

OFFICE OF THE COMMISSIONER MEETING
EXECUTIVE SUMMARY

Mitchell

Date: Friday, March 4, 1994

Time: 8:30 a.m. - 10:00 a.m.

Location: Parklawn, Commissioner

Subject: Tobacco

Attendees: Dr. Kessler, Mr. Mande, Ms. Thompson, Mr. Zeller, Ms. Porter, Mr. Mitchell, Mr. Hunter, Dr. Wykoff, Mr. Light, Mr. Dahl, Mr. Doyle, Mr. Budich, Dr. Wright, Dr. Bernstein, Ms. Lorraine, Ms. Witt, Ms. Lenahan, Ms. Hardy, Mr. O'Hara, Mr. Adams, Ms. Knoth, Mr. Hubbard, Mr. Lazerow, Ms. Berbakos

Meeting Purpose: To brief the Commissioner on the status of action items discussed 2/28.

Background: In the 2/28 meeting three groups were established to address FDA's concerns regarding tobacco. The following is a list of the action items and the person or persons responsible for that item.

Investigational Team

Gary Light, Tom Doyle, Jim Dahl, Jim Hunter, Jack Mitchell, Mitch Zeller - Informants, flavor houses, information on processing procedures, nicotine, followup leads

Ann Witt, Catherine Lorraine - liability cases (including identifying additional names that may need additional contact)

Kevin Budich - interviewing other government agencies

Diane Thompson, Jan Hardy, Donna Lenahan - legislative history and analysis

Ilisa Bernstein - petitions, patents

Carol Knoth - search for literature/articles/books

Andrew Lazerow - tobacco tour, tobacco stock market

Science of nicotine - Mitch Zeller, Ilisa Bernstein, Randy Wykoff and staff

Legal Theory - Margaret Porter, Catherine Lorraine, and David Adams

Tab A - Transcript of 2/28 Day One program

Tab B - February 28, R.J. Reynold letter to Dr. Kessler

Executive Secretariat Contact: Liz Berbakos, 443-8793



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NATIONAL MARKET COVERAGE

TRANSCRIPT

FOR	FDA (Office of External Affairs) Call #38	STATION	WABC TV ABC Network
PROGRAM	Day One	CITY	New York
DATE	February 28, 1994 8 PM	AUDIENCE	
SUBJECT	Cigarettes and Nicotine		

BROADCAST EXCERPT

FORREST SAWYER, ANCHOR: Good evening. I'm Forrest Sawyer, and this is DAY ONE.

Tonight: A DAY ONE investigation that took the government by surprise.

There's something that tobacco companies don't want you to know.

CLIFF DOUGLAS, AMERICAN CANCER SOCIETY: The industry manipulates nicotine, takes it out, puts it back in, uses it, as if it were sugar being put in candy.

JOHN MARTIN, REPORTER: Why are you artificially spiking your cigarettes with nicotine?

JOSEPH D. BETHEZI: We are not in any way doing that.

SAWYER: Cigarettes, they'll hook you fast, and it's not just an accident of nature.

REP. MIKE SYNAR (D) OKLAHOMA: They don't want anybody looking at their product, so that they can doctor it, they can alter it.

SAWYER: A DAY ONE investigation that could change the tobacco industry forever.

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SAWYER: Tonight, a DAY ONE investigation that could completely transform the tobacco industry. It was back in 1964 that the Surgeon-General declared cigarettes to be hazardous to your health. After that, cigarette companies were forced to change the way they labeled and advertised their product. It was the

biggest challenge the powerful cigarette industry had ever faced--until now.

For nearly a year, DAY ONE has been investigating nicotine, the ingredient in cigarettes that keeps smokers addicted, and we've discovered that cigarette manufacturers have been carefully controlling levels of nicotine in cigarettes. Late last week when word of our investigation got out, the Food and Drug Administration announced that it is now considering whether to regulate cigarettes as drugs, and Congress is planning to hold hearings on the issue next month, hearings that could be the first step toward a ban on cigarettes as they are now manufactured.

Clearly, the story is just beginning, and this investigation from John Martin is what started the new cigarette war.

JOHN MARTIN, REPORTER: From these tobacco fields comes one of the world's most profitable and addictive substances. To many smokers, cigarette smokers are simply leaves rolled in white paper. In reality, cigarettes are a complex, scientifically-engineered product about which little is known publicly.

Do you think the tobacco companies have been open and honest with people about what's in their product?

REP. MIKE SYNAR (D) OKLAHOMA: Absolutely not. In fact, they've done just the opposite. They've basically blocked any attempts for us to give an honest accounting to the American public of the ingredients within the product.

MARTIN: One ingredient contained in these tobacco leaves is known, nicotine. The 1988 Surgeon-General's report identified nicotine as a highly addictive drug and said: This is why smoking can be as difficult to quit as heroin or cocaine.

One of the writers of the report was addiction expert, Dr. Jack Henningfield.

DR. JACK HENNINGFIELD, ADDICTION EXPERT: The cigarette is essentially the crack/cocaine form of nicotine delivery.

MARTIN: Now, a lengthy DAY ONE investigation has uncovered perhaps the tobacco industry's last, best secret, how it artificially adds nicotine to cigarettes, to keep people smoking and boost profits.

The methods the cigarette companies use to precisely contain the levels of nicotine is something that has never before been disclosed to consumers or the government.

For years, growing and blending tobacco was an art. But about 30 years ago, it began evolving into something quite different.

1960S PROMOTIONAL FILM ANNOUNCER: In Liggett & Myers' laboratory, modern science makes certain that the smoker gets precisely what he expects to get.

MARTIN: And one thing that smokers are supposed to get is nicotine. That was made clear decades ago by a Philip Morris official. He wrote this confidential internal memo:

Think of the cigarette pack as a storage container for a day's supply of nicotine. Think of the cigarette as a dispenser for a dose unit of nicotine. Think of a puff of smoke as the vehicle of nicotine.

It was here in Winston-Salem, North Carolina, that the manufacturing process began to change. The RJR Reynolds Tobacco Company pioneered a 2-step process to make cigarettes more cheaply and to control the level of nicotine.

Step 1. It developed reconstituted tobacco, which is made from stalks and stems and other wastes that it used to throw away.

DON BARRETT: American public doesn't understand that the tobacco--it's not a natural tobacco leaf, that so much of the cigarette is so-called reconstituted tobacco, because it's a manufactured product.

MARTIN: Don Barrett sued the American Tobacco Company on behalf of a client who has since died of cancer. Barrett discovered a great deal about how cigarettes are manufactured.

BARRETT: They would take the material, the dust, the tobacco dust that fell on the floor, and they would sweep those up, and they would dump them in a big bin, and they would use that to make the so-called reconstituted tobacco.

MARTIN: The processes involved in controlling the nicotine level are company secrets. This former RJR manager asked to be interviewed in silhouette.

ANONYMOUS FORMER RJR MANAGER: On the average, the currently marketed brands contain about 22 reconstituted tobacco. The cut-rate or generic brands typically contain usually about double that.

MARTIN: DAY ONE commissioned a laboratory analysis that confirmed the industry's heavy use of reconstituted tobacco. In one brand from RJR, it compromised a quarter of the cigarette. In another, about a third.

Even though reconstituted tobacco allows the companies to produce cigarettes more cheaply, there are problems: poor taste and less nicotine. So, here's what the companies do in step two. They apply a powerful tobacco extract containing nicotine and

flavor to the reconstituted tobacco. This process, too, is meant to be secret. Of the 5 companies we contacted who supply the extract, only one would talk to us on camera.

VAN NAUHEIS, V.P. DR. MADIS LABORATORY: The tobacco people are very secretive of what they use. Some of them, I would think, if you ask them whether they use tobacco, they might just say they don't, you know.

MARTIN: Van Nauheis is a vice president of Dr. Madis Laboratory. He told us how they make this concentrated extract that is rich in nicotine.

NAUHEIS: You put the solvent on it, whatever solvent it is, water or alcohol, and then you just percolate it, and after you percolate it, you concentrate it. It's basically the same as if you're having a drip coffee pot. It's kind of a syrupy consistency, you know, like molasses.

MARTIN: Why would the tobacco companies use this nicotine-rich cigarette?

ANONYMOUS FORMER RJR MANAGER: They put nicotine in the form of tobacco extract into a product to keep the consumer happy.

MARTIN: They're fortifying the product with nicotine. Is that correct?

ANONYMOUS FORMER RJR MANAGER: The waste filler. Yes. They are.

DR. C. EVERETT KOOP, FORMER SURGEON GENERAL: Well, as you describe that, which I've heard for the first time, it makes my blood boil, because what they are now selling is not a natural tobacco product, which happens to have nicotine in it, but they are selling a nicotine dispenser, and that is quite different.

MARTIN: To try to verify that nicotine is being added to the reconstituted tobacco in cigarettes, we went to the American Health Foundation, a respected research center in Valhalla, New York. At DAY ONE's request, the foundation separated and then analyzed the reconstituted tobacco portion of several brands of RJR cigarettes.

Reconstituted tobacco ordinarily contains 25% or less of the nicotine in regular tobacco. But the samples we tested had up to 70% of the nicotine that would be found in regular tobacco. Bogdan Propkopchick performed the analysis.

BOGDAN PROPKOPCHICK: I was kind of surprised because I expected it to be less. The most likely explanation is that some nicotine has been added, either with flavoring agents or just by itself.

MARTIN: Why are you adding nicotine to your cigarettes?

JOSEPH D. BETHEZI: We are not in any way doing that.

MARTIN: You're not adding nicotine?

BETHEZI: No. No. We don't do that.

MARTIN: Joseph D. Bethezi and John Robertson are R.J.R. scientist involved in tobacco research.

You know about tobacco extracts.

BETHEZI: I do know about tobacco extracts. They, they, they're used as flavor materials, and it's very common in the tobacco industry.

MARTIN: Is there nicotine in those?

BETHEZI: A water extract of tobacco would have nicotine in it.

MARTIN: How much?

BETHEZI: Just like a water extract of, of, of, of the coffee bean would have caffeine in it. And--

MARTIN: So, would this be a little bit or a lot?

BETHEZI: It's hard for me to say. I don't know what a little bit or a lot would be. But I think that--

MARTIN: Well, how much does it have?

BETHEZI: I think any company involved in the manufacture of tobacco and whose consumers are demanding a wide range of tar and nicotine products, they have blending and reconstituted tobacco techniques for reaching those, that range of tar and nicotine in their products.

MARTIN: But how much nicotine is added? The companies control the dosage precisely, according to this former RJR manager.

In commercially sold cigarettes, what percentage of tobacco extract is nicotine?

FORMER RJR MANAGER: That, that really depends on what level the process calls for. In other words, I can say to you: I want it at 1%. I want it at 5%. I want it at 10%. I want it at 15%.

MARTIN: It's this ability to control the exact dosage of nicotine with tobacco extract that is so alarming to Dr. Greg Connolly, a Massachusetts health official.

DR. GREG CONNOLLY, MASS. HEALTH OFFICIAL: Tobacco extract is taking nicotine out of tobacco leaf. It's a drug called nicotine. It's a euphemism. It's like calling heroin poppy seed oil. It's a drug. It's a drug. It's a drug.

MARTIN: Publicly, the companies say, they are adding this extract just for the flavor. But there is evidence to contradict that. First, an extract industry manager told DAY ONE cigarette makers also use his product to give reconstituted tobacco a, quote, kick. That kick, he says, comes from nicotine.

Second, even RJR's own researchers say they believe nicotine is a primary reason people smoke. They have identified nicotine's effect on the body, its ability to reduce anxiety and increase mental alertness. In this 1992 study, co-authored by RJR's Dr. Robinson, they wrote: The beneficial effects of smoking on cognitive performance are a function of nicotine absorbed from cigarette smoke.

In addition, patents owned by the cigarette companies showed they are well aware of the science of dosing and delivering nicotine. According to this 1980 patent obtained by DAY ONE, Loew's, the parent company of cigarette maker Lorillard, held the rights to a system that is especially attractive in enriching the nicotine content of reconstituted tobacco.

Dr. John Slade, an expert in nicotine addiction has researched cigarette patents.

DR. JOHN SLADE, NICOTINE ADDICTION EXPERT: My conclusion from looking at this is that the tobacco companies have been doing this for a very long time, fine-tuning the nicotine content of their products.

MARTIN: LTR Industries, a French subsidiary of Kimberly Clark, even advertises in a trade journal that its process for treating reconstituted tobacco permits adjustments of nicotine to your exact requirements.

There's another way nicotine is added to cigarettes, and it begins, perhaps surprisingly, at docks like this one in Newark, New Jersey. It is here that nearly pure nicotine is brought ashore to be combined with alcohol. It's called denaturing. The mixture can then be applied to tobacco during the manufacturing process for, among other things, flavoring.

As these trucking records show, Philip Morris, for example, received thousands of gallons of this alcohol mixture during the

MARTIN: But the FDA has indicated it doesn't need Congress's permission to act, though it wants its guidance. Even without legislation, the FDA believes it already has the legal authority to act on its own, and given the evidence now under consideration, the agency could ban all cigarettes with addictive levels of nicotine-- in other words, virtually every single cigarette on the market.

KOOP: I would think that if I were the administrator of FDA, and I learned that nicotine was being added to cigarettes to increase the amount of nicotine present, that I would view that cigarette as a delivery device for the use of nicotine, which is under ordinary circumstances a prescription drug, and I would think that demanded regulation.

SAWYER: John, this is really a remarkable story. But regulation's a very big word. When they talk about regulating the cigarette industry, what do we, what do we mean?

MARTIN: It means that the cigarettes would have to be certified as safe and effective, as any other drug is, by the Food and Drug Administration.

SAWYER: What about the cigarettes being sold today? Can they be certified?

MARTIN: Many of them could not, because they have higher levels of nicotine than the Surgeon General has said is addictive, and, certainly, the FDA would have them banned on the market.

SAWYER: Remarkable. What does the tobacco industry say about all this?

MARTIN: Well, they say they're not really adding nicotine, that they're moving it from one part of the tobacco product to another, and they presumably could offer a cigarette that is simply the leaf and not this reconstituted filler material. However, that would raise the amount of nicotine, and it probably wouldn't help them avoid regulation.

SAWYER: Well, obviously there's a lot more to come here. You're still working on this story?

MARTIN: We're going full speed ahead this week.

SAWYER: And we will watch for that next development next week. John Martin, thanks very much.

1980s. The cigarette makers say this mixture leaves only a tiny amount of nicotine on the tobacco. Still, any kind of nicotine manipulation disturbs critics like Cliff Douglas of the American Cancer Society.

CLIFF DOUGLAS, AMERICAN CANCER SOCIETY: Public doesn't know that the industry manipulates nicotine, takes it out, puts it back in, uses it as if it were sugar being put in candy. They don't have a clue.

MARTIN: Neither, apparently, do members of Congress.

SYNAR: Well, it disgusts me.

MARTIN: Were you aware of that?

SYNAR: No. I wasn't. They don't want anybody looking at their product, and the reason is exactly what you just went through, so that they can doctor it, they can alter it, they can do anything with it, and they can literally jeopardize the health of the American public without having any consequence.

MARTIN: The tobacco industry boasts that it makes cigarettes with various yields of nicotine, as demonstrated over the years, when it tests them on a machine like this one. The industry says the availability of low-tar, low-nicotine cigarettes gives consumers a choice.

HENNINGFIELD: Scientifically, the low-tar, low-nicotine cigarette notion is basically a scam.

MARTIN: Jack Henningfield of the National Institute of Drug Abuse argues that these low yields for the most part are attained not by removing nicotine, but, rather by using filters and air holes. But smokers get around this, he says.

HENNINGFIELD: They take a few extra puffs. They inhale a little bit more deeply. They beat the machine. They beat the cigarette. They get all the nicotine their body needs to maintain addiction.

MARTIN: Actually, if the companies wanted to take out all the nicotine, they could.

The truth is, you could take all the nicotine out right now in cigarettes and sell them. Couldn't you?

BETHEZI: We have not done that.

MARTIN: But you could do it.

BETHEZI: Well, as scientists and engineers here at R&D, I think that that could be done. But I think the real issue here is that we as a company are providing a legal product to people who are looking for a pleasing sensory experience with mild pharmacology.

MARTIN: So, why don't cigarette makers take the nicotine out of cigarettes?

KOOP: Cause they wouldn't sell cigarettes. If cigarettes didn't give you a bang, they wouldn't sell them.

MARTIN: Philip Morris knows this from its own experience. In 1991, it test-marketed Next, a denicotinized cigarette that it withdrew from the market because without nicotine few smokers would buy it.

How tobacco companies manipulate nicotine and their reluctance to take it out strongly suggests that they want smokers to get nicotine, and they want them to get it in controlled doses.

Several months ago, when we tried to get a reaction about all this from the Food and Drug Administration, the agency declined comment, but immediately sent out investigators to look into the matter on their own.

Then, learning of our DAY ONE broadcast tonight, the FDA sent out this letter on Friday.

Quote: Evidence brought to our attention is accumulating that suggests the cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction.

That's why the FDA says it may have the legal basis on which to regulate these products.

CONNOLLY: If the industry could put nicotine into Nabisco Shredded Wheat and get compulsive breakfast eaters, I'm sure they'd do it.

MARTIN: But they can't, of course. That's because nicotine is regulated in every other form, including nicotine patches and nicotine gum, which people use to quit smoking. Cigarettes are the exception. That's because the tobacco industry has been highly successful in getting Congress to protect it from regulation, according to Dr. Connolly, the Massachusetts health official.

CONNOLLY: They exempted the cigarette from the Federal Hazardous Substances Act, Controlled Substances Act, Toxic Substances Act, Consumer Product Safety Act. Every major piece of health legislation since 1964 has had a specific exemption for cigarettes.

SYNAR: And the lobby of tobacco is probably one of the most pervasive lobbies in Washington, D.C. Wherever 2 members of Congress are gathered together, you can probably find tobacco money.

MARTIN: But the FDA has indicated it doesn't need Congress's permission to act, though it wants its guidance. Even without legislation, the FDA believes it already has the legal authority to act on its own, and given the evidence now under consideration, the agency could ban all cigarettes with addictive levels of nicotine-- in other words, virtually every single cigarette on the market.

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TABB



February 28, 1994

JAMES W. JOHNSTON
Chairman and
Chief Executive Officer

David A. Kessler, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
Department of Health & Human Services
Rockville, MD 20887

Winston-Salem, N.C. 27102
919-741-7925

Dear Dr. Kessler:

This letter is intended to clarify one simple fact: that R.J. Reynolds Tobacco Company does not increase the nicotine in its cigarettes above what is found naturally in tobacco. In fact, our processes reduce the amount of nicotine in cigarettes when compared to unprocessed tobacco.

Reynolds manufactures and sells a broad range of cigarette products designed to appeal to the tastes of today's adult cigarette smokers. Smokers have increasingly demanded lower "tar" cigarettes. As a result of the processes used to lower "tar", nicotine has also been reduced. Over the past 40 years, the average "tar" and nicotine in cigarettes sold in the U.S. has declined by more than 60%.

The variety of cigarettes available is, in large part, a result of blending techniques developed over a long history of cigarette manufacture and research. In addition to traditional tobacco blending techniques, various other techniques are available to cigarette manufacturers, including puffing of tobacco, filtration, air dilution, tobacco reconstitution and others, in order to enable manufacturers to reduce the "tar" and nicotine yields in their cigarettes. As a result of these various techniques, the sales weighted averages of "tar" and nicotine yields in the United States today are 11.5 milligrams and 0.8 milligram, respectively.

In the early 1950's the sales weighted averages of "tar" and nicotine yields were 36 milligrams and 2.7 milligrams, respectively. Most cigarette brands were in a narrow band around this average. Flue-cured tobacco naturally contains 2.5 to 3.5 percent nicotine, burley tobacco contains 2.75 to 4.0 percent nicotine, and Oriental tobacco contains 0.5 to 1.8 percent nicotine in the cured leaf. Finished cigarettes generally contain approximately 1.5 to 2.5% nicotine by weight, less than the natural cured leaf.

"We work for smokers."

Dr. David A. Kessler, M.D.

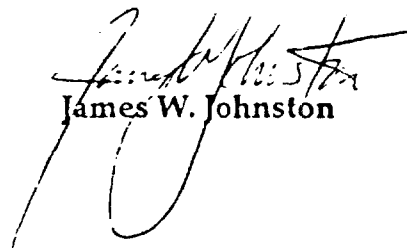
Page 2

February 28, 1994

The broad range of cigarette products available today provides smokers with a wide selection of tastes, "tar" and nicotine yields. The "tar" and nicotine yields in cigarettes are published by the Federal Trade Commission and the yields for each brand are provided in every advertisement for that brand in accordance with the law. The processing of certain tobaccos enables us to manufacture cigarettes consistent with the published "tar" and nicotine levels despite the nicotine variations from leaf to leaf and crop to crop.

Let me repeat, so that it is absolutely clear: R.J. Reynolds Tobacco Company does not increase the nicotine in the tobacco we use in the manufacture of our cigarettes.

Sincerely,



James W. Johnston