

Peter Barton Hutt Testimony

Major Points

1. Science at FDA today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips.
2. To correct this problem, Congress must commit to a two-year appropriations program to increase the FDA employees by 50 percent and to double the FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8 percent across all segments of the agency.
3. During the past 20 years Congress has enacted more than 100 statutes that directly impact FDA, without providing money and personnel to implement them.
4. There are numerous unfinished FDA safety programs because of a lack of FDA resources.
5. During the past 20 years, faced with its ever-increasing responsibilities, FDA appropriations have resulted in a gain of only 817 employees and a loss of more than \$300 million to inflation.
6. FDA regulation of food, dietary supplements, and cosmetics have been hit especially hard.
7. The deterioration of the FDA Field Force has been equally severe.
8. Science is at heart of everything that FDA does. Without a strong scientific foundation -- adequately funded by Congress -- the agency will flounder and ultimately fail.

Testimony
of
Peter Barton Hutt
before the
Subcommittee on Oversight and Investigations
of the
Committee on Energy and Commerce
House of Representatives
on
Science and Mission at Risk: FDA's Self-Assessment
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Mr. Chairman and Members of the Subcommittee, I am Peter Barton Hutt. I am a Senior Counsel at the Washington, D.C. law firm of Covington & Burling LLP and a Lecturer on Food and Drug Law at Harvard Law School where I have taught a course on food and drug law for the past fifteen years. During 1971-1975 I served as Chief Counsel for the Food and Drug Administration (FDA). I appear before you today in my capacity as a consultant to the Subcommittee of the FDA Science Board that prepared the recent report on "FDA Science and Mission at Risk."

It is meaningless to discuss the scientific needs of FDA without first analyzing the resources -- both money and personnel -- currently available to the agency to accomplish its public health mission. At the first meeting of the Subcommittee I therefore volunteered to prepare a report that would document both the increasing responsibilities imposed on FDA by Congress during the past two decades and the reduced appropriations provided for the agency. My report is included in the Subcommittee's report as Appendix B and is attached to this testimony. Because of its central importance in demonstrating the need for additional congressional appropriations for FDA, I request that my report be included in full in the record of these hearings.

Introduction

Science at the Food and Drug Administration (FDA) today is in a precarious position. In terms of both personnel and the money to support them, the agency is barely hanging on by its fingertips. The accumulating unfunded statutory responsibilities imposed on FDA, the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to FDA for premarket review and approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates -- coupled with

chronic underfunding by Congress -- have conspired to place demands upon the scientific base of the agency that far exceed its capacity to respond. FDA has become a paradigmatic example of the “hollow government” syndrome -- an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates. For the reasons set forth in my report, Congress must commit to a two-year appropriations program to increase the FDA employees by 50 percent and to double the FDA funding, and then at least to maintain a fully burdened yearly cost-of-living increase of 5.8 percent across all segments of the agency. Without these resources the agency is powerless to improve its performance, will fall only further behind, and will be unable to meet either the mandates of Congress or the expectations of the American public.

Congress and the nation therefore have a choice. We can limp along with a badly crippled FDA and continue to take serious risks with the safety of our food and drug supply, or we can fix the agency and restore it to its former strength and stature. If Congress concludes to fix FDA, however, this cannot be done cheaply. It will be necessary to appropriate substantial personnel and funds to reverse the damage done to FDA in the past two decades.

Accumulating Unfunded FDA Statutory Mandates

My report first addresses the tremendous problems encountered by FDA in implementing the burgeoning number of new statutory responsibilities imposed by Congress each year. Table 1 lists more than 100 statutes that directly impact FDA enacted by Congress only since 1988 -- an average of more than six each year. These are in addition to the core provisions of the Federal Food, Drug, and Cosmetic Act of 1938 itself and another 90-plus statutes directly involving FDA that were enacted during 1939-1987.

Each of these statutes requires some type of FDA action. Many require the development of implementing regulations, guidance, or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific knowledge or expertise for the agency adequately to address them. Yet none of these statutes is accompanied by an appropriation of new personnel and increased funding designed to allow adequate implementation. In the history of our country, no other Federal regulatory agency has ever faced such an onslaught of new statutory mandates without appropriate funding and personnel to implement them. Instead, the agency is expected to implement all of these new unfunded congressional mandates with resources that, in the corresponding time, represent at best a flat budget. Not surprisingly, many of the new congressional mandates languish for years or cannot be implemented at all.

In addition to the laws listed in Table 1, which directly require FDA to take action, Congress has enacted a number of statutes of general applicability that place a large administrative burden on FDA in conducting its daily work. Representative statutes of general applicability that require substantial FDA resources for compliance are listed in Table 2. For example, in order to promulgate a regulation, FDA must at a minimum include, in the preamble, not only full consideration of all the substantive issues raised by the regulation itself, but also a cost-benefit analysis, an environmental impact discussion, a federalism evaluation, a small business impact statement, a determination whether there is an unfunded mandate impact on state or local governments, and an analysis of paperwork obligations. The proposed and final regulations must be reviewed and approved by the Department of Health and Human Services (DHHS) and the White House Office of Management and Budget (OMB). However well-intentioned, these responsibilities place a major burden on FDA and require that scientific

resources be diverted from other areas in order to assure compliance. This has led FDA to avoid rulemaking wherever possible and to substitute informal guidance or to take no action whatever on important regulatory matters.

The statutes of general applicability are not the only directives that have a strong impact on FDA. Every President in the past 40 years has issued one or more Executive Orders that impose additional obligations on FDA. A representative sample is set forth in Table 3. These Executive Orders have the same binding status as a statute and can have as great or greater impact.

The combined weight of these unfunded FDA statutes, statutes of general applicability, and Executive Orders is tremendous. Each includes additional responsibilities for the agency without commensurate appropriations for personnel and funds. The result is that, with relatively flat funding and a very large increase in what the country expects from the agency, FDA is falling further and further behind.

These unfunded mandates cascade down on FDA from all sides of the political spectrum. It is not a problem caused by partisan politics. Nor does my report question the justification for these mandates. Rather, it is the undeniable fact that these mandates are unfunded, and thus that FDA lacks the capacity to implement them, that is objectionable. The country cannot withhold the requisite scientific resources from FDA and then complain that the agency is incapable of meeting our expectations.

Unfinished FDA Safety Programs

The lack of adequate scientific personnel and the resources to support them has had a major adverse impact on important FDA regulatory programs to assure the continued safety of marketed products. For example, on several occasions FDA has established

comprehensive reviews of products after they have been marketed, either at the direction of Congress or on its own initiative. Virtually all of these reviews remain unfinished for lack of agency resources. Ten specific examples are provided on pages 10-12 of my report.

Lack of Adequate FDA Appropriations

No one outside FDA has enough information about the agency to conduct a zero-based budget analysis for FDA. It is likely that FDA itself has numerous materials that would bear upon such an analysis, but the agency states that it is not able to make those public.

My report therefore pursues a different approach. Attached are tables that present a partial statistical history of the congressional appropriations for FDA personnel and funds for the past 20 years, compiled from publicly-available sources. Tables 4 and 5 cover the 20-year period of 1988 - 2007. As the last column in Table 5 shows, from 1988 to 1994 FDA's appropriated personnel and funding kept even with its increasing responsibilities and exceeded inflation. The agency's appropriated personnel increased from 7,039 to 9,167 (a gain of 2,128 people) and its funding from \$477.504 million to \$875.968 million (a gain of \$398.464 million). In 1994, however, FDA hit a brick wall. From 1994 to 2007 the agency's appropriated personnel decreased from 9,167 to 7,856 (a loss of 1,311 people), returning it almost to the same level that was appropriated 20 years earlier. FDA's appropriated funding during this time increased by \$698.187 million, but this was only about two-thirds the funding needed to keep up with FDA's fully burdened cost-of-living increase of 5.8 percent, compounded yearly. Thus, over the entire 20 years FDA gained only 817 employees -- an increase of 12 percent -- and lost more than \$300 million to inflation, while faced with implementing the new statutes listed in Table 1 and the agency's substantial other core responsibilities under the 1938 Act. Confronted with a

burgeoning industry as documented in Table 6, it became increasingly impossible for FDA to maintain its historic public health mission.

My report contains numerous examples of the impact of this lack of personnel and funds on FDA programs, particularly dealing with food and regulatory enforcement. The science functions within the FDA Center for Food Safety and Applied Nutrition (CFSAN) -- which include dietary supplements and cosmetics -- have been hit especially hard. In the 15 years from 1992 to 2007, CFSAN suffered a reduction in force of 138 people, or 15 percent of its staff. During the same period, Table 1 shows that Congress enacted several important new laws creating major new responsibilities for CFSAN, all of which required substantial scientific expertise for implementation.

The deterioration of the FDA Field Force -- which must daily make scientific evaluations of FDA-regulated products -- has been equally severe. Between 1973 and 2006 there was a 78 percent reduction in food inspections. FDA conducted twice the number of foreign and domestic food establishment inspections in 1973 (34,919) then in did for all FDA-regulated products in 2006 (17,641). The inability of FDA adequately to police the importation of food and drugs into the United States has been well documented by Congress during the past two years.

Conclusion

We must all recognize that FDA can increase its attention to high priority issues, or take on entirely new responsibilities, only in the following two ways. First, FDA can divert personnel from other priorities, thus leaving those other areas neglected. This is what happened with contaminated pet food, one of the many areas which have been neglected because of a lack of agency resources. Second, Congress can determine to provide adequate funding for all of the

responsibilities that the country expects FDA to implement. But it is clear that, unless Congress adopts this second approach, FDA will of necessity be forced to follow the first.

Science is at the heart of everything that FDA does. Without a strong scientific foundation, the agency will founder and ultimately fail. The scientific resources needed by FDA to carry out its statutory mission cannot be sustained on a minimal budget. Congress must commit to doubling the current FDA funds, together with a 50 percent increase in authorized personnel, within the next two years. From then on, it is essential that the FDA budget at least keep up with inflation and perhaps even more. Another report should be prepared in five years to offer advice on the state of science at FDA at that time and the resource needs that remain.