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Health, Education and Human Services Division

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December 8, 1995

The Honorable Nancy L. Kassebaum
Chairman, Committee on Labor and
Human Resources
United States Senate

Dear Madam Chairman:

The Congress, industry groups, and others have raised concerns about delays in the Food and Drug Administration's (FDA) approval of new medical device, pharmaceutical, and biologic products. In the last 5 years, the Congress provided additional funding and staff positions to enable FDA to meet its existing mandates as well as new responsibilities under the Prescription Drug User Fee Act of 1992 and the Mammography Quality Standards Act of 1992. Since his appointment in December 1990, FDA's current Commissioner has made a number of organizational changes intended to improve agency performance.

Critics of FDA have contended that the additional resources the Congress provided have been devoted to increasing staff in the Office of the Commissioner instead of increasing product approval staff. They also raised concerns that there has been an undue centralization of authority in the Office of the Commissioner. Because of these concerns, you asked us to develop information on several indicators of change in FDA's structure since the current Commissioner was appointed. Specifically, you asked us to describe (1) changes in the number of staff positions in the Office of the Commissioner, staff offices, and product centers; and (2) changes in decision-making authority of the Commissioner and the heads of FDA's principal operating units.

To develop information on changes in the number of staff positions, we compared FDA's full-time equivalent (FTE) data from fiscal years 1990 and 1995.[1] To identify

[1]Before fiscal year 1992, FDA excluded FTEs associated with its stay-in-school program from the total FTE number. Therefore, the agency excluded 73 ceiling-exempt FTEs from

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changes in decision-making authority, we reviewed Federal Register notices and FDA documents. We also interviewed officials at FDA headquarters and field offices as well as former FDA officials. We performed our work from February 1995 to October 1995 in accordance with generally accepted government auditing standards.

In summary, we found that total FDA staff increased about 20 percent, from 7,807 in fiscal year 1990 to 9,355 in fiscal year 1995. The Office of the Commissioner received 4 percent of the increase; staff offices received 11 percent; and product centers and the Office of Regulatory Affairs (ORA) received 85 percent.[2]

FTEs in the Office of the Commissioner increased by a net of 64, or 84 percent, through the transfer of FTEs from ORA and the Department of Health and Human Services' (HHS) Office of the Secretary to FDA's Office of Chief Counsel. However, the number of staff reporting directly to the Commissioner decreased. Meanwhile, FTEs in staff offices increased by 168, or 21 percent; about two-thirds were allocated to the Office of Management and Systems, which consists mostly of administrative support personnel. FTEs in the product centers generally increased or stayed about the same, as will be discussed later. During this period, there was no single change in direction regarding centralization or decentralization of decision-making authority. Rather, some changes decentralized product approval and other programmatic authorities, while other changes increased centralization of functions such as policy development.

BACKGROUND

FDA is the principal consumer protection agency in the federal government--an estimated 25 cents out of every U.S. consumer dollar is spent on FDA-regulated products. To accomplish FDA's mission, the Congress appropriated more than $963 million to FDA for fiscal year 1995.

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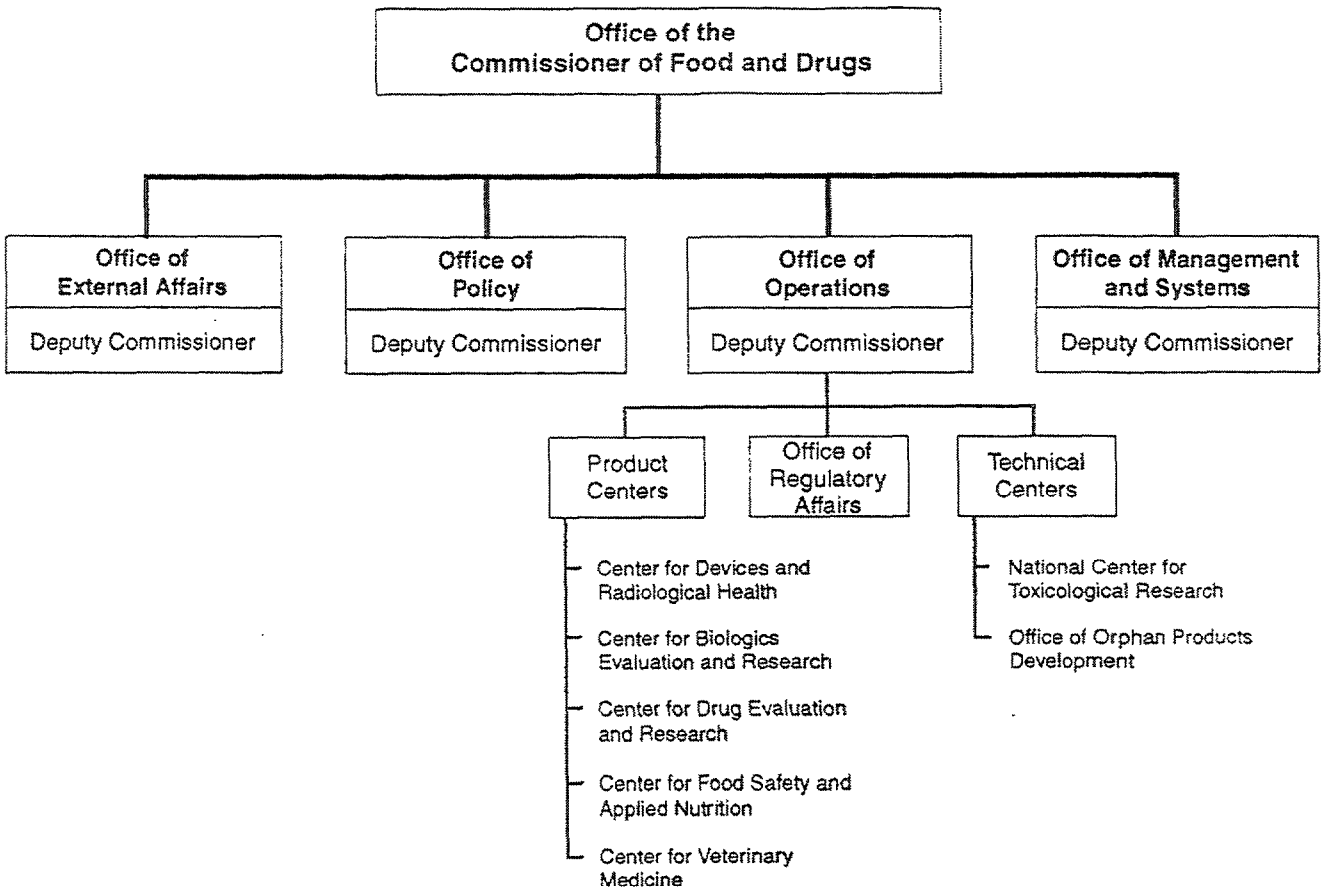
its total for fiscal year 1990, and we excluded them also. For fiscal year 1995, FDA included 68 previously ceiling-exempt FTEs in the total FTE count, and we included them in our total count for that year as well.

[2]Of the new FTEs, 453 were supported from fees paid by manufacturers pursuant to the Prescription Drug User Fee Act of 1992.

FDA's current management structure consists of the Office of the Commissioner[3] and four staff offices. Staff offices, which are headed by deputy commissioners, include the Office of Policy, the Office of External Affairs, the Office of Management and Systems, and the Office of Operations. (See fig. 1.)

[3]For purposes of this discussion, the Office of the Commissioner is defined as the Commissioner's immediate office along with the Offices of Executive Secretariat, Chief Counsel, Special Investigations, Internal Affairs, and Equal Opportunity and Civil Rights. In fiscal year 1995, 32 of the 140 FTEs in the Office of the Commissioner were devoted to the Commissioner's immediate office, which includes his Senior Advisor, Executive Assistant, Chief Mediator and Ombudsman, Special Assistant for Investigation, and others.

Figure 1: Organization of Selected FDA Offices



Note: The Office of External Affairs includes the Office of Public Affairs, the Office of Health Affairs, the Office of Legislative Affairs, the Office of Consumer Affairs, the Office of AIDS and Special Health Issues, and the Office of Women's Health.

In the Office of Operations, there are five product centers--the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), the Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Veterinary Medicine (CVM)--and two technical centers--the National Center for Toxicological Research (NCTR) and the Office of Orphan Products Development (OPD). The Office of Operations also includes ORA.

CHANGES IN FDA FTE POSITIONS

From fiscal year 1990 to fiscal year 1995, FDA's number of FTEs increased about 20 percent. The Office of the Commissioner received 4 percent of the increase; staff offices received 11 percent; and the centers and ORA received 85 percent. The Congress provided funding for additional FTEs to enable FDA to meet its increased responsibilities under the Mammography Quality Standards Act of 1992 for certification and inspection of mammography facilities and under the Prescription Drug User Fee Act of 1992 for reducing review time to expedite the drug approval process.[4]

During this period, the FTEs allocated to the Office of the Commissioner increased 84 percent and FTEs in staff offices increased 21 percent.[5] This change in the Office of the Commissioner's and staff offices' FTEs represents a slight increase from 11.2 to 11.8 percent of total FTEs within FDA. The percent of FTEs in the centers and ORA increased 19 percent. This represents a slight decrease from 88.8 to 88.2 percent of total FTEs. (See table 1.)

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[4]Of the agency's total fiscal year 1995 FTEs, 453 were associated with the Prescription Drug User Fee Act of 1992: one FTE went to the Office of the Commissioner; 32 to staff offices; and 420 to centers and ORA.

[5]Staff offices include the Office of Policy, the Office of External Affairs, the Office of Management and Systems, and the Office of Operations/Immediate Office.

Table 1: FTE Changes

	FY 1990	FY 1995	Percentage increase
FDA	7,807	9,355	20
Commissioner's Office	76	140	84
Staff offices	799	967	21
ORA/centers	6,932	8,248	19

Note: In October 1994, 66 FTEs were transferred from ORA and HHS' Office of the Secretary to FDA's Office of Chief Counsel, which is part of the Office of the Commissioner.

Source: FDA.

In this period, some FTEs were shifted from the Office of the Commissioner, while 66 were added--about one-third from HHS' Office of the Secretary and the remainder from ORA--for a net gain of 64 FTEs. All of these FTEs were in the Office of the Chief Counsel. Detailees varied in number from month to month, but as of April 1995, 19 staff were detailed from various centers and ORA to the Office of the Commissioner, and 7 staff were detailed to staff offices. Occasionally, staff are also detailed from the Commissioner's and staff offices to ORA and the centers. For example, in April 1995, one staff member was detailed from the Commissioner's office to CFSAN, and five staff members were detailed from the Office of External Affairs and the Office of Management and Systems to centers and ORA.

In fiscal year 1995, more than 75 percent of FTEs in staff offices were allocated to the Office of Management and Systems; the remaining staff resources went to the Office of Operations, the Office of Policy, and the Office of External Affairs. FTEs in the Office of Management and Systems (which consists mostly of administrative support personnel, including budget and accounting personnel, contract and procurement specialists, and other specialists) increased 16 percent from 627 to 729--the largest increase in staff office FTEs.

The number of FTEs in the centers and ORA also changed between fiscal years 1990 and 1995. FTEs increased in CDER, CDRH, CBER, CFSAN, CVM, ORA, and OPD, while FTEs stayed the same in NCTR. (See table 2.)

Table 2: Changes in Center and ORA FTEs

	FY 1990	FY 1995	Percentage change
Center for Drug Evaluation and Research	1,225	1,550	26.5
Center for Devices and Radiological Health	860	1,109	29.0
Center for Biologics Evaluation and Research	549	809	47.4
Center for Food Safety and Applied Nutrition	823	871	5.8
Center for Veterinary Medicine	258	267	3.5
Office of Regulatory Affairs	2,974	3,376	13.5
National Center for Toxicological Research	243	243	0.0
Office of Orphan Products Development	14	23	64.3

Source: FDA.

CHANGES IN DECISION-MAKING AUTHORITY

Even though the number of staff in the Office of the Commissioner increased, the number of persons reporting directly to the Commissioner decreased. In addition, some programmatic decision-making authority has been delegated from the Commissioner to the deputy commissioners, center directors, and others at lower levels. There have also been changes in administrative authority across FDA.

From December 1990 to June 1995, the number of persons reporting directly to the Commissioner decreased from 23 to 13. Reporting to the Commissioner now are a deputy commissioner for each of four staff offices as well as staff in the Commissioner's office. Product and technical

center directors and the Associate Commissioner for Regulatory Affairs who previously reported to the Commissioner now report to the Deputy Commissioner of Operations.[6]

The Commissioner has decentralized certain important programmatic authorities. For example, the Commissioner delegated authority to CDRH and CBER to approve, disapprove, or withdraw approval of applications for investigational device exemptions and premarket approvals for medical devices.[7] The authority to approve new drug applications and supplements for oncologic drug products has been decentralized to CDER, while the authority to work jointly to approve any combination drug containing a biologic, medical device, or drug has been decentralized from the Commissioner to the centers. CDER, CVM, and ORA also now have the authority to issue written notices on patent information, current good manufacturing practices, false and misleading drug labeling, new animal drugs, and feeds with new animal drugs.

FDA also gave center directors and supervisors the authority to delegate approval of procedures for certain administrative functions, such as work scheduling and flexible workplace criteria. In addition, the Commissioner has established a strategic staff person within the Office of Management and Systems to coordinate the development and implementation of an agencywide information system strategic plan. The authority to coordinate cross-cutting policy issues and regulatory development has also been centralized from each center to the Office of Policy. For example, according to FDA officials, the Office of Policy has used its authority to streamline regulatory development by creating an FDA-wide tracking system for Federal Register notices and instituted a review of proposed rules that have not been finalized in an effort to eliminate the backlog.

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[6]In addition, directors of four offices--the Office of Public Affairs, the Office of Health Affairs, the Office of Legislative Affairs, and the Office of Consumer Affairs--now report to the Deputy Commissioner for External Affairs instead of directly to the Commissioner. Also, the Office of Women's Health, established in 1994, and the Office of AIDS and Special Health Issues report to the Deputy Commissioner for External Affairs.

[7]Investigational device exemptions are needed when a device is used in clinical trials.

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FDA officials reviewed a draft of this correspondence. They generally agreed with its contents and provided clarification and additional information. We incorporated their comments where appropriate.

We will send copies of this correspondence to the Commissioner of the Food and Drug Administration and make copies available to others upon request.

If you or your staff have any questions, please contact me at (202) 512-7119 or Bruce D. Layton, Assistant Director, at (202) 512-6837.

Sincerely yours,

Mark V. Nadel
Associate Director, National and
Public Health Issues

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