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FDA REGULATIONS

Sustained Management Attention Needed to Improve Timely Issuance

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SUMMARY OF GAO TESTIMONY BY MARK V. NADEL ON SUSTAINED MANAGEMENT ATTENTION NEEDED TO IMPROVE TIMELY ISSUANCE OF FDA REGULATIONS

This testimony is based on the GAO report FDA Regulations: Sustained Management Attention Needed to Improve Timely Issuance (GAO/HRD-92-35, February 21, 1992), which is being released today. The GAO report disclosed that the Food and Drug Administration has experienced major delays in developing regulations and publishing them as final rules. Based on its review of FDA regulations in process as of April 1991, GAO discovered the following:

- Within the past 30 years, FDA has accumulated about 388 regulations that it (1) began to develop but never completed or (2) published in the Federal Register as proposed rules for public comment but never published as final rules.

- Of the 388 regulations in process, 51 percent were in an active work status and 49 percent were either in an inactive work status or the status was unknown.

- Three hundred one regulations that had been published as proposed rules in the Federal Register have been in process an average of 9 years.

- Fourteen regulations that FDA considered "significant" and prepared for signature by the Secretary of Health and Human Services and review by the Office of Management and Budget took an average of 5 years to develop and issue and the time in process ranged from 15 months to 9 years.

- Forty-five regulations required by federal statute had been in process an average of 4 years.

In August 1991, the FDA Deputy Commissioner for Policy announced a new initiative to improve the management and flow of FDA's regulations. As part of this initiative, the agency established a Regulations Council to oversee and, when needed, direct the management of the rulemaking process.

While the establishment of a Regulations Council represents a positive step, GAO believes the Commissioner of Food and Drugs should also develop a single automated tracking system that monitors progress on all regulations. This system would serve as the primary basis for identifying delays and initiating appropriate actions to overcome internal barriers to timely issuance of all FDA regulations.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss our report[1] on the problems Food and Drug Administration (FDA) officials need to address in their efforts to improve the agency's rulemaking process. At your request, we reported on the total number of FDA regulations that were under development and review as well as actions planned by FDA to issue its regulations in a more timely manner. In addition, we identified areas for improvement in FDA's system for managing its regulations workload. This morning I will discuss (1) the amount of time it has taken FDA to issue regulations, (2) some factors that cause delays, and (3) some FDA efforts to reduce delays and improve its rulemaking process.

To prepare this report, we collected and analyzed data on FDA regulations in process as of April 1991. We also reviewed internal FDA documents, including agency studies to identify weaknesses in regulation development and issuance. We also interviewed FDA officials on the agency's ability to track the development and review of regulations and its plans for improving the regulations issuance process.

In brief, we found that FDA has experienced major delays in developing regulations and publishing them as final rules. Furthermore, FDA lacks an effective agencywide system for managing its regulations workload. FDA has, however, begun to address problems with its process for promulgating and issuing regulations. In August 1991, for example, the FDA Deputy Commissioner for Policy announced a new initiative to improve the management and flow of FDA's regulations. As part of this initiative, the agency established a Regulations Council to oversee and, when needed, direct the management of the rulemaking process.

While we support this agency initiative, we also believe that the Commissioner of Food and Drugs should develop a single automated tracking system that monitors progress on all regulations. This system would serve as the primary basis for identifying delays and initiating appropriate action to overcome internal barriers to timely issuance of all FDA regulations.

BACKGROUND

FDA, an agency within the Department of Health and Human Services (HHS), plays a vital role in assuring consumer protection and safety. To provide needed guidance to the food, drug, and cosmetic industries as well as the public on the $1 trillion of products it regulates, FDA develops regulations and

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[1]FDA Regulations: Sustained Management Attention Needed to Improve Timely Issuance (GAO/HRD-92-35, Feb. 21, 1992).

publishes them in proposed and final form in the Federal Register. Accordingly, improving the process by which regulations are developed within FDA is critical to the agency's effectiveness.

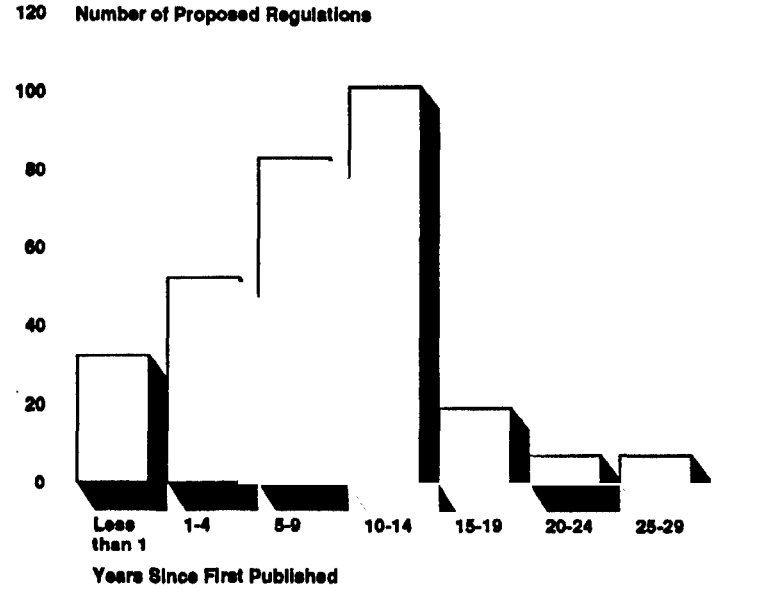
Primary responsibility for regulation development and issuance lies with FDA's headquarters staff. In recent years, about 98 percent of FDA documents (regulations and notices) published in the Federal Register have been signed by the FDA Commissioner and other FDA headquarters officials under authority delegated by the Secretary of HHS. The Secretary signed the remaining 2 percent.

LARGE BACKLOG OF REGULATIONS AND LENGTHY PROCESSING TIME

Within the past 30 years, FDA has accumulated about 388 regulations that it (1) began to develop but never completed or (2) published in the Federal Register as proposed rules for public comment but never issued as final rules. Of the 388 regulations, FDA said that 51 percent of the regulations were in an active work status as of April 1991. The other 49 percent were either in an inactive work status or the status was unknown.

FDA was not able to tell us when development work began on each of the regulations in process as of April 1991. Instead, to measure delays in issuing final regulations, we reviewed the 301 (out of the total 388) regulations that had been published in the Federal Register as proposed rules, and used the initial proposed rule publication date as the starting point. The average length of time the 301 proposed regulations were in pending status awaiting final publication in the Federal Register was 9 years. The range in the number of years these 301 were delayed may be seen in figure 1.

Elasped Time Since 301 Proposed Regulations Were First Published in Federal Register (Apr. 1991)



Even the regulations that FDA considers very important and gives high work priority status to take a long time to develop and issue. The regulations that FDA considers "significant" are prepared for signature by the Secretary of HHS and reviewed by the Office of Management and Budget (OMB) before publication in the Federal Register. From 1986 through 1990, FDA published as either proposed or final rules 40 significant regulations.[2]

Our work focused on the 37 significant regulations that had not been replaced, withdrawn, or otherwise completed as of April 1991. Twenty-two of these were issued as final rules but we could analyze only 14 of the 22 because FDA could not establish a starting date for the others.

The time the 14 final regulations were in process ranged from 15 months to 9 years. The average time it took to develop and issue these regulations was 5 years. Obtaining HHS and OMB approvals added an average of 8 months to the overall process.

Even after being published as proposed rules, significant regulations stayed in pending status for several years. It took FDA 3 years on average to obtain public comments, revise, and issue the 22 final regulations after they were published as proposed rules. Of the 15 proposed regulations that had not been issued as final rules, 5 had been pending from 2 to 5 years and 2 for more than 5 years.

FDA also has been slow to issue many of the regulations required by federal statute. Of the 388 regulations that were in process at FDA in April 1991, 45 were required by federal statutes (see attachment I). These regulations had been in process an average of 4 years. FDA officials said that they were actively working on 37 of the 45 regulations. They could not determine the status of the remaining 8.

Although five laws set specific deadlines for issuing certain regulations, FDA had missed deadlines in each law as of December 1991. Three of the five federal statutes were enacted in the 1980s. These were the Drug Price Competition and Patent Term Restoration Act of 1984; the Vaccine Compensation Amendments of 1987; and the Generic Animal Drug and Patent Term Restoration

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[2]These regulations dealt with such issues as current good manufacturing practices; food labeling requirements; irradiation in the production, processing, and handling of food; menstrual tampon labeling; and tamper-resistant packaging. As of April 1991, of the 40 significant regulations, 22 had been issued in final, 15 had been published as proposed rules (including 2 interim finals), 1 final rule was to be replaced by a new regulation, 1 proposed rule was withdrawn by FDA, and 1 interim final rule was outstanding because OMB suspended final review.

Act of 1988. For each statute, FDA failed to meet deadlines that required issuance of regulations "within one year" after enactment of the respective statutes. The two other laws, the Nutrition Labeling and Education Act of 1990 and the Safe Medical Devices Act of 1990, had regulation issuance deadlines in 1991 that were not fully met.

VARIOUS FACTORS CONTRIBUTE TO DELAYS

Several factors lead to delays in issuance of FDA regulations. FDA itself identified the following institutional barriers to timely regulation issuance in a July 1990 letter to the Chairman of the Advisory Committee on the Food and Drug Administration.[3]

- Emergence of significant problems during the regulations development process that require reevaluations of previous agreements on regulation content.
- Lack of resources.
- Competition among priorities within the agency with other regulatory and enforcement activities, such as the application process for premarket product approval.
- Required reviews within FDA, and by HHS and OMB.
- Need to coordinate with other agencies.
- Uncertainty as to the appropriate scope of review.

The desire to reach consensus on pertinent issues during the development of regulations is another factor that FDA officials said delays the issuance of regulations.

Inadequate Central Tracking To Keep Management Informed Contributes to Delay

We believe that the lack of a comprehensive automated regulations tracking system contributes to issuance delays. FDA top management is not adequately informed about the overall regulations workload and, consequently, is not able to better establish priorities for issuing regulations. This is due in

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[3]Correspondence from the Acting Commissioner of Food and Drugs to the Chairman, Advisory Committee on the Food and Drug Administration, July 9, 1990. The Advisory Committee on the Food and Drug Administration was established in May 1990 by the Secretary of HHS to examine FDA's mission, responsibilities, and structure.

part to FDA's incomplete centralized tracking system for monitoring its rulemaking activities. While FDA's Division of Regulations Policy (in the Office of Regulatory Affairs) is responsible for directing, managing, and coordinating the agency's rulemaking activities, it has no mechanism in place to systematically analyze the entire regulation workload and prepare management reports.

In 1987, the Division of Regulatory Policy developed a centralized automated system for tracking documents it receives from the FDA centers for publication in the Federal Register. Data in this tracking system, however, are often incomplete and the system does not contain information on regulations under development in the various centers. Consequently, the Division is unable to provide top FDA management with status reports on all rulemaking activities.

The lack of an effective regulations tracking system was evident in March 1991 when FDA was unable to provide this Subcommittee with a complete and timely response to its request for information on the extent of the agency's regulations backlog. An FDA official acknowledged the system's incomplete data and said that one reason FDA had so much difficulty responding to the request was that no one had ever asked for such data and the agency did not systematically maintain the information.

FDA Has Expedited Some Regulations

Despite institutional barriers to timely issuance of regulations, FDA has shown that some barriers can be overcome. The development of the regulations required by the Nutrition Labeling and Education Act and the Safe Medical Device Act are examples, albeit atypical, of how timely issuance of regulations can be achieved. In an effort to develop and issue regulations within the timeframe permitted, FDA gave these regulations priority treatment. The agency assigned specific staff the responsibility for developing and tracking the progress of the regulations. FDA staff used an automated tracking system and prepared biweekly status reports for the FDA Commissioner and other high-level managers for use in monitoring the development and processing of the regulations. In our opinion, the process used to develop these regulations yielded recognizable success even though FDA missed some of the specific statutory deadlines.

FDA ACTIONS PLANNED TO IMPROVE THE REGULATORY PROCESS

In August 1991, the FDA Deputy Commissioner for Policy announced a new initiative to improve the management and flow of FDA's regulations. The primary objectives of this initiative are to (1) focus management attention on the rulemaking process, (2)

streamline the process to the extent possible, and (3) develop information systems to effectively manage the process. The agency established a high-level Regulations Council to oversee, direct, and manage FDA's rulemaking process. The Council is intended to play a central role in policy management, setting priorities, allocating resources, and proposing changes to the rulemaking process.

In December 1991, FDA announced that 89 pre-1986 regulations that were not being worked on had been formally withdrawn. FDA plans to identify other candidates from post-1985 proposed regulations for withdrawal. This approach is similar to actions FDA took in 1985 to reduce its regulations backlog. At that time, 14 of 142 pre-1980 regulations were eventually withdrawn.

CONCLUSIONS

While a number of factors contribute to delays in issuing FDA regulations, better management of the process is needed. This could not only reduce delays but also assure that top management will be better able to establish priorities for completing final regulations.

FDA's ability, through regulations, to effectively address public health problems and enforce compliance with federal law could be jeopardized unless the FDA Regulations Council is able to improve the rulemaking process. Meaningful progress on improving the timeliness of regulation issuance will not be made if FDA continues to permit large regulation backlogs to develop. Consequently, providing top management with the information needed to establish agencywide rulemaking priorities on a continuous basis is a key step in allowing management to focus on timeliness issues and the entire rulemaking process.

RECOMMENDATIONS TO THE COMMISSIONER OF FOOD AND DRUGS

To improve internal management oversight of the FDA regulation process, we recommend that the Commissioner of Food and Drugs develop a single automated regulation tracking system that (1) monitors the progress being made on all regulations under development; (2) generates recurring reports to top agency officials; and (3) serves as the primary basis for identifying delays in issuing regulations and initiating appropriate actions, when necessary, to overcome internal delays in the development of individual regulations.

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Mr. Chairman, this concludes my statement. I will be happy to answer any questions you may have.

ATTACHMENT I

Status of FDA Regulations in Process That Are Required by Legislation[a](Apr. 1991)

Public Law/regulation	Under development	Published as proposed regulations
1. Safe Drinking Water Act (P.L. 93-523, Dec. 16, 1974)		
Bottled Water Standards; Establishment and Upgrade Bottled Water Standards for Seven Inorganic and 24 Organic Chemicals	X	
Bottled Water Standards; Subject Mineral Water to Quality Standards for Bottled Water	X	
2. Medical Device Amendments of 1976 (P.L. 94-295, May 28, 1976)		
Automated Differential Cell Counter		X
Hydrophilic Beads for Wound Exudate Absorption		X
Infant Radiant Warmer		X
Nonabsorbable Gauze, Surgical Sponge and Wound Dressing		X
Nonabsorbable Gauze for Internal Use		X
Porcine Burn Dressing		X
3. Orphan Drug Act (P.L. 97-414, Jan 4, 1983)		
Orphan Drug Regulations		X
4 Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417, Sept. 24, 1984)		
Abbreviated New Drug Applications for Human Drugs		X
5 Alcohol and Drug Abuse Amendments of 1986 (P.L. 99-570, title IV, Oct. 27, 1986)		
Current Good Manufacturing Practice and Quality Control Procedures in Manufacturing, Packaging or Holding Infant Formula	X	
Infant Formula Microbiological Testing and Consumer Complaints		X
6. National Childhood Vaccine Injury Act of 1986 (P.L. 99-660, title III, Nov. 14, 1986) as amended by the Vaccine Compensation Amendments of 1987 (P.L. 100-203, title IV)		
Review of Warnings, Use Instructions, and Precautionary Information Contained in Package Inserts for Certain Vaccines	X	
7 Generic Animal Drug and Patent Term Restoration Act (P.L. 100-670, Nov 16, 1988)		
Implementation of Title I of the Generic Animal Drug and Patent Term Restoration Act	X	
Patent Term Restoration for Animal Drugs (Title II)		X
8. Nutrition Labeling and Education Act of 1990 (P.L. 101-535, Nov. 8, 1990)		
Food Labeling Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision	X[bc]	
Food Labeling Petitions Permitted by the Nutrition Labeling and Education Act of 1990	X[c]	
Adjectival Descriptors; General Principles, Petitions	X[c]	
Food Labeling Nutrition Labeling of Raw Fruit, Vegetables and Fish, Guidelines for Voluntary Nutrition Labeling of Raw Fruit, Vegetables and Fish; Identification of the 20 Most Frequently Consumed Raw Fruit, Vegetables, and Fish; and Definition of Substantial Compliance	X[d]	
Food Labeling Definitions of Terms Describing the Cholesterol, Fat, and Fatty Acid Content of Food	X[bc]	
Food Labeling Health Messages and Label Statements, General Principles	X[bc]	
Food Labeling Health Messages, Antioxidant Vitamins/Cancer	X[c]	

(continued)

ATTACHMENT I

Status of FDA Regulations in Process That Are Required by Legislation[a] (Apr. 1991)

Public Law/regulation	Under development	Published as proposed regulations
Food Labeling: Health Messages, Calcium/ Osteoporosis	X[c]	
Food Labeling: Health Messages; Fiber/Cancer	X[c]	
Food Labeling: Health Messages, Fiber/ Cardiovascular Disease (CHD)	X[c]	
Food Labeling: Health Messages, Folic Acid/ Neural Tube Defects	X[c]	
Food Labeling: Health Messages, Lipids/Cancer	X[c]	
Food Labeling: Health Messages, Lipids/CHD	X[c]	
Food Labeling: Health Messages, Omega-3/CHD	X[c]	
Food Labeling: Health Messages, Sodium/ Hypertension	X[c]	
Food Labeling: Health Messages, Zinc/ Immune Function	X[c]	
Food Labeling: Nutrition Label Format	X	
Food Labeling: Serving Sizes	X[bc]	
Food Labeling: Use of Descriptors with the Names of Standardized Foods	X[c]	
Butter: Nutrient Content Claims Use	X[c]	
9 Food, Agriculture, Conservation, and Trade Act of 1990 (P.L. 101-624, Nov. 28, 1990), title XIII subtitle B National Laboratory Accreditation		
Regulations related to standards and procedures for laboratories.	X	
10 Safe Medical Devices Act of 1990 (P.L. 101-629, Nov. 28, 1990)		
Classification of Transitional Devices	X	
Devices for Which Premarket Approvals Have Not Yet Been Required; Revision of Classification or Requirement to Remain in Class III	X	
Exemption of Humanitarian Devices	X	
Medical Device Reporting Regulations, Distributor Reporting Regulations	X[ce]	
Medical Device Reporting Regulations, User Reporting Regulations	X[ce]	
Medical Device Tracking Regulations	X	
Medical Devices, Reports of Removals and Corrections	X	
Premarket Review of Combination Products	X	
Requirements for Summaries of Safety and Effectiveness in Submissions for Premarket Notification	X	

[a]These laws required FDA to issue regulations but did not mandate in every case the specific categories of rules listed. FDA decided on the specific regulations.

[b]FDA had proposed five similar rules in the Federal Register under the agency's general rulemaking authority prior to enactment of the Nutrition Labeling and Education Act of 1990. FDA is revising the proposals developed under general rulemaking and plans to repropose four regulations implementing the new law (Two of five proposed regulations are combined and will be reproposed as one rule.)

[c]In commenting on a draft of this report, FDA indicated that these proposed rules were issued in November 1991.

[d]In commenting on a draft of this report, FDA indicated that these final rules were issued in November 1991.

[e]FDA combined these two rules and published them as one proposed regulation entitled Medical Devices: Medical Device, User Facility, Distributor, and Manufacturer Reporting, Certification, and Registration.

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