CATO HANDBOOK FOR CONGRESS

Policy Recommendations for the 108th Congress

CATO INSTITUTE
Washington, D.C.

39. The Food and Drug Administration

Congress should

- modify the Food, Drug and Cosmetics Act of 1938 to allow pharmaceutical companies to opt out of Food and Drug Administration testing requirements and to use alternative organizations to certify product safety and efficacy and
- allow individuals the freedom to use any non-FDA-approved product.

Under current law, the Food and Drug Administration must approve all pharmaceuticals and medical devices before they can be marketed. Although the process is often termed an FDA testing program, that agency does little if any actual testing. For example, the developer of a new drug uses its own labs or hires another private company to conduct animal tests on the drug for safety before proceeding to clinical trials for safety and efficacy in people. These tests often are conducted by a medical school department or a consulting firm. When each phase of the testing is completed, the pharmaceutical company submits the details of the testing process, evidence of adherence to FDA protocols, and the test results to the FDA.

FDA officials review the test results at each step, and if they are satisfied, they give the pharmaceutical company permission to proceed to the next step in the testing process. When all the tests and trials are complete, FDA officials review all the information—often measured in hundreds of pounds or linear feet of reports rather than number of pages—and decide whether the company can market the drug and advertise it to physicians for the treatment of specific diseases and conditions. The FDA exercises very strict authority over what manufacturers can say about their products. Interestingly, over half of product uses are so-called off-label uses as physicians discover that products approved to counter one ailment can be

helpful in preventing or treating other problems. For example, aspirin designed for pain relief turns out to be effective in preventing heart attacks.

Up to 10 years may be necessary to complete the development, testing, and approval process. Some estimates suggest that the cost of bringing a new product from conception to market is on average $400 million. According to the Office of Technology Assessment, the cost of bringing a new pharmaceutical to market is so great that most companies will begin the process only if the market for the drug is expected to be greater than $100 million a year. As a result, companies focus on drugs expected to be ''blockbusters,'' which can be used by essentially everyone with a disease in the expectation that the drug will ameliorate or cure the disease with a marginal risk of causing adverse side effects.

In response to complaints about constantly increasing delays in the drug approval process, the federal government devised a method by which pharmaceutical manufacturers pay FDA to hire and retain additional drug application reviewers. The user charge system has reduced the time needed for some phases of the approval process.

The Human Costs of FDA Delays

As an agency, the FDA has a strong incentive to delay allowing products to reach the market. After all, if a product that helps millions of individuals causes adverse reactions or even death for a few, the FDA will be subject to adverse publicity with critics asking why more tests were not conducted. Certainly, it is desirable to make all pharmaceutical products as safe as possible. But every day that the FDA delays approving a product for market, many patients who might be helped suffer or die needlessly.

For example, Dr. Louis Lasagna, director of Tufts University's Center for the Study of Drug Development, estimates that the seven-year delay in the approval of beta-blockers as heart medication cost the lives of as many as 119,000 Americans. During the three and half years it took the FDA to approve the drug Interleukin-2, 25,000 Americans died of kidney cancer even though the drug had already been approved for use in nine other countries. Eugene Schoenfeld, a cancer survivor and president of the National Kidney Cancer Association, maintains that ''IL-2 is one of the worst examples of FDA regulation known to man.''

In the past two decades patients' groups have become more vocal in demanding timely access to new medication. AIDS sufferers led the way. After all, if an individual is expected to live for only two more years, three more years spent testing the efficacy of a prospective treatment does

that person no good. The advent of the Internet has allowed individuals suffering from specific ailments and patient groups to use websites and chat rooms to exchange information and to give them an opportunity to take more control of their own treatment. They now can track the progress of possible treatments as they are tested for safety and efficacy and are quite conscious of how FDA-imposed delays can stand in the way of their good health and even their lives.

Reforming Access to Drugs

So long as the FDA maintains a monopoly on drug approval, however, the agency will remain a bottleneck, slowing the advent of new drugs and the use of ''old'' drugs in new circumstances.

It is time for Congress to break the FDA's monopoly on drug and medical device approval, and on information dissemination about drugs and devices, and to allow individuals to take better control of their own health care.

First, the Food, Drug and Cosmetics Act of 1938 should be changed to allow drug companies to seek certification of their products from nongovernmental organizations. Those organizations would have an incentive to move quickly to design and execute the laboratory tests and human studies that are appropriate for evaluating the safety and efficacy of personalized drugs. Instead of the FDA's approval being required before drugs are marketed, the nongovernmental organizations would be allowed to certify new drugs for particular uses and new uses of old drugs. Those certification organizations would have incentives to allow products on the market as quickly as possible but also incentives to be as honest as possible in evaluating the safety and efficacy of products. After all, like Underwriters Laboratory, those organizations are selling their reputations, which, if damaged, would cause them to lose their customers.

Different kinds and levels of certification should be allowed, with full disclosure of information on safety and efficacy. For example, a testing organization might classify a certain drug as ''risky,'' with the recommendation that it be used only in life-threatening situations when no other therapy is available. Pharmaceutical manufacturers would be permitted to certify their own products if they chose to forgo the use of an independent certification organization. As a compromise with a fully free system of certification, manufacturers as well as private testing organizations might be required to label their products ''Not FDA Approved.''

Some pharmaceutical manufacturers might oppose breaking the FDA's monopoly. Larger companies especially are used to doing business with the agency; they are comfortable with the confidence the public has in FDA-approved drugs; and they could see continuing FDA regulations imposing costs that they could absorb but that their smaller competitors could not. Those attitudes are even more reason to allow private certification.

More fundamentally, in a free society individuals should be free to take care of their physical well-being as they see fit. The advent of the Internet gives individuals even more access to information about medical products and treatments. Individuals should be allowed to choose the treatments they think best. Such liberty does not open the door for fraud or abuse any more than does a free market in other products. In fact, informed consent by patients probably will become more sophisticated as the market for information about medical treatments becomes more free and open.

Suggested Readings

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