Chapter 1

Death by Bureaucrat

■ Chapter Overview

The essence of this chapter is expressed in one Latin phrase—*nullum gratuitum prandium*—there is no free lunch. We live in a world of scarcity, a world of trade-offs. Scarcity requires that we make choices, and every choice is associated with an opportunity cost (the value of the best foregone alternative). Chapter 1 examines trade-offs in the context of the Food and Drug Administration's (FDA) approval process for new prescription drugs. The trade-off faced by the FDA is this: Either the agency can approve new drugs quickly, or it can delay approval to allow for more thorough testing. Rapid release of new drugs into the market allows ill people to benefit from safe and effective drugs at an early date. But shorter testing periods and rapid release also increase the probability that new drugs may be ineffective or even hazardous. Thorough FDA testing reduces the likelihood that an approved drug is ineffective or unsafe, but it also prevents ill people from benefiting from these drugs during the lengthy review period. This is indeed a "terrible trade-off," because each choice carries with it a high opportunity cost.

■ Descriptive Analysis

In approving new prescription drugs, the FDA is faced with a trade-off between Type I and Type II errors. A Type I error occurs when the FDA approves an unsafe or ineffective drug. In contrast, a Type II error occurs when the FDA delays the introduction of a safe, efficacious drug.[1] Figure 1-1 illustrates the trade-off between these errors. The horizontal axis shows the level of scrutiny, or testing, performed by the FDA on a particular new drug. At 0% scrutiny, the FDA does nothing before allowing the drug on the market. Clearly, in this situation the probability of a Type I error is at its highest, as is the potential cost to society of such an error. Alternatively, at 100% scrutiny, the FDA exhaustively scrutinizes every new drug to the point where a Type I error is (virtually) impossible but the probability (and expected cost) of a Type II error is enormous. Thus, as the FDA's level of scrutiny increases, the potential cost to society from receiving a "bad" drug diminishes, but the potential cost to society from *not* receiving a "good" drug increases.

In Figure 1-1, the expected total cost of errors is the vertical summation of the expected costs of Type I and Type II errors. The expected total cost of errors curve reaches a minimum at S^*, where the FDA's scrutiny imposes the lowest possible *total* cost on society (C^*). In an ideal world, society would benefit greatest if the FDA were to set its level of new drug testing at S^*. The evidence suggests that the FDA does not do this, however. Because FDA bureaucrats have more to lose (their jobs and reputations)

[1] The rationale for the FDA is that, absent government oversight, private firms would produce unsafe drugs. Hence, the appropriate null hypothesis is that a proposed new drug is unsafe (or ineffective). Type I errors occur when the null is true but is incorrectly rejected: Thus, a Type I error occurs when an unsafe or ineffective drug is approved by the FDA. Similarly, a Type II error occurs when the null is false but is incorrectly accepted: We have a safe, effective drug being incorrectly delayed or rejected by the FDA.

from approving unsafe drugs than they have to gain from rapidly approving safe, efficacious new drugs, the FDA is biased toward minimizing Type I errors. Thus, we observe the FDA testing at higher levels of scrutiny, such as at S^{FDA}, where the cost of a Type I error is C^{I} and the cost of a Type II error is C^{II}. The total cost to society from this higher level of scrutiny is C^{FDA}, which exceeds C^{*}, the minimum cost.

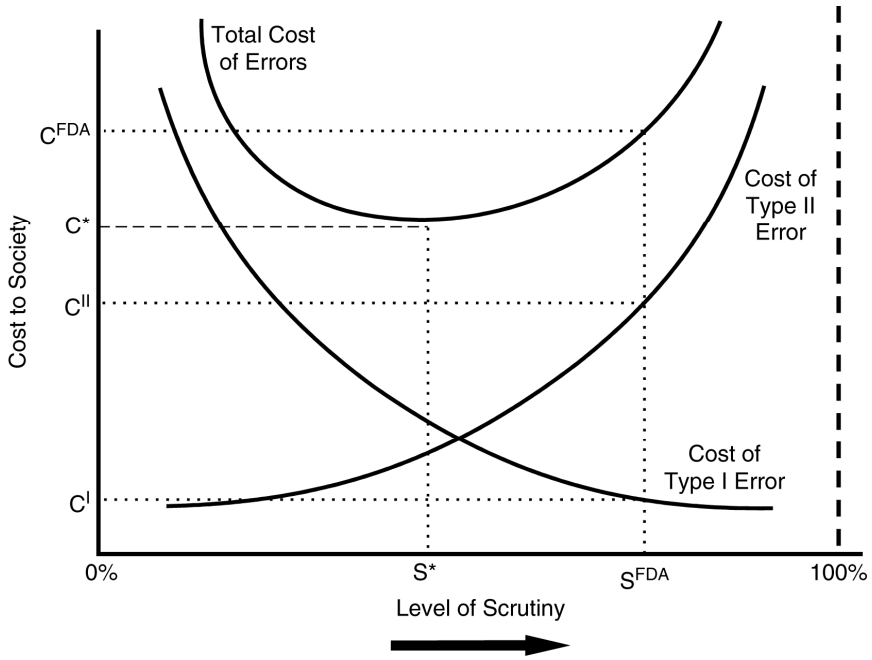

Figure 1-1 The Level of FDA Drug Testing

A crucial change to U.S. drug regulation came in 1992, with the passage of the Prescription Drug User Fee Acts. These laws mandated FDA performance goals in reviewing and acting on drug applications within set time periods, in return for charging fees on drug manufacturers' submissions. The FDA has used these fees to expand its drug review staff and facilities, and the fees now comprise more than half of the agency's drug review budget.

The results have been stunning. Approval times for new drugs have been cut to ten months and instead of lagging the developed world in drug introductions, the United States now leads the world. In the 1980s, less than 10 percent of new drugs were introduced first in the United States before anywhere else in the world. Today, more than two-thirds of new drugs are approved in the United States first. Indeed, for the last decade, the FDA has approved drugs more quickly than any other regulator.

The acceleration in the drug review process has stimulated a major increase in pharmaceutical research and development and an increase in pharmaceutical innovation. There has been an outpouring of new drugs, most notably for the treatment of cancer and the prevention and treatment of heart disease, but also extending across the board to many other diseases. Despite having to pay for FDA review, pharmaceutical firms have earned higher profits. Most importantly, the lives of many thousands of people have been saved or extended. In addition, because drug approval elsewhere is likely to come sooner once the FDA has approved a drug, people in other nations have benefitted, too.

■ Chapter Answers

1. There are three reasons. First, it is costly for people to communicate their wishes to the FDA, so many will rationally decline to do so; hence their preferences likely will be ignored. Second, the owners of pharmaceutical companies surely have strong opinions about what is "best," and their opinions may differ from those held by consumers. And finally, there may be considerable differences across consumers and even across companies as to the "best" policy. Hence, FDA employees are forced to rely on their own judgment when designing and implementing policies.

2. These employees—like all humans—take into account the incentives *they* face. For the reasons outlined in the answer to question 1, as well as because Type I errors are much more apparent that Type II errors, the incentives facing FDA employees are generally much different than the incentives facing the typical consumer.

3. The structure of industry likely would have little bearing on the types of errors that drug firms are prone to make. Firms in a highly competitive drug industry would seek to introduce safe, efficacious drugs, because substitutes for a firm's product are typically close and numerous. If a firm were to introduce an unsafe drug it would immediately lose its market share to its many competitors. The case is similar for an oligopoly or monopoly; alternative drugs that the monopolist *could* produce compete with the ones it *does* produce. This substitution potential acts as a quality monitor. Regardless of the industry's structure, individual firms' brand-name capital plays a key role in maintaining drug quality. In a nutshell, if a firm introduces an unsafe product, the market value of the firm will drop, imposing costs on the firm's owners.[2]

4. A shift in responsibility for errors could reduce the incidence of Type II errors in new drug testing and approval. Currently FDA bureaucrats are largely unaffected by Type II errors and are strongly affected (to the point of losing their jobs) by Type I errors. Restructuring agency responsibility for errors—making bureaucrats more responsible for Type II errors and less or equally responsible for Type I errors—would act to shift the agency's overall level of scrutiny toward S^* in Figure 1-1.

5. The advantages of moving to the regulatory system described would be a reduction in the FDA's current high level of mandated new drug testing, i.e., a reduction in Type II errors. Thus, new drugs would reach the market more quickly than they do now and the drug industry would have more incentive to invest in research and development on a variety of drugs (the faster that drugs reach the market, the sooner that drug companies earn profits on them). Prescription drug knowledge on the part of physicians would have to increase, which is an advantage to patients because doctors will know better what drugs are available and what to prescribe. A foreseeable disadvantage would be that physicians would spend more time learning about new drugs and less time learning about non-drug developments in their medical specialties.

6. The "best" mix is to minimize the expected total costs of error. In this particular example, the optimal level of scrutiny would be that which minimized the total death rate. (This example is a good one to use for the benefit of those students who object to putting a dollar value on human lives.)

[2] For a related article see: Mark L. Mitchell, "The Impact of External Parties on Brand-Name Capital: The 1982 Tylenol Poisonings and Subsequent Cases," *Economic Inquiry*, October 1989, pp. 601–618.