38. Third-Party Certification

Congress should

- strip the Food and Drug Administration of its authority to regulate medical devices and allow manufacturers to rely on third-party organizations to certify those devices, or, short of that,
- carefully monitor the FDA pilot program to evaluate the performance of third-party organizations' reviews of medical devices in preparation for allowing third-party certification of medical devices;
- repeal the FDA's authority to review drug efficacy, or, short of that,
- allow manufacturers to opt out of FDA review of efficacy; and
- repeal legislation that requires Environmental Protection Agency registration or notification before new chemicals are put on the market.

Government Environmental and Risk Regulations Cost Money, Lives, and Health

As government expenses go, the $17 billion that taxpayers laid out to operate the federal regulatory agencies in 1997 isn't a lot of money. It represented only about 1.5 percent of the federal budget. Regulations, the products of those agencies, are far more costly and a major drag on the economy. In 1997 regulations cost at least $710 billion, and that figure does not include the benefits forgone because of the money spent to comply with regulations.

Costs of environmental and risk reduction regulations have escalated more rapidly than other regulatory costs, jumping from $79 billion in 1977 to $188 billion in 1997 (in 1995 dollars). In 1977 environmental

and risk reduction regulations accounted for about 12 percent of total regulatory costs; in 1997 the percentage had nearly tripled to 33 percent of the total.

In addition to costing money, regulation causes unnecessary deaths when it delays the marketing and use of life-saving drugs and medical devices. According to one estimate, FDA-imposed delays in the marketing of drugs that were already used in other countries resulted in 200,000 deaths over the past 30 years, and FDA-imposed delays in the marketing of medical devices resulted in several thousand deaths and unnecessary pain and suffering for thousands of other people.

Improvements in life expectancy are closely tied to increases in income, with which people can purchase better housing, food, education, and medical care. Every dollar spent on regulation is a dollar taken from someone's pocket, reducing his purchasing power. Economists have calculated that every additional $5 million to $50 million spent on regulations is associated with a premature death. Regulations that are intended to save lives do, indeed, cause death.

The Alternative to Government Regulation of New Products: Self-Certification and Third-Party Certification

Major federal environmental and risk reduction regulations are intended to prevent dangerous chemicals and products from reaching the market and consumers. FDA approval is required before medical devices can be placed on the market or drugs prescribed. EPA licenses are necessary before pesticides are marketed, and that agency has to be notified and provided with certain product and safety information before any chemical can be marketed.

The government regulatory apparatus that deals with medical devices and new chemical products—whatever their intended uses, including drugs and pesticides—can be closed down. In its place, manufacturers can self-certify the safety of their products or contract with third-party firms to test and certify safety.

The market provides many guides to the safety and efficacy of products. When a shopper is confronted with a choice between a brand he knows and one he doesn't, he may decide to purchase the one he knows, even if it is more expensive. Brand names, valuable commodities because they produce repeat sales, are, in fact, a guarantee of safety and quality. Most companies remind consumers of their commitment to quality products in

advertisements and package inserts that state the companies' guarantees of satisfaction or a replacement product or refund of the purchase price.

Some products have, however, become associated with risk, and consumers may require more than self-certification, so manufacturers may want independent confirmation of the safety of their products. The market can and does respond to those needs without government intervention.

Everyone spends every day in close proximity to a lethal energy source, and most people never think about the danger, much less worry about it. The government doesn't regulate that energy source. Instead, for over 100 years, since well before the federal government imposed its environmental and risk regulations, Underwriters Laboratories has certified the safety of electrical appliances (and many other devices). UL, a private, third-party certification organization, prepares guidelines for the construction of safe wiring and appliances, tests and certifies electrical products at the manufacturers' expense, and inspects manufacturing facilities to ensure that manufacturing standards are met.

The most familiar product from UL is its ''mark,'' which appears as a tag or label on electrical devices. Wholesalers, retailers, customers, developers, builders, and insurance agencies look for that mark, and they are unlikely even to consider a product without it. UL enforces its standards through contracts, and it withdraws its mark from products if manufacturers no longer meet UL requirements. Moreover, UL can and does issue public announcements when products are unsafe.

There are many other third-party certification organizations. Some certify the safety of safety devices—hardhats, face shields, gloves. The American Dental Association establishes and enforces standards for dental products. Green Seal, which contracts with UL for its testing needs, certifies products that it judges to be environmentally friendly.

All those organizations are active in developing standards, better tests, and more efficient processes because they have to compete with other organizations that seek the same business. All of them also recognize that their continued business depends crucially on making accurate determinations of safety. Third-party certification is more than able to replace government regulation of medical devices, drugs, and chemicals now regulated by the FDA and the EPA.

Congressional Actions: FDA

Given political reality, Congress will not abolish the FDA or eliminate FDA authority over medical devices or drugs, but it can accelerate third-

party certification of medical devices and allow the market to measure the efficacy of drugs.

Congress Should Strip the FDA of Authority to Regulate Medical Devices and Allow Manufacturers to Rely on Third-Party Certification

Before 1976 manufacturers could bring medical devices to market without FDA approval. The FDA had authority, however, to prosecute manufacturers and vendors for false or misleading advertising, and it forced the withdrawal of unsafe devices through that mechanism. There is no evidence that FDA premarket regulation of medical devices has produced any increases in safety that justify the costs and delays occasioned by regulation.

Stripping the FDA of premarket regulatory authority over medical devices would open the door to an alternative, more efficient method of ensuring that safe and effective devices reach the market. Reliance on the market will enlist the talents of manufacturers, certification organizations, wholesalers, retailers, and medical professionals who value their reputations and are seeking to expand their markets. In the event a consumer decides he was harmed by a device, he will be able to turn to the legal system to seek remedies and protections. Everyone in the market knows that the publicity generated by such a legal action can cause economic havoc, and every such action is a major caution to any manufacturer or third-party certification organization about the perils of cutting corners.

If FDA regulations are lifted, some manufacturers may still prefer FDA review of their devices because they believe FDA approval will increase the value of their products. They should be allowed to contract with the FDA for certification.

Congress Should Carefully Monitor the FDA Pilot Program in Preparation for Allowing Third-Party Certification of Medical Devices

Congress has recognized that the Medical Device Amendments of 1976 that direct the FDA to determine whether devices are safe and effective for their intended uses also made the FDA a bottleneck in the marketing and use of medical devices. Congress has tried to ease the bottleneck by mandating changes at the FDA, with little effect. The FDA approval process is always behind schedule, manufacturers are often in limbo wait-

ing for FDA decisions, and devices that are used in Europe are not available in the United States.

The Food and Drug Modernization Act of 1997 instituted several changes in the FDA's procedures for approving the marketing of medical devices. It imposes strict deadlines for FDA action on medical devices, but such deadlines have been imposed before with little effect. It exempts some low-risk devices from the approval process.

The act also instituted a pilot program that allows manufacturers to contract with third-party organizations to carry out tests and to certify that some (generally moderately risky) devices comply with requirements for safety and efficacy. The FDA retains the decisionmaking role in that process. The FDA reviews the work of the third-party certification organization, decides if it is adequate, and decides whether or not the device can be marketed.

Congress can carefully monitor that program to see that the FDA provides a fair test of third-party certification organizations' capabilities. If the organizations show themselves to be competent, Congress can recognize the power of the market to measure safety and efficacy and eliminate the FDA's monopoly control over market entry.

Congress Should Repeal FDA Authority to Review Drug Efficacy

The FDA has reviewed drugs for safety since 1938. As a result of the thalidomide scare in the early 1960s, Congress held a series of well-publicized hearings about drugs. According to Peter Barton Hutt, former general counsel at FDA, Congress's addition of the requirement that the FDA review drugs for efficacy was a misplaced response to safety problems. There had been no demonstration of any need for efficacy reviews.

The FDA does not use its own laboratories to evaluate safety and efficacy; it has neither the scientists nor the specialized equipment nor the access to patients that is necessary. Instead, drug manufacturers contract with laboratories, hospitals, and universities to obtain the necessary information. That information is then reviewed by the FDA at a pace that elicits many complaints from manufacturers who have valuable drugs that they get onto the market and into medical practice only years after they are developed and after people who could have benefited from them have suffered and died.

Determining efficacy takes far more time and costs far more than safety testing. In fact, efficacy testing is unnecessary; the market can and does measure efficacy.

Uninformed consumers do not purchase drugs from manufacturers. Drugs are prescribed by physicians, dispensed by pharmacists, evaluated for their efficacy by hospital committees, and, frequently, paid for by insurance companies. Effective drugs will be purchased again and again. They will be recommended by health professionals. The other ones will not.

The FDA has loosened the efficacy-testing requirement for some drugs. AIDS activists persuaded the FDA to suspend the efficacy requirement for drugs that have been shown to be safe and that have a reasonable chance of being effective against AIDS. The FDA has also suspended the efficacy standard for generic drugs. Manufacturers of those drugs need show only that the performance of their products is similar to that of the drugs on which they are based. Generic drugs are widely accepted by physicians and patients, but, of course, both physician and patient have the right to demand the ''pioneer'' drug on which the generic one is based.

Congress can repeal the requirement for FDA efficacy reviews in full knowledge that the market for medical drugs will sort out the effective ones. The elimination of the efficacy review would speed the entry of drugs to market and increase the number of drugs on the market. Furthermore, more money would be available for investing in basic research.

In the absence of FDA efficacy reviews, manufacturers would look for third-party organizations to provide some information about efficacy. In different cases, the manufacturer might desire evidence greater than, equal to, or less than the FDA now requires. The level of evidence would depend on the competition the drug faced in the market and other considerations. Of course, the market for third-party organizations would be competitive. Ones that did slow work would be penalized by the market. Ones that did sloppy work that caused manufacturers to expend money and effort on drugs that weren't effective would be penalized more severely.

Congress Should Allow Manufacturers to Opt Out of FDA Efficacy Review

Congress can require that the FDA review drugs for safety and then allow manufacturers a choice. They could elect to have the FDA review drug efficacy, or they could opt out of the FDA efficacy review. If they opted out, they could market drugs with a disclaimer that said, ''Determined to be safe by FDA. FDA has not reviewed efficacy data for this drug and takes no positions on the efficacy claimed for it.''

Many manufacturers who opt out of FDA review will elect to pay a third-party organization for development and review of efficacy data. This

competitive market will allow the survival of the FDA if it works well in comparison with the third-party organizations. Competition might even result in the FDA's emerging as the premier efficacy review agency.

Congressional Actions: EPA

Any move by Congress to allow third-party certification of the chemicals now regulated by the EPA will be greeted with howls from environmental activists and regulatory agency officials. The activists and officials will loudly proclaim that only their diligence prevents the poisoning of the population by chemical and pesticide manufacturers. A moment's reflection is enough to convince most people that manufacturers don't want to poison their customers. Moreover, manufacturers are well aware of the liability they face if their products are shown to be unsafe. Manufacturers desire to cultivate and maintain good relations with customers, and the power of the market to distinguish among competing products on the bases of price and effectiveness, combined with third-party certification, is enough to guarantee that chemicals will be safe enough under their intended conditions of use.

Congress should repeal legislation that requires EPA registration or notification before new chemicals are put on the market. Congress can start the process of transferring responsibility for chemical safety by making changes to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). FIFRA requires that the manufacturer or importer of a pesticide provide the EPA with detailed results of testing the pesticide for adverse effects on humans and other life forms in the environment, and the EPA then decides whether the agent can be licensed for particular uses. TSCA requires that the manufacturer or importer of any ''new'' commercial chemical supply the EPA with whatever testing information is available, and then the EPA decides whether additional tests are needed before the chemical is introduced into commerce.

If Congress passed the responsibility for the safety of chemical products to manufacturers, most manufacturers would immediately seek expert information about and independent certification of the safety of their products. To supply that need, third-party organizations would spring up to test and certify chemicals. Councils of experts, such as the American Council of Government Industrial Hygienists, would provide recommendations about conditions for safe uses of the substances. Consensus organizations, such as the American National Standards Institute, would also proba-

bly be interested in providing the tests and analyses necessary to certify a substance as safe enough for its intended use.

Wholesalers and retailers will find it in their interests to sell certified chemicals and to base their advertising on the certification. Formulators, who mix chemicals for specific applications, and food processors, who use chemicals, will choose certified chemicals to attract customers. It is entirely possible that some certification marks will come to be associated with more rigorous standards, and the buyer can choose between and among different products on the basis of certification, costs, and other factors.

Suggested Readings

Campbell, Noel D. ''Replace FDA Regulation of Medical Devices with Third-Party Certification.'' Cato Institute Policy Analysis no. 288, November 12, 1997.

Goldberg, Robert. ''Breaking Up the FDA's Medical Information Monopoly.'' *Regulation*, no. 2 (1995).

Yilmaz, Yesim. ''Private Regulation: A Real Alternative for Regulatory Reform.'' Cato Institute Policy Analysis no. 303, April 20, 1998.

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