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The Tobacco Institute

March 9, 1995

1994-1995 ACTIVITY
FOOD & DRUG ADMINISTRATION PROPOSALS
TO REGULATE TOBACCO PRODUCTS

February 25, 1994
FDA Commissioner Kessler writes to Coalition on Smoking OR Health, stating that he believes FDA has authority to regulate tobacco products and points to "manipulation of nicotine" as basis. However, he wants Congressional guidance before embarking on regulation.

February 28
ABC-TV airs story alleging "nicotine spiking" on "Day One" program.

March 3
Congressmen Synar (D-OK) and Durbin (D-IL) circulate "Dear Colleague" letter seeking cosponsors for H.R. 2147, to give FDA regulatory authority over tobacco products. Senate companion is S. 672, by Senator Bingaman (D-NM).

March 4
ASH files petition to FDA for regulation of cigarettes.

March 7
Coalition on Smoking OR Health submits new petition to FDA asking for classification of cigarettes as drugs.

Day One airs second story on nicotine and ingredients.

March 10
Congressman Waxman (D-CA) writes Attorney General Reno calling for Justice Department investigation of "the tobacco industry's failure to report the addition of nicotine to cigarettes as required by Federal law" on ingredients reporting.

March 14
Kessler submits Freedom of Information request to Federal Trade Commission for data on nicotine values. Similar requests are made by Congressman Lancaster (D-NC) and Dr. John Slade, on behalf of the American Society of Addiction Medicine.

Day One airs third story on nicotine.

March 16
In hearing on agriculture appropriations bill, Kessler and Subcommittee Chairman Durbin discuss potential for regulation of tobacco by FDA. HHS official states that department has asked for Justice Department investigation of cigarettes and nicotine; later, HHS issues clarification that such a request has been discussed with the DoJ, but not formally referred for action.

Same day, Tobacco Institute holds briefing for 23 Members on nicotine issues. Coalition on Smoking OR Health also holds congressional briefing.

March 24
Philip Morris files lawsuit against ABC-TV for libel on Day One.

March 25
House Energy & Commerce Subcommittee on Health & the Environment, chaired by Waxman, holds oversight hearing on issues related to tobacco products and nicotine. Kessler and Tobacco Institute are among witnesses.

April 7
President Clinton mentions FDA investigation of nicotine in response to question at Town Hall Meeting.

April 8
National Public Radio airs story on cigarette ingredients.

April 12
Six tobacco companies release list of ingredients added to tobacco in the manufacture of cigarettes.

April 13
Waxman holds press conference to release material he alleges shows nicotine manipulation.

April 14
Waxman subcommittee holds oversight hearing for chief executive officers of seven tobacco companies. Subcommittee requests documents from companies.

April 19
Coalition on Smoking OR Health testifies before Durbin subcommittee urging regulation of tobacco products by FDA.

April 28
Waxman subcommittee holds oversight hearing for two former Philip Morris scientists, Victor DeNoble and Paul Mele.

May 1
New York Times story reports that 91-percent of respondents to telephone survey believe cigarettes are addictive.

May 2
New York Times story includes statement by Federal Trade Commission official that FTC is studying alternative tar and nicotine test methods.

May 12
Coalition on Smoking OR Health filed statements from April 14 hearing with FDA in support of petitions for regulation of cigarettes.

May 17
Waxman subcommittee hears Joseph Califano, representing Columbia University's Center on Addiction and Substance Abuse.

May 23
Congressman Meehan (D-MA) and six other Members write Attorney General Reno requesting DoJ to "initiate a series of criminal investigations into tobacco company activities and statements."

May 26
Waxman subcommittee hears James Glenn, president of Council for Tobacco Research.

May 31
President Clinton mentions FDA's study of nicotine in remarks at swearing-in ceremony for Council on Physical Fitness.

June 13
Coalition on Smoking OR Health writes all Members of Congress urging FDA regulation.

June 15
House Rules Committee rejects Synar and Durbin request to be allowed to offer language from H.R. 2147 as amendment to agriculture appropriations bill.

June 21
Waxman subcommittee hears Kessler on recent FDA activities regarding high-nicotine tobacco leaf, Y-1.

Justice Department officials meet with Meehan to discuss request for investigation.

June 22
Waxman subcommittee hears Thomas Sandefur, chief executive officer of Brown & Williamson.

June 24
Congressman Charlie Rose (D-NC) requests information from FDA regarding agency's consideration of potential regulation of tobacco products.

June 30
Senator Ford writes Attorney General Reno regarding Meehan request.

June
Waxman writes National Cancer Institute asking for study of FTC test method for measuring tar and nicotine yields.

July 19
FDA sends "partial response" to questions raised by Congressman Bilirakis (R-FL) at June 21 oversight hearing.

July 20
Federal Trade Commission asks National Cancer Institute to convene consensus conference to study cigarette testing methodology and to recommend any changes.

July 21
Republican members of Waxman subcommittee send two separate letters to FDA requesting information and documents as follow-up to June 21 hearing.

July 27
Lancaster writes Kessler opposing FDA regulation of tobacco.

August 2
FDA Drug Abuse Advisory Committee holds public hearing and considers staff questions on tobacco products and nicotine. Committee agrees that "Cigarettes and other forms of tobacco are addicting" and that "Nicotine is the drug in tobacco that causes addiction" but declines to recommend threshold level that causes addiction.

August 5
Waxman subcommittee was to hold oversight hearing on tobacco sponsorship and advertising, but postpones hearing indefinitely.

August 18
FDA sends additional documents to Bilirakis.

August 19
Congressman Barlow (D-KY) writes Kessler opposing FDA regulation of tobacco. [Throughout the summer, additional Members write FDA on the issue.]

August 28
Jack Anderson column asserts that Kessler may have "October surprise" for tobacco industry.

September 12
FTC's expert on tobacco advertising is detailed to FDA to work on tobacco issues.

September 13
Institute of Medicine (an arm of the National Academy of Sciences) issues report including call for regulation of tobacco products to fight youth smoking.

September 23
Congressman Lancaster and others write FDA requesting status of its investigation of tobacco.

September 29
FTC announces proposed consent agreement with American Tobacco Company regarding advertising of Carlton cigarettes. FTC states "Consumers will not necessarily get less tar because the ratings published in the ads are obtained by smoking machines that do not reflect actual smoking, in part because they do not take into account such behavior as "compensatory smoking.""

October 3
Waxman writes Kessler urging response to Congressman Bliley's (R-VA) July 21 request for information "within the next two weeks."

October 4
Coalition on Smoking OR Health announces nationwide petition drive by "Citizens to Protect Our Children From Tobacco" through early December. Will collect signatures calling on Congress, the Administration and FDA "to ensure that tobacco products are regulated (without banning them), including the way they are manufactured, sold, labeled, advertised and promoted; that the public's health is protected from the dangers of tobacco use to the greatest extent possible; and that children are not encouraged to smoke or given access to tobacco products."

FDA official says that agency is continuing its "investigation into whether there is a basis for the agency asserting jurisdiction over nicotine-containing tobacco products."

October 7
Republican members of Waxman subcommittee and selected members of full committee write Kessler expressing concern that FDA has been unresponsive to their July 21 requests for information.

Rep. Boehner (R-OH) inserts statement in Congressional Record on "Tobacco Products and the Myth of Underregulation."

October 8
Congress recesses for elections. H.R. 2147 and S. 672 are effectively dead for the session.

October 14
USA Today editorial calls for FDA regulation of tobacco products as well as ban on vending sales and $1 per pack tax increase. Response from Tobacco Growers Information Committee is printed.

October 26
Wall Street Journal article asserts that U.S. Tobacco Co. manipulates nicotine levels in snuff. U.S. Tobacco issues statement refuting allegations.

November 3-4
American Society of Addiction Medicine to hold conference on "nicotine dependence."

November 10
FDA writes Congressman Lancaster stating that FDA continues to investigate "nicotine-containing tobacco" toward making a decision whether such products are subject to its jurisdiction.

December 1
Congress adjourns.

December 5-6
FDA Drug Abuse Advisory Committee meeting is postponed.

December 5-6
At request of FTC, ad hoc committee of President's Cancer Panel holds consensus conference on tar and nicotine test method. Recommended changes include testing under various smoking parameters to result in range of potential yields; graphic representation of range of yields on packaging and advertising; listing of "other hazardous smoke constituents" on packaging and advertising. Report will go to FTC and to Congress in 1995.

December 16
Nine Members of House, led by Congressman Bart Gordon (D-TN), write to White House Chief of Staff Leon Panetta urging Administration to ensure that FDA does not attempt to assert jurisdiction "over tobacco products marketed without therapeutic claims."

December 19
Coalition on Smoking OR Health says that it has filed petition for RJR's new experimental cigarette, "Eclipse," to be regulated as drug.

January 4, 1995
Congress convenes.

January 10
Tobacco Institute presents polls showing public opposition to FDA regulation of tobacco. R.J. Reynolds Tobacco Company and allied organizations present petitions opposing additional regulation of tobacco.

January 11
Coalition on Smoking OR Health presents petitions calling for FDA regulation.

February 2-3
FDA Drug Abuse Advisory Committee is tentatively scheduled to meet, but no meeting is called.

February 18
National Journal article, "Ganging Up on the FDA," states that FDA's study of whether it should regulate tobacco is still on track.

February 25
Reps. Waxman and Stearns (R-FL) debate FDA regulation of tobacco on CNN's "Newsmaker Saturday" program.

February 27
Reps. Coble (R-NC) and Clement (D-TN) circulate Dear Colleague letter refuting Coalition on Smoking OR Health letter's characterization of Tobacco Institute's polling on FDA regulation.

March 8
Kessler delivers speech to Columbia Law School on youth smoking and "addiction" issues, noting that FDA's study continues. New York Times story states, "Officials say the agency will announce the results of its investigation sometime this summer..."

April 6-7
FDA's Drug Abuse Advisory Committee is scheduled to meet. First day is closed session; no detailed agenda available.

Kennedy Kaufman Jeffords Mikulski

Brand + Food

4/6 FDA

Admins proposal

KLS Consumer protect, access

Ken

Kessler

Cons. protection

mission + reform

admin. autonomy

(Hth + Safety)

Glickman

SE Stds & Fed Reg

(Others to follow)

AK Foods + Vet. products

Q+A –

Jeffords

Q Other areas w/ cut authority that we can help?

A Export

reduce admin. burden

modifying statute to enable

FDA to respond/consist. w/ technol.

[Umpires
non Rx drugs

Kennedy
Reduce FDA's
reg. burden...

Q Cost-ben. rule
imposed on agencies FDA
risk ratio benefit to consumers?

A Regulatory burden

limitations to method
those who impose
costs aren't always
receiving benefits

Q So

First

Q+A FDA + docs

[illegible]

Q+A Concerns about agency:
~~facilities~~ Taj Mahal
delays in approving Rx / devices
outside experts

[illegible]
Export Concerns

Access

Hatch's interest

structure
FDA making
Chg. different
scattered
testing: mission

Priorities
Some areas will meet
higher focus
than other areas

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allocation of agency personnel
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Than in other offices

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