

Chapter 1

Introduction

On September 17, 1999, Jesse Gelsinger died at the age of 18 as a result of participating in a medical experiment at the Hospital of the University of Pennsylvania. Gelsinger had a mild form of a rare metabolic disorder called ornithine transcarbamylase deficiency (a missing enzyme), a condition he could control with drugs and a low-protein diet. The severe form of the disease caused infants to die a few weeks after birth. Dr. James Wilson of the University of Pennsylvania had a promising therapy for the disorder and wanted to try it. The therapy involved replacing defective genes with genes that would produce the enzyme. The replacement involved injecting a virus (adenovirus) that had the relevant gene. The therapy was promising not only because it might cure this disease but also because it was one of the first tests of gene therapy itself, a general method that could treat a variety of diseases. It was risky, though, because the virus itself could cause trouble.

For reasons that are still unclear, the therapy went awry, and Gelsinger died from multiple organ failure. In hindsight, it became clear that many errors were made. Gelsinger was not fully informed of the risks. Wilson had apparently failed to report less serious problems with other patients that might have led officials to look more carefully at the proposed experiment. Plus, Wilson had a financial interest in its success. (The relevance and seriousness of these errors, and others, has been disputed: see Miller 2000.) As a result of these errors, Wilson's entire institute was prevented from doing research on human subjects, and rules were tight-

ened all over the United States (and possibly in other countries too). The investigation of this case is still going on, six years later.

Note, though, that Gelsinger was reasonably healthy and did not need the therapy. He agreed to be a subject because he wanted to help the infants. (He said to a friend, “What’s the worst that could happen to me? I die, and it’s for the babies” [Stolberg 1999].) But the babies would die anyway. Why couldn’t the new therapy be tested on them? It could do no harm, and it might work.

There were reasons for using an adult (personal communication from Arthur Caplan, Aug. 23, 2002). First, the logistics of using babies would be difficult. The experiment would have to be done quickly after suitable subjects were identified. Evidently, though, the logistical problems were not so great as to prevent the researchers from initially thinking about an experiment on babies.

Second, the trial was a “phase 1” trial, which means that its “purpose” was to assess side effects, dosage, and so on. And it would be difficult to assess side effects in babies, who would live for a shorter amount of time than adults, if the therapy failed to help. The rules did not allow anyone to consider the possibility (however remote) that the therapy might actually have helped. Because there was officially no benefit (because the official purpose was not to assess benefit, although benefit could have easily been assessed), fully informed consent was required according to United States regulations (e.g., Department of Health and Human Services 2002).

Given this second constraint, the question was whether parents could consent. It was concluded that they could not. Why? Because they were “coerced” by their child’s disease into agreeing (Miller 2000). Or perhaps because they were under such stress that they could not decide rationally in the very short time that they would have.

Notice that I use the passive, “it was concluded.” The responsibility for this principle is difficult to locate. Wilson’s team had initially proposed to try the experiment on infants. Miller (2000) blames the Food and Drug Administration, but Wilson had apparently engaged in self-censorship and did not even get as far as asking the FDA. Rather, he was advised by the director of Penn’s Bioethics Center, Arthur Caplan, that using infants would not fly. Caplan has said that he was not giving his

own opinion about what should be done but simply informing Wilson of the consensus view in the field of bioethics.

I do not want to dwell further on the facts of this case. That would take at least another book. Rather, I want to discuss the principles involved. Suppose it is true that the experiment could have been tried on infants who would have died anyway.

In what sense are parents “coerced” into agreeing? The relevant sense is that the therapy has a very low but nonzero probability of a large benefit—that is, saving their infants—and a low probability of causing a small harm, such as allowing the parents to keep false hopes alive for a few more days or weeks. Faced with such a decision, many rational people would consent. The prohibition of the research on infants took that decision from them; someone knew better what was in their best interest.

Such an offer of benefit shares one feature with true coercion. If I point a gun at you and say, “Your money or your life,” it is reasonable for you to give me your money. Any rational person would do it, just as any rational person would accept the offer of a potentially life-saving therapy. So coercion involves presenting people with decisions that a rational person would make only one way, but the converse does not follow: decisions that can be rationally made one way are not necessarily all coercive.

What is the difference? Coercion seems to involve a threat of a loss. But that is not quite right, because “loss” and “gain” are relative terms. I shall argue later that the critical difference is that coercion involves the threat of a net loss for everyone relative to the status quo, what economists call a “deadweight loss.” True coercion is sometimes necessary, as when we threaten punishment to prevent crime; but it is not a good way to recruit subjects for medical experiments.

In sum, it is conceivable that the death of Jesse Gelsinger was the result of an error in reasoning, a confusion on the part of almost everyone involved. It may have resulted from a principle of bioethics.

Such errors are found throughout the enterprise of applied bioethics. Of course, bioethicists who influence these outcomes would not admit to errors. I shall argue here, though, that they truly are making errors.

1.1 What this book tries to do

The principles of coercion and informed consent are examples of a set of principles applied by the new field of applied bioethics. These principles sometimes have the force of law, yet some of these were not adopted by any legislature nor promulgated by any regulatory agency. They come from a kind of consensus among people who call themselves bioethicists. Bioethicists have some form of academic training, usually in philosophy. However, the field of applied bioethics has to some extent taken on a life of its own, with its own degree programs, local consultants, and committees. It is this applied field that I am “against.” It has become a kind of secular priesthood to which governments and other institutions look for guidance, but it lacks the authority that comes from a single, coherent guiding theory in which practitioners are trained.

It is interesting to contrast bioethics and economics. Today, economists advise governments, corporations, and universities, and they are taken seriously (although one might argue not seriously enough). Economics has a coherent theory of what it is doing, and the theory has withstood empirical challenge, or modified its assumptions in response to evidence. Economists cannot predict the future all that well, but they can give the best advice there is about how to make decisions under uncertainty, and they can explain at length why it is, in fact, the best advice.

Applied bioethics, by contrast, tends either to be suspicious of theory, or else it attempts to apply different, sometimes competing, theories (Caplan 1992; Wikler 1994). The major text in the field, Beauchamp and Childress (1983, and subsequent editions), presents utilitarian and deontological (non-utilitarian) theories as if they were both relevant, despite their divergent positions on many issues. In practice, bioethical advice tends to be based on tradition and intuitive judgments. Often, its advice is reasonable and leads to good outcomes. But, as in the Gelsinger case, we might well ask where these judgments get their authority to override considerations of consequences. If the consequences of a decision are clearly expected to be worse—as in the case of testing the therapy on healthy adults instead of babies who had nothing to lose—where do bioethicists get the authority to cause harm?

It could have a coherent theory paired with an expertise in the knowledge of that theory. Namely, it could embrace utilitarianism. Utilitarian-

ism holds that the best option is the one that does the most expected good (“maximizes expected utility”). Such a theory would never yield decisions that clearly go against the good of those involved, such as the decision to use healthy adults in the experiment. Expertise is involved in less clear cases because the prediction of expected good is often complex and far from obvious. Utilitarianism, when applied, draws on economic theory, which also makes predictions of expected good in complex situations.

It also draws on an applied field called decision analysis, which, in turn, is based on decision theory, a mathematical approach to the analysis of decisions. Indeed, the discipline of decision analysis is the closest thing to applied utilitarianism. Decision theory, like utilitarianism, defines the best option as the one that does the most expected good. The main difference between what is called utilitarianism and what is called decision theory is that the latter does not usually concern itself with trade-offs across people, where one option is good for one person and another option for another person. But the theory can be extended to handle this case.

I should note that decision analysis, as practiced, often takes non-utilitarian factors into account, that is, factors, such as fairness, that do not concern the good of any individual people. But I shall stick mainly to the limited form of decision analysis that considers only the good of individuals, with no separate idea of “social good” except for the sum of what is good for individuals.

I should also note that much of the scholarship in bioethics is, in fact, based on utilitarian theory and looks favorably on that theory. I am, as I have said, talking about bioethics as it is applied, not scholarship. Perhaps the utilitarian scholarly writings would have more influence on practice if they were combined with the tools of decision analysis.

In this book, I want to discuss several issues that engage bioethics today, and then show how these issues can be illuminated by applied utilitarianism, in the form of decision analysis. Thus, what I have to say is “against bioethics” but it is also “for” an alternative.

I shall not carry out a formal decision analysis of every issue. Indeed, I shall sketch such analyses for only a few issues. This is not a textbook

of decision analysis.¹ Rather, I shall point to the relevant elements of decisions that would have to be included in an analysis. In some cases, it is clear that some of these elements are very difficult to quantify, and a full decision analysis requires quantification. For example, a decision may hinge on some value that is difficult to measure, such as the harm that is done to a person when his wishes are violated after his death. In such cases, I think it is still a contribution to point out where the difficulty is. The fact that we have trouble measuring this value does not imply that it doesn't exist, and it does not imply that it no longer determines the answer about what we should do. If we make the decision in some way other than by using our best guess about the quantity in question, then the decision-analytic approach tells us the conditions under which we would make the wrong choice.

It is surely true that the subjective estimation of values and probabilities required for decision analysis is prone to error. The question is, compared to what? (This is a common question asked in decision theory.) The alternative is often some rule. Yet, in many cases, the rule is almost certain to make even greater errors. For example, as I shall discuss later, the decision about fetal testing should, according to decision analysis, depend heavily on the mother's values concerning birth defects, miscarriage, and abortion (Kupperman et al. 1999). Surely, better decisions would result from even a crude attempt to measure such values—even so crude as asking the mother how she feels about these outcomes—rather than from imposing some fixed rule on everyone, such as “amniocentesis after age 35.” In other cases, the alternative is not a fixed rule but someone's intuitive judgment. We have learned that such judgments are both highly variable from person to person and also subject to systematic biases (Baron 2000).

Decision analysis is also difficult and time consuming. I shall not be recommending, though, that it be done very often. Rather, I shall argue that our thinking about issues should be informed by its perspective. This is why, in this book, I shall dwell mostly on discussions of what is relevant in decision analysis and what is not.

¹For that, see: Baron 2000 for a quick introduction. Some of the many introductions are: Keeney and Raiffa 1993; von Winterfeldt and Edwards 1986; and Hunink et al. 2001.

I shall also make use of the general perspective on decision making that utilitarian decision analysis provides. This perspective is quantitative: it makes distinctions between large and small benefits, between large and small harms, and between high and low probabilities, even in the absence of precise quantification. It is thus less likely to suffer from being penny wise and pound foolish. It also looks at the big picture, focusing on all consequences; it can do this because it thinks of good and harm quantitatively so that they can be compared across different kinds of outcomes. It does not isolate immediate effects, or effects that are psychologically salient. It also compares possible options to each other, not to some nonexistent utopian ideal, nor just to the status quo or the result of doing nothing. Finally, it is future oriented; decisions, after all, affect the future, not the past. This general perspective provides us with a useful way to think about decisions, even if we do not make use of a single number.

Similar to economic theory, decision analysis need not have the last word. Economists don't usually control policy. They do provide the background assumptions for policymakers. If bioethics were to take decision analysis as its basis, it would have the authority of a single, well-reasoned theory, an authority it now lacks. If officials then wanted to override its recommendations, they would at least know what they were doing. Decision analysis will not provide a philosophy on which everyone could agree, but the usefulness of a theory may have little to do with its consensual acceptability (Wikler 1994). People do not agree about economic theory either.

If, on the other hand, decision analysis came to be trusted as a theory, consequences for people would be better, because producing the best consequences is the goal of decision analysis. Perhaps there is some reason against this, in morality or religion, but good consequences are, by definition, good. So giving them up for the sake of some other principle at least requires a difficult trade. Trust in decision analysis, like trust in modern medicine, economics, or other sciences, takes time to develop.

In the next chapter, I shall sketch very briefly a point of view on some of the history and principles of bioethics. Then, I shall describe the basic argument for utilitarianism and its use in decision analysis. I shall not do this in detail. Subsequent chapters will raise some of the subtle issues, and a full explication of these theories is well beyond the limited scope

of this book. But I shall at least try to show that the theory does have a foundation.

The rest of the book will examine illustrative issues chosen mostly because they are of current interest to me and many others. In the conclusion, I try to take a somewhat broader view of the implications of utilitarianism for health and human well-being in general.