The FDA Cannot Be Reformed

BY ARTHUR E. FOULKES

The past year or so has been tough on the Food and Drug Administration (FDA). In that time, the agency has taken heat over the discovery of a statistical correlation between antidepressants and "suicidal thinking and behavior." It has also been accused of sitting on information regarding another statistical correlation, this time between pain drugs such as Vioxx and an increased risk of heart attack or stroke. And it was accused of failing to foresee (and do something about) last fall's flu-vaccine shortage. All of this has led to negative publicity, congressional hearings, and (of course) calls for a bigger budget and more authority for the FDA.

But giving the FDA new powers and more money will only make things worse. The agency is beyond being "reformed." Here is why.

Monopoly

First, the FDA is a legally protected monopoly. It has the sole authority to ascertain the safety and effectiveness of all new drugs and medical devices for the U.S. market. Like all such monopolies, the FDA faces no competition and therefore offers a lower standard of service at a higher cost than would otherwise be the case.

In Europe, for example, makers of low-risk medical devices such as tongue depressors are free to certify that their products meet European Union standards, while private "notified bodies" compete with each other for the business of certifying new, higher-risk devices. This competition gives each notified body an incentive to be both thorough and expeditious. "As a result," Henry Miller, formerly with the FDA, writes, "approval of new medical devices in Europe takes only half as long as in the United States, shortening the development process by roughly two years without compromising safety."[1]

Furthermore, bringing a new drug to market in the United States is "more lengthy and expensive than anywhere in the world," according to Dr. Miller. It now typically takes between ten and 15 years to bring a new drug to the U.S. market at a cost of over $800 million.[2]

All this means the overall supply of new drugs and medical devices in the United States is kept artificially low, driving up the price of existing products. (In this way, large established pharmaceutical companies with expertise in dealing with the FDA benefit from the agency's regulatory regime.) It also impedes the development of marginally profitable health-care products designed to help people with more unusual conditions.

Skewed Incentive System

Another reason the FDA cannot be reformed is its lopsided incentive system. With the exception of politically sensitive drugs, such as new treatments for AIDS, the agency's employees have little incentive to speed new drug approvals and strong incentives for sometimes needless delay. There is often little cost to delaying the introduction of a drug or medical device, while there is a potentially enormous cost—in negative publicity, career damage, and so on—to FDA approval of a drug that is found to have a potentially dangerous side effect. As a result, FDA officials have an institutional tendency to err on the side of caution—even if this keeps a potentially helpful drug or medical device off the market for months or even years. As political scientist Daniel Carpenter has written, "because learning more about [a]

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drug requires additional studies and additional time to review them, *there is always a value to waiting*."[3] This cautious posture—whether it takes the shape of delayed approvals, advertising restrictions, or other types of obstructions—can result in needless suffering and death.

For instance, the FDA for many years prohibited aspirin makers from advertising the potential cardiovascular benefits of their product since the agency had not originally approved it for that purpose and despite widespread knowledge that aspirin therapy could significantly reduce the risk of heart attack in males over 50. In the words of economist Paul H. Rubin, "The FDA surely killed tens, and quite possibly hundreds, of thousands of Americans by this restriction alone."[4]

In another example, the FDA approved the gastric-ulcer drug Misoprostol in 1988—three years after it had been available in other countries. Analyst Sam Kazman estimated—using the FDA's own figures—that this delay may have led to between 20,000 and 50,000 unnecessary deaths.[5]

These are just two examples and obviously do not include the needless suffering resulting from the drugs and medical devices that were *never developed in the first place because of the FDA*. At least two studies have led researchers to believe that the agency dramatically reduced the number of new drugs introduced each year in the U.S. market after its powers were significantly expanded in 1962.[6] (One study, by Sam Pelzman, showed that before 1962 an average of 40 new drugs were introduced each year. After 1962 that figure fell to just 16.)

Mission Impossible

A final reason the FDA cannot be reformed is that it has an impossible task. The agency is charged with weighing the risks and benefits of new drugs and devices for *everyone*. This is preposterous. All drugs have potential side effects. Yet no person, committee, or bureaucratic agency can know what level of risk is appropriate for all people. Only individuals themselves can possibly make this choice because only they know their own circumstances. By attempting to set an acceptable level of risk for everyone, the FDA merely prevents some people from exercising an option they might otherwise be willing to take. The FDA's one-size-fits-all standard cannot possibly "fit-all" since everyone has a different level of risk tolerance.

Private companies could replace the FDA in cases in which consumers demanded product safety and efficacy assurance or whenever manufacturers believed their products would benefit from a private certifier's "seal of approval." Private quality-assurance certifiers already exist in the markets for many consumer products and even—informally—many health-care products.[7] Private providers of assurance for medical products would have market-incentives to protect their reputations for accuracy and fairness while having a further incentive—something the FDA lacks—to act expeditiously.

Americans like to believe they live in a free country. But how free is a land in which bureaucrats and politicians decide which health-care options are legal and which are not? No one is made better off by having peaceful options in life denied him. The FDA is beyond being reformed. It should be abolished.

1. Henry I. Miller, "Americans Are Dying for FDA Reform," Hoover Institution, April 9, 2001.

2. "Backgrounder: How New Drugs Move through the Development and Approval Process," Tufts Center for the Study of Drug Development, November 1, 2001.

3. Daniel P. Carpenter, "Groups, the Media, and Agency Waiting Costs: The Political Economy of FDA Drug-Approval," *American Journal of Political Science*, July 2002, pp. 491–92.

4. Paul H. Rubin, "FDA Advertising Restrictions: Ignorance Is Death," in Robert Higgs, ed., *Hazardous to Our Health?* (Oakland, Cal.: Independent Institute, 1995), p. 30.

5. Cited in David Henderson, *The Joy of Freedom* (Upper Saddle River, N.J.: Prentice Hall, 2002), p. 277.

6. "Theory, Evidence and Examples of FDA Harm," FDAReview.org, a project of the Independent Institute, http://www.fdareview.org/harm.shtml.

7. See Daniel B. Klein and Alexander Tabarrok, "Do Off-Label Drug Practices Argue Against FDA Efficacy Requirements?" George Mason University, March 2003, http://mason.gmu.edu/~atabarro/DoOffLabel18.pdf. Also see "The Sensible Alternative: The Voluntary Provision of Assurance," FDAReview.org, www.fdareview.org/voluntary_assurance.shtml.