#### The Influence of Values on Medical Research

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## **ABSTRACT**

Mainstream views of medical research tell us it should be a fact-based, value-free endeavor: what a scientist (or her funding source) wants or cares about should not influence her findings. At the same time, we also sometimes criticize medical research for failing to embody certain values, e.g. when we criticize pharmaceutical companies for largely ignoring the diseases that affect the global poor. This chapter seeks to reconcile these perspectives by distinguishing appropriate from inappropriate influences of values on medical research. It divides this broad question into two narrower ones, the Role Question (at what points in the research process is value influence potentially acceptable?) and the Content Question (when value influence is potentially acceptable, what specific values should researchers use?), and then draws on the philosophical literature on values in science to explore answers to each of them.

**KEYWORDS:** values in science, research ethics, bias, medicine, bioethics, inductive risk, value free ideal, objectivity

### 1. Values and medical research: a tension

The history of medical research offers many cautionary tales in which scientists or those making use of scientific research allowed their personal interests or values or desires to influence their results. Research has shown that drug trials funded by pharmaceutical companies are systematically more likely to produce results favorable to those companies (Lexchin et al. 2003). In many cases, this can be traced to questionable (or worse) research practices. Pfizer, for example, selectively withheld data on 74% of patients enrolled in trials of the anti-depressant reboxetine (Eyding et al. 2010). There is similar evidence that toxicological trials funded by industry are much less likely to find evidence of toxicity, as can be seen in research on bisphenol A (vom Saal and Hughes 2005). Tobacco companies' desire for profits notoriously led them to downplay or ignore clear evidence that their product was responsible for millions of deaths (Oreskes and Conway 2010).

Though money is often a crucial source of bias, it isn't the only one. Many scientists have been guilty of "hyping" their results (Intemann 2022). Though they may be motivated by a sincere desire to spread the word about an exciting and potentially beneficial discovery, in many cases such exaggeration has ultimately proven harmful — as, for example, in the case of oxytocin, dubbed the "moral molecule" (Yong 2012). Feminist scholars have documented countless cases where scientists' preconceived ideas of gender have led them astray (Okruhlik 1994; Fausto-Sterling 1992), and history offers us many examples of political interference in science, from the Soviet Union (John 2019) to the United States (Viglione 2020; Tollefsen 2018).

In response to these and other examples, scientists have developed norms, rules, and procedures designed to keep values out of the scientific process. Innovations like the blinding of researchers, and the randomized assignment of study participants to experimental and control groups have been put in place to prevent scientists' values and biases from influencing their conclusions. Preregistration requirements aim to reduce selective publication (Warren 2018). Norms surrounding conflicts of interest — which are increasingly moving beyond disclosure requirements to outright bans — are designed to insulate medical research from industry influence (Godlee *et al.* 2013; de Melo-Martin and Intemann 2009). And principles of academic freedom aim to make it harder for external actors, including the government, to influence scientific research (Nathan and Weatherall 2002).

These reflections might lead one to think that medical research progresses best, or can reach its full potential, in an environment where personal, social, and political values play a minimal role. In tension with this, however, is the fact that we sometimes criticize medical research for its failure to embody or reflect certain values. Consider, for example, the "10/90 gap": the claim that only 10% of medical research funding is focused on diseases that affect 90% of the world's population (Commission on Health Research for Development 1990; Ramsay 2001; Callender 2020). Pharmaceutical companies spend huge amounts of money trying to develop the next incremental cancer drug, while dedicating few resources to developing more effective or less expensive treatments for problems like dengue or leishmaniasis, which largely affect the global poor. The complaint here is not simply that pharmaceutical companies are being driven by profits; it is that they are *not* adequately aligning their research with a different value: the (global) common good.

We can see a similar endorsement of value-guided science in the mission statements of many scientific organizations. The AAAS Statement on Scientific Freedom and Responsibility, for example, states that, "[Scientific] freedom is inextricably linked to and must be exercised in accordance with scientific responsibility. Scientific responsibility is the duty to conduct and apply science with integrity, in the *interest of humanity*, in *a spirit of stewardship for the environment*, and with *respect for human rights*" (AAAS 2017, my emphasis). Many institutions also include statements encouraging scientists to work to promote diversity through their research. *Cell*, for example, asks authors publishing in their journal to provide "information about efforts to ensure diversity in cell lines or genomic datasets used for a study, efforts to ensure sex/gender balance in research subjects, efforts to ensure that any study questionnaires are prepared in an inclusive way, self-identification of authors as members [of] minority groups, support that any authors have received from programs designed to advance minority scientists, and efforts made to promote gender balance in citation lists" (Sweet 2021). Some of this information is published alongside articles.

Putting these observations together, on the one hand we have many cases where the intrusion of values into medical research has been pernicious. This has led researchers to take steps to try to insulate their work from the influence of values. On the other hand, we also seem to want medical researchers to embrace certain values beyond the simple pursuit of truth and to have those values shape their work. What, then, can we say about how values should or shouldn't influence medical research? In this chapter, I will try to make some progress towards answering that question — though, as we will see, it is not a question that has a simple answer.

# 2. Two Preliminaries

2.1 Epistemic vs. non-epistemic values

Philosophers of science commonly make a distinction between epistemic and non-epistemic values.<sup>1</sup> Epistemic values are those that, directly or indirectly, are truth-conducive. They are typically taken to include accuracy, consistency, breadth, simplicity, and fruitfulness (e.g. Kuhn 1977). In order to be true, a theory must accurately capture aspects of the world or make accurate predictions about the world, so accuracy is directly truth-conducive. A theory that has broad scope, in the sense that it makes predictions concerning a broad range of phenomena or across a broad range of contexts, isn't for that reason more likely to be true. But a broad theory is indirectly truth-conducive, since it is generally easier for scientists to test theories that make a broad (vs. narrow) range of predictions (Douglas 2013). Although there are many interesting questions to be asked about epistemic values, including exactly which things should count as epistemic values and how conflicts among them should be managed (Longino 1995), the idea that some set of epistemic values must guide scientists throughout the research process is not controversial.

The cases I mentioned at the outset of this paper, however, concern *non-epistemic values*. Non-epistemic values can come in many forms, but the ones most obviously relevant to medical research include personal values (e.g., a scientist's desire for fame, or a pharmaceutical company CEO's desire for profits), social values (e.g., social norms concerning beauty), ethical values (e.g., principles directing us to protect the vulnerable), and political values (e.g., principles dictating what government actions are legitimate). Henceforth, when I use "values" in this chapter, I mean to refer only to non-epistemic values, unless I explicitly indicate otherwise.

## 2.2 Splitting the question

In order to evaluate the influence of values on medical research, it will be helpful to distinguish the *content* of a value judgment from the *role* that it plays. In some cases, criticisms of the influence of values on science focus on the content of those values. For example, we may criticize one pharmaceutical company for choosing which drugs to develop purely on the basis of profitability, while praising a second for prioritizing drugs which would have the greatest impact on global health. In this case, our criticism of the first company is not based on the judgment that values should play no role in setting research priorities. (After all, we praised the second company!) Our complaint here is with the content of the value judgment: we (perhaps for ethical reasons) believe pharmaceutical companies have an obligation to look beyond profits in order to promote health.

In other cases, though, criticisms focus on the role values play. Suppose, for example, that a scientist covers up evidence of an extremely rare but serious side effect of some vaccine, in order to promote public uptake of the vaccine. In this case, we may endorse the value motivating the scientist's action. Perhaps we agree that the vaccine is, overall, extremely safe and effective and so think that everyone ought to get it. But, despite sharing the scientist's goal of widespread vaccination, we may nevertheless criticize the scientist's action, because we don't think that evidence of serious side effects should be kept from the public, even in the service of a good cause.

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<sup>&</sup>lt;sup>1</sup> Roughly the same distinction goes by several names: cognitive vs. non-cognitive values, or constitutive vs. contextual values. I won't worry about subtle differences between these distinctions, since they will not matter for the purposes of this chapter.

Let us, then, split our original question in two. We can ask, in what aspects of research is the influence of non-epistemic values potentially appropriate? And then we can ask, of those aspects, what specific values ought researchers employ?<sup>2</sup> I will call the former the *Role Question* and the latter the *Content Question*.<sup>3</sup>

## 3. The Role Question

I will discuss the Role Question first, because it may appear to have an easy answer. It seems obvious that values can appropriately influence scientists' decisions about what topics to research. There is nothing objectionable about a scientist choosing to study treatments for lung cancer over treatments for hair loss, based on her judgment that the former addresses a more pressing social need. It is also widely accepted that values must constrain research methodology: it is ethically unacceptable, for example, to conduct potentially harmful research on subjects without their informed consent. And it seems clear enough that values must play a role when scientists are preparing their results for publication or presentation. A scientific journal article or press release should emphasize the important results of a study — the most important benefits of a new treatment regimen, or the most serious risks associated with a new drug. Judgments of importance, though, are value judgments, since what a person regards as important will depend on what she cares about (Schroeder 2022a).

In contrast to these aspects of science where values do seem like they ought to play a role, proponents of the *value free ideal* for science (VFI) argue that there is a "core" part of the research process where (nonepistemic) values should play no role. Precisely how to define this core is a matter of disagreement among VFI proponents (and, indeed, many don't offer a precise definition), but on most views it includes gathering evidence and making inferences from evidence to conclusions (Douglas 2009, ch. 3; Elliott 2022a). Very loosely, we could state the view this way: values can appropriately play a role in the planning stages of science — when scientists are deciding what to investigate, and when deciding what methodologies meet ethical standards. And values can appropriately play a role after research is done, when scientists are deciding what to do with the knowledge they have gained. But during research itself — when scientists are in the lab or in the field, so to speak — they should be dispassionate seekers of the truth. Their values or goals or ambitions should not influence what they see as evidence, how they characterize evidence, or what conclusions they take their evidence to support.

Of course proponents of the VFI recognize that this aspiration is impossible to meet in practice. Like all human beings, scientists' perceptions will be colored by their values, and their reasoning will be influenced by their values. But, according to the VFI, we should strive to eliminate these influences. Double-blinding in a clinical trial, for example, can be understood as a technique to minimize the potential for a scientist's values to influence the way she characterizes evidence: if a researcher does not know which trial participants received the drug and which the placebo, then her desire to declare a drug effective cannot influence the way she characterizes patient outcomes.

The VFI, then, offers a (partial) answer to the Role Question: it asserts that there is a central part of science that we can mark off as a space which should, ideally, be free of the influence of non-epistemic values. This view was for a long time the dominant view among philosophers of science, and it probably

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<sup>&</sup>lt;sup>2</sup> There are two versions of this question. One asks about what values it is permissible or acceptable for researchers to employ; a second asks about what values it would be ideal for researchers to employ. Though these questions are importantly distinct, for reasons of space I will for the most part run them together in this chapter. See Douglas (2014) for one discussion that highlights this distinction.

<sup>&</sup>lt;sup>3</sup> The core question I address in this chapter has been dubbed by Holman and Wilholt the "New Demarcation Problem". See Holman and Wilholt (2022), Koskinen and Rolin (2022), and Resnik and Elliott (2023). Though I think there is a great deal of value in that framing of the issue, I believe much of the growing literature on the New Demarcation Problem suffers from running together the Role and Content Questions.

remains the dominant view among the public. Recently, however, philosophers have become increasingly skeptical of the VFI. They have offered several reasons for that concern, but I will focus on what is called the *argument from inductive risk*.

One thing scientists must do is determine if the evidence they have collected supports some hypothesis or not. Given the inductive nature of scientific reasoning, however, the available evidence never establishes or refutes a conclusion with complete certainty. In endorsing a hypothesis, then, there is always some risk of error. How confident must a scientist be, before endorsing a hypothesis? Or, equivalently, how great a risk of error is tolerable when deciding to endorse a hypothesis? Richard Rudner (1953) pointed out that the answer to this question appears to depend on how serious the costs of error are. Suppose someone asks you whether a previously-malfunctioning TV in a patient's room has been repaired. If you are 90% sure that it has, it might be reasonable for you to say "yes" or "I'm pretty sure it has". But if someone asks you whether a previously-malfunctioning ventilator has been repaired and you are 90% sure it has, you should not say "yes" — you should say that more investigation is required. Why the difference, given that your evidence was equally strong in each case? Because the consequences of a mistake are much more grave in the second case, it is reasonable to be more cautious, to insist on a higher standard of proof. Similarly, Rudner suggests, the level of confidence a scientist needs before endorsing a hypothesis should depend on the consequences of error. A pharmaceutical study, for example, should go to great lengths to rule out a potentially lethal side effect, but need not pay as much attention to a minor one.

Heather Douglas (2000) both broadened and strengthened Rudner's insight by pointing out that decisions with a similar impact happen throughout the scientific process. She discusses a set of toxicological studies of dioxin. In the studies, groups of rats were dosed with dioxin at various levels for two years, and then were autopsied to look for the presence of cancerous growths on the liver. Samples from the rats' livers were mounted on slides and assessed by pathologists. When looking at the very same slides, different pathologists came to different judgments — they frequently disagreed about whether a particular slide showed evidence of cancer. This disagreement was not resolved by asking the pathologists to employ a standard system of evaluation.

This disagreement raises two questions. First is the question of what individual pathologists should do when they see what they regard as a borderline or ambiguous slide. Classifying borderline slides as cancerous will reduce the risk that the study will declare dioxin to be safe when it is in fact carcinogenic (i.e., it will decrease the risk of a false negative); but it will increase the risk that the study will declare dioxin to be a carcinogen when in fact it is not (i.e., it will increase the risk of a false positive). Classifying borderline slides as lacking evidence of cancer will have the opposite effect: increasing the risk of a false negative, while reducing the risk of a false positive.

The second question is how the study as a whole should treat the slides about which pathologists disagree. One approach would be to classify a slide as showing evidence of cancer if even one or two pathologists classify it as cancerous. A second approach would be to classify a slide as showing evidence of cancer only if most or all pathologists classify it as cancerous. The former approach will reduce the risk of false negatives while increasing the risk of false positives; the latter approach will have the opposite effect.

So, how should scientists negotiate these choices? There is no purely epistemic reason to favor false positives or false negatives (Wilholt 2016). Douglas argues that scientists should consider the costs of each type of error, which will depend on the details of the situation. In the dioxin case, a false positive

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<sup>&</sup>lt;sup>4</sup> Throughout, I will present the researcher as having two options: endorse a hypothesis, or not. In fact, scientists typically have three options: endorse a hypothesis, reject it, or withhold judgment. This simplification won't impact the argument. See Wilholt (2016).

(declaring dioxin a carcinogen when it is not) would lead to economically inefficient overregulation, as industrial facilities would presumably be required to spend money reducing dioxin pollution - money that would be wasted, if dioxin is not actually dangerous. A false negative (failing to declare dioxin a carcinogen when it is one) would harm human and animal health, as dioxin pollution would presumably not be regulated. To decide, then, how to classify borderline slides or how to categorize slides about which pathologists disagree, we must make a value judgment: do we care more about avoiding economically inefficient overregulation, or about protecting human and animal health?

Douglas's point, then, is that even in "core" parts of the research process, scientists may face decisions that call for them to make value judgments: to weigh, for example, the seriousness of one type of error against the seriousness of another type of error. Although some philosophers have challenged Douglas's conclusion, the general consensus is that these challenges fail, and cases like Douglas's show that we cannot mark off a central "core" of science, and declare that, ideally, it should be free of the influence of non-epistemic values.<sup>7</sup>

Indeed, there is a growing literature identifying other choices that are plausibly part of the "core" of science that appear to raise similar issues (Biddle and Kukla 2017). Consider, for example, decisions about how to define or operationalize concepts, what study endpoints to employ, what classification systems to use, and what aspects of a system to model in a simulation. None of these decisions can be made on purely epistemic grounds. And, depending on the situation, particular decisions may increase the frequency of one type of error while decreasing the frequency of another. Or, particular decisions may make a study more useful for one purpose but less useful for another. Thus, for reasons similar to those given by Douglas, it appears that these decisions require consideration of non-epistemic values.

Value judgments, then, may be appropriate throughout the scientific process — they may have a role to play even when characterizing evidence (as in Douglas's dioxin case) or when deciding whether the available evidence supports some conclusion (as Rudner argued). Does that mean that anything goes, that we should welcome values into the core of science? Of course not. Nearly all philosophers writing about the role of values in science accept that most kinds of value influence on core aspects of science are pernicious. It is clearly inappropriate for a scientist to simply ignore evidence because she fears it will prevent her from publishing or profiting off of her results. Accordingly, philosophers have tried to develop criteria to distinguish appropriate from inappropriate value influences on the core of science.

The most influential family of proposals aims to ensure that non-epistemic values play a role that is in some important sense secondary to epistemic considerations. For example, Douglas (2009), distinguishes cases where values function as evidence ("I will endorse this hypothesis, because I want it to be true"; "I will interpret the evidence in this way, because doing so will yield the outcome I favor") from cases where values are used to determine how to weigh evidence or to assess the sufficiency of evidence ("Because widespread belief in this hypothesis could be harmful, I will only endorse it if the evidence is

<sup>&</sup>lt;sup>5</sup> Philosophers disagree about how this "must" is to be interpreted. Some mean to claim that scientists *ought* to make a value judgment here — that the only sensible or morally appropriate way to decide how to handle borderline cases requires deciding whether we place greater value on overregulation or on protecting health. Others mean to make the stronger claim that situations like this *force* scientists to make a value judgment — that whatever choice scientists make here, it will (perhaps implicitly) amount to valuing one outcome more highly than another. As Ward (2021) shows, this disagreement is largely traceable to different understandings of what we mean when we say that some choice is "value-laden". This issue is not central to the points I want to make in this chapter, so I'll set it aside.

<sup>&</sup>lt;sup>6</sup> In order to actually answer this question, we'd need much more detail. We would want to know, for example, how costly overregulation would be, how much impact unregulated dioxin pollution would have on human and animal health, and so forth. 
<sup>7</sup> See Elliott (2022a). The most often cited challenge comes from Betz (2013), whose argument builds on the earlier work of Jeffrey (1956).

<sup>&</sup>lt;sup>8</sup> See Schroeder (2020) for a discussion of the challenges involved in defining "Covid-caused death", and Stanev (2017) for complications arising from the choice of endpoint in clinical trials.

very strong"; "Because I am especially concerned with public health, I will treat borderline cases as showing evidence of toxicity"). She argues that the former sort of value influence is unacceptable while the latter sort is potentially acceptable. Similarly, Daniel Steel (2014) develops a proposal according to which non-epistemic values may justifiably influence science only when they don't conflict with epistemic considerations. Essentially, non-epistemic values should come into play only when epistemic values themselves fail to decisively resolve some decision (as, for example, when choosing among alternative reasonable ways to operationalize some concept, or when classifying ambiguous evidence).

Spelling out the details of this sort of approach will require more work. But, assuming something like it is correct, it suggests this answer to the Role Question: in "core" parts of scientific research — when scientists are collecting and characterizing evidence and determining whether that evidence supports a particular hypothesis — non-epistemic values must play a secondary role to epistemic considerations. That is, it is appropriate for scientists to appeal to non-epistemic values, but only in cases (such as the case of the slides with borderline evidence of cancer) where epistemic factors are substantially indeterminate. In other parts of the scientific process — for example, when deciding what topics to research, what ethical constraints to place on research methodology, or when deciding how to utilize the products of research — non-epistemic values may play a primary role, outweighing epistemic considerations. It is appropriate, for example, for a scientist to insist that research participants be permitted to withdraw from a study at any time, even if she knows that withdrawals will reduce the epistemic value of the study, by reducing its sample size and introducing a potential source of bias.

# 4. The Content Question

By itself, that answer to the Role Question is clearly inadequate to distinguish cases where the influence of non-epistemic values on science is appropriate from the cases where it is inappropriate. That is because, as noted earlier, there are some cases where the influence of values on science is inappropriate due to the content of those values. Earlier we saw some straightforward examples of this (e.g. the pharmaceutical company that exclusively focuses on profits). In this section, I will use a more complex case to explore four different answers to the Content Question: when researchers are permitted to employ non-epistemic values, which specific values should they use?

Although we are now essentially certain that smoking causes lung cancer, the evidence supporting this conclusion mounted over a period of time, moving by degrees from a suspicion to a probability to a virtual certainty. Nevertheless, even as the evidence became more and more compelling, tobacco companies continued to assert that the connection between smoking and lung cancer was unproven, and that more research was needed (Oreskes and Conway 2010).<sup>10</sup> Their actions were clearly motivated by a non-epistemic value — a desire for profits — and have been widely and appropriately condemned.

But what, exactly, did they do wrong? The discussion of the last section suggests that we cannot condemn them simply for allowing values to influence research or their interpretation of research. Further, the role values played in their reasoning is arguably consistent with our answer to the Role Question. Recall that Douglas and Rudner specifically identified decisions about the sufficiency of evidence as ones that can appropriately be influenced by values. As we saw, there are cases where being

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<sup>&</sup>lt;sup>9</sup> For an alternative approach that questions the idea that non-epistemic values should always play a secondary role to epistemic considerations, see Brown (2013).

<sup>&</sup>lt;sup>10</sup> To be clear, tobacco companies did more than simply assert that more evidence was needed, as Oreskes and Conway document. Here, though, I will focus only on their oft-repeated claim that the connection between smoking and lung cancer was unproven. It is also worth noting that tobacco producers continue to pursue similar strategies. The Korean Supreme Court, for example, recently accepted the argument that, although it may be certain that smoking causes lung cancer at a population level, that does not support concluding that even a heavy smoker's lung cancer was caused by smoking (Broadbent and Hwang 2016).

90% sure of something is not sufficient to assert it as fact. (Recall the previously-malfunctioning hospital ventilator: being 90% confident it has been fixed should lead one to say that more investigation is needed.) It therefore appears that Douglas's view would license tobacco companies to appeal to values when determining how much evidence is needed to accept a link between smoking and lung cancer.

If, then, tobacco companies did not necessarily use values in an inappropriate way, what did they do wrong? The obvious answer is to look to the *content* of their values. The problem wasn't that they allowed values to influence their assessment of the sufficiency of evidence. The problem was the specific values they employed. In order to insist that the increasingly compelling evidence supporting a link between smoking and lung cancer was nevertheless insufficient, one would need to value corporate profits much, much more highly than public health. *That* was their mistake: a company ought not place that much more weight on their profits, than on grave threats to public health. In the remainder of this section, I will look at four different ways to vindicate this criticism.

The most permissive answer to the Content Question would place no limits on the values scientists may choose. In order to explain what was the tobacco companies did wrong, we can pair this permissiveness with a requirement of transparency. Thus, what I will call the *Transparency Answer* says that, when scientists are licensed (by the answer to the Role Question) to employ values, they may use any values they like, so long as they are open about those values.<sup>11</sup> On this view, the problem with the tobacco companies' actions was not that they insisted on an extraordinarily high standard of proof. It is that they were not open about what they were doing: they did not explain that they were employing such a high standard, or that such a high standard implies valuing profits much, much more highly than smokers' health. Indeed, a failure to reveal such critically important information arguably qualifies as deception-by-omission.

A second approach to the Content Question, which I will call the *Ethics Answer*, seeks to limit the range of values scientists may employ with reference to ethical standards. Though of course the nature of ethics is subject to much disagreement among philosophers and the general public, there are nevertheless ethical standards that are widely accepted, such as prohibitions against certain kinds of deception and harmful actions. Working from widely-accepted standards like these, bioethicists have developed codes of medical ethics requiring informed consent from research participants, humane treatment of non-human research subjects, and so forth. We might try to employ similar ethical reasoning to determine which values it is ethically acceptable for scientists to employ, and which values are ethically unacceptable. This sort of approach would allow us to directly criticize tobacco companies: according to every mainstream theory of ethics, it is unacceptable to place a dramatically higher value on corporate profits than on consumers' lives.<sup>12</sup>

A third approach would be to "democratize" these value judgments by directing scientists to defer to the public, at least when it is possible to determine what the public values or wants. In Douglas's dioxin case, for example, scientists might try to balance worries about public health with worries about economically inefficient regulation by asking how the public would balance those considerations. This could be determined by doing public opinion research, convening a focus group of the public, or inviting members of the public onto the research team as "citizen scientists". In the case of smoking and lung cancer, it is obvious that the public would place greater value on public health than on tobacco companies' profits, and thus would insist on a much lower standard of proof than the tobacco companies

(2008).

<sup>&</sup>lt;sup>11</sup> Something like this view is essentially the status quo in many scientific fields (Schroeder 2022a). Although few philosophers rely exclusively on transparency in answering the Content Question, many have argued that transparency will be an important part of an answer. See, for example, Elliott and Resnik (2014), McKaughan and Elliott (2018), and Elliott (2022b).

<sup>12</sup> For examples of this sort of approach see Kourany (2010), Brown (2020), and elements of Douglas (2009). More generally, see the discussion in Schroeder (2022b). It is also, implicitly, the approach many scientists take. See e.g. Hoffman and Stempsey

evidently employed. The *Democracy Answer* would therefore criticize tobacco companies for employing a standard of proof that they knew (or should have known) was wildly out of sync with public expectations.<sup>13</sup>

Finally, a fourth answer to the Content Question, the *Diversity Answer*, takes a very different approach. Rather than trying to tell individual scientists or research teams what values to use, as the first three answers do, it takes a systems-level perspective. Helen Longino (1990), for example, argues that what is needed is a diversity of perspectives within the scientific community, so that a range of different approaches are pursued. A diversity of perspectives by itself, though, may not be of much value, since some perspectives may come to dominate others (for example, because their supporters have more money or social influence). Longino thus supplements her call for diversity with norms governing the interactions among those putting forward different perspectives, including requirements that all parties have an equal opportunity to voice criticisms of alternative approaches, that sincere criticisms be addressed, and so forth. On this view, then, we can say that the problem with tobacco companies was that they dominated the public debate concerning smoking and lung cancer: they shut down other voices, and did not sincerely engage with their critics.<sup>14</sup>

We have, then, four proposed answers to the Content Question.<sup>15</sup> According to the Transparency Answer, scientists may employ whatever values they like, so long as they are open about what they are doing. According to the Ethics Answer, scientists should restrict themselves to values that are ethically acceptable. According to the Democracy Answer, scientists should aim to use the values that the public would want them to use. And according to the Diversity Answer, scientists should aim to cultivate a community where a variety of different perspectives are pursued, and the results are then given a fair hearing.

Which of those is the right or best answer to the Content Question? That is currently a subject of much discussion among philosophers of science. I therefore won't attempt to resolve it here. Elsewhere, though, I have suggested that a full answer to the Content Question will leave a place for all of these views: in some contexts, it may be appropriate to insist on nothing more than transparency; in others, ethical acceptability may be key; and so forth. But I have argued that when it comes to the "core" of scientific research that will ultimately be presented to the public or used to inform policy, the Democracy Answer will loom large. When presenting information to a regulatory body, such as the FDA, or when speaking directly to the public, scientists should aim to employ the standards of proof, classification systems, and concept definitions that reflect what the public cares about. <sup>16</sup>

That said, it is worth emphasizing that in many cases a choice between these answers is not necessary. First, note that transparency is fully compatible with the Ethics, Democracy, and Diversity Answers, so there need not be any conflict there. Second, the values endorsed by the Democracy Answer will

<sup>&</sup>lt;sup>13</sup> For examples of this sort of approach see Kitcher (2011), Internan (2015), Lusk (2021), and Schroeder (2017; 2021; 2022a; 2022c). The same idea is favored by many in the field of science and technology studies. See e.g. Evans and Plows (2007). As several of the above authors note, this type of approach needn't require simple deference to the views of the majority. In cases where public expectations have been shaped by ignorance, morally unacceptable values, or processes that consistently marginalize certain groups, it may be appropriate to work from an idealized conception of the public — deferring, for example, to the expectations that in some sense the public *should* have. And in other cases it may be appropriate to seek compromise positions. (See Schroeder 2023 for discussion.) I leave aside those complications here, as they are not relevant to the case of smoking and lung cancer.

<sup>&</sup>lt;sup>14</sup> This approach has largely developed from the feminist philosophy of science literature. It is also the answer Oreskes (2019) gives, suggesting she views this, perhaps in tandem with the Transparency Answer, as identifying the primary problem with tobacco companies' handling of research on lung cancer and smoking.

<sup>&</sup>lt;sup>15</sup> These are, of course, not the only four possible answers to the Content Question. My impression, though, is that most extant proposals are in some way related to one of the four, or combine them in some way.

<sup>&</sup>lt;sup>16</sup> See the citations in note 13, above, and note that in some cases the emphasis should be on an idealized version of the public.

frequently be compatible with the Ethics Answer, because the values of the public at large will in many cases lie within the range of what is ethically acceptable. <sup>17</sup> Finally, nothing about the Diversity Answer precludes any individual scientist or research team from taking a Democratic approach — the Diversity Answer simply recommends ensuring that a plurality of views are pursued and given a fair hearing. Further, I think an argument can be made - though I don't have the space to explore it here - that the Democracy and Diversity Answers can in most cases be made to coincide. Bringing together diverse representatives of the public, having them deliberate about the non-epistemic values relevant to research, and then conducting research in accordance with their recommendations might be a way to satisfy both Answers simultaneously (Schroeder 2022d).

## 5. Lessons for Medical Research

How can the observations of the preceding sections be used to inform medical research? The critical first step - a precondition for applying any answers to the Role and Content Questions - is to ensure that both producers and consumers of medical research have a good understanding of the ways in which that research is influenced by values. In some areas, I think that understanding already exists. The impact of values on choice of research topic, constraints on research methodology, and dissemination of research are already widely recognized and accepted. And there is also a fairly wide understanding of the illegitimate influence of values on the "core" parts of research. Though there is certainly room for further education, many public observers of science (including those, such as science journalists, who present research to the public) are aware of the potential for data falsification, p-hacking, and other actions that involve prioritizing non-epistemic values over epistemic values, and are thus illegitimate according to our answer to the Role Question.

As we saw above, however, in some cases values can *legitimately* influence "core" parts of medical research. This kind of influence is much less commonly recognized. Outside of a few philosophy and STS journals, it is rare to see an explicit discussion of the values researchers employed when deciding how to define concepts, choose study endpoints, construct classification schemes, or handle ambiguous data. In large part, I suspect that this is because researchers themselves often do not realize that they are making these decisions in ways that, at least implicitly, reflect values.

Let me give one example. Because it is often impossible for medical research to fully account for human variability, many decisions about research methodology and about how to operationalize concepts have the effect of prioritizing the interests of some over the interests of others. Consider the Covid vaccine effectiveness statistics that were widely publicized beginning in late 2020. The effectiveness of specific vaccines was typically represented using a single percentage or small set of percentages. ("This vaccine is 86% effective at preventing infection and 96% effective at preventing death.") But, of course, the actual impact of a vaccine on any particular individual likely varied based on a host of factors, perhaps including age, underlying health conditions, environment, social contacts, mask-wearing habits, Covid prevalence in their community, and so forth. Concretely, the reduction in risk due to a vaccine for a healthy 30-year-old who works from home and occasionally makes short trips to a grocery store wearing an N95 mask is likely different from the reduction in risk due to a vaccine for a 65 year-old with multiple underlying health conditions, who works in a crowded, poorly ventilated warehouse for 50 hours per week, wearing a loosely-fitted cloth mask. Thus, the statistic most applicable to the former individual is likely different than the statistic most applicable to the latter individual.

<sup>&</sup>lt;sup>17</sup> Further, in some cases where the public holds views that are ethically unacceptable, the Democracy Answer may have resources to set those public views aside (Schroeder 2022c).

Suppose we have decided that we must present vaccine effectiveness statistics to the public using a single number. (Perhaps this is because we lack the resources - money, time, research participants - to produce multiple measures of effectiveness, or because we judge that multiple statistics are likely to be too confusing for the public.) We must still choose whose situation the single statistic will be tailored to - something we can accomplish through choosing what kinds of individuals we enroll in a clinical trial. One option would be to seek a wide variety of participants who are, collectively, representative of the community at large. That would have the effect of producing a statistic that represents something like the average level of protection conveyed by vaccines. Such a choice might seem appealingly egalitarian, since it gives equal weight to everyone's situation. However, there might also appear to be a compelling reason to produce a statistic that specifically represents the situation of the vulnerable, since they are at the greatest risk and thus arguably have the greatest need for accurate information about vaccines. Or perhaps we should produce a statistic that focuses on those individuals who follow government recommendations (e.g., concerning mask-wearing and social distancing), on the grounds that all individuals have a social obligation to follow that guidance.

My point is not to advocate for any particular vaccine statistic; it is to point out that there is a meaningful question here with an important ethical dimension — a question that I have not seen any extensive discussion of. Further, the decision matters. If I am given information about vaccine effectiveness that does not accurately characterize my situation, that may adversely impact my decision-making. If vaccine effectiveness statistics overstate the amount of protection I have, I might choose to take certain risks (e.g. going to large social gatherings), thinking I am much more protected than I actually am. And if vaccine effectiveness statistics understate the amount of protection I have, I might make unnecessarily cautious choices, foregoing the benefits of reopening my business, visiting family, or taking advantage of social services that are only available in person.

Note that nothing about this case is specific to measures of Covid vaccine effectiveness: a similar issue arises any time we have reason to think that the impact of a medical intervention will systematically vary in ways we can't adequately capture in our research results. Although the ethical dimensions of this issue are in most cases ignored, there is one context where it has been noticed, both by scholars and by the public: the sex imbalance in much clinical research. Historically, many clinical studies enrolled research subjects that were exclusively or disproportionately male. The results of those studies were then used to inform clinical treatment of both male and female patients. There is ample evidence that this practice has harmed female patients. For example, female patients have commonly been prescribed doses of certain medications, such as zolpidem, that were too high, since research had failed to recognize that male and female bodies process certain drugs at different rates. And female patients have been assessed for cardiovascular disease using diagnostic and treatment criteria developed through research on male subjects - when we now know that cardiovascular disease affects males and females differently. <sup>19</sup>

That, then, is one example of a kind of decision, common in medical research, where values should play a role - but where those values usually receive little or no discussion. When we cannot produce research or statistics that accurately reflect variable human responses, we should think carefully about whose situations we wish to characterize. Recognizing the value-laden dimensions of decisions like that is a critical first step, and would itself constitute a major advance towards a more reflective approach to

<sup>&</sup>lt;sup>18</sup> For this reason, the issues discussed here are not simply issues of communication, or how we frame our results. In many cases, methodological decisions undertaken during the research process will *determine* whose situation our results speak to. Having collected data in a way tailored to the situation of the healthy, young, mask-wearer; there may be no way — short of conducting an entirely new study — to determine the precise impact of the same vaccine on an older, maskless worker with underlying health conditions.

<sup>&</sup>lt;sup>19</sup> For discussions, see Johnson *et al.* (2014) and Nowogrodzi (2017). The issue is also sometimes picked up by the mainstream press. See e.g. Westervelt (2015); Jain and Bruzek (2022).

medical research. Once we have achieved that, we can then turn to the question of how to negotiate those choices - by, for example, comparing transparency, ethics, democracy, and diversity-based proposals.

#### 6. Conclusion

Medical research, or at least most of it, has as its ultimate goal to improve human health and well-being. It is not surprising that values have an important role to play in that type of endeavor. Though in some contexts we may be inclined to think of scientists as dispassionately searching for the truth, that would be a bizarre view to hold when it comes to medicine. Surely we want and expect medical researchers to be motivated by a desire to improve our lives. Nevertheless, it remains true that there are many documented cases where the influence of values on medical research has clearly been pernicious. And many of the steps researchers, journals, and other institutions of medicine have taken to minimize the impact of such values — including randomization and blinding in clinical trials and conflict of interest rules — have, at least in many cases, been beneficial. Put together, these observations suggest that working out what influence values should have on medical research is going to be complicated: we can neither reject values as inappropriate or as sources of "bias", nor can we broadly welcome them into research. We must therefore take on the task of determining when values should influence medical research, and when they shouldn't.

In this chapter, I suggested that a helpful way of tackling the issue is to divide it in two. The Role Question asks in which aspects of research the influence of non-epistemic values is potentially appropriate. Although it is widely accepted that there is an important role for such values to play in certain aspects of science, such as selection of research topic and dissemination of results, I suggested they also have a role to play in "core" parts of science - though I argued that that role must be carefully limited, so that non-epistemic values play a secondary role to epistemic considerations.

The second aspect of the original problem I dubbed the Content Question. It looks at the cases where (per the answer to the Role Question) non-epistemic values can legitimately play a role, and it asks which specific values medical researchers should employ. Here, I distinguished four potential answers: the Transparency Answer, the Ethics Answer, the Democracy Answer, and the Diversity Answer. Adjudicating among these Answers is the subject for another paper, but, fortunately, I suggested that in many cases we need not choose, since the Answers coincide or at least are compatible with one another.<sup>20</sup>

<sup>&</sup>lt;sup>20</sup> I thank Alex Broadbent, for extremely helpful comments on an earlier draft of this paper. I am also indebted to Kevin Elliott and Greg Lusk for discussion on several related issues.

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