

History
of the
U.S. Food and Drug Administration

Interviewee: William K. Hubbard

Interviewer: Suzanne W. Junod, Ph.D.
Robert A. Tucker

Date: July 27, 2005

Place: Rockville, MD



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TOPIC OF INTERVIEW: FDA History

LOCATION OF INTERVIEW: Rockville, MD

DATE OF INTERVIEW: July 27, 2005

INTERVIEWER(S): Suzanne W. Junod, Ph.D.
Robert A. Tucker

INTERVIEWEE: William K. Hubbard

FDA SERVICE DATES: 1979 - 2005

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Interview with William K. Hubbard

July 27, 2005

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, the interview is with William K. Hubbard, retired Associate Commissioner for Policy and Planning, Office of the Commissioner. The interview is taking place in Rockville, Maryland, on July 27, 2005. Involved in the interview are Dr. Suzanne White Junod and Robert Tucker of the FDA History Office.

Bill, we like to begin the interviews with a brief oversight of your personal history and educational background, and then move into your employment, particularly with this agency.

WH: Okay. I was born on January 12, 1949, in Rocky Mount, North Carolina, where I grew up, then went to college at the University of North Carolina-Chapel Hill, graduated in 1970, and then moved to Washington almost out of happenstance with a couple of friends from college, and then got some menial jobs on Capitol Hill, where I worked for about a year.

Then a recruiter from the then-Office of Education, which was part of the old Department of Health, Education and Welfare, met me and offered to get me some interviews, and that culminated in a job offer at the Office of Education as a GS-4 clerk typist. They attempted to hire me as a program assistant, but in those days, it was when

the Vietnam War was winding down, and it was very difficult to get a federal job without veteran service points.

Interestingly enough, I had also gotten at the same time an offer from the Watergate Committee to work with them. My senator, Sam Irvin, was chairing that committee, and I had an offer of that, but ended up taking the HEW job because it seemed like a permanent, full-time position.

RT: Bill, what degree did you get from the university?

WH: It was a B.A. with a double major in history and American studies.

RT: Thank you.

WH: And so, anyway, I took the job at HEW and worked at the Office of Education down in Southwest Washington near the main HEW building for five years. And then, looking for a greener pasture, I went over to the Environmental Protection Agency for one year but was assigned as essentially a budget analyst deep down in a program and didn't particularly like it or the work location. So I began to apply for jobs as a GS, I believe, 11, and was offered a job by the Navy Department in a shipbuilding program; but at the same time, I had applied months ago for a job at FDA, in the Office of Planning and Evaluation. And one day I got a call for an interview.

As you will recall, the hiring process was then very lengthy. I had applied for dozens of jobs and usually got back a little slip that said, "Thank you for your interest."

But in this case, I never heard back. However, finally I got a call one day from what was then Jake Barkdoll's office to come in for an interview on Friday afternoon. And I came in -- this was in March or April of 1979 -- and it was a good interview. But I told them I had this offer from the Navy, and they said, "Well, we're interested," and I said, "I've got to tell the Navy Monday, so you've got to either tell me you're going to give me the job or I'm going to take this Navy job," because it was a promotion to, I believe, a GS-11. So they decided they would have personnel offer me the job that Monday, so I started a few weeks later at FDA.

RT: Was that as a GS-11?

WH: A GS-11, I believe, and on the 10th floor of the Parklawn Building as a program analyst in the planning staff of the Office of Planning and Evaluation. I worked there for about two years. Around that time Commissioner Don Kennedy created an Office of Policy Coordination, which had a group called the Policy Coordination Staff. They were the ones who assisted the commissioner in sifting through major policy initiatives. They had a vacancy and asked me to come over on a detail -- I believe it was 1981 -- and I did. After working there for some weeks on detail, they said, "We'd like to offer you a job, which goes to a GS-14," whereas the journeyman level in the Planning Office went to a 13. By then I think I was a 12 or 13 because I had been promoted in the planning group. So I went to work in the Office of Policy Coordination for a couple of years.

When Art Hayes became Commissioner, he decided, at the insistence of the Center directors, that this policy coordination group was too powerful or too much of an

intrusion, because of the way Kennedy had set it up. Whenever a Center director wanted to bring an issue forward for the Commissioner's decision, they would send the issue to this group, essentially me or one of my like analysts. We would then send out paper to other centers and Paul Hile, the ACRA [Associate Commissioner for Regulatory Affairs], and the General Counsel and others and say, "Center director A wants to do this thing. What do you think?" and then we'd get back in these various opinions. Then someone like me would write up a memo to the commissioner saying, "Center director A wants to do this. This is the opinion of the other Center directors, the General Counsel," dah-dah-dah-dah, and then I would make a recommendation based upon that as to what the commissioner should do. That was a very orderly process but insulting to the Centers that a GS-13 staffer would have that sort of coordinating role.

The agency had a planning retreat about that time, at which time John Villforth and others complained vigorously that this Policy Coordination Staff was a barrier between the Centers and the Commissioner, and I think he in fact had a point, because to have a GS-12 or -13 doing that analysis was indeed a layer between the Commissioner and his senior officials.

It was very orderly in that you make sure that all opinions were gathered, but it perhaps gave them too much power.

So Commissioner Arthur Hayes agreed and abolished the Policy Coordination Office. Part of the Policy Office had the executive secretariat function, which was then called the Executive Communications Staff. So they created in its stead, largely under Mark Novitch's leadership, an Executive Secretariat, which had the mail-processing side as well as a sort of policy coordination side, but with not nearly the influence that old

group had. So I was transferred into that group more or less automatically when the Office of Policy Coordination was abolished.

I worked there for a couple of years, and that was . . .

SJ: What year was that roughly?

WH: This would be '82 or '83. I think I went there in '81 and perhaps it would be '83 by the time the Exec Sec was created and all that.

RT: The date you just referenced, was that when the Policy Board was established?

WH: No. The Policy Board existed earlier in the '70s. In fact, when I was in the Planning Office, we had created a thing called a "concensor," and around that conference table was a series of buttons, and the way they did things -- this was in the Commissioner Max Schmidt days and the early Commissioner Donald Kennedy days. An issue would be brought forward, and then the members of the Policy Board would push a green or a red button, and the concensor would tally those.

The Policy Board existed. I think the Policy Board was created by Charlie Edwards and existed on through the Schmidt-Kennedy-Hayes-Young days. It continued to exist in some fashion under Dr. Kessler but was essentially eliminated during his tenure. I can explain more of that when we get to it. The Policy Board existed for probably about fifteen years or so. I always thought it was a good format for bringing the right people together, but there were reasons why that changed that I can discuss later.

So the Exec Sec at that point was Dan Brand, and the person who really supervised the Exec Sec at the time was Mark Novitch, in his role as Deputy Commissioner.

Now, the early '80s was a period during which they began these early morning meetings that go on to today, in which senior staff meet with the Commissioner, Deputy Commissioner, first thing in the morning and talk about what happened yesterday and what happens today. Early on, it was just the Deputy Commissioner, the General Counsel, the Leg [Legislative] Director, the Public Affairs Director, and the Exec Sec, with occasionally another invitee, and occasionally the Commissioner would come in. Don Kennedy had created that sort of concept. Arthur Hayes continued it with Mark Novitch essentially running it. Then it was continued with Frank Young, and then David Kessler expanded it when he came, and it became known as the "8:30," and I can talk more about that. Of course, it continues today. Dr. McClellan used it, and Lester Crawford uses it. Although it's the "8:40" now. But if you want to talk a little bit more about how the process worked, I can go into that at some point. Some of that can be historically interesting.

Anyway, we're back to '83. I'm in the Executive Secretariat, and Art Hayes leaves in late '83. Mark Novitch is Acting, and clearly wanted the job, but it was unclear who would get it.

Eventually Secretary Margaret Heckler decided that the next commissioner needed to be a biotech expert, because she was familiar with the Route 1 corridor in Boston, biotechnology was just emerging as a big deal, and Boston was one of the centers of it. So she essentially sent her folks out to find a biotech person. In fact, I once met

with the person that first went to Frank Young. I worked with him during the Bush transition down in the Humphrey Building.

So they start a search for a biotech expert, and one of them that came to mind was Frank Young, who had been at this early biotech conference in California known as the Asilomar Conference in 1975. He presented himself as a biotech expert, which he was. So, after the initial interview, he was brought to New York and met with HHS Secretary Heckler, who was visiting New York. He was dean of the University of Rochester Medical School at the time, and she offered him the job. So he came in 1984 as Commissioner and kept the same structure that Hayes had used, with Mark Novitch as deputy. But then Mark ultimately moved on, and Dr. Young brought in another deputy, John Norris, for whom I was once assigned as a chief assistant during the latter part of his time at the agency.

SJ: John Norris is certainly remembered around FDA, and not in an entirely positive vein.

WH: Well, John was a very gregarious guy. Dr. Young came in, as most commissioners do -- and I've had many commissioners tell me this -- they come in with an attitude that the career people are substandard; that the private sector has the good people, and the people who can't do good work go to the government. That's a very common phenomenon you find among political appointees and senior executives who come into the government but never worked in the government. Drs. Hayes and Young both appeared to feel that way upon their arrival.

I remember Dr. Hayes, when he left, gave a talk to the Policy Board in which he basically said, "You know, I've got to tell you guys, I thought very lowly of you when I came, and I thought you were all going to be a bunch of bureaucrats, and I realized by the time I left that you're far and above people I worked with at universities and other places, and you're very talented." I don't think he was just being nice on the way out. I really do believe that the politicals become surprised by the capabilities of the career civil servants, particularly the higher-achieving ones that they often deal with on a day-to-day basis.

So Dr. Young thought he was going to bring people in to teach them how to manage FDA. He viewed himself as a management expert, as he had reorganized the University of Rochester's Medical School. He had used John Norris and another consultant to do that, and so he thought John would be the perfect person. In fact, he had brought John and this other person in -- I think Lane something -- as consultants who were going to reorganize FDA. You may recall that they had all these teams of people who went out and looked at the agency and came back with a long series of reports on enforcement and organization, on personnel, whatever.

Most of that stuff didn't emerge, but a few things did in the so-called Action Plan in which he had 10 major Action Items -- improve food safety, speed up drug approval, and develop a new focus on biotechnology, whatever. In fact, I was one of the authors of a portion of that plan. Joe Levitt did most of the drafting.

SJ: The plan itself was well received at the time.

WH: Yes. I believe it was a good thing to do, although, to be honest, I remember I was tasked three years earlier by Mark Novitch to write a memo to Hayes coming in. They gave him the usual briefing book. And then there was about a three- or four-page cover memo saying, "Here's the briefing book. Let me give you my perspective of the big issues." I wrote the thing, and Mark Novitch made a few changes to incorporate additional views. And it basically was to speed up drug approval, improve food safety, etc. I mean, these were the issues that any one of us at that time would have said were the things that needed to be done.

SJ: But the communication element was novel at that time.

WH: Exactly.

SJ: FDA employees were not used to hearing anything from their top leaders about where they wanted the agency to go in terms of priorities and milestones.

WH: I think that's right.

SJ: To actually have it written down made it -- at least everybody down the line could feel as if they were on the same page and could understand the new perspective.

WH: And so CDER [Center for Drug Evaluation and Research] -- what was then called Bureau of Drugs -- knew that their priority is speeding up drug approval. Of course, that

was every commissioner's priority from Mac Schmidt on, after the so-called drug lag was "discovered" in the middle '70s.

So this Action Plan was put together, and it became the sort of driving force for Dr. Young.

Getting back to your question about John Norris, John was hired subsequently as Deputy Commissioner. Before that, however, John and this other consultant were tasked with writing the first draft of the Action Plan. I remember being in with Dr. Novitch when he came in, and we all sort of flipped through the first draft. It was this very long, wordy, dense document, and I remember Mark basically put it down at some point and said, "This is not going to work. It's just not even intelligible for our purposes," and Dr. Young concurred with him. I believe Dr. Young was surprised to learn he wasn't getting what he needed. Dr. Young ended up having Joe Levitt, who was brought in from GC as a young lawyer, and me rewrite the Plan. I think there were 10 chapters. Joe wrote eight of them and I wrote two of them, and helped a little bit on two others. You know, we wrote this thing into the document that eventually emerged, which was much shorter and more to the point, which, of course, was a huge assist.

As for Joe, he became a rising star at that point. We can talk more about that if you want.

John Norris was hired as deputy commissioner, but I never thought he was here long enough to really learn the business of FDA. He wasn't really an expert, and I think he didn't have a particularly successful tenure here at FDA.

RT: I think a lot of the career FDAers questioned his expertise.

WH: Absolutely. And, again, he was a relative novice about FDA, wasn't here that long, didn't even learn the organization all that well, and I think Dr. Young eventually came to think much less of him than he had at first, because I know when he would leave town and John would be Acting, he would sort of say, "Don't let him make any decisions while I'm away," but then Dr. Young was a very controlling manager and would have said that to about any of us. I mean, he didn't delegate a lot. He wanted to make major decisions and he wanted to keep control. In some ways, he and Dr. Kessler were alike in terms of staying constantly in touch. If he was traveling in Europe, it was like, "Don't do anything without me," so he very much wasn't a delegator.

I guess most commissioners aren't delegators, although perhaps some are. Dr. Henney was more of a delegator, but we'll get to that.

John only stayed about two years. There was a stock market crash around '86 or '87, and John was heavily invested in the stock market, and so I think that hurt him financially. I think he felt the need to go out and replenish some of his financial resources.

RT: Well, Dr. Young, as I recall, was interested in all things going on, particularly in the emergency and epidemiological area.

WH: Right.

RT: He would come down and become personally involved in what was going on in

that area.

WH: Well, in fact, as you'll recall, Dr. Young went on to do that in OASH [Office of Assistant Secretary for Health], and I think that one of the unspoken truisms was that he was one of the first people who recognized the potential for terrorism in the biological area, for terrorists to use agents like that. And, in fact, I think Richard Clarke has commented since he left the White House how Dr. Young was worrying about the biohazards way back in the '80s but couldn't get anybody to pay any attention. Dr. Young was very much concerned, and often said, "Look, I know as a scientist, you can cook this stuff up and put it in the air or the water or the food supply or whatever and kill a lot of people, and we need to care more," and he wasn't getting a lot of audience on it.

RT: I recall that the Chilean cyanide threat occurred under Dr. Young's tenure.

WH: Yes, and that may have been one of the things that really prompted his overall interest in this area. You should certainly interview Ron Chesemore if you haven't on that incident. There was a lot of skepticism that such a dramatic act as shutting down Chilean imports should be taken based on what I think was three grapes. By the time they tried to do confirmatory tests, the grapes had been used up, there wasn't enough juice left, and so the ORA professionals, I believe, would have looked more and waited before they took such drastic action, because they weren't sure that the cyanide was there. I think it was a sense that Dr. Young had sort of jumped the gun. But to some extent, he may have been trying to get what I'll call attention. By now you're into the

first Bush administration.

SJ: My interpretation as a historian was, at the time, some funny things were going on as well because the story was actually given to Herb Burkholz, who wrote a book called *FDA Follies*, and told the story there. I wondered about whether there was something going on there. Why would they give that story out to a writer unless there was a reason? There had to be an explanation as to why that story went outside the agency in the way that it did, and I haven't figured it out. In 1959, the cranberry scare, the cranberry crisis, was a case in which the Secretary was trying to make a statement about the Delaney clause, and his intent to enforce it.

WH: Right.

SJ: I felt as if there were similar motivations in play . . .

WH: I think there were, but he hurt himself quite a bit, I think, because he . . .

SJ: Because it didn't turn out to be anything.

WH: Exactly.

SJ: Cranberries, though, did turn out to be a problem.

WH: And he really raised the alarm, and the career professionals at FDA were sort of thinking, let's go slow. The Department Secretary, Dr. Sullivan, I think, was in a go-slow mode -- he was the new Secretary under [President] George Herbert Walker Bush.

But Dr. Young was determined that we had a major health crisis here. And, in fact, he called up Vice President Dan Quayle. Kay Hamarik called up and got the Vice President's secretary and said, "This is the Commissioner at FDA for the Vice President." Dan Quayle picked up, "Hello," and he basically told him all this and said, "You know, I think we've got a major problem here," and that got the administration exercised about it. But the Secretary, who was in a go-slow mode too, felt that had preempted his decision-making because Dr. Young he was essentially jumping over his head. I think the Secretary and his staff felt that they were put in a no-win situation because if they didn't support him in shutting down the imports of Chilean fruit and something happened . . . But Dr. Young in essence dumped the problem on them and they had to make the decision, and so the only choice was to agree, and I don't think they wanted to agree. I think they, if this had been kept out of the press, they would have said, "Let's keep looking. Let's do more surveillance. If we find more, we'll take more drastic action." Nothing more was ever found. Of course, the Chileans were furious and all that.

I think some people did feel -- I didn't see a lot of this, but I think some people felt Dr. Young was a little bit too aggressive in worrying about some of these things. For instance, during that period, he would move his car every week or so. He wouldn't park in the same parking place because he was afraid the Chileans were going to blow him up. You may remember that there had been a Chilean official blown up down here on one of

the traffic circles in Washington.

But, again, on your point, he clearly was identifying with potential threats: using the food supply or the drug supply to harm people before most people were really thinking about it.

The Chilean grape thing was an unfortunate exercise, and I think ultimately the various court rulings and GAO examinations and all upheld FDA's position. But, still, there was some lingering resentment about it.

Anyway, there was a point in there somewhere where I was offered a job down in the OASH, in their Exec Sec, and this was around 1985, the year after Dr. Young arrived. So I went there to be a branch chief in the OASH Executive Secretariat for one year.

And then I was asked to move up to the Secretary's office. By then, it was Otis Bowen. They had an Executive Secretariat as well, and so they asked me to come to the Secretary's Executive Secretariat, and I moved there, partly with the lure of a promotion to a GS-15. I was a GS-14 in OASH. So I worked for Otis Bowen for one year in their Exec Sec -- it wasn't the FDA portion. That was a guy named Dennis Strickland. For what was then called ADAMHA [Alcohol, Drug Abuse and Mental Health Administration], I was the staff person for the various staff offices down there, the offices of public health and the planning office and all that. I enjoyed that quite a bit. I had a lot of access to the Secretary. It was a very informal environment. I could eat in the Secretary's private dining room, got a parking place, and lots of other little perks and all.

But in 1987, Joe Levitt had created a position and by then, Joe was the Executive Assistant to the Commissioner and had the Exec Sec under him. He had also created a little group, much like that old office of Policy Coordination but small, with a different

name. They were very careful not to use that word “policy,” because there were still hard feelings among Mr. Villforth and others about that OPC. Joe asked me to come over as a GS-15 and work for that group. I remember the Secretary’s folks came in that morning and said, “Well, you’re going to FDA,” and I said, “Yeah.” And there was the Executive Assistant to the Secretary who said, “I just spoke to Dr. Bowen and I asked him if he had done anything to piss you off.” And he said no. So they said, “Well, we’re here to tell you that at 4:30 today, you’ll be a GS-15 if you’ll stay.”

SJ: How could that happen?

WH: Well, they could do it that fast in the Secretary’s office. If the Secretary said it, it was done. I actually enjoyed working there quite a bit. The commute was better since I lived in Virginia. But I accepted Joe’s offer, and I had enjoyed working at FDA for the previous five or six years. So I came back to FDA after that brief interregnum as the director of his small group.

Joe Levitt was the Executive Assistant, and then there was the Policy Coordination Group, which was, I think, called the Office of Program Management. It was a carefully crafted term. They didn’t want to call it the re-creation of the Policy Office, although that in fact was what it was. Since the early 1970s, beginning with Charlie Edwards, commissioners realized increasingly that staff support was needed on some of these things. I mean, I’m sure you know well that in the pre/Edwards days, there wasn’t the kind of infrastructure there is now.

I remember Dr. Edwards once told me when he got there, they would open their

mail every morning. He and the Deputy Commissioner and their secretaries would open the mail every morning. Their congressional mail would go to a small legislative group that Gerry Moyer headed, for example.

SJ: Bob Wetherell's group?

WH: Before Wetherell. Gerry Meyer did legislation before Wetherell.

Anyway, the Commissioner and his secretary would open the mail every morning and route things to the Center directors or to other staff to deal with. And it was a much more -- they did their own legislation, their own press. There wasn't a Consumer Affairs Group then; there wasn't a Planning Group to speak of. So they had this incredible increase in staff. And, in fact, you see that all through government.

When I first started in the Office of Education, I remember once being asked to go over and pick up the Commissioner of Education in another building and then go over to the Secretary of Health, Education and Welfare's office. I was a GS-4.

A meeting on some management objectives, and it was all very informal, just a small group of people. I remember thinking that, at the time when I left, the chances of a GS-4, even a GS-14, getting near Tommy Thompson was zero. And so you had this structure. All these staff people at all these levels, and planning people, and the legislative people, and the public affairs people, and all down the line.

Anyway, I came back as head of this little group toward the end of Dr. Young's tenure, and I worked with him another two years. He stayed on as Commissioner till '89. Then I think the Chilean grape incident, along with some other things, caused Dr.

Sullivan to conclude he needed to make a change.

Dr. Young had once been close to Dr. Sullivan. One of the things that Dr. Young had done when George Herbert Walker Bush was elected was he went to Dr. Sullivan and said, "I was a former medical school dean. You worked as a medical school dean. I know how the government works. I've been to Washington. Let me come down and manage your transition," and Dr. Sullivan agreed.

So Dr. Young brought me with him, along with a couple other people. We went down to the Secretary's office, set up an interim staff, and I began to organize meetings for Secretary Sullivan and was essentially his staff for a short while. Kay Hamrik came down for a time. And Dr. Young was really managing the Secretary's office, and the Secretary was not yet confirmed. He was the Secretary-designate. And Secretary Bowen had left, and the Undersecretary -- what was then called the Undersecretary -- was Acting Secretary for a period. Dr. Young, I think, perhaps proved himself not as knowledgeable at that level as he had been at the agency level, because there were lots of feelings that I think some of the political appointees from the Bush White House didn't agree with him on. But ultimately, Dr. Sullivan said, "I'm fine now. You can go back to FDA."

Not too much longer after that, the Chilean grapes happened, and then, again, I think Dr. Young was essentially offered the option to leave, and he went to Dr. Mason, the Assistant Secretary for Health. Dr. Mason created a position for him in the Emergency Operations Group down there as a Deputy Assistant Secretary for Health. Dr. Young really plunged into that with his usual vigor and interest and became very active in that whole emergency preparedness area and beefed up that office quite a bit; in fact, he was in this building much of the time, down on the fourth floor, although he

never came up to the FDA, since he was basically checked out of FDA, which is understandable.

RT: So he was functioning at upgrading emergency preparedness.

WH: Right. He mostly built up that group.

TAPE 1, SIDE B

WH: For instance, when Hurricane Andrew struck Florida, he went down there and was very involved in getting the PHS response going to that.

SJ: He was Commissioned Corps.

WH: Right. So he basically started a second government career. But he stayed out of the FDA.

Jim Benson became Acting Commissioner at that point. This was still in the Sullivan period. He was Acting for well over a year, and he would even tell you that he was offered the job. There are various opinions about that. Secretary Sullivan clearly liked him a lot. Jim was very organized and did a good job of going down to meet the Secretary, being prepared with materials, arguments one way or the other, briefings, presentations. I was very much involved in that myself.

It was actually a good period in that sense, and in fact it was during that period

that the food labeling effort got going. Although Dr. Young actually first teed up the food labeling exercise, Joe Leavitt had come to me around 1988 and said, “We really need to be looking at nutrition labels.” And I was tasked with putting together sort of a white paper on nutrition labeling. The nutritionists had wanted to do something about nutrition labeling for years. If you recall, there had been a voluntary nutrition label done by Peter Hutt and Charlie Edwards around 1971 or ’72. It required that if you make a claim, you had to do nutrition labeling, or you can do it voluntarily, but you don’t have to do it. It wasn’t mandatory nutrition labeling.

I remember both Charlie and Peter told me the story about how they had the idea. Peter Hutt oversaw drafting the regulation, along with Howie Roberts, the head of the Bureau of Foods. I remember both Peter and Dr. Edwards told me the story about how Peter gave Dr. Edwards this big, thick reg, and said, “I’ve got this reg you asked me to do for nutrition labeling,” Charlie said, “Well, put it there on my desk.” He set it there on the corner of his desk, and he said, “Come back in two weeks.” And so Peter came back in two weeks and the reg was still sitting there on the desk, untouched. And Peter said, “Well, what do you want me to do about the nutrition labeling?” And Dr. Edwards said, “Publish it.” Of course, there was no reservation authority then on regs, so we had our own rulemaking authority, and didn’t have to clear the reg through HHS.

But what he had done, which is the way I think things should be done, the Commissioner had gone to the Secretary and other senior officials and said, “We’ve got this idea. It’s a really good thing to do, putting nutrition labeling, voluntary, but mandatory, you could make a claim,” and he had gotten everybody to agree on policy. No paper ever went anywhere. Of course, back then there was an unwritten

understanding that, okay, if a senior official like the Commissioner says okay, and you've sent their recommendation, then you'll respect his judgment, but he'll also be responsible if things go wrong. But you won't micromanage. So he'd gone down to Secretary Weinberger or Richardson and gotten the okay. And they just sent the reg to be published, because you didn't have the clearance of OASH and the Secretary's office, OMB, and the Small Business Administration, all of those places that a reg must now go through. In fact, I think one of the untold stories about FDA and the government during that period is the time delay in regulations review that began in the Carter administration.

SJ: The Paperwork Reduction Act was under President Carter.

WH: Right. Regulation volume was fairly low level in the Carter Administration. It really got picked up with Reagan, and then each administration has increased its oversight. Now, rules must go through, *ad nauseam*, clearances. In fact, the Secretary now signs it, because, if you recall, Secretary Schweiker removed a "reservation of authority" for major rules, and authority which FDA had since 1906. IN essence, the Secretary took back authority to promulgate regulations that FDA had been given at its inception.

So, anyway, Dr. Young recognized that nutrition labeling from the Edwards era was somewhat outdated. I did this white paper that basically says there ought to be mandatory nutrition labeling. And we ought to define all these descriptors like low fat, high fiber, and others, and we ought to regulate health claims in some sort of meaningful way. Before we could go very far with that, however, he was gone. But Jim Benson and,

by then, the new Secretary had come in. So Jim Benson basically took it to the new Secretary. The Undersecretary was then a woman named Constance Horner, who was very skeptical. This was an administration that was new, and was skeptical of regulation, and concerned about over-regulation. But the food industry supported it. For example, former Deputy Commissioner Sherwin Gardner was at the GMA [Grocery Manufacturers Association], and he was basically saying publicly, “We need better nutritional labeling rules.”

So, with the industry support, there was an effort with the USDA and the FTC and others to look at it, and this ultimately resulted in our selling the Secretary on making a major announcement at the National Press Club. It was March 13, 1989 -- or was it 1990? It was one of those two years. It got front-page, above-the-fold *New York Times* and *Washington Post* coverage. Understand that you had a new Secretary looking for news, looking for coverage, saying look at me, I’m here and I’m important too. That really was a big deal to them, a headline on the “CBS Evening News” and the whole bit. And so that impressed him and his team very much. That had been part of our strategy, because we felt like within a regulatory-adverse administration, we wouldn’t be able to do something mandatory like that without getting a senior political appointee to support it. And we got Dr. Sullivan really interested in food labeling, and that resulted in very regular meetings with Dr. Sullivan, first with Jim Benson, Joe Levitt, and me, and Fred Shank.

Dr. Kessler came in late '90, and he was very much on board with what we were trying to do. FDA actually proposed regulations in 1990 to require mandatory nutrition labeling. While we were reviewing the comments of that, Congress saw essentially all

the good news on this issue, and my view was that they wanted some of the credit. So they then got involved and wrote a bill and passed NLEA [the Nutrition Labeling and Education Act] in October of '90.

I actually tried to watch its _____. I was watching C-SPAN when I knew it was coming to the floor of the House. But I turned away to get a Coke or something, and they passed it while I was going to the kitchen. It was one of these unanimous consent items, and it was passed quietly with no debate.

RT: Do you recall who was the sponsor of the legislation?

WH: On the House side, it was Henry Waxman. But it also got a lot of support from the ranking member of the Energy and Commerce Committee, chaired by Ed Madigan of Illinois. There's a story on that, too, we'll get to later.

On the Senate side, Senator [Ted] Kennedy, Senator [Howard] Metzenbaum, and Senator [Orrin] Hatch -- all those were very supportive. So it was really a big partisan thing.

This was really about codifying what FDA was already supposed to do. The problem for the agency, though, was that it forced us to revoke the 1990 regulations and redraft them.

SJ: Getting it done.

WH: Yeah, exactly. It forced us to throw out all of those rules we had done and redo

them. Of course, we had to do it according to the new law, and there were some changes.

The basic thrust, mandatory nutrition labeling definitions and all that, stayed there, but there were a lot of details in the new law.

RT: I was going to ask, Bill, did the initiative for this really come from within the agency rather than from the Congress? Is that correct?

WH: Absolutely, no question about it. Although the fact that GMA had realized there was cacophony in the marketplace was important, because if the major food processors had opposed nutrition labeling, it probably wouldn't have happened.

I remember Connie Horner, the Deputy Secretary, was sort of the resident conservative there in Sullivan's group, and was very skeptical. We had a meeting with her, and she said, "You know, I don't believe in regulation unless you absolutely have to have it," and we said, "Well, the industry wants it." And she said, "I don't believe you."

And I was tasked with going back and getting statements from Sherwin Gardner and others saying, "The industry is supportive of this." And only then did she drop her opposition.

RT: Were there any congressional hearings at all on the issue?

WH: I don't recall any congressional hearings.

Again, this was Congress taking some of the credit for something that was going to happen anyway. If there was a congressional hearing, I'm not aware of it. There may

have been some very low-level hearings. And we had held some public meetings around the country.

Nutrition labeling became a big deal from that period, and one of the advantages was it gave us enormous opportunity to interact with the Secretary, because that kind of access is very important. It builds trust, so that when you needed to come to him for something, you got a call back, you got a meeting, whatever, and he really bought into that. The fact is, he was leaving after President Clinton was elected. We had a little ceremony in which we gave him a mocked-up can, "Sullivan's Baked Beans." He said, "You know, I get a lot of these things, secretarial plaques and all," he said, "but this is one that I will really cherish." And I know that when he retired from his medical school deanship, his staff, who had been with him as Secretary, called me and said they wanted to make a big deal out of food labeling at his retirement dinner. And he, in fact, still, to that day, a couple of years ago, felt that was one of his major achievements as Secretary, was doing the food labeling. In fact, if he hadn't been there at the end, when it really came to a crunch with President Bush, if he hadn't been willing to stand up for it, we wouldn't have gotten it done, because the agency was too low in the political pecking order back then.

We could talk more about that later.

So now we're in 1992.

SJ: Now, wait a minute. I don't want to skip the chronology. You were there when Jim Benson was working on a generic-drugs crisis.

WH: Well, part of it. Well, generic drugs actually happened on Dr. Young's watch.

I wasn't one of the leading principals on generic drugs. I was involved in some areas that I'll talk about. But Jim Benson, Tom Scarlett, Bruce Burlington, Bob Eccleston, and maybe Joe Levitt, were more involved than I. So I can talk a little bit about it, but those other people, if you really want the history of that, you need to talk to other people. Although, ironically, I've often said about generic drugs is that it actually ended up helping us in many ways, because we got a big boost in resources, and we got new authorities. Unfortunately, that's often the case -- and you know this quite well as a historian. If you look at FDA's history, it's through the tragedies and the problems, that's when you get help -- you know, *Silent Spring*, thalidomide, sulfanilamide, generic drugs, you name it. Those are the things that have gotten FDA boosts in money and resources. Just asking has never gotten us anything. And I can tell you an anecdote about Jane Henney when we get to it, if you'd like, that's very much on point.

But anyway, now we're at the point of the generic drugs "scandal." The biggest involvement I had is that there was a feeling there was a need for a study, an internal examination. The Hill people came rushing out here and started demanding documents, and at one point some Hill staffer even came to the building without notice and started going through files. At that point, Tom Scarlett basically stopped them at the elevator and said, "You're not taking anything out of here." That put him in a position of opposing John Dingell and other investigators and probably was the beginning of his leaving, essentially being pushed out. Of course, that caused a lot of ill will because many of the career people felt that Dr. Young should have stood up against that and said, "If he's going, I'm going too." The problem is, in that environment, they would have

said that's fine, too, and he didn't want to go. He, as all Commissioners do, wanted to stay. In fact, if you look at the history, they all want to stay. I guess Don Kennedy was the last one that really left totally voluntarily.

So Hank Dausch, who had been the Deputy Legislative Director, and I then had moved over to Joe Levitt's office, and we were tasked with examining the generic drug process and doing a report on whether it was vulnerable to corruption. The problem is -- and I learned a lot from that -- we made a fundamental mistake by letting Jim Benson and others set parameters. For instance, they would not let us even physically walk up there - - I think Generics were then on 17 or 16 -- and visit the office and interview staff and talk about the process. We could only talk with a few people at a distant location and look at some documents.

And so, ultimately, we wrote a report that said the process looked reasonable, "fundamentally sound," the way it was worded. The one major thing that we would recommended be changed was that the assignment of reviews be done randomly, because before a company could know which reviewer is going to get their application, and therefore a company can know Joe Blow is the guy that's going to have my document; I can bribe him. And if you give random assignments, the company would never know who's going to get their application. But Dr. Young and Jim Benson made us take that out in draft, because they said it would undermine the confidence the agency had in the reviewers. But, of course, in that environment, you shouldn't be worried about the confidence; you should be worried about fixing the problem. So we ended up issuing a report that said the process is "fundamentally sound" and we made a few dinky recommendations. But we never got the random-assignment thing because we were

made to take it out.

Well, then, of course, Dingell jumped all over that, so you kept hearing, “FDA concluded that the process is fundamentally sound.” And, of course, one of the things that the Congress ultimately demanded was random assignments, and they took credit for requiring it, of course.

If we had been left alone and allowed to say, “The process looks reasonable but you need to make sure that people can’t be targeted by using random assignments,” it would have been much better. But that report began to be characterized as a whitewash.

Now, I, as a relatively young staffer at the time, learned a lot from that, which is, if you’re going to take on an assignment like that, you’ve got to have some authority to do a decent study and present a report that can’t be amended. In other words, I wouldn’t do it again that way. I’d say these are my ground rules, but they gave me the ground rules and I accepted them, because as a GS-14-15, I didn’t have much choice. But I learned a lot from that.

The generic-drug problem ultimately caused the creation of the Edwards Committee, which I became the staffer on -- and I guess it was ’89 now -- and that gave me the opportunity to get to know David Kessler quite well, who was on that committee. So the generic-drug thing indirectly had a big impact on me, but I wasn’t one of the key players in testifying before Congress and developing policy and all that. But I do think it ended up costing Dr. Young his job and Tom Scarlett his job and caused a lot of change. But it also got us more money and some attention, and therefore had some good outcomes as well.

There was new interest in improving the agency, which set the stage for several

bills that were passed in that period. There was the Safe Medical Devices Act, there was the NLSA, the user-fee legislation, and there was the FDA Modernization Act. One made FDA statutory for the first time and the Commissioner a Senate-confirmed Presidential appointee. Remember that?

SJ: Yes.

WH: So we're at late '90 now.

SJ: Wait a minute. Let's go back. We missed a couple of things.

Somebody thought that you might have something to say about the agency's reaction to the AIDS epidemic.

WH: Yes.

SJ: And the personal-use import policy for drugs.

WH: Yes. One of the things that was a big deal that I worked on in that period was, the emergence of AIDS as a high policy issue. If you'll recall, the Reagan administration didn't want to talk about AIDS for a long time. But the AIDS activists concluded that, because Reagan was President, that the agency was sitting on lifesaving AIDS drugs and refusing to let patients have them, sort of a ban by the social conservatives. That was a very difficult thing for agency scientists to refute because we were very internally closed-

mouthed in that period. We didn't talk much about trials, we wouldn't talk about drugs in development, we wouldn't talk about IND's, we wouldn't talk about NDA's, and you may recall that that culminated in a big demonstration here around the building. I think it was probably '88.

I was something of a key person on planning for that, and I remember I came in that morning about four thirty, five o'clock to beat everybody else in because I was staffing Jim Benson on it. He got in the building, too, because he came in early. But many others could not get in that door. Dr. Young was out of town then, and I will say that a lot of the senior staff thought he arranged to be out of town during that period.

But Dr. Young did begin the process of reaching out to those folks. I think that, along with Tony Fauci at NIH and some folks at CDC, there was an effort within HHS at the working medical level to seriously interact with the AIDS activists. There were certain ones that were very, very active. Jay Lipher, for example -- I think he's since died. There was an effort to try to hear them out and explain to them how the drug-approval process worked.

There was also a parallel effort to use AIDS and emerging biotechnology to get us more resources, and that was largely successful. I was very involved in that. I put together a huge amount of data on IND's for biologicals and biotech products and AIDS IND's, and we did largely a road show in Congress and with the public to say that FDA is going to be getting all of this technology, and if we're not strong to get it through the system, it won't ever get out there to the public.

The AIDS activists initially were hostile to FDA and just wanted to force through radical change in drug review that said essentially once the IND was filed, let everybody

have it, and essentially lower review standards.

There was remarkable change among the activists between '87 and '91-'92 in which they ultimately concluded that a strong drug-review process was, in fact, absolutely necessary, and they eventually became tremendous defenders of the process. When the Competitiveness Council began to look at drug review in '89 and '90 -- and I'll talk more about that if you like -- and then later on with FDA reform, culminating in the FDA Modernization Act in the '96, '97, '98 period, the AIDS patient community was very supportive of FDA's views and concern about not lowering review standards.

Do you need to change tapes, Bob?

I developed a lot of information during that period to support FDA budget increases, which was successful. Dr. Young was successful in using that to get building funds for Building 29A, and then more money than was actually set aside, in which Dr. Young accumulated \$350 million for an FDA campus that was essentially lost when Newt Gingrich and the House Republicans rescinded it in 1995. That was a huge deal, to lose \$350 million in one fell swoop. We can talk about that if you like.

Dr. Young was determined to get money for facilities. He was indefatigable on the budget side. But it was very hard to get money in the Reagan administration, and so only certain programs could get funded, and AIDS did get funded, and AIDS did get funded.

Now, unfortunately, during that period, drug review was protected budgetarily, but other programs went down, such as food safety and devices. They were actually losing ground during that period.

One of the things I've done -- I hope it's in the box I've given you -- is some

analysis I did of the budget impact from 1971 to 2001 to show FDA's overall budget decrease in terms of buying power. I mean, the numbers went up, but with inflation taken into account, we actually went down in most programs.

Looking back to the AIDS activists in the mid-'80s, they were insisting on open access to all AIDS drugs, once the IND arrived, and importation from foreign countries. Within FDA, there was an effort to try to explain to them why that was a bad idea, and it was initially unsuccessful. They didn't want to hear it. They viewed all of the FDA people as largely political, hating gays, trying to keep them from getting drugs, and overly concerned about process. But, as I said earlier, there were efforts to reach out to them by Dr. Young, by Jim Benson, and then really in a big way by David Kessler. And this slowly brought them around.

But in the interim, in the late '80s, we had to do some things to lighten up on drug access, so we developed a policy that said if you had a disease for which there was no therapy in this country, you could go overseas and bring it in. That was really for AIDS. You'll remember Rock Hudson and AL-721 and all that. And so that began an influx of these drugs, although, as I said, as these groups got more and more sophisticated, they began to realize the fallacy in that. The drugs weren't working. Rock Hudson didn't benefit. But they needed to go somewhere for hope at the time.

SJ: Lessons learned from Laetrile?

WH: Exactly. You couldn't just tell them there was no hope.

SJ: But I was just appalled at the people in the agency who had not read anything about AIDS. I was talking to someone in Consumer Affairs who was so proud of the outreach work that Dr. Young was enabling them to do with the gay community -- educating them about AIDS/ When I first came to FDA, in a staff meeting with Ron Chesmore, he announced that we weren't sure that latex condoms would actually prevent the spread of AIDS. We thought so, but we definitely weren't sure about sheepskin condoms. We actually had to do the testing and back up what the Department was saying at the time on condoms. We had, therefore, made some progress in AIDS awareness.

So I'm up there in Consumer Affairs, and I'll never forget the staffer saying, "We're so excited. We're looking at this New York model on how they . . ." And I just looked at her and I said, "You know that the New York program was a disaster, don't you, that your model should actually be San Francisco?" and she just looked at me. I said, "Have you read Shilts' (Randy) book?" and she said no. And I gave her a copy of "And the Band Played On." I mean, they were very disorganized. Their heart was in the right place, but they weren't even looking at the right models. And FDA quickly caught up. I mean, everybody got up to speed. But that was a very interesting time, early on.

WH: I agree. And there was a real lag there.

Now, ultimately, AIDS got a lot of attention. Ellen Cooper coming into antivirals was a big deal. She really began to meet with these groups and go through data and talk about more than just the old way FDA used to describe it. And groups were brought in to be involved in the process. Remember? You may recall there were various committee

meetings held where the activists would come and sit and watch the debate, and slowly they began to be educated.

There was a lot of interest in drug review during that period. There was the AIDS push, and then there was the drug-lag concern, which had really matured. Don Kennedy was talking about it a lot in the late '70s. But by the '80s, it had become a really big deal. Drug companies were essentially saying, we're going to go to Europe first, and the research is going to go to Europe; people are dying. It wasn't just AIDS, it was cancer, it was Alzheimer's, all the drugs. And so there was an effort in that period to do things with drug approval to salve a lot of the interest groups. We did more and more compassionate IND's, not only in the AIDS area, but in cancer and other areas. We developed treatment IND's, you may recall, which were wider access to experimental drugs. Then, in 1989, we developed this thing where we would eliminate Phase II. If a drug showed promise in Phase I, we'd jump over Phase II.

During that period, there was a series of initiatives on drug review and access. We'd done the IND/NDA rewrite, I think, in '85. And so there was an almost annual drug review initiative to speed up drug approval. There was a fast-track effort, you may recall, but when Arthur Hayes was there, three high-profile drugs were recalled. They had been fast-tracked -- Oraflex, Zomax and Selacryn. Of course, the people that got dragged to the hearings on that were the career reviewers. Dr. Hayes was long gone. So the concept of fast-tracking was basically undermined. There was a sense you can't speed these things through. And, of course, the lesson for the reviewers was, if you hurry up under political pressure, when the drug blows up on you, the political appointee is not going to be there . . .

SJ: To back you up.

WH: Exactly. They're going to be long gone.

SJ: And you have to explain what went wrong . . .

WH: Yes. So there was an almost annual initiative, and I was involved in all those, culminating, to some extent, in, around '91, in accelerated approval, the only regulation I ever wrote, which was a good thing to do. But none of those things got to the fundamental problem of the agency's getting too much data and too many applications for the number of reviewers it had on staff.

During that period, the Competitives Council in the White House was asked to look at drug review by a guy named Boyden Grey and a guy named Alan Hubbard, who was a senior advisor to Vice President Quayle, under President George H.W. Bush, and a guy named David McIntosh, who later was elected to Congress. And, of course, the industry, the PMA [Pharmaceutical Manufacturers Association] under Jerry Messinghoff, who at that point was pushing for drug review changes. Then you had the activist groups, at least initially, saying FDA needs to get out of the way and let these drugs on the market. So you had a lot of pressure on the agency to step aside on drug review.

And early on, there were a lot of really unproven, even quack products that were being pushed as miracle drugs.

SJ: Yes. Interferons were being suggested as treatments for everything. For FDA, it was very difficult trying to convince the activists that drugs needed clinical evidence. But they didn't see it from our viewpoint initially.

WH: Each of those folks thought there was a drug that was the next magic bullet that could save lives, if FDA would just put them on the market. And so you had this synergy between these sort of ultraliberal AIDS activists and these almost rightwing conservatives who wanted regulation reduced, and that review came together in this Competitives Council review, which was led by a group of essentially free-market economists appointed by President George Herbert Walker Bush. It began its work just as David Kessler came to the agency, and I was a principal staffer on that. It was a very difficult period because we would go to these weekly meetings at the White House at which a different group would come in and make a presentation to this group around the table, and the few FDA folks there, except for Kessler, were not at the table and couldn't speak. I would be sitting against the wall and watch these groups come in, and they would invariably slam the agency: too conservative, too slow, need to lower standards, get drugs on the market faster, the companies will make more money, and patients' lives will be saved, the whole bit. And it was very difficult to argue otherwise because the audience, that committee, came in with mostly preconceived notions.

We did get some help, though. The AMA [American Medical Association] came in and basically said, "Well, doctors need some information. They need to know what works. But many of the Council members had a different view. "This is the way it will work. FDA will do an initial safety screen of the drug, some very quick-and-dirty thing

with animals or a few people, put the drugs out there, and then around the country, some doctors will prescribe drug A, some drug B, some drug C, and the drugs that were successful would ultimately become the ones that were prescribed.” And the AMA folks would say, “But you don’t understand. Doctors don’t have access to that kind of information. They don’t have time to do their own research. They depend on the FDA to make the judgment.” And you can’t make the doctors the researchers for an already marketed drug.” But, believe me, to that group, it was falling on deaf ears.

Well, then there was a physician on the group who was a Nobel-prize winner, the guy that they credited with eliminating smallpox, Dr. D.A. Henderson, and he was so reputable and well known, and became pretty outspoken. He didn’t care what they thought of him. And sometimes when these interest groups would come in, he would basically say, “I think we’re nuts.”

TAPE 2, SIDE A

RT: As we were turning the tapes, we had mentioned Dr. D. A. Henderson and your work with . . .

WH: The Competitives Council, which was this group intending to reform drug review. The lead person for the department was a woman named Connie Horner, the Undersecretary, who was sort of the resident conservative in HHS at the time.

Dr. Sullivan, the Secretary, was very little involved. In fact, at the end of that process, I got called to a meeting with him in which he was furious and said, “Nobody’s

been briefing me on this.” And I thought Mrs. Horner, who was his deputy, was. And he was really mad at her because there had been these numerous meetings at the White House and he was clueless. He felt that he had been completely sandbagged.

At the FDA level, we had attempted to communicate to him. But, of course, we assumed that his deputy was communicating more than we were.

But anyway, that review really brought out the intensity of desire to reform the drug approval process, and all those things that we had done -- treatment IND's, accelerated approval, more of compassion IND's, IND/NDA rewrites -- all those things had not really solved the fundamental problem that drug reviews were taking two or more years. Of course, the companies would always talk about it in terms of lives lost, but, in fact, they were saying our investment is being undermined and potential sales delayed.

Dr. Kessler was very careful with the Competitives Council. He was a new appointee, so he had to say to this group, “You’ve got to give me something I can sell. I can’t go in there and tell people they’re going to be guinea pigs.” And so he was very diplomatic.

Clearly that was a huge challenge to the drug approval process, and ultimately they issued a report, which we softened some, but it still had the overall thrust that FDA standards need to be lowered, FDA needs to seek less data, it needs to work more with the industry. But we did get them to put in there you need more resources for the program, because, really, that’s kind of what it came down to from our perspective.

We then segued over into an exercise that I did with Dr. Kessler and Mike Taylor. By then, Mike Taylor had been brought in as the Deputy Commissioner for Policy. While Mike was a food expert, he had some interest in drug review, and so we did some

fairly detailed analysis of where drugs were approved fastest and slowest. We were able to show that in the areas where you were able to put resources in and assure that when the application arrived, there was a doctor there to begin to review it, you could get those out in six to 12 months. So we showed how we were doing that for oncology and for AIDS. The agency had broken up the old anti-infective drugs division into two, anti-infectives and antibacterials, essentially, and antivirals. And the antivirals were all AIDS drugs. They were coming through the process very quickly because the division had that bolus of people.

So we invited in Jerry Mossinghoff, who was the head of the PMA at the time. There was Mike and me and Mossinghoff, and so we showed him the data and said, “Look. If you would agree to user fees to bring the reviewers up,” and we doubled them for HIV and cancer, “we could in turn guarantee review times as fast as these divisions do, in a year or less, from three years down to one.” There was a lot of discussion about what a “guarantee” meant.

Now, Mossinghoff was a smart guy. He said, “Look, I watched Lou England get fired as head of PMA for doing the Waxman-Hatch bill in which there was a tradeoff between generic availability and increased patent and marketing time for brand name drugs. He knew that the biggest problem was that trade associations often play to their lowest common denominator. You can make nine out of 10 companies happy, but if one Lilly or Merck or Pfizer is pissed off at you, you’re gone.

And so Mossinghoff, who accepted our argument, refused, however, to take the lead. He said, “But I will do this. I will bring the Board in. And if the Board of PMA” - - we called it PMA, which has since changed over to PHRMA -- “will agree, we’ll begin

negotiation with you.” That was huge; that was huge!

Now, the reason -- and it’s funny how things work out -- in my opinion that since they were willing to do that because the Competitives Council process didn’t get them what they wanted. We were able to successfully fend it off. Because their goal had been to cut the data requirements. That was their goal, to force FDA essentially to do a Phase I trial, approve the drug, and then do all additional testing in Phase IV, and they failed. So creating user fees was a fallback.

Another useful thing -- Mike Taylor, during his time as a lawyer at King and Spaulding, had worked with an emerging group called the Capital Venture Association or something like that. These were the money men that funded the biotech industry. They weren’t scientists. They were strictly entrepreneurs, investors. And we brought them in and gave them the same presentation. In oncology, we have this many reviewers per application, and this is the result. In antivirals, we have this many applications and these review times. In those other areas, we have this many applications and review times around three years. If you can find a way to give us the additional resources to get to similar resources in all drug-review areas, we will guarantee you 12 months or less. We’ll cut it down two-thirds.

And I remember those guys being impressed. These are moneymen. They didn’t know crap about the details of drug review. They wanted to make money on biotechnology because biotech was the big industry coming. And they said, “If you can promise that, that’s a deal. Just from an investment point of view, if you can do a two-thirds faster review and get on the market much faster, the kind of money that you’re asking companies to pay is peanuts. This was a no-brainer for them. They were strictly

looking at it as money invested over time and the expected return.

So, at that point, when the little guys, the little emerging biotech guys, were willing to pay user fees, that was important. They had no profits coming in because they had no products. They were living off investment income. But if they were willing to pony up user fees when they had no revenue, how the hell was Merck or Pfizer going to say no?

Well, again, we had gone to the Mercks too, and so Mossinghoff got the head of the board, a Warner Lambert executive, to come in, to show them the same data. And then they said, “We’re willing to begin to negotiate.” That began the negotiation for user fees.

Now, of course, the deal of user fees was a tradeoff. They paid the money, but we had to make promises. We couldn’t just take the money. We had to set up review goals. There was an exquisite negotiation about whether there were deadlines or ultimately there were “goals,” but there was an understanding it was essentially de facto deadlines for about 90 percent of the drugs. But it worked. And in fact drug review went from three years to faster and faster -- even faster than Europe. And at the same time, R&D shifted from Europe back to the United States. We became the place to invest in pharmaceuticals, and so jobs and investment returned to the U.S.

In Europe, as a matter of fact during the PDUFA [Prescription Drug User Fee Act] III negotiations, the Europeans wanted to follow our model. I remember showing Claude Allen, the then-Deputy Secretary of the department, a letter that had just come in that week to the Secretary from the European pharma, in essence, saying, “Our drug approval times are going up. You’ve got this remarkable success story, and R&D is

flowing out of Europe to the United States. Will you ask FDA to work with us to repeat the success in Europe?” But it was a remarkable letter that they would even actually put in writing a letter that said, we need your help to fix drug approval in Europe, when Europe had been held up all during the ‘70s and ‘80s as the model, if you’ll recall.

So, anyway, that was a drug approval story. So, in my view, the efforts by the AIDS activists and the conservatives to slash regulation ultimately set the stage for the user fees, which largely fixed the old “drug lag” problem.

Now, of course, you still have some of the issues coming back in FDAMA [FDA Modernization Act] that we can talk about.

SJ: What about PDUFA II. As I recall, industry and FDA were in perfect agreement, but Congress wanted a piece of it, and they extracted their pound of flesh, in terms of concessions. I was supposed to give a talk for new congressional staff in Georgia, for the veteran, Max Cleland. Max Cleland had been elected to Congress. My major professor was Harvey Young and Cleland was his master’s student. John Turner invited Max’s staff to a tobacco briefing which I was to do, weaving history into the current issue. Harvey invited Max himself, but he was unable to come. Well, nobody in the agency wanted me to do a tobacco briefing. So at the last minute, they gave me instructions to do this PDUFA, to bring in this PDUFA stuff. The staff got furious because they thought we had done a bait-and-switch on them. They wanted to know about tobacco, and they thought we were trying to lobby them to get behind PDUFA II. It was a total disaster, but it wasn’t my fault. I didn’t do PDUFA II. I did work on PDUFA III.

SJ: It just seemed ironic that all of a sudden with regard to something that had been clearly successful, Congress was holding the bill hostage till they could get the concessions they wanted.

WH: Some think that in PDUFA II, we gave away too much. But I think we reversed a lot of that in PDUFA III, and I know that I was certainly urging the folks that'll be doing PDUFA IV, before I retired, to put some new things on the table, and I think we will be successful in PDUFA IV in getting more money for adverse-reaction reporting, because, clearly, after Vioxx and others, better reporting is needed.

Now, the next big move in drug approval, in my view, is to fix that post-market side, and I think the industry knows it. They don't know how big the check is going to be. And they will resist. They will want it to be as small a check as possible. But I think it's got to be at least \$100 million a year, of course. Janet Woodcock's estimate is well above that. And so I think that will be the big push in PDUFA IV, which will begin this year to fix the post-market side.

Of course, there'll also be a need for new authority. We need authority to make these companies that promise to do these Phase IV studies do them, and I was urging legislation for civil money penalties for those who don't keep those study commitments. But this administration is not going to go for civil money penalties. We'll never get it through the Bush administration.

Okay. So that's sort of the drug approval story from my point of view, and the AIDS activists and all that.

I will just say about the buyers' clubs and all that, we were largely turning a blind

eye on the AIDS side of that point -- in terms of letting them bring drugs in from abroad. Now, we were being pretty aggressive on importing drugs everywhere else.

There was -- I don't know if you remember -- a guy named Hans Nieper in Germany. Remember that name? And you obviously remember laetrile. So while the AIDS drugs were basically being winked at, there was still fairly rigid opposition to importation of drugs elsewhere. I was very involved, as you know, with importation of drugs in the last year or so.

The agency was standing by its drugs, except for AIDS in the '80s and '90s, but allowing imported drugs, and I think quite rightly. Some of the AIDS drugs were clearly fraudulent . . .

SJ: That's an important change since I've come to the agency. We don't talk about quackery anymore.

WH: There's no resources. to devote to fighting an endless battle.

SJ: After I came to the agency -- I'll never forget being a part of this high-level meeting, in which some PR firm that FDA had hired came up with a campaign using cute little ducks as an image for quackery. That was not going to cut it, clearly. But the next image that the PR firm came out and tried was this huge cloaked thief, and I think we actually used that for a little while. But, as a historian, I was appreciating that neither one fit where we were. I think AIDS quackery is the only thing we recognized and labeled, and we didn't call it quackery, we called it -- health fraud -- these were things we

clearly recognized as ineffective drugs. That's when I think the change in title . . .

WH: And, again, the AIDS patients came to realize that. They saw themselves as victimized. But it took a while. Dietary supplements were another big challenge.

I remember somebody once said to me, "You guys just don't get it." I said, "What do you mean?" He said, "Congress is telling you we don't want you to regulate those things. We know you don't like them. We know you think they're health fraud. But OSHEA told you to back off." In fact, that's kind of what happened. Only when people die now under quackery will we do anything.

SJ: My question for you about the origins of OSHEA is, since this part of the institutional memory seems to have been lost. We all know that, or I thought we all knew, that the Proxmire amendment and FDA General Counsel Billy Goodrich's scheme for the three-tiered regulation had gotten nowhere. I mean, the public didn't accept it, Congress didn't accept it -- the first time FDA has ever had to suffer legislation saying you will not regulate this class of products stringently. I don't understand why, when Kessler's staff arrived to address the pending legislation, many of us all had the same experience. They just weren't listening and they didn't realize that there was a history there that they needed to be cognizant of. Now, maybe -- I understand many people think it was a train wreck that was going to happen anyway.

WH: Yes, I agree with that view . . .

David's critics would say he was displaying arrogance, much like he did with

tobacco, that he overstepped his bounds and got slapped down for it. In fact, from the Dykstra report and what Dr. Kessler was doing really energized the industry in a way that they were not before because we were taking harder looks. But that allowed us to deal with some of the major problems. So you could argue we'd better let sleeping dogs lie. I don't know.

I give Kessler a lot of credit. He came in, looks at this box of supplements that had been collected, and said, "This is all junk. It's not helping anybody, people are spending money on it. We need to do something about it. And some of them are just outright unsafe, such as ephedra." And so it was a brave thing to do. But, again, I think there was some hubris there. I don't think he realized the hornet's nest he was stirring up.

A Hill staffer once told me that they got more mail on dietary supplements than any issue since the Vietnam War.

SJ: But if they had paid attention to what happened to laetrile, it's virtually identical.

WH: Well, it's probably true. You're right.

But one of the problems is -- and that's why I always thought I had value here, being in the Commissioner's office probably longer than anyone else. There's some value in institutional memory.

I would often say to people, "Now, remember, we tried that in 1982." There's no institutional memory anymore. Commissioners come in de novo. How many commissioners have ever come to you and said, "Will you educate me?" Of course not.

And it's true of all government. They all think they're smarter than anybody else. This is true of all political appointees. "I'm so smart. Just give me a problem; I'll solve it." They don't care, don't know how their predecessors dealt with issues.

You know, if you could make commissioners sit down and say to them, "Let me tell you what happened when this was tried before," but staff don't speak up a lot now. The Center directors and all won't take on a commissioner. It's terrible. Institutional memory is diminishing, and it's worse every commissioner because fewer people stay very long. I mean, some senior staff are here for 10 years, and a few for 20. Now, they come in two, three years, and as for the political appointees, it's 18 months and they're gone, and they have no idea what happened before their time.

I remember on OSHEA, we had a very important phone call one night just before it passed. You may recall, Representative Waxman had been trying to stop the bill for two years. But there was a thing called a discharge petition in the House.

A discharge petition is a big deal because if a particular member gets enough signatures on a discharge petition, it goes straight to the floor for a vote. The speaker can't stop it. Committee chairman can't force it through the committee process. And so the discharge petition on OSHEA was about to have enough signatures. It's like two or three members or something short.

And Bill Schultz, who was Counselor to Waxman, calls up Kessler and says, "This thing's going to pass. What do you want us to do? We can either negotiate or just let it pass as drafted." So Kessler had a late-night call that went from about 10 at night till about one in the morning. He was very big on late-night calls. And it was Kessler, Phil Derfler, Fred Shank, and Mary Pendergast and me, and I think a couple other people.

I remember toward the end around one o'clock, as we were about to wrap it up, Dr. Kessler said, "I've got to call Bill back and tell him what to do." And I said, "David, my advice is let it go. Let Congress pass whatever they want, even though we won't like it. It will take us out of the game. We will have no authority essentially, maybe a little labeling or something. And then if there's a problem, they will own the problem, and they may come back and fix it. But if you try to get a little authority, they will pass a bill that puts in nominal FDA regulation, but we'll have no real authority," which is exactly what happened.

And I remember David came back into my office the next morning about 10 or 11 o'clock and said, "I just called Bill Schultz to tell him to get the best deal he can." He said, "I heard you last night. You've got a point. But in the end, if I can get any authority to protect people from these products, which I think are sometimes unsafe, I've got to get it."

Well, he was right from a medical point of view, but I still think I was right relative to the long term. The thing is, the industry would -- at least some companies have taken advantage of the law in a way that would be unsafe. And then when we were able to say, "Sorry, there's nothing we can do," Congress would have to change the law.

The way it works, the way the Congress can position it or take the blame, is we had the authority, we just didn't protect people. So the blame comes, it's sort of like the '06 to '38 act. You see, that was the point I was making. Inadequate authorities. You're putting in place the appearance of regulation with some authority, but not sufficient authority to really protect people, because there's no pre-market review and there's no required adverse-reaction data, there's no required data released to the agency of the data

the industry has. So you're basically in pre-'38. But I can understand his point of view. I still think I was right, and I've said that many times, that it would have been better just to be taken out of the game, let the industry overreact, put things out there and pay the price. Now we're stuck.

So that's sort of the DSHEA story, I think.

Now, let's see. In terms of time frames, Dr. Kessler's coming in now. And, of course, Kessler was a huge change because he came in wanting to do all of this stuff, and his critics would say make a name for himself and all that. But he clearly felt that he had this activist community, which said FDA needs to do a lot of things, and he had a burst of energy and he was a very bright, creative guy. He brought in a lot of new people. Of course, that was the cause of much consternation. He brought in a layer of people over the existing associate commissioners and other senior staff.

I remember asking him once why he didn't just put in all new people. He said, "I had two choices. I could go and replace all those people and cause a lot of ill will, and I could replace people all around that don't want to go where they're going to go, and maybe get grievances filed against me and all that, or I can put a layer in over them, and I chose to do the latter." Part of the problem with his approach, though, was that by making a lot of those new positions political appointees, it set a standard for politicals so that more politicals could be added by future administrations. I know that, for instance, the current administration felt protected that they could have as many as six politicals here because Kessler had that many. As long as you didn't have any more than Kessler, you're okay, because Kessler was viewed essentially as a Democratic commissioner, although he was appointed initially by a Republican.

So anyway, Dr. Kessler did a number of things that were really a boost to the agency's image. He worked with the AIDS activists and got PDUFA enacted. He tried to improve the medical device standards; particularly with the case of breast implants; he did nutrition labeling.

SJ: How much decision-making did he actually do on breast implants?

WH: He was pretty involved on it. I wasn't. I remember he asked once of me and Mike Taylor, "How did you guys avoid that, because you're involved in all the hot issues." And we laughed and kiddingly said, "Because we're smart. We didn't ever want to touch that issue."

SJ: The one thing they don't disagree with is that the product on the market is not a product that can take much stress -- it ruptures very easily.

WH: Oh, yes, right. But the ultimate relationship to disease and all that is still unproven.

SJ: That's still questionable, I agree, but the product itself, we should have been regulating that; they break too easily anyway.

WH: That's right. And I know Dr. Kessler was, you know, he really felt that the Center dropped the ball in terms of requiring decent safety data on implants.

SJ: We acquired a couple of breast implants for our collection, and my boss asked to borrow one for Bring Your Daughter To Work Day, and you can actually still see it. It's up in the Office of Women's Health. A group of teenage girls handling it for a morning left it a mangled, gooey mess. It was just disgusting.

But anyway, the point is if a bunch of teenage girls can rupture it in a morning, how did FDA miss this?

WH: On nutrition, there are lots of interesting stories there. We don't have time to go through them all, but as I said, we'd done an ANPR [Advanced Notice of Proposed Rulemaking] when Dr. Young and Jim Benson were running the agency then. We proposed regulations that Dr. Sullivan was very much behind. In fact, one interesting aside is that we were actually going to regulate fast-food restaurant labeling because there was no existing prohibition against it, and many consumers eat out nowadays. I remember telling Bill Schultz and others that drafted the NLEA [Nutritional Labeling and Education Act], "You really hurt us because we were going to at least make the Hardee's and the McDonald's do mandatory nutritional labeling. The NLEA exempted them forever from doing nutrition labeling. Later, we brought in all the fast-food firms' executives, and they agreed to do voluntary stuff, and now, if you ask, you can get nutrition labels. But you have to usually ask. You have to ask the clerk and they'll reach under the counter. Very few stores actually post it. I think McDonald's is pretty good, but most of the others don't.

Anyway, going back to the NLEA's beginnings, FDA's initial proposal was the

roadmap for NLEA. Then the NLEA passed and we had to re-propose under the NLEA structure in '92, and that process was very painful in that it culminated just as President Bush was leaving office in late '92. The final regs were completed early that fall and sent to OMB [Office of Management and Budget], but they were not approved. OMB didn't like it; they thought they were too regulatory.

We were anxious to get them out, obviously, and we had a little bit of leverage in that we had the incoming Clinton administration, and the Bush folks were worried that Clinton might redo them, although I think that was an illogical fear. The Bush folks expressed concern that the regs were too regulatory, and Kraft and other companies were complaining about some of the definitions and some of the requirements, such as type size and other things. The Secretary set up a process whereby we tried to negotiate with OMB and with USDA [U.S. Department of Agriculture], because Ed Madigan, who had been then a sponsor of the NLEA on the Hill, was now Secretary of Agriculture, and he was from Illinois, and meatpackers really hated the FDA label. That was because the meat guys at the time viewed a nutrition label as a bad thing because of its focus on fat -- all the attention then was on fat. The new label included all nutrients, of course, but focus was particularly on fat, and saturated fat, and the meat packers thought they would be adversely affected.

SJ: Sodium.

WH: Right. And so they wanted as minimal a label as possible, and they wanted small type size. They wanted a very simple label. We had developed this nutrition-facts label,

which is the one that you see now. The USDA label was a very simple little label that simply gave calories, fat, you know, 9 grams, dah-dah-dah, but has basically the format that existed before NLEA. And there was some translation that said one gram of fat is so many calories, whatever. It was, in our view, a totally inadequate label. Most food processors tended to line up behind the USDA point of view. So we were in a real dogfight to get those rules out.

At first, there was an effort for OMB to manage it. The OIRA chief tried to manage it, and then head of OMB. Then it went over to the President's chief of staff, a guy named Bob Zellick, who's now the Deputy Secretary of State. He attempted to negotiate between UDSDA and FDA/HHS, and that failed. And ultimately, he said, "Well, this has got to go to the President." It was the first FDA issue that had gone to the President in quite a while, I think, probably since saccharin, which went before Theodore Roosevelt. And so the meeting's scheduled with the President.

The President, by the way, had lost the election, and we were in that period before the new President was sworn in. I think it was November, late November or December. And then, of course, President Clinton would be coming in on January 20th of the next year.

And so there was a meeting scheduled with the President, the Vice President, Jim Baker, who was the chief of staff, and then the Deputy Chief of Staff, Bob Zellick, and then the two secretaries, Madigan and Sullivan, just those principals. Kessler wasn't allowed to go. I remember he and I sat in FOB-8. We watched the Secretary's limousine leave for the White House and then waited there for, I guess, two hours or something like that.

SJ: Now, what was the rationale for not including the Commissioner?

WH: Well, he was too low on the pecking order. This was the big boys.

SJ: Why did Mike Taylor go?

WH: Mike Taylor was not allowed in the room. Mike Taylor was the technical expert put out in the anteroom.

You should interview Mike, because he's got a great story about it. He was brought into the Oval Office a couple of times to answer questions.

I had a couple of contributions to that I thought were helpful, although perhaps inadvertently.

First of all, a few days before the meeting, there was a front-page story in the *Washington Post*, "Food Label To Go To President." That's one of the few things I've got for you today. I think it's down here in the box. And so it was a front-page, above-the-fold story by Malcolm Gladwin, who's now with the *New York Times*, I believe. And it describes how the interest groups -- all the meat guys and the food processors and all -- want to go with USDA's label, how the FDA folks had worked so hard to get these regs out. And then it has these quotes by these various administration, HHS, FDA, and other officials, and in all those quotes, it's always me.

It had all the right messages that there was a major decision coming forward that the President had to make, and he could be pro consumer or it could be pro industry.

And George Herbert Walker Bush was actually a pretty moderate guy and probably didn't want to, having lost the election, might not want to go down in history as anti-consumer on another thing. So that story was a good lead-up to the meeting.

Also, we got a call the day before the meeting from Marlin Fitzwater's office -- he was the President's press secretary -- wanting to know where's the press on it, because they weren't really close to this issue at all at the White House. They wanted to know where the press stood. So I put together a big press package, which was sent to the White House press office. It reflected the press pretty well because the press was 99 percent with FDA. I put in one editorial by the *Chicago Tribune* -- Madigan was from Illinois -- that suggested the USDA position, but, by and large, all press, editorials as well as news stories, including the *Time Magazine* cover and lots of other things like that, were on the FDA side. And I was told that at the meeting, the President turned to Fitzwater and said, "Where's the press on this?" and he said, I have this packet of articles, "The press is really with FDA." I think that helped.

And another thing they did that helped -- the night before the meeting, the White House asked for some examples of the labels. So -- and this was somewhat intentional and somewhat inadvertent -- all we had for the USDA labeling was basically a poor fax, so the copy looked bad. But for the FDA label, we had the just-invented laser printer, so we had some really nice production capability. So I printed them out on this really nice laser printer on high-quality paper, and Jerry Mande and I made multiple copies that were of high quality. We put in there variations of FDA versions. The label we see now, along with variations that allow flexibility. And each one was marked, 1, 1a, 1b, 2, 2a, 2b. They were all basically slight variations of the same label.

SJ: Because we had gone with a big PR firm, a big graphic designer.

WH: Well, we had done, actually, most of the work. But a graphics firm -- Greenfield Belser -- had helped us on a pro bono basis. And he did help. I mean, it was clearly beneficial to have professional assistance. But most of the label was done internally unlike, for example, the food pyramid, which the USDA paid a million dollars for.

TAPE 2, SIDE B

WH: This was a group effort.

So anyway, I sent this package over, and it's got like 10 pages of these nice FDA variations, and the last page is the USDA version, again, a poor copy of a fax. So when it's handed out to the group, the President is going through it. I think they thought there were like 11 choices. There wasn't really but two choices: FDA or USDA.

Well, the President ended up choosing 3c. The Secretary comes back from the meeting, calls Kessler says, "Come over." So Kessler runs over to the Secretary's office. I'm left there at FOB-8 with Phil Derfler, who was the lawyer on this. And then Dr. Kessler called us back a few minutes later because they didn't have a copy of the package. And the Secretary said, "The President chose 3c," but they don't know what 3c was. It was the FDA label. It was the one that essentially you see today. And so, then I rush across the street with it to show it to everybody, and then, of course, the Secretary called on everybody to have a big party to celebrate and they announced it to the press

and all that stuff.

We had to go back and make a few changes to the rules because then the goal at that point was to get the rules published before Bill Clinton was inaugurated, so as not to run the risk of having it re-revised. In fact, I think it was published on January 19th or something, literally a day or two before the inauguration. One of the incoming Clinton people called to ask if we wanted to do anything to change these. We said, "Please, no." We didn't get everything, but we got so much.

So the food-labeling effort not only got a good thing going, but it gave the FDA staff, I think, a morale boost that we had stood up for something, taken on a big battle with both political opponents and industry, and prevailed. It was probably the most monumental rulemaking we had done at that point, and may still be, but it was . . .

SJ: It was a challenge and a sacrifice to the staff -- to get that done in record time, because of the hammer clause.

WH: Right. Nights and weekends and an enormous amount of work, and I think people felt really good about it. And that label has survived quite well.

There's an effort now to make a few little changes, such as add transfat. In fact, I think the one thing that we probably downplayed then was calories and up-played was fat. We probably should have put more emphasis on calories.

In fact, our parents had it right back in the '50s; the key to weight control is calories.

SJ: Isn't that a perspective that comes after statin drugs?

WH: Maybe so. But I think the science has confirmed that it's calories in, calories out.

You know, you can sit around and eat low-fat foods all day, but if you eat too many calories and don't get any exercise, you're going to gain weight because your body's going to turn those calories into fat.

But anyway, so the food label was a good thing.

Now, see, what else was I involved in?

SJ: I have a note about medication guides.

WH: Oh, yes. That was an interesting thing.

Back in the '70s, Bill Vodra and others tried to take a look at drugs, to prepare a comprehensive redo of the whole drug system -- they developed the concept of generic drugs, treatment IND's, some sort of accelerated approval or fast-tracking for high-priority drugs. One of those was patient information.

And then you'll recall that Don Kennedy had wanted to make mandatory PPI's (Patient Package Inserts), and the Secretary at the time, Pat Harris, got very involved and she actually rushed those regs through in the waning days of the Carter administration. That was one of the first things that the Reagan people nixed.

In fact, I was in a little meeting once when we were going through the rules withdrawal process in which Art Hayes essentially said to me that revocation of the PPI rule was one of his mandates when he got the job. When he was hired by Secretary

Schweiker, he was told, “You’ve got to revoke the PPI regulation.” We were forced to go through this process that “examined” the issue, but, in fact, it was a preordained thing. It was just an exercise that we had to go through to meet the legal requirements for revoking a regulation.

SJ: But the only one that made it through was for the oral contraceptive.

WH: Right.

SJ: And that had a separate political influence

WH: Right. And we had the ability to do individual PPI’s, which we continued to do.

SJ: Which is why Barbara Seaman thinks she got the patient package insert.

WH: But the PPI effort in the ‘70s was for all drugs, and was considered by some to be too costly.

Now, I will say that there were legitimate concerns that the regulation would cost so much, because you had to print so much paper in the pharmacy. You didn’t have computers in the ‘70s, ’77, ’78, which drove costs up. So when Kessler came in, he recognized that technology had made PPI’s less costly.

One of the things that I remember about all those changes in drug regulation that were envisioned in the ‘70s was that most had been accomplished in the following years.

Generic drugs were done by Hatch and Waxman. We had done treatment IND's by regulation. We've got accelerated approval now. We've done a number of other things on the drug end. The one remaining piece by the mid-'90s was patient information, and because we had done good nutrition labeling for foods, Dr. Kessler was very interested in better drug information. And there was a real sense that you could save lives by giving people information, because patients got very little information about Rx drugs.

So Kessler ordered us to resurrect the old PPI regs from the '70s. But we changed them and also changed the name to "medication guides" because we were trying to follow on the pattern of nutrition labeling. We wrote a regulation in record time and sent it through the system. By then, Clinton was President. And the pharmaceutical industry and the pharmacists rose up, as they had back when Carter was president, and attempted to knock it down. They put a rider on the 1996 FDA Appropriations Bill: no funds shall be expended to do any patient information. It was an absolute prohibition. By this time, we had formally proposed this regulation, and we were very concerned that this legislation rider would be forever a prohibition against doing any patient information.

So we tried to get some support. [Donna] Shalala [Secretary of Health and Human Services] was not particularly supportive. She wasn't opposing us, but she wasn't prepared to put political capital into the effort.

So I was dispatched to go down and meet with Ted Kennedy, who was the chairman of the Health Committee, and explain to him how a Senate bill that had passed in the '70s had all these terrific ideas which had ultimately been implemented except for this piece that was undone. So he was willing to take it on, to block that appropriations bill, which had passed the House and came to the Senate floor.

SJ: That was directly with Kennedy himself?

WH: Absolutely. I spent several hours with his staff and with the Senator himself.

RT: Do you recall who the congressional member was that was leading the opposition to medication guides?

WH: It was Dan Coates of Indiana. He was sometimes called a senator from Lilly. Of course, the Indiana senators always had been influenced heavily by Eli Lilly, and Lilly has been one of the drug firms that always disliked FDA regulation.

Despite some drug manufacturer opposition to medication guides, the biggest impact was on the pharmacists, because they had to provide the information. By then, computers had emerged; thus they were able to print these little leaflets out pretty easily. But there was some ideological component to the opposition that didn't want an FDA requirement directly regulating them in that way.

Kennedy was willing to take the issue to the floor. So I went down there, briefed him at length one day and then the next day. And he was able to get one of the senators to sign on -- Paul Simons from Illinois, who was very distinguished and wore a bow-tie.

Anyway, Kennedy took it to the floor, and I had to give him a lot of background, so I went to the local Safeway up here and got a can of Alpo, which had very good nutrition information on the back, and also got an example of animal drug information given for owners, as well as some over-the-counter information. Kennedy was able to

put all that out on the Senate floor and say, “Look at all of the information you get on every consumer product but prescription drugs. And, in fact, dogs get better information than people do.”

RT: That’s right.

WH: Well, this was telecast on C-SPAN national television. I’ve got the tape if you ever want it.

Now, they positioned me right off the Senate floor in the Vice President’s Senate office to feed information in and answer any questions that came up. I couldn’t be seen on the Senate floor, but I was available nearby for questions.

After Senator Kennedy talked for a while, Senator Coates comes rushing out on the floor, walks up to Kennedy and confronts him. On TV, of course, they switch to music and you can’t see anything. I was watching it on the monitor in the VEEP’s office, and when they cut it off, I rushed out and went up to the staff gallery above the Senate floor. Of course, the TV viewers were only seeing the podium and music. But basically Senator Coates said, “You can’t do this, this is outrageous, comparing this to dog food,” and dah-dah-dah, and Kennedy is saying, “It’s not outrageous at all. You’re trying to block this bill.”

So they basically step over to a corner with the chairman of the Appropriations Committee, cut deal on the spot, and give us authority to do this. Now, the compromise bill scaled it back some. We were allowed immediately to do medication guides for significant drugs and then as needed for others. But it’s all we really wanted. It was a

huge win for the agency in that there had been an effort to block patient information forever. And not only did it not get blocked, but it gave us explicit statutory authority to do it. And then we went back and did the regulation a year later, and now that regulation is in effect. I don't think CDER uses it enough. But all the medication guides they do now are under that statute.

I informally cut a deal with the various industry groups to not complain anymore if we limited it to three to five drugs a year -- very informal, but if it was only three to five a year, they wouldn't say anything. Well, CDER, they do about one a year. And I told Bob Temple and others, "You have authority to do three to five a year. Why aren't you doing more?" But I think it's time-consuming for the Center.

Anyway, that was a big win for the agency, and now we'll have that authority in the future.

SJ: That was Kessler?

WH: Yes, Kessler was Commissioner.

SJ: Giving the testimony.

WH: Oh, yes.

Paul Simon was the senator, by the way, who helped Kennedy. The two senators. In fact, the *Washington Post* had an interesting story the next day about Ted Kennedy that said a lot of people think he's over the hill but then said, "Just yesterday, he showed

how he could take on the lions of the Republican Party and win.”

RT: This may not be entirely in context, but there’s also been a lot of discussion and interest in drug exportation and reimportation of the products, and some of the governments, state governments and others, have apparently contracted to buy the reimported drug at apparently a lower price. Do you have any experience with the issue?

WH: That was the issue that I was most involved in in my last year or so. As we discussed earlier in the ‘80s, except for the AIDS exception and a few importations of things like AL-721, we had pretty much barred the door to foreign imported drugs, although there was a steady amount of traffic of people going across the border to Canada, who lived on the border, and certainly people going into Mexico, to the pharmacies right on the border, and getting Valium and that sort of thing. But that was relatively low-level stuff and nobody was particularly concerned.

Then, when the Internet emerged around 1998, one of the first things that began to be sold on the market was prescription drugs. And I’d like to think we were fairly prescient, because I remember we said at the time that this was going to be a big deal and that we needed new authorities to deal with it.

In fact, I remember the first hearing I did -- I think it was 2000. I said to the members, “I think we can get the control of the Internet sales domestically. If there’s a site in Maryland, we’ve got tools between us and the Maryland Pharmacy Board to deal with it. My real concern is you’re going to see it move internationally. Sellers will start these foreign web sites.” And, in fact, I was absolutely right, and that’s where the real

heat and light came, because most domestic Internet pharmacies were legitimate, like the cvs.com or drugstore.com, or they're selling OTC drugs, which are not really a problem. The states can deal with them. But the emergence of these foreign web sites became a big deal, and the agency took the position that I think it should have, and it historically has, which is, these drugs are unapproved, they are potentially unsafe. They should not be imported.

The problem we ran into was, back in the old Hans Nieper days of the '70s and '80s, the volume was relatively little. We could identify by return address, and we could seize a lot of that stuff. But when this stuff started coming in from these foreign Internet sites, the volume became a problem because, as you probably know, the statute required us to identify the import, ascertain whether it should be entered, and if we determined there was a question about that, we were to detain it, and then send the addressee a letter giving them an opportunity to argue why the import is safe. And that works fine for commercial shipments, which is really what the law was passed to do.

In fact, you know quite well, the import law is really the old 1898 law. They incorporated it in the 1906 act. And I remember reading once -- maybe you gave me the debate about the '38 act -- and everybody was saying the import provisions from the 1906 Act were the only thing that worked. They're the only ones that carried over to '38 because they gave us the authority to look, to examine a product and determine whether to enter it or not. And that worked fine for molasses or flour or whatever, and any large commercial shipment, because if it was a drug, for instance, you could make sure that it met the requirements of the approval by checking with the Center, and then you could let it in. And if you need to hold it for a few days to check that, no problem. But all of a

sudden you had all these little packages with pills in them, and the import districts became amazingly overwhelmed and didn't have the manpower or wherewithal to do that.

RT: One of the arguments that seems to be proposed by maybe AARP [American Association of Retired Persons] and some other consumer groups is the question of, if, for example, a product made by, let's say, insulin made by Lilly, goes over to Canada, and the same product in the same package comes back at a lower price, it's hard to differentiate, I'm sure, from so-called perhaps valid reimports and those that are repackaged and offered for importation. Is there any accommodation considered before legislative initiatives are taken to recognize that kind of imports?

WH: I think, Bob, the career professionals here at the time I was leaving, if they had a choice, they would have cut that deal. They would have, if, in return for authority, turn back most of this stuff. They would have been willing, I think, to let in a few things from, say, Canada if you could make that the limited source.

You've got a political context here, though, where the administration is not going to do anything to undermine the industry's interests, and you don't want to legitimize cheaper imports that are price-controlled because you've also got an ideological opposition to price controls.

Now, the agency professionals are not looking at it with the political point of view or the price-control point of view. They're looking at it strictly from the drug-safety point of view: What would it take to ensure safety? Because all of these things

are *de facto* coming in now anyway, they see risk. In fact, there's probably a real risk, and it's probably going to get worse. So they would be willing to take that tradeoff, which is to give the inspectors the authority to turn back anything that doesn't come from a predetermined source. If you have a package of pills and it didn't meet some standard for entry, you wouldn't have to send a letter, you wouldn't do anything. You just give it back to the Customs afterwards and say re-export. And, of course, the pharmacies in other countries, after a few of them got shipped back, would stop sending them because it would be wasting the postage. And then you could set up a parallel system to allow in whatever you want to allow in under whatever standards you've got. But this administration is never going to go for that. And now when you've got control by both the Executive Branch and both houses of Congress, it's pretty easy to block legislation you really don't want, and that's been the history here for several years.

RT: At this point, the first segment of the interview is being concluded and at a later time will be continued to discuss other topics regarding Mr. Hubbard's career. Mr. Hubbard is leaving with the History Office several historical papers and artifacts from his career with the agency. This concludes the first recording.

END OF INTERVIEW