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EDITORIAL

FDA Under Siege: The Public at Risk

Since its earliest incarnation in 1906, the Food and Drug Administration (FDA) has linked its regulatory responsibilities with the conduct of original research. During the past year, a subcommittee of the FDA Science Board reviewed the agency's intramural science program. Its report, delivered in March 1997, vigorously supported in principle the importance of strong intramural research to the regulatory mission of the FDA but was severely critical of the existing program. While preparing its report, the subcommittee became aware of at least six comparable reviews of the FDA's intramural research since 1955, all of which presented similar findings and recommendations. This history is disturbing, and it raises two questions: Why does the FDA need an intramural research program, and why has the program consistently failed to meet expectations? In answer to the first question, the subcommittee presented three major arguments. First, a strong base of intramural research creates a climate of science and scientific communication within the FDA that enhances the recruitment and retention of high-quality scientific staff. Second, it creates a platform from which agency staff can interact as respected, knowledgeable, and impartial colleagues with the external scientific community, especially with the regulated industries. Third, it plays an important role in informing review and regulatory activities—particularly in areas of rapidly advancing science and technology—that cannot be met dependably from the extramural community in a manner that is cost-effective, competent, and free from conflict of interest.

The report recommends organizational and operational changes that echo those proposed in past reviews and suggests that under normal budget circumstances, its recommendations could be implemented largely by reallocation of existing resources freed up by improved efficiencies, consolidations, and the elimination of substandard research. However, the FDA is clearly not operating under normal budget circumstances. The agency's budget has been essentially flat in constant dollars since 1994, even in the face of increasing regulatory complexity and workload. Therefore, not only are the recommendations of the subcommittee in jeopardy but also the very survival of the intramural research program, as well as the principle of science-based regulation that has guided the FDA for over 90 years.

The FDA budget is under severe pressure, but not only because of balanced budget targets. The agency has become the object of heated political and industrial disfavor over a host of issues ranging from tobacco to the pace of its regulatory review activities. Politically visible champions of the FDA have been scarce, and the agency's budget has been an easy target. Since 1993, an increasing fraction of its funding has come from the Prescription Drug User Fee Act of 1992 (PDUFA I). These funds are restricted to the support of activities that expedite review of human drug applications and enable the agency to meet progressively tighter measures of performance. The FDA appropriation excluding the PDUFA funds has actually declined in constant dollars by about 10 percent since 1994 and will continue to decrease under the balanced budget agreement. Under PDUFA I, the FDA was permitted to use a small fraction of the restricted funds to support research activities that were deemed to be "related to the human drug review process," but in current discussions of PDUFA reauthorization, this modicum of interpretive license has been eliminated. As one immediate consequence, the FDA faces a loss of about 100 research positions.

This further restriction of PDUFA funds is symptomatic of a much deeper problem, which brings us to the question of why previous efforts to enhance the FDA's intramural research program have consistently failed. They failed because of inadequate scientific leadership, inadequate advocacy for science within the agency and its parent department, and congressional appropriations insufficient to meet both regulatory responsibilities and the sustenance of strong intramural research. The conjunction of a steadily increasing regulatory workload with insufficient appropriations will inevitably lead to erosion of the agency's research base. But in this time of unprecedentedly rapid advances in science and technology and their translation into new classes of medical products, such a course of action is extremely short-sighted. It threatens to degrade the quality of regulatory performance and compromise the FDA's capacity to protect the health of the U.S. public.

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