History

of the

U.S. Food and Drug Administration

Interviewee:	**Walter M. Batts**
Interviewer:	**Suzanne W. Junod, Ph.D.** **Robert Tucker**
Dates:	**December 13 & 20, 2011**
Place:	**Silver Spring, MD**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

National Institutes of Health
National Library of Medicine
Bethesda, Maryland 20894

Deed of Gift

Agreement Pertaining to the Oral History Interview of

Walter M. Batts

As a conditional gift under Section 231 of the Public Health Service Act, as amended (42 U.S.C. 238), and subject to the terms, conditions and restrictions set forth I, Walter M. Batts **, hereby give, donate and convey to the National Library of Medicine ("NLM"), acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at** White Oak, MD **on** Dec. 13, 2011 **and prepared for deposit with the NLM in the form of recording tapes and transcripts. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.**

Title to the tapes and transcripts shall pass to the NLM upon their delivery and the acceptance of this deed by the Director, NLM. The director, NLM, shall accept by signing below.

The NLM may provide for the preservation, arrangement, repair and rehabilitation, duplication, reproduction, publication, description, exhibition, display and servicing of the tapes and transcripts as may be needed and appropriate.

Copies of the tapes and transcripts, may be deposited in or loaned to institutions other than the NLM, including the U.S. Food and Drug Administration. Use of these copies shall be subject to the same terms, conditions, and restrictions set forth in this agreement.

The NLM may dispose of the tapes and transcripts any time after title passes to the Library.

Date: 12/13/2011 **Signed:** Walter M. Batts

I accept this gift on behalf of the United States of America, subject to the terms, conditions and restrictions set forth above.

Date:_____ **Signed:**_____
Director, National Library of Medicine

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

CASSETTE NUMBERS

GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

DATE: December 13 & 20, 2011 PLACE: Silver Spring, MD LENGTH:

INTERVIEWEE:	INTERVIEWER(S):
NAME: Walter M. Batts	NAME: Suzanne Junod, Ph.D. Robert Tucker
ADDRESS: Food and Drug Administration	ADDRESS: Food and Drug Administration

FDA SERVICE DATES: FROM: 1972 TO: 2011

TITLE: Directorate, Global Regulatory Operations and Policy

INDEX

INDEX

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

CASSETTE NUMBERS

GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

DATE: December 13 & 20, 2011 PLACE: Silver Spring, MD LENGTH:

INTERVIEWEE:	INTERVIEWER(S):
NAME: Walter M. Batts	NAME: Suzanne Junod, Ph.D. Robert Tucker
ADDRESS: Food and Drug Administration	ADDRESS: Food and Drug Administration

FDA SERVICE DATES: FROM: 1972 TO: 2011

TITLE: Directorate, Global Regulatory Operations and Policy

INDEX

INDEX

Interview with Walter M. Batts

December 13 & 20, 2011

TAPE 1, SIDE A

SJ: This is another in the series of FDA oral history interviews. Today, December 13, 2011, the interview is with Walter M. Batts, Directorate, Global Regulatory Operations and Policy, Office of International Programs. The interview is taking place at the White Oak campus of the FDA in Silver Spring, Maryland. Participating in the interview for the History Office is Dr. Suzanne Junod and Robert Tucker.

So, Walter, as we begin our interview with you, could you give us a brief resume of where you were born, raised, educated, and then move on to any experience you may have had after your college before joining FDA, and then we'll go in depth to your career.

WMB: All right. I was born in Petersburg, Virginia, in 1950, and moved around a little bit because my father was in the Army, and so we spent some time in other parts of the country. But I ended up back in Petersburg when I was about 10 years old, and stayed there until I graduated

from high school in 1968, at which time I attended college in Austin, Texas, at a school named Huston -- spelled H-u-s-t-o-n -- -Tillotson College. There I majored in mathematics and chemistry, and was fortunate to be inducted in a couple of honor societies, one named Beta Kappa Chi for work in the sciences, and another one, Alpha Kappa Mu, for overall general excellence over many subjects; a member of Who's Who in American Colleges and Universities, and a member of the track team; and in my senior year, President of the Student Government Association.

I was interviewed on campus my senior year by a member of the Food and Drug Administration who was an alumnus of the college and interested me in FDA, and so I filled out an application and applied, and it was one of the offers that I received for employment, and I decided to join FDA because I thought it would take advantage of both my math and my chemistry, because the job that I was offered was primarily to utilize my math training as an operations research analyst in the Division of Planning and Analysis in the Bureau of Drugs. And so I accepted that position and came on board with the agency on July 9, 1972.

SJ: Now, you were part of Project Hire, correct?

WMB: Correct.

SJ: Did you take the Civil Service Exam?

WMB: No. That’s a good question. I did not have to take the Civil Service Exam, and I recall, based on my grade point averages, I remember, I was given an equivalent score on the exam, as if I had taken it, but didn’t take it.

RT: What entry level did you come in at, what grade level?

WMB: I was hired as a GS-7.

RT: Okay.

WMB: And that was determined by a combination of training and grade point average and so forth.

RT: In your entry job description, was that as an investigator or . . .

WMB: No. As an operations research analyst, which is the job title that I was given, and that job series was one that is still here at the agency, I think, both in the Centers and in the Office of the Commissioner, in the Office of Planning and -- Policy and Planning, Office of Policy and Planning, here at the agency, still use that job series.

So I was assigned to analyze data relating to the timeliness, or lack thereof, of new drug applications over the years -- and it even continues to this day -- whether the agency approves new drugs fast enough. And a big issue at that time, there was a lot of work going on within the agency to look at the data about the processing time and trying to determine if things could be decided to improve the processing of applications, looking at the different steps in the process and how long the steps took.

RT: That was about 1972, then, when you came?

WMB: Correct.

RT: Was that before the AIDS crisis came up, because that put pressure on for faster drug clearance too.

WMB: It was before that, yes.

And I actually served a number of different roles in the Bureau of Drugs, in that Division of Planning and Analysis. At the time, the agency had a budget structure that referred to what they call PMS or Project Management System projects in the Bureau of Drugs, and in our division we had analysts that were assigned to work with people around the Bureau on different projects. And one of my assignments was to support the Division of Scientific Investigations that was headed by Dr. Frances Kelsey.

And it's interesting. I had lunch with one of my early supervisors, who told me that I was assigned to Dr. Kelsey, to work with her, because she had kicked out of her office three or four previous analysts that had been assigned to her because she didn't like their work. Anyone who knows Dr. Kelsey would appreciate that.

SJ: Talk a little about Dr. Kelsey. We always like hearing about her from people who worked with her.

RT: That was kind of a challenge to you, too, wasn't it?

WMB: Yes, it was, although I wasn’t told that at the time.

You may know Daniel Michels. I don’t know if you’ve done a history on him.

He was one of my early supervisors, and he told me, when we had lunch last week, that he assigned me to her because one of the last analysts he had, and he had nothing to lose.

SJ: She’d gone through all the others.

WMB: So even though I was relatively new with the agency, said, “I’ve got no choice.”

RT: These are some of the points that come out in these oral interviews that you wouldn’t know otherwise.

WMB: Yes.

RT: Points of interest.

WMB: And so, as it turns out, Dr. Kelsey and I and other members of her staff worked very well together, and I was always appreciative to her for a number of things, but

she nominated me for my first agency award, the Commendable Service Award for work that I had done with her. And I'm very proud that we were able to justify additional resources for what became known as the Bioresearch Monitoring Program, resulted in the hiring or the authorization to hire over 600 new positions to the agency, and not just in the Bureau of Drugs, but other bureaus, as they were called at the time, and in the field, because they required investigators going out to inspect the clinical investigators and some of these clinical trial bookkeepers. So I have fond memories of that.

And I also did some other work at that time in an area of the office that wrote compliance programs, and I had the opportunity to work under a gentleman by the name of Charles Piatt, who was a former investigator in the field and had come into headquarters to take this job, and there were a couple of other people on the staff who were excellent investigators. And although I've never been an investigator, have never worked in the field, I learned a lot from them and I was able to assist them in writing and evaluating compliance programs. So I did that work in those early days there.

And after a few years doing those things, then I was asked by the then-Bureau Director, Dr. J. Richard Crout, to

join his team in the Office of the Director as a Special Assistant working on various and sundry things. And one of my colleagues there as a Special Assistant, was Dr. Robert Temple, who you may know, is a 40-year veteran of the agency as well.

SJ: I don't want to interrupt, but I want to get this because when you came on board, the Supreme Court was just now ruling that we could move ahead on drug regulation as we had put it in the '62 Amendment, some of the proposed regulations. Were you aware of that? Was that part of what you were, that brought some excitement to the job?

WMB: It was.

SJ: General Counsel Peter Hutt was instrumental in bringing that through the courts and stuff.

WMB: Right. And I recall that my office -- and I got involved a little bit -- was very involved in the DESI project that was kind of the implementation of that, the Drug Efficacy Study Implementation project, which was to look back at a lot of drugs that had been approved prior to the requirement for efficacy to determine if they were in fact effective. And I remember doing some work with a

former FDAer, who you may know, Dr. Paul Bryan, who headed the DESI program at the time. And it was an exciting time because it was a big project that took many, many years. Even, I think, when I left the Bureau, it was still going on at that time, in the ‘80s [unclear] the Bureau.

RT: What year did you leave the Bureau of Drugs?

WMB: Well, just going back to my work with Dr. Crout in the Bureau Director’s office, and he had a deputy, Jerome Halperin, who also worked with the two of them there. They were kind of among, at least to my knowledge, the first people in the agency who recognized the importance of working with our counterparts in other countries. They had a team, international interest and good relationships with their counterparts in other countries at the time, and it was during those years, and now we’re talking about around 1980, when I first became involved in international activities with FDA, with the Bureau of Drugs.

And one of the big projects that Dr. Crout got started was a collaboration with the World Health Organization to, with the idea of let’s have a meeting with our counterparts around the world and develop closer relationships. And so

the World Health Organization agreed, and they cosponsored with FDA, or FDA with them, the first International Conference of Drug Regulatory Authorities, referred to as ICDRA. And that meeting still occurs today, to this day, every other year. A host country and the World Health Organization will cosponsor a meeting of drug regulatory authorities.

RT: That initial meeting, was it held in this country, or was it . . .

WMB: It was held in this country. It was held in Annapolis, Maryland, in 1980. And, interestingly enough, the theme of that meeting -- they had two themes -- communication and harmonization, and harmonization is a big buzz term even to this day. The agency continues to work with its counterparts to pursue harmonization initiatives.

SJ: Jerry Halperin, in his interview, talks about one of the biggest things coming out of that meeting being simply a name, a list of names and addresses.

WMB: Exactly.

SJ: Because up to that point, you guys had absolutely no idea who from the Middle East, for example, knew anything about certain drugs at this point.

WMB: That's true.

As it turns out -- and I hope you have a copy of the report from that meeting.

SJ: We do not, and we would like to have one.

WMB: I'll double-check my file before I leave, because I know I had one. I can picture the blue soft-cover book.

But the major outcome of that meeting was, as Suzanne says, a listing of the names, addresses, telephone numbers of the regulatory authorities around the world who attended the meeting so that folks could talk to each other about problems and share experiences.

RT: Before that, I suppose the communication was very spotty, if at all.

WMB: That's right. And it was done through the World Health Organization. If you needed to get a hold of

somebody, you would contact the WHO and hope they had it, and they'd put you in touch with somebody. Having contacts available was transforming.

RT: Real pioneering.

Now, this is an aside. I notice that your position in the various responsibilities was identified as Health Scientist Administrator. When did you come under the aegis of that particular term?

WMB: I acquired that term when I moved to the Office of Health Affairs in the Office of the Commissioner. And to sort of get us to that point, I was asked . . . Well, step back just a little bit.

Because I had gotten involved in international activities working with Dr. Crout and Jerry Halperin, I had a lot of interactions with the International Office in the Office of the Commissioner, which was headed by Dr. Stuart Nightingale and the Director of the International Affairs staff, and had done some work and travel with them. I represented the Bureau of Drugs in a trip to Egypt, I recall, back in 1983. It sticks out in my mind.

But I was asked to assist the Commissioner, Dr. Frank Young at the time, in participating in a big meeting that

the World Health Organization was holding on the rational use of drugs. And the formal name of this conference was the Conference of Experts on the Rational Use of Drugs. And I was called in on assignment, because of my background and knowledge of the Drug Center and various programs, to assist the Commissioner in this conference.

And, following that, I was asked to stay on permanently in the Office of Health Affairs in the International Affairs staff as a permanent staff member.

SJ: And how large was that at the time?

WMB: At the time, it was on the order of maybe about 10, 11, maybe 12 people, somewhere in that range. And the staff was headed by John Lupien, who left the agency a couple of years after that and went to work for the Food and Agriculture Organization. He had come into the Office of the Commissioner from CFSAN. He’s a food guy.

RT: That’s John Lupien.

WMB: John Lupien, L-u-p-i-e-n. And his deputy was a man by the name of John F. or Jack Harty, H-a-r-t-y. And John Lupien, as I said, left not long after I joined the

staff. I joined, I went there on a detail for the Conference of Experts in late 1985, joined permanently in early 1986, and shortly after I joined, John Lupien went to work in Rome for the Food and Agriculture Organization, FAO. And Jack Harty selected me as his deputy.

RT: You probably were promoted at that time, too, weren't you, to a 15 level? I assume you were a 14 over in Drugs.

WMB: I'm trying to think. I'm thinking that Jack Harty was a 15, and I was a 14.

RT: You became a 15 later, as I recall.

WMB: Yes, yes, shortly thereafter.

RT: In the Office of Health Affairs, they were involved to a substantial degree in international liaison. Is that correct?

WMB: That's correct. The head of the office which had responsibilities for more than international affairs was Dr. Stuart Nightingale. He was the Associate

Commissioner for Health Affairs, and his office had two other components. One was called the Medicine Staff; it was headed by a physician. And the other was the Health Assessment Policy Staff; Ron Wilson, who I think may still be with the agency, headed that staff. And then the third staff was the International Affairs Staff, where I was located. And there were maybe about a dozen on the International Affairs Staff, and they had a person that was responsible for Europe, someone that was responsible for Asia, someone who was responsible for international and multilateral organizations, someone who was responsible for Latin America, just kind of a one-person liaison to these various regions. We managed travel for the agency; the office still does.

RT: Was it during that period, or was it later, that the Chilean crisis came up, and one of the international staff persons lost his life in a plane crash?

WMB: Yes. During that time frame, as I said, I joined the staff in 1986 and became Deputy Director later that year, after John Lupien left. And in 1989, what was referred to as the Chilean grape crisis erupted. And as part of the agency's efforts to determine whether there was

in fact cyanide found in Philadelphia in grapes from Chile, Jack Harty, who was the Director, and an FDA investigator named Patrick Pouzar, from the Nashville District, went down to Chile to help investigate and see what controls did they have in place in the growing areas to protect grapes from possible sabotage or whatever, and I think they took two or three trips down there. But on the last trip, they were in a small plane doing kind of an aerial view of some of the growing areas, and the plane crashed. Both Jack and Pat were killed.

It was a very tough time for the office. I'll never forget sitting in my office, and a former FDAer named Arvin Shroff, who was with the Regional Operations office at the time, walked into my office and he said that there had been reports of a plane crash there involving Jack and Pat. So, for a couple of days, there was a very intense search for the plane. And I can recall being here on a Saturday working with the department's Office of International Affairs and on the phone with the Department of Defense, trying to mobilize resources through the Southern Command to help search -- a really difficult, intense time. And then getting the word late that Saturday that the wreckage had been found and there were no survivors.

RT: Did you succeed in leadership of the international staff after that?

WMB: After that, I did. I, subsequent to that, was selected by Stuart Nightingale as the Director of the International Affairs staff, replacing Jack Harty.

SJ: Tell us a little bit about him, working with him.

WMB: Just a terrific guy, one of my favorite supervisors. He was from the New England area, actually from Boston, complete with a Boston accent, and we used to have a lot of laughs in the office about that.

RT: I remember him. I went to the Boston office a time or two. I remember dealing with him.

WMB: Yes. He worked there before he came to headquarters. And there's a library in the District that was dedicated to his memory. I went up to the dedication. And he was an investigator by training, so he knew that part of the agency, and had come into headquarters and moved into the international area.

As I say, we would kid a lot about his Boston accent. I'll never forget, we had a summer student in one summer, and Jack wanted her to bring him a cat, and she didn't know what he was talking about. She said, "Excuse me, Mr. Harty?" He said, "Go down to the xerox room and bring me one of those cattons." And I said, "He's talking about a xerox box." But his accent, carton became catton. He was one of those people that did have a strong accent.

RT: Speech style.

WMB: Yes. Big Boston Red Sox fan, just a good guy, loved the agency. Had a couple of kids who worked for a short time as students in the agency, a wife who worked for the World Bank.

RT: You were in charge of that responsibility for a time. I don't want to jump ahead too far, but later there was a reorganization that I guess eliminated the Office of Health Affairs -- is that correct -- and then international activities migrated, I guess, to . . .

WMB: Migrated to what became the Deputy Commissioner for Internationally Constituent Relations.

RT: Yes.

WMB: And that’s when Sharon Smith Holston became the Deputy Commissioner.

Again, her responsibilities were I guess what Stuart Nightingale’s were, broader than just the international office because we were only one component of her office. And the constituent relations part of it was the Consumer Affairs Office, Women’s Health Office and Press Office.

RT: That was Sharon . . .

WMB: Sharon Smith Holston.

RT: Well, I didn’t mean to accelerate. Maybe there were some things you wanted to cover prior to that reorganization.

SJ: What was it like to take over a staff that was more or less grieving, I guess?

WMB: Well, somewhat difficult, but, on the other hand, it caused everyone on the staff to really become very close and to pull together and recognize that we had a job

to do and that Jack would have wanted us to continue to do it a certain way. And so in a number of ways it became "easy" because everyone was very cooperative and there was a spirit of camaraderie and teamwork that I've never seen before and never seen since, to come together and get the work done and help each other out. That wasn't your area but the area needed help, so you helped.

RT: The Chilean crisis, was that the only incident of that nature where products were involved which created international requirements for cooperative efforts? I think you got into some agreements, international agreements, along the way, too.

WMB: Yes. We began to develop a number of memoranda of understanding with different countries to improve communication and cooperation on problems.

RT: In the pharmaceutical area, wasn't that one of particular interest in getting an international understanding of FDA's requirements so the international trade barrier thing could be somewhat abated?

WMB: Well, also around that time, the U.S. government was involved in the latest round, at that time, of the GATT negotiations, General Agreement on Tariffs and Trade, and FDA had not been a player prior to that time. There had been previous rounds of GATT. The rounds are identified by various cities where the negotiations would start. The Tokyo Round, the seventh round of GATT. And we were invited by the U.S. Trade Office to participate because countries that they were negotiating with felt that some of the FDA requirements were trade barriers, could be viewed as trade barriers, and they wanted to make sure that FDA was at the table to explain why we had certain requirements and why they should be kept in place. And so I became involved in the early stages of those negotiations, got some support from the Office of the Chief Counsel.

SJ: Was that Linda Horton at the time?

WMB: Linda Horton.

SJ: Tell me a little about her role. My perception is, based on dealing with her later, actually, is that she, basically she went back to school to learn something about

international law because no one in the agency really had that expertise at the time.

WMB: That's true, that's true. And in these early days of these negotiations, Linda provided excellent support and advice, but the General Counsel's office wasn't directly involved. It didn't, at that time, seem to have the inclination, for that reason, to get directly involved. We'll provide you whatever legal support you need, and that's how it happened.

And so I personally participated in all the interagency meetings and developed U.S. government positions before we'd to the international meetings. We had a lot of battles with the U.S. Trade Rep's office, and I probably made a few enemies over there at one time because FDA was just hard-and-fast: We've got our regulatory requirements and they can't be changed. We do this by law.

And we had a huge meeting in Brussels in 1990 that was led by the U.S. Trade Rep, who at that time was Carla, Ambassador Carla Hills. And I'll never forget her standing before the U.S. delegation one night and saying that she was declaring that we were abandoning these negotiations because no agreement was better than a bad agreement. That

was kind of nice to be involved in from the standpoint that the U.S. government had held its ground, made a decision, and if we weren't going to get out of this what we needed to get out of it, then we were really going to get out of it.

SJ: Do you remember any specific issues that were particularly problematic or were a conflict for you?

WMB: Well, they were generally product regulation kinds of issues, because the Environmental Protection Agency (EPA) was similarly concerned, and I developed some close relationships with staff from the Environmental Protection Agency. We'd be in the same meetings trying to protect some of the environmental requirements that we had to enforce.

But things like basic process control, like good manufacturing practices, things that the trade people, not necessarily U.S. trade people, but foreign governments would identify as things that were unnecessary barriers to trade, and you'd have to justify why it's important to have these process controls.

RT: The Good Manufacturing Practices (GMP) philosophy or perspective I guess originated in the United States, or were there other nations that had something similar to guide the industry?

WMB: Well, other nations did have something similar. And you remind me of -- I'm kind of taking a step or two back, but I remember I was able to participate in one of the premier training courses at the time for FDA investigators after they were hired. And having been hired into headquarters and having to do some work related to the field, but not having been in the field, I was asked to participate in the basic training for drug investigators in 1976. It was held -- but they don't do it this way anymore -- but it was held for a month at the University of Rhode Island. So I went up there and participated in that to learn something about the field and drug investigation and all that goes on with enforcement activities. It was really valuable for some of the work I was doing in the Bureau of Drugs at the time.

And one of the films that was shown to all the investigators being trained was something called "No Margin for Error." This was a staple video.

RT: That was Fred Delmore's General Goal, zero defects, that concept?

WMB: I guess so. It told a story of a manufacturing problem that resulted in a label mix-up at a plant, and then there was this little girl that was interjected into the story somehow and what would happen if she took this medicine with the wrong label, and so how important it was to make sure that good manufacturing practices were followed and that there was no margin for error because of potential consequences. So, it had instilled in me, certainly, from the view of the investigator, how important those kinds of controls were.

Fortunately, other countries did have similar requirements in place, and one of the approaches to the negotiations was to contact our counterparts in other countries to make sure that they would join with their trade people in the negotiation so their trade people could better understand the importance of our regulatory requirements. And so it was very effective. The U.S. government wasn't just dealing across the table with other trade people and including themselves, who didn't know anything about FDA regulations.

RT: In those meetings or training sessions with multiple countries represented, was it necessary to have interpreters for the various languages, or were most conversant with English?

WMB: Most were conversant in English. And when you go to a big meeting like that, I remember the big meeting that I mentioned that Carla Hills made that statement, no agreement is better than a bad agreement, it was at the time, it was called the Brussels Ministerial in 1990, and so the ministers, the trade ministers from all the countries who were participating in the negotiations around the world came together in Brussels in 1990 with the idea of concluding these GATT negotiations, and the talks broke down. The U.S. pulled out, and it wasn't until years later, in Marrakesh, where the negotiations were finally concluded.

SJ: Now, were you representing both foods and drugs at the meeting?

WMB: Yes.

SJ: I guess medical devices weren't a big deal at that point in time.

WMB: Not a very big deal at that point, no. But, yes, I was representing the agency on both issues and had good . . . I had convened an agency-wide group of representatives from food, drugs, and we'd formulate our positions prior to me going down and talking to the U.S. Trade Rep and the other U.S. agencies to formulate the U.S. government position to take to the international negotiations.

RT: You've had quite a bit of involvement with working with different staffs at different levels. Were there any particular issues or problems that were more difficult than others to deal with in terms of fomenting good international activities for the agency? I guess that's maybe not fully stated. But have you always had, our Commissioners, have they universally been committed to this issue, or were some more outstanding than others in wanting to internationalize cooperation?

WMB: Yes.

RT: More recently, though, you've been involved, I think, in the placement of FDA personnel in foreign assignments.

WMB: Yes. Well, a couple stand out as being more active internationally than others, from different perspectives. Fortunately, I've had some interaction with all of the Commissioners who've been Commissioners since I've worked here, just from the standpoint of the office that I was in and the opportunities that I had because of things that I've worked on, going back to Dr. Alexander Schmidt, I can recall.

But Frank Young was the first one that I had a lot of direct contact with because of the Conference of Experts on the Rational Use of Drugs, and he did a lot of work internationally and represented the U.S. and FDA.

TAPE 1, SIDE B

RT: Walter, we earlier were talking about the Chilean grape crisis, and I think maybe you were going to tell us something about how that stimulated some changes and improvements in our laboratory operations.

WMB: Yes. That crisis was very interesting for a couple of reasons, but one is that the agency -- and no one really at that time had any idea what exactly to look for, what would happen to a grape if someone injected, tried to inject cyanide into it. Could you even inject cyanide into it due to the acidity and composition of the grape? And so the FDA had at that time, and still has, a very good research laboratory, the Forensic Chemistry Center, I believe, in Cincinnati. A good friend of mine headed it at that time, and still does, Fred Fricke. That lab did a lot of research on grapes and cyanide. It was determined that the agency really needed to do a better job of trying to anticipate certain problems and to do the research necessary to be prepared. And so that laboratory, as I recall, was staffed up a little bit to start doing some kind of foresight kind of research on the products that we regulate, so that was one good outcome. Of course, you never know what you don't know, maybe something else that will pop up that we couldn't anticipate or weren't ready for, but I think we're in a much better position now than we were then.

RT: We've had, historically, some problems with pesticide residues from other countries, Mexico being one,

where excessive application of pesticides may have resulted in residues in the products that were offered for import here. Do you recall any particular issues in that area? I think we've even had lead in some chinaware from other countries, too.

WMB: Yes, ceramic ware. That was a big problem and, in fact, resulted in us entering into a memorandum of understanding with China on ceramic are, and the Chinese promised to do certain tests of their own to prevent that.

There was also an incident that I recall being involved in with France. We had a pesticide called procymidone in wine that we had worked through with the French government.

And more recently we've had the melamine problems, which was intentional contamination from . . .

So there have been a number of problems over the years in international origin that required that we work with our foreign counterparts to address the problem.

RT: The melamine, what does that, what product or…

WMB: Well, this was something that was put in pet food coming out of China in 2008, and was one of the

incidents, one among a rash of incidents that occurred in a relatively short period of time and got the attention of Congress that resulted in an interagency task force headed up by former Secretary of Health and Human Services, Michael Leavitt, that led to the formation and establishment of FDA's foreign offices. Melamine was a substance used in countertops, as I recall, and was put into the pet food because it gave the, through analysis, it appeared that the product was something that it was not. It commanded a higher price and . . .

RT: So, was it more of a misbranding?

WMB: It was adulteration of the product that caused a product that injured a lot of pets, a lot of pets died, having ingested these pet foods that contained melamine.

RT: So, were those products prohibited as far as being imported to this country?

WMB: Yes. FDA stopped -- they issued an import alert and stopped the products at the border.

SJ: And wasn’t there -- there were also incidences of diethylene glycol contamination from China as well.

WMB: And in other places around the world.

SJ: And it had been going on for many years.

WMB: Yes, diethylene glycol in toothpaste from China.

SJ: Instead of glycerin.

WMB: Diethylene glycol in cough syrup in Haiti, a number of product safety problems of that nature.

RT: In more recent times -- I think you’ve been instrumental in this -- the agency has actually placed, you might say, residence offices or operational offices in other countries. Can you tell us how that came about and how it’s progressing, what the future may be in terms of placement of our field staff in other lands to do inspections for the agency?

WMB: Yes. As I mentioned, it goes back to the 2008 time frame, when a number of these product safety problems

seemed to be coming one after another, almost weekly; got the attention of Congress and Congress -- the first President Bush at the time established this interagency task force, with Mike Leavitt, the former Secretary of Health and Human Services in charge, that looked at these incidents and agencies' capabilities for responding; and also got the attention of Congress because placing staff overseas permanently is fairly expensive. And Congress was convinced that FDA indeed could do a better job if we went beyond our borders, which was the slogan that was coined at the time, the Beyond Our Borders Initiative. And rather than waiting until products with problems reached our borders and we're trying to find the problem, go back upstream and work with the foreign regulators and with the foreign industry, even, and try to prevent the problems from occurring.

RT: Was that initiative met with welcome or resistance on the part of foreign industry and government?

WMB: Good question. I think for the most part it was welcome, but it was mixed. Our very first foreign post was established in Beijing, China, and there's a very rigorous process that has to be followed to get approval to place

staff in a foreign country. First you've got to convince the State Department, and the Ambassador makes the ultimate decision. And then the embassy works with the Ministry of Foreign Affairs, or whatever the equivalent is called in the foreign country, for their approval. And the Chinese looked at this carefully and, of course, the questions from them as well as some of the other countries: Well, why are you really here? Are you really here to help us, or are you here to prevent our products from entering your country and the trade barriers so you can build up your own industry? But we were successful, I think, in convincing them that we were really there in the interest of public health, and that we had value to them of being there because it helped them improve the situation for products that are used inside their country. We could work cooperatively.

RT: Were there any countries, if it's discreet to mention them that opposed the idea, that didn't accept the concept of FDA, a foreign inspection agency, operating in their jurisdiction?

WMB: Well, let me put it this way. We have 13 foreign posts that we've opened up to this point, and we've

had support for all of them. There's one that is on the table and the subject of some discussions that we anticipate will also ultimately be approved, so it's been pretty much universally accepted as something that's of value to the foreign government to have FDA there to work closely with us.

RT: These foreign assignments, are those of inspectors or any other type of person?

WMB: They're mostly not inspectors. Of the roughly 30 people who we have deployed now in these various 13 posts, I want to say on the order of about 10 of them are inspectors, and they are only located in China and India.

RT: What would be the other people? What type of staff other than inspectors might be involved in these assignments?

WMB: Well, they are people with various agency backgrounds who have technical expertise in the various product areas and work with the countries and hold workshops and advise them on technical requirements and so

forth. They put them on a position description that's called International Policy and Program Analyst.

RT: Well, those probably would be regarded as possible helpers. In other words, I would think maybe those kind of personnel would be more welcome . . .

WMB: Than the investigator.

RT... than a regulatory person.

WMB: Probably true. We've heard our stories from the investigators about different inspections that they've been on and things that they've uncovered and things that they've seen going on to try to, you know, to detract them from doing good investigative work.

RT: We've interviewed a few folks that have been involved in those, and like you said, some have interesting anecdotes to share.

WMB: Right.

SJ: Well, what were some of the biggest challenges to getting these offices set up? I would have thought it would have been recruitment, but from what I understand, we've not really had a shortage of people applying. Now, whether they were the people that we need is a different issue. What's your sense of this?

WMB: Well, this has been a very challenging program in a number of respects because there are so many different things involved.

The challenges in going through the process, there was a process that the Department of State has pursuant to a directive issued by a former president, whose name escapes me, but it's called the NSDD-38 process. When we first heard of it, what in the heck is that? But it stands for National Security Decision Directive, and it prescribes how an Executive Branch agency needs to go about getting authorization to place staff in a foreign country. And the goal of the United States Government generally is to minimize the amount of staff that are out in another country because it presents security risks and all kinds of things, so they try to keep the footprint to a minimum. And so you've got to go through an application process and answer a number of questions: Why does your agency need

someone here, and why can't someone who's already at the embassy, a Foreign Service Officer, handle this for you, and so forth. Do you have the budget to accomplish this, because it is quite expensive, and so on and so on. And ultimately the Ambassador has to personally authorize it, and how many numbers of people, and what types of people, and all that. So that's an initial challenge.

Then the recruitment, Suzanne, as you mentioned. Although there are a number of people who think about doing a foreign assignment sounds exciting and so forth, but we, particularly in the early stages of this, the first group that went out, we wanted them to be very experienced people who knew the agency well, who could represent not only FDA but Department as well, because sometimes the Department relies on these people to do things, and, of course, you're representing the U.S. Government. And so they have to be experienced people with appropriate technical backgrounds, depending on the products we had the most interest in in that particular country.

And the move involves not only sending that person over, but their family, their wife, their kids, their dog, you know. And we had to learn a lot as an agency about how to do all this.

Fortunately, our good friends at the Center for Disease Control and Prevention (CDC), who'd had an international presence for quite some time, helped us a lot. We referred to some other agencies at some point. And it was interesting.

Soon I was getting calls from other agencies, saying, "We understand that you're working to set up these offices and having success. Would you help us out?" So we got it done.

And then there are challenges in, when a person goes over, they sign up for two years, a two-year tour. At the end of that two years, they can either extend, if we agree, or either side can not extend. But at some point, after the first group went over, about 25 percent of them did not renew and wanted to come back to the agency, and so for the investigators, ORA had made a commitment that they could come back in their old job as investigators. For the other employees, there was no such commitment, although the agency -- not that kind of commitment, but the agency said, "You will have a job somewhere in the agency." And the Centers have been that cooperative, and it hasn't been easy in some cases, but overall, the Centers and other Offices have been cooperative, so those who come back, come back to a job with the agency.

We had one person who retired at the end of their deployment, a long-time FDAer from the New England area, Michael Kravchuk. He'd been in China as the Deputy, Director of the FDA's office in China. But those are among the challenges we have to deal with.

RT: Has the Congress, in their oversight of operations, expressed any interest or any guidance, or have they left that to more of the discretion of the agency administration?

WMB: Well, when you say expressed interest, we had our first Government Accountability Office (GAO) report done on the foreign office initiative. And, in fact, it was probably done a year ago now. So it wasn't long after we got the program up and running that the GAO was interested in coming and looking at things, to see what we had done and how work.

Interestingly enough, the new Food Safety Modernization Act (FSMA), that was just signed into law by Congress in January of this year actually authorizes the establishment of foreign offices even though there is no basis, no legal basis for doing, but it was put in FSMA,

and FSMA also required a report on the progress of the foreign offices. So there has been a lot of interest.

RT: Okay.

SJ: Now, who was the first Commissioner that visited? Was it McClellan?

RT: The foreign office?

SJ: Yes.

WMB: No. They were established when Commissioner Von Eschenbach was here.

SJ: Okay. He was the first to visit. He visited China, I believe.

WMB: That was the first office. He actually went over, he and Secretary Leavitt, and officially opened the office.

SJ: I remember Mary Hitch talking about there were literally a couple of hitches that had to be dealt with in order to even declare it open.

RT: Are there any other areas, Dr. Junod, that you'd like to explore?

I think we've got a pretty good overview of . . .

WMB: Yes. Let me just say, I saw the more recent things.

The international program underwent another reorganization in the, I'd say 1990-ish -- no, no, no, 2000 time frame, when Sharon Smith Holston left and Mac Lumpkin became the Deputy Commissioner for what at that time was called the Office of International Scientific Affairs. And, again, in the early days it was more than just the International Office that reported to him. Also the Office of Combination Products and the Office of Pediatric Therapeutics, and they have since spun off, and just the Office of International Programs. And Mac Lumpkin did a lot to expand the program in terms of our bilateral relationships with our various counterparts, and we began having a lot of annual bilateral meetings to sit down with our counterparts in the European Union and Japan and

Singapore, Mexico, others, and have annual meetings to talk about issues of mutual concern, how we can better cooperate to prevent problems or resolve problems that came up.

And Melinda Plaiser was brought in to become the Associate Commissioner for International Programs. She had been in the Legislative Affairs part of FDA, and there were a number of reorganizations of the International Program under Melinda's leadership. And then Melinda left in 2008 and became the Regional Food and Drug Director in the Central Region.

And Mary Lou Valdez was selected as the new Associate Commissioner for International Programs, and she came to FDA from being the Deputy Director of the Office of Global Health Affairs at the Department of Health and Human Services, so brought to FDA a different perspective on international affairs from a Department perspective. And it was really under her leadership that the foreign offices, although they were established before she came, but she really did a lot to develop the offices and put various systems in place for the offices to be effective in accomplishing their various goals and objectives.

And then, more recently, this past summer, another reorganization to develop the Directorates that we talked about earlier.

And, as I had mentioned briefly before we started recording, from some research that I was able to do back in the ‘80s, I learned that the International Program of the agency seemed to have begun around 1966, and in the Office of the Associate Commissioner for Science which organized at that time, and the primary goal was to manage foreign officials who wanted to come and visit FDA and find out what we did. There was no way at that time for dealing with these people from foreign countries maybe the Commissioner’s secretary would say, “You want to come meet with the Commissioner?” But there became such a big demand that it was becoming a burden. So the early days just kind of started doing that and then expanded to more kind of ongoing relationships with the foreign counterparts, and communications, letter communications. Then through the other things that we talked about, the Offices developed and changed over the years.

RT: It’s been an expanding interest and an expanding commitment by the agency. Do you foresee that continuing?

WMB: Well, absolutely, because it has been expanding because of the increase in the amount of imports that FDA regulates that are coming into the country, and there are a

number of statistics that we see all over the place these days that 80 percent of the active pharmaceutical ingredients that go into medicines that are marketed in this country are imported, and I think 60 or 70 percent of the foods that we eat, and 75 percent of the seafood, is imported.

And so this, about a year ago or so, under Commissioner Hamburg's leadership, a task force on globalization was established that resulted in a report that was published this past summer, in June, called "The Global Pathway Report," and identifies the various challenges that we're facing now because of globalization, including the increase in products that are being imported, and recommending approaches to address the situation through four pillars, four major things that we need to be working on going forward.

The international program is not only here to stay, but it's viewed as a fundamental part of what the agency does and has to do to do its job. Even though we were developed as a fundamentally domestic regulatory agency because of globalization, we now have to become more of an international agency to deal with the things that we are responsible for regulating so that we can continue to

protect the American public, as they will be consuming these products that we are responsible for.

SJ: Talk a little -- you were certainly around when 9/11 took place. That's clearly a turning point in terms of how we looked at international work. I remember there were a lot of studies of CFSAN and other places of where the vulnerabilities were, both internal and domestic companies and foreign. What was your office's and your, perhaps, role? Talk to me about that period after 9/11, when I'm sure we were reexamining some of our assumptions about these things and realizing, perhaps, that we really just can't inspect everything that comes into the country.

WMB: Right, right.

Well, that's certainly one of our challenges from an international perspective, and this is highlighted in the "Global Pathway Report," that the supply chain for products can be very lengthy and very complicated, and there's even an example in the "Global Pathway Report" -- I think there were fish products or something coming from its origin someplace maybe in Asia to someone's table in the United States, a kind of chain, supply chain that's involved, and there are many places along that supply chain where things

can happen to cause a product to become unsafe, dangerous, what have you. And so after 9/11, there was a heightened sensitivity to this from the Office of International Programs' perspective. We facilitated a lot of dialogue with foreign countries about things that they had in place to protect products and things that we needed to do jointly to prevent products from becoming intentionally contaminated. So that has been a very important aspect of concern a number of international meetings have been held concerning this, and bringing in all the stakeholders, because industry has a very important role in this. And a number of the good manufacturing practices or other good practices kind of relate to things that the industry needs to do to help in this regard, emphasize the role of a number of stakeholders. And consumers have a role to play, too, of keeping their eyes and ears open, as well.

RT: Has there been any foreign resistance or trade barriers, if you will, to exports from this country, products coming from the United States. We've intimated earlier that there was concern the other way. How about our products going abroad?

WMB: Yes. That's an excellent question because we see this playing out a couple of different ways. One, our industry feels the brunt of this when they complain to the United States Trade Rep's office that this country has put in this requirement, and there's no reason for this requirement other than protection. How can you help us? And from time to time, FDA will get called to participate in a meeting to explain why something may not be necessary, or in some cases to explain why something, some requirement is a reasonable requirement from a scientific basis.

One of the things that we've had to be careful about in our foreign offices is that one of the goals of our embassies there is to promote foreign interest, and there are a number of agencies that have been in the embassies a lot longer than FDA, like the Department of Commerce or like the Department of Agriculture, whose mandate is to promote U.S. agriculture or other human products into other countries. And sometimes we will get called to join in on meetings at the embassy or that they're having in-country that relate to these trade concerns, and we have to be very careful.

We had to explain to the ambassador in at least one of the locations where we are that our mandate is public health and safety. And we've been successful in convincing

the U.S. Trade Rep's office and the ambassador, in this case, that we are, FDA is of better value to them in the long run by maintaining our sort of health and safety approach and focus than by getting into trade matters, so that when we are called upon and we do contribute, it's recognized that we're doing so from a standpoint of protection of the public health and a scientific basis for things, and not for the sake of trade promotion. So it's a very good point and one that we've had to deal with and continue to have to deal with, and we've been fortunate to be able to do it the right way.

One of the things I wanted to mention involves the negotiations that took place between the U.S. Government and the European Union over some few years, referred to as the Mutual Recognition Agreement. That was a goal, and the outcome involved FDA and a number of other agencies, including the National Highway Traffic Safety Agency and Federal Communications Commission and the Environmental Protection Agency and I think some others. And the goal was that we would accept each other's decision-making on products. I led the negotiations related to pharmaceuticals, and it was a significant challenge because the folks in drug compliance in FDA weren't really convinced that this was what we ought to be doing, and at

the end of the day, Congress wasn't convinced either. But it was a U.S. Government Executive Office initiative, and we were part of it, and I'd like to think that it was a success from the standpoint that we concluded the agreement and it was signed off on, and, in fact, exists to this day as a regulation in our CFR, but it's not implemented. And we had, not long after the agreement was signed, Deputy Commissioner at the time, Sharon Smith Holston, and I and some others from the agency participated in a very stressful hearing before Congress, who didn't like this idea of this Mutual Recognition Agreement at all, and so it was never implemented. And now the efforts . . .

SJ: What was their major concern?

WMB: Well, a couple. One, that we had a mandate to make these decisions ourselves and not rely on what was a preoccupation; and that it would require a lot of resources to get it done.

One of the compromises that got from the Europeans -- the Europeans always maintained, at the time, that they were one entity, although at that time, there were only 12 member states and now it's 20-something. We didn't think they all were equal in terms of the pharmaceutical

regulations. There were some whom we felt were pretty good and there were others we thought were pretty bad. And so we insisted -- and this was a big deal for them -- but we insisted and got them to agree that we would make decisions on a country-by-country basis based on our determination of whether we thought the country's system was equivalent to ours. That's a pretty resource-intensive process, going country-by-country. See, that was one of the things, but there was no way we could get an agreement on this side of things otherwise. We knew in our heart of hearts that we would be up to snuff. But the negotiations required a lot of time and effort.

Now, we continue to pursue sort of the fundamental goal of that, that rely on other countries and leverage resources as much as possible and we use the term mutual reliance rather than mutual recognition.

SJ: It sounds to me like that's something that just has to be done as you move overseas in general, whether Congress wants you to have sole authority, and you have to look at what they're doing to protect it and how that relates to you.

WMB: If you look at the number of import lines of FDA-regulated products coming into the country, and how it has grown exponentially over the years, and the number of resources that we have to combat it, which has stayed relatively stable, so there's this ever-increasing gap, and that we're only able to examine 1 percent, 1, uno percent of the products coming in, you've got to do something to assure yourselves that things are meeting the requirements. So it's definitely the way we've got to go, but it's just a matter of how you get there and where we need to go to make it happen.

And you may recall that I mentioned this whole issue of harmonization that we've been working on for quite some time and we continue to work on. You know, the idea first came up in that World Health Organization (WHO)-Food Agriculture Organization (FAO) first ICDRA meeting in Annapolis, Maryland, in 1980. The theme was communication and harmonization, and here we are over 20 years later and we're still working on our harmonization.

RT: They'll probably be an ongoing thing for the foreseeable future.

WMB: Well, now we have this Global Pathway Report, which has been endorsed by the agency and the Commissioner, and is our path forward to address these various issues; and recognizing that what has already been done through these various efforts that I've mentioned and some others that I haven't, and so we will continue to work internationally to get better and more information from our foreign counterparts working together. One of the pillars of this new report calls for a global coalition, so working with our foreign counterparts would let everybody know that we've got safety and quality of the products.

RT: Has the European Union promoted any of the harmonization, do you think, or was that more a fiscal policy?

WMB: They have absolutely promoted it. I mean, this was initially their initiative, and they have mutual-recognition agreements that are in place and active with a number of countries, and they receive data from them and information on the decisions that these other countries have made. The European Union relies to a great extent on that information, and have done so for a number of years.

They have embraced and are committed to what they call mutual recognition.

RT: Well, Walter, we've covered a lot of your career, and we may have still some things that we should include. We can always continue at a later time.

TAPE 2, SIDE A

RT: Today is December 20, 2011, and we're continuing the interview with Mr. Walter M. Batts to cover some things that were not included in the earlier session.

Walter, to continue now, while you were working in the Bureau of Drugs, Office of Planning and Evaluation, you were instrumental in the agency receiving authorization to hire over 600 positions. Could you tell us a little bit about how these folks were recruited and how procedures may have changed since those days in recruitment?

WMB: Well, this sounds more like a human resources question to me, and I don't have a whole lot to say about how the folks were recruited, other than the normal agency recruitment procedures, other than just from my knowledge of more recent recruitment procedures when there is a need

for a large number of people. There are a number of ways that are utilized to try to get the word out to various journals and other media.

But my main role was working with Dr. Frances Kelsey and her staff to justify the need for the positions because of problems that were being uncovered in the bioresearch monitoring program area, and once that justification was accepted by the Congress and they authorized the new program, then the normal personnel HR procedures took over to hire those.

RT: Was there an effort to get certain types of scientific disciplines?

WMB: Well, yes, and it was really a wide range of people, as with any kind of large program. It included the hiring of investigators in the field who would actually go out and inspect either the records of clinical investigators who were doing clinical trials in support of marketing applications; it included additional staff in Headquarters to manage these programs, and including Frances Kelsey’s Office of Bioresearch Monitoring; and various other support people that are necessary when you

bring on such a large number of people. We need folks across the board to support the program.

RT: This wasn't a part of the hiring initiative called Project Hire, was it?

WMB: No. This was later than that. Project Hire occurred in the early '70s, I think maybe '71, '72, because I was a member of Project Hire. I came in in 1972. But this program was a few years later than that. I think it was initiated in 1976, so it was on the heels of Project Hire, but it was a separate hiring initiative.

SJ: And not just for drugs, right?

WMB: That's right, not just for drugs.

SJ: So, agency-wide.

WMB: Not just for drugs.

SJ: So even though you were in drugs, it was crossing product fields.

WMB: Right, that's correct.

RT: I think you were also involved during your career, for monitoring minority employees in the agency. Can you give us a little history on that mentoring?

WMB: Well, that's interesting, and I was a little surprised that that issue came up, because I never really made a big deal of it. But I worked with a number of minority employees who sought advice on their careers and information that I could pass on to them that, from my experiences being a little ahead of them in my career here at FDA. There were a few individuals who served on details or temporary assignments in offices that I headed to get additional experience of various kinds, particularly international. So that was sort of the extent of it.

I had served a short time as a counselor for equal employment opportunity matters to help with follow-up on allegations of discrimination or things like that, but for a relatively short period of time. So that's really the extent of my involvement there, mostly kind of . . .

RT: So you were involved more in counseling and guiding these folks than actually in recruitment or hiring. Is that correct?

WMB: Yes.

SJ: What kind of changes have you seen in your years working for the government, sort of the place and in the perception of minority employees? Because FDA really didn't have too many for a very, very long time, and after 1962, the Civil Rights Amendment, that was really the first time we could start thinking about hiring professionals. Your observations would be helpful in taking a look at that issue a little more carefully.

WMB: Well, there have been issues that come up over the years, and I guess those issues helped to inspire the birth of the Blacks in Government (BIG) organization, which, quite honestly, I was never very active in personally. I attended a couple of their conferences. They would have some good training sessions that I attended in those conferences.

From my vantage point, me personally, in my career, I always felt that the agency had a good record supporting minority employees, and I think always had a strong program. And all of the Commissioners that I can think of have always made it clear that they supported affirmative

action and that type of thing, and we've had good leadership in that area over the years.

There a couple of people who stand out to me early in my career who headed that function, but Irene Campbell and Faye Calhoun, who really, I think, ran a good, solid program in the Bureau of Drugs. So that's from my perspective.

SJ: And they were themselves minorities?

WMB: Yes. Both of them were African American females.

SJ: Ph.D.'s, M.D.'s?

WMB: Faye Calhoun earned her Ph.D. degree, I think, after she left the program. She wasn't that when she was in the program but was in school when she was in the program, working on her Ph.D. Some folks might remember -- and I'm not sure they still exist or not, but the University of Southern California program called -- and I took a couple of classes myself -- an intensive-semester approach to learning, 10 classes all day, Friday, Saturday, Sunday, and Monday, and then you write a paper over a 30-day period, and at the end you have another Friday, Saturday, Sunday, Monday session. But she did earn her Ph.D. and eventually left FDA and went to NIH, where I think she retired.

RT: Did you give that intensive program a name. I just didn't pick it up if you did.

WMB: Well, it was referred to as the Intensive Semester, and it was run by the University of Southern California at a center in Washington that was called Washington Public Affairs Center.

There are a number of folks in the agency I know participated in it.

SJ: Now, you also worked with Sharon Smith Holston, and she's credited with helping mentor a lot of African Americans.

WMB: Yes. She mentored me.

I had the pleasure of working for her when she became the Director of the Office of Constituent Relations, and the international program was a component of her office. And after that, she became the Deputy Commissioner for International Constituent Relations. And prior to that, I knew her. I had interactions with her, and she was certainly a mentor to a number of minority employees at the agency.

RT: You probably made some foreign visits? Did you, and, if so, were there any significant or interesting experiences you had as an emissary for our country elsewhere?

WMB: Well, all of my trips I would say were interesting and I think valuable for the purpose of the trips, and I considered them all being important because I was representing the agency and the Department, representing the U.S. Government. I had the opportunity to interact with just a host of folks from ambassadors on down to counselor-level staff in the embassies and counterparts to FDA in foreign governments.

The one thing that probably sticks out to me as the most interesting thing -- and I had a lot of safe travels and travels that otherwise stand out -- but I recall one visit. I was traveling to Brussels for meetings with representatives of the European Commission as part of the negotiations of the Mutual Recognition Agreement(MRA), and there had been an issue with dioxin contamination that had come up just prior to me leaving on that trip, and the Europeans were very interested in it because it involved some of their products that were being exported to the United States. And, of course, the FDA issued an import bulletin or something that prevented those products from coming into the country, so they got very interested as to what was going on.

And I'll never forget that when I arrived in Brussels and got to my hotel room, there was a message from the U.S.

Ambassador to the European Union, who at that time was a gentleman by the name of Stuart Eizenstat. And the message said that he wanted to see me right away and that he was sending a car to pick me up.

Of course, the embassies were always aware of travel of government employees anyway because they would have to clear it, so they knew what the schedule was and everything. And they knew that there was someone from FDA who was arriving there that morning, and he wanted to find out what was the story on this dioxin problem. Of course, I hadn't been directly involved in the dioxin problem, so I didn't have a lot of details. And given the time difference, there wasn't a whole lot that I could find out on that specific incident.

But the car arrived, and I got in the car and went to the embassy and met with the Ambassador, and the best I could, explained our procedures and what happens in certain situations, and what I knew and had read prior to my visit about what was happening here. I was able to at least satisfy him that FDA was doing something that made sense.

RT: What kind of product or situation did they have involving dioxin?

WMB: To be honest with you, I don't recall the specific details at all right now, but I do know it was a problem with dioxin residues on fruits and vegetables, but I'm a little sketchy on the details.

SJ: Dioxin is a pesticide.

RT: We've covered kind of a broad area of your management responsibilities. What would be the most difficult part of your job that you could identify? And what could the agency do to maybe alleviate some of those kinds of challenges in the future?

WMB: Well, I would say that, for the things that I was involved in, the most difficult challenges involved, first, making sure that I was representing the FDA position when I went forward outside the agency, and frequently that meant making sure that the folks in Drugs and Foods and Medical Devices were at least roughly on the same wavelength that I could carve out of that a position that everybody could live with even though it may not have been ideal to any one of them.

But then, that was only the first step, because then I would go to interagency meetings where then we had the

Environmental Protection Agency and the Department of Commerce, the Consumer Product Safety Commission (CPSC), the U.S. Department of Agriculture (USDA), who all had some very different regulatory responsibilities but all a little bit different and authorities a little bit different, and then trying to make sure that we could craft a U.S. Government position that satisfied everybody. It may not have been ideal for FDA or for any one of them, but then we could take to the Europeans or wherever else, or to the rest of the world, in the case of the GATT negotiation, and try to prevail. So it's always been a challenge to try to work your way through those steps and still represent the agency in a way that I could come back and say we got what we needed; we could still regulate food and drugs.

RT: Was there a leader change between agencies in the international arena to foment consistent policies? In other words, did USDA and others have an international staff that you had on going liaison?

WMB: Yes, yes, yes. They all did.

RT: Did you have any meetings periodically, kind of a get together and iron out whatever issues may be divergent among them?

WMB: Yes. And for the trade negotiations, USTR, the United States Trade Representative's office, managed that for the most part, because it was their job to try to go into the international negotiations with a coherent U.S. position. And so my counterparts in those other agencies or other departments would join.

Now, HHS was never very active in these negotiations, and so I would go as an FDA representative, but I would be working with Department of Commerce-level representatives; for the USDA, Agriculture-level representatives. So that part of it was a little interesting. But we never, I never got pushed around or anything. The Department was always there to back us up and follow what we were doing and weigh in if necessary, which was not too often. FDA has always been a very well-respected agency, and given what we do, people, representatives from the other agencies would always appreciate what our responsibility was and what we had to do. And so we were able to participate and interact successfully.

RT: Well, as you have indicated, the Department of Commerce would seem to be a logical coordinator. Was the Department of State ever much interested in issues of Food

and Drug and USDA, or are they more policy, government policy oriented?

WMB: Well, the Department of State always really played their role from looking at things from the diplomacy side and how things fit into larger U.S. government policies and relationships. But, again, they understood and respected FDA's role and the fact that we were not making up stuff to do, but we were implementing the Food, Drug and Cosmetic Act passed by Congress, so there was nothing much they could say about that.

RT: During your many years in this area, do you have in mind any significant or great successes of the FDA in the environmental area? I know you touched on some in our previous session and some of the agreements that were reached and so on.

WMB: Well, I would say among the more significant things that FDA has accomplished internationally involves the harmonization work that has gone on with some of our counterparts, particularly with the European Union and some of the other large economies like Japan or Canada. The International Conference on Harmonization is a good example

of that and where we have been able to meet the part of our law that says that we are to participate with our -- I'm not quoting exactly; I'm kind of paraphrasing it -- but that we are to participate through various processes with our foreign counterparts to reduce the burden of regulation on the industry. So to the extent that we can harmonize requirements and reduce the burden on industry to try to meet our requirements and Canada's requirements and the Europeans' requirements, than we are making some significant strides towards meeting our mandate. And those have involved, which I also consider as a significant achievement, partnerships and just really solid relationships with our counterparts in other countries through formal bilateral meetings that we would have regularly. I know those include other countries too: Singapore, for example, Australia, New Zealand, Mexico.

And also the ability to work with the Chief Counsel's office to develop what had become known as confidentiality commitments that allows us to share non-public information with our foreign counterparts to facilitate our regulation of products and protection of the public health, and that was kind of a groundbreaking achievement because it's always a little tricky and everybody's always sensitive about dealing with information that is not in the public

domain, that in many cases the industry is very concerned about the possibility that things could get into the public domain and they don't want it in the public domain, but the ability to share it with the foreign counterpart or to get similar information from them that allows us to do a better job of regulating products which allows to achieve, and to protect that information from public disclosure.

RT: The Soviet Union, of course, at times has been not our closest ally. Has that country engaged in international commerce to a significant degree, and, if so, with the United States?

WMB: There are certainly products that are exported from Russia to the United States. As I recall, looking at the charts that the Division of Import Operations and Policy produces, they are not very high up on the list, like at the top five or anything like some of these other countries I've mentioned are, but we have had interactions with them on various areas maybe. They've sent some delegations here. But the interactions with them are not nearly as significant as with all the other countries that I mentioned.

RT: Suzanne, do you have any points that you'd like to explore?

SJ: Well, we talked about the GATT, the General Agreement on Trade and Tariffs.

WMB: Yes, I think I did the first time.

SJ: I thought so, someone has asked for a little more detail. And I know that . . .

WMB: I don't think there, other than what I said the other day and then what I've said today about the challenges of developing positions interagency and going internationally.

One thing I would like to talk a little bit about, which I get questions about a lot, because there are a lot of people who are interested in the international arena and want to know how they can get involved, and I've got a few suggestions there.

First, if anyone is interested in getting involved in FDA's international programs, they should learn as much as they can about those programs, and we have a very good website that lays out all of our programs and what we do.

And we in the Office of International Programs have some initiatives that serve to inform the agency about what's happening internationally and stimulate thinking globally.

One is something that we call the International Forum where we currently, once a month, are providing a presentation from one of our offices about what's going on. And from talking to people, I know there are some who listen to those things regularly. Whether it involved a product in their Center or not, they want to listen to what's going on.

And then we have the Commissioner's Lectureship Series that has brought in some really top-notch international movers and shakers, and we encourage people to look for those, to participate in those.

And we've brought in, the first lecturer was Dr. Julio Frenck, who's the former Minister of Health in Mexico, who I had the pleasure of meeting in Mexico. He was the Minister of Health and is now the Dean in the School of Public Health at Harvard. And we brought in Sir George Alleyne, who's a former Minister of Health in Barbados and former Director of the Pan American Health Organization, who gave a very nice talk.

And then we brought in Dr. Margaret Chan, the current Director General of the World Health Organization. She

really gave a nice presentation. She really gave a nice presentation and drew a lot of participation from our agency.

And then, more recently, Dr. Nils Dilaure, who's the head of the HHS Office of Global Affairs, and also the U.S. Government's representative to the World Health Organization Executive Board.

Participating and listening to those types of things can help us to expand one's knowledge base in the international arena.

And then each of our Centers has an international either focal point of an international office that manages their international activities. And so anyone who works in the Center, I would look for opportunities that that they might get involved in some of the Center for International Activities, which was how I initially got involved in international affairs, the Bureau of Drugs back in the mid-'80s.

And then recognizing that we now have permanent offices overseas and that there's going to be a need to maintain staff in those offices as individuals serve their tours and they return to FDA, the need to replace them. We're setting up a pilot program now, which we look forward to, making a full permanent program, something that we call

the Foreign Post Opportunity Development Program, or FPOD. And there's information on our website about this. We're actually, we had, gosh, a bumper crop of applicants for this first small class in the first pilot program that we recruited. And so I encourage people, as that program continues, to apply and look for opportunities to get involved there.

And then for those in the agency who do inspections, our best investigators can join what ORA calls the foreign cadre, and make themselves available to do foreign inspections, which serves to give them a good background internationally and put them in a good position to apply for one of the inspector or investigator positions that we have in China, in India, right now just those two countries, but we could expand in the future.

SJ: And how important is foreign language skills as a component of their training?

WMB: Well, in some areas, foreign language is important, like in Latin America. So if folks want to prepare themselves, are interested in that area, then I would suggest getting started with that if they have the opportunity.

In some of the other areas, it's not as important for our work. For the European Commission, we're dealing with many countries that speak different languages, but they speak English when we're working with them as part of our work with the European Commission.

In a place like India that speaks English, there is little need to know other languages. English is sufficient. So, it depends, but usually English is sufficient, with few exceptions.

RT: So you really have more folks probably interested in international assignments than you have openings for. Is that correct?

WMB: Yes, that is correct.

SJ: A good place to be.

WMB: Yes. It's the wave of the future. The future is now in many respects, too, because everything is so global. All the products that we consume are not just products that we regulate, although the products that FDA regulates, a significant percentage of those products or components of those products are imported. But even in

other product areas, cars we drive, toys that our kids play with, although most of them say “Made in China,” but some of them are made elsewhere.

RT: Were there some other thoughts that have occurred to you since we last met, Walter that you’d like to address?

WMB: I don’t think so. I think you all picked my brain empty.

RT: We’ve covered a broad spectrum.

SJ: We’ll take that as a compliment.

WMB: Yes, yes.

SJ: Well, you certainly are just as you said, expanding exponentially. We see that ourselves, if for no other reason than because we’re on the same floor with your staff. But that’s definitely been a change since I came to FDA.

I remember Sharon Holston calling me into her office at some point, and she needed to give a speech on some of the more important things that had happened, around the year 2000 and wanted some predictions as to where things were going in the future, and that was, all I could say is the international field is going to be highly significant, and FDA is going to need to devote more resources to it.

Right after that, they started talking about putting out all the statistics and the charts showing how inadequate our inspection of goods and things coming in from other countries was. So at that point you know they're laying the groundwork for something.

WMB: Yes.

RT: Well, Walter, we appreciate very much your meeting with us, even a second time, to cover the important work you've done, and we certainly wish you success in your retirement or whatever you pursue thereafter.

WMB: Thank you very much. This has been rewarding to me and an honor to have the opportunity to add to the agency's history base. And, as you and I were talking the other day, I was thinking 40 years with the agency, and the

agency is like 105 years old, so a good chunk of the agency's existence, I've been here, when you think back on it that way.

SJ: You're right. Thinking of it that way, it is kind of a . . .

WMB: Thirty-some percent. So over a third of the agency's existence, I worked at FDA.

RT: Thank you very much, Walter.

WMB: Thank you.

END OF INTERVIEW