ORAL HISTORY OF WILLIAM B. SCHULTZ, ESQ.

This is the eighth in a series of interviews of William B. Schultz conducted by Stephen J. Pollak on behalf of the Oral History Project of the District of Columbia Circuit. This interview was conducted on Tuesday, December 21, 2021, in Washington, D.C.

Mr. Pollak: We're here again in the Pollak kitchen picking up on interview eight of your oral history. And the topic on the table when we concluded on November 20 was your service as Deputy Commissioner of the FDA and particularly, the saga of developing and sustaining a proposed rule limiting use of tobacco. So why don't you pick up there. I think you were just beginning to talk about assembling the developments of the proposal.

Mr. Schultz: Thanks, Steve, it's good to be here. As I've discussed before, everyone in public health knows if you can do something to cut tobacco use, the public health impact would be huge. Even if you could reduce tobacco use by 10%, you would save 50,000 lives. That's more people than die on the highways in a year, more than people killed by guns.

FDA had never regulated tobacco or thought it was in its jurisdiction. In the late 1970s, John Banzhaf, a professor at George Washington University Law School, filed a petition urging FDA to regulate tobacco. It was during the Carter Administration, and Don Kennedy, the Commissioner, turned them down. It went to the D.C. Circuit and the D.C. Circuit held that FDA acted appropriately. I don't think the court directly addressed the jurisdictional issue, but it said that the FDA did not have to get involved.

When David Kessler came to FDA as Commissioner in 1990, very early a few staff members there approached him and said we think you should consider regulating tobacco. The theory was that cigarettes contain nicotine and nicotine is a drug. In fact, FDA regulated nicotine as a drug for nicotine cessation products to help people stop smoking. And nicotine clearly has drug-like effects. It is addictive and it creates a tranquilizing effect, for example. As he's recounted this, he told them, "Give me some time to get settled in, and then come back to me and we'll talk about it."

By the time I got to FDA in 1994, this project was underway.

Mr. Pollak: This project being development of a proposed rule?

Mr. Schultz: Yes. Initially Kessler did an investigation. He had inspected manufacturing plants, and agents tried to gather evidence that they would use to show that the nicotine in tobacco products is a drug. The key question to classifying tobacco products as a drug was whether FDA could show intended use. The goal of the investigation was to establish that the tobacco company executives had the requisite intent to qualify the nicotine as a drug. And there was legal support for the proposition that intent didn't mean they advertised it or put the intended use on their label, but only that they knew this effect and desired it. And lots of documents were collected, including all the plans to get kids to smoke, scientific studies of addiction, and so on.

The second thing that they discovered is that almost all tobacco use begins when kids are under 18. If a child gets to 19 years old, it's very unlikely that he or she will begin smoking.

And the third point is based on data from the Centers for Disease Control and Prevention, that about 3,000 kids start smoking every day and 1,000 will die early as a result.

So David Kessler and the staff started developing a proposed rule, and there were two aspects. One was to limit advertising and the second was to limit access. Both were geared towards reducing tobacco use among children. The theory was that if you could reduce the initiation, you could have a big impact on how many people smoked and on how many died.

Since there were millions of people who were addicted, there was never any idea that you could eliminate nicotine or eliminate cigarettes, but the goal was to try to reduce the number of kids who started smoking. Advertising had been banned on TV by the Federal Trade Commission in the early 1960s, but there were frequent advertisements in magazines, in stores, at race car tracks, and in trinkets that the tobacco companies dispensed, including t-shirts and that sort of thing. The rule would have significantly restricted advertising. For example, in magazines, advertising was limited to those that were almost exclusively read by adults.

The second aspect limited access to tobacco products by kids. This included a federal rule that you had to be eighteen to buy tobacco or a tobacco

product. At that time, vending machines could be found anywhere, including in schools, and they were to be prohibited except in adult facilities such as bars. The proposed rule prohibited free samples, which was one way that kids first got exposed to tobacco.

Mr. Pollak: And Bill, would it be appropriate at this juncture to indicate when in this process of developing this rule you came to be a part of it?

Mr. Schultz: When I arrived, a lot of the investigation had been done. I think I've described the hearings, the Waxman hearings, where we worked very closely with FDA, particularly with Commissioner Kessler. And some of the preliminary thinking had been done about the proposed rule. But the rule hadn't been written. Most of the decisions hadn't been made. And we hadn't figured out how to get it cleared through the Administration, which included the Department of Health and Human Services and the White House.

Initially our focus was on the Department because we needed the Department and Secretary Shalala with us in order to have a chance of getting it cleared at the White House. The Department set up briefings, which was very unusual. In fact, I've never seen or heard of anything like it. The briefings were scheduled for the evening with the top-level officials in the Department, other than the Secretary and the Deputy Secretary. They included Chief of Staff Kevin Thurm; General Counsel Harriet Rabb; Jerry Kleppner, the head of legislative affairs; Claudia Cooley, the executive secretary; and several others.

After I got there, I led this effort for FDA. We would travel to the Department and brief them on what we were considering including in the rule. We probably had six or seven of these briefings. And they were brutal because the FDA officials thought about this only in terms of public health, and the HHS officials were. thinking about the politics and how it would play publicly. They were very practical, and we all learned a lot from these meetings. They had an important impact on the content of the rule.

So as these meetings were going on, the drafting began, and there were two tracks. One was a jurisdictional statement and the other was the proposed rule. In the jurisdictional statement, FDA declared that it had the legal authority to regulate tobacco. The statement used the documents FDA had gathered in its investigation to show intent, namely that the tobacco companies knew about nicotine's addictive nature and intended to cause addiction when they marketed cigarettes to children. David wanted to take the lead on that part of it because he had been very involved in the investigation.

Mr. Pollak: David Kessler?

Mr. Schultz: Yes. And that was his passion. This is the document that Ann Witt and I initially had drafted. I managed the rule, the regulation that established the rules for tobacco advertising and access to cigarettes.

This division engendered the only significant disagreement that David Kessler and I ever had that I remember. We disagreed on what kind of word processing program to use for the documents. I wanted to use WordPerfect,

which in those days was the word processing program of lawyers, and it was what I was familiar with. I think at that time it was the more popular program. David wanted to use Word, which was the program of scientists in those days. We couldn't agree, and so we decided that the rule would be in WordPerfect and the jurisdictional statement would be in Word.

There's a sequel, just jumping ahead. When we got ready to publish all this in the Federal Register, we sent these massive documents with hundreds of footnotes each to the Federal Register. It turned out the Federal Register was equipped to convert the WordPerfect document, namely the rule, into its typesetting and its fonts for publication in the Federal Register, but it could not handle the Word program with all its footnotes. It absolutely could not do it. So the jurisdictional statement ended up being published by photocopying each page, and that's how it was published in the Federal Register. It was never typeset.

Mr. Pollak: [Laughter.]

Mr. Schultz: The proposed rule cleared while I was on vacation in Nantucket, but I flew back for the announcement. I remember sitting in the Secretary's office before the announcement waiting for a notice that the documents had been delivered to the Federal Register. In those days this was done by car rather than by email, and there couldn't be an announcement of the proposed rule until the Federal Register had the document in hand. We were sitting in the Secretary's office waiting, and somebody called my staff at FDA, who were responsible for this.

They were having a problem printing the documents. The documents were huge and apparently the staff had too many windows open on the computer. As a result, there was probably a good hour delay before they got to the Federal Register. But ultimately, President Clinton made the announcement, and devoted his regular Saturday morning radio address to the tobacco regulation.[18] It was a great event.

Mr. Pollak: So, would it be fruitful for your history to identify the key players behind yourself and Kessler?

Mr. Schultz: If I can remember them. At FDA, the key players were Mitch Zeller, who led the investigation and ultimately, after Kessler left, was put in charge of the program. The program was closed down after the Supreme Court decision.[19] In 2010 Congress enacted legislation setting up the tobacco program, and Mitch came back to FDA to be the director of the agency's tobacco center, a position which he held until April 2022.

Second is Judy Wilkenfeld, who had been at the Federal Trade Commission, where she played a key role in the FTC's efforts to regulate tobacco advertising. She was probably the world's expert in tobacco advertising in the United States, and David Kessler brought her over to FDA.

Sharon Natanblut was another who had come from an advertising agency and she was very involved in the promotion issues.

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[18] Univ. Cal. Santa Barbara, *The President's Radio Address* (Aug. 12, 1995), https://www.presidency.ucsb.edu/documents/the-presidents-radio-address-297.

[19] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

On my staff, the Office of Policy, Bill Hubbard was my Deputy and Catherine Lorraine, was a lawyer who had been in the Office of General Counsel. Lisa Barclay was my assistant whom I brought from my time with Congressman Waxman. I'm sure I am forgetting others, but those are the people who come to mind in the Commissioner's Office.

And then from the Office of Chief Counsel, I worked very closely with Margaret Porter, who was Chief Counsel, because we needed her support in order to do this. There were several lawyers from the Office of Chief Counsel who were detailed to work on these two projects. There were many, many others throughout FDA who played key roles.

And let me go to the Department for a minute. The key players there other than Secretary Shalala were Kevin Thurm, the Chief of Staff and later Deputy Secretary; Harriet Rabb, the General Counsel; Claudia Cooley, who was head of what was called "Exec. Sec."; Jerry Klepner, who was head of Legislation; Phil Lee who was Assistant Secretary of Health; and Bill Corr, who was in the Office of the Assistant Secretary and later became Chief of Staff. It was the top people, the leaders in the Department who were all involved in this.

Mr. Pollak: So, it was August 11, 1995, that the proposed rule was published?

Mr. Schultz: I should emphasize with respect to the proposed rule that while I was in charge of the rule any significant policy decision was made by Commissioner Kessler, and there were many, many decisions and many disagreements to be resolved.

Under the Administrative Procedure Act, in order to issue a regulation, the agency must first issue the proposal, receive comments from the public, and then issue a final rule that takes into account the comments, and for the significant comments explain why they were rejected or accepted. Once the rule becomes effective it has the force of law, just as though it were enacted by Congress.

And then, of course, there is the opportunity for judicial review where the rule can be challenged on the ground that it is inconsistent with the statute or inconsistent with the Constitution. It may also face a challenge for procedural reasons, such as the agency didn't give an adequate opportunity for comment or didn't explain why significant comments were rejected.

After we published the proposed rule, we prepared for the avalanche of comments. It was said at the time we got more comments on that rule than any rule that had ever been issued. We wanted to be on a very fast track and FDA had a history of taking years and years to go from a proposed rule to a final rule. It wasn't unusual for FDA to take six or eight years to issue an important rule, and we were aiming to issue the final rule one year after the proposed, which was considered breakneck speed. It turned out that the vast majority of comments were the same or could be categorized and dealt with pretty easily.

Mr. Pollak: The same in what way?

Mr. Schultz: Some of them were postcards saying, "Don't take my cigarettes away." They were common comments, and they could be categorized. But there were maybe

30 substantial comments, a lot from the tobacco industry and some from public interest groups, that raised the issues of authority and policy that we had to deal with. So we put together teams to review the comments and identify the issues, and then decisions had to be made.

One issue that we now had to struggle with was the legal authority, arguments that that FDA didn't have legal authority to regulate tobacco.

There were two aspects to this. Product may be regulated as a drug if it is intended to have a therapeutic effect or if it is intended to affect the structure or function of the body, such as a diet pill. Here the nicotine met the structure/function test, so the issue was whether the companies intend this. But there was a second problem: To be marketed drugs and medical devices have to be safe and effective. And we could show that this was effective in terms of its addictive effect, in terms of its effect on the brain, but it was an obvious challenge to show it was safe. It was the most dangerous legal product on the market.

We developed a theory that safety should be viewed in a comparative way and compared to the alternatives. Our argument was if this is medical, we had the authority to ban it. That would be one option. It's unsafe. But that would create a black market and it wouldn't really eliminate the product. And it wouldn't necessarily help people because cigarettes would be available to this addicted population, who would use them with the same harmful effects. We then argued that it was better from a public health point of view to regulate the

product under FDA authority than to ban it. That was the best argument we could come up with.

The White House Counsel, Judge Abner Mikva, recognized that this was going to be an issue for the White House, and so he did a very smart thing. He set up a meeting for me to make these arguments to Walter Dellinger, the Head of the Office of Legal Counsel. OLC acts as the lawyer for the President outside the White House.

We sent Walter our analysis. He read it. I met with him. He asked me a lot of questions, and then said, "I think it's a sound argument." He blessed our argument. He said, "This will probably go to the Supreme Court and it is probably going to be five to four, but I don't know which way it's going to come out." This turned out to be a very, very good prediction.

Mr. Pollak: And how did you prepare for the meeting with Walter Dellinger? Or did you have it all in your head because you've worked on it so long?

Mr. Schultz: I don't specifically remember how I prepared but I'm sure I spent a lot of time preparing for it. Ultimately the Department and the White House cleared the final rule. We didn't know when it was going to be issued. After the proposed rule was issued, I received many, many calls from reporters. And there was only one question that they had and one thing they wanted to know: When are you going to publish the final rule? And I said, well, I'm happy to answer that. I know exactly when we're going to publish it. The proposed rule was published in the middle of my vacation in August 1995 and I'm sure the final rule will be

published in the middle of my vacation scheduled for August 1996. And it turned out it was. It was accurate information.

The President decided that August was a slow month and before he went on vacation, he was going to announce the final rule. And once again, I came back to D.C. from my vacation and we prepared talking points for the President. They were prepared at FDA, went through HHS, and they made changes and cleared them. And then my job was to go to the White House and walk the White House staff person through them. Her name was Jennifer O'Connor, and I think she was assigned to the Domestic Policy Council. I took a disk with the talking points – in those days we couldn't email documents – to her office in the Old Executive Office Building, and she put the disk in her computer, and it couldn't read it. That was because the Word or WordPerfect program that HHS was using was a more recent version. It turned out that the only computer that could read this disk was at the secretary's desk outside the Office of the President in the White House. We went over there and were able to print it out and make edits.

As we were working, various people at the White House that I'd been working with came by to say hello, and then the next thing I know, the door from the Oval Office opens and out comes the President, former President Jimmy Carter, and various other high-level officials. Jen introduces me to President Clinton and tells him who I am. And he's interested in talking about the tobacco rule.

This was classic Bill Clinton form; he was knowledgeable about the substance of it and interested in discussing it. But he also told me something we didn't know, which is that he and the White House had been trying to reach a deal with members of Congress that would have meant we didn't have to issue the rule. He said that it had fallen apart, so the rule would go ahead.

The next day, there was a press conference, and the President announced the rule. Previously it had been put on display by the Federal Register, and within minutes we were sued by the tobacco companies.

My memory of the President's press conference is that he took our talking points and improved them. He went three steps past them in terms of sophistication and knowledge. I thought it a remarkable performance.

And the coda is that this is the summer of 1996 and the election was held in November. It was not a close election as everybody had thought it would be a year before. The tobacco rule turned out to be a plus. Senator Dole made some mistakes having to do with tobacco in the debates. And I think Clinton actually won Kentucky in that election.

Mr. Pollak: Do you want to say anything about the process as government performance measure? Something more general about the need and the incubation of a rule and how government performs in that circumstance?

Mr. Schultz: I think this was a unique government experience in that it was an aggressive, creative regulation that had the potential to have an enormous impact on public health. But it had major pitfalls and political consequences and aspects to it that

are unlike any executive action or action taken by an agency that I can think of. There were enormous challenges to getting it done so quickly, and getting it through the government processes, which are generally designed to be cautious and conservative.

I don't know of anyone who could have done this other than David Kessler. Many, many people at three levels of government, FDA, HHS, and the White House, dedicated a portion of their life to it, were enormously skillful, and really believed that they were going to do something that was going to save thousands of lives.

Mr. Pollak: Well, it strikes me as a uniquely creative endeavor because there was no bed of facts that existed as to how you would regulate or what you would do. You had to make it up all completely from scratch.

Mr. Schultz: Right, we had to put it together from scratch, based on the investigation.

Mr. Pollak: And you had good experts.

Mr. Schultz: We had very skilled people. FDA had no expertise in tobacco. On the team was a single person with a history of working on tobacco, Judy Wilkenfeld, whom I mentioned and who had spent so much time on advertising at the Federal Trade Commission. She really did understand the mentality of the companies. FDA did an amazing investigation that, in combination with documents obtained by trial lawyers, created a massive amount of information. There were also tobacco company whistleblowers that ended up working with FDA.

As a result, FDA was able to put together a very powerful case in terms of jurisdiction. Because of David Kessler and others, tobacco was more and more in the news, and there was increasing interest in regulating it and trying to limit the health damage from tobacco.

Mr. Pollak: Well, let's turn to the legal challenge, what it was, and your role in addressing it.

Mr. Schultz: And then, after that, I want to talk about the legislation, too, during this time.

Mr. Pollak: Let talk about the legislation since that came first chronologically.

Mr. Schultz: While all this was going on at FDA, there was an effort by state attorneys general, in some cases joined by trial lawyers, to hold the tobacco companies accountable for all the damage they had done. As you can imagine tobacco creates enormous health costs for Medicaid and Medicare for the treatment of lung cancer, heart disease, and so on. After the cases were filed, there was an effort not only to resolve all the lawsuits, but also to address FDA regulation. FDA was not part of the negotiations, but representatives from the White House were, particularly Bruce Lindsey, a close confident of President Clinton.

We at FDA were very skeptical since a settlement could have deprived the agency of the ability to take public health regulatory actions. In the end, we were able to convince the White House not to sign on and those negotiations fell apart. Sometime later the cases were settled without touching FDA's activities.

Meanwhile there was also an effort to enact legislation that would have confirmed FDA's jurisdiction. And this way, we would not have had to deal with litigation or the questions about our jurisdiction.

Mr. Pollak Who spearheaded that legislation?

Mr. Schultz Henry Waxman in the House and John McCain and others in the Senate. Interestingly, Tennessee Senator Bill Frist, a medical doctor, was very involved. I'm sure Senator Kennedy was an active participant also.

The White House lead was Elena Kagan, on the staff of the Domestic Policy Counsel, and I was the lead negotiator and expert from FDA. And it turned into a massive bill that had funding for NIH and other activities. But the most controversial sections would have confirmed FDA's jurisdiction.

And so there were many nights of negotiating over this. I can remember nights when Senator Frist was negotiating. We lost the cloture vote, meaning that we couldn't overcome a filibuster, which would have required 60 votes. There were 53 votes to override a filibuster, including 11 Republicans. So it ultimately did not pass.

Meanwhile the companies had brought a lawsuit in North Carolina that was handled by the Justice Department. The district court case was handled by lawyers from the Federal Programs section of the Civil Division. I was very involved in preparation for the arguments. I attended the arguments and participated in moot courts. In the district court, we won a partial victory.

For the appeal to the Fourth Circuit, Walter Dellinger, now the Acting Solicitor General, chose to argue it himself. This was unusual because the Solicitor General usually argues exclusively in the Supreme Court. His decision to argue it shows how important the case was to the Clinton Administration.

We went through all the preparation and then Walter, his assistants, David Kessler, and I rode in a van to Richmond, Virginia, where the Fourth Circuit is located. While we were in this bus Walter was firing questions, to assist in preparation for his argument. The argument went on for hours.

We lost the case, with a dissent from Judge Hall. Rehearing en banc was denied 6-3. And so it then went to the Supreme Court, but by this time I left FDA for a position as head of the appellate section of the Civil Division at the Department of Justice. Seth Waxman was now the Solicitor General, and he chose to argue the case in the high court. I was very involved in preparing him, in his moot courts, and so on. David Kessler and I attended, but it didn't seem to go well.

We lost 5-4. In her majority opinion, Justice O'Connor discusses a series of laws Congress had passed touching on tobacco that she concluded meant Congress intended that tobacco products remain on the market. She also discussed the instances where FDA Commissioners had been asked by Congress or elsewhere about jurisdiction, and they had consistently rejected the idea of regulating tobacco products. So the Supreme Court held that FDA has no jurisdiction. Justice Stephen Breyer wrote a strong dissent joined by three other justices that adopted our theory of the case.

Mr. Pollak: So?

Mr. Schultz FDA then had to close down the tobacco program. Now the only way FDA could get jurisdiction was through legislation. That took ten years, and I worked

on the bill after I left the Administration and was in private practice. Ultimately, the legislation was passed in the first year of the Obama Administration and was signed into law. It created a big program at FDA, funded by user fees, a program with a bigger budget than the entire Federal Trade Commission. It was a long wait but we got to a good result.

Mr. Pollak: Well, you want to close out your time at FDA?

Mr. Pollak: Let's talk about David Kessler's departure.

Mr. Schultz David Kessler was appointed two years before the end of the Bush Administration. By the end of Clinton's first term, he'd been there six years and he was ready to leave. When this was announced it was a very big deal.

David had several deputies, but the Deputy for Operations, which oversaw all the centers, was Mike Friedman. And Mike was appointed the lead Deputy and then began a process for deciding who the next Commissioner would be. I was one of the ones considered. The interviews were conducted by groups from the White House and from the Department, including Harold Varmus, head of the National Institutes of Health, Sally Katzen, head of the OIRA, the regulatory part of the Office of Management and Budget, and several others.

The candidates included Mike Friedman, Jane Henney, who had been the Deputy for Operations before Mike, and Mike Taylor, who had been my predecessor. There were various other people, but I think David Kessler felt it should be a doctor. And the Commissioner of the FDA had almost always been

a doctor. I don't know who David recommended, but Jane Henney, who had previously worked at NIH, was selected.

Mr. Pollak: And is she a doctor?

Mr. Schultz Yes, and I think David later reconsidered his position on this, but she was selected. I stayed and helped her through her confirmation but then decided to leave. I had had such a great role and so much authority under David Kessler and then in the interim two years as well, because even though Mike was essentially the Acting Commissioner, we shared many of the responsibilities and Secretary Shalala looked to me for many of the most important decisions. But it was clear now that Jane was FDA Commissioner, she needed to do it on her own. So at that point I started thinking about what my next job ought to be.

Mr. Pollak: And was it a disappointment not to get to be the head of the FDA?

Mr. Schultz: There were a lot of people who supported me. I thought I could do a very good job, probably a better job than the other candidates. I thought I was very prepared for it. I had been Kessler's number two person on all the major policy issues. But it wasn't something I was counting on. It wasn't a devastating disappointment but I'm sure I was disappointed.