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September 1997

FOOD AND DRUG  
ADMINISTRATION

Regulation of Tobacco  
Products



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**Health, Education, and  
Human Services Division**

B-270742

September 29, 1997

The Honorable Thomas W. Ewing  
Chairman  
The Honorable Gary Condit  
Ranking Minority Member  
Subcommittee on Risk Management  
and Specialty Crops  
Committee on Agriculture  
House of Representatives

On August 11, 1995, the Food and Drug Administration (FDA) proposed a regulation to prohibit the sale of cigarettes and smokeless tobacco to individuals under 18 years of age and to restrict advertising of these products. In addition, the regulation requires manufacturers to comply with labeling requirements and to fund public education programs that discourage persons under 18 years of age from using cigarettes and smokeless tobacco products. The final rule and jurisdictional determination were published on August 28, 1996.

Between June 1994 and October 1995, the Subcommittee requested on several occasions copies of FDA documents concerning the agency's efforts to regulate tobacco products and the potential effects of this regulation on tobacco growers. FDA did not fully comply with these requests.

To assist the Subcommittee in understanding the potential impact of FDA jurisdiction over regulating tobacco products, you asked us to obtain internal memorandums, notes from meetings or conversations, electronic and other written communications, and other documents from FDA related to 12 specific requests for information concerning the activities that led to FDA's proposal to regulate the sale of tobacco products. In addition, you asked us to describe how FDA developed the tobacco regulation, evaluated regulatory options, and determined its jurisdiction over tobacco products.

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**Scope and  
Methodology**

Because we were not able to obtain many of the documents related to the information you requested, most of the documents we examined were from the public record accompanying FDA's tobacco regulation. (See app. I for details on the 12 specific requests and the information we were able to obtain.) About a dozen documents we examined were, however, part of a confidential record associated with the regulation. These documents were

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considered confidential because they contained trade secrets or confidential commercial information.

To describe the actions taken by FDA to develop the proposed tobacco regulation, evaluate regulatory options, and determine jurisdiction over tobacco products, we obtained information on the duties and responsibilities of each employee involved in tobacco regulation activities at FDA and the Department of Health and Human Services (HHS) and interviewed key FDA officials involved in these activities. We also obtained a list of people from outside HHS and FDA who were contacted by agency officials on tobacco-related issues.

Except for the limitations resulting from FDA's refusal to provide us with the documents we requested, we conducted our study between December 1995 and June 1997 in accordance with generally accepted government auditing standards.

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## Results in Brief

Our efforts to obtain information that would enable us to adequately describe the activities that led to FDA's proposal to regulate tobacco products were obstructed by FDA's and HHS' refusals to provide many of the documents requested by the Subcommittee and by GAO. Through interviews with FDA officials and staff, we obtained testimonial evidence on some FDA actions prior to the publication of the final rule and jurisdictional determination on August 28, 1996. However, without the documents requested, we could not verify this information.

Throughout our study, FDA and HHS officials refused most of our requests for tobacco-related documents in the possession of agency officials that were not included on either the public or confidential record or an index of these documents. The officials cited several reasons for declining our requests. They stated that first, the proposed tobacco regulation was part of an ongoing rulemaking and release of the requested information would jeopardize the integrity of this deliberative process; second, releasing the requested information and communications with officials employed by the Department of Justice would negatively affect the government's position in ongoing litigation related to the proposed tobacco rule; and third, the requested information was obtained from confidential sources and its disclosure could undermine pledges of confidentiality. In addition, they noted that communications with officials employed by the White House are subject to a possible claim by the President of executive privilege, which only he can waive.

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Although we informed FDA and HHS that these factors do not limit our statutory right of access to the information, officials were unwilling to be forthcoming. (See app. II for a more detailed discussion of our legal authority to obtain FDA documents.) Applicable law requires each federal agency to “give the Comptroller General information the Comptroller General requires about the duties, powers, activities, organization, and financial transactions of the agency” (31 U.S.C. 716(a)). The law does not exempt information that is litigation sensitive or confidential. It provides an exception for information related to the deliberative process, but then only if the President or the Director of the Office of Management and Budget determines that disclosure “reasonably could be expected to impair substantially the operations of the Government” (31 U.S.C. 716(d)). While information can be exempt from disclosure to GAO based on a claim of executive privilege, the President has made no such claim.

Since FDA refused to provide us many of the documents that we requested, the information we obtained about FDA’s tobacco regulation activities came primarily from interviews with key FDA staff who participated in FDA tobacco-related investigations, developed regulatory options, and assessed FDA’s jurisdiction to regulate tobacco. Although these staff participated in regular meetings on these issues over several years, including numerous briefings of the Commissioner, they could not recall whether there were minutes of these meetings or written summaries of internal discussions. As a result, we could not verify the testimonial evidence provided to us about FDA’s tobacco regulation activities. In addition, FDA officials would not discuss the specific regulatory approaches they considered prior to the rule’s publication nor would they provide internal documents addressing the options they considered and their internal analyses of FDA’s jurisdiction.

According to the FDA Commissioner at that time, the activities that led to FDA’s decision to regulate tobacco products began during the first 6 months of 1991, when the Commissioner and senior FDA officials met to discuss public interest petitions calling for FDA regulation of tobacco products. (See app. III for more details on FDA’s tobacco regulation activities.) The Commissioner told us that at that time he did not consider tobacco regulation an immediate FDA priority. However, the Commissioner encouraged several senior FDA officials to examine the addictive properties of nicotine and whether tobacco manufacturers controlled nicotine levels in cigarettes. According to several FDA staff who performed this work during 1992 and 1993, the Commissioner briefed HHS officials on the initial results of FDA’s study in September 1993 and sought the advice of the

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Assistant Secretary for Health about how to respond to the petitions. FDA provided an informal response in a February 25, 1994, letter to the petitioners. According to the letter, an accumulation of new evidence suggested that cigarette manufacturers may intend for their products to satisfy purchasers' nicotine addiction. The letter further indicated that "Should the agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis on which to regulate these products under the drug provisions of the Act."

According to FDA staff, they visited tobacco manufacturing facilities and met with academicians, officials from other regulatory government agencies, tobacco-industry informants, and other experts. FDA staff further noted that following congressional hearings in March and June of 1994, FDA's investigation of the tobacco industry intensified.

According to FDA staff, FDA's investigation culminated with its issuance of the proposed rule and accompanying analysis regarding the agency's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products and its proposal to regulate the sale and marketing of tobacco products to children and adolescents. After reviewing about 700,000 public comments about the proposed rule and jurisdictional analysis, the final rule and jurisdictional determination were published on August 28, 1996.

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## Agency Comments

We received comments from HHS on a draft of this report and met with FDA and HHS officials concerning their comments.

In general, HHS believed that our report focused too much on issues related to their refusal to provide us access to documents rather than on what we learned from those that were provided. They contended that the documents provided to us and interviews with senior FDA officials and the Commissioner were sufficient to ensure that GAO was informed of every key event that led to the issuance of the tobacco regulation. Although HHS acknowledged our authority to conduct legitimate oversight and indicated that they attempted to accommodate our study, they reiterated the reasons why they refused our request for documents not on the public record.

In our view, however, not having such documents limited our ability to report fully on FDA's investigation, development of regulatory options, and jurisdictional analysis and determination or verify the information senior FDA officials provided us during interviews. Moreover, since FDA and HHS refused our request for an index of these documents, we could not narrow

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our document request. As a result of these limitations, we could not fully address the 12 requests for information related to FDA's investigation or the development of the regulation.

HHS also provided technical comments, which we incorporated into the final report where appropriate.

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We are sending copies of this report to the HHS Secretary, congressional committees, and other interested parties. We will also make copies available to others upon request.

Major contributors to this report were John Hansen, Assistant Director; Claude Hayeck; Peter Oswald; and Jonathan Barker. Please call Mr. Hansen at (202) 512-7105 if you or your staff have any questions.



Bernice Steinhardt  
Director, Health Services Quality  
and Public Health Issues

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## Abbreviations

FDA	Food and Drug Administration
HHS	Department of Health and Human Services
CRS	Congressional Research Service

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# Response to the Subcommittee's Request for Information About FDA's Tobacco Regulation Activities

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In a letter dated November 28, 1995, the Subcommittee asked that we obtain 12 specific information items that included lists of individuals involved in tobacco regulation and tobacco-related documents. With one exception, FDA refused to provide us with documents that were not included in either the public or confidential record. This appendix summarizes our efforts to obtain each of these lists and documents.

1. A list of all FDA officials or employees participating in the consideration of how the Federal Food, Drug, and Cosmetic Act would be applied to tobacco products.

On March 28, 1996, we requested a list of FDA employees involved in the tobacco rule's development, excluding employees who provided only administrative support. For each employee, we requested that FDA provide us

- a description of the employee's primary activities,
- when the employee first became involved with tobacco issues,
- the employee's supervisor,
- whether the employee possessed original documents not part of the public record,
- whether the employee had contacted individuals outside HHS, and
- whether the employee had undertaken any tobacco-related travel.

During April 1996, HHS provided us a list of 119 FDA and 20 HHS staff members who were involved in tobacco issues, along with the additional information requested on these employees.<sup>1</sup> Table 1 summarizes this information.

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<sup>1</sup>FDA did not provide us information for eight staff members who were no longer working at FDA.

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Response to the Subcommittee's Request for  
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**Table I.1: Primary Responsibilities of FDA Staff Working on Tobacco Issues Between 1994 and 1996**

<b>Unit</b>	<b>Number of staff</b>	<b>Primary responsibilities</b>
Commissioner of Food and Drugs	1	Provided overall leadership and direction on the development of the proposed tobacco regulation and accompanying jurisdictional analysis.
Office of the Commissioner	4	<p>Developed overall policy on regulating tobacco products.</p> <p>Investigated the content and control of nicotine in cigarettes and the marketing of cigarettes, and analyzed assorted tobacco products.</p> <p>Drafted, edited, and reviewed drafts of the regulation, and jurisdictional analysis.</p> <p>Advised other FDA staff on the jurisdictional analysis and on the development of the proposed regulation.</p>
Office of Chief Counsel	14	<p>Conducted background research related to legal issues in the proposed regulation, the agency's enforcement discretion, and private litigation involving tobacco issues.</p> <p>Provided legal advice on the development of the legal theory for the proposed regulation and jurisdictional analysis and the interpretation of the medical device provisions of the statute.</p> <p>Assisted in compilation of the administrative record for the jurisdictional analysis.</p> <p>Prepared and reviewed drafts of the jurisdictional analysis.</p>
Office of Policy	8	<p>Participated in drafting the 1994 letter to the Coalition on Smoking OR Health, and analyzed tobacco regulation in other countries.</p> <p>Organized and oversaw the development of the proposed regulation.</p> <p>Researched scientific, policy, and legal issues involved in the preparation of the proposed rule.</p> <p>Analyzed evidence relevant to FDA's jurisdiction over tobacco products.</p> <p>Provided advice on the Federal Trade Commission's tar and nicotine testing methodology.</p> <p>Drafted, edited, and reviewed drafts of the regulation.</p> <p>Researched, drafted, and reviewed drafts of the jurisdictional document.</p>
Office of Special Investigations	4	Participated in the agency's investigation of the tobacco industry, with duties that included visiting cigarette filter and paper companies, and tobacco farms; interviewing former tobacco company employees; and collecting, analyzing, and reviewing documentary evidence.
Office of Criminal Investigations	3	Participated in the agency's investigation of the tobacco industry, with duties that included visiting tobacco companies and cigarette filter companies; interviewing current and former tobacco company employees; and collecting, analyzing, and reviewing documentary evidence.

(continued)

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<b>Unit</b>	<b>Number of staff</b>	<b>Primary responsibilities</b>
Center for Drug Evaluation and Research	12	<p>Participated in the agency's investigation of the tobacco industry, with duties that included visiting tobacco companies, reviewing and analyzing tobacco company documents, and coordinating the review of tobacco industry-sponsored scientific articles related to nicotine pharmacology.</p> <p>Provided advice on FDA's past treatment of tobacco products and the physiological effects of nicotine.</p> <p>Researched legal, policy, and scientific issues involved in the preparation of the proposed rule.</p> <p>Summarized patents relating to tobacco.</p> <p>Reviewed the Federal Trade Commission's tar and nicotine data to determine trends in tar and nicotine from 1982 to 1997.</p> <p>Reviewed and analyzed scientific data on nicotine's pharmacological effects, and provided advice on the chemistry and properties of nicotine.</p>
Center for Devices and Radiological Health	3	<p>Reviewed and analyzed scientific data on nicotine's pharmacological effects, including tobacco company-sponsored data, and provided scientific advice on and analyses of these data and consumer use of tobacco products.</p> <p>Helped draft portions of the jurisdictional analysis, and reviewed drafts of the rule.</p> <p>Researched a variety of policy and regulatory issues concerning the regulation of devices.</p>
Center for Food Safety and Applied Nutrition	3	<p>Participated in the agency's investigation of the tobacco industry, with duties that included collecting and analyzing documentary evidence and researching the potential economic costs and benefits of the proposed rule.</p> <p>Coordinated research with other laboratories performing analytical tests of cigarettes, flavorings, and other parts of tobacco products.</p>
Center for Veterinary Medicine	1	<p>Assisted in preparing the legal analysis of FDA's jurisdiction over tobacco products, focusing on past cases where FDA regulated products without promotional claims.</p>
Office of External Affairs	2	<p>Prepared for anticipated hearings, wrote press materials, and managed the agency's congressional relations.</p>
Office of Health Affairs	2	<p>Researched a variety of policy, regulatory, and scientific issues regarding the regulation of tobacco.</p>

(continued)

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<b>Unit</b>	<b>Number of staff</b>	<b>Primary responsibilities</b>
Office of Operations	3	Coordinated administrative support for the overall project, including investigative activities and analytical activities with laboratories.  Coordinated the agency's review of scientific data on nicotine's pharmacological effects, including tobacco company-sponsored data, and provided scientific advice on and analyses of these data.  Attended internal agency meetings on regulation and enforcement activities by state governments and FDA contacts with state officials.
Office of Public Affairs	1	Researched policy and public health issues regarding the regulation of tobacco products, and participated in drafting portions of the preamble to the proposed rule.
Office of Planning and Evaluation	2	Organized and conducted research on potential economic impact of the proposed rule, and wrote the analysis of impacts published with the proposal.
Office of AIDS and Special Health	3	Reviewed and analyzed scientific data on nicotine's pharmacological effects, and assisted in drafting portions of the jurisdictional analysis.
Forensic Chemistry Center, Cincinnati District Office, Office of Regulatory Affairs	24	Participated in the design of studies on smokeless tobacco, and performed analyses of cigarettes and smokeless tobacco to determine their chemical properties.
St. Louis Laboratory, Center for Drug Evaluation and Research	15	Performed chemical analyses of tobacco products, and provided consultation to FDA headquarters on scientific matters related to jurisdictional issues.
Baltimore District Office, Office of Regulatory Affairs	3	Visited tobacco companies, collecting samples for analysis where possible, and provided expertise on the chemistry and properties of tobacco products.
Los Angeles District Office, Office of Regulatory Affairs	1	Investigated nicotine levels in commercial cigarettes, and developed methods to look at the chemical properties of cigarettes.
Atlanta District Office, Office of Regulatory Affairs	1	Visited tobacco companies; collected, analyzed, and reviewed documentary evidence; and interviewed former tobacco company employees.

Based on the information provided to us on each employee, we learned that the most-often mentioned supervisor of tobacco-related activities (cited by 27 staff) was the FDA Commissioner. In addition, 41 staff reported that they possessed tobacco-related documents that were not included on the public record, 59 staff had contacted individuals outside HHS on tobacco-related issues, and 33 staff had tobacco-related travel.

2. A list of any government employees, organizations, or individuals with whom FDA officials discussed the potential requirements of any FDA rule related to tobacco products.

On July 26, 1996, and on November 22, 1996, we requested from HHS information on FDA and HHS employee contacts with individuals outside

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HHS. HHS' General Counsel replied on January 30, 1997, stating that FDA was gathering and would provide the information to us, with three exceptions. First, confidential sources would not be identified because, according to HHS, doing so would undermine FDA's pledge of confidentiality. Second, HHS would not disclose the identity of persons employed by the Department of Justice in order to protect the U.S. government's position in pending litigation. Third, HHS would not identify contacts with persons employed by the White House because, according to HHS, it could not waive privileges available to the White House regarding this matter. However, in an August 2, 1996, letter responding to our request for this information, an Associate Counsel to the President referred us back to HHS and FDA. HHS and FDA officials said that this did not alter their original position.

On March 19 and April 9, 1997, HHS provided lists of outside contacts made by FDA and HHS employees in connection with the investigation and jurisdictional analysis related to the regulation of tobacco products.

The contacts included 34 staff from other federal government agencies, including the Department of Agriculture; the Bureau of Alcohol, Tobacco, and Firearms; the Occupational Safety and Health Administration; the Centers for Disease Control and Prevention; the Federal Trade Commission; and the U.S. Patent and Trademark Office. In addition, FDA staff contacted 42 people with private companies, such as tobacco manufacturers and suppliers. FDA staff also contacted 26 people who represented law firms and 23 people who worked for state governments, including several who represented state attorneys general or academic institutions. There also were contacts with 8 representatives of public interest groups.

3. Any memorandums, notes from conversations, or electronic or other written communications describing the procedures to be used or activities to be pursued by FDA in considering the regulatory options available to FDA once it asserted jurisdiction over tobacco products.

FDA and HHS officials would not provide us with tobacco-related documents in the possession of FDA staff who participated in developing the regulatory options available to FDA that were not on the public record. As a result, we could not determine to what extent, if at all, documents fitting this description existed.

FDA and HHS officials told us that they believed the public record adequately described the processes for determining FDA's final rule and

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jurisdictional determination. For example, the final rule described several regulatory options that were not included in the final rule and the process that FDA followed in conducting its jurisdictional analysis.

4. Any memorandums, notes from conversations, or electronic or written communications prepared by any FDA employees, or by any other individuals at the request of or on behalf of either FDA or HHS, of any analysis of the regulatory options (or lack thereof) available to FDA once it asserted jurisdiction over tobacco products, including any discussion of what type of regulation would be required under the Federal Food, Drug, and Cosmetic Act and related regulations.

FDA and HHS officials refused to provide us with this information and reiterated that the final rule discussed the rationale for selecting certain options and included some discussion of why other options were not selected.

5. Any memorandums of any meetings involving representatives of FDA convened to discuss the potential requirements of any FDA rules related to tobacco products.

FDA and HHS officials were not sure whether documents fitting this request actually existed. However, we could not determine whether or not any of these documents were in the possession of FDA staff because FDA refused us access to documents that were not included in the public record.

6. Any memorandums or other written communications (including electronic mail) from any government officials reviewing, criticizing, endorsing, authorizing, or approving potential requirements of any FDA rules related to tobacco products.

Although the FDA Commissioner told us that he could not recall any FDA staff indicating that they opposed the final rule or disagreed with FDA's determination that it had jurisdiction to regulate tobacco products, we could not verify this because we were not provided documents in the possession of FDA staff that were not on the public record.

7. All memorandums, reports, correspondence, or other memorialization of contacts between representatives of FDA and representatives of any of the following respecting potential requirements of any FDA rules related to tobacco products, including discussions of potential conflicts or overlapping or conflicting jurisdiction between other applicable federal

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and state laws and any such potential requirements: the Federal Trade Commission; the Department of Justice; the Bureau of Alcohol, Tobacco, and Firearms; any state official; the U.S. Patent and Trademark Office; or any component part of HHS.

We obtained one letter from a Department of Justice attorney to an attorney representing a tobacco company and one letter from FDA requesting information from the Federal Trade Commission on tar and nicotine in cigarettes. Both documents were on the public record. Neither concerned the potential requirements of the proposed rule or conflicting jurisdiction.

FDA's Associate Chief Counsel for Enforcement told us that other Department of Justice documents not on the public record were protected from disclosure because disclosure of communications with officials from the Department of Justice would negatively affect the government's position in the ongoing civil litigation between the U.S. government and the tobacco companies. He noted that the final rule describes correspondence from the Bureau of Alcohol, Tobacco, and Firearms, which submitted comments that were addressed by FDA. He also cited information from states that was in the administrative record and in the comments to the rule. For example, a state official provided information on smokeless tobacco, which is included in the jurisdictional analysis, and attorneys general from several states submitted comments on the proposed rule. These comments, some of which we reviewed, are a matter of public record. The Associate Chief Counsel for Enforcement also noted that some materials on the public record are from the Centers for Disease Control and Prevention. FDA's jurisdictional analysis also contains comments referring to published studies from the National Institute on Drug Abuse.

FDA informed us that agency officials contacted representatives of the Patent Office regarding the Y1 Brazilian tobacco patent and other patents for Philip Morris and R. J. Reynolds products. An HHS official told us that most contacts with other federal and state agencies were oral.

8. All memorandums of conversations, reports, or any documents (including notes and electronic mail) reflecting any meetings or conversations occurring since January 1, 1993, between any FDA officials or employees and any party or lawyer representing any party involved in any lawsuit filed against one or more cigarette manufacturers.

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The FDA Commissioner told us that while he tried to limit his contacts to state government officials, it was possible that private lawyers hired by states to assist them in the litigation may have been present at some meetings he attended.

We examined correspondence between FDA and tobacco companies and their attorneys that were on the public record. We also examined letters regarding petitions to regulate nicotine and the validity of the agency's jurisdiction over tobacco. The public record also contains documents involving state and private litigants.

9. Any internal memorandums, reports, or documents (including notes and electronic mail) concerning (a) the economic impact of regulations under the Federal Food, Drug, and Cosmetic Act for tobacco products; (b) consideration of alternative regulatory proposals considered by FDA concerning tobacco products; and (c) the views of anyone at FDA supporting or opposing the approach to regulations set forth in FDA's proposed regulations concerning cigarettes and smokeless tobacco, including views that FDA lacks statutory authority to regulate tobacco products.

The FDA economist responsible for developing FDA's economic analysis told us how he developed the analysis that was included in the rule and identified the government and private sector officials he contacted regarding the analysis. He also gave us copies of several supporting documents that were identified in the proposed rule, including a Price Waterhouse report prepared for the Tobacco Institute and internal memorandums and electronic mail involving discussions with other economists and Department of Agriculture officials knowledgeable about the tobacco industry.

In February 1996, the FDA economist told us, based on his analysis, that over a 10-year period, a 4-percent reduction in tobacco sales would displace about 10,000 tobacco industry jobs, about 6,000 of which would be among tobacco growers. The final rule reduced the estimated loss of jobs among tobacco growers to about 5,700.

Again, FDA would not provide us copies of internal documents addressing regulatory options or internal views addressing policy or regulatory issues that were not on the public record. Therefore, we could not verify this information.

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10. Any internal memorandums or other communications (including notes and electronic mail) concerning discussions relating to the "additional requirements" that may be imposed by the FDA if the goals set forth in the proposed regulations are not met.

This proposed requirement was dropped from the final rule. While the preamble to the rule discusses "other alternatives" that were considered in setting up the current rule, the rule does not address "additional requirements" that would be imposed if the objective of reducing smoking among children and adolescents by 50 percent in 7 years was not achieved.

11. All internal memorandums or other communications (including notes and electronic mail) concerning how the following letters would be or were covered: June 24, 1994, letter from Chairman Charlie Rose to FDA Commissioner David Kessler; October 27, 1994, letter from Chairman Rose to FDA Commissioner Kessler; December 14, 1994, letter from Chairman Rose to HHS Secretary Donna Shalala; and May 30, 1995, letter from Chairman Thomas W. Ewing to FDA Commissioner Kessler.

An HHS official told us that notes of meetings and records of discussions concerning how to handle these requests were not retained by the persons involved. We could not, however, verify this statement because we were not provided an opportunity to examine documents in the possession of the staff who worked on this issue that were not included in the public or confidential record.

12. With respect to the letters listed in query 11 above, the names of any individuals who participated in conversations, meetings, or other communications concerning the manner in which FDA or HHS would answer the letters; the names of any individuals who participated in the development and approval of responses dated October 11, 1994, and December 19, 1994; and the names of any individuals who made the decision to withhold documents from the Congress.

In a July 15, 1996, letter to the Chairman, the Deputy General Counsel of HHS addressed this issue. Her letter identified FDA and HHS staff involved in handling the Subcommittee's request.

FDA and HHS officials also provided us with copies of internal memorandums related to the four Subcommittee requests. These memorandums, sent by the Associate Commissioner for Legislative Affairs to "each person involved in the nicotine/tobacco effort," requested certain

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FDA staff to provide the requested documents, except for copies of sensitive documents that relate specifically to the agency's confidential investigative operations, including such items as notes of interviews, summaries of meetings, interview schedules, and summaries of questions to be asked. However, FDA refused our request for copies of these documents and would not provide us a list of the documents provided by FDA staff.

In response to the third part of this query, an HHS official told us that no decision was made to withhold documents from the Congress. Instead, FDA and HHS contend that certain documents were not provided to the Subcommittee because their release would (1) jeopardize the integrity of the deliberative process, (2) negatively affect the government's position in ongoing litigation related to the proposed tobacco rule, and (3) identify confidential sources and undermine pledges of confidentiality.

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# GAO's Legal Authority to Obtain FDA Records

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FDA and HHS officials have refused to comply with requests by both the Subcommittee and GAO for certain tobacco-related documents or an index to such documents. These documents were in the possession of agency officials and were not included in either the public or confidential record of the tobacco rulemaking.

As discussed earlier in this report, the officials cited four reasons for declining both the Subcommittee's and our requests for documents: (1) the proposed tobacco regulation was part of an ongoing rulemaking and release of the requested information would jeopardize the integrity of this deliberative process, (2) releasing the requested information and communications with officials employed by the Department of Justice would negatively affect the government's position in ongoing litigation related to the proposed tobacco rule, (3) the requested information was obtained from confidential sources and its disclosure could undermine pledges of confidentiality, and (4) communications with officials employed by the White House are subject to a possible claim by the President of executive privilege which only he can waive.

In an opinion prepared for the Subcommittee, the Congressional Research Service (CRS) considered the four arguments advanced by FDA and concluded that none "would appear to raise a substantial legal basis" for withholding the information from the Subcommittee.<sup>2</sup> According to CRS, numerous decisions of the Supreme Court "establish and support a broad and encompassing power in the Congress to engage in oversight and investigations that [reach] all sources of information that enable it to carry out its legislative function."

Following unsuccessful efforts to persuade FDA to provide the information, GAO wrote to the Secretary of HHS on November 22, 1996, explaining our legal right of access to FDA records. GAO's request relied on section 716 of title 31, U.S. Code, which requires each federal agency to "give the Comptroller General information the Comptroller General requires about the duties, powers, activities, organization, and financial transactions of the agency."

In our letter, we told the Secretary that the four arguments relied on by FDA for withholding the information we requested did not restrict our statutory right of access and that

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<sup>2</sup>Congressional Research Service, Refusal by the FDA of Document and Information Requests with Respect to its Proposed Regulation of the Sale and Distribution of Cigarettes and Smokeless Tobacco Products (Washington, D.C.: The Library of Congress, Aug. 19, 1996).

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The law provides an exception from [section 716] only for certain kinds of information, and then only if it is determined by the President or the Director of the Office of Management and Budget that disclosure "reasonably could be expected to substantially impair the operations of the Government." . . . Information could also be exempt from disclosure to GAO based on a claim of executive privilege. However, assertion of that privilege has been reserved to the President.

In her January 30, 1997, response to our letter, the Deputy General Counsel of HHS declined to provide us the documents we requested, citing essentially the same four reasons previously cited.

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# Chronology of FDA's Tobacco Regulation Activities

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The following summary of FDA's tobacco regulation activities is based primarily on interviews with the FDA Commissioner and key FDA staff involved in this effort. In general, we could not verify the testimonial evidence they provided because FDA refused to give us notes, memorandums, and other documents in the possession of FDA staff that were not on the public or confidential record.

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## Public Petitions Prompt FDA Regulatory Involvement

According to the former FDA Commissioner, FDA initiated its examination of the need to regulate tobacco products in early 1991, in response to citizen petitions from such organizations as the Coalition on Smoking OR Health and the American Medical Association. These petitions, submitted from the late 1980s through 1991, asked FDA to regulate low-tar and low-nicotine cigarettes and denicotinized cigarettes as drugs under the Federal Food, Drug, and Cosmetic Act.

Shortly after joining FDA, the Commissioner said he met with several top FDA officials, including the Chief Counsel and the Associate Commissioner for Public Affairs, to discuss these public petitions. The Commissioner said that he and the other officials agreed that tobacco regulation was an important issue that warranted FDA's consideration, but that it was not among the top priorities at that time. Nevertheless, the Commissioner said he requested these individuals to develop a working knowledge of tobacco issues as a framework for responding to the petitions. He also asked them to consider broader approaches to tobacco regulation than suggested by the petitions.

According to the Commissioner, a small team was formed to initiate work on the tobacco issues raised in the petitions. The Commissioner and other FDA officials indicated that the team included representatives from the Offices of the Commissioner, Chief Counsel, and Policy. According to the Commissioner, from mid-1991 through 1992, the team reviewed the scientific evidence on the addictive nature of nicotine and researched how tobacco companies could reduce or remove nicotine from cigarettes. The team used this information to consider the appropriate regulatory role for FDA and to develop options for responding to the petitions.

During 1993, the Commissioner said he met periodically with the team to discuss the possible manipulation of nicotine by tobacco manufacturers as well as FDA's regulatory role and response to the petitions. According to the Commissioner's calendar, a representative of the principal public petitioner, the Coalition on Smoking OR Health, attended an August 1993

meeting with the Assistant Secretary for Health. Subsequently, in September 1993, the Commissioner and team members told us that they met with the HHS Assistant Secretary for Health to obtain his guidance on how FDA should respond to the petitions. According to FDA staff who attended the meeting, the Assistant Secretary encouraged FDA to address the issues in the petitions. Subsequent to the meeting, in late 1993, the Commissioner instructed the team to draft a response to the petitions. In a letter dated February 25, 1994, FDA provided an informal response to the Coalition on Smoking OR Health that intended "to frame the issues for the broader public debate that will be necessary to resolve them." The letter indicated that if the agency were to conclude, based on an appropriate record, that cigarette vendors intend people to buy their products to satisfy their nicotine addiction, then FDA would have the legal basis to regulate these products under the provisions of the Federal Food, Drug, and Cosmetics Act.

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## **FDA Intensifies Its Tobacco Investigation**

In March and June 1994, the House Energy and Commerce Subcommittee on Health and the Environment held hearings focusing on allegations that tobacco manufacturers controlled the nicotine content of cigarettes to maintain their addictive effect. In preparing for these hearings, the number of FDA staff working on this issue grew from about 5 to more than 30, according to agency officials. During this period, FDA staff told us they visited three cigarette manufacturers and other tobacco-related industries, including a manufacturer of cigarette paper in France.

At the March 25, 1994, hearing, the Commissioner presented the results of FDA's study up to that time. He testified that accumulating evidence suggested that cigarette manufacturers may control smokers' choice by controlling the levels of nicotine in their products in a manner that creates and sustains an addiction in the vast majority of smokers. The Commissioner concluded that this was sufficient cause to consider the question of whether cigarettes should be regulated as drugs.

On July 21 and 22, 1994, the Commissioner convened a day-and-a-half meeting, which focused solely on regulating tobacco products. In addition to the Commissioner, meeting participants included seven staff from the Office of the Commissioner, FDA's Chief Counsel and two other attorneys from her office, three staff from the Center for Drug Evaluation and Research, three investigators, and three staff from the Office of Public Affairs, including a speech writer. According to the meeting agenda, FDA staff discussed the agency's policy objectives, goals, and message, as well

as the agency's investigative and regulatory strategies. According to the Commissioner, papers were disseminated at the meeting. However, none of the staff we interviewed who attended this meeting could recall whether meeting minutes were recorded or whether summaries of the regulatory or investigative strategies discussed were written.

Following the July 1994 meeting, FDA staff told us that their tobacco-related activities became more focused on the agency's authority to regulate tobacco products, how tobacco companies manipulate nicotine, and how the tobacco industry markets cigarettes to children and adolescents. To carry out this work, FDA officials told us that two teams of high-ranking staff members were established. The first team, headed by the Commissioner, assessed whether FDA had authority to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act; the second team focused on developing options for regulating the sale and marketing of tobacco products and was headed by the Director of the Policy Development and Coordination Staff in FDA's Office of Policy.

The FDA teams were assisted by the agency's criminal and special investigators, research scientists, and attorneys. FDA team members met with confidential tobacco-industry informants; searched and analyzed the scientific literature, including epidemiological information and studies on nicotine addiction; discussed with academic and industry researchers the pharmacology of tobacco products and nicotine; examined patents and statistical materials; and obtained marketing data. They also reviewed confidential tobacco-industry documents, including some received anonymously in the mail, concerning cigarette manufacturing and control of nicotine levels. In completing their work, the teams sought advice from federal officials with many government agencies. These included officials from HHS; the Department of Justice; the U.S. Customs Service; the Department of Agriculture; the Bureau of Alcohol, Tobacco, and Firearms; the Occupational Safety and Health Administration; the Centers for Disease Control and Prevention; the Federal Trade Commission; the U.S. Patent and Trademark Office; and the White House.

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## Regulatory Options Considered by FDA

By late 1994, FDA staff had considered the agency's jurisdictional authorities and the types of restrictions FDA could apply and began drafting a regulatory proposal. According to FDA staff, one of the reports on which they based the regulatory proposal was a 1990 Public Health Service report called "Healthy People 2000." This report established the objective of reducing the use of tobacco by children and adolescents by roughly half

by the year 2000. Although FDA staff said they considered a number of regulatory options, they would not reveal any information about the alternatives, other than those that were presented in the proposed rule and final rule. HHS' Deputy General Counsel and FDA's Associate Chief Counsel for Enforcement told us that staff could not discuss matters that were part of the deliberative process. FDA staff acknowledged, however, that a draft outline of the proposed rule regulating the sale and marketing of tobacco products to children and adolescents and proposed jurisdictional determination were reviewed and approved by the Commissioner. FDA officials, including the Commissioner, stated that senior HHS officials also were consulted as the draft proposed rule and jurisdictional analysis moved forward in early 1995. Subsequently, a draft of the proposed rule and jurisdictional analysis was provided to the Office of Management and Budget and the White House for review and comment.

In August 1995, after receiving approvals from HHS, the Office of Management and Budget, and the White House, the proposed rule and jurisdictional analysis were published in the Federal Register. The supplemental information accompanying the proposed rule cited several options considered by FDA officials. These include (1) advertising restrictions, ranging from a full ban on advertising to restrictions on advertising and promotional practices that children actually view; (2) requiring tobacco manufacturers to monitor the sales and distribution of retail establishments; (3) requiring package inserts to contain educational information on cigarettes and smokeless tobacco products; (4) setting the permissible age for purchase at 19 instead of 18; and (5) restricting rather than prohibiting sales from vending machines. Although FDA officials declined to discuss internal agency considerations of regulatory options, the proposed rule explained why some options were not selected and why a decision was made to focus on restrictions on marketing to adolescents.

From the publication of the proposed rule and jurisdictional analysis in August 1995 until January 1996 and from mid-March to mid-April 1996—when FDA reopened the comment period to permit comments on specific documents added to the public record—FDA officials reported that they received a record volume of comments on the rule—about 700,000 pieces of mail. Many of the FDA staff members who served on the two investigative teams were assigned responsibility for analyzing these comments; comments involving legal issues were referred to the Office of General Counsel. In August 1996, about 5 years after FDA

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**Appendix III  
Chronology of FDA's Tobacco Regulation  
Activities**

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officials initially discussed this subject, the final rule and jurisdictional determination were published.

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