especially poor women, women of color, and indigenous women (Armstrong 2003; Roberts 1997; Waggoner 2015). The value behind these gender norms, models, and laws is *fetal-centrism.* It holds that the health, wellbeing, and rights of pregnant women are separate from, often opposed to, and relatively less important than those of their developing fetuses and potential children.

Fetal-centrism is common in medicine and healthcare in the US. Concerns about causing birth defects have limited medical research by excluding women from clinical trials (Baird 1999; Epstein 2007; Langston 2016). These policies were based on one "fundamental misconception": "*All women are always pregnable and therefore* (through the magical operation of the mind characteristic of unconscious sexism) *always pregnant*" (Merton 1993, p. 387). Policies excluding "women of childbearing potential" from clinical trials have rendered medical knowledge *androcentric* (based more on male bodies) and thus negligent of women's health (Bueter 2015; Merkatz and Junod 1994). Fetal-centrism is also embedded in regulations and clinical guidelines that take hazards to fetuses to be a *special* form of risk for which pregnant women are *uniquely* responsible (Kukla 2010; Lyerly et al. 2007, 2009). In obstetrics, even routine pregnancies are monitored like "high risk" ones to protect the fetus. Increased surveillance can decenter pregnant women, reducing them from active subjects to passive patients or even inert objects (Freeman 2015; Ginzberg 1989; Lyerly et al. 2007, 2009; Rothman 1989). In turn, fetal-centric practices in obstetrics can alienate and disembody women from their own bodily experience of pregnancy (Duden 1993; Young 1984). For instance, healthcare

professionals discount women's own testimony of uterine contractions and instead privilege fetal-heart monitors (Freeman 2015). Even further, recent public-health programs from the Centers for Disease Control promote "preconception health": first by lumping all women of reproductive age (i.e., 15–44 years) together as "prematernal" and then by encouraging them all to prepare for their assumed future fetus's health (Waggoner 2015).

According to fetal-centric reasoning, the fetus deserves the status of a full human person or, at least, a distinct patient from the pregnant woman (Duden 1993; Mahowald 2006). Fetal-monitoring technologies have enabled this individuation, and more recent innovations in maternal-fetal surgery prioritize fetal health (Duden 1993; Lupton 2014; Lyerly et al. 2001; Rothman 1989). Furthermore, fetal-centrism skews our reasoning about risks to the maternal-fetal unit by *stigmatizing* interventions on pregnant women for their health while *encouraging* extra measures when there is any risk to the fetus (Langston 2016). This double standard for intervention is justified by "the pursuit of absolute zero risk to the fetus," which is untenable and neglectful of women's health (Lyerly et al. 2009, p. 40, 2007).

Feminists have criticized these fetal-centric values in medicine *in so far as they decenter women's health, limit their agency, and neglect their interests.* Feminists suggest more critical conceptions of the moral relevance of the gestational tie. For instance, if the fetus is understood as a dependent part of the woman, it might have partial or potential personhood rather than the full moral status of an actual person (Mahowald 2006). Feminists also promote more engaged, cooperative, and egalitarian relations between doctor and patient, recognizing the importance of patient expertise and values in medical decision making (Freeman 2015; Kukla et al. 2009; Mahowald 2006). Nonetheless, when a value system is dominant in society, it is likely to find its way into science (Longino 1990). Fetal-centrism remains prevalent throughout the US healthcare

system, and there are many facets through which values and gender norms saturate medicine. These dimensions include ontological beliefs about embryos/fetuses and (possibly) pregnant women, ethical commitments about their moral statuses and responsibilities, and pragmatic issues about patient-provider relations and the agency of women.

In debates over the morning-after pill, one form of fetal-centric values played a decisive role in prompting and producing a drug label about its mechanism. Yet, in this case, the focus was on the *earliest* stages of embryonic development around the time of conception: in the eight weeks before an embryo becomes a fetus, during the period between the fusing of egg and sperm (fertilization) and its implantation onto the uterine wall. Furthermore, unlike other varieties, the operative fetal-centric values here were *pro-natalist*, obliging pregnant women to continue their pregnancy regardless of maternal wellbeing, even in the case of sexual assault.[17] Women's health advocates criticized these values because of how they decentered women, yet the dominance of fetal-centrism was strong enough to negate their criticisms.

3. Zygote-Centrism and the Case of Plan B's Drug Label

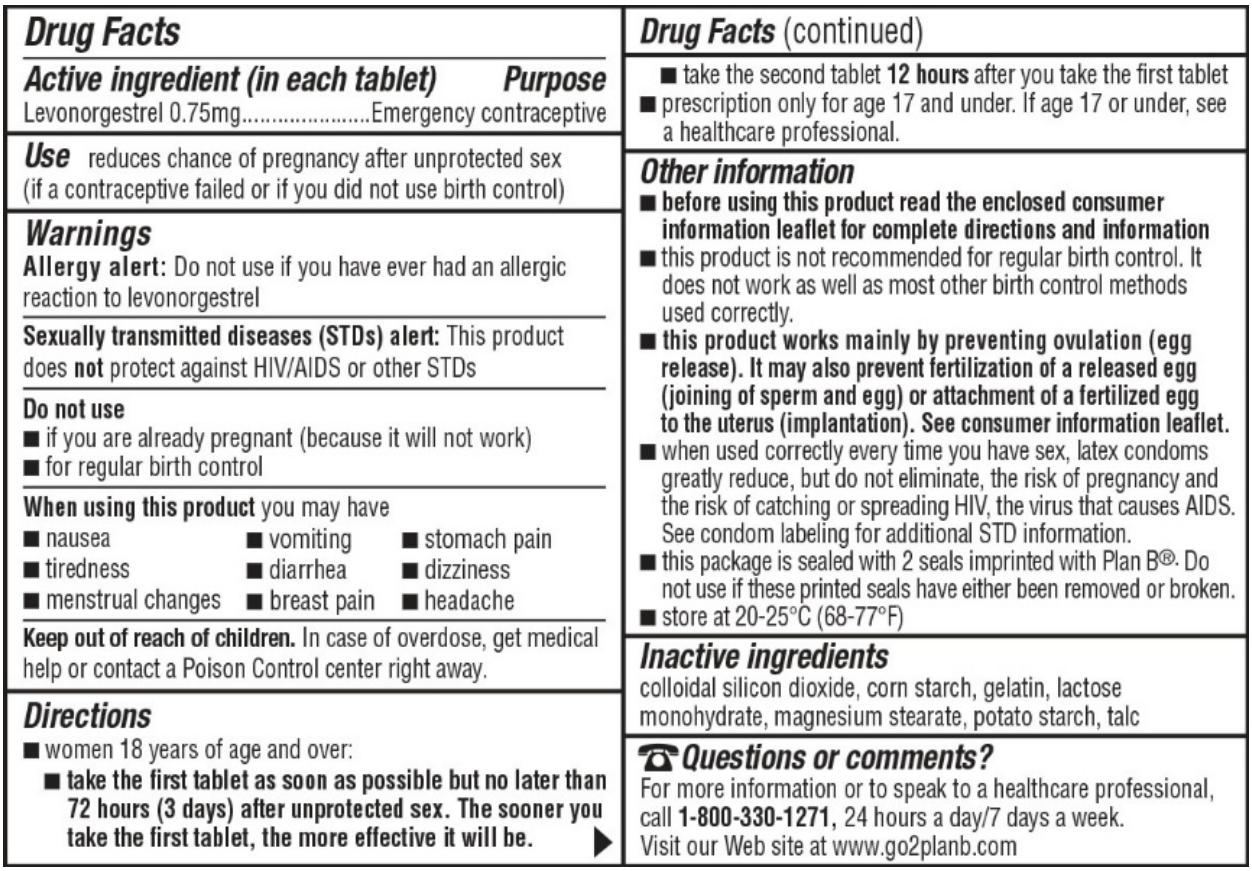
Morning-after pills are one form of emergency (post-coital) contraception that reduces the chances of pregnancy when taken after unprotected sexual intercourse. It is commonly used as a prophylactic for pregnancy after birth-control failure, unprotected sexual intercourse, or rape. In 1999, the FDA approved the morning-after pill Plan B (a progestin-only formulation of levonorgestrel) for prescription-only sale to women 18 and over. Subsequently, at a 2003 meeting between advisory committees, women's health advocates collided with anti-abortionists

[17] In contrast, some fetal-centric values are permissive of therapeutic abortion, such as teratologists who may discourage continuing pregnancy because of the risks of birth defects for the fetus, rather than any maternal condition or need (Löwy 2017). These *non-natalist* fetal-centric values are the subject of chapter 5 in part III.

and social conservatives over a supplemental application for switching Plan B from prescription to over-the-counter access without an age restriction. Women's health advocates wanted to increase access to this effective postcoital pill—regardless of how late it acted—while anti-abortionists sought to protect zygotic life by opposing such a pill. Although beyond this chapter's scope on the pill's mechanism, other critics of the switch also worried that it might promote adolescent promiscuity and disease transmission—despite disconfirming evidence available at the time (Jackson et al. 2003; see Wynn and Trussell 2006a, 2006b).

While advisers overwhelmingly voted for the switch (23 to 4), the FDA commissioner delayed approval for over two years, resulting in the resignation of Susan Wood, director of the Office of Women's Health. In her public resignation letter, she suggested the reason was ideological rather than "based on scientific and clinical evidence," citing Thomas Henry Huxley: "Science commits suicide when it adopts a creed" (Wood 2005, p. 1650). Although regulatory decisions always involve scientific and political considerations, both proponents and critics of the switch criticized the FDA for being "political" rather than "scientific," i.e., that "politics trumps science" (Grimes 2004; compare, e.g., Drazen et al. 2004; Stanford et al. 2004). Nonetheless, according to the US Government Accountability Office, the FDA's decision to deny the switch to over-the-counter was "unusual" because of the top-down nature of the delay and the commissioner's justification based on concerns about adolescents (GAO 2005). Furthermore, the few advisers who opposed the switch, as well as the FDA commissioner, were political appointees of President George W. Bush, a strong opponent of contraception and abortion (for more on other aspects of the FDA decision, see Prescott 2011; Wynn and Trussell 2006a, 2006b).

While the agency eventually approved the drug for over-the-counter sale, it was the only



Drug Facts

Active ingredient (in each tablet) **Purpose**
Levonorgestrel 0.75mg.....Emergency contraceptive

Use reduces chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings

Allergy alert: Do not use if you have ever had an allergic reaction to levonorgestrel

Sexually transmitted diseases (STDs) alert: This product does **not** protect against HIV/AIDS or other STDs

Do not use
- if you are already pregnant (because it will not work)
- for regular birth control

When using this product you may have
- nausea
- vomiting
- stomach pain
- tiredness
- diarrhea
- dizziness
- menstrual changes
- breast pain
- headache

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away.

Directions
- women 18 years of age and over:
  - **take the first tablet as soon as possible but no later than 72 hours (3 days) after unprotected sex. The sooner you take the first tablet, the more effective it will be.**

Drug Facts (continued)
- take the second tablet **12 hours** after you take the first tablet
- prescription only for age 17 and under. If age 17 or under, see a healthcare professional.

Other information
- **before using this product read the enclosed consumer information leaflet for complete directions and information**
- this product is not recommended for regular birth control. It does not work as well as most other birth control methods used correctly.
- **this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation). See consumer information leaflet.**
- when used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. See condom labeling for additional STD information.
- this package is sealed with 2 seals imprinted with Plan B®. Do not use if these printed seals have either been removed or broken.
- store at 20-25°C (68-77°F)

Inactive ingredients
colloidal silicon dioxide, corn starch, gelatin, lactose monohydrate, magnesium stearate, potato starch, talc

Questions or comments?
For more information or to speak to a healthcare professional, call **1-800-330-1271,** 24 hours a day/7 days a week.
Visit our Web site at www.go2planb.com

Figure 2.1*: The official "Drug Facts" for Plan B sold over-the-counter. Note the mechanism listed in boldface after the third bullet under "Other information." Image source: FDA (2006, public domain).*

drug to feature an age restriction (18+). Furthermore, its new label featured an unprecedented "drug fact" on the carton conveying in detail the mechanism and its uncertainty: "this product works mainly by preventing ovulation (egg release). *It may also prevent* fertilization of a released egg (joining of sperm and egg) or *attachment of a fertilized egg to the uterus (implantation)*" (figure 2.1, from FDA 2006, my emphasis). Given the controversy around its approval in the broader context of fetal-centrism, what was the role of values in this unique and powerful drug label?

3.1. Zygote-centrism and its critics

Zygote-centrism is the set of values and gender norms that prioritize the health, wellbeing, and "rights" of fertilized eggs (zygotes) over those of the pregnant women who carry them. This view of women's reproductive health is particularly common in the "pro-life" or "right-to-life" movement, which was started by Roman Catholics in the 1960s (Williams 2016). Accordingly, in medicine these values are upheld primarily throughout the Roman Catholic healthcare system, such as the Catholic Health Association (CHA), the Catholic Medical Association (CMA), and the US Conference of Catholic Bishops (USCCB). During the time of these debates, the bishops oversaw 12% of US hospitals and required their adherence to the values and norms in the *Ethical and Religious Directives for Catholic Health Care Faculties* (USCCB 2001; see CFFC 2005; Miller 2015). Unlike their critics, who typically maintained a secular stance in public, zygote-centrists often expressed religious beliefs and affiliations, typically from socially conservative branches of Judeo-Christianity, such as Mormonism and Roman Catholicism. Compared with their critics, the zygote-centrists in this debate included professors from relatively less prestigious universities (e.g., University of Utah, University of South Florida), non-profit researchers who also practiced in family medicine, internal medicine, or pharmacy, and representatives of the "pro-life" movement (e.g., Human Life International, American Life League). A couple were present at the FDA meeting as voting consultants—notably the physician Joseph Stanford—and non-voting members of the public. Zygote-centrists published their reviews in less mainstream journals of medicine and pharmacy—including *Archives of Family Medicine* and *Annals of Pharmacotherapy*—as well as journals affiliated with Catholic organizations and Christianity—such as *Health Progress* (CHA), *The Linacre Quarterly* (CMA), and *Ethics and Medicine*.

Note well: Despite strong connections to Catholic institutions, zygote-centrism is not simply *the* Catholic, *the* Christian, or even *the* religious view (but rather the "pro-life" view). For one, Catholics are a heterogeneous group in their beliefs and practices regarding reproduction (see Miller 2015, on Catholics for a Free Choice), and many zygote-centrists are non-Catholics, such as Mormons, Evangelical Protestants, and conservatives in general (Williams 2016). Additionally, socially progressive Christian and Jewish sects supported increased access to emergency contraception at the FDA meeting (FDA 2003, p. 240). Nonetheless, zygote-centrism is historically rooted in Catholic theology, and it remains the dominant view among the Roman Catholic Church's hierarchy.

Various women's health advocates have criticized this view of women's reproductive health. As we saw in chapter 1, throughout the history of the emergency contraception, there is a blurry line between researchers, doctors, feminists, and pharmaceutical representatives that advocated for increased access to the drug (ChoGlueck 2019; Prescott 2011). The individuals who criticized zygote-centrism included professors from relatively more prestigious universities (e.g., Princeton, Stanford, Edinburgh), non-profit researchers (some of whom also practiced in obstetrics-gynecology), and business executives. Several were present at the FDA meeting as either voting advisers—notably the demographer James Trussell—or non-voting pharmaceutical representatives. These defenders of the morning-after pill published their studies and opinion pieces in mainstream journals of medicine—such as *the New England Journal of Medicine*, *the Journal of the American Medical Association, Human Reproduction*, *Fertility and Sterility*, and the *American Journal of Obstetrics and Gynecology*—as well as journals affiliated with self-described "pro-choice" and "family planning" organizations—including *Contraception* (Association of Reproductive Health Professionals and the Society of Family Planning) and

Population Briefs (Population Council).

While joined in their antagonism toward zygote-centrists and social conservatives, these various women's health advocates are not unified camp in terms of their beliefs, interests, or strategies. For instance, while some pathologized pregnancy and considered the drug a "cure," others rejected this medical model of pregnancy and its implicit devaluation of women (Prescott 2011). Furthermore, their judgment diverged at times, such as their disagreement over the testability of claims about the mechanism (see sub-section 4.2). Despite lacking unity, they opposed the zygote-centric view along several dimensions. The main sites of conflict were the *ontology* of when a woman's pregnancy begins and another human life starts, the *ethics* of preventing and ending pregnancy, and the *pragmatics* of healthcare and medical decision-making.

3.2. Ontologies of reproductive health

Zygote-centrists defined 'conception' and 'abortion' to include earlier stages of embryological development than did their critics. For zygote-centrists, fertilization is the moment at which *human life* begins and a pregnancy is conceived (i.e., 'conception'); therefore, the termination of pregnancy, i.e., 'abortion,' includes inhibition of development any time after a spermatozoon and ovum fuse (Larimore et al. 2004; Wilks 2000). In addition, zygote-centrists have included the zygote and later stages of embryonic development in the category of *human persons* (Wilks 2000, p. 19). To justify this ontology as "medical" (rather than merely religious or ethical), doctors have appealed to *Mosby's Medical, Nursing, and Allied Health Dictionary* (Anderson 2002) for the "orthodox" or "traditional medical definition of pregnancy" (Wilks, 2000, p. 15; Larimore et al., 2004, p. 690).

For many of their critics, on the other hand, 'conception' was synonymous with implantation, so 'pregnancy' begins once an embryo implants into the endometrium. Accordingly, 'abortion' excludes pre-implantation interference, which they define as "pregnancy prevention" rather than "pregnancy termination" (Glasier 1997, p. 1063; Trussell et al. 2004). Some women's health advocates criticized these zygote-centric beliefs because they could limit woman's legal access to abortion (Gold 2005). Yet, unlike zygote-centrists, the advocates of emergency contraception did not have a common stance on when human personhood begins. Gynecologists and medical researchers criticized the ontological categories of zygote-centrists by appealing to the America College of Obstetrics and Gynecology (ACOG) standardized terminology (Hughes 1972) and the "Common Rule" for human subjects research from the Department of Health and Human Services (HHS 2009, sec. 46.202.f).

3.3. Ethics of reproductive health

These ontological beliefs dovetailed with ethical values, moral principles, and sexual norms. Zygote-centrists argued that zygotes as human persons deserve full moral status. Thus, any interference after fertilization constitutes abortion, which violates "the first right of all humans—the right to stay alive" (Wilks 2000, p. 20; see also Larimore and Stanford 2000; FDA 2003, p. 213). Zygote-centrists also adhered to the sexual norms that confined legitimate contraceptive use to cases of rape treatment and prior to fertilization (Ashley and O'Rourke 1997). While generally opposed to contraception, Catholic healthcare ethics allows this limited use in hospitals for emergencies, codified by USCCB (2001) directive #36:

> Compassionate and understanding care should be given to a person who is the victim of sexual assault. Health care providers should cooperate with law enforcement officials and offer the person psychological and spiritual support as well as accurate medical information. A female who has been raped should be able to defend herself against a

> potential conception from the sexual assault. If, after appropriate testing, there is no evidence that conception has occurred already, she may be treated with medications that would prevent ovulation, sperm capacitation, or fertilization. It is not permissible, however, to initiate or to recommend treatments that have as their purpose or direct effect the removal, destruction, or interference with the implantation of a fertilized ovum.

In contrast, the critics of zygote-centrism generally suggested allowing a greater expression of women's self-determination, such as through pregnancy planning and prevention with Plan B (Coeytaux and Pillsbury 2001; Grimes 2002). Some women's health researchers and gynecologists argued that emergency contraception could be a legitimate therapeutic option *regardless of when it acts* because of the financial, psychological, and medical benefits for women (Trussell et al. 2004; ACOG 1997). While some of them focused on the maternal risks of pregnancy, others emphasized the social benefits, such as how greater access to morning-after pills could be a cure for the "epidemic" of unplanned pregnancy (Grimes et al. 2001; see also Prescott 2011; Trussell et al. 2004). Women's Capital Corporation (the original drug sponsor) also promoted sexual norms of responsible planning by choosing its brand to send the "right public health message" that "when Plan A fails, you can go to Plan B" (Prescott 2011, p. 106).

3.4. Pragmatics of reproductive health

Connected to these divergent beliefs are *practical* differences including political and economic strategies and models of doctor-patient relations. As anti-abortionists, zygote-centrists sought to protect zygotic life by limiting access to abortifacient drugs and spreading information about their postfertilization potential via scientific publication (e.g., Kahlenborn et al. 2002; Wilks 2000). With this information, the USCCB lobbied for material exemptions for zygote-centric employers and institutions from legal requirements to furnish patients and employees with insurance coverage for such drugs (Miller 2015, p. 185). Furthermore, zygote-centric physicians

and pharmacists refused providing or filling prescriptions with postfertilization potential (Larimore and Stanford 2000, p. 133; Wilks 2004).

While seemingly permissive, the bishops' *Directives* limit women's agency by allowing for treatment only after testing for ovulation and pregnancy (USCCB 2001, dir. 36). Thus, recent survivors of rape are subjected to the clinical-ethical judgment of hospital staff whether the threat to zygotic life is sufficiently low to offer treatment (Cataldo and Moraczewski 2001, Chapter 11). Furthermore, women are much less likely to be offered or prescribed emergency contraception at Catholic hospitals (Smugar et al. 2000), *with over 80% of Catholic hospitals never providing access* (Bucar 1999). Despite stressing the importance of informing women of their hospitals' restrictions (Pennsylvania Catholic Conference 1993), zygote-centrists justified the paternalistic displacement of the woman's agency to protect not only embryos from abortion but also the institution of (heterosexual) marriage from corruption and the Church from scandal (e.g., Ashley and O'Rourke 1997; Pope John Paul II 1998).

The advocates of emergency contraception criticized zygote-centrists for decreasing women's health and agency over their bodies rather than making them the primary decision-maker. Before FDA approval, Trussell and his colleagues promoted emergency contraception through publicly accessible information online, by phone, and elsewhere (see Trussell et al. 1998). Because requiring a doctor's prescription suggested "special paternalistic scrutiny" of women, feminist health advocates like Francine Coeytaux and Barbara Pillsbury (2001) pushed for over-the-counter access without prescription or age restriction, supported by women's health researchers (Ellertson et al. 1998, p. 229; Grimes et al. 2001).

Yet, promoting women's rights and access with medication entangled the advocates of emergency contraception with commercial interests, specifically in developing its market (see

also Murphy 2012). Sharon Camp, for instance, founded International Consortium for Emergency Contraception (ICEC) to increase access to the drug and then Women's Capital to distribute it more widely in order to reduce prices and increase women's choices; nonetheless, her company relied on the Hungarian pharmaceutical Gideon Richter for manufacturing (Prescott 2011, pp. 103–4). Furthermore, Barr Pharmaceuticals' subsequent acquisition of Plan B from Women's Capital entailed further dependence of women's health advocates on pharmaceutical companies who offered wider access in exchange for increased commercialization and medicalization.

Thus, zygote-centrists espoused various beliefs, commitments, and strategies that contained a host of normative elements. Their critics challenged their ontological views of when conception happens and, more importantly, over whether it entails new moral status. Rather than focusing on women's health and wellbeing, zygote-centrists prioritized the rights of zygotes and the responsibilities of pregnant women to protect them. These anti-abortionists relied on the gender norms about "good mothers" who selflessly protect zygotes and "bad mothers" who carelessly use abortifacient contraceptives. To enforce these gender norms, zygote-centrists promoted knowledge about the abortifacient mechanism, strategized to limited Plan B's access, and lobbied for exemptions to legal requirements to provide emergency contraception. Next, we see how these zygote-centric values enabled specific judgments about scientific evidence and how that zygote-centric reasoning resulted in the debated "drug fact" about its mechanism.

4. Values in Science: Managing Uncertainty about Implantation

Returning to Plan B's label (fig. 2.1), why did the FDA accept this claim about its mechanism as

a “drug fact”? Where did its advisers’ confidence come from? This section discusses the reasons scientific advisers and biomedical researchers gave for attributing or withholding fact status to the claim that Plan B may also prevent implantation (along with ovulation). By *fact status*, I mean the epistemic constitution of the claim as a scientific fact, involving a well-evidenced empirical claim about the natural world. While scientists have a different vernacular of scientific facts as observations or data, society widely associates “scientific facts” with relative certainty and value-freedom and (often) affords them acceptance, confidence, and authority (Jean and Lu 2018). This conception of scientific facts is epistemic, historic, and social: facts are a sort of knowledge claim, and the ascription of fact status to a claim is a historical event debated and accomplished by human actors (similar to Fleck 1979). Thus, I am not interested in the ontology or reality of facts, nor do I intend to reduce their epistemic status to their social construction; rather, this section aims to analyze the reasoning process behind scientists’ assignment of fact status to this claim about Plan B in these regulatory contexts.

This section examines the various ways that scientists manage uncertainty with value judgments. I argue that this epistemic dependence of facts on values entails the *deep entanglement* of the two. Synthesizing previous accounts of values in science, I connect four distinct ways of handing uncertainties (namely relevance, sufficiency, interpretation, and description) involving value judgments but operating at different levels of analysis and decision-making (see ChoGlueck 2018). For instance, Longino’s (1990, 2008) account focuses on how value-laden background assumptions provide heuristics, which determine which observations are *relevant* evidence for a theoretical claim. Douglas’s (2009) account, in contrast, focuses on the more concrete level of inductive risk and the *sufficiency* of evidence for accepting a hypothesis. She includes data *interpretation* and *characterization* as cases of inductive risk, and Kevin Elliott

(2011) elaborates how extrapolating results and *describing* phenomena also involve judgments with societal implications.

For Plan B's "drug fact," zygote-centric values were responsible for the judgments made at each of these levels. This mode of establishing scientific knowledge by deep entanglement, I argue, exemplifies the *constitutive* sense of value-ladenness. I will analyze this complex epistemic situation by providing a survey of disagreements related to value judgments at different "depths" of uncertainty: (4.1) semantics (or description), (4.2) standards, (4.3) interpretations, and (4.4) heuristics (or relevance). Moving through these categories, we will see divergent judgments at each level and the interactions between them.

4.1. Semantics: What does the phrase 'postfertilization effect' mean?

Just about everyone involved in decision-making process took the phrases 'postfertilization event' and 'preventing implantation' to denote the antagonistic effect of levonorgestrel on zygote development within the fallopian tube or uterine cavity. However, their connotations diverged because even describing an effect can involve value judgments (Douglas 2009; Elliott 2011). For zygote-centrists, 'preventing implantation' occurred *between* human persons and, moreover, *against* a person, connoting abortion and the violation of the "right to life" (Wilks 2000; Kahlenborn et al. 2002). In contrast, many women's health advocates took this antagonistic effect to occur solely *within* a person. Before resistance from zygote-centrists, 'preventing implantation' connoted to women's health advocates the different benefits for women users, such as improving their safety by avoiding the side effects of suppressing ovulation (Chang 1967) or increasing efficacy by extending effectiveness from three to six days after intercourse (Grou and Rodrigues 1994). Then, in response to zygote-centrists, advocates of emergency contraception

later came to connote 'preventing implantation' with *a risk to women* by posing a barrier to access (Díaz et al. 2003). Accordingly, zygote-centrists set the terms of the debate with their anti-abortion values.

Zygote-centrists also advocated 'a postfertilization effect' to connote a sense of *remote possibility* with a very low likelihood.[18] According to their own statements, zygote-centrists were interested not only in postfertilization effects "definitely proven to exist or proven to be a common event" but also "rare but important events…even if the possibility is judged to be remote" (Kahlenborn et al. 2002, p. 468). At the meeting, Stanford insisted the committee take seriously postfertilization effects that occur "at times" or at least "some of the time," and it is this zygote-centric sense of remote possibility which held (FDA, 2003, pp. 270-71).

4.2. Standards: How much evidence for an anti-implantation effect is enough?

For most FDA advisers, an antagonism of Plan B with implantation seemed either too poorly evidenced or "so speculative" beyond warranting any confident assertion (FDA 2003, pp. 31, 266–269, 393, 342). Only zygote-centrists claimed that the evidence weighed in favor of implantation or at least that "there's data on both sides" of the debate (FDA 2003, pp. 199, 269–71). To understand these divergent judgments about the weight of evidence, we move beneath the surface level of semantics to the next level of uncertainty involving standards and inductive risks (Douglas 2009).

To minimize the risks to zygotic life, zygote-centrists required relatively less evidence by promoting standards of "biological plausibility" or the existence of rare events. In his bioethics review article, pharmacist John Wilks argued that if hormones affected any implantation factor,

[18] I thank Kevin Elliott for helping me elaborate this contrast.

they would risk zygotes' "rights" because of "the multifactorial nature of embryo implantation" (Wilks 2000, p. 20). To minimize such risks, Wilks thought that evidencing the biological plausibility of indirect effects on endometria and the less than 100% effectiveness of ovulatory suppression was sufficient to assert a postfertilization effect.

Similarly, Stanford argued along with physicians Chris Kahlenborn and Walter Larimore that because zygote-centric patients deserve the right to informed consent and providers the right to conscience, evidencing "rare but important events" was a sufficient standard (Kahlenborn et al. 2002, p. 468; Larimore and Stanford 2000, p. 130). They maintained that this standard had been met because: emergency contraception pills are insufficient to suppress ovulation *every time* (as evidenced by indirect hormonal markers); their constitutive chemicals affect the endometrial histology and uterine hormone receptor levels; and during drug trials, both pre- and post-ovulatory treatment reduced pregnancy counts.

This standard was criticized by the advocates of emergency contraception, who imposed a much higher burden of proof because of the risk to women's access. Biologist Horacio Croxatto argued that effects on endometrial receptivity were insufficient evidence because markers of receptivity were established in rats but not humans and such alterations are likely inconsequential "in real life situations" (Croxatto et al. 2001, p. 118). Without the direct connection of these effects to lower implantation rates in humans, the available evidence marshalled by zygote-centrists was insufficient to satisfy their alternative standard.

However, not all women's health advocates were as willing as Croxatto to reject outright the *possibility* of a postfertilization effect. Realizing that zygote-centrists were interested in the remote sort of possibility (see sub-section 4.1), Trussell and his colleagues argued that the research at that time could not provide the level of certainty and thus the empirical test required

to assuage their doubts (Davidoff and Trussell 2006). Nonetheless, a postfertilization effect looked to them "speculative, since virtually no evidence supports that [implantation] mechanism and some evidence contradicts it" (Davidoff and Trussell 2006, p. 1777). They cautioned against allowing the zygote-centric standard and their "politics of doubt" to further impede the access of women, yet it was this standard that determined the label.

4.3. Interpretations: Does a given study evidence an anti-implantation effect?

This divergence of judgment continued through deeper layers, moving from weighing sets of data into the interpretation of data themselves (Douglas 2009; Elliott 2011). Some zygote-centrists considered trial data from the World Health Organization (WHO) the best evidence for a postfertilization effect. During the FDA meeting, pharmaceutical representative Carole Ben-Maimon concluded that "there really is no data to suggest that there's any impact on implantation or fertilization" (FDA 2003, pp. 267–8). Zygote-centrist Stanford objected, contending that "the most to date compelling piece of data on the side that says this may work after fertilization at times…is the data that it's effective up to four or five days after" (FDA, 2003, p. 270). He claimed that because the drug was still 60% effective around five days after treatment, the study "suggests that it is working after fertilization some of the time" (FDA 2003, p. 271).

Stanford's claim is based on the WHO's multicenter, randomized trial led by Helena von Hertzen. Pregnancy rates increased after delaying treatment beyond three days post-coitus, reducing efficacy from 80% to 60% (Von Hertzen et al. 2002, table 4). Her team interpreted this pattern as "a trend towards a *lower* efficacy with longer delay" (Von Hertzen et al. 2002, p. 1809, my emphasis). Stanford's *reinterpretation* of the data as *sustained* efficacy that evidenced postfertilization inhibition was immediately challenged by FDA-chairwoman Linda Giudice,

who argued that the alleged "five-day window can be interpreted" instead as the result of very late ovulation and fertilization because sperm can survive in the uterus up to five days (FDA 2003, p. 272).

The WHO study was one of the only (debated) pieces of evidence zygote-centrists presented at the meeting for a postfertilization effect. Stanford focused on the enduring horizontal trend of time elapsed and extrapolated a *sustained* anti-fertility ability. His interpretation is likely based on his zygote-centric interest in the remote possibility of implantation prevention for its risk to any individual zygote's life (see sub-section 4.1). Unconcerned with such risks, Von Hertzen and Giudice focused on the downward vertical trend of effectiveness and extrapolated the *lowered* ability of the drug to prevent pregnancy with longer delays. Despite alternative interpretations and unanswered criticism, the zygote-centric judgment stood.

4.4. Heuristics: What counts as evidence for an anti-implantation effect?

Descending into a deeper level of uncertainty, we turn to how values as heuristics provide theoretical guidance for empirical inquiry (Longino 1990, 2008). In the Plan B debates, background assumptions guided how individuals demanded and collected more evidence. Ectopic pregnancy, in addition to its risks for women, had additional moral salience for zygote-centrists as the deplorable loss of human life to inviable implantation outside the uterus. Moreover, they highlighted how observational data on ectopic rates could provide mechanistic insights: if the morning-after pill slows smooth-muscle relaxation in the fallopian tube or reduces endometrial receptivity, then the rate of extrauterine to intrauterine pregnancies should be higher in women who use the pills (Larimore and Stanford 2000, p. 129). The only study these zygote-

centrists found that measured ectopic pregnancy rates had a small effect size. They found this "supporting the possibility of one or more postfertilization effects," and they demanded a "much larger series of hormonal [emergency contraception] pregnancies" for confirmation (Kahlenborn et. al, 2002, p. 467).

Some advocates of the morning-after pill criticized zygote-centrists' reliance on observational data, instead demanding more experimentally rigorous evidence to protect women's access. For instance, rather than relying solely on indirect measures of embryological development (e.g., observational statistics, receptivity markers, hormone levels) already available, Croxatto and his colleagues designed a series of experiments to pinpoint implantation rates to meet their standards of evidence (see sub-section 4.2). They counted the number of eggs ovulated, fertilized, and implanted with levonorgestrel administration at various times throughout the ovarian cycles of rats, *Cebus* monkeys, and humans. In each study, they found that post-coital treatment affected only the rate of ovulation, not fertilization or implantation, so they took the debate to be settled, and the threat to access quelled (see Population Council 2005). This methodologically strong, disconfirming evidence was available at the time of labeling, but it did not make an impact.

4.5. Constituting the "drug fact"

Originally, Barr Pharmaceuticals was planning to include the mechanism only on the less regulated parts of the label, as is common (FDA, 2003, p. 292). However, five members of the advisory committee strongly suggested describing the mechanism "at the point of purchase," so Barr and the FDA eventually decided to include it on the official labeling as a "drug fact" on the carton and later on the FDA website (FDA 2003, pp. 319, 398ff, 2006, 2013). Its phrasing comes

from zygote-centrist Stanford, who suggested avoiding the contested term 'abortion' and instead using "something along the lines of Plan B may work to prevent pregnancy by preventing fertilization or preventing implantation" to accommodate "people at different points of understanding" (FDA 2003, pp. 326–7). (This way, the label would not simply say that "Plan B does not cause abortion.") While this hedged language might appear to be a *compromise*, note well that it was based on zygote-centric values for its connotations and standards (i.e., the remote possibility of abortion), interpretations (i.e., the WHO trial as evidence for a sustained anti-fertility effect), and heuristics (i.e., limited evidence on ectopic pregnancy). At the time of labeling in 2006, only zygote-centrists endorsed the claim that Plan B may prevent implantation as a well-evidenced "drug fact." While others were willing to label Plan B with a remote possibility of this anti-implantation effect, they did so only because of zygote-centric women's rights as patients to informed consent and the current untestability of such a rare effect. Nonetheless, they suggested that this postfertilization possibility should be undermined: "Women should also be informed that the best available evidence indicates that Plan B's ability to prevent pregnancy can be fully accounted for by mechanisms that do not involve interference with postfertilization events" (Davidoff and Trussell 2006, p. 1777).

In addition to the operation of zygote-centric values in managing uncertainty at specific levels, there was also an *interaction* between the levels. For instance, judgments at the levels of semantics (4.1) and standards (4.2) interacted, such as when Trussell and colleagues allowed for unsupported "speculative" claims about implantation because the zygote-centrists' remote sense of "may" rendered the claim untestable empirically (unlike Croxatto and the zygote-centrists). Likewise, judgments about meaning (4.1) influenced interpretations of data (4.3), such as when Stanford took the WHO data as evidence *for* implantation prevention because he was interested

in the remote possibility of any aborted zygote. Additionally, weighing the evidence (4.2) was related to categorizing data as evidence (4.4), such as Croxatto's disparagement of the available indirect measures and his lab's later attempts to provide more exacting evidence to protect access.

Thus, because scientists managed uncertainty at various levels with value judgments that interacted across them, this claim's status as "drug fact" was *thoroughly* constituted by the zygote-centric view. This interactivity transcended levels by reinforcing judgments and rendering their competing evaluations coherent, thus exemplifying how "drug fact" and value were *deeply* entangled. Such entanglements further complicate the possibilities of value-freedom. While the constitutive sense of value-ladenness explains how values enter scientific knowledge, it does not tell *why* certain values prevail. To answer that question, we now consider the social function of "drug facts" from regulatory science in the broader economy of knowledge.

5. The Value of Science: Powerful Knowledge about Implantation

Now, why do values come to constitute knowledge? Philosophers of science have noted how social context colors and sustains certain values in science, such as the porous interface between science and society regarding theories of gender (Lloyd 2005; Longino 1990) and the linkage of first-order scientific errors with second-order regulatory mistakes (Shrader-Frechette 1991; Cranor 1993; Douglas 2009). To understand why values come to constitute knowledge, we turn to the social value of that knowledge—its social utility and currency—as a political and economic tool for accomplishing certain goals. The *social utility* of knowledge is the set of cultural conditions that enables groups to accomplish their goals, while the *social currency* of knowledge allows them to justify their actions to others epistemically.

Scientific facts are useful and reliable knowledge, but they also have social lives that go beyond their scientific origins (Howlett and Morgan 2010). As we saw in chapter 1, mechanistic knowledge about emergency contraception can be a tool of social power for or against women's agency and access. In this case, I argue that Plan B's "drug fact" about implantation was value-laden in an additional sense involving its asymmetrical social function. In the broader context of fetal-centrism, it has the *social utility* to differentially enable zygote-centrists to achieve their political goals at the cost of the values and wellbeing of women. More generally, knowledge is value-laden in the social sense when its social utility relies on its currency in the power structures of society. To explain how the utility of knowledge depends on context, this section contrasts the social function of drug labels for emergency contraception between the US and France.

Beginning with the US, the FDA's label was useful to two groups: on the one hand, it gave zygote-centrists the social currency to refuse providing Plan B against their wishes, and on the other, it afforded the producers of the drug financial currency to expand their market.[19] Zygote-centrists could now back-up their claims about abortifacient potential of Plan B with an authoritative label to refuse financing, providing, or taking the drug. Zygote-centric practices of provider refusal increased throughout the decade, especially in pharmacies with "conscientious objectors" (Davidson et al. 2010), despite professional censure from the ACOG (2007). Most women's health advocates preferred no label at all because of how this hedged claim was being used to support anti-abortionists' goals (Gold 2005; compare with Davidoff and Trussell 2006). Yet, they had succeeded in the switch to non-prescription access, albeit limited to 18+, which would expand women's access to the drug and open a profitable over-the-counter market. Between 2002 and 2010, the percentage of women of reproductive age who had used emergency

[19] I thank Tom Gieryn and Kevin Elliott for pressing me to take this compromise seriously.

contraception increased from 4% to 11% (2.1 to 5.8 million) (Daniels et al. 2013). More access meant more returns: Barr Pharmaceuticals' annual sales of Plan B doubled to 80 million USD once over-the-counter (Crary 2007). After Teva acquired Barr's assets in 2008, the sales of Plan B continued to increase (see Teva Pharmaceutical 2017).

This economic compromise, however, was limited between the producers of Plan B and anti-abortionists who refused to provide. It did *not* extend to those women who relied on their zygote-centric employers for insurance coverage of the costly, time-sensitive drug that had doubled in price (Berenson, 2006; Stein, 2007). Furthermore, insurance providers found utility in the FDA's information for refusing to cover emergency contraception because of the legal currency of its claims about implantation (see Guttmacher Institute 2017, on state-level legislation). To truly understand why zygote-centric values had come to constitute the "drug fact" we need to turn to these uses of this mechanistic knowledge for refusals by anti-abortionists.

The proceedings of *Burwell v. Hobby Lobby Stores Inc*. exemplify the asymmetry of the social utility of the "drug fact." After President Barack Obama signed the Patient Protection and Affordable Care Act (also known as "Obamacare") in 2010, HHS decided that new insurance plans must provide women full coverage of all FDA-approved contraceptives as preventative healthcare. In response, the craft-store chain Hobby Lobby and the Christian-bookstore chain Mardel claimed that HHS violated their religious freedom *because* according to the FDA some services like Plan B act abortifaciently. The appeals court acknowledged the "ongoing medical debate" about Plan B based on conflicting amicus briefs, but it decided not to "wade into scientific waters" since all parties agreed that other contraceptives had postfertilization

potential.[20] At the next legal stage, the Supreme Court relied on the FDA's (2013) description from Plan B's label, and it ruled in favor of the business owners, allowing them and other closely held, for-profit firms to refuse covering abortifacients for their employees.[21]

The US situation, in which fetal-centrism is a dominant social force, sharply contrasts with France and elsewhere in Europe, where the label no longer reads "may prevent implantation." After attending the ICEC meeting in 1996, André Ulman (a developer of the abortion pill) returned to France to found HRA Pharma. Responding to the rise in unplanned teenage pregnancies, his company brought NorLevo (equivalent to Plan B) to the French market in April 1999 as a prescription and then over-the-counter within a month. The following year, the French legislature made NorLevo free for minors at pharmacies and available through school nurses (Moreau and Gainer 2012). HRA Pharma now supplies dealers throughout Europe and the globe, including Japan, South Africa, and Venezuela (ICEC 2017).

Earlier labeling in NorLevo's patient insert described the mechanism as "unknown" though possibly anti-ovulatory or anti-implantation (HAS 2015).[22] Yet, many women's health advocates had increasingly come to see this hedged association with implantation action as a groundless threat to the emergency-contraception market outside France, especially in the overwhelmingly Catholic country of Italy (Belluck 2012). This suspicion was further solidified by newer negative studies with novel methods, e.g., artificial endometrial constructs (Lalitkumar et al. 2007). These negative results even convinced some zygote-centrists of Plan B's impotence

[20] *Hobby Lobby Stores Inc. v. Sebelius*. 13 (2013). See footnote 3. https://www.ca10.uscourts.gov/opinions/12/12-6294.pdf.
[21] See note 16.
[22] Labeling prior to 2015 reads: "*The exact mode of action of NorLevo is unknown.* At the doses used, Levonorgestrel could block ovulation, preventing fertilization, if the sexual intercourse took place in the hours or days prior to ovulation, this is at say at the time when the risk of fertilization is highest. It could also prevent implantation. On the other hand, it is ineffective when the implementation process has begun." (HAS 2015, p. 9, my emphasis, translated from French).

postfertilization (e.g., Austriaco 2007; Reznik 2010). (Other zygote-centrists continue to holdout, especially Kahlenborn and his colleagues (2015), who advise the Catholic Medical Association (2015).) Subsequently, the International Federation of Obstetrics and Gynecology issued a report (with ICEC) citing evidence that these drugs "cannot prevent implantation of a fertilized egg," so "[l]anguage on implantation should not be included in [levonorgestrel-only emergency contraception pills'] product labeling" (FIGO and ICEC 2008). Responding to these developments, HRA Pharma filed to change the label in 2013 to clarify the mechanism as *only* anti-ovulatory and to emphasize the inefficacy of the drug if taken after ovulation (Belluck 2013; see HAS 2015).[23]

The social life of this "drug fact" suggests an important question: How could the same piece of information that the French manufacturer was removing from its label be the scientific premise of a high-stakes US court case? In addition to divergent value judgments about uncertainty from section 4, what allowed for this contemporaneous discrepancy in the demand and uptake of knowledge across the Atlantic? Particularly because of the epistemic authority of the FDA, the "drug fact" in the US had social currency in the Supreme Court, solidifying dominant values and power imbalances through an apparent value-free "drug fact." American medicine is generally fetal-centric, limiting the rights and agency of women (pregnant, nearly pregnant, or possibly pregnant) to the health and interests of her developing fetus (see section 1). Zygote-centrists have additional institutional power in the US, including the growth of Catholic hospitals, the lobbying of the US bishops, and the weaker separation of church and state (CFFC

[23] The new labeling from 2015 reads: "The main mode of action is to block and/or delay ovulation by suppression of the luteinizing hormone (LH) peak. Levonorgestrel interferes with the ovulation process only if it has been administered before the initial increase in LH level. *Levonorgestrel has no effect emergency contraceptive if administered later in the cycle*." (HAS 2015, p. 9, my emphasis, translated from French)

2005; Miller 2015). Relatedly, "religious freedom" laws such as the Religious Freedom Restoration Act have protected the expression of religious providers' beliefs over those of their would-be recipients. The US insurance system entangles employers in the healthcare system because most insured individuals receive coverage from their work rather than the state (Barnett and Berchick 2017). Unlike in France, the US legal and medical cultures legitimate the power of would-be providers to refuse furnishing medical services, rather than the rights of women as patients and the priority of their values. These power asymmetries are exacerbated by *patriarchy*, i.e., the systematic inequality between cis-gender men and "weaker" genders like women, neglecting women's interests and weakening advocacy for their rights (hooks 2004; Manne 2018).

Thus, these power imbalances in the US intersected differentially to empower zygote-centrists to accomplish their goals of limiting access to Plan B. These social structures created the epistemic conditions for providers to impose their values on potential users, with zygote-centrists utilizing this "drug fact" paternalistically as a tool to withhold drugs and refuse coverage. As I discuss further in chapter 3, these "successes" for zygote-centrists came at the cost of disabling women by limiting their access, compromising their health, and disrespecting their values and right to self-determination.

While the social value of knowledge is analytically distinct from the constitutive functioning of values, pragmatics link the two senses. Pragmatic goals motivated knowledge production toward "useful" and "powerful" sorts of information. They also influenced the management of scientific uncertainty and determined the social currency for the consumption of such knowledge. The production of knowledge fits into different economies of knowledge with associated political and financial currencies. Hence, knowledge can be value-laden in how it

functions in certain social structures, such as how knowledge about implantation inhibition continues to empower zygote-centrists to control women and their bodies.

6. Conclusion: The Value of Hedging Your Hypotheses

In sum, distinguishing the constitutive and social senses of value-ladenness allows us to see how and why facts are value-laden. This approach provides a synthetic account of the various roles that values can play in the constitution of facts. It connects previous accounts of values in science by conceptualizing them as analyses at different but interacting levels of uncertainty (ChoGlueck 2018). Attending to the social value of science illustrates how the broader economy of knowledge affects the utility of facts, such as enabling providers to impose their views on their patients and compromise women's health and agency. Furthermore, the epistemic entanglement of science and context suggests both that ethical and political values are inexorable from reproductive knowledge. In a fetal-centric society, biomedicine, healthcare, and regulatory science are inseparable from the politics of reproduction.

This chapter on the content and context of this drug fact has broader social significance. For one, it shows how even apparently *hedged hypotheses* can be value-laden in both senses. My analysis undermines Gregor Betz's defense of value-free scientific advice.[24] According to Betz, adopting "plain hypotheses" would require scientists to make ethical judgments by setting standards of evidence according their valuation of social risks. To avoid making value-judgments, scientists instead ought to communicate uncertainty for policy-making by formulating "hedged hypotheses that make the uncertainties explicit" (Betz 2013, p. 212). His examples for communicating "practical certainty" include showing the range of possible

[24] I thank Kevin Elliott for suggesting this line of critique.

interpretations and using epistemic modalities, such as "it is possible that…" (see also Betz 2017).

This "solution" is not, as Betz suggests, a value-free one because even hedged hypotheses rely on value-laden assumptions about selecting the body of evidence (see sub-section 4.4; also John 2015). Furthermore, different senses of "may" (or "it is possible that") can be constitutively value-laden, such as how the remote sense of possibility operative in the "drug fact" is based on zygote-centric values (see sub-section 4.1). Moreover, official association of this drug with implantation, even just the hedging language of "may," was positive enough for zygote-centrists in the US to exert power over women and their bodies in pharmacies and through (lack of) insurance coverage (see section 5). Thus, Betz's hedging strategy can also be contextually value-laden: the unequal distribution of power in society enables powerful actors to accomplish their goals with hedged claims *as if the hedging was not there*. Accordingly, this case casts doubt on the value-freedom of Betz's proposal.

Rather than defending such value freedom, I aim for this critical analysis to inform normative efforts to improve the inevitable value-ladenness of regulatory science for social justice and the common good. Fallacious beliefs in value-freedom can be pernicious: the perceived value-freedom of the "drug fact" enabled zygote-centrists to abuse it for their own ends, imposing their values on women and compromising their health and self-determination. Exposing the zygote-centric value-ladenness of this fact deflates its political and legal legitimacy in the US. My critical analysis of this asymmetric utility and its paternalistic consequences in this chapter has direct relevance for a more normative analysis of which values and whose values are illegitimate in regulatory science. Looking at how value-laden knowledge enables the imposition of one group's beliefs onto marginalized communities, the next chapter turns to this question

with the framework of epistemic injustice.

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Chapter 3.

What After the Morning-After Pill?

Sexist Values and Epistemic Injustice in Medicine

Abstract: Feminist philosophers of science have proposed a variety of arguments against sexist values in science. This chapter articulates a novel normative framework based on epistemic injustice, integrating the ethical and epistemic aspects of regulatory science and reproductive health. This analysis demonstrates how sexist values and gender norms can hinder the epistemic autonomy of individual knowers and contribute to patriarchal oppression. I argue that the sexist values of anti-abortionists that prioritize zygotic health are illegitimate in this context because they cause epistemic injustices and perpetuate epistemic oppression. This chapter uses the case of the morning-after pill (emergency contraception) and its drug label from the US Food and Drug Administration that it "may prevent implantation." Anti-abortionist providers created this label and used it to justify their refusals to supply or finance the medicine. This zygote-centric knowledge enabled them to shape potential users by instructing "good mothers" that they ought to protect zygotes and punishing "bad mothers" by refusing their requests. This approach advises against new institutional structures that protect the "right to conscience" and "religious freedom" of healthcare providers because these systems will contribute to further epistemic injustices.

1. Introduction

Contextual values can play legitimate roles in scientific judgment, such as choosing topics, setting aims, managing uncertainty, and communicating results (Douglas 2015; Elliott 2017; Longino 1990). Yet, even if we grant that science is value-laden, important questions remain:

which values are legitimate in science? *Whose* values, and in what *contexts*? For feminists, these questions become even more pressing when the values are sexist, the power relations are unequal, and the subject is reproduction.

Take a recent case at the US Department of Health and Human Services (HHS). Last year, the department announced a new division for Conscience and Religious Freedom in its Office of Civil Rights. This division now provides enforcement of protections for healthcare providers in their "fundamental and unalienable rights of conscience and religious freedom," including their right to *refuse* patients with certain services they deem morally objectionable (HHS 2018). One of the primary motivations for this division involves *the morning-after pill* (an emergency contraceptive), which many healthcare professionals refuse to provide women based on religious or ethical opposition to abortion (Cantor and Baum 2004; Davidson et al. 2010). For instance, Catholic hospitals are much less likely to offer or prescribe women emergency contraception, even following sexual assault (Bucar 1999; Smugar et al. 2000). Likewise, pharmacists who oppose abortion act as "moral gatekeepers" for women's access, some of whom refuse to stock emergency contraceptives (Chiarello 2013). Unlike the case with abortion pills, these refusals are based on the *contested value-laden* claim that emergency contraceptives may cause abortion. As we saw in chapter 2, anti-abortionists and women's health advocates disagree over how the morning-after pill works, and their empirical disagreement over "the facts" is rooted in different ontological, ethical, and political values. Which societal values ought regulatory agencies use? Are providers' values and beliefs more legitimate than those of patients, or can they be balanced? What is appropriate and fair in the context of reproductive health?

Feminist philosophers of science have provided a variety of way to distinguish legitimate from illegitimate influences of values on the sciences, especially sexist values (e.g., Anderson

2004; Goldenberg 2015; Kourany 2010; Lloyd 2005; Longino 1990). Acknowledging that science is inevitably value-laden, their normative accounts have provided important insights into the challenges of the entanglement of ethics and epistemology, particularly on the legitimacy of values in the processes of knowledge production itself. Yet, their approaches typically focus on either the epistemic detriments of sexist science or its unjust consequences.

In this chapter, I present a new normative framework based on epistemic injustice for adjudicating the illegitimacy of values and norms in science. This approach accounts for the dynamics between the epistemic and ethical dimensions of value-laden science. I connect the production and use of scientific knowledge with its social stakes and ethical consequences, particularly how sexist values allow for the enforcement of unjust gender norms for reproduction. The frameworks of *epistemic injustice and oppression* help us articulate the wrongs done to individuals and collectives in their capacity to know, which knowers perpetuate as knowers, and which institutions perpetuate as epistemic institutions (Fricker 2007; Dotson 2014; Pohlhaus, Jr. 2017; for more, see Kidd et al. 2017). As we shall see, one of the primary benefits of this approach is the ability to integrate human rights and social justice into epistemology. This integration allows us to criticize how certain values are used in science for injustice in reproductive health and policy, particularly how the system of patriarchy with its sexist gender norms (Manne 2018) resists the liberation of reproductive justice (Ross 2006).

In this chapter, I argue that sexist values and norms are illegitimate in women's reproductive health because they coerce epistemic autonomy and enable epistemic oppression. I will concentrate on the specific sexist ideology known as *zygote-centrism*, which focuses scientific and medical attention on fertilized embryos (zygotes) rather than on women (and other people with uteruses, such as some transgender men) and their interests. In chapter 2, I

contended that knowledge about the morning-after pill has been laden with these values. Here, I show how this knowledge has led to *novel forms of epistemic injustice and oppression* that compromise epistemic autonomy and perpetuate the system of patriarchy. More specifically, this value-laden knowledge has harmed individuals by deceiving and imposing certain beliefs on them in a disrespectful and coercive manner. At the collective level, these harms contribute to the epistemic oppression of women by shaping them through knowledge into oppressive gender norms of "good mothers" and punishing those who deviate from these norms ("bad mothers") with forced pregnancy. Furthermore, some of these harms disproportionately affect women of color and poor women, exemplifying what Black and intersectional feminists call *reproductive injustice* (Roberts 1997; Ross et al. 2017). Beyond mere violations of individual choice or access, these social injustices illustrate how (epistemic) patriarchal oppression intersects with structural racism and classism (Ross 2006).

By connecting philosophy of science with social epistemology and feminist scholarship, this analysis has three main philosophical upshots. First, it provides philosophers of science with a socially relevant and ethically robust framework for adjudicating legitimate from illegitimate values in science (Elliott 2017; Fehr and Plaisance 2010; Hicks 2014). Second, values in regulatory science leads to unique forms of epistemic injustice involving epistemic autonomy, and we find here with patriarchy a novel example of epistemic oppression (in the sense of Dotson 2014). Third, this chapter draws out some of the practical and epistemic aspects of patriarchy, involving the relation of paternalism to misogyny and sexism (Bartky 1988; Manne 2018).

This analysis also has broader impacts. The World Health Organization lists these "emergency contraceptives"—taken after sexual intercourse to reduce the chance of unwanted

pregnancy—as a core essential medicine (WHO 2017, p. 40, 18.3.1). Virtually all women in the US have used contraception at one point in their lives (Daniels, Mosher, et al. 2013), and over last decade, 11% (5.8 million) of US women of reproductive age had used emergency contraception specifically (Daniels, Jones, et al. 2013). This analysis allows us to critique structural barriers to access for morning-after pills, such as institutional protections for provider refusals. If certain organizational features contribute to epistemic injustice like sexist values, they are also illegitimate in regulatory science. Because access to these drugs is often entangled with claims about the mechanism, it is important to address the relationship between medical knowledge, institutional structures, and drug access.

Section 2 begins with epistemic injustice and patriarchal oppression. Section 3 looks at how sexist values entered the science at the US Food and Drug Administration (FDA) with the morning-after pill and how the drug label that emerged was deceptive. Then, section 4 analyzes how that science was used for patriarchal ends outside the FDA to coerce women as patients[25] through that value-laden knowledge. The final discussion in section 5 treats three objections to this argument, including the possibility of a value-free solution, providers' rights involving religion and conscience, and patients' right to know.

2. Sexist Science and Epistemic Injustice

Rejecting the *value-free ideal* of science (see Douglas 2009), feminist philosophers have suggested that feminist values provide a better guide to research than their sexist alternatives.

[25] I recognize that the FDA and pharmaceutical companies might understand the primary status of these individuals as "consumers" rather than "patients." Nevertheless, I refer to the people who want/need the morning-after pill primarily as "patients" or "potential users," in part because I focus on the downstream effects of values in science for healthcare.

They have critiqued sexist values in science from a variety of angles, especially with engaged case studies of gender bias in science (see Richardson 2010). One approach is characteristic of *feminist empiricists*, who emphasize the *epistemic* detriments of sexist science. They argue that sexist values can bias hypotheses by leading to self-fulfilling samples of evidence and that sexism has proven unreliable empirically given the oversights of homogeneous groups (Anderson 2004; Clough 2013; Goldenberg 2014, 2015). For instance, looking at the case of evolutionary accounts of female orgasm, Elisabeth Lloyd (2005) has critiqued sexist values primarily in terms of their problematic epistemic consequences. That is, when values like androcentrism are widespread among biologists, reinforcing existing adaptationist values, they obscure relevant evidence about the unique aspects of female sexuality. This critique shares similarities with the work of Helen Longino (1990), who argues for the benefits of a more diverse scientific community because of how differences in background beliefs can improve criticism. Yet, Lloyd's critique goes a step further: not only are feminist values epistemically beneficial, but sexist values are detrimental for science. Because they go unquestioned, sexist values like androcentrism and procreative-focus befuddle evidential reasoning and damage the empirical adequacy of science. Lloyd (2005, p. 255) strongly suggests "jettisoning" the background assumptions involving these values because "they have all been implicated in badly reasoned or badly supported evolutionary explanations."

Contrasting (or supplementing) these feminist empiricists are more *justice-oriented critiques* of sexism in science. In addition to its epistemic detriments (which they do not contest), these feminist philosophers argue that sexist science is wrong on the *ethical grounding* that it oppresses women and other marginalized groups. Janet Kourany (2010), for instance, has argued that in addition to the epistemic goals of science, there are ethical and political goals to achieve

in order to be *socially responsible*. Sexist values along with others ought to be rooted out for more egalitarian ones that promote human flourishing. Likewise, Kourany (2016) contends that there ought to be restrictions on research in areas like cognitive differences by race and gender that contributes to social inequality because of how they are perennially misused to justify social domination. Thus, this justice-oriented approach evaluates the legitimacy of values in science on ethical principles and social consequences, in a manner congruent with several other philosophers of science who emphasize the importance of ethics, politics, and other non-epistemic values (Brown and Havstad 2017; Elliott and McKaughan 2014; Hicks 2014; Pinto and Hicks 2019). For instance, Kristin Shrader-Frechette (2014, 2018) contends that philosophers ought to assess environmental science in terms of both its scientific integrity and its protection of public interests, particularly environmental justice.

This paper presents a new normative framework that accounts for the epistemic detriments of sexist science, its unjust social consequences, and the interrelation between the two. I combine aspects of feminist empiricism, particularly from Longino's social norms for objectivity, with other feminist scholarship related to morals, justice, and power relations. This *integrated* approach to the epistemic and ethical aspects of science allows us to criticize how values and norms in medicine harm individual knowers and how they perpetuate the system of patriarchy through value-laden (sexist) knowledge. Furthermore, it connects the epistemic autonomy of individuals with larger structural forces involving power, sex, and gender, which is particularly important in the realms of reproductive health and regulatory science. While my approach focuses on the illegitimacy of certain values, I do not wish to suggest that science ought to be value-free. Instead, I suggest an ameliorative approach to normativity that reforms

regulatory science to better address women's health and wellbeing through feminist-based criticism (see chapter 5).

More specifically, I adapt an expanded framework of epistemic injustice to understand the production of sexist knowledge and its social consequences. *Epistemic injustice* in its original, more narrow sense refers to the wrongs that affect people in their capacity as knowers (Fricker 2007). Following Miranda Fricker's groundbreaking work, much of the literature focuses on concrete practices of epistemic discrimination, such as deflated credibility (testimonial injustice) and the systematic inability to make sense of one's experience (hermeneutic injustice) (see Kidd et al. 2017). But we can conceptualize epistemic injustice more broadly. Encompassing a wider literature, Gaile Pohlhaus (2017) provides an expanded conception of epistemic injustice, including the wrongs done to a knower as a knower, *which knowers then perpetuate as knowers, and which institutions perpetuate as epistemic institutions*. For her more systematic understanding, Pohlhaus points to the work of Kristie Dotson (2014) on *epistemic oppression*. Dotson argues that Fricker's individual cases of epistemic injustice involving testimony and hermeneutics are instances of a more systemic problem: how systems of oppression exclude underprivileged groups from contributing to dominant systems of knowledge. For instance, women of color have been excluded from academic discourse not simply because of bad luck or decreased credibility, but rather because the shared epistemic resources that were dominant actively scrambled, erased, or disregarded their contributions (Dotson 2012). Dotson argues that epistemic systems are resilient to radical change, pointing to the concept of *meta-blindness* from José Medina (2013), who demonstrates how privileged people are cultivated as knowers to be insensitive to their social positions and the limitations of their worldview.

This chapter continues to rethink epistemic injustice like Dotson and Pohlhaus as more systematic and structural problem of epistemic oppression. Epistemic justice broadly construed is a virtue of institutions, so the vice of epistemic *injustice* is a structural feature of an organization that can work without overtly prejudiced agents and still manifest the individual injustices from Fricker (Anderson 2012). My adapted conception of epistemic injustice helps us collect together the disparate pieces involved in knowledge production and use in regulatory science and healthcare. While our epistemic responsibility and agency requires a minimal knowledge of self and others, it also involves knowledge about the empirical world (Medina 2013). Thus, the framework of epistemic injustice and oppression allows us to interrogate the interrelation between scientific knowledge, healthcare, and social justice (Carel and Kidd 2014; Wardrope 2015). In biomedicine, for instance, healthcare professionals discount pregnant women's own testimony of uterine contractions by relying instead on fetal-heart monitors, thus usurping women of their *epistemic privilege* over their own bodies (Freeman 2015).

Taking the expanded framework of epistemic injustice in new directions, I articulate how the system of patriarchy functions in healthcare epistemically, through our knowledge and epistemic practices. As conceptualized by bell hooks (2004), *patriarchy* is a political and social system in which cisgender men dominate weaker genders, including cisgender women, and furthermore are taken to be *justified* in their domination. Patriarchy oppresses all women, girls, transgender people, and non-binary individuals; however, it does so in different ways and to different degrees because of how patriarchy intersects with other systems of oppression such as white supremacy, capitalism, and colonialism (Collins and Bilge 2016). This is why hooks often uses the extended moniker "imperialist white-supremacist capitalist patriarchy" (2004).

More specifically, we'll focus on the *unjust gender norms of reproduction* in heteropatriarchy, which elides non-procreative forms of human sexuality and imposes procreative responsibilities on people with uteruses. Accordingly, heteropatriarchy attempts to collapse the categories of "people with uteruses" to "women," and then "women" to "mothers." Accordingly, it uses gender norms about "good mothers" and "bad mothers" to enable (cisgender) men and male-dominated institutions to force the risks and responsibilities of pregnancy on people with uteruses (see, e.g., Armstrong 2003; Kukla 2010; Lyerly et al. 2009; Waggoner 2015).

In her recent book *Down Girl*, Kate Manne (2018) has dissected the system of patriarchy into a form of governance with two "branches" for different functions: sexism and misogyny. The branch of *sexism* functions for the justification of patriarchy. Sexist ideology differentiates men from women according to ideologies of so-called "natural" sex differences. Gender norms assign roles to different groups, reserving those for "women" to be subservient, affording less power and authority over "men." The resultant androcentrism of our knowledge leads to systematic ignorance about those with female bodies, their unique abilities, and their health and wellbeing (Bueter 2017; Lloyd 2005; Tuana 2006).

According to Manne, *misogyny* in contrast supports patriarchy by punishing deviations from sexist gender norms of those "bad women" who step out of line. Manne describes in detail the various reactions and backlash of patriarchy that condemn and punish women who neglect their duties assigned by sexist ideology. For instance, anti-abortionists celebrate "good mothers" who sacrifice their bodies for their children, yet they also penalize "bad mothers" who deprive fetuses of their entitled birthright (see Manne 2018, pp. 91–100).

But if misogyny puts down "bad women," what holds up "good women" (and "good mothers")? To draw out both the positive and negative norms of motherhood, I will add a middle branch of *paternalism*, which shapes women into subservient "good mothers." If misogyny is the stick for *punishment*, then paternalism is the carrot for *discipline* (in the sense of Foucault 1979). For instance, practices such as dieting, exercising, modesty, and ornamentation attempt to construct ideal bodies, which are unequally imposed, and to produce compliant women (Bartky 1988). In contrast to the *reactive* punishments of misogyny, patriarchy *proactively* controls women to protect its traditional social order. As Sandra Lee Bartky contends, these disciplinary practices shape women's subjectivities through an internalized structure of the self. That is, paternalism's proactive control of women pressures them to adopt a certain view of femininity that shapes their subjective experiences toward oppressive norms, e.g., the shame incurred by cultural narratives about female obesity and beauty. Bartky focuses on the ways that patriarchy produces docile bodies, which are sexualized and feminized for men. We can also apply this concept to reproduction for how patriarchy shapes women into "good mothers" who ought to *sacrifice* themselves and their bodies for their children (actual or potential) and families. In the context of medicine, sexist paternalism has long been standard practice, and feminist bioethicists have criticized gendered assumptions in medicine. For instance, by default medicine considers patients as passive and feminine and the doctor-patient relationship as apolitical, and this medical paternalism contributes to women's oppression, particularly poor women of color (Roberts 1996; Sherwin 1992).

Let's now focus on the two functions of these branches: justification of the patriarchal order (via sexism) and enforcement (via paternalism and misogyny). These two functions corelate to the two senses of value-ladenness from chapter 2: a *constitutive* sense, related to value

judgments and the uncertainties of a scientific claim, and a *social* sense, related to the claim's political utility and the social stakes it serves. Distinguishing between the constitutive and social senses of value-ladenness allows us to analyze first how *sexist* values enter science "upstream" and then how that authorities used that science "downstream" in healthcare *paternalistically* and *misogynistically*. Before looking at the social functions of this knowledge in section 4, we consider the production of knowledge at the FDA in section 3, focusing on value judgments in regulatory science. In each case, we will connect the epistemic injustices occurring at the individual level with the epistemic oppression at the collective level.

3. Sexist Values in Science: The "Drug Fact" about Plan B

This section demonstrates how sexist value judgements in science can harm knowers in their capacity to know and contribute to epistemic oppression. Accordingly, we turn to the case of Plan B's drug label from the FDA. Plan B (active ingredient: levonorgestrel) is a morning-after pill, which is a form of emergency contraception taken after sexual intercourse to reduce the chance of pregnancy. As we saw in chapter 1, since the development of morning-after pills in the 1960s, there have been long-standing concerns about their mechanism from both women's health advocates and anti-abortionists (ChoGlueck 2019). Women's health advocates have tried to increase access to this pill to bolster women's agency in reproductive decision making. Anti-abortionists, especially Roman Catholics, resisted increased access because of the pill's potential to act after fertilization on zygotes. As we saw in chapter 2, the advocacy of anti-abortionist science advisers at the FDA resulted in the production of a "drug fact" laden with zygote-centric values (see fig. 2.1).

3.1. Zygote-centric value judgments in Plan B's drug label

After the FDA approved Plan B in 1999 for prescription-only sale, the drug company applied for over-the-counter sale without a prescription (Prescott 2011). Women's health advocates were unsatisfied with access limited to prescription holders and adults (18+)—restrictions they disparaged as "special paternalistic scrutiny" without scientific or legal justification (Ellertson et al. 1998, p. 229). Conservatives, especially anti-abortionists, resisted the switch to over-the-counter access, which happened in the turn of the "right to life" movement toward contraceptives during the (George W.) Bush era of abstinence-only education (Miller 2015). Much opposition came from conservatives who alleged that the morning-after pill would increase sexual promiscuity and disease (Wynn and Trussell 2006a). However, there was special focus on the drug's *mechanism of action* because of moral concerns about abortion and the uncertainty of the science at the time. This epistemic-ethical concern from anti-abortionists about the mechanism is the focus of these next two sections.

During a science advisory meeting at the FDA in late 2003, there were several advisors who were anti-abortionist that expressed concerns about Plan B, particularly Dr. Joseph Stanford (University of Utah, Family and Preventative Medicine). An FDA advisor appointed by Bush, Stanford was a "Right-to-Life" Mormon (Stanford 2011a, 2011b). Prior to the meeting, he co-authored journal articles on the morning-after pill's mechanism, abortion, and informed consent (Kahlenborn et al. 2002; Larimore and Stanford 2000). At the meeting, representatives from the drug sponsor (Barr Research) and the President of the American College of Obstetrics and Gynecology (ACOG) claimed that Plan B works by preventing ovulation and possibly fertilization, but *not* implantation (FDA 2003, pp. 30–31, 36–37). Regarding the prevention of implantation, Dr. Carole Ben-Maimon (President of Barr) argued that "The studies are not

available. … there's no data that's definitive in either way. But, again, I think logic precludes us from assuming that that's the mechanism of action" (FDA 2003, p. 267). Yet Stanford disagreed, citing patients' right to know:

> I'd like to offer a little bit of a different opinion on that issue, and I think it is an important issue for women who want to have a clear idea of the best evidence of how this works and for their informed consent for use. I don't think it's quite as clear-cut as has been presented that there's no data on one side and all data on the other side. (FDA 2003, p. 267)

He contended that Plan B acted after fertilization "at times" or at least "some of the time" because it was effective in observational trials five days after treatment (FDA 2003, pp. 270–71). Stanford suggested that this "five-day window" was evidence that the drug could be acting on implantation after ovulation had already occurred.

Closer inspection of his publications reveals the values that Stanford used for his judgment about the mechanism (see chapter 2). Anti-abortionists like Stanford believe that 'pregnancy' and 'life' begin at fertilization along with full human personhood, meaning that fertilized eggs (zygotes) have a "right to life" (Larimore et al. 2004; Wilks 2000). Accordingly, they hold a variety of *zygote-centric* beliefs about reproductive rights and politics, and these values influenced their judgments about the mechanism. For them, at the level of description, the phrase of 'preventing implantation' is a mechanism with a special moral valance: it denotes an *ethically* salient relation occurring between human *persons* and, moreover, *against* a person. Thus, the phrase 'preventing implantation' connotes abortion, which for these zygote-centrists is the immoral violation of the zygote's "right to life" (Kahlenborn et al. 2002). As Stanford noted, the zygote-centrist would describe a drug with this mechanism as functioning "to *kill* a fertilized egg" (FDA 2003, p. 289, my emphasis).

At the level of standards of evidence, these values influenced how Stanford and others weighed evidence for or against the postfertilization effect. Anti-abortionists wanted to minimize the risks to the life of zygotes, so Stanford and his colleagues required evidence *not* of mechanisms "definitely proven to exist or proven to be a common event," but instead of "rare but important events…even if the *possibility* is judged to be *remote*" (Kahlenborn et al. 2002, p. 468, my emphasis). This standard of remote possibilities influenced Stanford's interpretation of the "five-day window," which he used as the evidence of a postfertilization effect at the meeting. Because delayed efficacy might imply that the drug had not suppressed ovulation completely, he inferred that interference after fertilization was possible "at times" albeit rare. These retractors used this concern about labeling and informed consent to justify their votes against over-the-counter sale in their letter to the editor of the *New England Journal of Medicine*: "Package labeling needs to be modified to state adequately that Plan B may at times act after fertilization and thus allow informed consent for women who personally believe that life begins at fertilization" (Stanford et al. 2004).

In contrast with these anti-abortionists were women's health researchers and advocates, who criticized these value judgments that minimized the risks to women's access to emergency contraception. For instance, FDA-chairwoman Dr. Linda Giudice (Stanford University, OBGYN) immediately challenged Stanford's judgments about the trials because "a five-day window can be interpreted with the sperm being in the reproductive tract for 72 to 96 hours with a very late ovulation and with an effect of the levonorgestrel on a decreased release of the sperm in the cervical mucous or in the crypts of the fallopian tubes" (FDA 2003, p. 272). Similarly, two other advisors, Dr. Frank Davidoff (Institute for Health Care Improvement) and Dr. James Trussell (Princeton University, Population Research), criticized Stanford's standard of remote

possibility in print. Davidoff and Trussell argued that zygote-centrists were using an unreasonable standard based on a "politics of doubt" aimed at impeding women's access and justifying provider refusals (2006, p. 1775). They rejected the burden of proof implicit in the standard of remote possibility as unfalsifiable empirically: "Beyond that lack of information [about the mechanism] lies the more subtle logical difficulty—some would say the *impossibility*—of *proving* the lack of existence of any particular mechanism" (Davidoff and Trussell 2006, p. 1777, my emphasis). Without this burdensome standard, a postfertilization effect looked "*speculative*, since virtually no evidence supports that [implantation] mechanism and some evidence contradicts it."

Because of the divergence of these value judgments, Barr Pharmaceuticals was planning to include the mechanism only on the less regulated parts of the label, such as the package insert as they had previously (FDA 2003, p. 292). Several advisors also resisted any additional labeling based on zygote-centric concerns (FDA 2003, pp. 322, 329, 330). For instance, Dr. Alastair Wood (Vanderbilt, Pharmacology) considered it distracting and gratuitous: "I would caution, however, against studding the outside of the packet like a Christmas tree with all sorts of issues. I'm particularly concerned about putting things on the outside of the package which are unsupported by data" (FDA 2003, p. 341). However, five of the 27 voting advisors agreed with Stanford's zygote-centric judgments about the mechanism and strongly suggested describing the mechanism "at the point of purchase" (FDA 2003, pp. 319, 398–409).

The FDA delayed Plan B's approval for two years, which the US Government Accountability Office called "unusual" because of the top-down nature of the decision and the commissioner's justification based on concerns about adolescent girls ages 11 to 12 (GAO 2005; for more, see Prescott 2011). When FDA eventually approved the drug, rather than saying

nothing in the "Drug Facts"—which is the norm—Barr added an unprecedented label to the outside of the carton: "this product works mainly by preventing ovulation (egg release). *It may also prevent* fertilization of a released egg (joining of sperm and egg) or *attachment of a fertilized egg to the uterus (implantation)*" (FDA 2006, my emphasis, fig. 2.1). This label is the only instance of a mechanism on the official "drug facts." The same description was later added to the FDA's website (FDA 2013), which had significant consequences for women's access.

Thus, zygote-centric values were decisive in the constitution of this "drug fact" that Plan B "may also prevent implantation" (for more detail, see chapter 2). These zygote-centric values from advisers like Stanford justified scientific judgments involving the meaning of terms, the standard of evidence, and the interpretation of research. Crucially, the process ignored relevant criticisms from those without zygote-centric values. Regardless of alternative interpretations and critical judgments, the pharmaceutical company wrote the label under pressure from anti-abortionists, with the complicit backing of the FDA. We now turn to the issue of epistemic injustice resulting from this zygote-centric knowledge.

3.2. Deception and sexism as epistemic injustices

What epistemic wrongs resulted from this production of knowledge at the FDA? At the individual level, this process wronged patients by *deceiving* them about the *quality* of the knowledge itself, particularly its shaky evidential grounding and its value-ladenness. At the collective level, this process imbued knowledge with values that were sexist and perpetuated them though value-ladenness for oppressive ends. I will treat these two levels in turn and explain their interconnection.

First, at the core of this case of knowledge production, there is a deception that resulted in an effective lie to patients. In a sleight-of-hand, its framing as a "drug fact" cloaked the value-ladenness of the knowledge and misrepresented it as *scientific.* The problem is not that knowledge production should have been completely free of all human values, which would assume the dubious value-free ideal of science. Because of the uncertainties of science and the authoritative place of science in society, it is often not possible to exclude societal values from scientific reasoning (ChoGlueck 2018; Douglas 2009; Elliott 2017; Longino 1990). Instead, the deception involves the distortion and misrepresentation of the communal norms of the scientific *process*. As Longino (1990) argues, scientific objectivity requires criticism across a diversity of values and the uptake of those criticisms. For knowledge to be scientifically objective[26]—as a "drug fact" ought to be—any value judgments in the process need to be transparent, subjected to scrutiny, and then resolved in a transformative manner. However, the process ignored criticisms from women's health advocates during the meeting and in print, obscuring the zygote-centric values necessary to this label's constitution. Based on Longino's transformative ideal for objective (value-laden) science, it is a deceptive to call this claim a scientific "drug fact" before it has withstood proper scrutiny. Furthermore, because it is not objective, the drug label does not deserve the credibility that comes with its FDA authorization.

Now, how exactly is this deception an *epistemic* injustice? There are two reasons that this distortion wrongs individual patients epistemically, the first is related to autonomy and the second to ethical consequences. For one, by relying exclusively on one set of values (viz., zygote-centrism from anti-abortionists), this case of knowledge production disrespects the

[26] I am talking about *interactive* or *structural* objectivity. For other senses of scientific objectivity, see Lloyd and Schweizer (2014), Daston and Galison (2007), and Douglas (2009).

epistemic autonomy of patients to choose their own values. In bioethics, this ethical principle falls under the *respect for autonomy*, which includes the self-determination of patients in matters of belief and decision-making (Beauchamp and Childress 2013). Patients have a variety of stances on zygotes and their alleged rights, yet the "drug fact" is premised on background assumptions that value zygotic life. As we have seen, scientists who do not share these values make different judgments about the possibility of a postfertilization effect. The "drug fact" then indiscriminately imposes that small set of values on all potential drug users, irrespective of their own beliefs.

This disrespectful obscurity has adverse effects on patients who do value zygotic life, those who do not, and those who are uncertain. Because this deceptive information ignores patients' individual beliefs, it has undesirable consequences for decision making. It lacks *applicability* and *usefulness* for patients to make ethical deliberations. For all potential users of this drug, this information is not useful because the values essential to its constitution remain obscure. What are patients to do when they find out that it "may also prevent implantation"? For patients who disagree with the values of these anti-abortionists, the operative standard of evidence is not congruent with their beliefs. Thus, they would likely disagree with the value judgments, were they familiar with the cited evidence, rendering the information inconsequential to their own decision. Yet, for patients who are uncertain about early life ethics or do not know whether they should assign value to zygotes, the label suggests this is a piece of information is something they *ought* to consider when making their decision (more on this in subsection 4.1).[27]

[27] I thank Manuela Fernandez Pinto and Robyn Bluhm for helping me distinguish between the various effects on the epistemic autonomy of these different groups.

This misinformation incapacitates the epistemic autonomy of all patients, even zygote-centrists. Particularly for those patients who *do* believe in zygotes' right to life, this "drug fact" is not useful, again undermining their right to self-determination. Because all parties admit that the drug works *primarily* by delaying ovulation, even zygote-centric patients could use the drug at times with the proper guidance in line with their values (i.e., prior to fertilization). Yet, this vague, hedged claim does not provide zygote-centric patients any information about how to use this drug in a manner that reduces the risks to zygotes. Even if, as Stanford argued, it works after fertilization "some of the time," the label does not tell patients when this time window occurs and whether they fall within it. By erring on the side of brevity, the "drug fact" does not provide enough information for how to use the drug consistent with one's personal values, i.e., balancing the risks to zygotes and the benefits to the user. Without this information on weighing risks and finding potentially safe uses, it encourages *complete disuse o*ut of apprehension or fear of the remote possibilities of inhibiting implantation. The "drug fact," therefore, guides the zygote-centrist towards excessive caution, and it completely disregards the potential benefits of preventing pregnancy for the user.

Moving to the level of collective injustice, this production of deceptive information accomplishes the patriarchal function of *producing sexist knowledge*. Recall that the function of sexism is for the justification of the patriarchal order (Manne 2018). Unlike with sexist values, anti-abortionists can appeal to scientific knowledge as an independent "value-free" source of information to justify their actions. As Longino (1990, p. 218) notes, "'Letting the data suggest' is a recipe for replicating the mainstream values and ideology that feminists and radical scientists reject." *Particularly in this context*, these zygote-centric values from anti-abortionists are a sexist ideology because they justify the reduced social power of women and, more specifically, anyone

who can get pregnant. As we shall see, these values reduced patients' access to contraception according to their duties to zygotes. For instance, zygote-centrists are willing to sacrifice women's health for the rights of zygotes, such as in Catholic Hospitals that refuse to provide emergency contraception after fertilization and rarely offer the drug (USCCB 2009, directive 36; Smugar et al. 2000). Because of the time-sensitive nature of the drug, this delay increases a woman's chance of unwanted pregnancy, which incurs physical and psychological harms, particularly in the case of sexual assault. Accordingly, denials limit women's agency to *not* be pregnant by narrowing their reproductive rights to the alleged rights of zygotes.

This sexism is a form of *epistemic* oppression because it is not only the sexist ideology and its values but the value-laden "drug fact" that limits women's agency. As I argued in chapter 2, zygote-centrism is a form of *fetal-centrism* because it devalues the women carrying developing zygotes or fetuses as mere "fetal containers" or "maternal environments" for more "precious cargo" within (Lupton 2012; Purdy 1990; Rothman 1989). Fetal-centrism is a dominant force of gender-based oppression in medicine that limits women's access to contraception and abortion based on their maternal responsibilities. As Dotson (2014) conceptualizes *epistemic oppression,* it is a higher order of epistemic exclusion, beyond the testimonial and hermeneutical injustices from Fricker (2007). This injustice involves the *inadequacy* of dominant shared epistemic resources for addressing the exclusion of marginalized groups. Epistemic oppression is enabled by the *resilience* of epistemic systems, such as white supremacy or patriarchy, to perpetuate themselves with inadequate resources for self-criticism. The values and norms of patriarchy are resilient: in so far as knowledge is value-laden, the information itself both *contains* these sexist values and gender norms and *perpetuates* them through its unnoticed value-ladenness.

These epistemic injustices involving deception and sexism are connected through patients' experiences of social forces in medicine. With the effects of these sexist value judgements, patriarchy manifests its values in science as justification for women's reduced agency and medical access. This wrong at the collective level also wrongs individual knowers by disrespecting their values. Even zygote-centric patients are harmed by the results of the advocacy of science advisers like Stanford, the acquiescence of the pharmaceutical company, and the complicity of the FDA. Yet, it is important to contextualize these injustices within a larger structural oppression of people with bodies who can get pregnant. In addition to noting the sexist function of this information, we now move to the downstream effects of these upstream values in science. We see how the utility of that knowledge in society hinges on its relation to enforcing gender norms.

4. The Social Utility of Sexist Science: Keeping Women "in Their Place" as Mothers

Following from the values in knowledge production is the social function of that knowledge in society. The sexist values laden in this "drug fact" enabled several important consequences related to patients' access to emergency contraceptives. In this section, I argue that these uses of science constitute additional epistemic injustices beyond deception and sexism. The knowledge further enabled the *coercion* of patients' epistemic autonomy, both proactively and reactively. Moreover, would-be providers limited women's access to this pill through denials and refusals, particularly to marginalized groups of women. Far from being incidental, the effectiveness of the information for these functions evidences the *social utility* of this science for patriarchal ends.

Manifesting the sexist values from the previous section, this enforcement involves perpetuating sexist *gender norms.* During the FDA hearings, witnesses referred to different

images of motherhood and women's bodies, involving competing models of female sexuality, decision making, and responsibility (Wynn and Trussell 2006a, 2006b). In turn, the information from the FDA has served as a patriarchal tool for shaping women into "good mothers" and punishing "bad mothers"—norms defined wholly by the ideology of zygote-centrism from anti-abortionists. Furthermore, these refusals to provide healthcare have disproportionately affected women of color and poor women. These compounding effects are the result of racism and classism intersecting with patriarchy in what Patricia Hill Collins (1999) conceptualizes as the *matrix of domination* (see also hooks 2004). This section begins with the first social function of the label as a paternalistic warning, and then moves to the second function of the label for punishment, which is rooted in misogyny.

4.1. A warning for "good mothers"

According to zygote-centric science advisers, the primary function of this label was to provide patients their *informed consent* about how the drug works related to abortion (FDA 2003, p. 267). For instance, Dr. Susan Crockett (OBGYN), from the advisory committee on reproductive health drugs, voted against making Plan B available over-the-counter in part because of the lack of informed consent (for women like herself):

> I think as a young woman in this country of childbearing age that *truth in labeling* is very important, and I think if you don't print on the label that this may affect a fertilized egg in an unfavorable way that *you're removing my choice and my ability to make the decision* about how I am affecting my body and my pregnancy. And so I would very strongly agree that that needs to be on the outside of the package. (FDA 2003, p. 408, my emphasis)

Like Stanford, Crockett argued that it was crucial to patients' autonomy to have this information (Stanford et al. 2004).

However, as I discussed in subsection 3.2, it is doubtful that the function of this label is for patients' informed consent. Even for zygote-centric patients, the label is too vague to provide them with guidance for how to use the pill and reduce the risk to zygotes. At best, it prompts them to look elsewhere. At worst, it discourages *all* use of emergency contraception—a recommendation that is unnecessary and rash. Patients might be able to use this drug in accordance with their zygote-centric values. So, if not for their informed consent, what is the real function of this drug label for patients?

With increased access to the morning-after pill, anti-abortionists were concerned that the potential users—assumed to be cisgender women, especially adolescents—would be unable to make "good" decisions because of their female bodies. For instance, during the public forum at the FDA hearings, Jennifer Taylor (Human Life International) bemoaned the moral corruption at the root of requests for the morning-after pill:

> Another common thread that runs through these stories [from patients at this public forum] is *the inability to control themselves* in sexual situations. As a young woman how sad it is to know that these women are *slaves to their bodies* and that the organizations they represent lead them to believe that they themselves cannot control themselves, but have to rely on pumping themselves full of drugs. (FDA 2003, p. 239, my emphasis)

From the zygote-centric perspective, women who are "slaves to their bodies" might not take the risk to zygotes into account when choosing whether to take the pill, or they might take the risk too lightly.

Many anti-abortionists thought it was the duty of women as "good mothers" to respect and protect zygotic life, so they feared that greater access to the morning-after pill created (literally) perverse incentives for women to embrace their sexuality without their reproductive responsibilities. Julie Brown (American Life League, President) testified during the public forum to these social dangers, especially for young women:

> Pills such as Plan B are designed with one purpose in mind: to destroy the evidence that a sexual encounter has occurred that could result in the conception of a child. *The emergency in this case is a baby.* If these pills are made available over the counter, adolescents who might have given such a result a second thought will not be inclined to take pregnancy into consideration before engaging in risky sex. (FDA 2003, p. 214, my emphasis)

Exemplified by the testimony from anti-abortionists like Taylor and Brown, "good women" ought to control *themselves* and only have sex if they can carry the pregnancy to term. Yet, while "good mothers" ought to protect zygotes (and fetuses) by not using the drug after fertilization, anti-abortionists were less than optimistic about their abilities and integrity. These concerns about women's irresponsibility motivated a desire to point users toward what anti-abortionists considered "the right decision."

Rather than promoting epistemic autonomy by providing informed consent, this label does the inverse. The warning limits agency by disciplining it, discouraging against deviations from sexist gender norms for a "good mother" (and therefore a "good woman"). Other warnings, instructions, and recommendations aimed at guiding patients' behavior surround the bold-font text that the pill "may also prevent implantation" (see fig. 2.1). This technical wording comes from Stanford, who insisted against using the word "abortion" because "the language needs to be unambiguous for people at different points of understanding" (FDA 2003, p. 327). Furthermore, under the more common medical definition of 'abortion' as occurring after implantation, even a pill that works after fertilization is not necessarily 'abortifacient' (ACOG 1997; Glasier 1997). The label warned users of these risks to *encourage* them in their alleged responsibility to protect zygotes. Creating the label was based on the presumption that potential users as "good mothers" *ought* to care about a zygote's life and its alleged rights and that they *ought* to take this knowledge into consideration when making reproductive decisions. Thus, the drug label functions to discipline women's agency toward their supposed maternal duties.

Zygote-centric gender norms about reproductive responsibility justified this limitation of women's access to morning-after pills. The responsibility for continuing a pregnancy once fertilization has happened, regardless of the circumstances, burdens cisgender women and those with uteruses as "the Reproductive Other" under patriarchy. This responsibility even extends to the survivors of sexual assault in certain anti-abortion institutions, such as at Catholic healthcare facilities. For instance, while emergency contraception is the standard of treatment for preventing pregnancy after rape, Catholic hospitals will not dispense the drug to all survivors because of their restriction on abortion (USCCB 2009, dir. 36).

Stanford and his zygote-centric colleges criticized others for assuming that "all patients will not care about a postfertilization effect," yet their warning label makes an even worse assumption about potential users (Kahlenborn et al. 2002, p. 468). Rather than taking potential users to be full subjects capable of choosing their own values and weighing the risks accordingly, this label paternalizes them by instructing them what their values *ought* to be (zygote-centric) and how they *ought* to act (don't risk it!).[28] The label could have supplied patients with enough information to understand the uncertainties of the mechanism and to act according to their values, zygote-centric or otherwise. Instead, it takes the potential user of the morning-after pill to be an *epistemically unreliable subject* who is able—and maybe even likely—to deviate from the norms set by the sexist ideology of zygote-centrism.

Thus, this label assumes a distrustful view of the potential users of this pill. This attribution of a truncated or circumscribed subjectivity is, according to Gaile Pohlhaus (2014), a form of "othering." It reduces full subjects to "semi-subjects," who are not fully capable and thus prone to failure, vice, and treachery. This brings us to the epistemic injustice of the label as a

[28] I thank Robyn Bluhm for helping me to formulate this insight.

warning about the risk to zygotes. Pohlhaus (2014) argues that "othering," or the attribution of a truncated subjectivity, is the primary harms of epistemic (testimonial) injustice. Contrary to Fricker, who maintains that epistemic harm involves the *objectification* of subjects, Pohlhaus contends otherwise: perpetrators can still accept the subjectivity of their victims albeit in a narrow, distrustful manner. Likewise, in this case, possible users are "othered" according to the sexist gender norms of zygote-centrism. It is the duty of those with uteruses to be "good mothers" who value zygotic life, and it is their responsibility to take measures to protect it.

Why is this imposition of a truncated subjectivity an *epistemic* injustice? First, as an imposition, it is forceful, coercing the epistemic autonomy of patients. Zygote-centric beliefs about the "right to life" are imposed forcefully on patients through value-laden knowledge, such as through the presumptive choice of standards of evidence. Furthermore, this coercion works *covertly* and *surreptitiously* without patients' awareness. The label compels non-zygote-centric patients to *internalize* this truncated subjectivity by believing and acting on this drug label. For instance, even before interacting with healthcare professionals, a potential user might understand this warning label as requiring them to abstain from using the drug and thus accept the inevitability of their pregnancy. Such disuse would be in full accord with the gender norms of zygote-centrism, which both function to protect zygotes and, more fundamentally, to dominate women and others who can get pregnant.

As a proactive form of control, this label has an oppressive function at the collective level. Recall that *paternalism* is the middle branch of patriarchy, shaping individuals toward the gender norms of sexist ideology. Such proactive control is often accomplished via self-discipline, such as how dieting, exercising, and ornamentation produce docile and compliant women with

sexualized and feminized bodies (Bartky 1988). These practices shape women's subjectivities through an internalized structure of the self, both how one is perceived and what one knows.

In this case, the drug label as a warning *instructs* women to consider the risks to zygotes and organize their own behavior around such risks. Ultimately, it shapes potential users to sacrifice themselves and their bodies for their (potential) children and families. These norms of "good motherhood," while seemingly benevolent, aim not at women's flourishing but rather at control, coercion, and domination. They censure placing any risk on the developing embryo, while ignoring the risks to and trade-offs for women's health and neglecting women's self-determination.

We see this same distrustful, sexist paternalism in fetal-centric reasoning elsewhere. For instance, when working with pregnant women, doctors are often biased toward not intervening *unless* for reducing fetal risks in the "pursuit of absolute zero risk to the fetus," and this neglect of women's health increases their risk of morbidity and mortality (Lyerly et al. 2009). Likewise, labels from the US Surgeon General discourage *all* pregnant women from drinking alcohol during pregnancy, even though only 5% of alcoholic women give birth to babies with fetal-alcohol syndrome (Armstrong 2003). These fetal-centric values covertly shape people with uteruses into the subservient role of the Reproductive Other assigned them by sexist ideology. This is not to say that reproduction is *inherently* oppressive in itself, but that essentializing those who are able to be pregnant as "potential mothers" and "obligatory reproducers" is a paternalistic practice in the service of patriarchy (Waggoner 2015).

Thus, producing this label had an additional harm at the individual level beyond merely deceiving patients, involving how it constituted their subjectivity in a narrow way as epistemically untrustworthy. This imposition of a limited subjectivity served patriarchal ends by

paternalistically shaping cisgender women and those who can get pregnant into subservient givers of their bodies following sexual intercourse. These wrongs are *epistemic* in nature because they perpetuate oppressive values and norms through knowledge and practices of informing. Yet, as we will see, these proactive measures of imposing values and paternalism can only go so far, so patriarchy employs additional means of enforcement and control.

4.2. A tool for punishing "bad mothers"

Complimentary to the norm of "good mothers" is that of "bad mothers," and the FDA drug label has proven quite useful for anti-abortionists in *punishing* those whom they take to fall in this latter category. The primary form of punishment has come through two forms of denials for healthcare provisioning from anti-abortionists. While some anti-abortionists are professionals who claim "conscientious objector" status to directly deny healthcare to patients, others are employers who defend their "religious freedom" to indirectly refuse their employees through limited insurance coverage. Both forms of punishment impose pregnancy on women through refusing contraceptives.

First, based on claims about the mechanism, would-be providers have refused to dispense the morning-after pill. For instance, in his systematic review with Stanford of contraceptive mechanisms, anti-abortionist Dr. Walter Larimore (University of South Florida, Family Medicine) reflected on how this research changed his prescribing practices with the Pill:

> The most difficult part of this research was deciding how to apply it to my practice. … Finally, after many months of debate and prayer, I decided in 1998 to no longer prescribe the Pill. As a family physician, my career has been committed to family care from conception to death. Since the evidence indicated to me that the Pill could have a postfertilization effect, I felt I could no longer, *in good conscience*, prescribe it—especially since viable alternatives are available. (Larimore and Stanford 2000, p. 133, my emphasis)

Even though Plan B is now available over-the-counter without a prescription, refusals can still come through pharmacists, who can limit availability through different stocking practices and opt-outs (Chiarello 2013; Shacter et al. 2007). Currently, six states explicitly allow pharmacists to refuse emergency contraceptives, and an additional five provide more general protection for refusals that may include pharmacists (Guttmacher Institute 2019). Despite its availability to women under 18 with a prescription, many pharmacists refused to provide emergency contraception to adolescents, and they refuse at higher rates to Spanish-speaking women than English speakers and at rural pharmacies than urban ones (Sampson et al. 2009).

Refusals are especially common in emergency rooms at Catholic hospitals, which have grown to constitute over 10% of hospitals in the US through mergers with non-Catholic hospitals (CFFC 2005; MergerWatch and ACLU 2013). Their ethical and religious directives limit the use of emergency contraception to pre-fertilization for preventing pregnancy after rape (USCCB 2009). Catholic hospitals are more likely than non-Catholic hospitals to prohibit discussion, prescription, and dispensation of the morning-after pill to rape survivors, despite its being the standard of care (Smugar et al. 2000). Accordingly, 82% of Catholic hospitals reported that they did not provide morning-after pills, and only 22% provided referrals (Bucar 1999).

Undergirding these refusals from anti-abortionists is their belief in the empirical claim that this pill is an abortifacient—which the FDA "drug fact" corroborates. As Stanford, Larimore, and their colleague Dr. Chris Kahlenborn (Internal Medicine) recognized, because of conscience clauses, the science of emergency contraception has "legal implications for healthcare providers who either prescribe or have objections to prescribing these agents" (Kahlenborn et al. 2002, p. 468). Larimore and Stanford (2000, p. 130) bemoaned how few physicians knew of the possibility of a postfertilization effect from contraceptives, despite

mentions in the *Physicians' Desk Reference*, medical textbooks, and medical journals. Part of the social utility of this official drug label has been to spread the conclusions of their review article, informing anti-abortion providers more widely about the mechanism with the scientific authority of the FDA.

Moving to the second form of refusal, there have also been significant cases of denials to cover the insurance expenses of emergency contraception by employers under the banner of "religious freedom." In the US, it is common for one's employer to provide healthcare insurance as a form of non-monetary compensation for employment (i.e., benefits in kind). This privatized system of health benefits entangles employers in their employees' healthcare options, leading to conflicts over women's health, transgender health, and more (see Florczak 2018). Anti-abortion organizations, especially the US Conference of Catholic Bishops, have been lobbying for expanded "conscience clause" protections for religious employers to exclude abortifacient contraceptives (Griffin 2015; Miller 2015, pp. 184–5). The Affordable Care Act ("Obamacare," passed in 2010) required health insurers to cover all FDA-approved contraceptives, including Plan B, as "preventative health services." Since then, there have been over one hundred legal cases challenging this contraceptive mandate under the First Amendment and the Religious Freedom Restoration Act of 1993 (Tschann and Soon 2015).

In the cases objecting to abortifacient contraceptives, the FDA's drug label has been crucial. For instance, when the craft-store chain Hobby Lobby and the Christian-bookstore chain Mardel sued the federal government, they cited the FDA's own information that some services like Plan B act abortifaciently (Supreme Court of the United States 2013). The information on the FDA website came directly from the drug label (FDA 2006, 2013). This claim was opposed by many women's health researchers and advocates, who submitted a brief of *amici curiae*

charging that the label was out of date since "later studies have led to the conclusion that [levonorgestrel] does not cause changes to the endometrium (uterine lining) that would hamper implantation" (Physicians for Reproductive Health et al. 2013, p. 16). Nevertheless, the Supreme Court appealed to the FDA's information to rule in favor of the business owners, allowing them and other closely held, for-profit firms to refuse covering these alleged abortifacients.[29]

These acts of "conscientious objection" and "religious freedom" are best understood as practices of *moral gatekeeping*, i.e., "process of social control in which providers uphold cultural and societal values by distributing resources in ways that reward those who comply with normative standards and punish those who do not" (Chiarello 2013). Many pharmacists justify their denial of service as a conscientious objection to abortion, based mostly on religious and moral beliefs, especially from Catholics and Evangelical protestants (Davidson et al. 2010; Griggs and Brown 2007). In addition to protecting from coercion and conscience violation, the new HHS division for Conscience and Religious Freedom aims to expand protections for providers from unfair discrimination, likely into the public healthcare facilities (Federal Register 2018).

However, unlike pacifists who object to military drafts, anti-abortion healthcare professionals are not forced into being gynecologists or pharmacists. Whereas (legitimate) protections for conscientious objectors support those with less power from being coerced, healthcare professionals are the powerful party on whom patients depend. Rather than supporting their patients, these professionals spurn their duties and impose their personal moral beliefs on their patients (Fiala and Arthur 2014).

[29] *Burwell v. Hobby Lobby Stores*, 573, U.S., 1, 9 (2014). They cite FDA information in footnote 7. https://www.supremecourt.gov/opinions/13pdf/13-354_olp1.pdf.

Thus, at the individual level, these acts of refusal and denial of healthcare coerce patients, albeit in a manner different from the more surreptitious and proactive form of paternalism. Unlike with the warning function of the label, its refusal function is a more obvious and reactive form of coercion. Patients explicitly present their want or need for the morning-after pill while their pharmacists, physicians, and hospitals reject the request, and their employers refuse to cover the cost of workers' healthcare. As Carolyn McLeod (2010) argues, this is not a "mere inconvenience" but a *harm* to patients because it interferes with their ability to continue seeking the drug and to maintain their moral identity and sense of security. These refusals either shame women away from the drug or force them to look elsewhere for the medication itself or for the necessary funds. Refusals also impose the physical and mental health risks that come with pregnancy onto patients because emergency contraception is only effective within 72 hours, and its effectiveness decreases during that period. Furthermore, this is a case of "forced gestation" that wrongs women by compelling them into a state of physical intimacy with and occupation by an unwanted entity (Little 1999, p. 301). Here, the threat to bodily integrity comes not only from the sexist values of authorities, but the justification of their right to refuse based on sexist knowledge.

Even if we grant that this coercion is wrong, why is this a specifically *epistemic* form of injustice? Unlike other forms of coercion, these refusals are based on and justified by the value-laden "drug fact." That is, the credence in and credibility of this knowledge claim about how this drug works forced cisgender women and those with uteruses into an unwanted and risky state of pregnancy. The social function of this knowledge follows from epistemic practices of institutions—like the FDA, Supreme Court, and various hospitals and pharmacies—in so far as they are epistemic entities. This deceptive and sexist claim was one of the main enabling factors

in these pharmacists' denials and legal cases like *Burwell v. Hobby Lobby*. Before the Supreme Court, the 10th Circuit Appeals Court determined that "we need not wade into scientific waters here" because all parties agreed that at least some contraceptives act after fertilization (namely, intrauterine devices and some emergency contraceptives) (10th Cir. 2013, n. 3). Yet, the Supreme Court relied on the FDA for its epistemic authority, despite the obscured values constituting the claim. Thus, the "drug fact" is a social tool of control for zygote-centrists to justify their refusals, and the use of this deceptive, value-laden knowledge is an epistemic injustice perpetuated by epistemic institutions.

Furthermore, moving to the collective level, these coercive refusals also constitute an epistemic oppression because of their specific patriarchal function: punishment of "bad women." These impositions of pregnancy (and possible motherhood) on women and others who can get pregnant are acts of *misogyny* that police and enforce sexist gender norms (Manne 2018). Whereas paternalism disciplines women into becoming "good mothers" who sacrifice their bodies for their children, misogyny punishes "bad women" who do not. Anti-abortionists used the label for the implementation of zygote-centric ideology to *punish* "bad women" who might threaten zygotes by attempting to use the morning-after pill. Whether at pharmacies, in Catholic emergency rooms, or through denied insurance, these refusals are hostile reactions to behavior perceived as "unbecoming to a mother."

Sexist stereotypes about women's sexuality and responsibility were prevalent amongst the critics of Plan B (Wynn and Trussell 2006a, 2006b). Even if some refusing pharmacists do not hold conservative attitudes about women's sexuality, their denial reinforces stereotypes that stigmatize women who are sexually active as "promiscuous" and "out of control" (McLeod 2010). Nevertheless, denials to provide this pill have likely been based on these same

condemnations of morning-after-pill users. Exemplified by the testimony during the public forum from Brown and Taylor, anti-abortionists view users as sexual deviants who have rejected the "proper responsibility of mothers" to accept a child as the *natural* outcome of sex. According to their misogynistic logic, *don't do the crime (sex) if you can't do the time (pregnancy)*. Withholding the medicine from "bad mothers" forces them to conform to these sexual norms, and the drug label legitimates such actions because of the FDA's authority.

Compounding these misogynistic practices from patriarchy are *intersecting dominations* from other unjust structures. Beginning with structural racism and white supremacy, feminist scholars (especially women of color) have demonstrated how racism is gendered and how misogyny is racialized. Moya Bailey (2016) calls this intersection *misogynoir*. For instance, when racialized stereotypes about Black women depict them as hypersexualized, it systematically discounts their testimony of sexual assault as untrustworthy. Furthermore, from the outset, society sees Black women already as "unfit" mothers. Accordingly, one central aspect of the oppression of women of color has been the systematic barriers they face to accessing reproductive healthcare, such as governmental support for their pregnancies (Roberts 1997; Ross et al. 2017).

Because of these compounding effects, the imposition of pregnancy *disproportionately* affects the health of Black women and other women of color. For one, women of color face outright discrimination, as young Spanish-speakers are refused the morning-after pill at twice the rates of English-speakers (Sampson et al. 2009). Furthermore, because of structural racism, women of color are more prone than white women to the risks of morbidity and mortality. For instance, Black women face two to three times the risk of dying from pregnancy than do white women (Tucker et al. 2007). Women of color are also more likely to become seriously ill during

pregnancy (Creanga et al. 2014). Because women of color face higher consequences when forced to carry pregnancies further, it is a heightened, racialized case of misogyny—misogynoir—when healthcare professionals refuse them the morning-after pill.

Additionally, refusals based on this drug label have disproportionately affected poor people. After an anti-abortionist denies someone a drug, that person must spend extra time to search and travel to find an alternative provider, even in the case of a referral, and these tasks are more financially burdensome on people of lower socioeconomic status. This search burden further reduces the effectiveness of emergency contraception, increasing the likelihood of an unwanted pregnancy with the associated cost of abortion. Poor women have higher chances for refusal because most states require women on Medicaid to have a prescription for financial coverage (KFF 2016). Thus, despite over-the-counter access, women on Medicaid are subject to increased scrutiny from their physician (to get a prescription) and then their pharmacist (to fill it), further encumbering their access. Black women are also more likely than white women to be recipients of Medicaid, so these refusals compromise their access disproportionately (KFF 2018). Furthermore, increased protections for providers' rights by the new HHS division will only increase the instances of these events, particularly in publicly funded facilities. These structural barriers to access and the protection from providers make refusals harder for poor women and women of color.

The drug label and its credibility are the epistemic grounding for these refusals, not despite these structures, but rather as the key epistemic conditions for their realization. This section has shown how sexist values in science enable downstream epistemic injustices like othering and coercion via value-laden knowledge. The social problems that result from these specific values in science follow from larger oppressive structures, explaining the influence of

zygote-centric values in the first place. More specifically, the epistemic injustices aimed at individuals fit into larger systems for epistemic oppression, such as for paternalism, misogyny, misogynoir, and classism. Through the social utility of knowledge for patriarchal ends, the sexist values in regulatory science are *imposed* on women—for some more than others—in a way that that limits their agency and enables powerful parties to dominate them.

5. Discussion: The Values and the Rights of Providers and Patients

I have demonstrated that the problems with this drug label are not only epistemic but also structural, so this chapter has two normative conclusions—one regarding knowledge production and the other involving institutional practices. First, I argue that the zygote-centric values of anti-abortionists are illegitimate in women's reproductive health because these sexist values enable epistemic injustice and oppression. Feminist philosophers of science have given other good reasons to think that various forms of sexism are detrimental for scientific knowledge or social justice (Anderson 2004; Kourany 2010; Lloyd 2005). My analysis reveals the epistemic detriments of sexist values, the social utility of such knowledge for paternalism and misogyny, and the interrelation between these two within a broader system of patriarchy.

Accordingly, moving to my second conclusion, I argue that providers should not receive institutional support for refusing services to patients based on their value-laden claims. These protections allow them to impose their sexist values on their patients, limit their epistemic autonomy, and dominate their epistemic resources. Instead, we ought to prioritize the values and agency of patients in managing uncertainty about scientific claims and in organizing the practice of healthcare. While beyond the scope of this chapter, I argue more positively in chapter 5 why and how feminist values can improve regulatory science in the realm of reproductive health.

Providing further institutional support for provider refusals, like the new HHS division, will only exacerbate epistemic injustices.

In this discussion, I will respond to three objections to my analysis, related to the challenges of value pluralism in medicine. First, I consider whether my epistemic-justice approach assumes too much ethical framework, responding that such is necessary in highly politicized cases. Second, I discuss whether such restrictions on refusals violate providers' right to conscience, arguing instead that such refusals compromise their moral integrity. Third, I consider whether patients have a right to know about the mechanism, and I deliberate the FDA's responsibility to provide such.

5.1. Objection 1: The epistemic injustice approach assumes too much ethics

First, one might wonder whether this approach relies too heavily on one set of ethical values or one form of social justice. Feminist empiricists have relied on epistemically oriented approaches to critiquing sexism in science in part because they do not assume feminist ethics. Likewise, one of the objections to an epistemic-ethical approach such as Kourany's (2010) ideal of socially responsible science involves the *source* of values. Matt Brown (2013) asks: whose values count as "socially responsible" ones, particularly given the value pluralism and conflict in society?

Likewise, one might object that my epistemic-justice approach assumes too much about ethical values and social justice. The problems I have discussed follow from the ethical quagmire surrounding abortion rights and the different beliefs over what constitutes justice in the realm of reproductive health. Thus, one might object to any approach that appeals to epistemic injustice and oppression using feminist theory because it relies on the very societal values so heavily

debated. As alternative solutions, the objector might propose a "pure" empirical approach, or one may focus on the language used to communicate the risk.

I respect the more epistemically oriented approach of feminist empiricists and even utilize their work to analyze this case. Nonetheless, I am skeptical of the potential for resolution over Plan B's mechanism without appealing to a set of societal values and notion of social justice. Given the politics surrounding cases like this one, we need to address ethics and epistemology jointly, and this requires assuming an ethical framework. As discussed in chapter 1, doctors and researchers have debated the mechanism of the morning-after pill for over half a century. Divergence over the mechanism of the progestin-based pill has decreased somewhat since the 2000s, even among Catholic priests and doctors (see, e.g., Austriaco 2007; Reznik 2010). I believe that this shift is both ethical and epistemic: partly due to increased concern for the rights of rape survivors (Holbrook 2010; Talone 2010) and because of innovative methods for assessing mechanisms more precisely (Gemzell-Danielsson et al. 2013; Lalitkumar et al. 2007). Despite some convergence between zygote-centrists and their critics, there remains a small minority of influential (mostly male) scientists and physicians who maintain that Plan B may have a postfertilization effect, and they have the ear of the Catholic Medical Association (CMA 2015; Kahlenborn et al. 2015). Accordingly, I doubt there will be any *definitive* resolution over the empirical matter between anti-abortionists and women's health advocates because of how entangled values are in their assessments of the facts.

What if we suppose that the mechanism was not value-laden *constitutively* and that those with different values agreed that this drug acted abortifaciently?[30] This would be much like the case with emergency contraceptives using an antiprogestin (ulipristal acetate) and the medical

[30] I thank Bennett Holman for suggesting this possibility.

abortion pill RU-486 (mifepristone and misoprostol). Unlike with Plan B, it is uncontroversial that these compounds *can* act on a zygote before implantation. Even if providers and researchers disagree over the ethicality of abortion, their values do not influence their judgments about how the pills work.[31] Even so, knowledge about the mechanism would still be value-laden in the *social* sense, as it enables anti-abortionists to justify their refusals in courts and religious hospitals (see chapter 2.5). Thus, it would still provide anti-abortionists more leverage to accomplish their political goals than it affords women's health advocates to increase access to these pills. Because the "drug fact" would still be socially value-laden as a political tool for control through refusal, it would enable sexist paternalism (that shapes women into "good mothers" who protect the life of zygotes) and misogyny (that punishes "bad mothers" with imposed pregnancy). Thus, even if the uncertainty were to evaporate, which I maintain is unlikely, reproductive politics would still surround the claim. Therefore, the "drug fact" would continue to limit women's epistemic autonomy and enable epistemic injustice—just without deception.

I maintain the need for appealing to feminist ethics because I am also skeptical of value-free solutions for communicating the mechanism to patients and non-specialists. Along such lines, Gregory Betz (2013, p. 212) contends that scientists ought to communicate uncertainty for policy-making by formulating "hedged hypotheses that make the uncertainties explicit" rather than "plain hypotheses" that rely on value judgments. His examples for communicating "practical certainty" include showing the range of possible interpretations and using epistemic modalities, such as "it is possible that…" (see also Betz, 2017). Yet, even hedged hypotheses

[31] They would still have semantic disagreements because of their values, e.g., zygote-centrists understand the phrase 'may also prevent implantation' to have important ontological and ethical significance (see chapter 2.4.1).

rely on value-laden assumptions about selecting the body of evidence (John 2015), and the necessity for value judgments extends further into science than communicating results, particularly when the science has social stakes and ethical consequences (ChoGlueck 2018; Douglas 2009; Elliott 2017; Longino 1990). Furthermore, the FDA's association of Plan B with implantation, even with hedged language (i.e., "may also prevent implantation"), was enough for zygote-centrists to secure legal legitimacy for refusing their patients the drug—as if the hedging was not even there. Accordingly, this case casts doubt on the value-freedom of Betz's proposal.

Instead of avoiding value judgments, I suggest more transparency in communication the ways about how different values lead to different assessments of the evidence. Dan McKaughan and Kevin Elliott (2013) have suggested a strategy of "backtracking" for making value judgments more transparent, allowing listeners to understand research framing and explore alternative interpretations. Note, however, that value transparency does not avoid or exclude societal values but renders their influence more explicitly discernable. Once transparent, we can evaluate those judgments and hold them to the demands of science and justice, as I have in this chapter.

5.2. Objection 2: Providers have a moral right to conscience and religious freedom

Moving to the second objection, one might worry that I have been too hasty with the religious and conscience rights of providers. Particularly over the morning-after pill, bioethicists have debated heavily the rights of pharmacists and physicians to refuse or deny drugs (Cantor and Baum 2004; Card 2007; Del Bo 2012; Fenton and Lomasky 2005; Fiala and Arthur 2014; McLeod 2010). Possible defenses of such refusals include: professionals should not forsake their morals to be employed; such freedom is integral to a healthy democracy; and "simple refusal" is

not overly burdensome or harmful (Cantor and Baum 2004; Fenton and Lomasky 2005; contrast with McLeod 2010).

One must balance these defenses on behalf of providers' rights against their professional obligations to their patients.[32] For one, their refusals impact their patients' health more than professionals'. Further, refusals can shame women about their own choices, discourage them from continuing to search, and reinforce sexist ideas about women's promiscuity (McLeod 2010). Accordingly, there cannot be an *absolute* right to conscience, but rather a more *limited* right to refuse at times, possibly obliging objectors to give referrals to more willing providers (Cantor and Baum 2004). This situation entails the need for compromises. However, at least in some cases, I anticipate a "zero-sum game" between two sets of irreconcilable views, where it is in the patient's interest to access this pill and where the only provider who can do so in the timeframe of effectiveness refuses based on ethical or religious principles. This is not a mere thought experiment as the effectiveness of emergency contraceptive pills declines after 72 hours (Cleland et al. 2014). Furthermore, zygote-centric organizations like the US Catholic Bishops and the University of Notre Dame have rejected several attempts at compromise involving referrals and external funding from the Obama administration, arguing that even special accommodations for religiously-owned non-profits and corporations burden their exercise of religion (Griffin 2015; Tschann and Soon 2015). When zygote-centrists refuse to compromise, what then are the limits to their conscientious refusal?

Considering refusals of emergency contraception, the Ethics Committee of the American College of Obstetrics and Gynecology has offered the following guidelines for preserving the *moral integrity* of providers (ACOG 2007, reaffirmed 2016). (1) Refusals ought not impose

[32] I thank Kevin Elliott for suggesting I discuss the limits of healthcare professionals' rights directly.

providers' beliefs on patients. Such impositions would violate patients' right to autonomy. (2) Providers should consider the impact of their patients' wellbeing. Their primary duty is to promote their patients' health, and even for cases in which zygotic/embryonic health diverges, the provider's *primary* patient is the woman and their basic obligation is toward her. (3) A valid refusal must rest on sound, well-evidenced science. This guideline is particularly relevant for refusals of emergency contraception, which have "been complicated by misinformation and a prevalent belief that emergency contraception acts primarily by preventing implantation" (ACOG 2007, p. 4). (4) Providers must consider whether refusals are discriminatory. Such acts ought not reinforce an unfair distribution of resources or oppress marginalized groups.

I suggest we employ these guidelines, which cover a variety of ethical and epistemic considerations. Accordingly, we see how refusals in this case transgress all four criteria. Regarding autonomy (1), I have argued that refusals based on this "drug fact" coerce the agency of individual patients by imposing zygote-centric values through the knowledge itself. Moving to patient wellbeing (2), the judgment that this pill may act postfertilization is based on a zygote-centric view of reproductive health that deprioritizes women's health for concerns about the zygote. Regarding scientific integrity (3), I have argued that calling this claim a "drug fact" is deceptive and that it is closer to misinformation. The committee agrees: "Although even a slight possibility of postfertilization events may be relevant to some women's decisions about whether to use contraception, provider refusals to dispense emergency contraception based on *unsupported* beliefs about its primary mechanism of action should not be justified" (ACOG 2007, p. 4, my emphasis). Finally, looking at injustice (4), we have seen how these refusals are a misogynistic punishment of "bad women" and how poor women and women of color bear the burden disproportionately. Because all four criteria fail to hold, I conclude that refusals do not

preserve providers' moral integrity, but rather put it in jeopardy. Thus, when compromise fails, providers cannot refuse on epistemic-ethical grounds. Instead, they ought to provide women the drug.

5.3. Objection 3: Patients have the right to know how the morning-after pill works

Moving to the final objection, I would like to consider how my proposal relates to the right to know of patients and consumers.[33] Systemic ignorance about their bodies has long been a source of women's oppression (Tuana 2006). Furthermore, given the uncertainties surrounding the science, and the importance of values in managing them, it is not clear where the truth (or empirical adequacy) lies about the mechanism regarding postfertilization. More information promotes women's freedom, so more information from more perspectives—even zygote-centric ones—might be better than less. Excluding zygote-centric values from women's reproductive health would limit knowledge production and put certain knowledge "off limits." Thus, from a feminist perspective, one might worry that my first conclusion (that zygote-centric values are illegitimate in women's reproductive health) violates women's right to know and contributes to this pattern of paternalistic withholding. One might worry that excluding certain values is akin to "withholding" or "suppressing" information about the mechanism. Thus, an objector might contend that such exclusions would be oppressive, akin to the social control by ignorance of days past.

I share the concerns about systemic ignorance and how it can be oppressive. However, I maintain that excluding zygote-centric values from women's reproductive health would not violate the right to know or contribute to women's oppression. Recall that the claim that Plan B

[33] I thank Erin Nash for discussing this concern about patients' right to know.

"may prevent implantation" is deceptive because it has not withstood the scientific scrutiny required of an objective "drug fact." Because of its appearance as value-free knowledge, it purports more authority and credibility than it deserves. Furthermore, it is too vague to enable decision making, even for zygote-centrists, other than encouraging complete disuse. Accordingly, this claim leaves consumers without the knowledge needed to act in an informed manner.

This objection also relies on the false assumption that more information is more liberating. Yet, feminists have shown how vague disclosures about risk can oppress women, such as how reproductive-risk warning are used by business owners to offload their responsibility for providing pregnant women with a clean environment (Kukla 2010). The key issue in the politics of information has to do with the social stakes of knowledge, that is, the social function of knowledge in society. As I have argued, this "drug fact" has two patriarchal functions, involving paternalism and misogyny. These real-world consequences are not unrelated to the sexist values laden in the knowledge claim. Rather, they are the manifestations of how sexist knowledge functions in patriarchy to dominate women. The social consequences of knowledge production are not independent of the process itself, and we need to include the evaluation of regulatory science in terms of its consequences.

This objection also faces legal and institutional problems. Why, for instance, must the FDA disclose the perspective of anti-abortionists about the mechanism on Plan B's label when no other drug label has this information? The motivation for a special exception comes in part from concerns for zygote's rights, but it also serves the social function of enforcing sexist gender norms about motherhood. Even if we grant that patients have a right to know about the mechanism, it is doubtful that this ethical responsibility for informing patients falls on the FDA.

Furthermore, given the connection of zygote-centrism to religious groups like Catholics, and the separation of Church and State in the US Constitution, there are legal issues about violating the establishment clause with zygote-centric value-ladenness. If any institution bears the responsibility for informing patients about this risk, it would be special interest groups, not a secular public-interest regulatory agency.

6. Conclusions: Exclude Zygote-centric Values, Don't Protect Their Refusals

After responding to these objections, I affirm the importance of a feminist framework, and I support limited conceptions of providers' rights and the FDA's responsibility to inform patients. Accordingly, I maintain my conclusions: there is a compelling case based on epistemic injustice for excluding zygote-centric values from regulatory science and for removing institutional protections for provider refusals of the morning-after pill. Both measures will reduce the epistemic injustices done to individuals and the epistemic oppression of marginalized groups.

My analysis has three implications for philosophy, including philosophy of science, social epistemology, and feminist philosophy. For philosophy of science, this chapter provides a novel alternative account for why sexist values specifically are illegitimate in science. While allowing for a pluralism of values might improve science in other cases (Longino 1990), it is better in regulatory science about reproductive health to exclude zygote-centric values because of their epistemically unjust effects. Other feminist philosophers of science have criticized Longino for implicitly allowing ethically unacceptable values into science, or at least not providing enough reason to exclude them (Anderson 2004; Goldenberg 2015; Hicks 2011). Granting the value-ladenness of science, I think our epistemic practices and products are answerable to the codependent demands of science and justice, particularly promoting epistemic autonomy and

preventing epistemic oppression. While my conclusion might be the same as the value-free ideal (that sexist values are illegitimate in science), I maintain this conclusion not because sexism is a societal value, but rather because it impedes the aim of epistemic justice. Philosophers of science have called attention to the importance of more socially relevant and ethically informed philosophy (Elliott 2017; Fehr and Plaisance 2010; Hicks 2014; Shrader-Frechette 2018). Unlike with other epistemic-ethical proposals (e.g., Kourany 2010), my epistemic-justice approach has the benefit of integrating epistemology with ethics, which rejects a dualism of epistemic and ethical aims and thus avoids concerns about wishful thinking (see Brown 2013; Douglas 2015). That is, excluding sexist values from regulatory science would be mutually advantageous for knowledge production and social justice, rather than one or the other.

Second, for social epistemology, this case study contributes to understanding novel forms of epistemic injustice occurring in science and medicine, particularly because of value-laden knowledge. For one, deceptively presenting value-laden knowledge as "value-free" can disrespect users' own values and hinder their decision making. Additionally, knowledge laden with unethical values can have unjust downstream effects during knowledge use, such as imposing providers' values on patients and coercing individual subjectivities toward oppressive gender norms. Close attention to other case studies in science and medicine might provide beneficial for elaborating the frameworks of epistemic justice and oppression.

Third, for feminist philosophy, this analysis supplements Manne's two-branch account of patriarchy (sexism and misogyny) with a third branch (paternalism). While some coercion in the service of patriarchy is *reactive* misogyny in response to the violation of gender norms, I have shown how other forms of coercion are more *proactive*. I illustrate this sexist paternalism with the social function of the "drug fact" as a warning label, aimed at shaping women into "good

mothers" prior to any punishment. Including both proactive and reactive forms of social control into our analysis of patriarchy provides a fuller picture of the relations between knowledge and power and the complementarity of gender norms for "good" and "bad" women.

My proposals raise important questions about value pluralism in regulatory science within a democracy. For one, what is the proper place of feminist values in health policy? I anticipate that creative feminist practices will more positively promote epistemic justice than zygote-centric values and provider protections. Following Medina (2013), the only true counter to epistemic oppression is epistemic *resistance,* and such has been the strategy of the feminist women's health movement (Bueter 2017; Tuana 2006). Resisting epistemic patriarchy in regulatory science and reproductive health involves a variety of challenges, such as relating medical ethics to context and practice, understanding patient values in their wide diversity, and overcoming power imbalances in medicine exacerbated by social inequalities. For innovative solutions to these challenges, I look toward intersectional approaches from researchers and health activists in the reproductive justice movement (see Ross et al. 2017). Furthermore, in chapter 5, I explore how feminist values have improved regulatory science through epistemic-ethical reform of sexist values entrenched at the FDA.

Yet, one might wonder: are sexist values and gender norms ever legitimate in regulatory science within a democracy? There are good reasons to think that sexist values beyond zygote-centrism are not helpful for investigating human evolution (Lloyd 2005), society (Anderson 2004), or health (Bueter 2017; Kourany 2010). As supported by feminist science studies, the precise problem with sexism often differs based on the case—as one might expect for such a problematic set of beliefs and practices! Nonetheless, epistemic injustice might prove to be a fruitful, socially engaged approach for delimiting the interrelation of ethics and epistemology,

particularly for challenging the male dominance that remains in science, regulation, and healthcare.

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Part II.

Informing Patients about Risks:

Package Inserts for Oral Contraceptives

Overture.

Hysterical Housewives, Radical Feminists, and the Gendering of Expertise About the Pill[34]

In January 1970, US Senator Gaylord Nelson began collecting testimony from "the experts" about oral contraception. His special hearings on the Pill were motivated by Barbara Seaman (1969), who advocated in *The Doctor's Case Against the Pill* for full disclosure of its many health risks—particularly fatal blood clots. While the British government had halted prescriptions for riskier dosages months earlier, the US Food and Drug Administration (FDA) maintained in their "Second Report on the Oral Contraceptives by the Advisory Committee on Obstetrics and Gynecology" that the Pill was still "safe within the intent of the legislation" (1969, p. 6848).

[34] This essay was published in *Lady Science* (volume 54, March 2019) in syndication with *The New Inquiry*. Available online at: https://thenewinquiry.com/blog/hysterical-housewives-radical-feminists-and-the-gendering-of-expertise-about-the-pill/.

Although women contributed to the Nelson hearings as experts and as protesters, sexist gender norms about expertise shaped who was seen as credible and who was thought to have disturbed the proceedings. Women participating in the hearings occupied different positions, some as doctors and scientists, whose judgment reinforced the status quo in male-dominated medicine, and others as lay experts, whose contributions were dismissed as being hostile or uneducated. In the background were widely shared racialized convictions about the Pill as a tool for population control.

Nelson's hearings attracted media attention as well as protests from the radical feminist DC Women's Liberation group led by Alice Wolfson (Watkins 1998). These feminists called out the sexist underrepresentation of women among the experts initially called to testify. The senators (all white men) patronized the protesters and dismissed them as "disturbances" and "disruptions" (NH, 15, pp. 6000, 6053).[35] Nelson even told the protesters that "you are prejudicing your own case" with their presence at the hearing (NH, 15, p. 6395). After the protesters contemptuously passed out pills for the men to take—asking them "to think of it circulating through their bodies while listening to testimony"—Nelson closed the hearings to the public (Sigal 1970).

The DC Women's Liberation group provoked the senators and the public to think more critically about expertise and gender. Out of 36 experts, only five who testified were women, invited by Nelson solely in response to the protestors. While some historians like Andrea Tone

[35] As a convention for citing Senator Nelson's congressional hearings and its appendices, I use the following: NH [for Nelson Hearings], Volume # [either 15,16, or 17], and page number. There are over 30 volumes from the hearings before the US Senate Subcommittee on Monopoly of the Select Committee on Small Business on "Competitive Problems in the Drug Industry." Three pertain to oral contraception in 1970: volume 15 covers Jan. 14-15 & 21-23; volume 16 covers Feb. 24-25, Mar. 3-4; and volume 17 includes appendices containing supplementary material submitted to or collected by the committee. All are available electronically through ProQuest Congressional Database, Legislative & Executive Publications. Hearing IDs: HRG-1970-SBS-0008, HRG-1970-SBS-0009, & HRG-1970-SBS-0010.

(Tone 2001, p. 248) overlook these women as mere "medical experts" (see also Kline 2010, p. 110; Marks 2001, pp. 150–51), others like Elizabeth Siegel Watkins argue that their contributions were limited primarily along class lines. In *On the Pill*, Watkins notes that "it would be too simple to categorize these women as 'anti-feminists'," and yet "their conception of 'women's best interest' was clearly colored by their socioeconomic position as upper middle-class professional women and varied considerably from the ideas of others" (1998, p. 118). When compared with the men who testified, women were much more likely to have financial conflicts of interest: nearly all of them prescribed the Pill (and could be accused of medical malpractice) or crafted population policies involving birth control.[36]

These women experts were situated in male-dominated medical fields, which directed their professional judgment away from women's health. For instance, Dr. Elsie Carrington, an OBGYN professor at Woman's Medical College of Pennsylvania, determined that the Pill's social benefit of limiting population growth outweighed any risks for individual patients. She testified that glucose tolerance may be reduced by progestin in the Pill, although adverse effects and long-term implications were unclear. "Medical and social benefits of such effective contraceptive agents are undeniable," she reasoned (NH, 16, p. 6658). "Continuance of their use is warranted and in fact essential for many of our individual patients and certainly for our society." The global "population problem" had motivated the initial research for the Pill, and it continued to shape the regulation and use of contraception (Marks 2001, pp. 13–40).

Interestingly, Carrington's female body and her feminine gender went unmentioned by the senators as seemingly irrelevant, rendering her testimony sex/gender blind. The presence of women like Carrington increased the credibility of the Nelson hearings, undermining an easy

[36] See chapter 4.2 on conflicts of interest by gender.

takedown of the hearings as totally excluding women. Yet their participation at such small numbers functioned more as tokenism, and it strengthened the group consensus that the Pill was safe enough.[37]

The sex and gender of other experts, however, did attract attention, in part because of racist concerns related to population policy. Take Dr. Mary Lane Cobb, the Clinical Director of the Margaret Sanger Research Bureau in New York, who was also the only Black witness present (AWAHSWA 2019). One Senator clumsily asked her to testify "to the women of America… whether or not *you* take the pill" (NH, 16, p. 6647). Cobb responded that yes, she had taken it, knowing the risks, because she simply could not tolerate another pregnancy. She described the decision as a "personal" one, highlighting its non-generalizability to other women.

Unlike with Carrington's testimony, the senators did not take Cobb's as sex/gender blind. Possibly due to her blackness, the committee saw Cobb as especially different from themselves. Thus, Cobb was made to testify as a hybrid expert-user, assuring them about the competence of doctors and the ability of users (like herself) to weigh the risks and benefits rationally. The senators welcomed this placation, as many experts voiced their fears of how poor women and women of color might overreact to learning about the risks of the Pill, create an epidemic of "unwanted Nelson babies," and then exploit the welfare system (NH, 15, p. 6206; 16, pp. 6483, 6818; for context, see Roberts 1997, pp. 202–45).

Cobb gave the only perspective from someone who used the Pill, yet her hybrid status limited her ability to represent non-expert users, whom Senator Nelson had promised but refused to question (NH, 15, p. 6000). Descriptions of lay users during the hearings painted a negative picture of women's ignorance, irrationality, and emotionality. Dr. Alan Guttmacher, President of

[37] See chapter 4.3 on expert witnesses' judgments about safety.

Planned Parenthood Federation, presented a condescending view of women's intellectual abilities: "I do not think that you are going to be able to educate the American woman…. I think you can educate the American doctor. *He* is educatable" (NH, 16, p. 6568, my emphasis). Guttmacher feared a "panic reaction" of discontinuation from users, so he suggested that it was better to withhold some information about the risks.

Contrasting the calm and informed judgments of women like Cobb and Carrington, the Senate hearings represented "normal" women as a group in highly stereotypical ways. This gendered duality created the impression that feminine emotions and "disturbances" from potential Pill users were out of place in this masculinized scientific and policy discussion. To the physicians, researchers, and senators, non-expert women on the Pill were either confused, simple-minded housewives susceptible to "mass hysteria," or they were radical feminists "disrupting" the rational debate by prejudicing sound judgment with alarmism.[38] This gendering reinforced the status quo much to the benefit of pharmaceutical companies.

These Senate hearings were monumental in part because they resulted in the FDA's first insert for informing patients directly—the subject of the next chapter. While we take a patient's right to know for granted today, it was not standard in research or clinical practice in 1970 (Faden and Beauchamp 1986; Rothman 2003). Radical feminist protesters at the back of the proceedings also contributed a sense of public outrage and shame to the hearings. Their efforts pressured the FDA to make future meetings more public, and their persistence catalyzed the women's health movement and set the stage for other patient movements in later decades (Epstein 1996; Nelson 2015; Watkins 1998).

[38] See Kukla (2005) for more on the history of "mass hysteria" in medicine and Western culture.

While women have challenged patriarchal health policy in a variety of roles, their contributions continue to be limited by problematic gender norms about expertise. Even with issues related to women's health, men continue to monopolize policy making. Women total over half the population, yet they hold merely 20-25% of elected offices in the US (CAWP 2019). And now, thanks to Twitter, we get regular, bite-sized reminders. In early 2017, US Senator Patty Murray, re-tweeted the photo of an all-cis male group of House representatives: "A rare look inside the GOP's women's health caucus" (Murray 2017). Senator Murray was pointing out the irony that this group—which excluded anyone who could become pregnant—was proposing to eliminate maternity coverage. To reverse this historically entrenched problem and improve women's health, policy making needs both a better representation of women and more critical attitudes about the gendering of expertise.

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Chapter 4.

Keeping Women Ignorant and On the Pill:

On the Relationship Between Informed Consent and Social Justice

Abstract: What counts as the *informed* condition of informed consent, and how should drug labels implement this informing? This paper explores the ethical-epistemic dimensions of informed consent through the first major case of informing patients directly at the US Food and Drug Administration (FDA): the first package inserts specifically for patients included with the Pill (oral contraceptives) following the 1970 Nelson Senate Hearings. According to prominent bioethicists, to achieve informed consent, physicians ought to increase patients' *understanding* through effective, oral communication rather than just *fully disclosing* information to them. However, as exemplified by the case of the Pill's drug label, these existing accounts ignore important ethical-epistemic aspects of informed consent and do not adequately capture the interdependence of knowledge and social justice (and, inversely, of ignorance and oppression). I argue that bioethics should focus less on abstract ideals of informing and more on their use in practice, exemplified by gender politics in regulatory science. With a historically engaged, ethical-epistemic analysis, I illustrate how powerful, mostly male parties in medicine have misused ideals of informed consent to keep women ignorant about their reproductive health for population control and financial gain, particularly poor women and women of color. For instance, with the support of pharmaceutical companies, doctors argued against full disclosure because they thought it would "upset" or "frighten" them, leading to "emotional" rather than "rational" reactions and population growth from "unfit" groups. I provide an alternative account of informed consent, which attends to the power relations of informing and the politics of

information. Accordingly, achieving informed consent requires ameliorating social injustice through medical information like drug labels.

1. Introduction

Providing patients informed consent is challenging, and the obstacles only increase as our scope broadens from individual patients to entire populations of consumers. While bioethicists often approach informed consent at the interpersonal level of doctor-patient relations, attention to the structural and cultural levels of informing provide new insights about informed consent, social justice, and systematic ignorance.

In 1970, the US Food and Drug Administration (FDA) made its first widescale attempt to inform drug consumers directly about a drug's risks. The previous year, feminist health advocates like Barbara Seaman (1969) had pressured the agency to fully disclose to the users of the Pill (assumed to be ciswomen)[39] its health risks, particularly the potentially fatal blood clots. However, by the time of its implementation, the FDA significantly shortened and simplified the package insert to facilitate patients' understanding and encourage them to consult with their doctors (see figure 4.1).

[39] It is important to note that there are many non-ciswomen, who can get pregnant, e.g., some transgender men and non-binary individuals, and thus face the risks of oral-contraception use. However, such nuances went unnoticed at the FDA and in the hearings, an issue beyond the scope of this paper. Accordingly, in this chapter, I rely primarily on the actor's category of 'women' to refer to the users of the Pill.

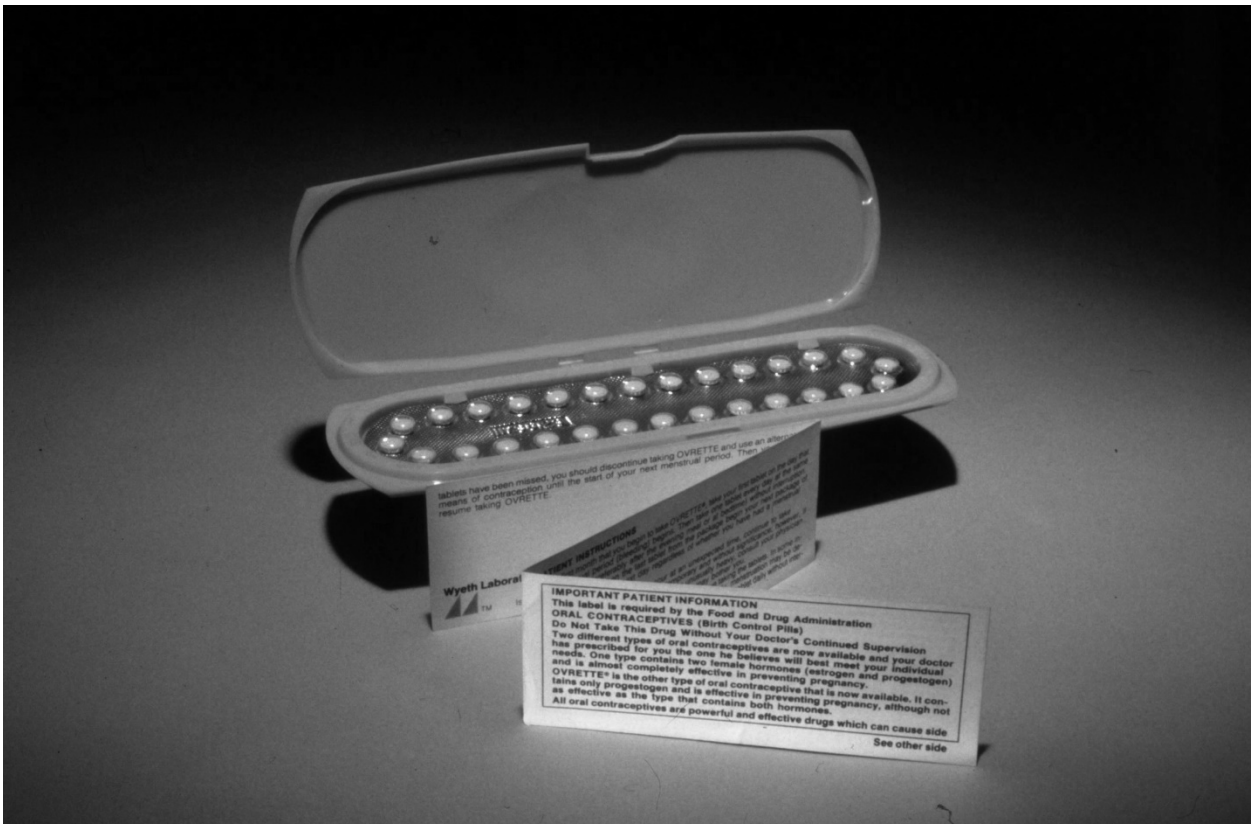

Figure 4.1*: The first package inserts FDA made specifically for users in June 1970. The insert stands in front of the oral contraceptive Ovrette manufactured by Wyeth Laboratories. Image Source: FDA (public domain).*

On the face of it, bioethicists might support this shift in the labeling strategy, at least based on their accounts of informed consent. While the law has focused traditionally on complete and detailed disclosure of health risks to patients in writing, several prominent ethicists have argued that informed consent is not primarily or even necessarily about *full disclosure*. Instead, they contend that informed consent requires the increased *understanding* of patients that comes with better communication face-to-face (Beauchamp and Childress 2013; Faden and Beauchamp 1986; Manson and O'Neill 2007). Thus, for the Pill, it is possible that feminists misdirected their demands and that the abbreviated package insert in fact better facilitated their informed decision-making than would have a more complicated, lengthy version.

While one might find this standard account of informed consent appealing in the abstract, I argue that we should abandon its implicit either/or framing of *full disclosure versus increased understanding*. In the case of the Pill, powerful, mostly male parties in medicine misused the lofty ideal of increased understanding to keep women ignorant and compliant. Some authorities considered women "ineducable" and feared their propensity to "panic." They were particularly concerned about noncompliance from women in "social areas" they deemed undesirable, such as poor population and people of color, and subsequent population growth.[40] They coopted the concept of informed consent for unethical purposes—involving the sexism and racism of physicians, the goals of population planners, and the commercial interests of pharmaceutical companies—resulting in a major miscarriage of social justice. Yet, existing accounts neglect the interdependence of knowledge and justice. Historically, systematic ignorance about female bodies has been one of the main sources of women's oppression, so feminists have produced and disseminated knowledge for political resistance (Davis 2007; Schiebinger 2008; Tuana 2004, 2006). Existing bioethical accounts ignore the political and ethical assumptions that have motivated strategies of claiming to "improve" communication and understanding to justify withholding and facilitate systematic ignorance.

Instead, I will provide a more socially attuned account of informed consent, which attends to the power relations of informing and the politics of information. Accounting for these neglected epistemic-ethical aspects of informed consent is important for bioethics because it prompts us to rethink the universal hierarchy that places the ideal of increased understanding over that of full disclosure. Rather than focusing on these abstract ideals, I suggest that we

[40] This case illustrates a larger structural problem of *reproductive injustice*: poor women, women of color, and other marginalized groups face special additional barriers to exercising their reproductive rights to have a child or not. For further discussion of reproductive justice movement, see section 2.3 in the introductory chapter.

address *the use of ideal concepts*, including how practices of informing are political, how medical ethics and epistemology interact, and how bioethics depends on social context. I suggest possibilities for improvement to attend better to the injustice and oppression in medicine by way of systematic ignorance. My account points to unequal access to knowledge for groups with more privilege and power, and it suggests socializing the burden for the responsibility of informing patients.

Furthermore, this analysis helps historians and philosophers of medicine understand how feminists in the late 1960s and early '70s challenged sexism and injustice in regulatory science and attempted to supplanting it with their own values and politics. Patients' movements have improved medical research and drug regulation with their critical antagonism and reform, such as the advocates of HIV/AIDS patients, women, and people of color (Epstein 1996, 2007; Nelson 2003, 2015). In chapter 5, I examine more recent events in this legacy of the women's health movement at the FDA. In contrast to that feminist success story, this chapter helps us better understand the efforts of earlier feminists, the push-back they faced from unjust structures, and their legacy of feminist resistance in regulatory science. We see how feminist health advocates were attentive to the social function of medical knowledge and provided important insights into the interdependence of ethics and epistemology.

My methodology for this chapter is a historically engaged analysis of the ethics of informing patients and their epistemic significance. Using an in-depth study involving the Pill, I draw on the arguments and critiques from historical actors, including politicians, doctors, regulators, and activists. My main primary source is the transcripts from the Nelson Senate

Hearings,[41] during which the patient package inserts emerged as the solution to the Pill's risks. I collected the 36 testimonies from expert witnesses, including their stances on safety of the pill, informed consent, and the patient inserts. Instead of a single-dimensioned approach, I have provided a "coupled ethical-epistemic analysis" that attends to the dynamic interrelation between ethics and knowledge (Tuana 2013; Katikireddi and Valles 2015). Accordingly, I analyzed how these expert witnesses tried to justify and frame their arguments about safety, informed consent, and for/against the package insert, as well as the interdependence between these value judgments. Using qualitative methods from grounded theory, I searched for patterns within the group of witnesses using positional and situational maps (Clarke 2005, pp. 125–35). In addition to tabulating witnesses' judgments, I paid special attention to their gender, area of expertise, and affiliation, and I noted any financial conflicts of interest. Historians are vague on the origins of the patient package insert, and they have not provided as in-depth of an analysis of the Hearings as presented in this paper. For instance, Laura Marks (2001) focuses less on the initial insert than later revisions up to the 1990s (see pp. 249-55). While Elizabeth Siegel Watkins (1998) does discuss the insert, informed consent, and the Nelson Hearings, she does not tabulate and analyze the stances of the witnesses (see pp. 103-31). Building on the important work of Watkins and Marks, this analysis contributes a more detailed study of the Nelson Hearings and the package inserts to the history of contraception and the FDA.

To critique existing accounts of informed consent, section 2 begins with how bioethicists

[41] As a convention for citing Senator Nelson's congressional hearings and its appendices, I use the following: NH [for Nelson Hearings], Volume # [either 15,16, or 17], and page number. There are over 30 volumes from the hearings before the US Senate Subcommittee on Monopoly of the Select Committee on Small Business on "Competitive Problems in the Drug Industry." Three pertain to oral contraception in 1970: volume 15 covers Jan. 14-15 and 21-23; volume 16 covers Feb. 24-25, Mar. 3-4; and volume 17 includes appendices containing supplementary material submitted to or collected by the committee. All are available electronically through ProQuest Congressional Database, Legislative and Executive Publications. Hearing IDs: HRG-1970-SBS-0008, HRG-1970-SBS-0009, and HRG-1970-SBS-0010.

discuss the epistemic dimensions of this concept, such as doctors' responsibilities to disclose and patients' capacities to understand. The following three sections move through three stages in the history of the Pill and the inserts about its health risks. Beginning with the initial demand for informed consent in late 1969, section 3 recounts the emergence of the risks of the Pill and the early demand by feminists like Seaman to provide women with full, written disclosure. Section 4 analyzes the US government's response at the subsequent 1970 Nelson Hearings, where expert witnesses reframed informed consent according to the ideal of increased understanding through oral communication and doctor oversight. Moving to the negotiations for implementing informed consent, section 5 examines Commissioner Edwards' proposal for the new patient package insert and its revision after feedback from doctors, industry, and the public in mid-1970. Section 6 then examines the broader relationship between systematic ignorance about women's health and oppression. Accordingly, I provide four considerations about implementing informed consent more critically to aspects of social justice.

2. Existing Bioethics on Informed Consent

Informed consent is one of the pillars of biomedical ethics and a major consideration for clinical and research ethics, so the concept and its practice have attracted considerable scholarly attention. Unsurprisingly, bioethicists' accounts of informed consent vary widely over the concept's ethical foundations, its clinical and research applications, and its relevance for crafting health policy. Yet, prominent accounts agree on the misguided nature of the earlier, legal tradition that focused on full disclosure.

For instance, many bioethicists justify informed consent on the fundamental principle of *respect for autonomy* in the tradition of the Belmont Report, following Ruth Faden, Tom

Beauchamp, James Childress, and the 1979 US President's Commission (Beauchamp 2011; Faden and Beauchamp 1986; see Eyal 2012). Autonomy is one of four fundamental principles in textbook versions of biomedical ethics, along with beneficence, non-maleficence, and justice (Beauchamp and Childress 2013). Accordingly, the guidelines for achieving informed consent are typically based on conditions of autonomous actions between individuals, such as intention, understanding, and coercion (Faden and Beauchamp 1986). Other bioethicists, like Nora O'Neill, have disagreed. With Neil Manson, O'Neill conceptualizes informed consent as a transaction between doctor and patient (or researcher and subject/participant) to protect individuals from unpermitted harm and abuse (Manson and O'Neill 2007). Unlike the first camp, the second rejects the claim that informed consent is an autonomous authorization to promote decision making and free choices. Instead, they consider it a "waiver" to communicate the content of a proposal for medical intervention and to make a conditional commitment allowing such intervention between persons (Manson and O'Neill 2007, p. 91).

Despite foundational disagreements, these bioethicists agree on two crucial points about implementing informed consent: the ideal of full disclosure of written information is inappropriate, while understanding and communication are essential. First, they agree that efforts to increase and clarify disclosures are insufficient to achieving informed consent because these approaches ignore patients' personal values, background knowledge, and local context. In their classic account of the history and concept of informed consent, Faden and Beauchamp (1986) argue that the law has traditionally focused on *objective* standards for adequate disclosure. For instance, both the reasonable person and professional standards ignore whether the information disclosed is *materially relevant* to the values and goals of patients or subjects. They consider, for instance, the case of two pregnant women with different values who hold different claims about

Caesarian-section delivery to be relevant to them personally. An athlete who wants to get back to running might be most interested in recovery time. In contrast, another woman who is less active and wants a large family might be more concerned about the increased risk of C-sections in future deliveries (Faden and Beauchamp 1986, pp. 303–4). Faden and Beauchamp argue that it would be unnecessary to fully disclose to both women the same information, including both recovery time and the increased risk of C-section. More generally, they contend that it would be inappropriate to fully disclose *every* risk to *every* patient, as they suggest the old legal standards imply.

Along similar lines, Manson and O'Neill (2007) critique the Belmont Report and the older Helsinki Declaration for imposing more exacting standards of *explicit* (non-implicit) and *specific* (non-generic) consent with extensive written documentation. They contend that this uniformity is inappropriate for different forms of treatment, e.g., invasive research versus merely intrusive research. Furthermore, such formalism is demanding on doctors and researchers and opaque for most patients. For instance, the parents of a deceased child might consent to the retention of tissue removed for autopsy (for future use in research) without realizing that 'tissue' means to whole organs like the brain and heart, which they would have desired to preserve had they known (Manson and O'Neill 2007, p. 14). Such attempts, they conclude, to satisfy an ideal of full disclosure are inadequate for achieving informed consent.

Second, and accordingly, rather than fuller disclosures, they argue that informed consent requires the increased *understanding* of patients that comes with better oral *communication*. In addition to the necessary conditions of intentionality and freedom from control, Faden and Beauchamp (1986) argue that an action only constitutes an autonomous act of informed consent when there is "substantial understanding." It is doubtful, they explain, that patients will

automatically understand disclosed information without expert guidance because of their lack of background knowledge and technical language and the difficulties of interpreting probabilities, processing new information, and managing emotional reactions (see also Beauchamp and Childress 2013). While a "core disclosure" might be useful for initiating conversation, the goal is one of *shared understanding*, which effective communication achieves. Likewise, Manson and O'Neill (2007) argue that successful consent is a transaction between persons requiring adherence to social norms of effective communication, the intelligibility and relevance of information, and the truth and truthfulness of the claims. Because some information will be irrelevant, incomprehensible, or misleading, good communication requires some degree of justified withholding (Manson and O'Neill 2007, pp. 57–64).

With their attention to the individual needs of patients in their local context, these bioethicists agree on the need to provide more than "mere disclosure" and instead increase patients' understanding by improving communication. "The central question" according to Faden and Beauchamp, "is not merely, 'What facts should the professional provide?' but 'What should the professional ask and say?' and … 'How should the professional act?'" (1984, 307). This imperative relies on a hierarchy of communication and understanding over disclosure (and oral means over written print). Thus, Manson and O'Neill call for a shift "from a *thin* 'informational' conception of informed consent to a *fuller* communicative account" (2007, 185, my emphasis). Furthermore, by subordinating the requirement to disclose fuller information (details about risks, etc.) to patients, these accounts prioritize in-person interactions with medical experts and healthcare professionals.

So, we see that bioethics have framed their debates around two ideals of informed consent, and they pit their newer ideal of increased understanding against the older ideal of full

disclosure from the law. As ideals from different traditions, these two concepts have differences. *Increased understanding* entails that patients deserve all (and only) the *relevant* knowledge, so the doctor ought to function as a mediator communicating with the patient to convey information, primarily through *oral* discourse. In contrast, the ideal of *full disclosure* requires they communicate a larger set of knowledge than what they consider materially relevant or intelligible. Here, doctors are *potential barriers* because of bias and manipulation, be it intentional or implicit. Thus, achieving full disclosure might require going around doctors as potential sources of ignorance and using alternative *written* methods. While these ideals are compatible in principle, note how bioethicists use one (increased understanding) to attack the other (full disclosure). As we shall see, this same fallacious reasoning encouraged by the either/or framing occurred at the Nelson Hearings.

I suggest we abandon this either/or framing, focus less on these ideals, and instead evaluate how they are used in practice.[42] Despite accounting for some of the epistemic-ethical dimensions of informed consent, these ethicists overlook larger political aspects of informing, including how the power dynamics between doctor and patient intersect with sex/gender, race, and class, as well as the commercial pressures from the pharmaceutical industry. Their framing cannot account for how powerful, mostly male authorities have abused and misused the ideal of increased understanding to keep women "in their place" as compliant consumers, family planners, and agents of population control. On the flip side, these accounts neglect the liberating power of information independent of physicians' control. Information can empower consumers who are kept ignorant systematically, such as women, people of color, and those with less

[42] I thank Janet Kourany and Thomas Stapleford for helping me to better articulate my stance toward these ideals, which appear compatible in principle. This framing, nonetheless, presents a false dichotomy that encourages either/or thinking and enables unethical uses of these ideals in practice.

education.

With an in-depth case study, the following sections explore how these epistemic-ethical dimensions of implementing informed consent involving the conditions for adequate informing that relate to social justice and oppression. The following sections provide the grounds for this critique, drawing primarily on my analysis of the Nelson Hearings and the patient package inserts that emerged. We begin with the increasing pressure on government to provide women fuller, more detailed information about the Pill and its risks.

3. Demanding Informed Consent: The Deadly Silence about the Pill

This section explores how advocates of women's health and consumers' rights first articulated the need for informed consent about the risks of the Pill.[43] During the late 1960s, it became increasingly clear that there were health risks associated with hormonal birth control. As usage spread throughout the decade leading up to 1970, scientists began to document the risks to women's health, but the acceptability of these risks remained contentious. Outsiders to medicine pressured doctors to break the silence and protect patient rights, especially the rights of women for informed consent. As we shall see, because common medical practices like paternalism and industrial hegemony were obstacles to women's access to information, the first demand of feminist health advocates was for full written disclosure of the health risks of the Pill.

3.1. History of oral contraception and its safety

It is difficult to understate the medical, social, and political significance of the Pill. When the

[43] In this section, I draw especially on histories of the Pill by Elizabeth Siegel Watkins (1998) and Lara Marks (2001), history of the FDA by Dan Carpenter (2010), and the history of bioethics by David Rothman (2003).

FDA approved the first hormonal contraceptive (Enovid) in 1960, it was the first of its kind, generating many new difficulties for doctors, family planners, policy makers, and activists. Oral contraception was laden with deep cultural significance in an era of tumultuous social movements and international relations, setting it apart from other drugs. For one, it offered different ethical and political prospects to different segments of society. For feminist activists and leaders, the promise of the Pill was reproductive rights and sexual liberation. It was relatively simple, more effective, and more discreet than other available forms of birth control, enabling women to control their fertility without their partners' knowledge. Such prospects explain the support of liberal feminists like Margret Sanger and Katharine Dexter McCormick, whose collaboration and financial support was crucial to their success (Marks 2001; Marsh and Ronner 2008, pp. 139–75). While interesting and important, this chapter does not focus on the ethics of birth control per se or evaluate whether the Pill was a tool of women's liberation.

Instead, I focus on the relation of contraception with *population control* and *eugenics*. Beginning in the 1950s, concerns about global population growth led to efforts for population planning. During this era, policy makers and scientists saw the so-called "population explosion" as a threat to international stability and smooth development in the Global South—ignoring the social determinants of poverty such as lack of economic opportunity, education, and the aftereffects of colonization by the Global North (Watkins 1998, pp. 67-72). Like sterilization previously, the Pill offered politicians a technological means of social control. Many feminist and civil-rights activists, particularly women of color, protested its use as a eugenic tool of oppression for keeping "unfit" poor people and people of color from reproducing (Roberts 1997). For instance, after her white doctor removed her uterus without her consent—a "Mississippi appendectomy"—Fannie Lou Hamer became a life-long opponent of birth control (Washington

2008, p. 190).

The second challenge was that women in the US and abroad used the Pill widely. Oral contraceptives became wildly popular within the first five years of approval because of the convenience of prescribing a "quick fix" over counselling, increased income for doctors, government subsidies for the Pill, and successful advertising by pharmaceutical companies (Watkins 1998, p. 35). In 1965, there were upwards of six million users (mostly in the US), and by the end of the decade, the figure had tripled to 18 million, covering 2% of the world's population of women and around 25% of married US women (Marks 2001, pp. 184–85). This demand created a massive, lucrative market for the pharmaceutical industry, with 32 products from 13 companies and profits well over $100 million by 1969 (Marks 2001, pp. 76–82).

Furthermore, the Pill was one of the earliest pharmaceuticals designed for use in otherwise "healthy" and "normal" women. The Pill was originally approved for treating menstrual irregularities; however, its developers, including Gregory Pincus, aimed to design a chemical means for controlling women's fertility for family planning and population control (Marks 2001; Marsh and Ronner 2008). The novelty of this preventative, "lifestyle" medicine made it difficult to weigh the risks when the benefit was not curing a disease. This challenge became clearer as the FDA began receiving reports of blood clots.

In 1960, when the FDA approved the supplemental application from the pharmaceutical G. D. Searle for the use of Enovid (10 mg: norethynodrel 9.85mg and mestranol 0.15mg) as a contraceptive, the agency limited the prescription to two years. This unique restriction was based on concerns about long-term use beyond the length of the trials possibly causing cancer (Advisory Committee on Obstetrics and Gynecology 1965). Searle's trials were designed to evaluate efficacy questions about the drug's "safety in use" (see Carpenter 2001, 185). In fact,

safety was secondary to their trial design, in an era of simpler toxicity testing. Historians Suzanne Junod and Lara Marks have defended the quality of the trials as being similar in size and length to those of comparable drugs at the time (Junod and Marks 2002; Marks 2001, pp. 106–15). Despite serious side effects in the original new drug application, such as abnormal bleeding, weight gain, and nausea, regulators were impressed by its nearly perfect efficacy, especially given the risks of pregnancy and childbirth at the time.

As usage of the Pill increased drastically, scientists began to identify the serious health risks. In late 1961 and early '62, there were the first reports of fatal or near-fatal blood clots (thromboembolism), particularly in the lungs (pulmonary embolism), totaling over 100 incidents by the end of the year (Jordan 1961; Watkins 1998, p. 81). In response the case series about the Pill, the FDA set up a committee to investigate the matter epidemiologically but found no larger pattern or statistically significant risk (Ad Hoc Advisory Committee 1963). Nevertheless, they recommended further monitoring.

In 1965, the FDA Commissioner appointed the first permanent advisory committee to review pertinent cases like the safety of the Pill and other issues in obstetrics and gynecology (OBGYN) (Advisory Committee on Obstetrics and Gynecology 1965; Junod and Marks 2002). The chairperson of the committee was Dr. Louis Hellman (Professor of OBGYN at the State University of New York). In its first FDA report, released in 1966, the committee determined that the health risks remained uncertain, granting that thromboembolism was a small possibility, while carcinogenesis was mostly unknown along with the risk of the known metabolic changes. However, the committee was certain that the Pill was highly effective for fertility control and for other gynecological disorders. Thus, the report concluded with the double-negative claim that the drug was *not unsafe*: "The committee finds no adequate scientific data, at this time, providing

these compounds unsafe for human use" (FDA Advisory Committee on Obstetrics and Gynecology 1966, p. 13).

In the meantime, the British Committee on Safety of Drugs (CSD) was better monitoring and standardizing the reports of adverse effects than the FDA (despite weaker regulatory power) (Marks 2001). In 1965, the CSD found more reports of thromboembolic mortality in users than non-users. After conducting two follow-up studies, they estimated that the relative risk of thromboembolic disease was about nine times greater for users (Vessey and Doll 1968). In June 1968, FDA Commissioner James Goddard (1966-68) responded by sending all US physicians a "Dear Doctor" letter. It acknowledged that "*there is a definite association between the use of oral contraception and the incidence of thromboembolic disorders.*" Nevertheless, the new labeling for physicians was hedged with a deflationary caveat: "The British data, especially as they indicate the magnitude of the increased risk to the individual patients, cannot be directly applied to women in other countries in which the incidences of spontaneously occurring thromboembolic disease may be different" (NH, 17, pp. 7022-23). The following year, Hellman's committee found that the association did exist on their side of the Atlantic, with a relative risk of 4.4 for American users versus non-users (FDA Advisory Committee on Obstetrics and Gynecology 1969).

The risks of cancer and other diseases were even more elusive. During the '60s, some scientists thought the Pill protected against cancer, while others argued that the carcinogenic potential exhibited in several species warranted more caution. After the FDA began testing on monkeys and dogs, companies withdrew two pills for their carcinogenic potential. During this period, there was heated debate over other health risks, such as changes in metabolism, the potential for diabetes, mood changes, and the risks of depression and suicide (see Marks 2001,

pp. 158-82).

In August 1969, Hellman's committee released their second report to the FDA. Chairman Hellman wrote the summary and other members signed it off. They acknowledged scientists established the thromboembolic risk but not cancer or metabolic risks. Because of its high effectiveness for preventing pregnancy, the chairman concluded that "the ratio of benefit to risk sufficiently high to justify the designation *safe within the intent of the legislation*" (NH, 17, p. 6848, my emphasis).

While some medical organizations determined that the Pill caused blood clots and cancer, others disagreed or withheld judgment. Doctors continued to look kindly on the Pill and prescribe it widely, while Pill users had mixed reactions, from continued endorsement to moderate support or persistent demand for disclosure of risks. Most women and their doctors learned about health risks from the media, which often sensationalized scientific reports. Unlike with other drugs that doctors would prescribe after a diagnosis, patients provided much of the demands for the Pill (Marks 2001; Watkins 1998).

Advocates of the Pill were less than critical of its safety for users. For many professionals in family planning, population control, and the pharmaceutical industry, oral contraception helped to achieve their economic and political goals. Prescribers also had vested conflicts of interest: doctors, for instance, benefited from regular visits for refills, and family-planning clinics like Planned Parenthood continued to endorse the Pill and worked to combat its negative publicity (Watkins 1998, pp. 96-102). To cast doubt on the research about health risks, Searle funded scientists to publish studies in the *Journal of the American Medical Association* that reinterpreted the British studies' data and criticized their conclusions (Drill and Calhoun 1968). Searle was following the same "Tobacco Strategy" from other industries of producing their own

science with pro-industry conclusions to undermine research that threatened their bottom line (Elliott 2013; Fernández Pinto 2017; Oreskes and Conway 2011). Accordingly, many users of the Pill were ignorant about the risks because industry *kept them ignorant* selectively.

3.2. Feminist demands to publicize the risks of the Pill

Between scientific uncertainties, widespread conflicts of interest, and the ignorance and paternalism of physicians, women had no access to reliable information on the safety of the Pill. At this time, the FDA only required the industry to prepare and disseminate information to physicians about prescriptions, such as instructions for use, dosage, and side effects (see Carpenter 2010, pp. 465–543, 585–634). The quality and quantity of information that patients received was up to the discretion of doctors and clinics and through industry pamphlets, which were notorious for excluding serious side effects and using flowery, naturalistic language.

Around this same time, new pressures arose from sources outside medicine to better protect the rights of patients, consumers, and women to voluntary, informed consent. During the 1960s and ‘70s, there was a shift from physician-dominated *bedside ethics* to more patient-focused *bioethics* (Rothman 2003). Physicians and researchers had previously focused on reducing risks and providing therapeutic benefits to patients, but the public began to question their unbridled authority and to champion the autonomy of patients and research subjects (see also Faden and Beauchamp 1986). News coverage of the Nuremberg Trials of doctors in Nazi Germany and later exposés of post-war abuses by American physicians and psychologists publicized the problems with unregulated medical discretion. The 1964 Helsinki Declaration of the World Medical Association recognized informed consent as essential to research ethics and valuable for therapeutic practice. Patients’ rights advocates began to cast doctors as domineering,

and malpractice suits against specialists rose. This push culminated in 1970 with the Patient's Bill of Rights, promulgated by healthcare professions and institutions, which included their right to receive adequate information (Rothman 2003).

For women patients specifically, the pressure for more information about the Pill came from the nascent women's health movement. Many women throughout the country participated in feminist consciousness-raising groups, which brought women together to share their personal experience of confusion, discrimination, and oppression. Some groups of radical feminists realized that male-dominated medicine's sexism and paternalism relied in part on the lack of medical knowledge of and about women, and they sought to resist oppression by collecting and spreading knowledge (Davis 2007; Kline 2010; Tuana 2006).

In October 1969, Barbara Seaman published her book *The Doctor's Case Against the Pill*—the first to provide a woman's perspective on the issue. Seaman was an editor at *Family Circle* and a columnist for the *Ladies' Home Journal*, and she sought to advise women as patients about their reproductive health. Drawing on interviews with physicians, scientists, and users, she made a compelling case for the lack of safety of the Pill and the systematic ignorance of users and many doctors. Seaman maintained that the Pill was unsafe because of a host of risks, including blood clots, stroke, loss of libido, sterility, cancer, heart disease, diabetes, genetic changes in fetuses, depression, irritability, etc. These risks were unacceptable, she contended, because of safer and equally effective alternatives, such as diaphragms, intrauterine devices (IUDs), condoms, and sterilization.

Most of all, she called for the need for informed consent through the full disclosure of withheld information:

> Unhappily, very few women anywhere are ever exposed to detailed explanations of alternatives. And so, for the vast majority of pill-using women, even in the United States,

> where we pride ourselves on ready access to the most intimate information, the deceptively easy act of swallowing the innocent-looking little pill is, in fact, an act of *uninformed* consent. (Seaman 1969, p. 5)

This ignorance was both unjust and dangerous, which she called "THE SILENCE THAT COULD KILL YOU." Furthermore, the medical establishment actively maintained this systematic ignorance of women about their bodies. It was the result of suppression by the drug industry, facilitated by doctors, family planners, population-control advocates, and the FDA. She criticized regulators for only providing doctors and pharmacists the lengthy list of side effects because this strategy left women to rely on industry propaganda, sensational news headlines, and underinformed and paternalistic doctors. Her solution to the problem was to circumvent traditional medical authority with a book-length exposé. In the tradition of investigative journalism, she sought to reveal the state of medicine, including medical studies and the political forces at play, directly to lay women. Her advocacy caught the attention of a senator who was running hearings on the drug industry and called a special hearing about the informed consent of Pill users.

Seaman and other women's health advocates found a common target in the pharmaceutical industry with the burgeoning consumer movement. Aimed at enhancing the interests and welfare of consumers, this movement was dispersed through government with the feedback between regulatory agencies and Congress, especially through congressional hearings. With the establishment of Medicare and Medicaid in 1965, the US Government became one of the major purchasers of pharmaceuticals. To investigate the cost of prescription drugs, Senator Gaylord Nelson (a democrat from Wisconsin) began a series of hearings in 1968 on "Competitive Problems in the Drug Industry." As the years went on, the hearings expanded to include other issues facing consumers, particularly drug safety and the enforcement of patient

consent. After Nelson read Seaman's book, he organized a special hearing on the Pill, announced in late December, "to explore the question whether users of birth control pills are being adequately informed concerning the pill's known health hazards" (NH, 15, p. 5921). The hearings ran from January 14 to March 4, 1970. They set off a media sensation about the Pill's safety and women's right to know and alerted many users to the risks previously unknown (Carpenter 2010, pp. 341–45; Watkins 1998).

Thus, while researchers became increasingly certain about the risks of the Pill, particularly thromboembolism, women remained largely unaware, confused, or ambivalent. Feminists like Seaman attributed this *deadly silence* to the neglect of doctors and suppression of industry. Concurrently, medicine was undergoing a tide-change as the advocates of patients, consumers, and women pushed for more attention to informed consent, especially through the disclosure of suppressed information. Some regulators and legislators were surprisingly receptive to this proposal. Not unsurprisingly, physicians and industry met these demands for full disclosure with resistance.

4. Reframing Informed Consent: The Nelson Senate Hearings on the Pill

How did the US government respond to this demand for informed consent? Because of the Pill's cultural significance and the FDA's weak post-market regulation, market removal was not really a live option. Thus, policy makers focused instead on women's *right to know*. Prior to major action from the FDA, the experts at the Nelson Hearings assented to patients' informed consent—but in a different sense than Seaman had proposed. At the widely publicized event, they pressured the FDA to leave informed consent within the doctor's authority to facilitate patients' understanding via oral discourse. On the final day of the hearings, the agency

announced the patient package inserts.

In this section, I analyze their arguments about safety, informed consent, and package inserts. My analysis focuses on patterns of reasoning among Nelson's "expert witnesses," involving their gender, areas of specialization, and affiliation, with special attention to financial conflicts of interest. These "experts" were mostly physicians and men. The few women who did testify were not lay users but providers, already in the business and politics of family planning and population control (see overture to chapter 4). Most witnesses judged the Pill to be *relatively safe* since the benefits for individuals and the population outweighed personal health risks—especially those with financial conflicts of interest. Typically, they used the ideal of *increased understanding* under medical authority to challenge attempts by the FDA to *fully disclose* more information directly to patients. Expert witnesses based their judgments about safety and informed consent on assumptions about the lack of decision-making capacities of Pill users, including their sex, gender, race, and class. Some considered women "ineducable" and feared their propensity to "panic." They were particularly concerned about noncompliance from women in "social areas" they deemed undesirable, such as poor population and people of color, and subsequent population growth. They were willing to place the burden of the health risks of the Pill on poor women and women of color because they determined it was the responsibility of these women to reduce population growth. Accordingly, these witnesses focused more on the economic and political value of the Pill for *population control*, arguing that full disclosure would lead to *mass hysteria* and a boom of "unwanted Nelson babies." In section 5, I evaluate the ethical-epistemic implications of this reframing of informed consent around population health, oppressive gender norms, and medical authority.

4.1. Governmental responses

After Chairman Hellman's 2nd report, FDA Commissioner Herbert Ley (1968-69) stood behind the safety of the Pill. Nonetheless, Ley expressed approval of Seaman's book and her case for a package insert aimed at patients. While he still thought the Pill was safe (enough), he asserted that women deserve to know about the risks, advocating publicly in print for "much greater information" to go to patients with something akin to physician's insert (Cohn 1969, p. A1). Yet, because of pressure from the Nixon administration, related to unrelated issues with an artificial sweetener, Ley resigned, and his advocacy was merely as a citizen. On this same day in December 1969, Senator Nelson announced his special hearing on the Pill.

In addition to Seaman's advocacy, Ley also credited his shift in thinking to the British government's action. Scientifically and policy-wise, the British CSD was quicker than the FDA to identify and manage the health risks of the Pill. After the CSD finding of increased clot risk for higher doses of estrogen, public pressure increased, and the CSD recommended that doctors prescribe doses lower than 5 mg (half the original dose of Enovid 10 mg). Within days, Searle lowered their dosage accordingly in the UK. In the US, the 10 mg formulation remained on the market until the late '80s (Marks 2001).

Despite the FDA's greater regulatory power, there was less centralization and standardized reporting to industry and government until 1966. Throughout the decade, there was push and shove between regulators and industry for the upper hand. For instance, following the 1st FDA report, the agency required Searle to conduct post-market experimentation (Carpenter 2010, p. 598). In a countermove, the industry resisted the '68 relabeling that acknowledged the British study's positive finding, and it successfully weakened the warning with a caveat against directly applying the British findings to the US (Carpenter 2010, p. 603).

Unlike the CSD and the nationalized healthcare in Britain, the FDA struggled with their authority over physicians because their official domain was over drug manufacturers rather than the private practice of medicine. Nonetheless, the relabeling of the Pill following the 2nd FDA report expanded the list of possible and definite risks to two pages. In mid-January 1970, Commissioner Charles Edwards (1969-73), Ley's successor, sent another "Dear Doctor" letter. While he acknowledged the importance of physicians' discretion, Edwards emphasized the importance of patients' informed consent by "full disclosure":

> As the prescribing physician, you are in the best position to determine the extent of your discussion of this material with your patient. In most cases, a full disclosure of the potential adverse effects of these products would seem advisable, thus permitting the participation of the patient in the assessment of the risk associated with this method. (NH, 17, p. 7017)

At this time, Edwards made no attempt to go *directly* to patients at this time or provide them a written disclosure. His reticence to sidestep doctors' authority would not last for long.

On January 14, 1970, just two days after Edwards issued his letter, Nelson began his hearings. The senator stated that his aims were two-fold:

> to present for the general public's benefit the best and most objective information available about these drugs: (1) where they are dangerous for the human body, and (2) whether patients taking them have sufficient information about the possible dangers in order to make an intelligent judgement whether they wish to assume the risks. (NH, 15, p. 5923)

Yet, from the beginning, these hearings on the safety or dangers of the Pill were more about improving patients' decision making with better information than deliberating market removal. Throughout the hearings, Nelson poised himself as a patient advocate and reiterated the need for more warnings and full disclosure like Edward's "Dear Doctor" letter. Furthermore, as already recommended by Seaman and Ley, the clearest option was a piece of printed information for patients, and the hearings functioned as a testing ground of sorts for its content and framing to

medical professionals.

4.2. Gender, expertise, and conflicts of interest

While Nelson advocated for the rights of women as patients and consumers, he was less interested in their voices. Whom did Nelson ask to testify, and whom did he not? Understanding the limitations of this set of expert witnesses is my first step in analyzing their responses to Nelson's two questions. As opposed to media sensationalism and "widespread drug company promotion misinformation," Nelson sought to evaluate the claims about the safety of the Pill "as objectively and scientifically as possible" (NH, 15, p. 5922). Yet, Nelson construed "scientific expertise" in a rather narrow sense, as medical experts, mostly men, family planners, and population-policy makers, and his selection criteria brought increased financial conflicts of interest. I note the presence of conflicts of interest because they are correlated with biased judgments that support pro-industry conclusions.[44]

Nearly every one of his witnesses had a medical degree (31 of 36), 14 of which specialized in OBGYN. Witnesses also represented other medical specialties, including general practitioners, surgeons, endocrinologists, internists, a psychiatrist, neurologist, cardiologist, and specialists in public health, hypertension, and breast cancer. Apart from a medical degree, the next most common professional feature was professorship at a college, university, or medical school (18 of 36), including professors of anatomy and statistics in addition to the above specialties, at public and private schools in the US, Canada, and UK. There were also three staff

[44] Researchers have demonstrated this bias from conflicts of interest throughout biomedical and environmental sciences, from tobacco smoking and soft drinks to medical drugs and devices (Barnes and Bero 1998; Bekelman et al. 2003; Lundh et al. 2012, 2017; Ridker and Torres 2006; Schillinger et al. 2016).

members of federal agencies like the FDA and NIH and one medical research institute.

Nelson's conception of "expert" was heavily shaped by the gender norms of the day (see overture to chapter 4; ChoGlueck 2019). Of these 36 expert witnesses, only five were women (including Anna Southam, Professor of OBGYN at Columbia, who did not testify in person). In 1970, women physicians numbered 7.6% of total physicians and 7.2% of OBGYNs in 1970 (Kline 2010, p. 14). While there was a proportional representation of women in the profession at the time, none of these women testified in the first half of the hearings in January. Their inclusion is largely the result of feminist protesters. Radical feminist activists from D.C. Women's Liberation (DCWL), including Seaman, protested the hearings three times, partially because of this exclusion of women from a hearing on women's health (Sigal 1970a).

The senators patronized and complained about these "disturbances" from DCWL, and Nelson suggested to the protesters that "you are prejudicing your own case" (NH, 15, p. 6000). The senator promised DCWL that there would be women to testify, but he treated them patronizingly, asking "would you girls have a little caucus and decide which one will talk one at a time… Your viewpoints will be heard, don't worry about that" (NH, 15, p. 6000). While some expert witnesses agreed with the accusations of the feminist protesters, others dismissed them in a sexist manner. For instance, following one "disturbance," David Carr (Professor of Anatomy at McMaster University) rejoined their question of "why are we being used as guinea pigs?" by appealing to the gendered dichotomy of strong *masculine* reason over weak *feminine* emotion: "I am afraid we *have* to face facts… We *have* to test everything on humans, and this is *tough*, but it is a *fact* of life" (NH, 15, p. 6003, my emphases). After the third "disturbance," in which the DCWL passed out pills to the men present to take and "to think of it circulating though their bodies while listening to testimony," Nelson ordered the police to remove the protesters (Sigal

1970a, p. 3). When they refused to leave, Nelson closed the hearings to the public and reconvened them with guards and without public access.

Accordingly, DCWL hosted a "Women's Hearings" on March 7, 1970, with around 100 attendants and a survey of women's experience with doctors and the Pill. Led by Alice Wolfson from DCWL, it covered studies on the safety of the Pill, new research, the IUD, and abortion, including testimony from women scientists and Seaman. The hearings featured critics of the drug industry and advocates of welfare rights. For instance, activist Etta Horn discussed how welfare policy required birth control for recipients and thus inflicted genocide against poor, Black families (Sigal 1970b; see also Valk 2010).

While Nelson later included more women, none of them were regular users without scientific or medical credentials. All the women experts who did testified spoke on behalf of their scientific, medical, or otherwise professional credentials, rather than as an advocate of women or for their personal experience as a Pill user. This exclusion of lay women was problematic because no one testified for users or as a women's health advocate outside medicine. Particularly because of the interest in informed consent, users and their advocates could provide the expert knowledge that comes from the patient and consumer's perspective about their epistemic-ethical needs.[45]

Those women who did testify as experts merely reinforced the group consensus. By judging the Pill to be relatively safe or withholding her judgment, not one of the women could be seen as a hysteric or alarmist who, like the activists, denounced the Pill as dangerous and

[45] Historians have echoed the activists' critique that Nelson refused women activists and patients the platform to speak (Watkins 1998, pp. 111-2; Marks 2001, pp. 150-51; Tone 2002, p. 248; Kline 2010, p. 110).

unsafe.[46] They were composed and calm, unlike the activists' "disturbance" in the back. This created the impression that emotions, as coded feminine, were out of place in this scientific and medical discussion, coded masculine.

The presence of other women experts served to pacify the senators about the abilities of women of color to act rationally and not overreact to learning about the risks of the Pill. For instance, Dr. Mary Lane Cobb (Clinical Director of the Margret Sanger Research Bureau), was also the only Black witness present (AWAHSWA 2019). At the end of her testimony, one senator clumsily asked if she had used the Pill or experienced side effects and to testify "to the women of America how you view the pill yourself, if you would tell us whether or not you take the pill. …It would be most helpful if you have enough confidence in the pill to tell us, have you ever used it yourself?" (NH, 16, p. 6647). Cobb responded that yes, she had taken it: even knowing of and having experienced side effects, like headaches, she could not tolerate another pregnancy. She described the decision as a "personal" one, highlighting its uniqueness. Yet, as the only woman of color, Cobb served a tokenizing role as the model for population-control advocates of responsible family planning.

The presence of women also undermined an easy takedown of the hearings as totally excluding women. Their participation at such small numbers functioned more as tokenism. For instance, Southam and Elsie Carrington (Professor of OBGYN at Women's Medical College of Pennsylvania) presented their scientific expertise as gender blind. While their feminine gender was unmentioned and seemingly irrelevant or incidental to their testimony, their presence enabled Nelson to rebut accusations from his feminist critics.

Rather than serving as women's health advocates, these women brought financial conflict

[46] Likewise, no women supported the patient insert, and two opposed it (Connell and Cobb).

of interest because of their professions. The expert witness who were women were much more likely to be affiliated to family-planning clinics or population-control organizations than were men. Whereas three of five women were affiliated with family planning or population control groups, a mere four of 31 men were. For instance, Cobb and Dr. Elizabeth Connell (Professor of OBGYN at Columbia and director of a family-planning clinic) had many patients on the Pill and thus faced the risk of malpractice litigation if it was found to be unsafe. Along with their advocacy for contraception and its benefits, the women who did testify also brought higher than average levels of education. This privilege left them largely unable to testify how less educated women might understand the risks and benefits or deal with the emotion burdens associated with such knowledge but without adequate training or resources.

Aside from gender, 11 of Nelson's experts were affiliated to organizations dependent on the Pill, so they brought *conflicts of interest* that biased them toward judging the Pill to be safe and withholding information about its risks. Seven witnesses were affiliated with family-planning or population-control organizations. Four witnesses testified as directors and board members of Planned Parenthood, the Population Council, and the Population Crisis Committee, and three were doctors at family planning clinics with patients on the Pill.[47] Dr. Alan Guttmacher (President of Planned Parenthood), for instance, voiced anti-regulatory sentiments. Guttmacher reserved the right of his organization and of the drug manufacturers to decide on the content of birth-control pamphlets, and he resisted governmental interference and imposition on these private companies (NH, 16, p. 6610).

Additionally, five of the witnesses were secondarily affiliated with drug manufacturers,

[47] Directors: Draper, Guttmacher, Hertz, and Piotrow. Doctors: Cobb, Connell, and Whitelaw.

either through consulting or funding for research.[48] For instance, Robert Kistner (Professor of OBGYN at Harvard) disclosed various companies including Searle had supplied and remunerated him (NH, 15, p. 6072). Drug companies remunerated Joseph Goldzieher (Director of Clinical Science at the Southwest Foundation) for consultation from his research institute (NH, 15, p. 6371). Despite repeated requests from Nelson, there were no representatives of the pharmaceutical industry who testified primarily on behalf of a company. Nelson took the absence of industry representative to be the absence of industry's voice (NH, 15, p. 6153). However, these industry-funded witnesses provided a means for industry to make its perspective heard vicariously through "corporate ventriloquism" (see Bsumek et al. 2014; Holman and Geislar 2018; Segal 2018). For instance, evidenced by his own experience with large companies having withdrawn trials from his research institute, Goldzieher objected to FDA regulations on drug testing for being "so prohibitive" as to impede development of safer alternative contraceptives (NH 15, 6378), falsely suggesting that market forces prioritize drug safety.

Nelson claimed that "All viewpoints will he heard," including those of radical feminists and industry spokespeople (NH, 15, pp. 6154, 6000). Rather than aiming democratically to include the women most directly affected, he seems instead to have wanted a "balance" of experts with different scientific, medical, and professional credentials and divergent judgments (NH, 15, pp. 6021, 6154; 16, p. 6817). Nelson intended to oversee the FDA's actions with a fair set of hearings, but his list of witnesses drew from a small, demographically homogeneous group

[48] Industry affiliations: Connell, Davis, Goldzeiher, Kistner, and Meier. One of these conflicts of interest went against the Pill: Hugh Davis (Professor of OBGYN at Johns Hopkins) disclosed that he was in a joint venture with Ortho Research Foundation developing an IUD as a competitor to oral contraception—though he denied a conflict of interest against the Pill (NH, 15, p. 5941). In addition, Harold Williams (the only lawyer to testify) had formerly represented patients suing drug manufacturers in five cases and remained on another, though he claimed he was in the process of being formally removed (NH, 15, p. 6296).

of experts. Furthermore, corporate ventriloquism masked industry's presence, with unchecked conflicts of interest. Accordingly, Nelson brought a limited set of expertise to bear on his questions: mostly physicians, mostly men, and a host of biases toward the safety of the Pill.

4.3. Question #1: Is the Pill safe?

In part because of this limited set of expertise, the responses that these witnesses made to Nelson's two questions (about safety and informed consent) moved beyond the *health risks* for women to the broader *social risks* for medical authority, population control, and private commercial interests. While most experts acknowledged the potential harms for women, they determined that overall the benefits of a highly effective form of birth control outweighed them for individuals' family planning and for population control. While the hearings began in January with equal numbers of witnesses testifying that it was either safe or unsafe, by February and March the aggregate assessment leaned more toward the Pill's safety rather than its unsafety. By the end, most of the witnesses testified that that the Pill was *relatively safe* for its approved purpose of contraceptive use.[49] Only men and only physicians claimed that the Pill was unsafe, and OBGYNs were the least likely among physicians to make a judgment of unsafety.

Despite their different beliefs and values, these experts appealed to a *relative* conception of safety rather than an absolute one.[50] Not one witness claimed it was "absolutely safe" for

[49] Out of 36 witnesses, 19 determined it was relatively safe: Bole, Carrington, Cobb, Connell, Cutler, Davis, Draper, Edwards, Goldzieher, Guttmacher, Hellman, Kane, Kistner, Legator, McCain, Peterson, Ryan, Schulman, and Whitelaw. Of the remaining, 9 argued that it was unsafe: Ball, Hertz, Kassouf, Laragh, Ratner, Spellacy, Williams, Wood, and Wynn. 8 withheld judgment: Carr, Clark, Corfman, Lewison, Meier, Piotrow, Salhanick, and Southam.

[50] Different value judgments included: different conceptions of safety; different views about proper use and "the user"; different ideas about the risks, benefits, and weights of them; and different attitudes about social stakes of making a judgment about the Pill's lack of safety.

indiscriminate use.[51] Many appealed to a *medical* or *clinical* concept of relative safety (especially those with conflicts of interest), where one balances the risks and benefits based on the beliefs that all risks are relative and there is no perfect or completely safe treatment. Most of the experts who employed this medical concept of safety judged the Pill to be safe for general uses but only with the right medical expertise, discretion, and caution.[52]

Along similar lines, a small group of experts appealed to a *legal* or *regulatory* sense of relative safety that balanced risks against benefits but further included reference to federal laws, FDA policy and standards, and the official labels of drugs.[53] Hellman (Chairman of FDA advisory committee) had concluded the 2nd FDA report that the Pill was "safe within the intent of the legislation" because its established risks were outweighed by two big benefits. First, it could alleviate the "population problem," and second it provided "personal benefits" to women for whom another child would be a hazard or burden (NH, 15, pp. 6205-6).[54] Furthermore, he constrained his judgment within (what he took to be) the proper limits of government. He did not think the agency should play "big brother" to physicians in the face of no good alternatives (NH, 15, p. 6213). While recognizing that "this was a hedge," he stood behind the report's conclusion, knowing that it would keep the drug on the market (NH, 15, p. 6214). Commissioner Edwards stood by the judgment of his chief adviser Hellman, that while potent the Pill was "safe under the

[51] Three witness did claim it was generally unsafe for nearly any use (Ball, Ratner, and Williams) because it led to "internal pollution" (NH, 16, p. 6744) and functioned like a means of "chemical warfare" (NH, 16, p. 6496; 15, p. 6219).
[52] 16 witnesses judged the Pill to be medically safe: Bole, Carrington, Cobb, Connell, Cutler, Davis, Draper, Goldzieher, Guttmacher, Kane, Kistner, Legator, McCain, Peterson, Ryan, and Whitelaw. Six others determined that the Pill was medically *unsafe* because either it posed serious and grave risks that outweighed the potential benefits, or it was not medically safe for the general population: Hertz, Kassouf, Laragh, Spellacy, Wood, and Wynn.
[53] Only three witness used the legal sense of relative safety (Edwards, Hellman, and Schulman), none of whom claimed that it was unsafe.
[54] Hellman based this conception of relative safety on the 1962 Kefauver-Harris amendments upon legal consultation with William Goodrich, the FDA General Counsel.

conditions of labeling" determined by the same standards for all other drugs (NH, 16, p. 6781).[55]

Despite some dissention, most of the witness leaned toward an assessment of safe, at least in the relative sense and under the FDA labeling with doctor supervision. There are two components of this judgment that deserve additional attention, involving the alleged social and personal benefits. First, a crucial component for Hellman and others was the benefits of the highly effective Pill for *population control*. While Nelson agreed that the "the rapid growth of the world population is disastrous," he argued against Hellman that accounting for the social benefits in determining the Pill's safety was inappropriate: "when we talk about risk, we are concerned about safety of an *individual* patient" (NH, 15, p. 6212, my emphasis). The inclusion of the social benefits, he later suggested, easily allows doctors "to make a sacrifice of a patient for purposes of some wider sociological gain" (NH, 15, p. 6485).

Second, apart from overlooking women's health, even the alleged "personal benefits" proffered by Hellman reflect classist and racist assumptions about reproductive policy. Hellman presents the following "exaggerated example":

> A patient I saw about 2 weeks ago who had a pulmonary embolism—she did not die—from the oral contraceptives. Therefore, she could no longer take the oral contraceptive. She is colored: she came from a ghetto area, she had two children. Her husband has a poor job. But she had managed to get a job herself and to go to night school to complete her high school diploma. When we got through discussing her pulmonary problem and the oral contraceptive, she said to me, "Doctor, what can I use that will be as sure as these contraceptives? Because another child would put me right back on welfare." (NH, 15, p. 6206)

Hellman raised the specter of poor woman of color returning to welfare to demonstrate the

[55] Edwards' judgment involved a qualification that relied on FDA labeling, allowing established risks to be "acceptable" only if "under the right supervision" (NH, 16, p. 6816). He also appealed to the FDA's legal charge to regulate the safety of drugs, which according to Goodrich depended on the conditions of treatment and the range of different circumstances for population-level safety (NH, 16, p. 6783). While the 1938 Food, Drug, and Cosmetic Act did not define safety, subsequent committee hearings in '62 did balance risk against benefit (NH, 16, p. 6813).

"personal benefits" of the Pill, but his example easily reads as an additional "social benefit" for those who want poor Black women off government support. Hellman insinuates that *these sorts of women* ought to accept the risk the blood clots, both for themselves and for society. The so-called "welfare queen" is a racist myth about poor Black mothers who intentionally and greedily reproduce for public assistance. Nonetheless, the stereotype is widespread among white people, and it has strongly shaped debates over welfare reform (see Roberts 1997, pp. 17–19). Again, Hellman's judgment about the safety of the Pill focused more on population health and policy than on women's health, particularly those women most marginalized by society.

Ultimately, it seems to have been this conclusion from Hellman's committee that secured the Pill's continued market availability in the US, bolstered by the aggregate judgment of the witnesses. Edwards agreed with this report that the Pill was safe in the legal sense by preventing hazards for the (poor, Black) user who benefited herself and society despite the established risk of blood clots. Furthermore, if its external advisors and the congressional witnesses generally agreed that it was safe, the FDA could keep the Pill on the market and look for alternative post-market solutions. For these reasons, the practical focus of the Nelson Hearings was less on safety than informed consent.[56]

[56] Unlike the case in Britain, where the CSD recommended against higher dosages of estrogen, this judgment of relative safety preventing direct governmental intrusion into the sales and prescriptions of the Pill. Accordingly, one might reason that the Pill's social, cultural, economic, and political significance, along with the huge number of users, precluded the possibility of withdrawal. However, the FDA historically has been conservative with both approval and removal of drugs. In addition to pharmaceutical pressure, this tendency results from internal institutional forces: much of the FDA's power stems from its reputation, and approvals and withdrawals come from the same office. Also, the FDA's power over the market is reduced after approval since it is unable to regulate prescribing practices, such as "off-label" uses (Carpenter 2010).

4.4. Question 2: Do women have enough information to decide about the Pill?

Aside from the safety of these contraceptives, Nelson wanted the public to know "whether patients taking them have sufficient information about the possible dangers in order to make an intelligent judgement whether they wish to assume the risks" (NH, 15, p. 5923). Nelson's well posed question presumed that women *could* make intelligent decisions—an assumption not widely taken by medical professionals and other authorities then. Furthermore, during this time of transition in medical ethics, the meaning and bounds of "informed consent" were unclear, both at the FDA and elsewhere (Faden and Beauchamp 1986; Rothman 2003). While nearly all the expert witnesses took informed consent to be important to medical practice, they generally opposed the FDA's move to fully disclose to patients more information about the risks of the Pill with a printed patient insert. Alternatively, they emphasized the need for better oral communication because it is the responsibility of the physician to facilitate patients' understanding. Here, I argue that their paternalistic reframing of informed consent was based on the witnesses' beliefs about sex, gender, race, and class of users and their interests in overseeing women, controlling population growth, and avoiding market regulation.

Recall that FDA officials had supported the proposal for full disclosure to ensure patients' informed consent, which they thought was currently unmet. Endorsing Seaman—who characterized the problem as a deadly silence—Ley favored the insertion of the information companies provide doctors printed in lay language (Cohn 1969). Commissioner Edwards similarly advised physicians to provide "a *full disclosure* of the potential adverse effects…permitting the participation of the patient in the assessment of the risk associated with this method" (NH, 17, p. 7017, my emphasis). He initially thought that the traditional *oral* means of communication by physicians would enable such disclosure. However, by the end of the

hearings in early March, Edwards became skeptical of physicians' ability to fulfil their responsibility, especially for patients who only see their doctors once every two to three years (NH, 16, p. 6807). Witnesses and senators cited a *Newsweek* poll from early February 1970 that two out of three Pill users reported that their physicians did not tell them about the health risks (NH, 16, p. 6628). Accordingly, Edwards thought that the agency needed to assume the responsibility to inform patients by alternative means (NH, 16, p. 6784).

Nearly every witness present who discussed informed consent believed that it was necessary, and most determined that it was unsatisfied.[57] Only Guttmacher from Planned Parenthood contended that informed consent was unnecessary and unqualified paternalism inevitable:

> I think the doctor has to make the decision. I do not think such a disclosure is going to do much good. I think it is going to do great harm…I think the patient, after she had read all of this [drug label], is going to come back to the doctor and say, what shall I do? (NH, 16, p. 6620)

Nine witnesses either determined that it unsatisfied or remained unsure.[58] In contrast, Connell, who was also affiliated with a family-planning clinic, valued informed consent but thought it was largely satisfied, at least at her clinic where she could confidently affirm their practices (NH, 16, pp. 6518-19).

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[57] Two-thirds of the witnesses (24 of 36) made comments on informed consent. 20 claimed that informed consent was necessary at least in principle: Ball, Cobb, Connell, Davis, Edwards, Goldzieher, Hertz, Kane, Kassouf, Kistner, Laragh, McCain, Meier, Peterson, Piotrow, Ratner, Ryan, Salhanick, Whitelaw, and Wood. Only one said it was unnecessary (Guttmacher). Advocates' justifications differed. Some claimed that informed consent was the right of women qua patients because of the highly experimental state of the technology (NH, 15, pp. 6039, 6122) and because patients are the ones who bear the burden of the health risk (NH, 16, pp. 6461, 6545). Others argued that it was a right of women qua consumers in a capitalist society faced with a marketplace of choices (NH, 16, pp. 6487, 6608), exacerbated by the deceptive and manipulative drug companies (NH, 15, p. 6121; 16, p. 6755).

[58] Of those who expressed an opinion, most (5) thought informed consent was unsatisfied (Ball, Davis, Edwards, Kassouf, and Peterson), although several (4) expressed uncertainty instead (Goldzieher, Kistner, McCain, and Ryan). Only 2 thought informed consent was satisfied: Connell and Schulman.

Nevertheless, even among the advocates for patients' rights, most witnesses were unsupportive of—and even resistant toward—the full-disclosure ideal of informed consent suggested by Seaman and endorsed by Ley, Edwards, and Nelson. Instead, most experts (who voiced an opinion) advocated for an alternative ideal aimed at the *increased understanding* of patients.[59] While these ideals are compatible in principle, in practice witnesses used one against the other. (Note that this is just like how bioethicists argue today.) With one exception, all witnesses with financial conflicts of interest related to pharmaceutical companies, family planning, or population control appealed to this ideal of increased understanding.[60]

Several of the critics of full disclosure argued that written information would be useless at best and confusing or harmful at worst.[61] While many recognized the insufficiency of oral counseling and the necessity of some written information, they often viewed printed leaflets as supplementary.[62] Rather than the *comprehensiveness* of information (i.e., a fully laid out disclosure), they supported its *comprehensibility* (i.e., toward a more substantial understanding) by women as lay people, patients, and consumers. Thus, they emphasized the importance of interpersonal communication for complex, uncertain information.

Reframing the initial proposal for full disclosure, the advocates of this alternative ideal argued for a shift toward *increased understanding* because of three related factors: the necessity

[59] While three supported the ideal of full disclosure (Edwards, Hertz, and Kassouf), 10 witnesses appealed to the ideal of increased understanding: Davis, Cobb, Connell, Goldzieher, Guttmacher, Kistner, McCain, Meier, Ryan, and Wood. Two witness tried to reconcile or balance the two conceptions: Laragh and Peterson.
[60] Excluding Hertz, the eight other witness with these conflicts of interests appealed to the ideal of increased understanding: Cobb, Connell, Davis, Goldzieher, Guttmacher, Kistner, Meier, and Peterson).
[61] Critics include Cobb, Connell, Goldzieher, Guttmacher, Kistner—all of whom had financial conflicts of interest—and Kane.
[62] Among these, 4 advocated for the necessity of written information: Ball, Kassouf, Schulman, and Wood. Six emphasized that printed leaflets were only a necessary supplement to good counseling: Davis, Edwards, Laragh, McCain, Meier, and Ryan.

of expert judgment, patients' lack of intellectual ability, and patients' emotionality. Regarding the first, Cobb argued that medical professionals know to pass along information about risks only when relevant: "We tell them, by and large, the side effects which they are most likely to encounter." For Cobb's clinic at the Margaret Sanger Research Bureau, thromboembolic statistics were always "relevant," but others were less pertinent: "But I do not feel that it is practical to go down a list of vague complaints with a patient. I myself have noticed in practicing medicine that the more you suggest to a patient, the more she will turn up to complain about. People are suggestible beings" (NH, 16, p. 6642-43). Likewise, Davis and Kistner discussed how physicians take a history and relay relevant information rather than telling patients all the possible but improbable complications (NH, 15, pp. 5933, 6082). Connell maintained that experts can make scientific information practicable for lay women since the information was uselessly uncertain without professional guidance (NH, 16, p. 6518).

Second, these advocates of increased understanding pointed to the lack of patients' intellectual capacities for understanding technical, scientific, and medical information. Goldzieher emphasized the obstacles to achieving full disclosure that come with patients' education, socioeconomic status, and "cultural pattern" (a coded way to refer to race, ethnicity, and nationality) (NH, 16, p. 6355). Third, and conversely, these expert witnesses suggested that patients would be prone to emotional responses like "confusion" and "panic" rather than rational decision making without their doctors' guidance (NH, 16, pp. 6509, 6569-70). They voiced concerns that full disclosure would "upset," "frighten," or "alarm" women away from continuing to take the Pill (NH, 16, pp. 6509, 6546, 6668).

Regularly referring to patients or "laymen" as less capable, their beliefs about the sex and gender of Pill users strongly flavored their judgments. Descriptions of lay users during the

hearings painted a negative picture of women's ignorance, irrationality, and emotionality. For instance, Goldzieher, who advocated for increased understanding over full disclosure, patronizingly acknowledged that while some women are capable, they are in the minority:

> *On occasion* I have had patients who have discussed with me various methods of contraception and then came back with [Physician's Desk Reference] in their hand, and quizzed me about the side effects of the pill *like a trial attorney*…But how many women like this do you suppose there are? …There are other women, on or off the pill, who have been *frightened* by misinformation and distortion of facts. They deserve to have all the information they can understand and utilize. Unfortunately, few physicians have the power of communication, as well as the exact information, to carry out this task as well as one would wish. Finally, we must recognize that *there are vast numbers of women who simply do not have inquiring minds like those that fill this room, and do not have enough education to comprehend much more than the simplest facts of biology*. A misguided effort to 'inform' such women leads only to *anxiety* on their part, and loss of confidence in their physician. (NH, 16, 6355, my emphasis)

In addition to his dismissive tone, note that the vast majority of the "inquiring minds those that fill this room" were men. Accordingly, suggestions from experts such as Goldzieher to "simplify" the information typically involved gender norms and stereotypes about the "average woman" and her inability to reason.

Arguing against full disclosure, Guttmacher—likely the most renowned and powerful witness present—presented an especially condescending view of women's intellectual abilities. In the pamphlets from Planned Parenthood clinics, which Guttmacher noted served "the medically indigent," there was no written mention of the health risks: "We certainly know our doctors are thoroughly instructed in the potential dangers. We assume that in conversation with patients, they pass on this information to them" (NH, 16, pp. 6614). He contended that a written measure aimed at full disclosure would be "impractical" and harmful because women are simply not as intelligent as men:

> Now, *I do not think that you are going to be able to educate the American woman* as to what she should or should not do with regard to the pill. I think you can educate the American doctor. *He is educatable*. … My feeling is that when you attempt to instruct

> American womanhood in this, which is a pure medical matter which I am afraid *she has not the background to understand*, you are creating in her simply a *panic reaction* without much intellectual background. And this is what I think has been unfortunate. (NH, 16, p. 6568, my emphasis)

Guttmacher's choice of gender pronouns and references to "American womanhood" illustrate the way that his perceptions of the sex/gender of users diminished his assessment of their cognitive abilities. Particularly given the prominence and power of Planned Parenthood in the US and around the world, Guttmacher's justification for withholding full, written disclosure to avoid "a panic reaction" is troublesome.

Expert witnesses' judgments argued against full disclosure based on beliefs about the race and class of users. For instance, John McCain (a practicing OBGYN in Atlanta and a clinical professor at Emory) posited a special standard for communicating with socioeconomically disadvantaged patients and women of color. A critic of full disclosure and advocate of increased understanding, he contended that "indigent patients" are in a "separate category" because they face different risks from pregnancy. When Nelson retorted whether there was not a high percentage of such patients who were nonetheless capable cognitively, McCain replied that the issue is more about the *non-compliance* among certain "social" groups, a coded way of referring to African Americans and other people of color:

> Obviously, there are individuals in all economic walks of life for whom this can fairly apply as well. But there are *social*, I suppose, would be maybe a better word—there are *social areas* in which one can anticipate that contraceptives of a mechanical nature can be, will be utilized inadequately by a husband or by a wife or by both. For that reason, then, one is not saying that the oral contraceptive is more dangerous than the mechanical method of contraception. One has to compare the risks of the oral contraceptive against the unwanted pregnancies that will occur if that mechanical method is not uniformly employed. … As to where one draws the line, there is the responsibility for information for the patient, there is the responsibility on the doctor for the outcome of unwanted pregnancies and ill that they carry for the physicians. (NH, 16, p. 6483, my emphasis)

McCain clearly thought withholding information from some "social" group of poor women,

likely women of color, was justified by their alleged inability to comply with medical instructions. Furthermore, he believed it was the responsibility of doctors to keep *these women* compliant, on the Pill, and not pregnant because of the "ill" for doctors.

More generally, witnesses feared the *social risks* of health warnings to compromise the efforts of family planners and population-policy makers. Recall how witnesses like Goldzieher and Guttmacher characterized users' discontinuation from full disclosure about health risks as an *irrational, emotional* reaction. Such specters of an epidemic of unplanned pregnancies reflect the sexist conception of "mass hysteria" (see Kukla 2005). Mass hysteria is a commonly held understanding of the maternal body as anxious and monstrous; according, bodies that are or can be pregnant conjure fear as uncontrollable, non-complaint, and a threat to social order.

Worries about an epidemic of mass hysteria abounded in the 2nd round of hearings in February when Nelson recruited more family planners to testify and as the hearings gained publicity. Connell, for instance, charged that the coverage of the hearings had been alarmist, likely leading to more unplanned pregnancies:

> We are just now beginning to see the first of the pregnancies of women who *panicked* in January [last month], stopped their pills and did not seek or use another means of birth control. These women will not be here to testify, but they now bear within their bodies mute testimony to the effectiveness of *induced fear.* (NH, 16, p. 6509, my emphasis)

Such reactions, she charged, "by the adverse publicity" of the press spanned from "middle- and upper-class women" to "her culturally deprived sister in the ghetto." While it was too early to detect a rise in pregnancy, Connell contended that at Planned Parenthood clinics phone inquiries had doubled and Pill requests had dropped by 20-30%. Such discontinuation raised worries about population growth: "I am sure that such information will be most gratifying to opponents of the pill. However, I can only say that it strikes *profound fear* in the hearts of those of us who deal daily with women and population problems" (NH, 16, p. 6513, my emphasis). Tongue in cheek,

witnesses and Senators referred to this alleged rise in unwelcome pregnancies as the "unwanted Nelson babies," which Phyllis Piotrow (Population Crisis Committee, Board Member) estimated at 100,000 (NH, 16, pp. 6689-91, 6818). Piotrow and others insinuated that, through his hearings, Nelson was responsible for encouraging these emotional reactions that left women with no recourse but unwelcome pregnancy. Like Hellman's testimony, much of the concern of this "population crisis" is the financial burden it might place on the welfare system, particularly by poor women of color.

In contrast, a minority of population-control advocates argued that full disclosure was not necessarily such a terrible initiative. After McCain rejected the proposal for full disclosure, Nelson retorted that withholding information for population control unjustly subverted individual rights for the alleged common good:

> I think the most critical matter facing humankind is the overpopulation of the planet. I have friends who feel that way and think, therefore, you had better not tell anybody about the side effects because one of the benefits of the risk-benefit ratio includes the question of overpopulating the planet. *I have never understood that to be the responsibility of the physician, to make a sacrifice of a patient for purposes of some wider sociological gain.* But this is the attitude of many people who have talked to me, including many of the doctors that I have talked to. Their position is that disclosing the concern of the profession and the facts about the pill threatens the cause of birth control and limitations in population growth. …*They conclude that population control is so important that no one should be informed about the pill for fear they will not use it.* I think that is a very dangerous posture to assume and defend. (NH, 16, p. 6485, my emphasis)

Earlier in the hearings, Nelson had balked at how Hellman's report balanced the safety of individuals with population safety (NH, 15, p. 6212). Similarly, Nelson rejected the same population-based reasoning here regarding the social risks of information about health risks.

Likewise, two leaders of population-control organizations were concerned about the long-term effects of withholding information. Piotrow contended that women deserve to know the risks, which were already late in coming. Furthermore, if further side effects arise, she

figured that bad press about a cover-up would decrease use of the Pill (NH, 16, p. 6691). Likewise, Piotrow's colleague William Draper (Population Crisis Committee, Co-Founder and Chairman) thought more publicity and transparency would provide long-term benefits even with some initial rise in pregnancy from discontinuation (NH, 16, p. 6692). Thus, a minority of population-control advocates were more concerned about compromising their own agenda by resisting full disclosure than any short-term losses.

In addition to their interests in limiting population growth, many of advocates of the ideal of increased understanding had *financial* conflicts of interest because of their pharmaceutical affiliations. All the witnesses who consulted for and were remunerated by the pharmaceutical industry appealed to this ideal of increased understanding. Likewise, family-planning clinicians like Cobb and Connell opposed the ideal of full disclosure and advocated instead for increased understanding. The industry found many allies in the family planning and population control: recall that both Goldzieher and Guttmacher argued for reducing market regulation (NH 15, p. 6378; 16, p. 6610). Despite its alleged absence, the pharmaceutical industry found a vicarious voice in these financially interested witnesses.

In sum, we have seen how witnesses justified the ideal of increased understanding, as an alternative to full disclosure, because they believed that the Pill users were naïve and emotional women, with uncontrollable female bodies, who were insufficiently rational and lacked the prerequisite cognitive abilities. Furthermore, they feared for the effects of full disclosure on poor women and women of color, whom they believed were particularly non-compliant, leading to population growth and reducing sales of contraceptive products. Because of the social, economic, and political risks of full disclosure, most witnesses pushed for increased understanding which kept women under medical authority for their access to information.

4.5. Either increased understanding or full disclosure

Now, one might ask: why did these witnesses pit the ideal of full disclosure against that of increased understanding? Is it not possible to have some "core disclosure," as suggested by Faden and Beauchamp, from which informed consent begins? While there were two witnesses who seemed to advocate for both full-disclosure and increased-understanding ideals, they ignored the tensions. John Laragh (Columbia, Professor) called for the need to "fully disclose new observations" to patients and to "simplify" information at the same time (NH, 15, p. 6165-7). He did not, however, suggest how to go about such simplifications while also retaining comprehensiveness.[63]

While compatible in principle, the two ideals were posed by witnesses as alternatives in practice. According to their reasoning, the ideal of increased understanding entails that patients have only *relevant* knowledge that is necessarily *partial*, while the ideal of full disclosure requires their full knowledge beyond what is immediately relevant and assumes their ability to analyze and comprehend. Thus, both conditions are not able to be fulfilled at the same time: it is not possible to disclose everything and only disclose what is relevant; nor to explain in full detail and to simplify the details to make it comprehensible for non-specialists; nor to present various perspectives and interpretations without partiality, while also offering a clinical judgment about the correct interpretation. That is, while compatible in principle, the ideals could conflict in

[63] Peterson also argued that not enough information was available in simple everyday language for women or families to use for making decisions and that doctors need to make information comprehensible with comparisons of more familiar risks, e.g., smoking, aspirin, abortion, etc. (NH, 16, p. 6761). However, Peterson also argued that women deserve the "full picture," which includes all these truths, details, side effects, and disadvantages (NH, 16, p. 6765).

practice.[64]

One of the main tensions lies in the ideal of *medical autonomy* implicit in each ideal, and the bounds of proper medical paternalism. With the ideal of increased understanding, the doctor is a necessary mediator between the full, complex store of knowledge and the lay patient. Here, expertise is a benefit rather than an impediment to informed consent. In contrast, with full disclosure, the physician is a potential barrier to the patient's becoming informed because as a transmitter the physician might fail to disclose by forgetting, withholding, or biasing knowledge. Thus, the ideal of full disclosure points to the *limitations of expert authority* as an impediment to patients' access to information. While the patient in both lacks knowledge, only the ideal of full disclosure accounts for how the relationship with doctors itself can be the *source* of such ignorance. Accordingly, achieving full disclosure may requiring going around the traditional bounds of medical counseling, which is often oral communication, to written disclosures in print that can provide an independent source of knowledge.

In sum, most witnesses, especially those with conflicts of interest, argued against giving women full disclosure because of the social, economic, and political risks based on problematic stereotypes and ethically unacceptable reasons. They reframed informed consent instead as aimed at increased understanding, keeping women under medical authority for their access to information. On the final day of the hearings, Commissioner Edwards followed Hellman and most other expert witnesses that the Pill was "safe under the conditions of labeling" and that the real problem was one of uninformed consent (NH, 16, p. 6781). While he continued to endorse

[64] Both McCain and Ryan both advocated for increased understanding because they struggled to determine how much information would constitute Edward's "full disclosure" (NH, 16, pp. 6483, 6545).

full, written disclosure and even made an official proposal for the patient package insert, the tide of popular medical opinion was rising against him. In the next section, I consider the development of the insert through two revisions and the ethical-epistemic implications of its shift from the ideal of full disclosure to that of increased understanding.

5. Compromising Informed Consent: The Development of the Patient Inserts

This reframing at the Nelson Hearings of informed consent for increased understanding had consequences for implementation. Moving from reasoning and debating about informed consent to attempting to implement it, this section examines the revision of the Pill's patient package insert between March and June 1970 (see appendix 1 for the three versions of the inserts). I analyze the ethical-epistemic implications of this shift from the insert as fulfilling the ideal of full disclosure to facilitating increased understanding by comparing the input of different stakeholders, primarily radical feminists, the medical establishment, and the drug industry.

As the goal shifted from full disclosure to increased understanding, the revision process compromised the package insert ethically and epistemically. The insert that eventually emerged was Seaman's legacy (see fig. 4.1), accomplished because of support from legislators and social movements. However, her original intent to end the deadly silence with full disclosure was frustrated by resistance from oppressive forces in medicine and industry. I contend that the product of this negotiation was a compromised version of informed consent. Rather than enabling women's agency and access to information, it harmed them in three ways by actively maintaining their ignorance. First, the final insert disarmed them of the ability to prevent fatal blood clots. Second, it forced women, particularly marginalized groups of women, to accept the health risks and be unwitting agents of population control. Third, it allowed doctors to keep

"demanding" users (i.e., "bad women") on the Pill. Thus, the final insert enabled the paternalistic and misogynistic oversight of women and female bodies by physicians in the interest of pharmaceutical companies.

5.1. First version of the patient package inserts

On March 4, 1970—the final day of the hearings—Edwards proposed the first version of the patient package inserts, which he called a "patient information sheet" (NH, 16, p. 6785; see appendix 1.1 for the first version). While acknowledging the risks of the Pill, the commissioner thought that its safety could be ensured "under the right supervision" rendering the known risks "acceptable risks to take" (NH, 16, p. 6816). Since physicians were not providing enough oversight, Edwards thought that the FDA ought to intervene and fulfill this function by providing users the information directly. While potentially groundbreaking, this patient-specific label was continuous with earlier FDA policies.[65]

The first version was a paragon of full disclosure: the details were abundant, and the scope was wide (see table 4.1 for a comparison of the content of the three versions). At nearly 750 words written in lay language, the insert began with a note about the Pill's effectiveness and the leaflet's function as a "reminder of what your doctor has told you." It then provides a lengthy

[65] Patients did receive simple instructions with their drugs, though without mention of safety or efficacy (NH, 16, p. 6804). In the early '60s, the FDA began requiring drug manufacturers to include with each prescription the full instructions for use, dosage, and side effects, but only for *physicians*, out of a concern for unregulated doctors, especially with the increased potency of new drugs (see Carpenter 2010, pp. 465–543, 585–634). In addition to patient instruction and physician labels, the agency produced one patient-specific warning two years earlier for isoproterenol inhalers because of sudden deaths resulting from excessive use. The patient warning, added in June 1968, reads: "*Warning*: Do not exceed the dose prescribed by your physician. If difficulty in breathing persists, contact your physician immediately" (Federal Register 1968, p. 8812). As Edwards noted, there would be a marked difference in scope and detail between this inhaler warning and the Pill's new insert (NH, 16, p. 6785).

***Table 4.1**: Contents of the three versions of the patient package inserts. Note that the third and last version was paired with a booklet that was not included. See appendix 1 for the contents and structure of the inserts and booklet.*

Contents	**Version 1**	**Version 2**	**Version 3: insert**	**+ booklet**
Word count	744	124	161	800
Potency	✓	✓	✓	✓
Effectiveness	✓	✓	✓	✓
Blood clot warning	✓ (7 lines)	✓ (1 line)	✓ (1 line)	✓
Contraindications	✓			✓
Special problems	✓			✓
Add'l instructions	✓			✓
Normal reactions	✓			
Serious reactions	✓			✓
Possible reactions	✓			✓
Cancer warning	✓			✓
When to notify dr.	✓	✓	✓	✓

warning about blood clots, including its "definite association," relative and absolute risk estimates, and warnings signs:

> There is a definite association between blood-clotting disorders and the use of oral contraceptives. The risk of this complication is six times higher for users than for non-users. The majority of blood-clotting disorders are not fatal. The estimated death rate from blood-clotting in women not taking the pill is one is 200,000 each year; for users, the death rate is about six in 200,000. Women who have or who have had blood clots in the legs, lung, or brain should not take this drug. You should stop taking it and call your doctor immediately if you develop severe leg or chest pain, if you cough up blood, if you experience sudden and severe headaches, or if you cannot see clearly.

The leaflet continues with six contraindications, nine "special problems" requiring further supervision, and 10 lines of instruction for missed/irregular periods and breastfeeding. It then provides 10 "normal" reactions, six more "serious" ones, and 12 "possible" others. The last section contained a cautious note about cancer: "Scientists know the hormones in the pill (estrogen and progesterone) have caused cancer in animals, but they have no proof that the pill causes cancer in humans. Because your doctor knows this, he will want to examine you

regularly." The leaflet concludes with a "reminder" to inform the doctor of "any unusual change" and to have regular checkups (NH, 16, pp. 6800-01).

The patient's insert was not a "literal translation" of the physician label; nevertheless, it was an attempt "to try in a simple fashion to alert the woman to the fact that there was an increased risk and then to give her some idea of the magnitude of this, especially in relation to the most important, that is, the fatality" (NH, 16, p. 6802). Furthermore, to avoid stepping on medical turf (or at least to minimize his footprint), Edwards framed the insert as a "reminder" that was referential to medical authority. He insisted that it would not interfere with the doctor-patient relationship in the case of well-supervised women. Instead, it would inform those users without doctor supervision (NH, 16, p. 6806). While trying to account for patient comprehension and respect medical authority, the insert featured a diversity of content and a depth of scope suggesting the agency's willingness to circumvent medical authority. Thus, Edwards original attempt aimed to provide something closer to full disclosure than merely facilitating conversation between doctor and patient.

Nelson commended Edwards for his courage and far-sightedness in implementing this new measure (NH, 16, p. 6805). One of his aims for the hearings was to produce an insert, and he felt accomplished in fulfilling government's duty to publicize information for citizens (NH, 16, p. 6818). Edwards had promised to post the new insert in the *Federal Register* (the official journal of the US federal government). However, that version differed significantly from the first, an early sign of resistance from doctors and industry and the shift from full disclosure.

5.2. Second version of the patient package insert

While Edward's justification was much the same as in the hearings, his first *official* proposal in

the *Federal Register* was quite different in its content (see table 4.1, appendix 1.2 for the second version). Dated March 26, 1970, the second version of the insert was substantially shorter—less than 125 words—and more limited in scope and detail than the first. While it began discussing the potency and effectiveness of the drug and the need for supervision, the risk of blood clots was shortened to a much less comprehensive single sentence: "Rare instances of abnormal blood clotting are the most important known complication of the oral contraceptives." Rather than specifying contraindications, special problems and instructions, various sorts of reactions, and the risk of cancer, the second version only listed five signs of when to notify the doctor: irregular/missed periods and four symptoms of clotting. For detail about the effectiveness, contraindications, warnings, precautions, and adverse reactions in lay language, the proposal required such information be available to patients *upon request*. However, the agency left the specifics to the manufacturer. Of the seven sentences, four referred users to their doctors for supervision, counseling, and examination (Federal Register 1970a, pp. 5962–63).

When Wolfson from DCWL got news of the revision, she called for a sit-in to protest this "watered-down version of the insert" at the office of Robert Finch, Secretary of Health, Education, and Welfare, who oversaw the FDA and Edwards. She contended that it had become a "'non-warning,' which would serve the moneyed interests of the drug industry and population control freaks, but not women who are dying and maimed from pill usage." The following week, she and Seaman met with Finch, Edwards, and Surgeon General Jesse Steinfeld, all of whom walked out of the meeting and refused to explain the changes. Wolfson thought the insert did not meet full disclosure: "An effective pill insert encompassing all of the known and suspected side effects of birth control pills is the least we can expect from an agency whose alleged purpose is to protect the public." Because the insert "does not provide *full disclosure* of all that is known

about potential adverse effects of the drug," she began a letter campaign to Finch, suggesting women demand all the information available and a public hearing (Wolfson 1970, p. 6, my emphasis).

Over the following months, the FDA received more than 700 letters from individuals mostly using DCWL's outline. They supported the measure but asking for more information along with a public hearing, particularly to give a platform to users' voices. Likewise, consumer advocates pressed for more disclosure (for more, see Watkins 1998, pp. 122-26).

Most of the pushback was more about the *symbolic* significance of the insert rather than its actual content. Letters came from the medical establishment that disapproved. Various professional groups opposed the insert with the same sentiments expressed at the Nelson hearings: that it would interfere with doctor-patient relationship, alarm patients, and not provide individualized information. Furthermore, doctors contended that a written insert was an improper mode of disclosure and that it was ultimately the physicians' responsibility to counsel patients not the role of government. Some individual physicians found the information unbalanced: either the proposal was too alarmist by omitting the risks of pregnancy, or it was too cautious by omitting risks of depression and for breastfeeding (Federal Register 1970b, p. 9001). Family planning and population control advocates expressed concerns about the social risks of more information.

As expected, industry opposed nearly every aspect of the proposal. The Pharmaceutical Manufacturers Association (which represented over a hundred firms) and several companies contested any mandate to provide patient-focused information, a responsibility they attributed to physicians. Additionally, they objected to every aspects of content, including the characterization of the relationship with thromboembolism as "causal" (versus "correlative"), the five symptoms

listed, and the omission of the risks of pregnancy (Federal Register 1970b, p. 9002). While Planned Parenthood did not send in a letter, Guttmacher's testimony strongly suggests its disapproval of the proposal.

Thus, opposition to this already-simplified version of insert came from doctors to preserve their authority and those with commercial interests in promoting the uninterrupted sale and use of the drug. Edwards and his agency found themselves caught between the advocates of patients/consumers, who pushed for full disclosure, and the advocates of doctors, industry, and population control, who resisted it. The tension pushed the already compromised proposal further away from full disclosure.

5.3. Third and last version of the patient package insert

Dated June 4, 1970, the third and last version of the insert was around the same length as the prior (161) but with even less details (see table 4.1, appendix 1.3 for the third version). The new insert instructed users of the necessity of their doctor's oversight now at the very beginning: "Do Not Take This Drug Without Your Doctor's Continued Supervision." While now described as "fatal," blood clots were described as mere "side effects" rather than "complications." Gone was the brief list of symptoms, which were moved to a new *supplemental booklet* "on the effectiveness and known hazards of the drug including warnings, side effects and who should not use it." Edward provided required features for the booklet, including effectiveness, estimates of the risks of thromboembolism, five serious side effects, any contraindications, nine conditions in need of special supervision, six frequent side effects, seven possible side effects, instructions for missed periods, the risks of breastfeeding, and a statement on cancer (including lack of proof in humans). This booklet was intended to supplement the insert, which now lacked any significant

content itself (Federal Register 1970b, pp. 9002–3).

While the 800-word booklet resembled the original insert, women had to go *through* their doctors to get it. Furthermore, its existence went unknown by most users. In a letter Seaman considered "historic" and kept pinned above her desk for decades, Secretary Finch acknowledged her influence on the revisionary process:

> I just wanted you to know that I read your book *The Doctors' Case against the Pill* and it was a major factor in our strengthening the language in the final warning published in the Federal Register to be included in each package of the pill.…I recognize that you and your associates [from DCWL] feel that this is still inadequate, but I hope you will agree that it is an improvement over the second draft.[66]

Seaman reflected that this final version with the booklet at least counted as a "reinstatement" of Edward's promise. Yet, she lamented that until the responsibility was shifted to pharmacists, most women did not receive the insert (and thus the booklet) for the first five years from their doctors (pictured in fig. 4.1).

5.4. The wrongs of shifting from full disclosure to increased understanding

I argue that this revision compromised the inserts' integrity and content, rendering it a failure for women's health. The emergence of these patient inserts was merely a *symbolic* victory for women, feminists, and consumer advocates—an "olive branch" from Edwards, as Suzanne Junod describes it (2007, p. 104). It appeared to push back against sexist, authoritarian medicine and the hegemony of industry, which might well be an "important turning point in the doctor-patient relationship" as argued by Watkins (1998, p. 127). While I appreciate its symbolic significance, it is important not to allow a silver lining to distract us from the storm cloud. In this subsection, I

[66] Letter from HEW Secretary Robert Finch to Seaman, 4/27/70, and attached note in Seaman's hand. At the Schlesinger Library, Radcliffe Institute, Harvard University, in Seaman's Professional Correspondence, Carton 1, Folder 43, call number 82-M33--84-M82. I thank Zoe Hill at Harvard for helping me locate this letter.

identify three issues with this shift that resulted in three wrongs to the women who used the Pill because of their epistemic dependence.

In its shift toward the ideal of increased understanding, the insert became increasingly less liberating and more oppressive for women in three ways. First, by keeping the Pill on the market unchanged, the strategy took the risk of blood clots to be acceptable at face value, disappearing women's health for the health of others. Medical experts, who were less focused on women's health than in the health of the population, had deemed the Pill *relatively safe*. Accordingly, the debate in the US shifted focus *away from* the risks to women's health and *toward* medical authority and women's right to know. This judgment about risk acceptability constitutes a *sexist* neglect: rather than prioritizing women's health, this strategy sacrificed it for population control. That is, it assumed the universal, prima facie *acceptability* of risks such as blood clots, depression, and other side effects, because of the benefit of averting "the population crisis." Such sexist neglect of women's health in the service of population planning was particularly oppressive for those women less valued for their reproductive abilities. Exemplified by Hellman's judgment about the "personal" and "social" benefits of the Pill, these value judgments burdened poor women and women of color with the risks to avoid their becoming "welfare queens."

Second, regarding informed consent, doctors and policy makers justified their resistance to full disclosure with sexist, racist, and classist beliefs. During the hearings, witnesses represented Pill users as lacking intellectual capacity and profuse with emotionality. Rather than giving women more information by default, they deemed it better to rely on doctors to decide if the patient was capable. Doctors reserved their right to withhold information to women who they deemed less rational, overly emotional users. Such reasoning it sexist: it treats women as

children and essentializes them as non-rational. Here, population-control advocates were particularly concerned about the abilities of poor women and women of color to comply with medical instructions. They would refuse to disclose the risks when they believed it might lead to pregnancies from women whose incompliance. These eugenic concerns and fears are racist and classist: they expose an unwillingness to support families of colors and poor families based on perceptions that "those people" are too burdensome on society.

Third, the insert became successively less informative, with less details and a narrower scope of information and with increased burdens to access (see table 4.1). *Accordingly, it kept women ignorant of the risks to their health.* In place of reliable and detailed information, the insert directed women to their doctors either for inspection, counseling, or the new full-disclosure booklet. The insert-booklet compromise made doctors epistemic gatekeepers with ultimate authority over their access to medical knowledge. Thus, the last version left patients subordinate to their physicians without an official means of surpassing or circumventing them if necessary.

Accordingly, the ignorance maintained by this epistemic dependence *wronged* women in at least three ways. For one, it worsened women's health*: the insert-booklet strategy disarmed women of the capacity to prevent fatal risks such as blood clots*, intensifying their susceptibility to disease and death. Increasing the epistemic dependence of women, as the insert encouraged, would do nothing to prevent blood clots from happening. Without telling women of the warning signs of a stroke or how to prevent it, the insert was useless for improving their health. Note that preventing blood clots and other diseases was *not* the intention of the insert at all because experts and advisors perceived the Pill to be relatively safe under the right supervision. Accordingly, their value judgments about the acceptability of the risk had implications for the oversights the

label.

By incapacitating women from preventing risks themselves, the last version of the insert *offloaded* the risks of the Pill from the producer to the consumer without the latter's notice. Industry had sided with doctors by attributing to them the responsibility of providing patients with health information, further downplaying their own accountability. Focusing on persevering the integrity of doctor-patient relationship in turn shifted attention away from industry, which could continue to market and profit without any real change.

The second and third harms involves *forcing* women to accept the health risks of the Pill, involving paternalism and misogyny (see chapter 3). *By keeping women ignorant and subordinate to their doctors, the last version of the insert promoted a paternalistic treatment of users as "good women" who are compliant and responsible for family planning*. It directed them away from becoming deviant "bad women" who reject gender norms by demanding more information rather than complying without question. While all forms of medical paternalism seek to provide the patients with benefits and to avoid harms, this form of paternalism intersects with patriarchal oppression. This *sexist paternalism* proactively guides users toward being "good women" who are obedient to authority and sacrifice themselves by accepting certain risks as necessary for their families and for society.

In this case, the insert mitigated the warning to avoid mass hysteria leading to an epidemic of "unwanted Nelson babies." Authorities like Guttmacher worried that informing women about health risks would lead them to shun their duties as responsible mothers and family planners, resulting in discontinuation of birth control. They imposed this burden of responsibility (and the health risks incurred) disproportionately on marginalized groups of women to be agents of population control.

The third harm of this strategy involved a reactive misogyny: *keeping "bad women" who were perceived as "demanding" on the Pill*. With the last version of the insert, women still had to go through their doctors to receive the full-disclosure booklet. This setup gave doctors ultimate authority over women's access to this information, *enabling* them to withhold it. This reactive coercion in the service of patriarchy is what Kate Manne (2018) calls the structural form of *misogyny*: based on sexist reasoning, misogyny is the punitive arm of patriarchy that keeps "bad women" in line by policing their nonconformities. Such withholding would pressure women into continuing to use the drug, forcing "demanding" women to go through their doctors. Note how "being demanding" is gender-coded language for women who are unduly untitled. Inversely, proper entitlement to information is male-coded, a privilege afforded to men. Deviating from the gender norms of docility and self-sacrifice by demanding more information, women like Seaman pressured the FDA to break the deadly silence. The radical feminist protesters were likewise seen as "bad women" because they deviated from the gender norms of docility, compliance, and self-sacrifice.

Despite the risks to women's health and well-being, the insert facilitated an active form of ignorance, whereby drug companies and physicians were able to keep information out of the reach of women who might discontinue their alleged responsibility of planned parenthood. Here, we see how this misogynistic denial of women's right to full disclosure promotes a variety of interests, including patriarchy, capitalism, and even eugenics. This confluence of factors illustrates how these different systems of oppression support each other, what bell hooks (1984) calls *white supremacist capitalist patriarchy*. Women under patriarchy are not entitled to information that they cannot handle, especially when their actions could compromise commercial profits and eugenic policies. By punishing women with ignorance and thus uninformed consent,

doctors and the industry acted misogynistically in their resistance to full disclosure at the Nelson Hearings and during the revision process.

Feminists and consumer advocates (even Nelson) recognized these problems with the policy and tried to resist it. Through protests, an alternative women's hearing, and letter-writing campaigns, they voiced their discontent. Nonetheless, the insert that eventually accompanied the Pill in late 1970 was more oppressive than either Seaman's or Edwards' initial proposals. Rather than promoting women's health, agency, or liberation, the revision compromised this insert ethically and epistemically. Paternalistic and industrial interests coopted the ideal of increased understanding to keep women beholden to their doctors and on the Pill. Rather than speaking against one ideal of informed consent, this story suggests a larger problem in bioethics regarding the interdependence of ignorance and oppression.

6. Discussion: A More Socially Attuned Account of Informed Consent

So far, we have seen how mostly male authorities in medicine have misused ethical ideals of informed consent for unethical and oppressive purposes. Their reasoning about safety and informed consent involved value-laden assumptions about the sex, gender, race, and class of users, which were based on sexist stereotypes, racist concerns, and eugenic politics. Accordingly, their reframing of informed consent under the ideal of increased understanding did not liberate women or improve their health. Instead, their reasoning justified the revision of the package insert to keep women ignorant, on the Pill, and under the control of doctors and pharmaceutical companies.

Moving beyond the debates over the risks of the Pill, this section discusses the broader implications of this episode for bioethics and medical epistemology, especially the

implementation of informed consent in regulatory science and reproductive health. At the intersection of ethics and epistemology, value judgments enter decisions about safety and informed consent. I discuss the patient package insert within the larger context of the women's health movement as a case of epistemic injustice and oppression. I argue that the available decontextualized accounts of informed consent fail to capture important social and political dimensions. In their place, I suggest we look beyond individual autonomy and interpersonal dynamics to understand and implement the *informed* condition for informed consent. To combat campaigns of systematic ignorance, I emphasize the importance of ensuring equity in access of underprivileged groups to medical knowledge and more broadly socializing the burden of responsibility for informing.

6.1. Systematic ignorance and women's oppression

Radical feminists challenged sexism and injustice in regulatory science and attempted to supplanting it with their own values and politics. They were attentive to the social function of medical knowledge and provided important insights into the interdependence of ethics and epistemology. This episode in the early women's health movement points to the interdependence of ignorance and oppression.

As discussed in the new fields of agnatology and ignorance studies, there are many forms of non-knowing that involve oppression (Gross and McGoey 2015; Proctor and Schiebinger 2008). As Nancy Tuana (2006, p. 6) has described, there things "we do not even know that we do not know" where certain values and interests block such knowledge. Take the ignored anatomy of the clitoris, which for centuries focused only on reproduction and elided its sexual function for pleasure (Tuana 2004). Feminists have resisted and transformed such androcentric renderings of

female sexuality and reproduction, enabling women to know about their bodies (Lloyd 2005; Schiebinger 2001). Further, Tuana also discusses knowledge which "they do not want us to know," where powerful, male-dominated groups systematically cultivated ignorance because of threats to authority, power, and profit. Here too, feminists have sought to inform women about their health as part of women's liberation.

In medicine, a classic example of resistance to oppressive ignorance is *Our Bodies, Ourselves*, written by the Boston Women's Health Book Collective during the same time as the Nelson hearings. As argued by Kathy Davis (2007), the book does not just relay knowledge about women's health, but it also promotes a certain sort of knower: one able to partake in the feminist politics of health. The book has the reader consider her own body and experience; it debunks medical discourse as absolutely certain and value-free; it juxtaposes women's local experience as knowledge and thus criticizes traditional medicine. This oppositional stance toward mainstream medical knowledge engenders resistant readings and encourages careful reflection and interrogation of *Our Bodies, Ourselves* and other medical sources of information. Davis argues that this connection between knowledge and resistance is evident in the various translations of the book into other languages, which provided push-back on the assumptions of the original authors, who were white, college-educated, middle-class, and American, so that they could repurpose the book for their own context. That is, by challenging the ignorance of and about women, *Our Bodies, Ourselves* challenged their oppression epistemically.

In this manner, ignorance can enable injustices of a particularly epistemic nature—epistemic injustice—those which harm knowers as knowers, those which knowers perpetuate as knowers, and those which institutions perpetuate as epistemic institutions (see Fricker 2007; Pohlhaus, Jr. 2017). Epistemic oppression, furthermore, is the persistent exclusion of entire

groups of knowers that hinders their contribution to knowledge production by infringing on epistemic agency (Dotson 2014). As we have seen, the final insert did more to restrict women's access to information than to promote it. It incapacitated their epistemic agency and rendered them beholden to their doctors for an alleged "increased understanding." The insert kept users ignorant, subordinate, and compliant as "good women." What more can we learn about informed consent from this case of epistemic injustice and oppression?

6.2. Knowledge and social justice

Without a more socially attuned account of informed consent, we overlook how medical information relates to political context and social injustice. As discussed in section 2, bioethicists have provided varying accounts of informed consent, but they converge on the need to provide more than "mere disclosure" and instead facilitate understanding by improving communication between doctors and patients (Faden and Beauchamp 1986; Beauchamp and Childress 2013; Manson and O'Neill 2007). At least on a strict reading, these accounts could support advocates of the ideal of "increased understanding" during the Nelson Hearings and the revision of the patient package insert. Yet, this reasoning is ethically, politically, and socially problematic because of its unethical assumptions, intentions, and consequences. *How should bioethicists respond to such cooptation and misuse of seemingly intuitive and acceptable ideal of informed consent?*

The main problem is their implicit either/or framing of the legal ideal of full disclosure and the newer ideal of increased understanding, but this framing points to two deeper problems with existing bioethical accounts. First, because these accounts do not account for the context at hand, they fail to capture the key social and political dimensions at play. Instead, they assume a

universal hierarchy of understanding-over-disclosure and apply it to all situations. In contrast, we have seen that this hierarchy affords additional control to medical authorities, which they can use to discriminate and manipulate, and away from regulation of the powerful pharmaceutical industry.

Note that I am not arguing that full disclosure is always better for patients. Sometimes commercial entities use disclosure to evade legal responsibility and offload risk to consumers and patients. For instance, Rebecca Kukla (2010) has analyzed the ethical problems with one specific warning about reproductive risk: California Proposition 65. This state law allows businesses to provide disclosures to their customers of potentially harmful chemical rather than testing and removing them, particularly ones harmful to developing fetuses. Apart from whether these warnings constitute *full* disclosure (which they do not), Kukla argues persuasively that these strategies of disclosure are ethically inadequate because they pin risk management on the pregnant consumer (rather than business owners or government). Furthermore, they only serve to exclude pregnant women from the public by laying guilt on them about their irresponsible "bad motherhood" for putting their future children at risk. That is, certain warnings and disclosures—even if they provide all the essential information—are still oppressive because they exonerate corporate responsibility and place undue shame on pregnant women.

Thus, the real problem is not the ideal of full understanding per se, but the separation of bioethics from the political context of medicine. Such simplicity affords an intuitiveness to their accounts; however, it also allows them to be easily coopted, such as during the Nelson Hearings where sexist and racist gender norms received less scrutiny. Rather than abstracting from the concrete aspects of the world, we need to account for how informed consent relates to social contexts and political forces. The devil is in the details, and exposing these details makes justice

possible.

The second problem is related to the first: these accounts of informed consent are overly individualistic. By appealing to norms of communication and interpersonal understanding, they limit informed consent to a dyadic relationship between patients and their healthcare providers. Part of this focus on interpersonal dynamics follows from their justifications for informed consent. Recall that Faden, Beauchamp, and Childress follow the Belmont Report in grounding informed consent in the principle of autonomy, which is a separate principle from justice. This framing wrongly suggests that knowledge access is unrelated to social justice. Manson and O'Neill contend that informed consent is less about promoting individual autonomy than preventing exploitation of patients by providers. Despite their divergence, both instances assume that informed consent is mostly an interpersonal phenomenon, secured between a few individuals but separate from social justice.

However, as my analysis suggests, securing informed consent involves more than an individual patient's autonomy or the interpersonal dynamics between doctor and patient. Social injustice can violate informed consent, even if these structural problems have been less emphasized than the personal injustices and rights violations. Take the classic case of the US Public Health Service's (PHS) trails in Tuskegee, Alabama, where researchers merely observed the "natural" progression of untreated syphilis in poor, Black men without telling them of their disease or offering them penicillin once available. The outrage in 1972 upon publicity of these violations catalyzed requirements for informed consent during research, the protection of vulnerable groups of subjects, and oversight by institutional review boards. While the poverty and race of these men is regularly mentioned, many overlook the ways in which the PHS study is an example how uninformed consent is a structural form of racial and economic injustice

(Reverby 2009, 2012).

Like in these PHS study, the oppression that comes from uninformed consent results from disparities in knowledge between groups with varying degrees of privilege from education and scientific literacy. Take another classic case of uninformed consent, involving the involuntary sterilization of poor women and women of color throughout the past half-century. There is a long history of white doctors sterilizing poor people and people of color often without medical reason or consent while doing other procedures, such as Hamer's "Mississippi appendectomy," fitting within a larger pattern of structural racism and classism in medicine (Schoen 2005; Washington 2008). Often justified as training or "in the patient's interest," sterilization became a requirement for women receiving welfare fueled by racist concerns about welfare abuse (Roberts 1997). Today, Black women in the US are more likely than white women to be sterilized, which researchers attribute to disparities in their knowledge: Black women are less likely to know about alternatives and more likely to be misinformed about reversibility (Borrero et al. 2011). Therefore, it is not just ignorance but the *increased likelihood of ignorance* for women of color that contributes to the racial injustice of sterilization abuse through uninformed consent. Marginalized groups are less able to gain access to healthcare and medical knowledge, resulting in social injustices that go beyond the individual and interpersonal aspects prioritized by existing accounts of informed consent.

6.3. A socially attuned account of informed consent

Because of the interdependence of ignorance and oppression, we should abandon the framing around the ethical-epistemic aspects of informed consent in terms of abstract ideals of full disclosure versus understanding framing. As mere principles they obscure the rich landscape of

different ethical aspects of informing that deserve careful analysis. Instead of backing one or the other, we should attend more to how actors use these ideals in context, as I have sought to do this chapter. This shift to practice suggests we focus on the act of informing and the actors themselves.[67] My socially attuned account suggests four considerations for implementing informed consent, involving its ethical grounding, the accessibility of information, its burden on responsibility, and the social stakes of systematic ignorance.

First, I argue that social justice is the ethical grounding for implementing informed consent, particularly in regulatory science and reproductive health. Beyond individual autonomy or isolated interpersonal relations, I suggest that informed consent at the social level requires a wider approach. Rather than flipping the universal hierarchy to disclosure-over-understanding, part of the solution here is attending to *epistemic equity*: treating marginalized groups fairly by affording them the same opportunity to engage with knowledge. In struggles for more knowledge and control, achieving informed consent involves attending to the uneven access of underprivileged groups to medical information.

Second, in the politics of information, this means that we ought to make the *distribution* of quality information more even and the *procedure* itself fairer and more inclusive. This shift to the social aspects of informed consent also suggests we make information more *accessible* across divides of gender, race, class, and nationality. In this case, the detailed booklet was not only physically inaccessible, but also its existence was largely unknown. These barriers were unfair because they disproportionately affected women with less education and resources. A better strategy would require more compliance from pharmacists and doctors, which might necessitate

[67] I thank Thomas Stapleford for helping me develop this thesis and this more positive conception of informed consent.

legal changes in the FDA's power.

But, how can we work toward better informing members of epistemically disadvantaged groups about health risks, when disparities in education, literacy, and other epistemically-relevant resources pose such significant barriers to understanding? These concerns are often the basis for medical professionals' paternalism when they believe patient capacities are lacking. Even in achieving informed consent, the ideal of increased understanding relies on an implicit paternalism, which can be an additional source of oppression and impediment to epistemic equity. These disparities in intellectual capacity serve to justify continued practices of paternalism that entrust doctors alone with the responsibility for informing, to the benefit of pharmaceutical companies. Yet, as we have seen, physicians and drug companies have conflicts of interest that can compromise their judgment about safety and informed consent.

So, third, I suggest that we rethink the *burden of responsibility* of informed consent, and I contend that we ought to socialize the burden more broadly. Other segments of society should step in with resources and support as better advocates of patients. This case study illustrates how governmental agencies like the FDA can also shoulder some responsibility for informing patients as consumers but also how they need additional support to resist the problematic tendencies of the medical establishment and industry. Patient and consumer advocacy groups can provide this supportive role. Seaman and Wolfson, for instance, in 1975 founded the National Women's Health Network, which then advocated for women's right to full disclosure of health risks (Kline 2010, pp. 97–125). The Network continues to provide accessible information online about women's health, with a critical stance toward medical authority.

Additionally, self-help groups can support individuals by providing peer-to-peer support, without the hierarchy and authority of medicine that can compromise women's access to

information and their ability to use it. For instance, the National Black Women's Health Project, begun by Byllye Avery, began over a hundred self-help groups in the US and abroad during the 1980s to focus specifically on the health issues facing Black women. Avery (1990) thought it was vital for Black women to have community support to be able to use medical information. Therefore, she sought to provide Black women with the space to receive medical information and discuss it in the broader context of their lives with others facing similar hurdles.

Fourth, it is important that we recognize *the social stakes of systemic ignorance* when discussing informed consent. We must pay increased attention to how practices of informing can further marginalize oppressed groups, as well as the prospects for more liberating strategies. For instance, those whose reproductive capacities are less valued by society bear more of the burden of systematic ignorance. While many doctors and patients see drug labels as disposable, legalistic documents, I believe they have the potential to provide all patients with a reliable source of quality information *if produced in the right way*.

This socially attuned account invites questions about implementation and expertise, which are well beyond the scope of this paper. This chapter provides a starting point for combatting the oppression and social control maintained by the unevenness of ignorance from less than full disclosure to underprivileged groups. Nonetheless, we can improve our accounts of informed consent by better accounting for the social and political context and examining the ethical-epistemic aspects of informing.

7. Conclusion

In his history of the FDA, Carpenter argues that the Pill's patient package inserts, along with other special policies to protect fetuses in utero,

> reflected the degree to which American women as the 'ultimate consumers' of prescription drugs had come to define the concepts and assumptions of post-market regulation. Yet under continuing concerns about teratogenicity in the shadow of thalidomide, the rules also reflected a reigning conception of women as mothers, potential or actual. (Carpenter 2010, p. 614)

As we have seen, social norms about gender thoroughly shaped the US governments response to the risks of the Pill, including how senators sought expertise, how those experts judged safety, and how all parties involved operationalized 'informed consent.' Ultimately, rather than removing risky dosages off the market, as in the UK, the FDA chose to inform users about the risks of what they judged to be the "relatively safe" Pill, in part because of personal and social benefits for family planning and population control. Nevertheless, because of resistance from doctors and the industry against full disclosure of health risks, the agency instead provided women with a non-informative insert that referred them to their physicians for a fuller understanding.

I have analyzed this case—the first major instance of the FDA informing patients directly—to critique existing bioethical accounts of informed consent that focus on ideals like full disclosure and increased understanding. I challenge bioethicists to better account for how context shapes ethical concepts, especially how doctors and regulators implement them in practice. Rather than isolating informed consent from social justice, we need to understand its ethical-epistemic dimensions in the politics of information. With a more socially attuned account of informed consent, we can understand the compromises and failures of patient movements and work toward equity in medicine.

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Part III.

Revising Pregnancy Labels:

The Legacy of Thalidomide for Women's Health

Chapter 5.

Success, Failure, and Progress in Regulatory Science:

How Entrenched Values Shaped Pregnancy Labels at the FDA

Abstract: Philosophers of medicine have shown how epistemic values and commercial forces shape pharmaceutical research, but less how ethical and epistemic values interact, promote, and preclude progress in regulatory science. This chapter explores how ethical values and gender norms about pregnant women become entrenched in regulatory science, shape knowledge production, and influence drug regulation. I argue that progress in regulatory science comes through *epistemic-ethical reform*, with many of the constraints of democratic compromise and negotiation. My analysis provides a critical history and evaluation of the revision of the labeling system for counseling women about the use of prescription drugs during pregnancy at the US Food and Drug Administration (FDA). I conducted in-depth interviews with current and former staff involved in this revision, and I analyzed official reports, public comments, and advisory meetings. I contend that the revision of the pregnancy label was an improvement over the earlier

version which prioritized fetal health to the exclusion of pregnant women's health. For one, the information presented to doctors and their patients is more transparent, transformatively objective, and useful than the previous category system. Second, the revised label promotes a broader range of women's values and interests, including fetal health and women's health, and thus it supports pregnant women's exercise of a broader range of reproductive rights than before. Third, the revised labels promote pregnant women's voluntary participation in the process of science with pregnancy registries for post-market studies. Despite being an incomplete transformation of the labels, the revision is a feminist success story. Therefore, it offers an example for how to extricate fetal-centric values from regulatory science with feminist-based criticism and to replace them with alternatives more attentive to women's diverse interests.

1. Introduction

"Today is an important day in public health," announced a representative of the US Food and Drug Administration to a lively press conference in late 2014 (FDA 2014). The FDA had finally published a revised labeling system for informing pregnant women and their doctors about prescription drugs during pregnancy and breastfeeding. That representative, Dr. Sandra Kweder, made her triumphant statement after 17 years of careful planning and extensive consultation. Why was this new drug label so important, and why had the revision taken so long?

The new pregnancy labels replaced an older system from the late 1970s, one of several measures "directed toward reducing such risks to the unborn" involving *teratogens*, i.e., substances causing birth defects (Kelsey 1982, p. 193). The agency put that system in place following the "thalidomide tragedy" in 1961, requiring drug sponsors to label drugs as one of five categories to inform pregnant women and their doctors about teratogenic risk. However, the

prioritization of fetal impacts and the simplicity of the system became outdated scientifically, ethically, and legally. For one, following trends toward inclusion and diversity in medical research, the agency has come to focus more on women's health, particularly with the establishment of the Office of Women's Health in 1994 (Epstein 2007). Furthermore, since the late '70s, the use of prescriptions during the first trimester (when birth defects are most likely) has increased by 62.5%, with the use of four or more drugs tripling; more recently, most women (94%) take at least one prescription drug during pregnancy (Mitchell et al. 2011). Because drug use[68] in pregnancy is exceedingly common, counseling pregnant women about medications has come to involve balancing the risks of fetal exposure against the potential benefits of maternal treatment and the risks of untreated disease (Temming et al. 2016).

Using the revision process for the FDA pregnancy label, this chapter explores how ethical values and gender norms became entrenched institutionally in regulatory science and shaped our medical knowledge. While previous chapters focus on how societal values and gender norms can be laden in knowledge claims through individual value judgements, this last chapter looks at another multifaceted source of values in regulatory science: institutional history, practices, and rules. Revising this section of the labeling took nearly two decades, in part because of the tension between older policies focused on fetal health and newer, feminist-led initiatives aimed at also including women's health into maternal health regulations. This chapter recounts the story of how these issues of past concern—involving both fetal health and the newfound focus on women's health—shaped changes in drug regulation and labeling. Using interviews with current and former FDA staff, I analyze how regulators have responded to these entrenched values over

[68] By 'drugs,' I mean prescription medications approved by the FDA, rather than over-the-counter medications or illicit drugs in the colloquial sense.

time.

This case study provides us new insights into how *institutional* context shapes medical knowledge and progress, particularly the role of ethical values and gender norms involving sexism and feminism in regulatory science. Philosophers of medicine have shown how different approaches emerge and change in response to the epistemic values and aims of existing methodologies (Solomon 2015). Additionally, commercial forces shape how we conduct pharmaceutical research, what we know about drugs, and what we do not (Fernández Pinto 2017; Holman 2015; Holman and Elliott 2018; Jukola 2015; Stegenga 2016). Yet, in addition to the impacts of epistemic values and commercial forces, cultural shifts in ethics have also transformed medical decision-making, research, and regulation (Epstein 2007; Reverby 2009; D. J. Rothman 2003). Feminists have transformed medical research and practice by challenging sexist values and androcentrism in biomedicine (Bueter 2017; Schiebinger 2001; Tuana 2006). Turning to regulatory science in reproductive health, we see how ethical values like sexism and feminism become embedded in regulatory science through stories of "success" and "failure" and how that history shapes later progress and reform, both promoting and limiting knowledge production.

This chapter provides a critical history and evaluation of the pregnancy label revision, which has not yet received any scholarly treatment. I argue that the revision of the pregnancy label was an improvement upon the earlier version which prioritized fetal health. Despite being an incomplete transformation, the revision is a *feminist success story*. For one, the revision transformed the objectivity (in the sense of Helen Longino 1990) of the information presented to doctors and their patients to be more transparent and useful than the previous category system. Second, the revised label promotes a broader range of women's values and interests, including

fetal health and women's health, supporting pregnant women in exercising a broader range of reproductive rights than before. Third, the revised labels promote pregnant women's voluntary participation in the process of science through post-market pregnancy registries.

By engaging with regulators involved in making these changes, this analysis helps us to understand progress in regulatory science as an *epistemic-ethical reform*, with many of the constraints of democratic compromise. Other accounts of change and progress in regulatory science and medical epistemology recognize the step-wise improvements occur in reaction to commercialization, tensions between public and private interests, and alternative medical methodologies (Carpenter 2010; Holman 2015; Jasanoff 1990; Solomon 2015). Nonetheless, these accounts do not look at the dynamics between ethics and epistemology, such as the influence of ethical values on drug labeling or the question of social justice in institutional change. Unlike older historiographies of "scientific revolutions" that suggest scientific progress entails a complete transformation, the epistemic-ethical reform in regulatory science is less radical and complete because of negotiation and compromise within democratic governments. Transformative objectivity comes in degrees (Longino 1990), so amelioration of regulatory science on ethical and epistemic grounds remains possible by *partial* transformation. Accordingly, this chapter provides feminist philosophy of science a strategy for how to successfully integrate feminist values into regulatory science: through eroding entrenched sexist values with feminist criticism and gradually reforming policies with alternative values and norms that prioritize women's health and diverse interests.

By integrating philosophical analysis with sociological and historical methods, my analysis relies heavily on empirical methodology (Wagenknecht et al. 2015). Qualitative methods are useful philosophically for investigating scientists in their real-world contexts of

practice and identifying the problems they face (Osbeck and Nersessian 2015; Thorén 2015). By engaging with stakeholders, philosophers of science can conduct more socially relevant research to develop effective and appropriate science-based policy (Fehr and Plaisance 2010). In a preliminary interview with one former FDA staff (Susan Wood), I learned the pregnancy labeling revision was challenging and that they made little progress during her five years as director of the Office of Women's Health (2000-2005). Through snowball sampling, I collected three more in-depth interviews (Sandra Kweder, Ruth Merkatz, and Lynne Yao) between fall 2018 and spring 2019, totaling 4.5 hours of conversation (see appendix 2 for professional profiles of interview participants). I used semi-structured interviews with open-ended questions tailored to the expertise of each participant (see appendix 3 for sample questionnaire). The experience between these participants spanned the full 20-year period of the revision from 1994 to 2014, including envisioning and revising the proposal and then implementing the final rule. Furthermore, my participants provided a variety of perspectives institutionally as their positions spanned different FDA sub-groups (including the Office of Women's Health and the Center for Drug Evaluation and Research). According to federal regulations, my project is not generalizable "research" but rather oral history, so my interviews are exempt from ethical review. Nonetheless, I secured informed consent to record all conversations, which remain private unless approved by the participants. Furthermore, I plan to protect my subjects by allowing them to change any quotes in this chapter before publication and by providing them space to offer their alternative interpretation if desired. *This process of feedback is still on-going.* Readers should recognize that these individuals are presenting only their personal opinions and judgments and not representing the official position of the FDA past or present.

During these interviews, it became clear that the history of the FDA and research ethics played a significant role in the revision process, so this chapter also utilizes historical methods for collecting and analyzing sources. My participants pointed to important historical events involving thalidomide and the women's health movement, so I have also utilized secondary sources from Stevens and Brynner (2001) on thalidomide, Daniel Carpenter (2010) on the FDA, and Steve Epstein (2007) on diversifying medical research. Nonetheless, through the interviewing process, I developed my own timeline of major events and primary sources, and I present a novel historical account that goes beyond these secondary sources. I trace how different guidelines and policies embedded values into regulatory science and the agency's institutional memory, leading to a conflict of entrenched values over the pregnancy labels. Participants directed me to primary sources of interest, such as workshops, advisory committees, and guidance documents. Between oral interviews and written documents, I was able to triangulate between the different perspectives offered, including those based on participant testimony and memory, and those published by the FDA, the Governmental Printing Office, and academic journals, particularly in teratology.

Using the case of the pregnancy label revision, this chapter explores how ethical values and gender norms about pregnant women become entrenched in regulatory science, shape knowledge production, and influence drug regulation. Section 2 provides the historical background on issues and events of past concern that shaped these changes in the pregnancy labeling.[69] Here, I explore how stories of "success" and "failure" at the FDA have embedded specific ethical values into regulatory science, such as fetal-centrism and feminism. In Section 3,

[69] The official rule involves both pregnancy and lactation labeling (Federal Register 2014), but this paper focuses primarily on *pregnancy* because it has received the most attention.

I analyze the perspective of regulators who supported the pregnancy label revision and their efforts of reform. The section examines how regulators responded to these entrenched values and how their strategy changed over time. Section 4 discusses how ethical values have shaped our medical knowledge about fetuses and pregnant women.[70] I focus primarily on the question of whether the changes in the labeling constitute progress, and I argue that if understood as an epistemic-ethical reform, this label was an improvement over the shortcomings in the past.

2. The Legacy of Thalidomide for Women in Drug Trials

Perceptions of past "success" and "failures" in regulation continue to shape the present.[71] Thus, this section examines the values implicit in the history of the FDA to contextualize how the agency has made more recent decisions. My account situates the revision in the legacy of thalidomide at the FDA and reactionary efforts to increase women's participation in drug trials. This "success" of the FDA in 1961 with thalidomide led to the entrenchment of fetal-centric values, which came under increasing pressure in the 1990s with institutionalization of the women's health movement. Unlike with thalidomide, and in part because of it, the FDA had "failed" to promote women's health to protect fetuses, actual or potential. Women's health advocates were able to enact partial reforms within the FDA that had conceptualized women as "fetal containers," yet they postponed the battle over the health of pregnant women—including the pregnancy label—for another day.

[70] I recognize that not everyone who can become or is pregnant identifies as a woman, such as transgender men and non-binary people. Because this nuance escapes the notice of the regulations, I have not made it a focal issue, despite its importance. Accordingly, the paper will use the term 'pregnant women' to refer primarily to cisgender women.

[71] Throughout this section I use quotes around "success," "failure," and "tragedy" *not* to undermine their accuracy as descriptions, but rather to exhume and critically examine the values they embed in FDA history and memory.

2.1. The FDA's "success" with thalidomide

The history of the FDA is deeply entangled with the story of thalidomide. Some histories of the agency strongly separate the time before thalidomide from the era after (i.e., pre- and post-1962). For instance, Phillip Hilts casts thalidomide as the rupture between an outdated agency of weakness and a stronger, more modern agency that bases its regulations on science (Hilts 2003; contrast this with Carpenter 2010). This historiography is based largely on how instrumental the thalidomide story was for the 1962 FDA amendments, which codified FDA regulation of efficacy and oversight of clinical trials. Furthermore, historians often tell the story of thalidomide in a highly moralized manner, turning a series of events into a "tragedy" for medicine and yet a "success" for regulation. For instance, Stephens and Brynner (2001, p. xii) describe this sedative as a "dark remedy" that started with "shadowy beginnings" in Nazi Germany that has since progressed toward a more promising "search for causes and cures." Rather than taking these histories at face value, let us critically examine how thalidomide became a "success story" for the FDA.

Thalidomide was first sold over-the-counter in West Germany as Contergan in 1957. The pharmaceutical company Chemie Grünenthal advertised Contergan as "completely safe," despite knowing cases of nerve damage in users and birth defects in utero. As thalidomide spread to the United Kingdom and became widely used in obstetrics for morning sickness, insomnia, and nervousness, these case reports had accumulated by 1960. Despite suppression attempts by Grünenthal, the West German government restricted sales to prescription-only in 1961. After news reports of the epidemic of severe birth defects in 1962, Grünenthal removed Contergan from the market. Nonetheless, in West Germany alone, there were approximately 40,000 cases of

nerve damage and an additional 8,000 to 12,000 cases of birth defects, only 5,000 of which survived birth (Stephens and Brynner 2001).

Meanwhile in the US, the pharmaceutical company Richardson-Merrell had filed an application to the FDA in 1959 for Kevadon (thalidomide) to become the first over-the-counter sedative. The application was assigned to Dr. Frances Kelsey, a new medical officer who had researched the fetal impacts of quinine and had been an editorial associate for the *Journal of the American Medical Association*. Kelsey was immediately suspicious of the application when she recognized the same disreputable shills contracted by pharmaceutical companies to endorse their products. She also thought the human trials were too short and the rat study an inadequate analogue for human exposure. Worryingly, the company had run one of the largest drug trials in the US of over 20,000 patients, including nearly 4,000 women, 207 of whom were pregnant. Kelsey initial marked the application *incomplete*. After nerve damage reports surfaced in 1960, she required even more studies. Following removal from the German market after the headlines about birth defects, Richardson-Merrell quietly withdrew their application in March 1961 (Carpenter 2010; Stephens and Brynner 2001).

Kelsey is often remembered at the "heroine of the FDA" for averting the epidemic that occurred in West Germany, yet the fanfare only began four months after Richardson-Merrell withdrew its application. Dr. Helen Taussig was the first to present her finding to an American audience of physicians in April, yet this news did not attract much coverage. Then, on July 15, journalist Morton Mintz published a widely circulated article with the headline: 'HEROINE' OF THE FDA KEEPS BAD DRUG OFF OF MARKET (Mintz 1962). While kept off the market, thalidomide had been widely used: the next uptick in news coverage came two weeks later when the FDA announced that the drug had been distributed throughout the US. In an era before the

standardization of randomized control trials and informed consent, doctors had handed out the drug to their patients during the company's experimental trials. Senator Estes Kefauver nominated Kelsey for a presidential medal, and President Kennedy awarded her the Distinguished Civilian Service Medal the following month (Carpenter 2010).

Mintz trumpeted the story of thalidomide as a triumph of bureaucracy, which Daniel Carpenter describes in his history of the FDA as "a tale of regulatory success, replete with a protagonist (Kelsey) and an antagonist (the drug, or its manufacturer Merrell)" (Carpenter 2010, p. 253). Mintz had been tipped off by Kefauver, who had been struggling in Congress for years to get a bill passed that would reduce drug prices. He used Kelsey's story to focus attention on his reforms. Yet, the thalidomide story had nothing to do with drug prices, so Kefauver reworked the legislation to focus on the FDA's oversight of clinical trials. Prior to the new amendments, companies could distribute drugs widely in pre-market trials, which were outside FDA control. After Kennedy signed the Kefauver-Harris amendments into law in October 1962, the law required drug companies to submit trial plans (including informed consent of subjects) and allowed the FDA to cease their trials for safety reasons (Carpenter 2010; Stephens and Brynner 2001).

While the FDA had prevented a larger disaster of epidemic proportions, the events that did transpire domestically allowed the agency to strengthen its power through epistemic and ethical reform. In his analysis of the FDA's regulatory power, Carpenter argues that the recasting of the thalidomide episode as a both a "tragedy" and "success" fused together the agency's reputation as a policer of industry, a gatekeeper of the drug market, and a protector of consumers. For one, to protect patients' rights, the new law required the voluntary consent of patients as research subjects. Furthermore, the FDA had increasingly discovered that with the

newer, more potent drugs, regulating "safety in use" also required evaluating the therapeutic effect, which was outside its 1938 legal mandate. Yet, out of necessity, the agency had already begun to incorporate the regulation of therapeutic efficacy into its approvals and to require clinical trials. The 1962 amendments merely codified their previously uncoordinated controls (Carpenter 2010).

Along with a protagonist and antagonist, this success story also had *victims*: the human fetuses adversely impacted and their unwitting parents. Accordingly, this story also paints the FDA as *the protector of fetuses* (and derivatively pregnant women) who are vulnerable to drug-induced birth defects. This legacy of thalidomide—prioritizing protecting fetuses from drugs—had serious implications for regulation, focusing the agency's attention on threats to fetal health.

Reflecting on the impact of her decision to reject Kevadon two decades later, Kelsey (1982, p. 193) recognized that the agency had since taken many steps "directed toward reducing such risk to the unborn" involving teratogens. Before thalidomide, the agency required non-human animal experiments on fertility and teratogenicity only for food additives.[72] Afterward, they required one animal study on the impacts for fertility and general reproduction and two more on teratology (with different animal species) before testing the drug in "women of childbearing potential." The guidelines defined "women of childbearing potential" to apply to all premenopausal women, from those sexually active and inactive to those on and off contraceptives and those with partners on contraceptives (irrespective of sexual orientation; I return to this definition in subsection 2.2) (FDA 1977). While the agency allowed for clinical trials in pregnant women for pregnancy-related drugs, the 1977 guidelines did not *require* them because it "raises ethical questions yet unresolved" involving the safety of fetuses and pregnant

[72] For brevity's sake, I will refer to non-human animal studies as simply "animal studies."

women (Kelsey 1982, p. 195). In the meantime, FDA had also implemented surveillance procedures for birth defects of its marketed products, funded research on developmental toxicology, and began educational efforts about hazards of caffeine exposure to fetuses.

One of the biggest impacts for patients was the creation of a new label with a category system. As part of the agency's uniform *physician labeling* for prescriptions in 1979, the FDA created a special section of labeling for use in pregnancy, with five categories of teratogenic potential "according to the level of risk to the [yet to be born] infant" (Kelsey 1982, p. 197). The pregnancy section came under the "Precautions" header and featured sections for teratogenic and

Pregnancy Category	**Criteria**	**Common interpretation**	**Percentage of labeled drugs**
A	Negative result (no risk/adverse effect found) for fetuses in human trials	"Controlled studies show no [fetal] risk."	0.7% (7 drugs)
B	(1) Negative result in human trials but positive result in animal experiments, or (2) negative result in animal experiments and no human trials	"No evidence of [fetal] risk in humans."	19% (197)
C	Positive result (risk/adverse effect found) in animal experiments and no human trials	"[Fetal] Risk cannot be ruled out."	66% (682)
D	Positive result in human trials or reports, but maternal benefit may outweigh fetal risk	"Positive evidence of [fetal] risk."	7% (73)
X	Positive result in human fetuses, and maternal benefit does not outweigh fetal risk	"Contraindicated in pregnancy."	7% (73, including 20 teratogens)

Table 5.1: *The five categories for prescription drugs in the pregnancy section of the physician labeling rule (column 1) along with the FDA's criteria (column 2) from the Federal Register (1979). The common interpretations of the categories are listed from the Teratology Society's (1994) critical position paper (column 3) as well as one member of the society's analysis of the percentage of drugs labeled for pregnancy in each category from the Physicians' Desk Reference in the early '90s (column 4).*

non-teratogenic. In the former, the label had to designate drugs into one of the five categories A-B-C-D-X (see table 5.1; Federal Register 1979, p. 37464).

While suggesting a gradation of risk, the categories were not quite a cardinal scale of the likelihood of birth defects. Instead, they depended on the type of study (human trial or animal experiment), its finding (positive/negative result of risk to fetus), and the acceptability of the fetal risk (for benefiting pregnant women's health). *Category A* designated drugs for which human trials failed to demonstrate a risk or adverse effect for fetuses (i.e., negative result in humans). *Category B* denoted that either human trials failed to demonstrate a risk despite a positive result in animal studies or animal studies failed to demonstrate a fetal risk without any available human trials. *Category C* contained drugs where the fetal risk is unknown for humans but positive for animals. *Category D* applied to drugs with positive findings in human trials that might be outweighed by the benefits to the woman's health, such as a life-threatening disease without alternative drugs. *Category X* denoted contraindication, for drugs with positive findings in humans where the risk to fetus outweighs any benefit for the woman, such as fetal abnormalities. Despite their non-cardinality, the categories were commonly interpreted by doctors as such (table 5.1; Teratology Society Public Affairs Committee 1994).

While the original 1975 proposal of the label did not include statements on *maternal* health, the final rule did, albeit without a special category system (Federal Register 1979, p. 37452). Furthermore, the final rule was "revised to eliminate any direct suggestion that the possibility of the termination of pregnancy be discussed with the patient" because of a public comment objecting to abortion on ethical and religious grounds. Thus, in the beginning of these labels, this labeling was intended by the FDA more for *prospective* decisions about preventing fetal exposure and continuing/terminating medication, rather than for *retrospective* decisions

involving inadvertent exposure, continuing/terminating pregnancy, and the politics of abortion.[73] Without guidance, the labeling left doctors to weigh these risks and benefits and issue recommendations about abortion (if at all). Some doctors considered this strategy "an unrealistic and unfair burden on the practicing physician" (Brent 1982, p. 47).

Relatedly, news coverage of the "thalidomide tragedy" changed cultural attitudes about abortion in the United States because it altered perceptions of fetal vulnerability (Löwy 2017). After thalidomide, doctors more widely accepted that the placenta was not an impervious filter. Taussig, the first to present the birth defects to an audience in the US, published an article in *Scientific American* of malformed children. She insisted on including pictures of the children despite their harrowing nature. The thalidomide story broke while scientists connected the epidemic of rubella (German measles) with fetal malformations. The news coverage of these epidemics catalyzed the movement for abortion reform in the late '60s and early '70s, culminating with the US Supreme Court's recognition of women's constitutional right to abortion in 1973. Historian Ilana Löwy (2017, p. 78) argues that the decriminalization of abortion in the US and abroad created a new legal entity, *the "unacceptable" fetus*, which it was suitable to abort for "medical" reasons (rather than "personal" ones) via "therapeutic abortion."

Accordingly, the FDA's "success" with thalidomide ushered in a new regime for regulating drugs, fixated on the risks of medication during pregnancy for harming fetuses and supported by broader cultural shifts. Because this regime focused on the risks to fetuses, it embedded a form of *fetal-centrism* institutionally at the FDA through its policies and rules. To protect fetuses from harm, FDA policies monitored for birth defects, funded research on their

[73] This analytic distinction between retrospective and prospective functions of the label comes from my interview with Kweder (2018).

causes, and excluded most women from drug trials. The agency even made a special set of labels aimed at conveying the teratogenic risk of drugs to prescribers. All these efforts aimed at the prevention of birth defects, largely out of sympathy for deformed children and guilt-ridden parents.

While regulations included the health and interests of pregnant women at times, fetal health generally sidelined women's health. As Carpenter notes, the fetal-centrism of the FDA is particularly clear in the pregnancy label:

> these sections and their contents reflected the degree to which *American women* as the 'ultimate consumers' of prescription drugs had come to define the concepts and assumptions of post-market regulation. Yet under continuing concerns about teratogenicity in the shadow of thalidomide, the rules also reflected a reigning conception of *women as mothers, potential or actual.* (2010, p. 614, my emphasis)

While the FDA was catering toward pregnant women by creating a special labeling system, the focus was less on their status *as women* and more on their status *as pregnant*. Furthermore, as conveyed by the phrase "women of childbearing *potential*," the guidelines painted most women to be in a 30-year state of possible pregnancy. Connected with the protectiveness of the agency, this fetal-centric focus had significant impacts for research on drugs, as we shall see in the next section, by biasing trial samples toward *androcentrism*.

Note that the societal value embodied by these policies is unlike more *natalist* forms of fetal-centrism that promote birth obligatorily and oppose abortion categorically out of a reverence for fetal life (i.e., "pro-life"). For instance, zygote-centrists in part I believed that zygotes have a "right to life" that precludes a woman's right to abortion. Instead, rather than celebrating pre-natal forms of human life, the value embodied here is more directed toward minimizing human suffering. Accordingly, based on the (debatable and ableist) assumption that children with birth defects and their parents will be worse off, this value allows for therapeutic

abortion of "unacceptable" fetuses with likely birth defects. Hence, this fetal-centrism is permissive of abortion for certain cases, so it is decidedly *non-natalist* (contra Epstein 2007, p. 64). One should note that many disability advocates reject this reasoning as *eugenic* and *ableist* because it devalues the lives of those with mental and physical handicaps. Accordingly, disability advocates criticize blanket recommendations for selective abortion of non-fatal disabilities, such as Tay-Sachs and Down Syndrome (Garland-Thomson 2012; see Löwy 2017).

These specific (non-natalist) fetal-centric policies are also part of a larger ethical framework that emerged in the 1970s and culminated in the 1978 Belmont Report, which sought to protect *vulnerable populations* from exploitative researchers. During the 1960s, medical practitioners and organizations began to take the rights of patients and research subjects more seriously (D. J. Rothman 2003). Congress started a National Commission for the Protection of Human Subjects in 1974 following a decade of scandalous exposés, including the Public Health Service trials in Tuskegee, Alabama, and allegations of the National Institutes of Health (NIH) funding fetal-tissue research (Faden and Beauchamp 1986). One Scandinavian study involving the decapitation of fetuses post-abortion led to a call from anti-abortionists to ban funding for research on fetal tissue after abortion (Alexander 2004).

The 1974 National Research Act mandated ethics approval by local institutional review boards (IRB) for federal funding (Epstein 2007). Following the Belmont Report, the Department of Health and Human Services (HHS) created special protections in research for "vulnerable populations," including children, prisoners, handicapped or mentally disabled persons, pregnant women, and human fetuses (HHS 2001). Subpart B of this rule created strict conditions for researchers to receive IRB approval. It requires the board to place higher than normal standards

for the benefits of such studies, involving demanding conditions for fetal benefit and intellectual significance like the following:

> The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of *direct* benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than *minimal* and the purpose of the research is the development of *important* biomedical knowledge which cannot be obtained by any other means. (HHS 2001, sec. 46.204, my emphasis)

Depending on the beneficiary, the regulation then required informed consent of either the woman or, if the fetus is the sole beneficiary, both the woman and "the father" (for more, see Bagley 1993).[74]

These policies in FDA guidelines and HHS rules embedded fetal-centric values into regulatory science. Yet, while research ethics in the late 1970s and early '80s had come to focus on protecting vulnerable populations from exploitation, it was about to shift again. This time, the change came from another direction in medicine: the feminist women's health movement and its institutionalization in the federal government.

2.2. The FDA's "failure" with women's health

In part because of the FDA's "success" with thalidomide, its treatment of women's health became a "failure." The protectionist reforms from the Belmont era had the unintended and undesirable consequence of decreasing the representativeness of samples for ethical ends, particularly women. For instance, while more than 90% of investigational drugs were first tested in incarcerated (mostly male) people prior to 1972, by 1979 the figure was less than 15%. In their place were non-incarcerated people who again were mostly men (Merkatz and Junod 1994).

[74] While the regulation does not recognize the pregnant woman with the title of "mother," it inappropriately designates the impregnator the title of "father." This double standard wrongly suggests the man deserves certain paternal rights that undermine the woman's bodily autonomy.

Reformers decried the misguided protectionism of the FDA, such as the exclusion of women from drug trials based on 1977 guidelines for "women of childbearing potential." For instance, in the trials of the antiretroviral drug azidothymidine (AZT) for AIDS patients, women with HIV were underrepresented because of concerns about the risk to fetuses. A catch-22 stymied their participation: the 1977 guidelines required women participants to use intrauterine devices (IUD) as contraceptives, which they were unable to get because of their AID status. Drug trials were the only source of HIV/AIDS treatment at the time, so protesters at the International AIDS Conference in 1990 chanted (Epstein 2007, p. 85):

Women with AIDS can't wait 'til later;

We are not your incubators.

Feminist scholars at the time criticized the fetal-centrism in medicine related to the "fetal container" model of pregnancy, which treated pregnant women as mere "maternal environments" for precious, vulnerable fetuses (Purdy 1990; B. K. Rothman 1989). Women's health advocates charged that the NIH and FDA discriminated against women and treated them paternalistically. After eight years of IRB service, Vanessa Merton concluded that every exclusion of women from research was based on one "fundamental misconception": "*All women are always pregnable and therefore* (through the magical operation of the mind characteristic of unconscious sexism) *always pregnant*" (Merton 1993, p. 387). That is, whenever IRBs considered the participation of women, the question always arose, "but what if the women are pregnant?" (Merton 1993, p. 388). Merton argued that this preoccupation with pregnancy led to the unfair treatment of women participants through double standards. For instance, FDA guidelines required researchers inform women of reproductive risks and require women to use contraceptives but not men, despite the parallel possibility of sperm impacts for men.

Furthermore, the FDA guidelines for "women of childbearing potential" had led to an *androcentric* bias in research on drugs. In 1992, following a similar report about NIH (GAO 1990), the Governmental Accountability Office released a report titled *Women's Health: FDA Needs to Ensure More Study of Gender Differences in Prescription Drugs Testing* (GAO 1992). Because of a request from the Congressional Caucus for Women's Issues, GAO looked at the representativeness of pharmaceutical trials and the measurement for differences by sex/gender. One quarter of the companies surveyed reported not intending to recruit a representative sample of women, and half of respondents claimed the FDA had not asked them to include women. For more than 60% of drugs, trials underrepresented women relative to the disease population. Even for cases where companies included enough women, most studies did not report measuring differences by sex. Accordingly, the agency regulated most drugs based on knowledge primarily about male bodies.

In the late 1980s and '90s, the dominant ethical framework in medical ethics shifted from the Belmont era's regulatory protectionism *from the risks* of research for patients/subjects to the fair distribution of its *benefits* across society (Mastroianni and Kahn 2001). A tacit coalition of reformers targeted HHS, which contains NIH and FDA. They pressured the department first to require more inclusive sampling and second to measure differences by sex/gender, race, and age. Steven Epstein calls this new ethical framework the "inclusion-and-difference paradigm," which dethroned the universal "standard human" for more group-specific standards. During the '90s, it impacted policy at NIH and FDA, especially for research on the health of women and people of color (Epstein 2007).

While radical feminists in the women's health movement saw the medical establishment as a form of patriarchal oppression and sexist ideology, the movement's liberal feminists sought

to reform medicine. In government, this began at NIH with a 1986 requirement for grants to include women as subjects, expanded the following year to include people of color. In 1990, NIH created the Office of Research of Women's Health to oversee the inclusion of women and analysis by sex/gender, and President George H. W. Bush appointed Dr. Bernadine Health as the first woman director of NIH the following year. The NIH Revitalization Act of 1993 required federally funded research to have a representative sample by sex/gender and to report differences. NIH-reformer Dr. Florence Haseltine was particularly instrumental in expanding the agency's conception of *women's health* beyond reproduction (Bueter 2017; Schiebinger 2001).

Once in the FDA, advocates of women's health began to challenge its sexist and fetal-centric policies that resulted in androcentric research. In 1988, FDA recommended drug sponsors include women in trials and issued guidelines for subpopulation analysis (Merkatz and Junod 1994). Once Dr. David Kessler became commissioner of the FDA in 1991, he brought on Dr. Ruth Merkatz as his assistant on women's health issues. With masters and doctoral degrees in nursing, Merkatz was a registered nurse with clinical and research experience on high-risk pregnancies, and she had worked with Kessler at the Albert Einstein College of Medicine in New York as acting director of nursing and co-chair of the bioethics committee (see appendix 2 for Merkatz's professional background).

Kessler entered the FDA when several issues in women's health came to the fore, including the safety of breast implants and the HIV/AIDS crisis. He tasked Merkatz with keeping him updated on women's issues and asked that she focus on getting women into clinical trials. They organized an FDA task force on women in drug trials, and Merkatz organized a 1992 conference on the scientific, ethical, and legal aspects of women in drug trials. The main questions she posed involved the risks and benefits of fetal-centric policies:

> Is it necessary or proper to limit women's early entry into drug trials so as to avoid any and all risks to a *potential* fetus? Is the underlying premise of *zero risk to the fetus* applicable today? Is this principle in the best interests of women or future generations of both women and children? Might some risks be appropriate in terms of the overall good and future benefit? (Merkatz 1993, p. 165, my emphasis)

Note Merkatz's careful designation of the fetus as merely "potential" rather than "actual," which is implicit in the FDA's 1977 guidelines for "women of childbearing potential." During the conference, some presenters criticized these guidelines as "paternalistic" and "overprotective" of women who wanted to participate in trials (Federal Register 1993, p. 39408; Fletcher 1993). The guidelines excluded women from the early stages of clinical trials (phase I and early phase II), which measure drug tolerance, metabolism, and pharmacokinetics and set the dose and regimen. Because of lack of female data in early stages, the later stages (late phase II and phase III) were designed based on male responses almost exclusively (Merkatz et al. 1993). This androcentrism disallowed women as participants to make decisions about their (possible or actual) pregnancy, which Commissioner Kessler noted would constitute sex-based discrimination (Federal Register 1993, p. 39408).

Thus, on March 25, 1993, the FDA revised its 1977 guidelines for clinical trials, first withdrawing the restriction of "women of childbearing potential" from early stages of trials and second encouraging industry to include women in "reasonable numbers" (Federal Register 1993). FDA's decision to "lift the ban," as Merkatz sometimes describes it, was based on both scientific and ethical reasons, including the improvement of drugs for women and the increase of women's autonomy as trial participants (Merkatz et al. 1993).

While correcting for entrenched fetal-centric values, largely on account of their androcentric effects, these reforms did not reject the value of fetal life outright. The FDA maintained that its decision "does not reflect a lack of concern for potential fetal exposure or

indifference to potential fetal damage," and that companies need to take "appropriate medical precaution against [participants'] becoming pregnant and exposing a fetus" (Federal Register 1993, p. 39408). The agency suggested that researchers conduct pregnancy tests before admitting women and counsel them on any risk found in pre-phase animal studies.

More radical feminists criticized these FDA reforms as shy of social justice, particularly compared with NIH (Baird 1999). Merton (1993, p. 395), for instance, critiqued the requirement for "reasonable representativeness" as too weak, amounting to no more than "a 'pretty please' to pharmaceutical houses, with a gratuitous abandonment of regulatory authority." She also disapproved of the asymmetry of requiring women to use contraception and receive more counseling than men because it would likely pose a barrier to women's participation, resulting in further androcentrism.

Nonetheless, the liberal feminism of insiders was successful at the FDA in beginning to reform the sexism entrenched in regulatory policies against the backdrop of the FDA's "failure" to (require industry to) include more women in trials. The problems Merkatz was tackling were symptomatic of larger problems, so she was skeptical that a case-by-case approach would suffice, such as the FDA had done with the AZT trials. Merkatz suggested to Kessler a more "organized" approach to women's health with institutional and financial support rather than a single assistant. In 1994, Kessler established the FDA's Office of Women's Health—the second such office after NIH—with Merkatz as the first director (1994-97). Along with reporting to the commissioner and promoting women in trials, the mission of the new office also included setting the FDA agenda for women's health (Merkatz 2018).

2.3. The final frontier, the first defeat

Research ethics might be able to shift as a "swinging on the pendulum" from one conception of justice to another—such as from the protectionism of the Belmont era to the inclusion-and-diversity that succeeded it—but regulatory science is incapable of such quick, dramatic changes (contra Mastroianni and Kahn 2001). For one, regulatory agencies are caught between dueling pressures from *democratic* reformers to include public interest and *technocratic* reformers who emphasize scientific quality, so any reform must be negotiated (Jasanoff 1990). Furthermore, ethical values become embedded in regulations, policies, and guidelines, which further entrench values as social norms in institutional memory. Through an organization's perceptions of past successes and failures, entrenched values set its goals and priorities and define its horizons of what is attainable and what remains impossible. This institutional dynamic is particularly true for the FDA, whose regulatory power derives in part from the authority afforded by its *reputation* (Carpenter 2010). Accordingly, as values are institutionally entrenched, any change will be partial rather than total, a reform or decline rather than a revolution. And, as one commenter noted, any reform will be both forward and backward facing, based on some conception of the organization's history and a revision for the future: "No one wants to go back to 1960. But few argue that the regulations of 1977 are perfect" (Fletcher 1993, p. 214).

Following the establishment of the Office of Women's Health, one critical issue that remained untouched was the health of women who were not just potentially pregnant but *actually* pregnant. This was not just hindsight, but a key problem Merkatz noted early on. She had spent much of her nursing career working with women who had high-risk pregnancies, particularly with poor women of color, including her dissertation, titled *The Influence of Maternal Attachment and the Capacity for Empathy on Perception of Social Support among*

Pregnant Minority Women (Merkatz 1989). In addition to women's health research more generally, her 1992 conference focused on scientific, ethical, and legal questions in obstetrics specifically:

> What about pregnant and lactating women? Are drugs and other products being tested adequately in this population so as to know how they work? How will the unique problems and effects be identified? Must animal data and post-marketing surveillance be relied on almost exclusively? … If pregnant women are enrolled in trials, are there differences related to the informed consent procedure? (Merkatz 1993, p. 166)

One presenter lamented that pregnant women were a "true therapeutic orphan" because of the lack of drug trials including them, leaving doctors to rely on animal experiments with questionable clinical relevance (Frederiksen 1993, p. 195).

Ironically, pregnant women were the *final frontier* for women's health research by the mid-90s in several ways. Following the reigning inclusion-and-difference paradigm, there were good reasons to think that *pharmacokinetics* (how an organism affects drug metabolism) differed for pregnant and non-pregnant women. For instance, early in pregnancy, blood plasma volume increases to around one and a half the non-pregnant state, which increases cardiac output accordingly. As blood plasma increases, serum albumin (the protein that transports drug compounds) decreases, which could result in a higher percentage of unbound drug that the pregnant body would then distribute differently and excrete at higher rates. Pregnancy also might change drug absorption in the gastrointestinal tract. Progesterone (higher during pregnancy) slows the activity of smooth muscle, which reduces peak serum concentration and time-to-peak for orally administered drugs. Despite these physiological changes, doctors often did alter not the dose and dosing schedule in pregnant women (Frederiksen 1993).

And yet, these feminists knew that pregnant women's health was also the *first site of defeat* at the FDA in the late '70s. Kelsey (1982), for instance, had argued that including

pregnant women in trials would be futile because even a large sample might not be large enough to detect low potency teratogens. She used this inadequacy of trials to justify the FDA's primary reliance on post-market studies. Yet, her reasoning was clearly fetal-centric. She ignored the *maternal benefits* of including pregnant women because of the oversights for determining fetal risk. However, including pregnant women is not just for detecting fetal impacts but also setting the dose for the pregnant subpopulation.

Much of the reason for these clinical oversights was the general ignorance in medicine about drugs during pregnancy—*precisely because of the lack of women in trials* on the "fundamental misconception" that women are pregnable and thus always pregnant (Merton 1993). Some commentators have been pessimistic of the possibility of reforming this fetal-centric protectionism for pregnant women. Epstein (2007, pp. 261–63) doubts that "the plight of pregnant women" would be added to the inclusion-and-difference paradigm because he believed that this subset of women were not widely considered to be discriminated against specifically (apart from their being women) and because of the politics of abortion and "fetal rights."

Nonetheless, at the FDA, pregnant women's health was the new step, either in spite or because of its treacherousness. When Merkatz and her colleagues at the FDA announced in the *New England Journal of Medicine* that the agency was "lifting the ban," they concluded with two paragraphs on the remaining difficulties and prospects for testing drugs in pregnant women:

> Maximizing protection of fetuses from potentially toxic therapies is prudent, and fear of liability is understandable, but the result is that many drugs are ultimately used during pregnancy without reliable data on their maternal and fetal effects. … When a clinical trial represents the only source of a promising experimental therapy for a life-threatening condition, it is more obviously essential to include pregnant women. … Even in less urgent cases, the participation of women in formal studies may be appropriate when the drugs' use in pregnancy is likely. (Merkatz et al. 1993, pp. 295–96)

They announced the FDA's intentions to explore these issues in public workshops and conferences. In the coming years, the FDA would follow through with this promise, but its reforms would be anything but easy or swift. Unlike with other "therapeutic orphans" like pediatrics patients, Congress did not pass legislation for pregnant women that incentivized or required studies for their subpopulation to receive FDA approval. Instead, the advocates of women's health at the FDA would have to work creatively and tirelessly to ensure that drug regulation did not proceed under the assumption that pregnant women were mere "fetal containers." The pregnancy label became a focal point for this value conflict. Its revision brought together the epistemic needs of pregnant women, their ethical desert (what they deserve), and the lack of human trials on drugs on them.

3. The Long Road to Revision: Entrenched Values in Conflict over Pregnancy

While the "success" with thalidomide had embedded fetal-centric values in FDA's policies, its "failure" with women's health also led to the institutionalization of liberal feminism, its values, and its gender norms about women and pregnancy. This situation created a *conflict of values,* resulting in feminist-based criticism over the FDA's treatment of pregnant women's health and a subsequent series of reforms in regulatory science. Here, the pregnancy categories for preventing teratogenic risks to human fetuses came to the fore. Pregnant women often have an interest in the health of their fetus in the case of a wanted pregnancy, yet an uncritical overemphasis on fetal health was responsible for the lack of research on drugs in pregnancy and the exclusion of pregnant women from drug trials. In this newer era for women's health advocacy, such fetal-centric protectionism was out-of-date, negligent of women's wellbeing, and discriminatory against women's interests.

While these reformers might not describe themselves as *feminists*, their efforts were continuous with the *feminist women's health movement*: prioritizing the health of women, challenging biases in science that neglected women and their uniqueness, and attending to the non-reproductive aspects of women's health, even during pregnancy (Baird et al. 2009; Bueter 2017; Davis 2007; Nelson 2015; Schiebinger 2001; Tuana 2006). Likewise, they recognized that pregnant women were not receiving the drugs, information, and proper dosage they deserved.

With pressure from feminist health advocates like Merkatz, the fetal-centrism embedded at the FDA was changing, with less impacts on women's health in general but persisting problems for pregnant women's health. The fetal-centrism in past regulations was problematic for feminists because of its *androcentric* effects on medical research, i.e., research primarily based on male bodies might not apply to female bodies. Yet, even with the inclusion of female bodies in drug trials, pharmaceutical research typically occurred in the absence of *pregnant* (human) bodies. Therefore, entrenched fetal-centric values remained a hindrance to women's health because they created barriers to conducting pregnancy-specific research. This lack of research undermined the abilities of the pregnancy label to provide guidance to women and their doctors, regardless of their specific values and medical needs. Yet, the agency was not going to remove the pregnancy subsection, as both liberal feminists and fetal-centrists appreciated information about the use of drugs during pregnancy. The open questions were whether the agency would change the label, when, and how.

Advocates of women's health at the FDA spent two decades revising the pregnancy label and undertaking related efforts to improve data collection about drugs in pregnancy. In this section, I recount how these regulators responded to the values embedded in the FDA, including both the fetal-centrism of the past and the more recent feminism. These values shaped their

perception of *possibility*, *priority*, *necessity*, *failure*, and *success* in regulatory science. They impacted how the FDA produced information for prescribers, collaborated with external advisers, and regulated drug companies.

For one, fetal-centric and feminist values influenced regulators' sense of *horizons*, that is, what they considered possible, important, and necessary to change. For instance, earlier advocates of women's health considered a revision of the label impossible because of the lack of research on pregnant women, so they focused on improving that research by removing barriers. Later reformers considered a revision possible, and they used the existence of these on-going initiatives to justify the necessity of changing the labeling. These horizons set the agenda for knowledge production and regulation at the FDA, including what sort of information regulators suggested and required researchers to collect and drug companies to convey, as well as the methodology for accomplishing these tasks. For example, regulators became increasingly willing to pressure industry to conduct trials with pregnant women to obtain approval because of drug sponsors' continued reticence to conduct such trials and to provide empirically adequate warnings.

Values also shaped regulator's sense of *progress* by determining which events were successes, which were failures, and where they sought improvement. These perceptions also impacted knowledge production and regulation. For instance, because much of the FDA's history assumes the "success" with thalidomide, women's health reformers could not completely abandon measures to protect fetal health. Yet, emboldened by the "success" with getting women into drug trials, they used strategies of creativity, collaboration, and compromise to find ways of improving the health of pregnant women, as well as their fetuses, *without allowing the latter to overshadow the former*.

This section recounts the revision and implementation of the pregnancy labels by these reformers. To "get the ball rolling," Merkatz hosted conferences and meetings in the mid-90s. Her efforts attracted attention to the problems with the pregnancy labels, which teratologists were lambasting for different reasons related to unnecessary abortions. Eventually, the FDA organized a Pregnancy Label Task Force run by Sandra Kweder, who championed the revision through internal concerns about "the next thalidomide." In the late '90s and early 2000s, she relied extensively on external advice, and she found the support from others in the FDA to promote more data collection to populate the label with non-trial research. While nearly everyone involved in the revision effort agreed that the label had outlived its utility, they still faced a variety of conflicts. Before they could publish the proposed rule in 2008, they had to work through issues involving fetal risks, abortion, communication under ignorance and uncertainty, and expert judgment. Following the final rule in 2014, implementation has been successful in certain regards but remains challenging especially given the continued lack of human trials with pregnant women. After recounting this long road to revision, section 4 evaluates the new label.

3.1. Getting the ball rolling

It is not easy to be a reformer inside the FDA. Merkatz recalls this struggle:

> So what were up against at that time was dealing with promoting change within the FDA, which can sometimes be challenging. And it was hard enough for some of the centers, some of the offices, to deal with the issue of including women who might be at risk for pregnancy into clinical trials, let alone think about women who are pregnant in clinical trials. (Merkatz 2018)

While the agency could accommodate some changes, others seemed to be impossible for the time being—particularly involving fetal health.

One perennial issue Merkatz faced when discussing pregnant women in trials involved their capacity to give informed consent and the paternal rights of the men who had impregnated these women. As liaison to the commissioner, Merkatz tried to avoid the issue—in part because a man was often no longer involved. But there remained legal issues about informed consent because pregnant women and fetuses were a "vulnerable population" according to subpart B of the Common Rule for human-subjects research (HHS 2001).

Nonetheless, Merkatz maintained that these women could give consent for themselves—like any other adult. Furthermore, without these trials, doctors would not know how the drugs work in pregnant women and how to alter the dose accordingly. She framed this ignorance as an *ethical* problem that must be balanced against concerns about fetal impacts: "It's just as harmful to give a drug that has no effect as it is to give something that could be dangerous. I mean you could be treating someone for a condition thinking that there's a lot at stake, and you're not treating them because you're not able to reach a therapeutic dose" (Merkatz 2018). Women's health advocates would return later to this insight about dosage and efficacy to justify the importance testing drugs in pregnant women as ethically and scientifically necessary.

There was "general agreement" that nothing was known about the use of drugs during pregnancy, and this ignorance was "a big problem" (Merkatz 2018). Without human trials, the FDA decisions had to rely on animal studies and chance reports on adverse effects in humans. For instance, Merkatz recalled reports in 1992 that women taking angiotensin-converting-enzyme (ACE) inhibitors for hypertension had children born with skin anomalies and renal defects—sometimes resulting in infant mortality (Piper et al. 1992). These adverse-effect reports led to a prohibition of ACE inhibitors in pregnancy (Merkatz 1993).

Yet, rather than taking the helm, Merkatz was left to more passive and collaborative measures to promote the agenda for pregnant women's health: "It's really important when you are trying to promote change, when you get something started, that you come in not as the person who knows it all, but very quietly listening and trying to be helpful and bringing in a perspective that maybe they would consider." After revising the guidelines of women, Merkatz made drugs during pregnancy a priority. With some of the office's first funds, she hosted a workshop in 1994 on FDA-Regulated Products and Pregnant Women (FDA 1994; Nightingale 1994). She did this "to get the ball rolling" on the issue (Merkatz 2018).

One of the main conclusions from that conference was that the then-current pregnancy categories were not helpful for determining the correct dosage during pregnancy and post-partum. This issue was separate from fetal-centric concerns about birth defects, which had been the focus of the label via the categories (see table 5.1). In contrast, dosing required different sorts of studies: *pharmacokinetics* (the organism's influence on a drug) and *pharmacodynamics* (the drug's influence on an organism). Around this time, Merkatz began collaborating with a patient advocacy for epilepsy. The group was looking for better information on the use of seizure distorters during pregnancy because women with epilepsy needed to continue using some medication during pregnancy; however, some distorters are known teratogens, and they found that the labels were not satisfactory for balancing potential fetal impacts with women's health. Concurrently, the FDA began to receive more external pressure, but this time from a group of scientists in teratology. These external pressures increased the priority of revising the label.

3.2. Rethinking the label

In 1997, Dr. Sandra Kweder was a deputy director in the Office of New Drugs overseeing pediatrics and maternal health products (among other drugs) at the Center for Drug Evaluation and Research (see appendix 2 for Kweder's professional background). At that time, FDA was receiving "scathing" letters from the Teratology Society. In 1994, the society had published a position paper calling for the removal of the categories, which they derisively called "an anomaly in FDA product labeling" (Teratology Society Public Affairs Committee 1994). In their place, they suggested moving to a *narrative summary* of risks, as provided by other labels, including the risks to fetuses of not treating pregnant women's preexisting conditions. Furthermore, the society called for more guidance after inadvertent exposures involving continuing/terminating pregnancy. Of particular concern were the anxiety created by the categories and the subsequent "unnecessary termination of wanted pregnancies" based on ignorance (Teratology Society Public Affairs Committee 1994, p. 446).

In her own clinical experience as an internist with sick pregnant women, Kweder had found the labeling "frustrating," particularly for the *prospective* use of determining whether to begin or continue prescribing a drug during pregnancy. This pre-hoc decision is different from the post-hoc *retrospective* situation after accidental exposure whether to continue or terminate a pregnancy. Recall that, while the FDA had proposed originally in 1975 to include that the "possibility of termination of pregnancy should be discussed," the agency removed the reference to abortion guidance because of a public comment from anti-abortionists stating ethical and religious objections (Federal Register 1979, p. 37452). Teratologists were not pro-natal anti-abortionists, but they remained fetal-centric: while recognizing that the agency intended the

labels for making decisions only about prevention, i.e., prospective risk, they suggested the FDA change them to accommodate this other use related *primarily* to fetal health.

Their position paper was the result of the Teratology Society annual meeting in July 1992, which had a special session concerning the categories (Friedman 1993). Presenters accused the categories of misleading doctors and patients to infer an increasing gradation of fetal risk from A to X (see table 5.1). This assumption is problematic: companies labeled most drugs (66%) with category C *as a default* in the absence of human data, yet doctors often interpreted category C as denoting the (positive) possibility of risk, rather than the (negative) absence of evidence. Furthermore, companies labeled less than 1% of drugs category A (negative results in human trials), suggesting the agency defined the criterion too strictly. One FDA representative was present (Dr. Paula Botstein), who welcomed comments and suggestions but maintained that the agency had no plans for revising the labels.

The teratologist Dr. Anthony Scialli was particularly unsatisfied with the FDA response. An OBGYN and the editor-in-chief of *Reproductive Toxicology*, he castigated the integrity of the agency "so in love with its systems" for its "bad science." Furthermore, Scialli charged that the labeling system itself was resulting in a massive amount of "fetal death":

> As a result of the alarming and incomplete manner in which teratology information is presented in many labels, women may be advised to abort wanted pregnancies because of trivial exposures. The common occurrence of such misguided advice apparently is not recognized by the FDA. Marshall Johnson, a prominent teratologist, has often pointed out that a new pharmaceutical causing as many fetal deaths as are caused by the FDA system would never be permitted on the market. (Scialli 1992, p. 465, my emphasis)

Scialli soon became the vice president and then president of the Teratology Society, and he continued attacking the FDA and its labels (Scialli 1994, 1996). He argued that the categories like other lists of toxins provided a false sense of control and knowledge. Toxicity in fact depends less on the agent and more on dose, exposure time, and individual sensitivity.

Categorical warnings could "panic" patients, ignore the magnitude of the effect, and fail to convey the availability of diagnostic tests. He alleged that this "tyranny of lists" led to clinical errors that over-prevented exposure and resulted in unnecessary abortions (Scialli 1997).

The criticisms of Scialli and the Teratology Society were based on a similar fetal-centrism to that which motivated the pregnancy categories and other efforts avoid "tragedies" like thalidomide. The domain of teratology is the prevention, diagnosis, and management of birth defects, and this spans from developmental biology, toxicology, and epidemiology, to fetal medicine, genetic counseling, and obstetrics. While some clinical teratologists work directly with pregnant women, their ultimate focus is on the developing fetus. Yet, because of how exposure and diagnosis have outpaced treatment, and because of the normalization of abortion, the termination of pregnancy remains the primary means for clinicians to manage impacted pregnancies (i.e., "therapeutic abortion") (Löwy 2017). Accordingly, unlike the categories, these teratologists were interested in providing pregnant women and their doctors with better information, not just to protect fetuses or prevent abortion, but to make decision-making more evidence based.

However, regulators have a tenuous relationship with practitioners, in addition to different aims, and the FDA did not undertake the issue immediately. The FDA's primary domain is over pharmaceutical companies, not the practice of medicine, which often creates tensions between the agency and medical practitioners (Carpenter 2010). Furthermore, some of the fetal-centric concerns from teratologists differed from the inadequacies involving women's health, emphasized by the regulators like Merkatz who were best positioned to tackle the reform.

Like Merkatz, Kweder thought the agency need to revise the pregnancy labeling because it was adversely affecting women's health, which derivatively impacted fetal health. She thought

that the issues raised by the teratologists about unnecessary abortions based on no information were important, not just because they were "silly decisions" based on ignorance or because abortion was wrong. Instead, the problem with the labels was that they compromised pregnant women's health and "a sick mom doesn't make a healthy baby." Often doctors would use the lowest dose to avoid fetal impacts, but without a therapeutic dose pregnant women's health would worsen and require more hospitalization. Without information on the proper dose for pregnancy, doctors could expose women to risk without benefit, which Kweder reasoned was simply "wrong" (Kweder 2018).

Eventually, the FDA decided to rethink the label, in part because of Merkatz's 1994 conference and in part because of the teratologists' persistent agitation. Additionally, the agency had decided it was time to rework the entire physician labeling rule from 1979. The earliest efforts began with surveys to physicians in 1992, and at first the agency considered revising the pregnancy section along with the other sections (Federal Register 2000, p. 163). However, it eventually decided that the two initiatives should be completely separate, largely on account of the unique category system (Federal Register 2006, pp. 341–43). The pregnancy-lactation section was the only part of the label that received special, independent treatment.

In 1997, the agency organized a Pregnancy Label Task Force with Kweder as the leader. Trained as an internist in the military, Kweder was committed to improving the health of sick pregnant women, and she felt uniquely posed for the job unlike many others at the agency. The FDA had, on the one hand, toxicologists that Kweder described as "risk people" who looked for signal in animals and just "assume it must be skull and crossbones." This leaves sick pregnant women "caught between a rock and a hard place." On the other hand, there were obstetricians who were loath to prescribe any drug to a pregnant woman for her non-obstetrical needs. As an

internist, Kweder was more comfortable in this domain than either group, particularly after a two-year clinical fellowship at Brown supported by the FDA working specifically with sick pregnant women (Kweder 2018).

Throughout the revision process, Kweder sought outside feedback from scientists, patients, and practitioners, looking initially for assurance that revision was the right choice. The task force's first official event was a public meeting in 1997 focused on the categories. It sought feedback on changing the categories and explicating the distinct types of risk. They also considered distinguishing in labels the options before drug use and after inadvertent exposure as well as before pregnancy (Federal Register 1997). Her team then began to develop a new model, drawing on advisory committees for more specific guidance on how to revise.

She appreciated this external input from advisers, even the "irritants" in the Teratology Society, because of the *internal* pushback she was receiving from some sectors of FDA. While Kweder was committed to the revision, not everyone at the agency was as supportive, particularly because of the entrenched fetal-centrism from the legacy of thalidomide. She noted that developing new regulations is always difficult, so "you have to want it so badly." But her group faced additional resistance because of fears of "the next thalidomide":

> The first thing we had to every time we shared this at the draft stage [was] we had to clear it at [the] department. They had a lot of questions. Everybody had the same thought: "FDA? What are you thinking here? Why do you want to mess with this? You're going to get us in trouble." … Anything that's connected with pregnancy and babies is considered risky territory. They think, perhaps they have a tendency to see it as, you know, a political controversy. (Kweder 2018)

Much of the reason for these fetal-centric concerns was the remaining ignorance in medicine about the use of drugs during pregnancy. As Kweder put it, "The perception of risk is magnified in the absence of data." Because the FDA was privy to some few available studies, Kweder thought that "we need to have a strong role in righting this situation."

For instance, even in cases where studies did exist, drug companies wrote misleading labels. In general, sponsors would write labels with safety claims that overemphasized potential harm to fetuses to minimize their risk for liability. Their tendency to over-warn consumers in general only increased with the risks of drugs in pregnancy. For instance, companies labeled oral contraceptives category X, which contraindicates them for pregnancy and often results in anxiety and abortions for inadvertent exposure, despite studies suggesting that there was not a substantial risk with contraceptives (Kweder 2018).

According, the fetal-centrism embedded in regulatory science magnified the general disposition of industry to create misinformative labels, which warned against use during pregnancy *in the face of evidence to the contrary*. For instance, following the 2001 anthrax attacks, congressional staff aides and clerical staff—many of whom were young women and some pregnant—in Washington D.C. began to take ciprofloxacin as a prophylactic anti-biotic. However, when their doctors looked at the label from Bayer, Kweder recalled that "they may as well as kiss it goodbye. it sounded like the most dangerous drug in the world!" Yet, after working through the literature, her team found that there were enough studies published to recommend that "risk of anthrax far outweighed any risk to this medicine." Bayer simply had not reported the studies to the FDA and instead written a label overly protective of fetal health (Kweder 2018; see also FDA Pregnancy Team 2001). Without more scientific studies in humans and a careful collection of what existed, Kweder knew that any revision would be wholly inadequate.

3.3. Collecting more data to populate the label

The FDA Office of Women's Health was able to use the 2001 anthrax attacks as an opportunity to get funding from Congress to research maternal health (Wood 2018). While the representation of women in drug trials increased during 1990s, the same was not true for pregnant women. The catch-22 that had kept *potentially* pregnant women with HIV/AIDS out of the AZT trials continued to keep *actually* pregnant women out of other trials with less news coverage: drug sponsors remained concerned about the liabilities of testing drugs in pregnant women because of potential lawsuits on behalf of the fetus, making them less inclined to include this subpopulation (Bush 1994; Merton 1993). Industry kept women and their doctors ignorant about the safety of drugs in pregnancy by not including pregnant women in trials. *Instead* of conducting these studies, they would simply warn doctors against prescribing to pregnant patients in the label (Kweder 2018; Yao 2019).

Accordingly, the Pregnancy Label Task Force had to take a creative, multi-pronged approach to improving data collection to populate the label. While focused on improving the science behind the labels, this approach was not value-free. For one, feminist ethics had motivated the revision (namely, to improve pregnant women's health and interests). In addition, one of the primary areas of reform involved working through the challenges in research ethics on obstetrical patients, particularly how to get IRB approval for studies that benefit pregnant women in the face of fetal-centric regulations.

In the Center for Drug Evaluation and Research (CDER), Kweder's maternal health staff worked on the "scientific pillars" of the label. When women were likely to be exposed in trials, CDER pressed companies to conduct pre-market analyses of their data with a pregnant subgroup. They also developed guidelines for industry on conducting trials in pregnant women and using

animal experiments on breastfeeding to write labels (CDER 2005). They collaborated with NIH to increase the number of government-funded studies on pregnant women (Kweder 2018).

Outside CDER, Kweder found support from the Office of Women's Health, which Dr. Susan Wood directed beginning in 2000. After her doctoral degree in biochemistry and research fellowship in neuroscience, Wood worked in D.C. as deputy director of the Congressional Caucus for Women's Issues (1990-1995) and then at the HHS Office of Women's Health as director for policy and program development (see appendix 2 for Wood's professional background). Preferring "data driven" policy, she moved to the FDA to improve women's health through science. Like her predecessor Merkatz, Wood attributed the "gap" in research about pregnant women to fetal-centric regulations and scientific practices, especially IRB rules that "panicked" ethics committees (Wood 2018).

To support the revision efforts, Wood's office took several steps toward filling in the "gap" in research on pregnant women. First, following Merkatz, the office promoted data collection by funding research at universities on the dosing of common drugs in pregnancy—the vital pharmacokinetics and pharmacodynamics studies that industry was not conducting. The principle investigators (including Mary Hebert of University of Washington, James Fischer of University of Illinois, and Marlene Freeman of Arizona Health Science Center) recruited pregnant women taking common drugs that were vital for maternal health like anti-hypertensives, anti-biotics, and anti-depressants. They followed women through their gestation, recording blood concentration and blood pressure for drug concentration and dose-response (OWH 2019). Recruitment was challenging since it required extra procedures, and Wood recalled "often that's the last thing a pregnant woman wants to do." While recruitment was hard,

IRB approval was even more difficult. So, after the experience of overcoming these challenges, the Pregnancy Working Group wrote recommendations for other researchers (Wood 2018).

The aim of these studies was less the immediate collection of data than the ultimate shift in industry practices:

> Our goal wasn't to solve all problems of the world and search all drugs because we couldn't afford it and didn't have the resources. We were doing these as a sort of model, to say, "Look, you can do it, and FDA will put out some guidance on how to do it. You don't have to be afraid to do it. It can be done in this limited way." (Wood 2018)

Thus, Kweder's Pregnancy Labeling Task Force created a special Pharmacokinetics in Pregnancy Working Group led by Dr. Kathleen "Cook" Uhl to develop a guidance document for industry, so that they would overcome their fetal-centric aversion and improve labeling (FDA Pregnancy Labeling Task Force 2004). Uhl's guidance recommended how to design and analyze the result of such a study, with suggestions for labeling the dose and frequency for a pregnant women each trimester and post-partum.

In addition to funding this research and writing these recommendations, the Pregnancy Labeling Task Force also sought to improve the practice of pregnancy registries. When CDER approves drugs, it sometimes requires companies to conduct post-market surveillance studies on fetal and maternal outcomes, particularly if women who might become pregnant are likely to use the drugs. Other times, industry would voluntarily begin a registry. In the absence of human trials of pregnant women, which have experimental features like randomization and controls, these observational registries were the second-best sources of human data for safety. Yet, while these studies increased in the late 90s, industry practices were sporadic and ad hoc and often focused more on fetal health than maternal health (Wood 2018).

The task force wrote a guidance, led again by Uhl, on establishing a registry, including recommendations for design and analysis. They noted how such registries could lead to a change

in the drug's pregnancy categories because their primary function is the collection of pregnancy outcomes and the detection of birth defects (FDA Pregnancy Labeling Task Force 2002). Yet, as Wood emphasizes, they also wanted to capture data on maternal health and women's health through registries. Her office's job in the revision was to ensure that women's interest be served, not just providers. Accordingly, they began to collect the registries into one place on the website of the Office of Women's Health. She hoped this would make voluntary registration more user friendly for patients and doctors to enroll. She also hoped it would increase recruitment, which would bolster the knowledge women had to make decisions about their pregnancy (Wood 2018).

These efforts at the Center for Drug Evaluation and Research and the Office of Women's Health continued as Kweder's team developed an alternative to the pregnancy labels. The perception that pregnancy data was insufficient continued to stymie the revision effort. Wood recalls, for instance, a meeting with the FDA Commissioner Mark McLellan (2002-2004), where he was pleased with the newer version but thought that their efforts might be in vain without better data. While the concern never completely evaporated, the existence of these on-going initiatives to improve data collection helped their case.

3.4. Revising the label

Kweder's Pregnancy Label Working Group spent over a decade developing their proposed revision (1997-2008). Following the 1997 meeting, they created a working model, which they workshopped with two focus groups of obstetricians and gynecologists. In May 1999, they wrote a concept paper, which they presented and reworked for the FDA Reproductive Health Drugs Advisory Committee (Federal Register 2008). The working model at this time had abandoned the categories and provided separated risk summaries for fertility, pregnancy, and lactation—which

some commentators considered an improvement (Boothby and Doering 2001). While nearly everyone involved in the revision agreed that the label had outlived its utility, they still faced a variety of conflicts during the process (Kweder 2018).

Some of these obstacles involved the fetal-centric values entrenched in FDA policies and feminist-based criticisms to increase focus on pregnant women's health and decision making. For one, the agency had intended the categories to minimize the risks to fetuses alone and only for prospective use. Thus, a major oversight of the category system was its insensitivity to patient's needs and context, e.g., the maternal disease state, inadvertent fetal exposure, and retrospective use. While some providers liked the simplicity of the categories, that very simplicity neglected the various considerations that Kweder believed were important to understanding the "margins of safety" for individual women. Thus, Kweder's team replaced the categories with risk summaries that included statements about the research on fetal health that involved management of inadvertent exposure in addition to statements about maternal benefits and dosing during pregnancy.

Thus, removing the categories was not an abandonment of fetal health but a shift away from a very narrow form of fetal-centrism. *Moving from categories to summaries expanded the function of the label to include a broader set of interests that accommodated both fetal health and women's health.* For instance, risk perception changes with the morbidity of disease, such as how the same relative risk seems riskier for a self-limiting illness than a deadly disease; therefore, the new risk statements would state the relative risk rather than describing it qualitatively as high or low. The new label would also dedicate space to state dangerous complications for both pregnant women (e.g., not treating urinary tract infections, which could

become life threatening) and fetuses (e.g., not treating maternal asthma, which could hinder development), rather than emphasizing the latter *to the exclusion* of the former (Kweder 2018).

Another obstacle involving the conflict of values was how much animal data to include in the label, in part because listing positive animal studies could over-warn patients out of a misguided protection for the fetus. One camp thought that animal data was meaningless to prescribers because they often do not have the training to extrapolate from non-humans. In addition, not all animal studies provide good analogies to human physiology. The other camp was more optimistic of clinicians' scientific abilities and the relevance of animal studies. Particularly for the lactation section, Kweder was concerned about the misinterpretation of rat studies that found drug metabolites in rat breastmilk, "which basically meant don't do it" for clinicians. Yet, most non-humans are poor analogues for human lactation (other than cows), so she was skeptical of including results without explaining their relevance (Kweder 2018).

Thus, the issue of including animal data revolved around how they could simply reinforce fetal-centric values without providing any interpretative statements for including women's health. Rather than over-warning patients because of an uncritical implicit fetal-centrism—either to protect the fetus or avoid a lawsuit from the patient—Kweder wanted to provide information "in a way that helps people interpret it rationally." So rather than including everything or nothing, the group eventually settled on including "highlights" of the important studies and explaining their clinical significance. For instance, the new label would state the results of a rat study of an exposure at some level, translate that to an expected level of exposure in human pregnancy, and explain how that might impact a human fetus (Kweder 2018).

Kweder said they arrived at this decision through a "consensus process" of negotiation and compromise. This shift accommodated of a variety of values into decision making, rather

than the typical reliance on fetal-centric values by default. By unpacking the reasoning behind the warning, the revision would make the value judgments clearer. Without these details, regulators and their advisors worried that clinicians would avoid medicating pregnant women and recommend abortion for any inadvertent exposure. With some details and explanations, they hoped to improve decision making on both ethical and epistemic grounds.

Finally, fetal-centric values significantly impacted the timeline of the revision. While any change in regulation is time consuming, this rule was particularly encumbered with delays. The revision of the pregnancy labelling rule was supposed to follow that of the physician labeling. However, the two became decoupled as the former faced more resistance. The proposed and final rules for the pregnancy label came eight years later than that of the physician label (proposed rule: 2000 vs, 2008, final rule: 2006 vs, 2014).

Much of the reason for the delay was internal concerns about "the next thalidomide" and the potential for "political controversy." Kweder faced significant resistance from FDA toxicologists "who thought people like me were ready to release a sea of teratogens." Accordingly, when it came time to secure internal clearance, regulators were cautious and hesitant to approve the proposal (Kweder 2018). From her removed position in the Office of Women's Health, Wood conjectured that rather than business as usual, "everyone felt like 'No, before I sign off on something like this, I really need to understand what this is and what they're saying because something dreadful could occur'" (Wood 2018).

The *Federal Register* published the proposed rule in 2008, announcing the agency's plan to replace the categories with risk summaries. In the public comments that followed, most supported the revision. Several commenters, including the Teratology Society, said it would address existing shortcomings, improve accessibility, and enable better informed decision

making (Teratology Society Public Affairs Committee 2007). Many comments, nonetheless, opposed aspects such as wording and ordering, so the final version of the rule implemented a few significant changes based on public comments and some internal considerations already mentioned (Federal Register 2014). The final rule was published in late 2014, along with a guidance for industry (Division of Pediatric and Maternal Health 2014)

For one, the final rule in 2014 required that information about on-going pregnancy registries be included to "encourage participation in registries, thereby improving data collection in pregnant women" (Federal Register 2014, p. 4). Furthermore, the new rule required labeling list registries first (see appendix 4 for the organization and format of the label). In addition, the rule created a new section for "Females and Males of Reproductive Potential" to collect all the information about recommendation for pregnancy testing, contraception, and infertility into one place. The final rule also eliminated categories of likelihood of risk using magnitudes like "low," "moderate," or "high," which had taken some of the functional role of the now-discarded A-B-C-D-X categories.

Some changes directly promoted pregnant women's health. For instance, the rule required (when data were available) subsections on clinical considerations related to maternal and fetal health, including "Disease-associated maternal and/or embryo/fetal risk," "Dose adjustments during pregnancy and the postpartum period," "Maternal adverse reactions," "Fetal/Neonatal adverse reactions," and "Labor or delivery." Likewise, the end of the risk summary for breastfeeding must include the following: "The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for [name of drug] and any potential adverse effects on the breast-fed child from the drug or from the underlying maternal condition" (Federal Register 2014, p. 31).

When Kweder announced the new label in a press conference, she was triumphant: "Today is an important day in public health" (FDA 2014, p. 1). As I suggested above, the changes she oversaw reflected a shift in the label away from an uncritical fetal-centrism toward a broader consideration of women's health:

> It's our hope that this new system presenting information in drug labeling will help their healthcare professional and those women as they discuss treatment options. It's complicated—prescribing decisions made during pregnancy and lactation have to be very individualized about considerations for the mother, the fetus, and even the infant when the mother's breastfeeding the infant. (FDA 2014, p. 3)

With more details on research available and explicit statements about women's non-obstetrical needs, the new label would better promote a balance of women's health with fetal health. In addition, the new section on fertility also applied to men, which albeit small, signals a shift in the agency's perception of increased responsibility of men for their contribution to reproductive health.

Furthermore, with the inclusion of the announcement for pregnancy registries at the top of the risk summary, the agency intended to increase the voluntary participation of pregnant women in studies. These women would be unlikely to benefit directly from their participation. Yet, the emphasis placed on such participation by the label suggests an increased interest on the part of the FDA for pursuing creative solutions to extricating the fetal-centrism entrenched in regulatory science and replacing it with feminist alternatives.

3.5. Implementing the new rule

Implementation of the pregnancy labeling rule has been successful but remains challenging given the continued lack of trials including pregnant women. By 2014, Kweder's maternal health staff had been promoted to an organized *division* within the Office of New Drugs in the Center for

Drug Evaluation and Research. The current director of the Division of Pediatric and Maternal Health is Dr. Lynne Yao. She is a former pediatrician, specializing in pediatric nephrology, who learned maternal health in her time at FDA (see appendix 2 for Yao's professional background). Yao's division is the primary group overseeing the pregnancy label conversions (typically a six-month process), though it is not authorized to approve or deny applications like other review divisions. So far, they have finished the first cohort, and Yao estimates there have been around 1,500 conversions so far (Yao 2019).

After the approval of the new pregnancy labeling, everybody at the FDA participated in its implementation. As Kweder put it, "Once it's in place, it's gotta go." She was concerned that regulators and drug sponsors would react just as anxiously as doctors: "We knew once these started coming in, it would make people very nervous, just like the doctors when the pregnant woman walks in there—a deer in the headlights." To ease the transition, she educated inside and outside "like crazy" (Kweder 2018).

Despite their success with keeping on schedule, Yao's division has encountered some of the same issues as Kweder had involving the ambiguity of risk language, such as their use of phrases like "insufficient to inform on the risk" and "adverse developmental outcomes." After working with an advisory committee on risk communication, labels now state explicitly a conclusion on risk, the level of data, and the type of outcome (Yao 2019).

Other obstacles are new, reflecting resistance to the agency's shift away from simple categories. For instance, some advisers suggested that the labels were too densely worded and detailed. The division is currently looking for alternative forms of communication like graphs and pictures. Non-linguistic labels would be a novelty for the FDA (Yao 2019).

The division works with both the pediatrics label and pregnancy and lactation labels, and Yao noted that the latter are in worse state that the former. Pediatrics labels have improved since the '90s largely because of congressional efforts that require studies for pediatric populations for approval through the 2003 Pediatric Research Equity Act, reducing the need for off-label prescription (see Epstein 2007, pp. 117–122). In contrast, the pregnancy labels have been slower to advance because pregnancy studies are not legally required for approval and remain controversial for ethical reasons regarding the voluntariness of women's participation (Yao 2019), not to mention concerns about "fetal rights."

Despite the work of the Pregnancy Labeling Working Group, it does not appear that industry has taken the FDA's lead. Yao notes that, while her division has not received much pushback from drug sponsors, it is likely because they are still trying to mitigate the risk of liability. In their willingness to let FDA "take the hit on the lack of good information," industry abdicates its responsibility to collect higher quality information, and this neglect falls primarily on patients (Yao 2019).

In what might seem like déjà vu, the division is working on several efforts to improve data collection about pregnancy and lactation, involving efforts across the FDA and throughout HHS. They participate in a departmental Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), which focuses on gaps in pregnancy-related research. Yao's division also serves on several FDA working groups that followed the rule, such as the Pregnancy and Lactation Labeling Policy Working Group and the Obstetrics Working Group, which also includes the Office of Women's Health (Yao 2019).

While the remaining obstacles might seem disconcerting, Yao, her division, and the FDA remain committed to improving the labels and collecting more data to populate them.

Nonetheless, the same tendencies toward fetal-centrism and against women's health remain today, particularly in research gaps, albeit in different forms and to a lesser degree.

What more can we say about these changes? Has there been progress? How have values contributed to or hindered progress?

4. Change, Progress, and Reform at the FDA

So far, we have seen how regulators changed the pregnancy label in response to the fetal-centric and feminist values entrenched at the FDA. Overall, the labels have shifted to accommodate a broader set of values, particularly liberal feminist ones through a gradual, piecemeal process of reform in regulatory science. Feminist reformers saw past policy "failures" for women's health as part of the legacy of thalidomide, so they undertook measures to improve women's health and eventually even pregnant women's health. In this way, reformers moved from the "success" of getting women into clinical trials to another "success" with pregnancy labels.

I suggest that understanding these changes in regulatory science as an *epistemic-ethical reform* helps us to see how these were in fact progressive. While it is common to think of policy reform as a kind of progress in the political realm of democracy, this is not the case with science, even regulatory science that guides drug policy. There is a long history of conceptualizing change in science and medicine as revolutionary and groundbreaking, although this historiographical trend has declined (Daston and Galison 2007; Greene et al. 2016). Many historical accounts of the FDA likewise separate the agency's history between its pre-scientific era prior to thalidomide, overrun by quackery and pseudoscience, to its science-based regulation afterward (Hilts 2003; Young 1967; contrasted with Carpenter 2010). Nonetheless, regulators

themselves conceptualize their changes as small ameliorations of past regulatory failures. For instance, Kweder was proud of the progress despite the label's imperfections:

> I think, "Is it perfect?" No, of course it's not perfect. But you can't let that get in your way. You just have to keep going forward. You know, for me, taking care of those women who are pregnant—and who are just desperately desperate for any information that we could provide—was so telling about the importance of the patient in all of this. And this is really for the patient. This is for the patient, who is at a time in their life when decisions are really, and feel really, critical and scary. Where there's data to be brought to the table, we have a responsibility to bring it. (Kweder 2018)

Likewise, when her division is having trouble, Yao consults with scientists, practitioners, patients, and patient advocates to find innovative ways to improve communication (Yao 2019). *It seems as if the labeling system is never quite finished but is forever in a process of improvement according to new, shifting goals shaped by entrenched values.*

If progress in regulatory science approximates political reform rather than revolution, it shares many of the constraints of democratic compromise. Often, democratic reformers of regulatory science are concerned about special-interest capture while technocratic reformers criticize agencies for their scientific incompetence (Jasanoff 1990; Smith 1992). In between, Sheila Jasanoff proposes a *negotiated model* of regulatory science, in which science provides a "serviceable truth," and scientists offer expertise for public interests (Jasanoff 1990, p. 250). She argues that these measures enable advisers and regulators to utilize the power of science without sacrificing their credibility, flexibility, or expertise. While accounts like that of Jasanoff help us to understand *change*, they do not explain what constitutes *progress* in a more normatively thick sense of the term. Particularly from the perspective of socially relevant philosophy of science, such a normative account is desirable for helping regulators solve problems (Fehr and Plaisance 2010).

Other philosophers of medicine have explored the question of change and progress in regulatory science; however, they look more toward commercial forces and epistemic values than the influence of ethical values or the question of social justice in regulatory science over time. For instance, Bennett Holman suggests that step-wise improvements are common in medical epistemology in reaction to commercial forces more aimed at profit than truth (or empirical adequacy). For instance, Holman (2015) describes the emergence and development of randomized control trials (RCTs) at FDA as an *evolutionary arms race* between the pharmaceutical industry and the agency. The agency can improve regulatory science when it recognizes that industry has countered one of its strategy and when the agency then implements a countermeasure.

Also focused on epistemic factors alone, Miriam Solomon illustrates the emergence of new methodologies in medicine in reaction to the epistemic values of extant alternatives. For instance, Solomon (2015) explains the rise of the Evidence-Based Medicine (EBM) movement, which values analytic rigor and quantitative precision, as a response to medical consensus conferences, which instead value expertise and democracy (Solomon 2015, p. 226). Accordingly, the increased *pluralism* brings a form of medical progress because of the expanded coverage of medical methodology.

Yet, in this episode of change in medical epistemology, the alternative interests are not simply private versus public, and the alterative values are not analytic rigor versus scientific expertise. Instead, the conflicts here revolve around the ethics of reproductive health, the feminist women's health movement, and the information needed to make decisions. The dynamics between pharmaceutical companies and regulators exacerbate the conflict between

entrenched fetal-centric values and newer feminist values. Thus, to evaluate the possibility of progress, we need to look at the epistemic and ethical dimensions of this revisionary process.

In some ways, the revision is wanting, which regulators would admit. For one, the new sections dedicated to maternal health, dosing, and adverse effects remain optional: "omit if not applicable" (see appendix 4). Regrettably, these clinical considerations are likely to go omitted because of the continued lack of research with pregnant women and with no pre-market requirements for drug sponsors to including pregnant women in trials (even in "reasonable numbers" like with women in general). Furthermore, sponsors write the labels primarily for physicians, rather than for pregnant women. Without making the information accessible to pregnant women without medical oversights, there remains the continued potential for paternalistic treatment of pregnant women. Thus, in practice, pregnant women are likely to remain the secondary focus with the labels, which feminists would decry as "secondary citizen" status.

Nonetheless, while not quite providing a complete transformation, this revision is a significant improvement over the previous version in three regards, involving its value transparency and transformative objectivity, its utility for decision making, and its promotion of participation in science. First, it has improved on scientific grounds in terms of its *objectivity* in Longino's transformative sense, which involves exposing value judgments and subjecting them to criticism. Longino argues that a method of inquiry is objective to the degree to which it permits *transformative* criticism (Longino 1990, p. 76). That is, by increasing the diversity of a research community and including different values, and then by responding to the scientific criticisms those values elicit, the process of inquiry becomes increasingly more objective by degrees. Including a diversity of values, particularly excluded ones like feminism, can improve

science by breaking down dominant forms of reasoning and transforming of the community and its social processes of debate and negotiation.

As suggested by Longino's conception of objectivity, I contend that regulatory science can progress by an incomplete transformation through value-based criticism.[75] Because of feminist criticisms of fetal-centrism embedded in regulatory science, particularly the old pregnancy categories, the revised labels became more *transparent* about how value judgments underlie their interpretations and conclusions. The old system condensed a large amount of information that was plagued by uncertainty and epistemic gaps into a single category that prioritizes fetal health. In its place, the new labeling now conveys more detailed information, and this information is mediated by explanations for its relevance and importance to the health of fetuses and women. Accordingly, the previously hidden value judgments are more public and accessible by women and their doctors. With this increased transparency comes increased utility for a more diverse group of users who might not all share the same values (e.g., anti-abortionists, pro-choice advocates, and agnostics), goals (e.g., prospective vs. retrospective advice), or health conditions (e.g., a self-limiting illness vs. a life-threatening disease). *Thus, feminist-based criticism allowed the new labels to accommodate a variety of values and interests that consumers might hold.* This modest change is important for an institution with the democratic purpose of protecting women's health broadly construed rather than just those who are narrowly fetal-centric.

Second, because of this increased transparency and utility, the revised label is better for *medical decision-making* and *informed consent*. The previous label relied heavily on implicit

[75] While one might interpret Longino's view of scientific objectivity to require *complete* transformation for scientific progress, she does not appear to take this as her view (pers. comm.). Science is constantly changing, and because objectivity comes in degrees, so too does progress

assumptions about the value of fetal health and women's health that riddled the category system. Because of oppressive gender norms, these labels would guilt pregnant women into abortion based on little to no information, even in cases where women would have wanted to continue the pregnancy. For instance, after using a category C drug and then realizing she was pregnant, a doctor might recommendation abortion, and a woman might agree to avoid become a "bad mother." However, her decision would not be simply: in our fetal-centric society abortion is often portrayed as the decision of a "bad mother." Thus, without any information to guide her decision and consider her health benefits, the old labels limited pregnant women's agency by implicitly guiding them and their doctors toward fetal-centric decisions. Not only were these judgments hidden by the simplistic categories, but the system itself was confusing and misleading for doctors and patients. By providing patient with more detailed information, and explanations for interpretation, the new labels move away from unexposed fetal-centric values to a broader range of possibilities.

In terms of decision making, this label is an improvement upon several of the other labels in this dissertation. The morning-after pill's "drug fact" from 2006 was based on zygote-centric value judgments that had not been subjected to criticism. As argued in Chapter 3, the labels functions less to enable patient decision making and more to instruct women on what their values ought to be. The zygote-centric values laden in the label allowed it to serve as a sexist and paternalistic warning for women on how to be "good mothers" who protect zygotes by not using the morning-after pill. Likewise, in this case, the original pregnancy categories served a similarly paternalistic warning function, for how be "good mothers" who protect fetuses from harm by avoiding medication that might cause birth defects. Now, the revised label is *less paternalistic* by offering more details in the risk summaries and statements of maternal benefits so that doctors

and patients can make their own decisions weighing risks and benefits. It is still possible that doctors misuse the new label to sacrifice women's health to reduce any risk to the fetus without consulting the woman or considering her needs. However, the revision constitutes an improvement by reducing this possibility.

Likewise, this revised label is better for patient decision making than the patient insert included with the Pill in 1970. That label withheld information about the risks of the Pill and placed them in a supplemental booklet for full disclosure that patients could only get through their doctors. As argued in chapter 4, that strategy facilitated a sexist paternalism by keeping women's access to information under the control of their doctor. Here, in the information era, even the physician label is available to patients online, so women's access is less under doctor control. Furthermore, unlike with the categories, the pregnancy label provides doctors and their patients more of the information and more explanation of its importance.

This is not to say that the revised pregnancy label provides "full disclosure," which we saw in chapter 4 is a lofty ideal that can also be misused for protecting private interests in medicine. As Kweder and Yao note, industry often over-warns patients in their labels by withholding relevant studies. Yet, including all studies (particularly positive animal studies of limited relevance to humans) can nudge patients and doctors away from treating maternal conditions purely out of fear of fetal impacts. With the "highlights" format of the revision, the agency intends the pregnancy label's details to be less overwhelming and more digestible. The economic demands of medicine pressure doctors to spend less time with patients, who in turn pressure FDA for more simple labels. Nonetheless, Yao's division is not considering sacrificing detail and nuance for simplicity. Instead, they are looking for more accessible forms of communicating complex information (Yao 2019).

Yet, as I argued in Chapter 4, informed consent is not just contingent on individual patient autonomy, so we cannot evaluate the epistemic-ethical adequacy of this label apart from its relation to *social justice*. Here, I also want to defend the revised label because it better supports medical decision-making in the *diversity* of women's interests by making information more accessible and more widely useful. One of the major insights of the *reproductive justice* movement is that older frameworks focused primarily on negative reproductive rights for abortion (i.e., "pro-choice") are insufficient to promote all women's interests (Roberts 1997). In addition to the human right to *not* have a child, people also have a right to have a child and raise that child in a healthy, safe environment (Ross 2006). Thus, to promote reproductive justice more broadly, we need to create a society that actively supports this broader range of choices so that all people can have an abortion or not, depending on their choice, and parent in a healthy way (Ross et al. 2017).

By supporting the exercise of more reproductive rights with the relevant information, the revision increases the label's capacity for social justice in medicine. This revised label better promotes this *range* of choices than the original categories that focused narrowly on birth defects to the exclusion of women's health, deprioritizing maternal benefits, non-obstetrical needs, and dosing information. The new pregnancy labels, which also better convey information on breastfeeding and fertility risks for men and women, speak to a more comprehensive range of reproductive rights that patients need medical information to actualize. The new labeling, for instance, provides sections for information about how inadvertent exposure and retrospective decision making including continuing or terminating pregnancy (see appendix 4). Furthermore, along with the guidance on pharmacokinetics, the new labeling encourages dosing information to

better ensure pregnant women receive a therapeutic dose, discouraging a default use of the lowest dose to protect fetuses (which can harm both the woman and her fetus).

Third, this revisionary process of the label also increases participation in science, particularly by those previously excluded, thus enabling *procedural justice*. Several philosophers have argued that increasing public participation in regulatory science is a crucial means of democratizing value judgments in science-based policy (Douglas 2009; Elliott 2011; Shrader-Frechette 1991). Furthermore, public participation in regulatory science *as research subjects* can also promote a broader range of interests by increasing research's generalizability and applicability to excluded groups like pregnant women. Previous guidelines that excluded "women of childbearing potential" from drug trials were problematic not just because of their androcentric effects on knowledge but also because of their limitation on *who contributed* to knowledge production and thus *who could enjoy its benefits* (Mastroianni and Kahn 2001). It is true that participation in science can expose subjects to risks because of exploitation by researchers or drug companies, and it is important to pay attention to how the drug industry can co-opt democratic strategies of reform (Holman and Geislar 2018). However, more public participation of previously excluded groups as research subjects can also provide them with benefits like treatment when no alternatives exist (e.g., the AZT trials). Moreover, it can connect them to the scientific process and provide them the agency to help produce knowledge for others like themselves.

One of the main changes in the new labels is their prioritization of advertising pregnancy registries to increase participation, data collection, and ultimately the quality of knowledge about drugs in pregnancy. Regrettably, the prospect of universally required pre-market trials for pregnant women remains dim. However, reformers have creatively found alternative means of

voluntary participation, like post-market dosage studies and pregnancy registries. While the latter might primarily serve industry's' interests in mitigating liability, they will likely help women in the future protect their pregnancy from unwanted risks. Again, concern of cooptation is appropriate, but such apprehension does not justify inaction but rather cautious planning. In contrast to pregnancy registries, researchers design pharmacokinetic studies on maternal dosage primarily to improve pregnant women's health, particularly those with chronic conditions requiring medication during pregnancy. Accordingly, increased participation in these studies offer the prospect of providing solutions for those with chronic illness and disabilities to manage their condition with better information.

Hence, rather than a *complete* transformation, I suggest that change in regulatory science is closer to an ever-incomplete *amelioration.* In the case of the pregnancy labels, we witness one of these incomplete transformations that nonetheless constitutes progress along ethical and epistemic dimensions. Women's health advocates were critical of the fetal-centrism in the FDA and its androcentric consequences. However, unlike more radical feminists in the women's health movement who aimed to expunge women of their maternal responsibilities, these liberal feminists undertook more a more reformist approach, which was necessary given their position in the FDA, its fetal-centric history, and its general conservatism to change. The regulatory process of revision begun by Merkatz, led by Kweder, and supported by Wood and Yao was ultimately one of making the labels more inclusive of pregnant women's many interests and less presumptive about their maternal responsibilities. They challenged the implicit fetal-centrism of doctors and patients without an about-face that neglected fetal health. These reformers expanded the concern to better include women's health in terms of both obstetrical and non-obstetrical health and wellbeing. Their persistence is inspiring.

5. Conclusion

This episode constitutes a feminist success story. It is an example of how regulators can respond to entrenched values in regulations that devalue women's health and propose reforms in a manner more attentive to the wellbeing and interests of women in their wider diversity of values. This revision has been successful in ameliorating several problematic features of the previous version resulting from entrenched fetal-centrism. For one, the revision transformed the objectivity of the information presented to doctors and their patients to be more transparent and useful than the previous category system. Second, the revised label promotes a broader range of women's values and interests, including fetal health, women's health, and their interdependence, by enabling a broader range of reproductive rights than before. Third, the labels themselves promote pregnant women's voluntary participation in the process of science.

As Kweder noted, the revised pregnancy label is not perfect; however, its imperfections ought not detract from its improvements for pregnant women's health and wellbeing. Because of the entrenchment of values like fetal-centrism and feminism at the FDA, a complete transformation that liberates women from oppressive gender norms and maternal responsibility is not possible. Nonetheless, reform has allowed for a modest progress and an improvement of pregnant women's health, largely because of the persistence of women's health advocates within FDA. In the face of continued neglect of women's health, this episode provides hope that epistemic-ethical reform is possible. Furthermore, it provides a blueprint for feminist reformers with strategies of creativity, compromise, and collaboration.

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Conclusion.

Ethics and Epistemology Entangled in Drug Labels:

Extricating Sexism, Facilitating Feminism

1. An Epilogue on Entanglement and Extrication

The FDA has long been embroiled in controversies over reproductive health, telling "a story of the *entanglement* of politics, science and religious beliefs" involving ethics, gender, and knowledge about drugs (Shorto 2006, my emphasis). At times, leading scientists accused the agency of "being influenced by political considerations" and "political meddling" rather than being (properly) "based on scientific evidence" of safety and efficacy (Drazen et al. 2004, p. 1561; A. J. Wood et al. 2005, p. 1197). Simultaneously, its own scientific advisers lambasted the agency for its neglect of "women who personally believe that life begins at fertilization" (Stanford et al. 2004) and its "bad science" resulting in a massive amount of "fetal death" (Scialli 1992, p. 465).

From outside medicine, radical feminists charged the agency with mishandling women's health, protesting its labels for birth control that "would serve the moneyed interests of the drug industry and population control freaks, but not women who are dying and maimed from the pill" (Wolfson 1970). Likewise, other feminists criticized FDA policies that effectively excluded women from drug trials on the fallacious grounds that "women of childbearing potential" are "pregnable" and thus "always pregnant" (Baird 1999; Merton 1993). Even within the walls of the FDA, regulators struggled internally with the potential for "political controversies" in maternal-fetal health, vacillated over fears of "the next thalidomide," and delayed reforms for improving labeling (Kweder 2018). Some women's health advocates have left the agency out of principle over its neglect of women's wellbeing (S. F. Wood 2005). All the while, industry seeks to

maximize its profits and minimize its own liability, at times writing labels that overemphasize caution about fetal risks, while in others offloading the responsibility for informed consent to doctors and the FDA.

Across these episodes of labeling drugs about reproduction, we find the entanglement of ethics and epistemology: values shape regulatory science in ways that often complicate the process of knowledge production, at times *compromising* it, and at others *improving* it. These entanglements have created several challenges involving values in regulatory science. All too often, commentators, participants, and ethicists have relied on simple explanations and easy solutions, such as calls for separating science from politics completely, for entrusting doctors with patients' access to information, and for protecting the "rights" of healthcare professionals to refuse providing patients drugs. Rather than looking at only a single dimension of these controversies, I have provided a "coupled ethical-epistemic analysis" that attends to the interdependence of societal values and medical knowledge (Tuana 2013; Katikireddi and Valles 2015). Accordingly, I have taken an empirical, feminist approach that integrates history, sociology, and philosophy with a sensitivity to gender and power. By carefully analyzing these controversies, I untangled (analytically) how societal values and gender norms shape FDA drug regulation. I then critically examined how those influences impacted women and other marginalized groups. By engaging with regulators, I have begun to explore solutions for improvement by excluding sexist values and integrating feminism into regulatory science.

In this conclusion, I discuss three challenges for regulatory science in the realm of reproductive health. First, across these cases, there are many ways in which women's health has been unfairly devalued for other concerns in reproductive medicine, such as zygotic life, fetal health, and population control. Second, both knowledge and ignorance about their reproductive

health have oppressed women, especially poor women and women of color. Finally, powerful, mostly male parties in medicine (including doctors, pharmaceutical companies, and religious institutions) have misused ethical concepts and practices, such as informed consent, religious freedom, and medical paternalism, for unethical purposes. I offer these challenges in regulatory science to provide new directions for *socially relevant* philosophy on drug regulation, values in medicine, and feminist science studies (Fehr and Plaisance 2010).

I also begin to think about solutions for extricating the entanglements of values and science that are problematic. Not all these entanglements compromise regulatory science, and I suggest ways to reduce the influence of sexist values and facilitate feminist alternatives. For one, I provide a novel account of why sexist values and gender norms are illegitimate in regulatory science, specifically for reproductive health, involving epistemic injustice. In addition, I discuss who should be involved in decision making at the intersection of ethics and epistemology. While imagining some solutions, I also consider actual attempts at improvement, particularly the ability of the feminist health advocates at the FDA to criticize sexism and injustice in regulatory science.

Note well: this dissertation is neither a scathing critique nor an outright vindication of the FDA. The reality is somewhere in between, with healthy doses of sympathy and accountability. While the agency has been complicit at times in some of the problems I have described, I do not find it primarily responsible. For one, many of the problems we have seen involve other areas of medicine partially beyond the agency's domain, such as the corrosive hegemony of the pharmaceutical industry and the unchecked authority of medical practitioners. Moreover, these injustices are not isolated incidents, but rather comprise larger structural problems rooted in systems of domination such as patriarchy, white supremacy, and neoliberal capitalism.

Nonetheless, the FDA is one of the few organizations equipped with the legal (and cultural) power over the pharmaceutical industry and charged with a mandate in the public interest, so it is well posed to tackle parts of these challenges. As we saw in chapter 5, there is hope for progress in the agency's ability to reform sexist policies and reprioritize women's health. Nonetheless, I do not think the agency should act alone because it shares the responsibility to inform patients and consumers with other public advocacy groups. Ultimately, I hope that my research enables the agency to learn from its past and that it contributes to the improvement of drug regulation and labeling, particularly for the people most wronged in the past.

2. Challenge #1: Sexism Comes in All Shapes and Sizes

Philosophers and science studies scholars have recognized the role of societal values in regulatory agencies generally (Cranor 1993; Douglas 2009; Elliott 2011; Jasanoff 1990; Shrader-Frechette 1991) and to the FDA specifically resulting from commercial pressures (Biddle 2007; Carpenter 2010; Holman 2015; Holman and Geislar 2018; Stegenga 2016). But what about other values of a more ethical character related to sex, gender, race, & reproduction? In addition, feminists have criticized the injustice rampant in medicine (Sherwin 1992; Whatley 1988), especially sexism and racism in reproductive health (Armstrong 2003; Davis 1983; Duden 1993; Kukla 2010; Lyerly et al. 2009; Purdy 1990; Roberts 1997; Ross 2006; Rothman 1989) and the commercialization of female sexuality in pharmacology (Cacchioni 2015; Segal 2018; Tiefer 2006). Nonetheless, there has been no systematic analysis of sexism and injustice specifically in regulatory science or the role of gender norms in FDA decision making about reproduction. Accordingly, the first question posed by this dissertation is: *how have societal values and gender*

norms shaped the way that the FDA regulates drugs in the realm of reproductive health, specifically with drug labels?

In general, I have found that there are many ways in which other concerns in reproductive health have *sidetracked, deprioritized,* and *devalued* women's health. For instance, in part I, zygotic life took priority over women's health and wellbeing in the labeling and use of the morning-after pill (especially for survivors of sexual assault, women on public assistance, and women of color). Zygote-centric science advisers made value judgments to minimize the risks to zygotic life and inform users about the potentially abortifacient mechanism. These anti-abortionists relied on sexist gender norms about "good mothers" who selflessly protect zygotes and "bad mothers" who carelessly use abortifacient contraceptives.

In part II, population-control advocates ignored or suppressed concerns about the safety of women taking the Pill for countervailing concerns about population planning. They placed special burdens on women whose alleged responsibility it was to reduce population growth, namely, poor women and women of color. Thus, rather than *pro-natal* values (that promote birth and parenthood), these doctors, scientists, and other authorities relied on *anti-natal* values (that discourage childbearing) to keep marginalized groups of women on risky but effective birth control because they believed there were "social" and "personal" benefits. Furthermore, instead of providing women users full disclosure of the health risks, many doctors and scientists justified withholding information from some women based on diminutive views of their intellectual abilities and their emotional propensity to "panic." In contrast to zygote-centrists, these population-control advocates relied on unjust gender norms about "good women" who selflessly comply with medical directions to responsibly control the population and "bad women" who demand more information and agency, which are male-coded privileges.

Moving to part III, there continues to be a lack of research on pregnant women's health. This is the legacy of thalidomide and past FDA guidelines that excluded "women of childbearing potential" from drug trials to protect fetuses from birth defects. Unlike the zygote-centrists in part I, the fetal-centrism here embedded in FDA regulations resulted in *androcentrism* in drug research. Furthermore, through the category system, the old FDA pregnancy labeling prioritized information about fetal impacts to the neglect of the scant information about maternal health, particularly dosing during pregnancy. Yet, in contrast with the pro-natal zygote-centrists in part I and the anti-natalists who advocated population control in part II, this form of fetal-centrism was able to adjust to a *non-natalism* that allowed therapeutic abortion at times but less forcefully. The new labels now include clinical considerations to fetal and maternal health, including managing inadvertent exposure and maternal health needs, rendering the norms of "good mother" and "bad mother" less distinct and less overbearing. Thus, this form of fetal-centrism could accommodate an increased focus on pregnant women's health and reproductive rights through criticism by liberal feminist values. Nonetheless, the fetal-centrism entrenched at the FDA continues to detract from pregnant women's health because there remains a lack of research on pregnant women to prevent birth defects.

All three cases present a different form of sexist values and gender norms, which limit women's agency in medicine, reduce their access to drugs and information, and compromise scientific processes. *Sexism* is the unjust ideology that legitimates the social order of patriarchy, in which cisgender men dominate "weaker" genders (such as cisgender women, transgender men and women, and non-binary people) based on unjust gender norms (hooks 2004; Manne 2018). Throughout these cases, sexist values mostly came from men as doctors, scientists, or expert witnesses and from male-dominated organizations including the Catholic Church. (The problem

here is not religion but the misuse of religion for unjust purposes.) Conversely, most of the resistance to these values came from women, both inside and outside the FDA.

In part I, the zygote-centric values of anti-abortionists justified the limitation of women's agency and access to emergency contraception. Because of how anti-abortionists argued for the importance of patients' informed consent, the process ignored criticisms of their sexist value judgments, and the "drug fact" that emerged was a failure of the scientific process for objectivity in Helen Longino's sense. In part II, population-control advocates with anti-natalist values kept women ignorant about the health risks of the Pill and afforded their doctors increased authority over their access to information. These critics of providing women full disclosure appealed to sexist, racist, and classist stereotypes to make their case. In part III, the fetal-centric values entrenched in FDA policy rendered drug regulation more focused on male bodies for approval, and fetal-centrism justified labeling that focused on birth defects, rather than on maternal health needs. While the situation has improved, the fetal-centrism entrenched at the FDA continues to frame women as mere "fetal containers" rather than full agents.

In sum, *sexism comes in all shapes and sizes at the FDA.* Sexist values derived from different participants, such as science advisors, pharmaceutical companies, and even FDA's own culture. These judgments and policies have sacrificed women's health and wellbeing for everything in reproductive medicine from the health of their potential offspring to the growth of the population. Justifying the domination of women, these different forms of sexism have influenced drug labeling in diverse ways. While sexist values sometimes promoted knowledge production, at other times, they encouraged knowledge suppression. Part of the difference has to do with how women with different social identities with varying degree of power and privilege fit within the *matrix of domination* (Collins 1999). Women face different pressures in

reproductive medicine, as illustrated by the racist and eugenic history of the family planning movement (Roberts 1997; Washington 2008; Marks 2001). Furthermore, these differences reflect the different burdens placed on women throughout pregnancy and reproduction. For instance, prior to conception, sexist gender norms pinned women with the responsibility for *reducing* fertility for family planning. Yet, after conception, they shifted the responsibility of motherhood to *promoting* fertility to protect zygotic and fetal health.

To better understand these influences, this dissertation provides a more robust understanding of sexism in drug regulation. Such insights are essential for an agency serving a public that is mostly women, particularly given the devaluing of their health historically. Yet, how is the agency supposed to recognize sexism when its character varies from one drug application to the next? How can the agency make sense of the ways that sexist gender norms infiltrate scientific judgment when they remain implicit? And what about when they intersect with other stereotypes about race and class? Because of sheer multiplicity, this first challenge poses a serious obstacle to the prioritization of women's health when regulating drugs.

3. Challenge #2: Oppression through Knowledge and Ignorance

Following how sexist values and norms have shaped FDA drug labels, my dissertation further asks: *what are the ethical, epistemic, and social consequences of these influences on regulation for women's healthcare?* I have found two challenging consequences of the entanglement of ethics with epistemology, one on the relation of knowledge and justice and the other on ethical concepts with epistemic dimensions.

The second challenge is that *sexist values and norms have promoted both the production of knowledge and its active suppression.* Recall in part I how Plan B's "drug fact" was useless

for informing all patients, even zygote-centrists, because it encouraged complete disuse in all cases. The label did not align with the values of most patients, and it did not provide zygote-centric users the information for how to weigh the risk to zygotes against the benefits of using the morning-after pill. Instead, mechanistic knowledge was a tool of social control over women's agency and access: anti-abortionists used sexist "drug facts" for paternalism (shaping their subjectivity) and misogyny (refusing them drugs). The true purposes of this value-laden knowledge were to shape potential users into "good mothers" who protect zygotic life and to punish intended users as "bad mothers" who threatened zygotic life. That is, women were *made to know* that Plan B "may prevent implantation" to limit their access, dominate their agency, and control their bodies.

In part II, for contrast, population-control advocates withheld knowledge about the risks of blood clots, depression, and cancer for paternalism (controlling their access to knowledge) and misogyny (refusing them information). Rather than with knowledge, they made women to *not know* about the risks of the Pill for patriarchal domination, medical control, and pharmaceutical profit. While oppression came through knowledge in the first case (albeit misinformative), domination materialized in the second through the absence of knowledge, proactively maintained.

The *active* epistemic character of domination in part II contrasts that of part III, in which the ignorance about women's health about drugs was an *unintended* consequence of fetal-centrism in FDA policies. In Frances Kelsey's (1982) defense of the strategies taken to prevent birth defects and protect fetuses, she did not recognize their androcentric consequences, which only became clear later that decade (Merkatz and Junod 1994). Nonetheless, that ignorance contributed to the neglect of women's health, and the continued lack of research on pregnant

women remains a problem that is actively perpetuated by the risk-averse pharmaceutical industry (Yao 2019). Thus, like fetal-centrism, ignorance about pregnant women remains entrenched at the FDA. It has become a structural feature of the institution that women's health advocates are working to overcome.

Feminists have illustrated how systematic ignorance about women's bodies contributes to patriarchal oppression (Schiebinger 2008; Tuana 2004). As resistance, the women's health movement transformed this state of ignorance into knowledge for liberation (Tuana 2006). More generally, ignorance is produced and maintained *systematically* and *selectively*, especially by industry and the state (Elliott 2013; Gross and McGoey 2015; Oreskes and Conway 2011; R. Proctor and Schiebinger 2008). For instance, following the tobacco industry strategy of "doubt mongering," pharmaceutical companies often stress the uncertainty of science in order to justify an interpretation of research that supports private commercial interests rather than public health and welfare (Fernández Pinto 2017; Michaels 2008).

However, not all ignorance is unjust and oppressive. Feminists have long argued that methodological problems plague research on sex/gender differences (Fausto-Sterling 1992). Yet, the alleged existence of cognitive differences between men and women continues to be used to justify women's inferior status in society (recall the remarks of former Harvard President Larry Summers 2005). This is partially the result of the "social life" of controversial research, such as how genetic research on aggression and sexuality receives more media attention than neurobiological or environmental research on the same topics (Longino 2013). Because research on differences (by sex, gender, and race) has so often been misused to justify oppression, some ignorance of differences could be better for social equality than unlimited freedom of research (Kourany 2016).

With FDA drug labels as well, *medical knowledge and ignorance can either oppress or empower.* In general, this means that medical knowledge is not politically neutral: depending on the circumstances, one "drug fact" might have an oppressive social function while another piece of medical knowledge contributes to people's liberation. As we saw in part I, even the same sort of information (i.e., about the mechanism of Plan B) can be an instrument of social power for or against women's access to the same drug on different continents because of the differences the law and culture. While this insight on the interdependence of knowledge and power is not new—Michel Foucault (1980) called this the "politics of truth"—it has not been adequately engaged in medical ethics or epistemology.

The *politics of medical information* pose a significant challenge for regulatory agencies. First of all, the warnings on drug labels can function surreptitiously for sexist *paternalism* in service of patriarchy and private interests. In the case of Plan B, women's health advocates even dubbed this strategy a "politics of doubt," akin to the doubt mongering of the tobacco industry, leveraging the uncertainties of science to accomplish their political goals (Davidoff and Trussell 2006). Likewise, for the Pill, the insert-booklet compromise allowed doctors control of women's access to information. Second, medical authorities can use these labels for *misogynistic* purposes (in the sense of Manne 2018) to keep "bad women" in place within the bounds defined by sexist gender norms. For Plan B, misogyny involved using the value-laden "drug fact" to justify the refusals of providers to withhold the drug from "bad women" who threatened zygotic life. For the Pill, misogyny worked instead through ignorance, with refusals to provide knowledge to the "bad women" who demanded more information to keep them on the Pill.

Only by approaching informed consent at the political and cultural level have we begun to extricate sexism from the ethical and epistemic aspects of drug labeling. Yet, bioethics on

informed consent have largely ignored these epistemic-ethical aspects of the politics of information. Major accounts of informed consent overlook structural forces and cultural dynamics by focusing on the interpersonal level, such as the autonomy of individual actions or protection from harm by a doctor or researcher (Faden and Beauchamp 1986; Beauchamp and Childress 2013; Manson and O'Neill 2007). (One exception is the work of Rebecca Kukla (2010), who has argued that some strategies of informing do more to exclude pregnant women from public through shaming than providing knowledge for decision making.) If both knowledge and ignorance can be oppressive, including the information produced and regulated by the FDA, then doctors, businesses, and other organizations can use practices of informing (including withholding) for social control and domination. *Accordingly, it is crucial for socially engaged philosophers working on medical ethics and epistemology to connect informed consent with both individual agency and social justice*, whether it be women's liberation, reproductive justice, or epistemic justice. Otherwise, the agency remains aloof to how it contributes to oppression through drug labeling and regulation, and it cannot take steps toward promoting the common good.

4. Challenge #3: Using Ethics Unethically

By attending to the relations between ethics and epistemology in drug labeling, I have also unearthed a third challenge: *by avoiding the epistemic dimensions of ethical concepts and practices, powerful parties in medicine have misused ethics for unethical purposes*. Other philosophers of science engaged in coupled ethical-epistemic analysis have demonstrated feedbacks between ethics and epistemology in public-health research. For instance, in public health, epistemic features of research have ethically desirable/undesirable consequences, which

positively/negatively impact future research (Katikireddi and Valles 2015). I have focused on a different dynamic between ethics and epistemology involving social structures of domination that work through practices of informing: sexist values enter knowledge through value judgments, which produces value-laden knowledge with social utility for patriarchal ends, which in turn enables the oppression of women under patriarchy. Accordingly, knowledge production contributes to sexist oppression. Yet, this dynamic points to an additional entanglement of ethics and epistemology: in so far as our ethical practices *depend* on knowledge, when that knowledge is laden with unjust values, ethics can be compromised and *co-opted* for oppressive purposes. Only by recognizing the independence of medical knowledge and social justice can we fully recognize and combat this challenge.

We have seen three ways in which powerful authorities have used ethics for unethical purposes because of ethical-epistemic entanglements. First, the *informed consent* of patients (and the *right to know* of consumers) is an ethical concept that powerful interests in medicine have utilized to advance their private interests over public welfare. For instance, in part II, at a time when the practice of informed consent was becoming more accepted, doctors and the pharmaceutical industry resisted feminists' calls for full disclosure of the risks of the Pill. They argued instead that informed consent requires medical oversight for patients' increased understanding. Despite (or possibly because of) their reliance on sexist and racist stereotypes about Pill users, they were successful in keeping women ignorant about the Pill for population control and commercial profits. This ethically, epistemically compromised version of "informed consent" aimed at the ideal of increased understanding kept women completely dependent on their doctors for access to reliable information about birth control.

Even in more recent times, the concept of informed consent remains flexible enough for powerful parties to bent it toward their private interests. For instance, in part I, anti-abortionists rejected the switch of Plan B to over-the-counter access based in part on the rights of zygote-centric patients to know and the (unmet) necessity of a drug label on the mechanism (Stanford et al. 2004). Yet, this label was useless for the informed consent for zygote-centric patients because it did not equip them with the knowledge needed to weigh the risks to zygotes with the benefits of preventing ovulation/fertilization. Instead, the label had two patriarchal functions apart from informed consent: keep women off the morning-after pill and justify providers' rights to refuse.

Second, in the legal sphere, healthcare professionals and other organizations have misused the related concepts of *conscientious objection* and *religious freedom* to discriminate against women and impose their values (typically ethical-religious ones) on others. For example, in part I, anti-abortion pharmacists and hospitals relied on state laws to defend their legal rights to refuse providing services they deemed ethically objectionable (Davidson et al. 2010; Emerson 2011). The American College of Obstetrics and Gynecology (ACOG 2007) condemned these appeals to conscientious objection because of their lack of scientific grounding. Furthermore, in chapter 3, I argue that they lack moral integrity: refusals of the morning-after pill impose zygote-centric values on patients *through* value-laden knowledge, deprioritize women's health for zygotic health, and contribute to women's oppression, particularly for poor women and women of color. Corporations like Hobby Lobby have likewise appealed to the Religious Freedom Restoration Act of 1993 to justify their lack of coverage for employee insurance of emergency contraceptives (Tschann and Soon 2015). One key premise in their legal case was the mechanism of the morning-after pill, justified by the "drug fact" from the FDA that it "may also prevent implantation." This afforded them the social utility to defend their alleged "religious freedom" to

limit women's agency and access to emergency contraception at pharmacies, Catholic hospitals, and privately-owned corporations. Despite the deceptiveness of this "drug fact," it held water at the Supreme Court. According, protections for "religious freedom" in reproductive health allows professions not simply to determine their own personal beliefs about abortion, but also to decide which value judgments to make in empirical claims about contraceptive mechanisms. This entanglement allows powerful parties to coerce women toward their values under the banner of "freedom."

Third, based on sexist values, healthcare professionals and organizations have used the practice of medical *paternalism* for the oppression of women. Patriarchy proactively controls women by pressuring them to adopt a certain view of femininity that shapes their subjective experiences toward oppressive norms (Bartky 1988). Likewise, under the guise of "women's best interests," healthcare professionals have used practices of informing and withholding to guide women toward sexist gender norms. For example, in part I, the "drug label" warned women about the risks to zygotes, instructing them under the veneer of medicine that this risk was one they *ought* to value. That is, any "good mother" would selflessly protect her child, so if this pill "may prevent implantation," risking it would make her a "bad mother." In part II, population-control advocates believed that the established risk of fatal blood clots was acceptable at face value because of the Pill's benefits for women personally and for society at large. Yet, the "personal" benefits included keeping poor women of color off government assistance, and doctors imposed the "social" benefits on those same women whom they believed ought to bear the responsibility of reducing population growth.

Regulators have also contributed to paternalism based on sexist values. For instance, in part III, the FDA required industry to place drugs into one of five pregnancy categories, often

based on no human studies as industry had neglected to conduct them. To protect commercial interests, the old pregnancy labels tended to over-warn patients about fetal impacts while supplying no information about maternal benefits. Like zygote-centrism in part I, these fetal-centric rules encouraged pregnant women and their doctors to forego important medicines to avoid any possible risk to the fetus. Yet, in contrast to zygote-centrism, in the case of inadvertent exposure of a wanted pregnancy, these labels often guilted pregnant women and their doctors into abortion based on little to no information. Thus, the labels limited pregnant women's agency by implicitly guiding them and their doctors toward fetal-centric decisions without consideration of women's health benefits. In all these cases, sexist paternalism was fueled by ignorance or misinformation in the name of "women's best interests."

Particularly in the realm of reproductive health, these ethical-epistemic concepts and practices take on special *gendered* dimensions that often become further *racialized*. Feminists have long critiqued the implicit sexism in medicine's conceptualization of "the patient" and "compliance" (Sherwin 1992; Whatley 1988). Critical race theorists have illustrated how racist-sexist stereotypes, e.g., "the welfare queen," enter into policy making about reproductive health (Bailey 2016; Davis 1983; Roberts 1997). Feminists have also called for more attention to the ethical and epistemic practices that perpetuate injustices against women, such as misogynistic reactions (Manne 2018), deflated credibility in taking testimony (Fricker 2007), and limited views of subjectivity (Pohlhaus Jr 2014). This entanglement of bioethics with oppressive values and gender norms results from how knowledge is value-laden in its constitution and its social function. It poses a serious problem for an agency like the FDA that itself is tasked with *regulatory paternalism*: to determine the best interests of women as drug consumers. Without

critically evaluating and extricating these sexist values from drug regulation, the FDA will continue to struggle with misuses of ethics by those with power.

5. Thinking About Solutions: Extricating Sexism, Facilitating Feminism

The challenges in regulatory science involving reproductive health are many, but their magnitude does not make them intractable. For one, extricating the previously entangled aspects of drug regulation through careful analysis helps increase our understanding, and clarity is a major step toward improvement. Furthermore, by actively engaging across disciplines and with practitioners of regulatory science, we have the tools to accurately identify real-world problems and consider solutions. My third research question is: *which societal values and gender norms ought to influence drug regulation about reproductive health, and how ought this happen?* At the most general level, the answer from a feminist perspective involves extricating sexist values and norms from patriarchy, introducing more feminist criticism, and preventing coercive practices of putting women "in their place." Yet, the specifics, particularly regarding implementation, deserve further discussion. Accordingly, I would like to conclude by thinking about solutions with hypothetical proposals and reflecting on success stories at the FDA. I will briefly consider three areas of resolution, involving which values ought to guide regulatory science, who ought to make them, and how feminism could improve drug regulation.

First, while scholars have shown that there are many possible value judgments in science, it remains unclear how they should be made (Biddle 2015; Douglas 2015; Hicks 2014). Particularly in the context of regulatory science and reproductive health, I have argued that the frameworks of *epistemic injustice and oppression* provide a novel account of why sexist values are illegitimate in science and medicine: these values and gender norms have hindered the

epistemic autonomy of individual knowers and contribute to patriarchal oppression through value-laden knowledge. More generally, a broad conception of epistemic injustice (Dotson 2014; Fricker 2007; Pohlhaus, Jr. 2017) is helpful for exposing and criticizing epistemic-ethical challenges, particularly elaborating the connections between individual epistemic acts and structures of domination like patriarchy. Granting that science is inevitably value-laden, I suggest critically evaluating how values like sexism instantiate gender norms, which are then enforced in society for oppression through knowledge practices. By connecting knowledge production and use with these systems of domination, we can better *extricate* oppressive values and *prevent* further injustices. This *ameliorative* approach focuses on ethical-epistemic improvement and reform, which might better suit regulatory science than more radical and revolutionary stances.

Nevertheless, this is a positively feminist stance: regulators and science advisors ought to rely on feminist conceptions of justice and morals to extricate problematic entanglements from the scientific process. As we saw in chapter 5, feminist regulatory science is both possible and powerful. The challenges involve the omnipresent yet changing face of sexism, its influence on knowledge and ignorance, and its cooptation of ethical terminology. By making gender norms visible, identifying the social stakes of knowledge production, and providing more liberating alternatives, feminists can better direct drug regulation toward women's health and interests. Additionally, a critical stance toward the pharmaceutical industry, its cooptation of feminist language, and its "corporate ventriloquism" of women as "helpless" patients remains key (Holman and Geislar 2018; Segal 2018).

Second, because the production and regulation of drug information is highly antagonistic, with additional contention over reproductive health, it is even less clear *who* should be involved in these decisions about values and norms. Here, I have two things to contribute. For one,

scientific advisers can misuse their authority for oppressive purposes and compromise the integrity of the process, even in the face of criticism from women's health advocates. Thus, I am skeptical that more discussion would be helpful, *unless mediated and directed specifically toward the ethical-epistemic entanglements often underlying disagreement and contention*. That is, at least for discussions among scientific experts, I believe that there needs to be more explicit consideration of the ethical-epistemic dimensions of drug regulation. Thus, I would reword the question from "*who* should make the decision?" to "*how* should it be made?" Accordingly, experts in ethics and epistemology ought to supplement advisory committees of scientific experts, not for our values or perspective but our *critical, analytic,* and *discursive* capacities. For instance, philosophers have sought to enhance collaborative, cross-disciplinary scientific research with the Toolbox Project by improving cross-disciplinary communication about scientists' philosophical differences (O'Rourke and Crowley 2013). While regulators regularly turn to ethicists for advisory committees, the same is not true for socially engaged philosophers specializing in science and values. While this might seem like a "philosopher king" proposal, note that advisory committees are unpaid and that my proposal is less for philosophers to decide than for philosophers to facilitate, query, echo, and (at times) criticize. Instead, this solution is a form of social engagement for philosophers doing socially relevant research (Fehr and Plaisance 2010). Furthermore, this proposal seems plausible based on limited conversations I have had with FDA staff.

Again, while I believe that it is important for more mediated and directed discussion toward the ethical-epistemic dimensions of regulatory science and reproductive health, I do not think that critical discussion alone will improve regulation. *In general, the FDA and other governmental departments ought to place more explicit priority on women's interests, health,*

and wellbeing. That is, an intersectional, feminist conception of reproductive rights and reproductive justice are necessary. For instance, in part III, FDA leaders like Sandra Kweder in the Center for Drug Evaluation and Research continued to push through changes despite internal resistance. She did so because of the importance of new labels for the wellbeing of sick pregnant women. Likewise, in chapter 3, I strongly urge against the establishment of institutional protections for providers' "rights" to refuse patients services, such as the new Division of Conscience and Religious Freedom in the Office of Civil Rights in the Department of Health and Human Services (HHS). This organizational structure places the decision of making value judgments squarely in the hands of healthcare professionals, who tend toward sexist paternalism and misogyny in reproductive health. Providers are already at an advantage over patients, and patients' wellbeing suffers more from refusals than that of providers. Furthermore, restrictions on abortion contribute to women's oppression, and they disproportionately burden poor women and women of color. Likewise, to prevent further reproductive injustices, it is imperative that HHS and FDA increase protections for patients and the priority of women's health.

Third, I would like to turn to the question of implementation involving how to prioritize women's health, interests, and wellbeing. I conclude this dissertation by explicitly considering the prospects at the FDA for integrating feminist values into regulatory science. In part II, during the early 1970s, radical feminists faced considerable resistance to impacting the agency—except in a symbolic way. Yet, their impact laid the groundwork for later developments: during the '70s and '80s, the power of feminist voices increased as the feminist women's health movement became institutionalized with the National Women's Health Network (est. 1974), followed by other patient advocacy groups like the National Black Women's Health Project and ACT UP for HIV/AIDS patients (Avery 1990; Epstein 1996; Nelson 2015). Nonetheless, the

institutionalization of the women's health movement has required compromises with medical authority and a focus toward a more liberal brand of feminism, at times willing to align itself with corporations, colonial forces, and oppressive regimes (Murphy 2012). *Has the institutionalization of the women's health movement compromised its ability to criticize sexism and injustice in regulatory science involving reproduction?*

As we saw in part I, there were times at which the presence of women's health advocates was inadequate for change, exemplified by Susan Wood's resignation from the FDA Office of Women's Health following the continued delay of Plan B's switch (S. F. Wood 2005). Likewise, the creation of the HHS office for providers' "rights" is also a failure for women's health. It will likely lead to increased refusals in the public sector of health care and forced gestation based on sexist gender norms.

However, there are also *feminist success stories* in regulatory science. For instance, in part III, women's health advocates at the FDA were able to overturn the 1977 exclusion of "women of childbearing potential" because of its androcentric effects on drug research (Merkatz et al. 1993). Ruth Merkatz, the first head of the Office of Women's Health, who enacted this change, explained the problem in feminist terms by citing Simone de Beauvoir: "Representation of the world, like the world itself, is the work of men; they describe it from their own point of view, which they confuse with the absolute truth" (Merkatz and Junod 1994, p. 706). It is not common that insiders in the FDA cite feminist philosophers (nor that their actions truly align with their words!).

More recently, the revision of the pregnancy label was also a feminist success story because, if nothing else, it supports pregnant women epistemically to enact a broader set of reproductive rights than before. While the transformation of the label was incomplete, its

revision still constitutes a reform of the failures of the past. Thus, I remain optimistic of the potential for those advocates of women's health within the FDA to criticize sexism in its many sizes, to elucidate the politics of information, and to contest questionable uses of ethical concepts. There remains a continued need of vigilant resistance through feminist reform, which is possible albeit challenging. Fortunately, socially engaged philosophers can support regulators in these improvements. If we work together, progress in regulatory science is possible.

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Appendices

Appendix 1:

The Revisions of the Patient Package Insert through Three Versions

1.1. Version 1: From the Nelson Senate Hearings

Proposed by FDA Commissioner Charles Edwards on March 4, 1970[76]

WHAT YOU SHOULD KNOW ABOUT BIRTH CONTROL PILLS

(ORAL CONTRACEPTIVE PRODUCTS)

All of the oral contraceptive pills are highly effective for preventing pregnancy, when taken according to the approved directions. Your doctor has taken your medical history and has given you a careful physical examination. He has discussed with you the risks of oral contraceptives, and has decided that you can take this drug safely.

This leaflet is your reminder of what your doctor has told you. Keep it handy and talk to him If you think you are experiencing any of the conditions you find described.

A WARNING ABOUT "BLOOD CLOTS"

There is a definite association between blood-clotting disorders and the use of oral contraceptives. The risk of this complication is six times higher for users than for non-users. The

[76] Source: NH, 16, 6800-6801.

majority of blood-clotting disorders are not fatal. The estimated death rate from blood-clotting in women not taking the pill is one is 200,000 each year; for users, the death rate is about six in 200,000. Women who have or who have had blood clots in the legs, lung, or brain should not take this drug. You should stop taking it and call your doctor immediately if you develop severe leg or chest pain, if you cough up blood, if you experience sudden and severe headaches, or if you cannot see clearly.

Who Should Not Take Birth Control Pills

Besides women who have or who have had blood clots, other women who should not use oral contraceptives are those who have serious liver disease, cancer of the breast or certain other cancers, and vaginal bleeding of unknown cause.

Special Problems

If you have heart or kidney disease, asthma, high blood pressure, diabetes, epilepsy, fibroids of the uterus, migraine headaches, or if you have had any problems with mental depression, your doctor has indicated you need special supervision while taking oral contraceptives. Even if you don't have special problems, he will want to see you regularly to check your blood pressure, examine your breasts, and make certain other tests.

When you take the pill as directed, you should have your period each month. If you miss a period, and if you are sure you have been taking the pill as directed, continue your schedule. If you have not been taking the pill as directed and if you miss one period, stop taking it and call your doctor. If you miss two periods, see your doctor even though you have been taking the pill as directed. When you stop taking the pill, your periods may be irregular for some time. During this time you may have trouble becoming pregnant.

If you have had a baby which you are breast feeding, you should know that if you start taking the pill its hormones are in your milk. The pill may also cause a decrease in your milk flow. After you have had a baby, check with your doctor before starting to take oral contraceptives again.

What to Expect

Oral contraceptives normally produce certain reactions which are more frequent the first few weeks after you start taking them. You may notice unexpected bleeding or spotting and experience changes in your period. Your breasts may feel tender, look larger, and discharge slightly. Some women gain weight while others lose it. You may also have episodes of nausea and vomiting. You may notice a darkening of the skin in certain areas.

Other Reactions To Oral Contraceptives

In addition to blood clots, other reactions produced by the pill may be serious. These include mental depression, swelling, skin rash, Jaundice or yellow pigment in your eyes, increase in blood pressure, and increase in the sugar content of your blood similar to that seen in diabetes.

Possible Reactions

Women taking the pill have reported headaches, nervousness, dizziness, fatigue, and backache. Changes in appetite and sex drive, pain when urinating, growth of more body hair, loss of scalp hair, and nervousness and irritability before the period also have been reported. These reactions may or may not be directly related to the pill.

Note About Cancer

Scientists know the hormones in the pill (estrogen and progesterone) have caused cancer in animals, but they have no proof that the pill causes cancer in humans. Because your doctor knows this, he will want to examine you regularly.

REMEMBER

While you are taking _____, call your doctor promptly if you notice any unusual change in your health. Have regular checkups and your doctor's approval for a new prescription.

1.2. Version 2: First Insert in Federal Register

Proposed by Charles Edwards in the Federal Register on March 26, 1970[77]

ORAL CONTRACEPTIVES

(Birth Control Pills)

The oral contraceptives are powerful, effective drugs. Do not take these drugs without your doctor's continued supervision. As with all effective drugs, they may cause side effects in some cases and should not be taken at all by some. Rare instances of abnormal blood clotting are the most important known complication of the oral contraceptives. These points were discussed with you when you chose this method of contraception.

While you are taking this drug, you should have periodic examinations at intervals set by your doctor. Notify your doctor if you notice any of the following:

1. Severe headache.
2. Blurred vision.
3. Pain in the legs.
4. Pain in the chest or unexplained cough.
5. Irregular or missed periods.

***

[For any additional labeling, FDA required the following:]

The Commissioner also concludes that it is necessary that full information in lay language, concerning effectiveness, contraindications, warnings, precautions, and adverse reactions be incorporated prominently in the beginning of any such materials.

[77] Source: *Federal Register*, Volume 35, Issue 70. Washington, D.C.: National Archives of the United States, April 10, 1970. 5962-3. https://www.gpo.gov/fdsys/pkg/FR-1970-04-10/pdf/FR-1970-04-10.pdf.

1.3. Version 3: Final Version in Federal Register with Separate Booklet

Proposed by Charles Edwards in Federal Register on June 4, 1970[78]

ORAL CONTRACEPTIVES

(Birth Control Pills)

Do Not Take This Drug Without Your Doctor's Continued Supervision.

The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.

Safe use of this drug requires a careful discussion with your doctor. To assist him in providing you with the necessary information, (Firm Name) has prepared a booklet (or other form) written in a style understandable to you as the drug user. This provides information on the effectiveness and known hazards of the drug including warnings, side effects and who should not use it. Your doctor will give you this booklet (or other form) if you ask for it and he can answer any questions you may have about the use of this drug.

Notify your doctor if you notice any unusual physical disturbance or discomfort.

***

[For the booklet, FDA required the following:]

(1) A statement that the drug should be taken only under continued supervision of a physician.

(2) A statement regarding the effectiveness of the product.

(3) A warning regarding the serious side effects with special attention to thromboembolic disorders and stating the estimated morbidity and mortality in users vs nonusers. Other serious

[78] Source: *Federal Register,* Volume 35, Issue 113. Washington, D.C.: National Archives of the United States, June 11, 1970. 9002-3. https://www.gpo.gov/fdsys/pkg/FR-1970-06-11/pdf/FR-1970-06-11.pdf.

side effects to be mentioned include mental depression, edema, rash, and jaundice. The possibility of infertility following discontinuation of the drug should be mentioned.

(4) A statement of contraindications.

(5) A statement of the need for special supervision of some patients including those with heart or kidney disease, asthma, high blood pressure, diabetes, epilepsy, fibroids of the uterus, migrane, mental depression or history thereof.

(6) A statement of the most frequently encountered side effects such as spotting, breast changes, weight changes, skin changes, and nausea and vomiting.

(7) A statement of the side effects frequently reported in association with the use of oral contraceptives, but not proved to be directly related such as nervousness, dizziness, changes in appetite, loss of scalp hair, increase in body hair, and increased or decreased libido.

(8) A statement regarding metabolic effects such as on blood sugar and cholesterol setting forth our current lack of knowledge regarding the long term significance of these effects.

(9) Instructions in the event of missed menstrual periods.

(10) A statement cautioning the patient to consult her physician before resuming the use of the drug after childbirth, especially if she intends to breastfeed the baby, pointing out that the hormones in the drug are known to appear in the milk and may decrease the flow.

(11) A statement regarding production of cancer in certain animals. This may be coupled with a statement that there is no proof of such effect in human beings.

(12) A reminder to the patient to report promptly to her physician any unusual change in her general physical condition and to have regular examinations.

Optionally, the booklet may also contain factual information on family planning, the usefulness and hazards of other available methods of contraception, and the hazards of pregnancy. This

material shall be neither false nor misleading in any particular and shall follow the material presented above.

Appendix 2:

Professional Profiles of Interview Participants

Participant 1: Susan Wood, PhD

Relevant experience: former Assistant Commissioner for FDA Office of Women's Health

Date interviewed: 9/13/2018 (50m 59s)

Professional timeline:

- 1976-1990: Education
    - BS, Biology/Psychology, Southwestern at Memphis (Rhodes College), TN, 1980.
    - PhD, Biology, Boston University, MA, 1989.
    - Research fellowship, Neuroscience, Johns Hopkins University School of Medicine, MA, 1990.
- 1990-1995: American Association for the Advancement of Science Congressional Fellow and then Deputy Director of the Congressional Caucus for Women's Issues.
- 1995-2000: Department of Health and Human Services, Office of Women's Health, Director for Policy and Program Development.
- 2000-2005: Food and Drug Administration, Assistant Commissioner for Women's Health and Director of the Office of Women's Health.
- 2006-present: George Washington University, Professor of Health Policy and of Environmental and Occupational Health, the Director of the Jacobs Institute of Women's Health.

Participant 2: Sandra Kweder, MD, MA

Relevant experience: former Deputy Director of the Office of New Drugs in the FDA Center for Drug Evaluation and Research and leader of Pregnancy Labeling Task Force

Date interviewed: 10/4/2018 (1h 11m 16s)

Professional timeline:

- 1975-1984: Education
    - BS, Biology, University of Connecticut, CT, 1975-1979.
    - MA, Health Policy and Administration, University of North Carolina at Chapel Hill, NC, 1980-1981.
    - MD, F. Edward Hébert School of Medicine, Uniformed Services University of the Health Sciences, MA, 1981-1984.
- 1984-1997: Military service
- 1997-present: Food and Drug Administration
    - Deputy Director, Office of Drug Evaluation IV (nonprescription drug products; medical imaging products; pediatrics and maternal health products), Center for Drug Evaluation and Research, 1997-2003.
    - Deputy Director, Office of New Drugs, Center for Drug Evaluation and Research, 2000-2016.
    - Deputy Director, Europe Office, Office of International Programs, 2016-present.

Participant 3: Ruth Merkatz, PhD, RN

Relevant experience: former Director of the FDA Office of Women's Health

Date interviewed: 12/26/2018(1h 29m 59s)

Professional timeline:

- ?-1990: Education
    - BSN, Cornell University, NY.
    - MA, Nursing, Case Western Reserve University, Cincinnati, OH, 1978.
    - PhD, Nursing, Adelphi University, NY, 1989.
- 1979-1989: Clinical Experience
    - Acting Director of Nursing, Co-Chair of Bioethics Committee, Albert Einstein College of Medicine, Bronx, NY.
- 1991-1997: Food and Drug Administration, Washington DC.
    - Assistant to the Commissioner on Women's Health, 1991-1994.
    - Director of the Office of Women's Health, 1994-1997.
- 1997-2005: Pfizer, Director of Women's Health Program.
- 2005-present: Population Council, Director of Clinical Development, Center for Biomedical Research, NY.
- Present: Albert Einstein College of Medicine, Associate Clinical Professor, Department of Obstetrics and Gynecology, NY.

Participant 4: Lynne Yao, MD

Relevant experience: current Director of the Division of Pediatric and Maternal Health in the Office of New Drugs, FDA Center for Drug Evaluation and Research

Date interviewed: 3/7/2019 (59m 7s)

Professional timeline:

- 1981-1989: Education

    - BS, Biology, Yale, CT, 1981-1985.
    - MD, the George Washington University School of Medicine and Health Sciences, Washington DC, 1985-1989.
- 1993-1999: Walter Reed Army Medical Center, Washington DC.
    - Training in Pediatric Nephrology, 1993-1996.
    - Head of Division of Pediatric Nephrology, 1996-1999.
- 2000-2008: Fairfax Hospital for Children (Inova), VA.
    - Dialysis Director and Pediatric Nephrologist, 2000-2008.
- 2008-present: Food and Drug Administration
    - Medical Officer, Division of Gastrointestinal and Inborn Errors, Office of New Drugs, Center for Drug Evaluation and Research, 2008-2010.
    - Clinical Team Leader, Division of Gastrointestinal and Inborn Errors, 2010-2012.
    - Associate Director, Pediatric and Maternal Health Staff, Office of New Drugs, Center for Drug Evaluation and Research, 2012-2014
    - Director, *Division* of Pediatric and Maternal Health, Office of New Drugs, Center for Drug Evaluation and Research, October 2014-present.

Appendix 3:

Sample Questionnaire for Open-ended Interviews

1. First off, will you tell me a little about yourself and how you ended up at the FDA?
2. Could you tell me why the pregnancy and lactation labeling is important to the FDA?
3. Would you first describe to me your role in FDA initiatives related to women's health?
4. What was your role in the revision process of the pregnancy labels?
5. Can you recall some of the obstacles, tensions, and conflicts that arose during the process?
    a. *Follow up:* How did y'all handle those difficulties?
6. Could you explain to me how your office/division fits in the larger FDA?
7. Is there anything that you want to add that we haven't covered?
8. Is there anyone you think I should get in contact with to learn more?

Appendix 4:

Organization and Format for Pregnancy, Lactation, and Females and Males of Reproductive Potential Subsections[79]

8.1 Pregnancy

Pregnancy Exposure Registry (omit if not applicable)

Risk Summary (required subheading)

Clinical Considerations (omit if none of the headings are applicable)

Disease-associated maternal and/or embryo/fetal risk (omit if not applicable)

Dose adjustments during pregnancy and the postpartum period (omit if not applicable)

Maternal adverse reactions (omit if not applicable)

Fetal/Neonatal adverse reactions (omit if not applicable)

Labor or delivery (omit if not applicable)

Data (omit if none of the headings are applicable)

Human Data (omit if not applicable)

Animal Data (omit if not applicable)

8.2 Lactation

Risk Summary (required subheading)

Clinical Considerations (omit if not applicable)

Data (omit if not applicable)

[79]Source: Division of Pediatric and Maternal Health, "Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products — Guidance for Industry" (Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, 2014), 20, https://www.federalregister.gov/articles/2014/12/04/2014-28242/pregnancy-lactation-and-reproductive-potential-labeling-for-human-prescription-drug-and-biological.

8.3 Females and Males of Reproductive Potential (omit if none of the subheadings are applicable)

Pregnancy Testing (omit if not applicable)

Contraception (omit if not applicable)

Infertility (omit if not applicable)

Curriculum Vitae

EMPLOYMENT

New Mexico Institute of Mining and Technology
Assistant Professor of Ethics, Department of Communication, Liberal Arts, and Social Sciences, starting fall 2019.

EDUCATION

Indiana University, Bloomington
Ph.D. History and Philosophy of Science, Gender Studies minor, June 2019.
M.A. History and Philosophy of Science, Dec. 2016.
University of Notre Dame
B.S. Environmental Science, Philosophy major, May 2014.

SCHOLARLY INTERESTS

Areas of Specialization:	history & philosophy of science, philosophy of medicine, bioethics
Areas of Competence:	feminist science studies, STEM ethics, science & religion
Research Topics**:**	regulatory science, pharmaceutical drugs, reproductive health & justice, environmental health & justice

PUBLICATIONS

Peer-reviewed Articles

2019 ChoGlueck, C. "Broadening the Scope of Our Understanding of Mechanisms: Lessons from the History of the Morning-After Pill." *Synthese*. https://doi.org/10.1007/s11229-019-02201-0.

2018 ChoGlueck, C. "The Error Is in the Gap: Synthesizing Accounts for Societal Values in Science." *Philosophy of Science*. 85(4): 704-725. https://doi.org/10.1086/699191.

2017 Shrader-Frechette, K., & **ChoGlueck, C**. "Pesticides, Neurodevelopmental Disagreement, and Bradford Hill's Guidelines." *Accountability in Research*. 24(1): 30-42. https://doi.org/10.1080/08989621.2016.1203786.

Public Scholarship

2019 "Hysterical Housewives, Radical Feminists, and The Pill." *Lady Science*. 54. https://www.ladyscience.com/archive/no54.

GRANTS & AWARDS

2016—2019 Graduate Research Fellowship from the National Science Foundation (NSF grant no. 1342962).

2019 Victor E. Thoren Graduate Student Research Fellowship, the Department of History and Philosophy of Science and Medicine, Indiana University.

2018 Travel Support Grant, National Science Foundation & History of Science Society.

2017 Travel Support Grant, National Science Foundation & International Society for History, Philosophy and Social Studies of Biology.
2016 Jesse Fine Fellowship, from the Poynter Center for the Study of Ethics and American Institutions, Indiana University.
2016 Norwood Russell Hanson Prize, from the Department of History and Philosophy of Science and Medicine, Indiana University.

INVITED TALKS

2019 "Keeping Women Ignorant & On the Pill: The Relationship Between Medical Information & Social Justice." Indiana University South Bend, Public Forum for the Women's and Gender Studies Program. South Bend, IN. February 1.
2018 "Drug Information & Injustice: Lessons about Informed Consent from the History of the Pill." University of Notre Dame, History and Philosophy of Science Colloquium Series. Notre Dame, IN. October 23.
2017 "The Error's in the Gap: Synthesizing Accounts for Values in Scientific Reasoning." Norwood Russell Hanson Prize Lecture, Indiana University, Dept. History and Philosophy of Science and Medicine. Bloomington, IN. February 2.

CONFERENCE PRESENTATIONS

Papers Presented (refereed)

2019 "The Long Road to Revising the Pregnancy Labels: Fetal-centrism and a Feminist Success Story at the FDA." Values in Medicine, Science, and Technology Conference. Richardson, TX. May 23.
2018 "What After the Morning-After Pill? Values, Patriarchy, and Epistemic Injustice in Medicine." Philosophy of Science Association. Contributed Papers on Epistemic Injustice in Science. Seattle, WA. November 2.
2018 "'You are prejudicing your own case': Women as Experts, Users, and Disturbances at the 1970 Nelson Hearings on the Pill." History of Science Society. Special Presidential Flashtalk Session. Seattle, WA. November 2.
2018 "What After the Morning-After Pill? Values, Paternalism, and Epistemic Injustice." Consortium for Socially Relevant Philosophy of/in Science and Engineering. Atlanta, GA. June 6.
2018 "Drug Facts and Value-laden Labels: The Pill, Informed Consent, and the FDA's New Patient Inserts." Values in Medicine, Science, and Technology Conference. Session on Dissertation in Progress. Richardson, TX. May 19.
2017 "Why 'How It Works' Has Mattered: The Values of Knowing the Morning-After Pill's Mechanism." International Society for History, Philosophy and Social Studies of Biology. Symposium on Contraceptive Controversies: Perspectives on Birth Control. Sao Paulo, Brazil. July 18.
2016 "What After the Morning After Pill? Values in the Science and Regulation of Contraception." Society of the Philosophy of Science in Practice. Glassglow, NJ. June 18.

2015 "Academia and the Pesticide Industry: The Case of Neurodevelopmental Disagreement." The Collaboration Conundrum: Special Interests and Scientific Research. Notre Dame, IN. Nov. 6.

Posters Presented

2016 "Drug Facts and Value-Laden Labels: Contraceptive Controversy at the FDA." Philosophy of Science Association. Atlanta, GA. Nov. 4. *Refereed.

2014 "Protecting At-risk People and Consulting for Federal Agencies: Childhood Pesticide Harms and EPA Weight-of-Evidence." With K. Shrader-Frechette. Session on Socially Engaged Philosophy of Science. Philosophy of Science Association. Chicago, IL. Nov. 6. *Invited.

TEACHING EXPERIENCE

Associate Instructor (teaching assistant)

2015 Evolution of the Modern University, with Prof. James Capshew. College of Arts and Sciences core course, Indiana University Bloomington. Spring.

2014 Evolution, Creationism, and Society, with Prof. Elisabeth Lloyd. College of Arts and Sciences core course, Indiana University Bloomington. Fall.

RESEARCH EXPERIENCE

2015—2016 Research Assistant to Prof. Elisabeth Lloyd, Indiana University Bloomington.

DEPARTMENTAL SERVICE

Chair (President), IU HPS Graduate Student Association. May 2016-May 2017.
Climate committee member, IU HPS Graduate Student Association. 2017 to the present.

PROFESSIONAL SERVICE & AFFILIATIONS

Conference planning

Program committee, 9th Annual Values in Medicine, Science, and Technology Conference, University of Texas. Dallas, TX. May 23-25, 2019.

Program committee, 3rd IU Graduate Student Conference on History and Philosophy of Science and Medicine. Bloomington, IN. March 29-30, 2019.

Committee member, 1st IU Graduate Student Conference on History and Philosophy of Science and Medicine. Bloomington, IN. March 11-12, 2016.

External peer reviewing

Endeavor (1)
Philosophy of Science (1)
Synthese (2)

Member

Consortium for Socially Relevant Philosophy of/in Science and Engineering

International Society for the History, Philosophy, and Social Studies of Biology
International Philosophy of Medicine Roundtable
Philosophy of Science Association

COMMUNITY INVOLVEMENT & OUTREACH

Instruction

Volunteer instructor for diversity and inclusion workshops for InterAction Initiative, Inc. with local college students. South Bend, IN. 2017 to the present.

Blogging

Copy-editor, peer reviewer, and writer for ScIU science communication blog (http://blogs.iu.edu/sciu/author/cglueck/). 2017 to 2019.

2019 "Can science be value-free? The 'gap' argument." ScIU Blog. May 5.
2019 "Deceiving with doubt: How industry denies scientific evidence on the dangers of pesticides." ScIU Blog. March 19.
2018 "Joining science to liberal arts: The many ways of doing history and philosophy of science." ScIU Blog. November 6.
2018 "Sexual science: An interview with Justin Garcia." ScIU Blog. May 29.
2017 "The process of science and politics and the risks to education." With Briana Whitaker. ScIU Blog. December 19.
2017 "What are scientific facts?" ScIU Blog. October 31.
2017 "Science or politics? Reclaiming climate science for the people." ScIU Blog. April 22.