Congress of the United States

Washington, DC 20515

November 14, 2005

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Dear Secretary Leavitt:

Today, the Government Accountability Office released a report that confirms what has been increasingly evident for some time: politics trumped science in FDA's May 2004 decision not to approve over-the-counter sales of Plan B emergency contraception.[1] We are deeply opposed to this subversion of science, and we urge you to ensure that the upcoming decision on Plan B is based on the best available science instead of ideology.

We also ask you to explain why the Food and Drug Administration was unable to produce for GAO investigators any communications to or from the office of Dr. Mark McClellan, the former Commissioner. GAO was able to obtain sufficient information to complete its report. However, we still do not have a complete picture of Dr. McClellan's role. Dr. McClellan failed to answer questions provided to him by GAO. In addition, in the course of the investigation, GAO asked for copies of any communications to or from staff in the Commissioner's Office, including emails, that related to the Plan B decision. GAO reported to our staff that FDA said the agency could not produce such documents because the Office of the Commissioner deleted emails daily and did not retain written communications such as memos.

FDA's failure to provide any such communications raises serious questions about the agency's compliance with federal records management law. Under the applicable law, no records of the federal government may be "alienated or destroyed" except under the regulations promulgated by the Archivist and the schedules submitted by the agencies. Moreover, the systematic destruction or failure to retain records obstructs congressional oversight and raises questions about transparency and accountability at the agency.

The GAO Report

At our request, GAO began an investigation in September 2004 into FDA's May 2004 decision to reject the application of Barr Laboratories to sell Plan B emergency contraception over the counter.[2] GAO's final report describes an appalling level of manipulation and

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[1] Government Accountability Office, *Food and Drug Administration: Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual* (GAO-06-109) (Nov. 14, 2005).

[2] Letter from Gloria L. Jarmon, Managing Director for Congressional Relations, Government Accountability Office, to Representative Henry A. Waxman (July 21, 2004).

suppression of the science. As GAO reports, the expert advisory panel, the agency scientific officials in charge of over-the-counter and reproductive drugs, and the director of the Office of New Drugs all recommended approving Barr Laboratories' application, yet they were overruled in what seems to have been a political decision.

According to evidence found by GAO, it appears that the decision to reject Barr's application was preordained from the outset. GAO reports that multiple agency officials responsible for the scientific review of Plan B said that Dr. Stephen Galson, then-Acting Director of the Center for Drug Evaluation and Research (CDER), communicated to them before their review was complete that the application would not be approved. Though Dr. Galson denies these accounts, GAO also found that the official minutes of a January 15, 2004 meeting state that Dr. Galson told scientific officials before their review was complete that the Office of the Commissioner was recommending nonapproval. Other documentation recorded Dr. Galson as stating that the decision would be made at a higher level than usual.

These are remarkable revelations with serious ramifications. They depict an agency that placed political considerations ahead of its obligation to evaluate drugs based on the scientific evidence. We urge you in the strongest possible terms to repudiate the FDA decision and ensure future FDA decisions are based on scientific merit, not political ideology.

The Role of the Commissioner

GAO's investigation of the Plan B decision entailed an assessment of the roles of individual, higher-level FDA officials in the Plan B decision. One official whose actions GAO examined was Dr. Mark McClellan, the former FDA Commissioner. GAO's investigators learned that on January 15, 2004, Acting CDER Director Galson told FDA scientific staff that Dr. McClellan had concerns about the safety of Plan B for young women. GAO also learned that on February 18, 2004, the agency's scientific staff briefed Dr. McClellan on its determination that the over-the-counter application should be approved. Commissioner McClellan's then-deputy, former FDA Commissioner Lester Crawford, was briefed about Plan B issues as early as June 2002.

Though GAO's report provides a detailed and elucidating account of many of the events at FDA, Dr. McClellan's full role remains unclear. GAO investigators told congressional staff at a briefing in September that FDA officials could not provide GAO with any written communications or emails to or from the Commissioner's office about Plan B.[3] According to the GAO investigators, FDA informed GAO that the Office of the Commissioner deleted emails daily and the backup files were deleted every 16 days.[4] Furthermore, FDA informed GAO that

[3] GAO briefing of Congressional Staff (Sept. 19, 2005).

[4] FDA later informed GAO that emails are in fact retained for 16 weeks. Congressional Staff Conversation with GAO (Nov. 9, 2005).

the Office of the Commissioner did not retain *any* written correspondence, including memos, and therefore could not provide such documents related to Plan B from the Office of the Commissioner unless they happened to be otherwise available.[5]

These problems were compounded when Dr. McClellan himself did not cooperate with GAO's investigation. Instead of responding to GAO's questions about his role, he sent a brief statement noting that the May 2004 nonapprovable letter was sent after his March 2004 departure.

These facts raise significant concerns about the records retention policies of FDA. If what GAO was told is true, FDA's policy appears to violate federal records law. It also impedes responsible congressional oversight and shrouds the Commissioner's actions in unnecessary secrecy.

The Federal Records Act and other federal records management laws were written to ensure "accurate and complete documentation of the policies and transactions of the Federal Government."[6] To achieve this objective, the laws require the head of each agency to "make and preserve records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency."[7] Though agencies may vary in their record retention policies, certain standards apply to all agencies. One important requirement is that no records of the federal government may be "alienated or destroyed" except under the regulations promulgated by the Archivist and the schedules submitted by the agencies.[8] Electronic messages such as emails can be considered "records" under the Federal Records Act.[9]

This potential violation of records management laws and regulations is not a mere technicality. On the contrary, as the Plan B decision makes clear, retaining the documents of the agency head is essential for the transparent operation of government. An agency that does not retain the written correspondence and emails of its top official impairs the ability of the Congress and the public to understand the basis for important decisions and to hold responsible officials accountable. In the case of FDA, effective oversight of drug regulation and safety becomes immeasurably harder if the correspondence of the office of the most important official at that agency is summarily destroyed.

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[5] Congressional Staff Conversation with GAO (Nov. 9, 2005).

[6] 44 USC 2902.

[7] 44 USC 3301

[8] 44 USC 3314; 36 C.F.R. 1228.100.

[9] Armstrong v Executive Office of the President, Office of Admin. (1993, App DC) 303 US App DC 107, 1 F3d 1274.

Under federal records management law, you have important responsibilities to ensure the preservation of federal records such as documents and emails from the Office of the Commissioner. The applicable law provides:

> The head of each Federal agency shall notify the Archivist of any ... unlawful ... destruction of records in the custody of the agency of which he is the head that shall come to his attention and with the assistance of the Archivist shall initiate action through the Attorney General for the recovery of records he knows or has reason to believe have been unlawfully removed from his agency.[10]

We urge you to fulfill these responsibilities. We request that you investigate whether FDA disposed of written correspondence and emails at the Office of the Commissioner in the manner described to GAO and whether such practices are continuing today. If you confirm this practice, we urge you to notify the Archivist and to initiate legal action through the Attorney General to recover those records or seek other redress. In addition, we ask that you determine whether other divisions of HHS are improperly destroying documents or emails and take appropriate steps to address the problem.

Conclusion

The decision about whether to increase women's access to safe emergency contraception should be made in the sunshine and on the basis of the best science available. We urge you to renounce categorically the manipulation of science depicted in the GAO report and to investigate and reverse any policies that may have prevented investigators from obtaining a full and complete record of the decision to reject the Plan B application.

Sincerely,

Henry A. Waxman
Member of Congress

John D. Dingell
Member of Congress

[10] 44 USC 3106.

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