

## Toward a theory of medical fallibility

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No species of fallibility is more important or less understood than fallibility in medical practice. The physician's propensity for damaging error is widely denied, perhaps because it is so intensely feared. Patients who suffer at the hands of their physicians often seek compensation by invoking the procedures of malpractice claims, and physicians view such claims as perhaps the only outcomes more earnestly to be avoided than even the damaging errors from which they presumably arise. Malpractice insurance rates soar, physicians strike, legislatures intervene, and, in the end, health care suffers from the absence of a clear understanding of what medical error is, how it arises, to what extent it is avoidable, when it is culpable, and what relationship it should bear to compensation for harm. It is to this cluster of questions that we direct our efforts.

We seek to provide the basic outlines of a theory of medical fallibility. Such a theory, to be accepted as adequate, must account for certain basic data. Those data include the fact that medical error not only occurs, but seems unavoidable; that some medical error seems innocent even when severely damaging, whereas other medical error seems culpable; that the harm that results from medical error seems sometimes but not always to warrant compensation; that the error that causes harm seems sometimes but not always to warrant sanctions; and, finally, that the relationships among culpability, harm, compensation, and sanctions are obscure. To succeed, our theory must increase our understanding of why medical error occurs and must help us distinguish between culpable and innocent error—it must diminish the obscurity surrounding the relationships among harm, culpability, compensation, and sanctions. Finally, and most importantly, it must thereby provide a basis for a more rational societal response to the reality of error in clinical practice.

Medicine as a practice is more opaque than we normally take it to be. We approach it too easily with already well formed categories devised for other purposes such as those reflected in the sociology of the professions, the philosophy of the natural sciences, and the law. By so doing we overlook a unique blending of epistemological and social factors in the prac-

tice of medicine. For example, lawyers apparently assume that legislators and the courts are competent to determine when medical error is culpable and, correspondingly, when harmed patients are entitled to compensation, merely by applying the general principles with which our legal system handles torts. The reaction of the medical profession has normally been to claim prerogatives of professional jurisdiction in response. Relevant as the attitudes of both the legal and medical professions have been, both parties seem to assume that we already have an adequate understanding of the types of error to which physicians are liable.

We wish to construct a theory of medical error which will challenge this assumption. In order to do this, however, we have to turn away from the conventional discussions which center immediately upon the notion of medical responsibility, usually with some help from sociological studies of professional responsibility, and examine instead certain more fundamental notions which derive not from medicine understood as a profession, but from medicine understood as a science.

### Scientific Norms and the Sources of Error

Natural scientists tend not to have an entirely clear view of the normative character of their own activity, of the values that guide, constrain, and inform their activities. But there is a good deal of evidence for their finding plausible a distinction between *internal* and *external* norms. Internal norms are those which derive from the essential character of scientific activity as a cognitive pursuit. External norms are those which govern motives either for participating in or for making use of the results of scientific activity. Internal norms are concerned with such factors as verifiability, truth, and reason; external norms are

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concerned with such factors as curiosity, ambition, and social utility.

The recognized norms which are internal to scientific practice are perhaps fourfold. There is that which prescribes attention to central rather than to peripheral problems of the science in question. There is that which prescribes the standards of scientific craftsmanship—in the design of experiments, for example, or in the criteria of confirmation that determine when a claim is well enough supported to be accepted into the body of scientific knowledge. There is that belonging to the mathematical element in natural sciences which prescribes elegance and simplicity as the aesthetic hallmarks of distinguished theorizing. And finally, dominating all, there is that which prescribes the search for truth, that is, the search for a theory which will mark a gain in respect of truth relative to currently accepted theory.

These norms all presuppose that at any given moment a scientist's standards are necessarily set by the present state of his discipline. For that state he or she clearly cannot be held accountable; and there will be limits to the extent to which even the greatest thinker can revolutionize a science. Indeed, should everything be known about a given area of science, all *scientific* activity in that area would cease, even though work might continue on the practical applications of that knowledge. Therefore, where there is scientific activity, there is partial ignorance—the ignorance that exists as a precondition for scientific progress. And since ignorance is a precondition of progress, where there is the possibility of progress there is the possibility of error. This ignorance of what is not yet known is the permanent state of all science and a source of error even when all the internal norms of science have been fully respected.

Among external norms of natural science are those which are relevant to personal motives for entering upon a scientific career or for doing science. One of these prescribes a certain kind of honesty: assiduous care in acknowledging debts to others, and, above all, in acknowledging priority of publication. Such a norm is not internal to the practices of natural science in the way that the norms governing experimental design or theory construction are. Natural science could remain essentially what it is now, even if the norms about priority of publication were somewhat different. Natural science might for example, if it had had a different cultural history, have adopted the ideals of anonymity and impersonality which informed medieval architecture: who precisely built what is for that architecture relatively unimportant, and vastly unimportant compared with who precisely built what in modern architecture or who discovered what in modern science. Modern science is thus a competitive race, although one could have an internally impeccable science without the competition.

Some of the other external norms of natural science have a good deal to do with this accidentally competitive aspect of its activities: that which warns young scientists against making premature claims or

that which enjoins a certain kind of respect for the processes of election to a Fellowship of the Royal Society or to a Nobel Prize. But others concern the reasons which a particular scientist may have for doing this rather than that sort of science: such reasons as that inquiry, in some particular area, is likely to lead to socially useful discoveries. What some external norms prescribe may sometimes be at variance with what internal norms are held to prescribe. When, for good ecological reasons, Barry Commoner persuaded a distinguished colleague in chemistry to turn his attention to problems concerning the nitrates in agricultural soils, the other chemists in his department were disturbed because the problems involved are not central to chemical inquiry as presently understood. But the very nature of the disagreement exhibits the acknowledgment of the two sets of norms as distinguishable.

Note that it is *not* our contention that this classification of norms is good or bad, clear or confused, complete or incomplete, for any particular purpose; it *is* our contention that these norms, classified in this way, are as a matter of fact implicit in current sci-

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entific practice, and that practicing natural scientists will readily recognize them as distinguishable influences or pressures on their own behavior. What matters for our subsequent argument is that this understanding of the norms of natural science involves acceptance of one particular way of classifying scientific errors. For on this view all scientific error will arise *either* from the limitations of the present state of natural science—i.e. ignorance—or from the willfulness of negligence of the natural scientist—i.e. ineptitude. This classification is treated as exhaustive. Willfulness and negligence will arise when those motives which are to be restrained by the external norms of natural science—ambition, impatience, competitiveness, a great anxiety to do good in the world—are allowed to override the internal norms. One function then of at least some external norms is to

prevent extra-scientific matters from invading and corrupting scientific activity; they could be other than they are in some respects, but some such set of norms would always be necessary.

It is worth remarking at this stage that to the extent to which our account so far is successful—that is, in being a recognizable version of what scientists characteristically would acknowledge about their practice—it is likely to seem familiar and even trivial. But it is the unsurprising character of the account that itself invites surprise when we go on to claim that this view of the sources of error in science presupposes a mistaken view of natural science. What will the relevance of this argument be to medical science? This view of ignorance and ineptitude as the only sources of error has been transmitted from the pure to the applied sciences, and then, more specifically, from medical science to medical practice viewed as the application of what is learned by medical science. In order to understand this connection we must now examine the way in which the distinction between pure and applied science is customarily understood.

#### Pure vs. Applied Sciences

Applied sciences are commonly held to differ from pure sciences in two main respects. First, they are defined with essential reference to some practical aim, such as the building of bridges, the expansion of agricultural production, or the promotion of the health of men or of animals. Second, they are defined in terms of some subject matter which is identified in pre-scientific terms. Pure sciences, by contrast, are only accidentally related to practical aims, and they continually redefine their own subject matter. What physics is about it is for physicists to say. Further, there is a useful distinction to be drawn between an applied science and a technology. An applied science is, like a pure science, a body of theoretically-organized knowledge, even if the principle of organization points toward a practical goal. A technology is a series of devices for realizing certain ends. Engineers, agriculturists, and medical scientists are unlikely to be entirely innocent of technology, but not every one of them need be a technologist.

Just as the pure scientist can err from one of only two types of cause, so it is also with the applied scientist, on the view we are describing. If the physician prescribes a drug which turns out to have drastically unfortunate side effects on his patient, then *either* the limits of pharmaceutical and physiological knowledge are to blame *or* the physician was negligent, that is, he failed to act in accordance with the best knowledge available. On the assumption that the physician did not bring about the side effects from some willful intention, then one of these two causes must have been operative. Where a surgeon is concerned, lack of technological skill may also be a factor. But failures from lack of technological skill are themselves classified in terms of the view of the sources of error

which we have identified. Either they spring from the general level of the art: the technology in question just has not advanced far enough—in which case lack of technological, say of surgical, skill compares to scientific ignorance; or else, assuming he is not willful, the particular technologist has been negligent in either acquiring or exercising the requisite available skill. Hence technologies, as ordinarily understood, do not provide a counter-example to the account of error which we have imputed to the natural scientist's characteristic understanding of his own activity. The complexity of that last phrase is not accidental. For what we are suggesting is not that natural science requires this account, but only a particular dominant interpretation of natural science. What that interpretation is, why it is dominant, and what the alternative to it is are the questions to which we must turn next.

#### Reinterpreting Natural Science

Natural science did not in the seventeenth century discard quite as much of Aristotelianism as its philosophical protagonists supposed. What it retained included an inability to give a plausible account of our knowledge of particulars, of individuals—an inability for which Aristotelianism is notorious. For natural science, on a modern physicist's view just as much as on Plato's or Aristotle's, the objects of knowledge are universals, that is, the properties of objects classified by *kinds*, and the generalizations that link those properties. The scientist looks for law-like relationships between properties; particulars occur in this account only as the bearers of properties, and the implied concept of a particular is of a contingent collection of properties. To explain the behavior of a particular is nothing else than to subsume its particular properties under the relevant law-like generalization; to predict is to use the same stock of law-like generalizations about the relevant properties. Notice that on this view, predictive failure in science can only have two sources: factual ignorance as to the relevant laws or as to just which properties are present in a situation; or inferential error, such as when conclusions are drawn carelessly from the laws and descriptions of properties. Thus, where we are not ignorant, any inadequacy in our predictive powers must be attributed to the predictor, to his willfulness or his negligence.

What is it about *particulars* that escapes notice on this view? To answer this question, we must first say what we mean by "a particular." It will not do, for our present purposes, to give a syntactic definition in terms of the specification of some class of expressions, such as denoting expressions of a particular kind. The class of particulars with which we are concerned includes neither the square root of minus two nor the horizon. It does include such varied items as salt marshes, planetary systems, planets, dolphins, snowflakes, hurricanes, cities, crowds, and people. A particular occupies a region of space, persists through time, has boundaries, has an environment, has peripheral and more central areas, and characteristically

can split into two or more parts. Notice that in this use of "particulars," certain collectivities are particulars—states, herds, forests, crowds, and cities, for example. Every particular continues to exist and has the characteristics that it has only in virtue of the operation of some set of physical and chemical mechanisms. Some particulars—ice cubes and molecules are notable examples—are such that nearly everything that we might want to know about them can be explained simply by citing the relevant mechanisms. Further, the generalizations that describe their behavior are generalizations that we accept as impeccably reliable. Thus, roasted ice cubes melt, and we can predict with complete assurance that any particular ice cube that we roast will in fact melt. This is in large measure because there is little diversity—at least, of any sort that interests us—among ice cubes. Each example of the type is, roughly speaking, quite like any other. The basic mistake made by that interpretation of science which considers that all genuine scientific knowledge is of universals is to sup-

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pose that all particulars are of this kind. But this is clearly false. Many particulars—salt marshes, hurricanes, and the higher primates, for example—cannot be understood solely as the sum-total of the physical and chemical mechanisms that operate on them. What effects such mechanisms do have is affected by the particular history of that specific particular with all its contingent circumstances, contingent that is, and even accidental, relative to the operation of the mechanisms. One cannot expect therefore in the case of such particulars to be able to move from a theoretical knowledge of the relevant laws to a prediction of the particular's behavior. The history of the law-governed mechanisms and of the particular which is their bearer is, so to speak, an intervening variable which may always to some degree elude us.

It may be objected that this is a familiar point made in a misleading way. To predict any outcome, the scientist must possess not only accurate formulations of the relevant laws, but also knowledge of the initial and boundary conditions. Are we not merely saying that in the case of some types of particular we do not possess adequate knowledge of these conditions? This way of putting matters is however itself highly misleading. For the whole vocabulary of laws, initial conditions, and boundary conditions, has application to

situations where either we have a controlled and limited environment or else we have a natural environment resembling a controlled environment to a high degree, wherein the transition from one state to another by the operation of a specific mechanism is detached from its historical antecedents as well as from the interventions of environmental circumstance. There are indeed types of particulars whose past and future can be mapped entirely in these terms, such as the roasted ice cube, but there are also types of particulars with respect to which this is not so.

Hurricanes and salt marshes, for instance, interact continuously with a variety of uncontrollable environmental factors. No hurricane is quite like any other hurricane, no salt marsh quite like any other salt marsh. Certainly everything that occurs to and in a hurricane or a salt marsh is law-governed, but because we never know what historically specific interactions may impact on such historically specific particulars—for example, because of melting icebergs, flocks of migrating birds, changes in the temperature of deep sea waters, and so on,—we never know in advance which the relevant law-like generalizations will be (even if we know them all) and which the relevant boundary conditions are. Indeed, in order to have such knowledge, we would need to know in detail what the behavior would be of each potential influence on the particular subject of our inquiry. To understand perfectly the behavior of a given hurricane, we would need to have perfect understanding of the polar ice cap and the gulf stream. But these, too, are particulars interacting with their larger environments, which include among other things the very hurricane we wish to understand. We thus *cannot* have perfect knowledge of our hurricane, short of having a complete understanding of all the laws that describe natural processes, and a complete state description of the world. In short, perfect knowledge of that one particular hurricane is unavailable except under conditions of omniscience. Thus it is not so much ignorance either of the initial conditions or of the relevant laws, or even of both conjoined, that is in question; rather it is ignorance of the contingencies of the environmental context, a context that differs from that of experiment, more radically than has normally been allowed. Hence, in the context of actual practice, no amount of theoretical meteorological knowledge will enable us to do more than score a certain degree—although perhaps a high degree—of predictive success with hurricanes.

This difference between types of particular—ice cubes on the one hand and hurricanes on the other—in respect of our predictive powers is matched by a difference between the types of generalization by means of which we may reasonably aspire to describe their behavior. For that type of particular wherein the particular's history is crucial, wherein a theoretical knowledge of the mechanisms will by itself never be adequate for explanatory or predictive purposes, wherein the actual environment does not adequately match the conditions of the ideal environment

presupposed by the theory (as it sometimes does), the generalizations by means of which we effectively grasp their behavior will not be genuine universal law-like generalizations, but rather generalizations prefaced by "Characteristically and for the most part. . . ." Of such generalizations it is true that when we are in possession of the best possible formulation, we may still meet with counter-examples and yet not be supplied thereby with any good reason, even any *prima facie* reason, for discarding or revising our formulation.

Consider the example of smallpox vaccination. One in 1200 will experience dangerous and perhaps fatal effects, as a reaction to the vaccination. Although there must *be* reasons why some individuals succumb—factors that distinguish them from the majority who are unharmed by the vaccination—we do not know what those factors are. We thus cannot accept as a *universal* generalization the claim that vaccinated individuals, even of a certain sort, will not thereby be harmed. But we can accept with confidence the claim that characteristically and for the most part, vaccinated individuals will suffer no adverse consequences. *That* generalization is not refuted by the illness or death of the occasional individual. What, then, are we to say of an individual about to be vaccinated? Of course, the effect of the vaccination on him will be determined by natural laws, his condition, and perhaps the way he interacts with his environment subsequent to vaccination. But we do not and cannot know all the relevant laws and conditions, thus our knowledge of this individual is limited and our predictive ability is constrained. We can have reasonable, empirically based expectations, accepted with a high degree of confidence. But no more is available to us than that. Yet more would be needed to eliminate entirely the possibility of causing harm by giving the vaccine.

One observation should be appended to the argument so far. When we have spoken of law-like generalizations we have intended this to refer to genuine law-like probabilistic generalizations as well as to non-probabilistic ones. For our purposes there are no relevant differences between these. From this it does not of course follow that, as in the case of smallpox vaccinations, we may not on occasion be able *de facto* to assign a number to the proportion of individuals in a population who escape our formulation. But such a statement of a *de facto* proportion must never be confused with the kind of law found in, for example, statistical mechanics.

What is true of hurricanes and salt marshes is thus also true of animals and people. This is an empirical claim. That is, it is a question of fact about a given class of particulars whether or not the empirical, inductively founded generalizations with which we describe their behavior for explanatory and predictive purposes in our practical transactions with them can be simply deduced from the law-like generalizations of the relevant part of theoretical science. Where this is not so, practical experience becomes

relevant in a manner quite different from that in which practical experience is important in a laboratory. What is important to the theoretical or experimental scientist is experience in research, not experience of the distinctive features of the particular crystals or molecules or other entities which provide a subject-matter for the research. That is, the scientist does have an interest in those particular entities, but it is an interest in what they have in common that typifies the activities of research. Thus, principles of crystal formation or solubility are inferred from the observable characteristics of diverse particular crystals, but the *differences* among such crystals are not to the point; it is their *similarities* that support generalization. In contrast, what is important to the meteorologist, navigator, or veterinary surgeon is an understanding of particular, individual hurricanes, cloud formations, or cows, and thus what is distinctive about them as particulars is what is crucially important. How such particulars differ from one another in their diversity thus becomes as important as the characteristics they commonly share. Experience of a single entity over time is necessary for an understanding of that entity as a particular in all its distinctiveness, for its individual characteristics will not typically be inferable simply from what is known about the general—that is, commonly shared—characteristics of the *type* of entity of which it is an instance.

Our thesis is then that the Aristotelian inheritance of natural science, as a result of which natural science is defined so that it is concerned exclusively with the knowledge of universals, blinds us to the existence of particulars as proper objects of knowledge. In the process, it blinds us to the role of a type of generalization that is different in crucial respects from those law-like generalizations that are usually treated as the characteristic genre of the natural scientist. This thesis could be developed in either a stronger or a weaker version. Its stronger version would involve a challenge to that whole picture of natural science which makes theoretical physics the most fundamental of disciplines and then ranks chemistry and biology before the applied sciences. For in this stronger version the thesis would insist that nature consists of nothing but more or less complex particulars, that theoretical physics is the most abstract kind of knowledge, and that it therefore always has to be based on our knowledge of particulars gained by means of sciences of the concrete. The most fundamental sciences on this view would be the disciplines concerned with our practical transactions with particulars: medicine, veterinary medicine, engineering, military and political sciences, and so on.

But this stronger version of the thesis is unnecessary for our present purposes. Even on the weaker version of our thesis—namely that the dominant interpretation of natural science must be revised so as to allow a place for our knowledge of particulars alongside our knowledge of generalizations—it is clear that those sciences which do deal with particu-

lars require a view of error quite different from that which is derived from the dominant interpretation. To this topic we shall therefore have to return. But first, we must examine one more feature of our revised view of natural science.

### A Science of Particulars

The internal and external norms recognized by natural scientists do not always point in the same direction. Those S.S. doctors who performed experiments on living prisoners in Auschwitz did not violate any of the internal norms concerning truth-seeking and problem-solving. Indeed, it might even have been the case with at least some of them that they were quite exceptionally devoted to these norms and that this was why they flouted the external norms which for most of us place ethical constraints upon experimental practices. This example will serve to bring out a sense in which science is often thought of as non-moral or as morally neutral. The scientist discovers what he or she can. It is his or her duty to pursue empirical truth, but *qua* scientist he or she has no further concern with the social effect of the discoveries or the ethical status of the process of inquiry that led to them. *Qua* citizen, *qua* parent, *qua* teacher, he or she must have moral concerns. But this will always be a matter of norms external to science.

Underlying this view there is once again the position that the statements of fact made by scientists *qua* scientists are value-free. They are, after all, statements of fact. The familiar thesis that statements of fact cannot entail statements of value is often used to underpin this view of science. We shall not be concerned here with this general thesis. What we do want to assert is that once it is realized that science is properly concerned with particulars as well as with universals, then it has also to be recognized that a concern for certain values other than those belonging to truth-seeking and problem-solving is internal to science. For at least some of the types of particulars which are objects of scientific inquiry have to be understood as wholes which maintain themselves in the world or fail to maintain themselves in the world. They prosper and flourish or they fail and decline. We need to employ in speaking of them some concept very like Spinoza's *conatus in suo esse perseverandi*.

Thus not only does it make sense to speak of the good of such particulars, we cannot even study them without some reference to that good—without indeed an ability to understand the particular from the perspective of its own *conatus*, its own striving towards its own good. It may seem somewhat odd to speak of the good of a hurricane or a salt marsh; it is surely not odd to speak of a salt marsh as flourishing or a hurricane as failing. But the concepts of the good of a tree, of a dolphin, or of a gorilla are crucial to inquiry into trees, dolphins, and gorillas. Unless one understands what it is for a tree, dolphin, or gorilla to flourish, one simply fails to understand them. This is why for many purposes one cannot study animals such as gorillas with profit outside their natural habi-

tat or by methods other than those which approximate to participant-observation. But a condition of success for such inquiry is a treatment of the tree, dolphin, or gorilla with a kind of regard which is in fact ruled out by a purely experimental relationship, on the traditional view of that relationship as being governed only by the traditionally acknowledged internal norms of scientific research.

Hundreds of years of understanding nature as the mere instantiation of universals, where particulars are nothing more than specimens for study in the quest for general truths, have contributed strongly to the ecological violence which we have done to nature. That is, not merely the forms of our economy or of our technology, but also—perhaps surprisingly—those of our science have contributed to our estrangement from nature and from other species. To say this is in no way to decry experiment, the search for laws, or the construction of fundamental theory. It is to say that the norms which are internal to the project of understanding nature and the individuals within it turn out to be broader and more complex than has been generally acknowledged. The S.S. doctors were indeed violating a relationship to men and to nature which is an essential part of the project of understanding men and nature; they thus failed as scientists and not only as men and citizens. Being a scientist then is a morally complex matter. It is often thought that the moral problems of medicine spring primarily from its professional and not from its scientific character. *Qua* scientist the physician has no particular moral commitment except to truth and the like; *qua* physician he of course has those moral problems which arise from his professional relationship to his patients. This is the view that we are rejecting (although we fully recognize that the professional relationship does engender its own set of moral problems). The importance of rejecting it will become clear when we consider the moral dimensions of the problem of medical error. To the reformulation of that problem we now therefore return.

### Necessary Fallibility

Precisely because our understanding and expectations of particulars cannot be fully spelled out merely in terms of law-like generalizations and initial conditions, the best possible judgment may always turn out to be erroneous—and erroneous not merely because our science has not yet progressed far enough, nor because the scientist has been either willfull or negligent, but because of the necessary fallibility of our knowledge of particulars. For it is characteristic of empirical, inductively founded “characteristically-and-for-the-most-part” generalizations, as we have already noticed, that they may be the best possible instruments of prediction about particulars, and yet lead on occasion to unavoidable predictive failure as the evolving environment interacts with the particular with which we are concerned. What types of particulars must be understood, at least partly, in terms of this kind of generalization is an empirical question;

for that very reason it is also an empirical question to what degree of error we are liable in a given area. The nature of the gap between theoretically perfect predictive power and our actual predictive powers at their best is itself a notable subject for empirical enquiry, and the answers will certainly turn out to be very different in different areas. The necessary fallibility of the meteorologist may turn out to be of a very different degree than the necessary fallibility of the veterinary surgeon.

The recognition of this element of necessary fallibility immediately disposes of that two-fold classification of the sources of error which we have seen both to inform natural scientists' understanding of their own practices and to be rooted in the epistemology which underlies that understanding. Error may indeed arise from the present state of scientific ignorance or from willfulness or negligence. But it may also arise precisely from this third factor which we have called necessarily fallibility in respect to particulars. If this revision of our view of the sources of error were to be accepted, two very important consequences would have to be faced which fly in the face of contemporary medical attitudes and practices.

The first of these concerns the research programs of medicine. It is not common clinical practice to keep full and systematic records of medical and surgical error. Physicians and surgeons often flinch from even identifying error in clinical practice, let alone recording it, presumably because they themselves hold the very theory of error which we are engaged in criticizing—that is, that error arises either from their or their colleagues' ignorance or ineptitude. But without detailed records of erroneous diagnoses and prognoses, of unpredicted side effects, of failures of effect of treatment, and the like, we cannot provide the empirical basis necessary for any adequate theory of the limitations upon the predictive powers of physicians. Of course, there is nothing peculiar to physicians and surgeons about this lack of documentation of error. Political scientists, economists, and sociologists, for example, also do not usually keep systematic records of their own false predictions, and almost never advert to them in public utterance. Indeed, the only profession of which we know which fully and publicly documents predictive successes and failures is that of horse-racing correspondents in Great Britain. These journalists are engaged in systematically predicting the outcome of flat racing and steeplechasing. Their failures as well as their successes are fully documented in *The Sporting Times*; it is possible to make a precise quantitative assessment of the limits of the predictive powers of the best predictors. Thus, although genuine law-like generalization may not be available as a result of the best possible study that might be made of the behavior of hurricanes, horses, and *homo sapiens*, it may well be made about the predictive powers of those who study such phenomena.

The other consequence of our thesis is practical: it concerns the physician's liability for error and the

patient's attitude toward the physician. At present, the typical patient is systematically encouraged to believe that *his* physician will not make a *mistake*, even though what the physician does may not achieve the desired medical objectives, and even though it cannot be denied that *some* physicians do make mistakes.

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The encouragement of this inflated belief in the competence of the physician is of course reinforced by the practice of not keeping systematic and accessible records of medical error. Yet everyone knows that this is a false confidence. It is, one suspects, only recently that the chances rose above fifty percent that a randomly chosen patient with a randomly chosen disease who encountered a randomly chosen physician would benefit from the encounter. And the current high incidence of iatrogenic illness constitutes a medical problem of enormous proportions, well recognized within government agencies and segments of the medical profession, but only dimly suspected by the public at large. There is still a relatively high probability of a patient suffering from medical error.

It is just here that the moral dimension of a science concerned with particulars becomes important. What patients and the public have to learn is to recognize, accept, and respond reasonably to the necessary fallibility of the individual physician. The physician-patient relationship has to be redefined as one in which necessarily mistakes will be made, sometimes culpably, sometimes because of the state of development of the particular medical sciences at issue, and sometimes, inevitably, because of the inherent limitations in the predictive powers of an enterprise that is concerned essentially with the flourishing of

particulars, of individuals. The patient and the public therefore must also understand that medical science is committed to the patient's prospering and flourishing, and that the treatment of the patient is itself a part of that science and not a mere application of it. The patient thus must learn to see himself as available for clinical study by methods which aim at his good, but which may do him harm. Indeed, the familiar distinction, comfortable to the public but suspect to clinical researchers, between therapeutic medicine and medical research seems utterly to break down. Since the effect of a given therapeutic intervention on a given patient is always to some extent uncertain no matter how much is known about the general characteristics of interventions of that type, every therapeutic intervention is an experiment in regard to the well-being of that individual patient.

All experiments necessarily involve the possibility of failure in the sense that the expected or hypothesized outcome may not occur, whereas other outcomes, unintended and not usually specifiable entirely in advance, may occur. Thus the possibility of failure, and even of damaging failure, is linked conceptually—and not merely contingently—to the notion of experimentation, and therefore to the practice of clinical medicine.

It should seem obvious at this point that it is an error to link the notion of injury directly to the notion of culpability. A physician may not merely fail to cure, but may possibly damage a patient, without in any way violating the canons of impeccable practice. A common response to such outcomes is an attitude of humility in regard to the state of development of medical knowledge, but we are suggesting that what is perhaps more appropriate is humility in regard to the richness and diversity of individuals regardless of the state of medical science. If we are right, one consequence is that the hypothetical clinical practitioner who is fully informed of all the general principles that apply to medical practice—not merely to an extent reflecting the present state of medical knowledge, but even to the unachievable extent that represents the aspirations of medical research as an ongoing program of inquiry—even such an Olympian physician would be far from infallible. Indeed, he would stand humbled by the mysteries of individual diversity, and would know that an inquiry into the distinctiveness of each individual patient is an essential ingredient in his practice. And inquire as he might, there would always remain the prospect of his harming the patient whose well-being is in his trust, for even that inquiry itself, that effort to understand the distinctiveness of the patient, could be damaging in unexpected ways. And if such is the plight of our hypothetical physician, actual physicians of course are also limited by an irredeemably inadequate understanding of the individuals in their care.

Again, we may seem open to the charge that we have simply emphasized the obvious. Of course, good clinical practice involves respect for the importance of individual distinctiveness: witness the widespread

acknowledgment of the importance of the individual medical history as a part of competent clinical practice. But, again, we believe that the appearance of obviousness is illusory. For what we take it we have shown is not simply that a regard for the particular, for the individual, is essential to good medical practice. Rather, we have provided a theoretical account of why it is that knowledge about the individual patient is not merely essential, but is always and necessarily potentially inadequate to the extent that damaging error may result from conscientious, well-motivated clinical intervention by even the best-informed physicians.

It follows that injury is no proof of culpability. If physicians were to act as if they recognized this point, they might become far less reluctant to acknowledge, systematize, and learn from injury. But that would re-

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quire a widespread willingness on the part of patients also to acknowledge the point, and thereby to lower their expectations about what physicians can accomplish, and to refrain from assuming, even in the disappointment or despair that attends iatrogenic injury, that the physician is culpable.

The distinction between this view of the patient's role and attitude toward physicians and that which is current is too obvious to need emphasis. The first reaction of physicians to the invitation to dispense with the masks of infallibility is likely to be a humane alarm at the insecurity which a frank acceptance of medical fallibility might engender in the patient. But we wonder whether the present situation, in which the expectations of patients are so very often disappointed during medical treatment, is not a worse source of insecurity. It is certainly one key source of malpractice suits. Indeed, a consequence of our view ought to be a rewriting of the laws on malpractice and compensation for iatrogenic injury in such a way as to acknowledge the inevitability of medical error and to make the burden of proof on those who allege malpractice quite different than it is now. This last practical consequence may not itself make our thesis more credible to physicians, but it certainly ought to make it more interesting.

### Malpractice and Compensation Policy

We have said that the concepts of culpable medical error and of entitlement to compensation for injury have historically been more closely linked than is appropriate. John Boyden, in his study of medical injuries in hospital patient records, undertaken for the Commission on Medical Malpractice for the Department of Health, Education, and Welfare, proposes consideration of medical injury insurance which would compensate patients who suffer iatrogenic injuries, independently of whether or not such injury was the result of blameworthy medical treatment. The Boyden study thus accepts the distinction between injurious action on the one hand and culpable malpractice on the other, although it addresses no attention to the task of characterizing either category. The question of what constitutes culpable malpractice, like the question of what constitutes injurious medical activity, is of fundamental importance in the determination of a specific policy governing the relationships among culpability, sanctions, and compensation. We will not here attempt to answer this question, but do wish to shed some light on what sort of question we take it to be.

The determination of whether or not a given instance of medical action is an instance of malpractice is a question not of whether the action had undesirable consequences, but rather whether the action was justifiable as performed. To be sure, the question of the justifiability of an instance of medical intervention may involve a consideration of what the expected consequences are, and this consideration may involve reflection on the past consequences of similar medical interventions under circumstances similar in relevant respects. But none of that depends on the actual consequences of the intervention in question. The specification of the canons of good medical practice thus will depend heavily on an accurate understanding of what has worked in the past, and of the degree to which autonomy of judgment in clinical circumstances tends to be conducive to a good medical result. Once those canons are specified, however, whether or not they have been honored becomes a simple matter of fact, to the determination of which the subsequent well-being of the patient is not material.

A profession concerned to minimize malpractice should then specify as well as possible the canons of good practice, it should require as an inherent part of good practice the maintenance of accurate medical records including records of error and injury, and should adopt some effective mechanisms to identify culpable error. There should be procedures of due process, and sanctions for the performance of culpable error. But no injury to a patient should be required as part of the proof of any malpractice claim. If a violation of good medical practice is of a *kind* that is likely to cause injury that proper treatment would have avoided, the absence of *actual* resulting injury is simply not material to the claim that malpractice has occurred.

In this respect, malpractice, we are claiming, is properly viewed as a formal violation of rules, procedures, canons of practice—what philosophers among themselves would describe as a deontological offense. It is, of course, possible that there be a broad spectrum of degrees of seriousness of such offenses, and correspondingly of appropriate sanctions, ranging from the most gentle—calling the error privately to the attention of the offending physician—to the most extreme, at least within the profession: revocation of licence to practice.

On this conception, the primary burden for discovering malpractice, bringing charges, supporting claims, and imposing sanctions falls not to the individual injured patient, but to those who are concerned with the integrity of the medical profession, including perhaps most prominently the practitioners of medicine themselves. Injury at the hands of physicians is quite another matter. Having argued that the question of physician culpability is independent of the presence of injury to the patient, in the sense that there can be malpractice without injury and injury without malpractice, we need to reassess the relationship of injury to the entitlement to compensation. That is, we need to reconsider the formulation of a policy for societal response to iatrogenic injury.

No specific policy follows from our theory of medical fallibility, nor will we argue for any specific policy. Rather, we will focus attention on the question of what sorts of policy make sense in light of that theory, and we will thereby contend that a revision of current policy is in order. To do so, we will describe two alternative policies for which one could argue with the support of our theory of medical error—one in what might be called a liberal social-welfare tradition; the other in the spirit of what might be called a more conservative individualist viewpoint.

The liberal argument might go like this: The costs of medical care are borne broadly by all those who support it, including its specific beneficiaries. Where there is no specific beneficiary, a medical cost is absorbed into medical overhead. For example, some drugs purchased by hospitals are spilled, contaminated, made obsolete, or otherwise rendered useless. The costs of their original acquisition are passed on in various ways as a part of the overhead of operating a hospital. Obviously, such costs cannot be passed along to direct beneficiaries, since, by hypothesis, they are not used to the benefit of anyone.

Iatrogenic injuries incur costs—most obviously those resulting from the additional medical care that is required in the treatment of the injuries, but also including the secondary costs associated with disability in all its forms. One could, of course, argue that these costs ought to be borne by the individual patient since they are incurred in the treatment of particular patients, and hence specific beneficiaries of the expenditures can be identified. An alternative view of the matter, however, would be to view the costs resulting from iatrogenic injury as akin to those medical costs which cannot be associated with specific

beneficiaries, and hence become absorbed into the general overhead of medical care.

Iatrogenic injury, as we have argued, is to some extent inevitable. Whether or not one will fall victim to it is largely a matter of chance. It seems less than just to have the full burden of its costs compound the plight of those victimized by such injury. Consider once again the example of the smallpox vaccine. In fact, vaccination against smallpox is no longer used in the United States precisely because it has been so effective that the risk of falling victim to side effects of the vaccine is greater than the risk of getting the disease now that it has been largely eradicated. But this does not diminish the present usefulness of the example. If we were to plan a public health program of vaccination of a population of a million persons, we would have good statistical grounds for believing that one would succumb as a result of the vaccination. Let us ask what the best way might be of responding to such an instance of illness. We are aware that culpable error is possible; one might be given spoiled vaccine, incorrect dosages, or in some other way mistreated. But even if no such culpable errors take place, someone will likely succumb.

Of course, we could simply reflect the present situation regarding malpractice claims; that is, we could undertake the program with the view that whoever falls victim to the vaccine will be entitled to compensation if and only if the victim can prove that the illness resulted from malpractice. If no such claim can be supported, then whether or not the victim is treated may depend in part on the extent to which the victim has private means or adequate health care insurance.

But we might well prefer to anticipate the iatrogenic illness and to respond to it in a different way. The program of vaccination will incur costs which must be determined in advance. One can estimate to some extent how many people will be victims of the program, and how much it will cost to attend properly to them. One can then allow for covering such costs in the planning of the program, so that the statistically expected victim of the vaccine can be cared for as a part of the total vaccination program, simply because that victim's illness and the medical expenses associated with it flow directly from the program as a consequence that could be anticipated, even though the specific individual could not be identified beforehand.

It is easy to imagine every one of the potential subjects of the vaccination agreeing to such a provision for compensation; it is similarly easy to imagine objection to the prospect of being injured without compensation. It seems more just, when one knows that someone will be victimized by a program, to construe the costs of caring for the victim as part of the cost of that program, than to let the financial burdens of such care fall randomly where they may.

With respect to this example of smallpox vaccination, it seems clear that it is preferable to build into

the program of medical treatment an anticipation of the costs of iatrogenic injury. This example should be considered as a model or metaphor for medical care generally. Thus, since injurious medical error is unavoidable, and medical care will thus have its victims no matter how conscientiously it is provided, the need for compensation even in the absence of culpability can be anticipated in advance, and can be construed as an expected part of the total operating costs of a system of health care delivery. The basis for entitlement to compensation thus would become the fact of injury, and not culpability in its cause.

None of this is to claim that questions of malpractice and of entitlement to compensation are wholly unrelated. For punitive damages, one would have to show that one was victimized by battery or negligence. Perhaps even for compensation beyond the direct costs of medical care, one might have to show culpability. And, indeed, those who are responsible for providing compensation on the basis of injury, for example the writers of insurance policies, might well be intensely interested in the possibility of making claims against individual practitioners and collecting damages from them where culpability can be shown. But the striking difference between such a structuring of the system of compensation and the present system is that the burden of proof to show culpability would no longer rest with the victim of medical injury; for the victim, compensation would depend only on the fact of injury. The burden of proof for showing culpability would fall instead to those whose responsibility it is to maintain the integrity of the profession, and to those who, because of their involvement as insurers against medical injury, seek recompense for claims in cases when the claims result from culpable error.

But there is a conservative response to the sort of argument we have just presented. It might go like this: Those structures and institutions that provide social services, ranging from urban governments to medical insurance organizations, are simultaneously under ever-greater pressure to increase services and ever more stringent economic restraints. Further, as a matter of empirical fact, such organizations suffer from an inherent tendency to become ever less efficient and effective as they grow in size and scope, trying to respond to an ever-expanding range of human needs and wants. The consequence is that it is an error to expect our limping, faltering social institutions to be able to undertake such an enormous burden as that of underwriting the costs of compensation for iatrogenic injury. Even without that added economic burden, our health care system is currently flirting with fiscal collapse. The problem of responding to iatrogenic injury should not, therefore, be addressed on the model of the smallpox program, within which there is a high degree of predictability and control. Rather, we should recall again the model of the hurricane as an unpredictable and uncontrollable source of natural disaster. On this model, iatrogenic

injury, in those cases where it arises in the absence of culpability, is precisely a species of natural disaster, the costs of which must be borne as the costs of disaster are borne generally. That is, whereas some disaster relief is provided by private insurance and some, in cases of particularly large scale disasters, is provided by government intervention, there is no sense in which a doctrine of *res ipsa loquitur* applies; the fact of victimization by a disaster does not itself provide a basis for entitlement to relief or compensation. Individuals are prudent to insure against disaster, and government and charitable agencies appropriately provide relief within the limits of what they can afford. But falling outside the scope of either sort of relief are some cases that are simply disasters—a lamentable, but ultimately ineradicable, part of life. Even when the injury is clearly shown to be the result of physician error, no entitlement to compensation exists in the absence of demonstrable negligence or battery, for, as we have shown, in one of its forms physician error is most properly viewed simply as a kind of natural disaster.

The choice between policy responses of these two sorts will depend on a large number of complex considerations. What is notable, we think, is that both of these kinds of policy, one of which enlarges the scope of entitlement to compensation, and one of which reduces it, are alike in that they exhibit no direct conceptual linkage from physician-caused injury, through liability, to entitlement to compensation; nor is there a conceptual linkage from malpractice to culpably caused injury. In both these respects, the hypothetical policies we have considered differ from prevailing policy, which seems instead to be based on an outworn understanding of medical error.

We make no attempt here to resolve this question of policy. Rather, it has been our objective to clarify the nature of medical error as a preliminary to such policy determination. Actual policy specification will depend on judgments about the cost and efficiency of various ways of supporting health care, about the extent to which medical error is of the culpable sort, and about many other factors. We have raised the policy question because we believe that it requires reconsideration. We have affirmed the outline of a theory of medical fallibility in the belief that any acceptable policy must rest on a clear understanding of the nature and origins of the error to which it is designed to respond.

### Conclusion

It is time to take stock. There is a substantial and growing literature on the question of insurance against medical injury under a variety of programs. Over the last decade, the notion of compensation for injury to subjects in biomedical research has received considerable attention, and more recently, the notion of injury as a basis for entitlement to compensation has been extended to iatrogenic injury in therapeutic contexts as well. Thus, policy reform proposals, while they have not been adopted, are at least familiar.

What then is novel or valuable about what we have said?

The reasons we have offered in support of our conclusion that revision is necessary in our societal response to medical error include a new ingredient—that is, a theoretical exposition of why it is inherent in the nature of medical practice that error is unavoidable, not merely because of the present limitations of human knowledge or even the limits of human intellect, but rather because of the fundamental epistemological features of a science of particulars. That medical practice involves error not only assuredly, but necessarily, is a fact that should undergird a revised view about response to such error, and thus should contribute to strengthening the case for policy reforms.

We labor under no delusion that we have proposed a specific policy for response to medical fallibility or even a complete theory of it. Certain kinds of iatrogenic injuries do not result from errors at all—for example, predictable side effects of drugs which are utilized in full awareness of their side effects because,

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*... iatrogenic injury, in those cases where it arises in the absence of culpability, is precisely a species of natural disaster, the costs of which must be borne as the costs of disaster are borne generally.*

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all things considered, the decision to accept the side effects constitutes the best available response to the presenting symptoms. A complete policy regarding iatrogenic injury would have to include specification of just which sorts of injury constitute a basis for entitlement to compensation, and which sorts constitute a part of the discomfort and physiological disruption that attend medical treatment. Many other questions, as well, would need to be addressed before a specific policy could be affirmed. Nonetheless, we hope to have shown that while a philosophical analysis of issues in medicine cannot by itself resolve questions of policy, the attempt to fashion an enlightened policy toward medical error must rely in part on considerations drawn from the philosophy of medicine—an inquiry which we see as necessary to a more thorough understanding of medicine as a science and as a practical art.

And finally, we hope to have made a point about medical education. We often hear it said that exposure to the liberal arts is advisable for medical students, not for its practical utility, but because of the intrinsic rewards of liberal inquiry. We stand firm on the reality of such rewards, but that is by no means the whole case for humanistic studies in health care training. On the contrary, we take it that our inquiry into the nature of medical fallibility illustrates the way in which, even on utilitarian grounds, the interests of the medical profession would be well served by a more philosophically informed view of its own activities.