Is the FDA Becoming an Economic Regulator?

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Evolution of the FDA

The FDA's traditional expertise lies in the science of health and safety regulation, which grew in three major steps over the course of the 20th century. Congress created the agency in 1906 to remove dangerous and misbranded drugs from the market. In 1938, the regulatory process was significantly enlarged when Congress required that testing and approval of new drugs occur prior to marketing. In 1962, efficacy was added to safety as a criterion for drug evaluations, which further expanded the scope of review. Throughout this evolution, the agency retained a health and safety mission, acquiring and using scientific expertise. Other aspects of pharmaceuticals—from pricing to reimbursement to patent protection to the actual prescribing behavior of physicians—were left to other regulatory bodies or to the market.

Mandates for Economic Oversight

Three recent initiatives reflect an accelerating trend to change this paradigm. The Hatch–Waxman Act, enacted in 1984 and under Congressional reconsideration today, uses FDA regulation to determine intellectual property disputes between generic and brand-name drug manufacturers. Pending legislation to permit reimportation of prescription drugs would rely on the FDA's oversight of drug transportation to determine whether American consumers have access to drugs at lower foreign retail prices. Most significantly of all, more formative proposals to add pharmacoeconomic considerations to the drug approval process would direct the FDA to explicitly weigh the relative economic value of competing medications. The combined result of these initiatives would be an agency that is as involved in the economics of pharmaceuticals as it is in the science behind them.

Although discussion of this trend has been largely absent from public debates, its impact is starting to be felt within the agency. According to Benjamin English, Esquire, former FDA regulatory counsel, now with the law firm of Hogan & Hartson in Washington, DC, scientists who review new drug applications are increasingly facing "an external pressure that they don't want to deal with." Mr. England thinks that scientific regulators are "getting in over their heads" and that resulting stress and tension are beginning to permeate new drug reviews.

Three Economic Initiatives

The three initiatives place several new economic responsibilities within the FDA's domain. The Hatch–Waxman Act implemented a complex set of procedures to balance the interests of generic and brand-name drug manufacturers in order to reduce drug costs through generic competition. Among these procedures is the FDA's maintenance of a compilation of all drug-related patents (the “Orange Book”) and its special rules on patents. For example, a generic-drug manufacturer may test a brand-name drug in clinical trials before the applicable patents have expired, but it may not engage in marketing. Enforcement of the Hatch–Waxman Act brings the FDA into the realm of intellectual property regulation. It must maintain the Orange Book of patents and must decide when a proposed clinical trial is legitimate and when it is actually a disguised marketing effort. These responsibilities affect not only health and safety but also economic concerns.

To address cost pressures, Congress is considering whether to legalize the reimportation of American prescription drugs that have been purchased more cheaply abroad back into the country under FDA supervision. Critics of reimportation contend that safety will always be questionable; proponents argue that there is little cause for concern. Support for reimportation is motivated by economics, and in attempting to regulate cross-border drug safety, the FDA would actually become an arbiter of prices.

In some countries, the regulatory review of new drugs that use the same therapeutic mechanism as existing products includes evaluation of cost-effectiveness in addition to safety and efficacy. Proponents of such pharmacoeconomic reviews believe that they can screen costly redundant products from the market and that pharmacoeconomics should become a formal element of the FDA's review process for American drugs. Opponents contend that the market—government regulators—should evaluate the financial implications of new drugs. A mandate to conduct pharmacoeconomic reviews would complete the transformation of the agency into an economic decision-maker.

The FDA at the Crossroads

Given the growing importance of pharmaceuticals in American health care, it should not be surprising that economic factors are increasingly intruding on regulatory decision-making. Some observers, however, including Benjamin England, see a growing conflict between the FDA's traditional health and safety focus and competing concerns that are placing new burdens on the agency.

If the same agency is addressing both public health and economic issues, internal conflicts might be inevitable. Any economic regulatory role for the FDA should result from careful debate rather than from haphazard growth of its mandate.