

# History

of the

## U. S. Food and Drug Administration

**Interviewee:** Dr. James L. Goddard

**Interviewer:** Dr. James Harvey Young

**Date:** April 30 to June 19, 1969

**Place:** Atlanta, Ga.

Session 1

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This is the transcript of interviews conducted with James Lee Goddard, M.D., between April 30 and June 19, 1969, as part of an oral history project sponsored by the National Library of Medicine relating to the history of food and drug regulation in the United States.

Dr. Goddard served as Commissioner of Food and Drugs between 1966 and 1968.

James Harvey Young, Ph.D., the interviewer, is professor of history, Emory University, Atlanta, Georgia.

Dr. Goddard provided for photoduplication the cards of his daily appointment schedules, which accompany this transcript.

By terms of the Statement of Gift signed by Drs. Goddard and Young on March 14, 1970, the transcript is restricted from any examination and use until March 14, 1985.

Dr. Y.:

This is an interview with Dr. James L. Goddard being held on April 30, 1969, at his home at 1090 Churchill Downs Drive in Atlanta, Georgia. I am James Harvey Young of the Department of History of Emory University. Jim, we've known each other for quite a while. I consider this a wonderful opportunity to see your career as a whole, and particularly as it reached a climax that's important for this oral history project while you were Commissioner of the Food and Drug Administration from January 1966 through June 1968. And I'd like to start out this morning by seeking to understand how it is you got interested in medicine and then in Public Health medicine and look at your earlier career before you came to the Food and Drug Administration. How was it that you got interested in medicine?

Dr. G.:

It started back during World War II. At that time, the Army had a training program, the Army Specialized Training Program, where they took enlisted men and sent them to university campuses, primarily for training in engineering. I was selected from a basic training group in the Air Corps in Florida, I suspect just on the basis of the fact

that I had been in college prior to entering the service.

Dr. Y.:

You had enlisted in the Air Corps?

Dr. G.:

No, I...well, yes, in the Army. The Air Corps was part of the Army.

Dr. Y.:

Right.

Dr. G.:

I wasn't drafted. I volunteered through the draft mechanism, however. That was the easiest way to do it. I simply left college one week, turned up at the draft board and asked them how soon I could enter the service and they said, "Will next Friday do?" And so, the following Friday, I went in. At any rate, I was in basic training when I was selected and shipped to what was called a "Star Center" where testing was carried out and I passed apparently the test in basic engineering, and we were sent to Washington and Lee University. That was in, oh, early summer of 1943. Late that fall, or early in the winter, I would imagine it was in November, the Army apparently had, some little time previously, become concerned about the possibilities of a shortage of medical

officers if the war were prolonged, and so they decided to implement a program to take students through pre-med and med school, also under ASTP. The Navy had a comparable program, V-5, V-12 program. They administered a medical aptitude test at all the colleges and universities where there were ASTP units, and they gave one at our institution. Six of us that made the highest scores were then selected and sent to Temple University, and a pre-med group was formed from people sent from other institutions. This happened at a number of universities that were selected for their ability to train pre-medical students. Well, that was how I got into pre-med. Now, I wasn't a very good student in pre-med, not because I was totally disinterested, or because I wasn't capable, but simply I was young. I had never lived in a big city like Philadelphia before. I was really having a time of it. I didn't study as much as I should. But, nonetheless,...in fact, I came up to a certain point where a decision was to be made as to whether or not each individual was to be continued and sent to medical school, and I had to go before a review board made up of civilian physicians because my grades were so bad. Fortunately these doctors were rather understanding people, and they asked me if I thought I could make it in medical school. I said,

"Yes," and so they approved me to go in spite of the bad academic record. So I was assigned then to go to George Washington University School of Medicine, but because of the class starting date there was to be an eleven-months period of time that I would work at Walter Reed Hospital as a corpsman. That turned out to be very significant in my life, as I'll tell you later. And so, a group of us were sent to Walter Reed. As I recall, from that pre-med group in Philadelphia, Temple, there were four of us assigned for George Washington, four for Howard University, and four for Georgetown. The four for Howard were Negroes, and they went immediately. Their class cycle was such that they didn't go into Walter Reed to work as corpsmen. The eight of us...the four for G. W. and the four for Georgetown...were assigned to the medical detachment of Walter Reed to work as corpsmen, and I was assigned then to work on the neuropsychiatric service of Walter Reed Hospital as an attendant and office clerk in the N. P. section. It was there that I met my wife.

Dr. Y.:

Oh, she was working there at the time.

Dr. G.:

She was an Army nurse and had been overseas. This was in

November of '44 and she was working in the neuropsychiatric section. We met that November and we were married the following May. I started medical school in September of '45 just after V-J Day. Being married was an important influence on my stability as a student, and I did compile a good record in medical school. I graduated in the honor society group, the Smith-Reed-Russell Society. We didn't have an AOA chapter at G. W. By the time I graduated, we had two children and my wife was pregnant with the third. It was an exciting four years. In looking back on it, we had very little income. We were fortunate we had the G. I. Bill, because the war ended, of course, and I was discharged in March of '46. The program was dropped then and, fortunately, the Veterans Bill came through and we received, I think, ninety dollars a month. And that, plus the fact that I worked two and three jobs simultaneously the last three years in medical school and my wife was able to draw unemployment compensation and work one summer as a nurse, that was the way we got through medical school. We had no other financial assistance, but it was a great and exciting time for us. We had lots of fun and worked hard. That was how I got into medicine. Now, I had an early interest in it back before I went into the Army in World War II. Our next

door neighbor was a professional man in my home town of Warren, Ohio.

Dr. Y.:

Warren, Ohio?

Dr. G.:

Yes. That's where I grew up. I was born in Alliance, Ohio, thirty-six miles away from Warren, and most of my mother and father's family lived in Alliance.

Dr. Y.:

And that's where you went to college?

Dr. G.:

Yes. I went to Mount Union College for one year before going into the service back in Alliance, Ohio. So, I had observed this young, professional man, as I say, the next-door neighbor, and I had decided that that was an excellent kind of career, but frankly, at that point in time, I couldn't visualize having the financial assistance or capability of getting through a professional school.

Dr. Y.:

Had you read anything in the way of books that bent you toward medicine?



Dr. G.:

Oh, my. Yes. Oh, yes. I was an omnivorous reader as a child. I still am. I started out, we lived in the east end of Warren, and by the time I was twelve I think I had read my way through the East End Library, and I don't think that, if you read a great deal in those days, you could escape reading books that had some, certainly some books that were, certainly Magnificent Obsession or, let me see, Sinclair Lewis' books.

Dr. Y.:

Did you read Arrowsmith?

Dr. G.:

Oh, indeed, Just great. I read all of his books. I would go on an author binge. I would discover Thomas Wolfe and then do nothing but read Thomas Wolfe until I had read everything that I could lay my hands on that he had written. And so I not only read Arrowsmith but everything else that Red Lewis wrote.

Dr. Y.:

Did you read Paul de Kruif?

Dr. G.:

Oh, yes. The Microbe Hunters. What was the other...?

Dr. Y.:

The Hunger Fighters?

Dr. G.:

The Hunger Fighters. Yes. There wasn't much that I missed reading in those days. It was a source of great pleasure to me and still is, to enjoy reading as much as I do. I'm a fast reader which means that I can tackle a book in an evening, get through a 500-page novel. I can't go through a scientific treatise in that fashion, but a novel I certainly can.

Dr. Y.:

So that there was a kind of bent from reading and from observing your neighbor, so that when this happened in the Army...

Dr. G.:

It was a welcome opportunity, I can say that without question.

Dr. Y.:

Now, at George Washington, while you were in medical school, I know that you became acquainted with Harry Dowling. Would you talk about some of the influences in medical school and the way they may have shaped your interests?

Dr. G.:

It's fascinating when you look back on your own career, and this happens to all of us, to reflect on the kinds of people who have had an influence and the kinds of events that represent turning points in your life. Harry Dowling was one of our professors. He was professor of medicine at that time. I felt him to be a very learned man, and still do, as I've gotten to know him. A scholarly person. I'll never forget Harry Dowling at grand rounds one day at what was then Gallinger Hospital talking about a patient who had a complicated medical problem, and a resident raised the question of a new form of treatment that had just been written up. Dowling's answer was: "Be not the first by whom the new is tried, nor the last to cast the old aside."

Dr. Y.:

So he was an omnivorous reader, too.

Dr. G.:

Oh, yes, indeed. I know he always has been. Harry Dowling left G. W. shortly after my sophomore year in medical school and went out to the University of Illinois in Chicago. We felt very keenly his loss, because he was an excellent professor of medicine. He was replaced by Thomas McPherson Brown.

Dr. Y.:

Did you have any other professors in medical school who exercised a special influence on your thinking or the direction you were to take?

Dr. G.:

Well, that's the difficult thing to assess. Oddly enough, in medical school, I would say that the last area, the lowest priority area on my list of choices for a career would have been public health, and unfortunately, that was probably true of most people in my class. We had a professor of public health and preventive medicine who was just a dear old soul. He's now retired. He writes to me occasionally. We write back and forth intermittently. Leland Parr. But Dr. Parr really didn't teach much public health. He would come in and talk about what he had read in the newspaper that morning. And, as a result, most of us got sensitized against public health. So, I had that kind of influence. Other professors...we had some very exciting young professors. This was just after the war. Benny Manchester in cardiology was a real hot shot in this particular field. Brian Blades, professor of surgery, was excellent, but I never cared for surgery. He was an outstanding surgeon; still is...a thoracic surgeon. A great man in his own field. I remember some professors quite

well: Eritt Albritton, a professor of physiology. I really enjoyed physiology as a subject. It made great sense. I later worked with Eritt Albritton after he'd retired as professor of physiology at G. W. He worked at the National Institutes of Health, and here was a man who had to be retired because of the age limitations at the university, and he was as excited at working at N. I. H. in the Division of Research Grants as I was. And he had a very youthful outlook on these new activities. He was a wonderful fellow to know.

Dr. Y.:

I take it you didn't have any more idea about going into public health medicine when you got your M. D. than you had about going to medical school when you were in college.

Dr. G.:

You're absolutely right. I had no idea of that, in fact, I had decided I would go into internal medicine. This was the area that appealed most to me as I finished my medical school career. But I never did.

Dr. Y.:

Well, did you have that kind of an internship?

Dr. G.:

I had a general medical internship in the Public Health Service. It was interesting. I almost wound up in the Army instead of the Public Health Service, and again, it was one of those quirks of fate, you see, that influence the rest of your life. What had happened was that, throughout medical school, a group of us in our class retained an affiliation with the Army through the medical R. O. T. C. program at the University School of Medicine. I think we were paid thirty dollars a month. I'm not sure of that, but it strikes me that that was what we were given and, in exchange, we had to spend one day a month or two days a month drilling and lectures once a week. And then, in the summer, between our junior and senior year, we had to spend six weeks at Fort Sam Houston going through the Medical Field Service School, which meant we couldn't have a job that summer, and so there was quite a trade-off, but the thirty dollars a month was for the entire period of time in medical school. This was important. Well, as we came up on our senior year, of course, our main concern was where would we take our internship. Early in your senior year, you make application. You select the hospitals that you think that you'd like to be considered by and send them an application. This was a change from what had existed.

Where, prior to that, it had been entirely on the initiative of the individual, they now had a national coordinating mechanism. Everybody was notified on the same day, so that institutions weren't played off against one another. Well, I applied for three separate internships: one at St. Luke's Hospital in Cleveland, Ohio. Now, keep in mind that I was married then. My wife and I were just barely getting by, and she was pregnant with our third child. St. Luke's paid fifty dollars a month, so that would have posed a problem. I applied for a Public Health Service internship and an Army internship and that was all.

Dr. Y.:

They were more lucrative?

Dr. G.:

Yes. The Public Health Service and the Army internships both commissioned you as a list lieutenant or the equivalent. My number one choice was an Army internship. We had been assured because we were in the medical R.O.T.C. and had spent all of this time, one day a week in lecture and once a month in drill, and going to camp in the summer, you know, for six weeks, that we would be given first priority in selection for Army internship. So I had selected Walter Reed General Hospital. That was where I wanted to interne,

as I recall. Well, the day came when the announcements were made as to which hospitals had accepted your bids. I was on OB service at the time with Bob Greenley and Bill Dixon and Bob Greenley called downtown to the R.O.T.C. office to find out what our status was...had we been accepted. I can remember very clearly that he talked with the colonel, and he said, "Well, this is Bob Greenley and I'm calling about the internships. There are several of us here." I could only hear that end of the conversation, and apparently Bob had been accepted and he smiled. He said, "Well, how about Bill Dixon?" and the colonel then told him Bill was accepted for Battle Creek, Michigan, and he said, "Well, Jim Goddard is here." And he said, "Oh? Oh. Is that so?" He didn't say anything more and hung up. I said, "Well, how about it, Bob?" He said, "Well, the colonel said that you weren't acceptable under any condition." And I said, "Gee, what the hell. Here I am. I'm in the honor society. I've spent three years in this rinky-dink medical R.O.T.C. operation and now I apply for an internship and they tell me I'm not acceptable under any condition." I knew by then that the Public Health Service and St. Luke's both had agreed to accept me, so I accepted the Public Health internship offer and that was that. Except that a few days later, Bill Dixon, who



was with us at that particular moment when we were being informed, ran into the colonel, and he told the colonel: "You know that was funny the other day. Jim Goddard was really upset because he didn't get an internship offer from the Army." Now, this was in May or April, I've forgotten which, of '49, and the colonel said, "Why, I don't know why he should be upset. He's in the bottom third of the class and, after all, you know, we are trying to give these internships to people who are the best students, and we never promised everybody in R.O.T.C. an internship." Bill said, "Colonel, I think the Army has made another mistake. You'd better look into this, because Jim's in the honor society, and he's in the top third of the class, and probably the top ten percent," and he said, "I think you've screwed up." So, the colonel did and that same day he called me and he said, "Jim, I'm afraid an awful mistake has been made on this internship thing. I've just been talking to the medical people in the Pentagon." He wasn't a medical officer. He was a line infantry lieutenant colonel. "And," he said, "they have told me I could offer you any Army internship you choose. They'll put you in any one of their hospitals, because there's been an awful mistake. What's happened was that when you filled out the forms, you indicated that you'd

had some form of medical disability and injury in World War II, and so they put your forms back on the shelf, and held it there pending receipt of the medical records from the Medical Depot in St. Louis. Apparently, they just forgot about it, and they never got the medical record, and it was a clerical error. They didn't follow through on it, and they're very sorry, and they said now you can have any Army internship you want." Well, by then I had decided. I'd been in to talk to the people at the Public Health Service, and I was going to Cleveland Marine Hospital. That was fifty miles from where I'd grown up, and my sister was living in Cleveland where her husband was a dental student, and my mother was there. So, I told the colonel, "It gives me great pleasure to tell you what you can do with your internship at this late date." And he laughed. He was a good scout and so, just by that kind of a quirk, I wound up in the U. S. Public Health Service for my internship.

Dr. Y.:

And your commission dates from that point?

Dr. G.:

Yes, it does, from July 1, 1949. The internship was at Cleveland Marine Hospital which had been built around 1929 and was being run at that time by Dr. John Trautman, a very

excellent medical administrator, in my opinion, and I thought it was a good internship, in general. But to follow through on this business of how these things can alter your career, near the close of the internship, Dr. Trautman tried to get me to stay in the Public Health Service as a career. He made long distance calls to see if I could be trained as a flight surgeon at Pensacola, anything I was interested in, he wanted me to stay in. He was a very thoughtful fellow, but I had already decided that I would go out into general practice in a little farm town in western Ohio.

Dr. Y.:

What town was that?

Dr. G.:

Kalida, Ohio, a town of 500 people. Now about June of '50, the Korean War broke out. However, there was no national emergency declared, so the Public Health Service did not come under the Department of Defense as it does in time of war and national emergency, and so we were permitted to revert to an inactive reserve commission if we so desired, and I did, and went into practice. Had I taken that Army internship, you see, I would have been frozen into the service as my classmates who took Army internships were for

the duration of the Korean conflict. Now, that's important, too.

Dr. Y.:

Because that was one of your most important periods of rapid development in learning?

Dr. G.:

Well, that, and it just subsequently proved to alter the entire course of my life. I don't know what my career would have been had I gone to Korea, for example, which is where most of the young medical officers that year wound up. Ernie Beasley, who is now here in Atlanta, Georgia, as an internist, wound up as a paramedic in Korea. He made a number of jumps and was in the front lines quite a bit of the time. I don't know what my outcome would have been, but I wound up going into practice, staying there sixteen months.

Dr. Y.:

Why was it that you did make the decision to go into private practice?

Dr. G.:

Well, primarily because I wasn't really firmly decided after having completed most of the internship that I wanted

to go into a residency in internal medicine. I was unsure. I felt that I could do general practice, which the general rotating internship would permit you to do, and make up my mind more firmly before I committed myself to a given specialty.

Dr. Y.:

You really did view this as a time for making up your mind rather than a beginning of a life-long private career?

Dr. G.:

Yes, I think so. I'd been in private practice for about fourteen months when I came home one night, on a Thursday night, that was the afternoon that I closed the office. The wife and I would occasionally go to a movie, a drive-in, on Thursday night just to get away from the telephone. And, this being a small town, the telephone operator always kept track of all phone calls, and I called Molly when I got back in and asked her if there were any messages, and she said, "Yes. There's a telegram here, a collect telegram, from Wright Patterson Air Force Base." Well, I accepted the charges on it and said, "Go ahead and read it," because I remembered having taken care of an airman who had been injured in an automotive accident recently, and I thought it probably was related to him, but the fact

that it was collect seemed odd. At any rate, it was from the Public Health Service, and they said that they had a commission in the regular corps available for me if I were still interested. I think this was simply a routine telegram that they sent. The collect business, I think, was because they were so hard up at the time. They sent these to all the fellows who had reverted to inactive reserve within a given period of time, and if I were interested, I was to let them know. That sort of irked me that they would send me a collect telegram, but I got to thinking about it more and more in the subsequent days and the next couple of weeks and finally decided to drive down to Washington and see what they were talking about. I went down to see the Director of the Division of Personnel, Dr. Irv Dresher, and Dr. Dresher said, "Well, you don't want to come back into the Public Health Service." He said, "We don't have any good assignments available. You'd probably get stuck out on an Indian reservation or Coast Guard assignment." He said, "I just don't think that you'd better come back in. It's not for you. You know, we think you're good officer material but we just don't think that...". I said, "No?" "No," he said. Irv was a pretty shrewd amateur psychiatrist, and the more I thought about it...private practice was interesting but I could look down

that road, you see, and I knew I could spend twenty-five years in that endeavor and not really have any impact, and something made me feel...well, that wasn't why I had gone to medical school. It was a dissatisfaction with that type of activity, and so I went ahead and sold my office and house to another physician, and this all took place in the ensuing five or six weeks, and the first, oh, about mid-September, you see, this happened in July, when it all began, mid-September I showed up again in Washington and I said, "Well, I've sold my house and my office. Here I am." And they gave me a blank look and said, "Well, gee, we don't have any assignment for you." I said, "Fine. What am I supposed to live on? I thought you wanted me to come back in." "Yes, but you didn't understand. We have to have an assignment for you. Our budget is very tight right now." So they then sent me around to be interviewed by people, such as Dr. Jim Schaeffer who was then in charge of the VD program. The only opening he had was in Puerto Rico, and he didn't feel that that was a good place to send a married man because housing was too scarce. Most of the people that they sent me to had no openings at all--they were tight on "slots" as they called them. I remember the last interview I had that day, it was about 4 o'clock in the afternoon, with a Dr.

J. J. Weiskoff. J. J. was a recent joiner of the Public Health Service. He had come over from Europe. He spoke English with a thick accent, and he was in charge of the Employee Health Service Program for the U. S. Public Health Service. He was very cordial and genial, talking to me, but he didn't have a job either for me, and so I thanked him, and as I was walking down the hall to the elevator, I was really quite depressed. I had done something very foolish. I had sold my house and office and had to be out of it in a matter of weeks, and my income would stop, and they didn't have any job for me after they had asked me to come back in. I was just about to the elevator when down the hall came J. J. Weiskoff running, and he was yelling, "Hey chief boy, chief boy, come here." That was his favorite descriptor: he called everybody "chief boy." He said, "Guess what. I just had a phone call from the medical officer at the Denver Federal Center, and he decided to leave the Public Health Service and go out in private practice. Will you take that job?" I said, "You bet I will." So, this is how I got back in...in, really, into the Public Health Service again. I had that hiatus of sixteen months. I came back in on October 31st of 1951 and was assigned to the Denver Federal Center.



Dr. Y.:

Now, before we get into that, let me just ask another question. When you got to be Commissioner, you very often referred to your sixteen months in private practice. I take it that it was a good thing?

Dr. G.:

Oh, it was a very valuable experience. In retrospect, I drew on it under many kinds of circumstances, jobs that I had, such as Civil Air Surgeon with the Federal Aviation Agency. I didn't have to have anybody tell me what the problems of conducting physical exams were for the airmen in the private physicians' offices, or how a private physician might view a form from a federal agency, because I had chafed under having to fill out some of the same kinds of things. And certainly as Commissioner of Food and Drugs, where I was dealing with the pharmaceutical industry as a major part of my responsibilities. I could think back to those days in private practice where I would see as many as thirty detail men in a month. I knew what their activities were; I knew what their efforts were aimed at; I knew what the promotional schemes were in the firms.

Dr. Y.:

Had you had any bad experience with them?

Dr. G.:

No, not bad. I saw, as I say, thirty detail men a month. I did all of my own dispensing. I didn't write prescriptions except very rarely for extremely expensive items. The cost of the office visit was two dollars including the medicine when I was in practice. So, I had to buy drugs and had to see the detail men to find out what they had.

Dr. Y.:

But you didn't ever...

Dr. G.:

No, I never had a fight, no,...

Dr. Y.:

Or feel that you were being misled particularly. It's just that you saw the system in operation.

Dr. G.:

I had seen it...that's primarily it. I did engage in a good deal of questioning of what detail men told me. Don't forget I was perhaps newer in practice and closer to my medical school, pharmacology training, than many of the physicians they saw, so I would subject them to more questioning than perhaps some physicians would, and I used a limited

number of drugs. I had a small drug room where I kept my stocks of drugs. But I didn't have any run-in with them at all. The detail men, most of them, were very courteous, nice people to sit down and spend some time with. It was time-consuming, I will say that. It was very time-consuming.

Dr. Y.:

How about the problem of the education of the physician and the physician's keeping up with the cutting edge of medical practice and so on. It was to become such a problem.

Dr. G.:

I could see that as a problem even when I was in practice. I belonged to a county medical society. There were nine of us in that county medical society, and when I first started in practice, I talked to one or two of the other physicians in the county, particularly the younger ones, and asked them, "Now what do you do...how do you handle the problem when you want to go to the AMA meeting?" I remember one was coming up in Cleveland, as I recall, that year. I thought I would like to go back as it was the clinical session in December. "Oh," they said, "you just close your office up, and what we can do is if you've got any OB cases, we sort of cover for each other. We make an arrangement."

This young physician from a nearby small town said he'd be glad to help cover my practice when I went if I'd do the same for him. Dr. Lucas, I think his name was. I can recall thinking at the time that every time you closed your office, your income for that day stopped, you see, or for that period of time. That was a factor in my decision. I didn't think that was a very good thing, because I could see how you would become sort of tied to keeping the office open and not keeping up. I think the isolation of a small town practice in a town of 500 where I was driving the twenty miles to the hospital usually twice a day. I was doing home OB. My wife did all of my OB packs for me, keeping up my office, although she did not work in my office. The office was too small, really.

Dr. Y.:

What about reading?

Dr. G.:

Well, I got my journals, JAMA; Post-Graduate Medicine, I subscribed to that; a couple of free ones, like Modern Medicine, I think, was out then; GP, the Academy of General Practice journal. Those were the main ones that I read. Now, when you worked in general practice like this all alone,--the last twelve months, remember, out of

sixteen that I practiced, I had a hundred OB cases. On the average of every third day, I had one OB case. I closed the office up for all of them and stayed with the woman from the time she went into labor until she delivered, and a third of those were home OBs. I had about 25 to 30 patients a day whom I would see, plus my hospital calls, the OB and home calls. I drove about 4,000 miles a month, and so you would put in a good long day of it, maybe 18 hours, 16 hours for sure. And you really didn't see much of your family and children, and you really didn't have an awful lot of time to read journals. So this created another kind of dissatisfaction. You felt really tied to a situation that you couldn't control. I think that was a key factor. And you felt you could spend all of your life in that situation, not really having control over the practice, but being rousted out of bed in the middle of the night because there had been an accident on one of the bridges. The town had four roads, you see: north, south, east, west highways, and three of them had one-lane bridges within 2 or 3 miles of town, and I knew every Friday or Saturday night there would be an accident on one of those in the middle of the night, and I'd get hauled out by the State Highway Patrol. So these kinds of factors...

Dr. Y.:

You may have seen people who had gone that road and ended up...

Dr. G.:

Oh, I saw some of them. Dr. Niehyser of a nearby town died of a heart attack, forty-eight years old, you see. I said, well, I don't think I want to spend my career...I didn't have that idea when I went there, and I think I want to work in an organized structure. That was when I decided to go back into the Public Health Service. I never regretted that. It was great fun to be in the Public Health Service, the years from November of '51 to June 30 of '68.

Dr. Y.:

You went to Denver then as your first assignment?

Dr. G.:

Yes. Yes, I went to Denver as Medical Officer in charge of the Denver Federal Center Employee Health Program, and this was an activity that had been set up several years... two or three years...earlier and it was to provide on-the-job health care for federal employees. There were six thousand of them working at the Denver Federal Center, and there was a staff of nine nurses, a housekeeper, and a secretary when I went there, and I instituted at that time, not knowing any better, the first executive health program

in the federal government. I didn't ask Washington for permission. I just started doing it. It made sense, because I looked at what we were providing, it basically was an emergency service, with some people coming in because they wanted to see the doctor and that was it. Well, that didn't seem like a very rewarding kind of situation. We had a board made up of the heads of the federal agencies that supported this activity out of their budgets, and I suggested to them that one of the things we ought to do is to examine the key executives. Well, that was so popular, that within six months the board raised their contributions, of the agencies that participated (twenty-two federal agencies,) in order that I could hire a second physician. It really became a status symbol to get an executive exam, you see. And this got written up in Jerry Klutz's column in the Washington Post. I didn't realize I was starting something that had never been done in the federal government before. Of course, now it's rather commonplace.

Dr. Y.:

Had you learned about this from industry or was this something to do because you didn't have enough...?

Dr. G.:

It just made good sense, because the largest investment was

in the senior agency employees who were at an age when they might be expected to have some problems with their health, and to try to find them at an early stage. First, we hired a lab technician in order to do this, and then subsequently, we got the physician, and I was there from November 1 of '51 until May of '53, I believe. Let's see, yes, May of '53, and at that time I left the Denver Federal Center. Again, one of those chance occurrences. There had been a cocktail party. The regional medical director, Dr. Aaron Christianson was the RMD in Denver for the Public Health Service.

Dr. Y.:

The RMD?

Dr. G.:

The Regional Medical Director.

Dr. Y.:

I see.

Dr. G.:

And he was a very fine man whom I counted and still count, as one of my friends; certainly throughout my career in the Public Health Service, Chris was a good friend of mine. And at this cocktail party, he just very casually said, "Jim,



would you be at all interested in a residency in Public Health and Preventive Medicine?" I said, "Why, sure." And that was all that was said. And about six or eight weeks later, Dr. Robert Leslie Smith came from Washington, after calling me to find out if I would be in and to make an appointment, to find out where I would like to go on the residency. I, in the meantime, submitted some papers which Dr. Christianson had sent out to me. Now, I think Dr. Christianson was impressed by me as a physician because he had brought one of his children to me and I diagnosed measles before the spots erupted, you see, and Chris was puzzled as to what was wrong with his young girl. I sort of spotted the Koplik spots inside of the mouth and I said, "Chris, it's nothing serious. She's going to...Dr. Christianson...she's going to develop measles within the next twenty-four hours," and sure enough, she did. Well, this simply was that I was closer to clinical medicine than he had been as a regional medical director. As a career officer, he had gotten away from clinical medicine. So, he thought pretty highly of me and was very nice to me and got me into this residency program in Public Health and Preventive Medicine. Dr. Smith came out and went over all the residency opportunities available in local health work. That was where we started.

Chapel Hill, N. C., appealed to me because it was a university town and in a nice part of the country, and a smaller kind of town was more what my wife, Mildred, and I were used to, and it wasn't a big city like Boston or San Francisco where some of the other residencies were. So we accepted this assignment to go to Chapel Hill, and we went there in May of 1953.

Dr. Y.:

And it was at the medical school?

Dr. G.:

No, this was in a local health department, a four-county health department, Orange, Person, Chatham and Lee counties. Dr. O. David Garvin was the health officer. He was an interesting fellow, an odd person in some ways. He would worry more about people getting in to work on time in the morning and not leaving early at night than what they did all day long. But he was a very kind person, very nice to me. He had had a series of young men such as myself there as residents from the Public Health Service and I met one of them, Dr. Will David, who was about to leave shortly after I got there, and he introduced me to the people in the two counties that I was to be given responsibility for. They were Chatham and Lee counties.

Dr. Y.:

Now, the residency was a way of training you for kinds of responsibility that you couldn't have without it?

Dr. G.:

Right.

Dr. Y.:

You were in the Public Health Service as an officer but...

Dr. G.:

That is correct. I was then placed on loan to the State of North Carolina and, in turn, reassigned to the Orange, Person, Chatham and Lee Health Department to gain some experience in Public Health at the local level, because in working with the Public Health Service, you have to have an understanding of what happens at the state and local levels and not just the federal level, because the state and local levels are where the programs are carried out. And so, this was essential. It's also part of an approved program leading to your boards in preventive medicine, if you so desire. And so I was accepted as one of the...I think the Public Health Service was supporting, at that time, oh, three or four fellows and maybe as many as six, two in each year of residency. So I was sent, as I said, to Chapel Hill. My residency mentor was an interesting fellow, old Applewhite,

Dr. Applewhite, who had retired from the Public Health Service where he had served, well, I know that Apple was in the service before World War I, because he did a pit privy program down here in Georgia, back before World War I, and he used to tell us stories about his travels throughout the countryside, by horse and buggy and by train. So, Apple,--1916 to '46, would be thirty--he had been in the Public Health Service about thirty-eight or forty years before he retired and had taken the job as director of local health services with the State of North Carolina. There were two Public Health Service men on residency training that year in North Carolina, one in a town about forty or fifty miles away from Chapel Hill, and we would meet every other Saturday with Dr. Applewhite at either Chapel Hill or over in this other town and discuss our training program, what we'd been doing, and Dr. Applewhite would "take us up on the mountain and show us the Promised Land," as he used to say, and tell us of previous experiences that he thought were relevant to the work we were doing. Now, this was an important opportunity for me because Dr. Garvin was permissive enough to let you develop almost any kind of local health program in those two counties that you chose to do so. I did two major things: one was a cancer education program for cancer of the breast for women, using a film that the American Cancer

Society had produced on self-examination of the breast. I went around from community to community and got the theater managers--I had once worked in the theater business so I knew a little bit about that.

Dr. Y.:

Was that when you were in medical school?

Dr. G.:

No, in Warren, Ohio, while I was on high school. I worked my last two years in high school. I got the theater managers to let me use their theaters from eleven in the morning until one to have these sessions with women's club members and whoever we could get to come and showed these films, and I made myself available to answer questions. That was one program that we carried out that I started, and the other was...Dr. Garvin was very much interested in tuberculosis work. That was really his forte; he liked it, and so I decided that if that was his pleasure, I would give him more chest X-rays to read than you could shake a stick at. Now, we had a mobile unit. We had two of them. One was in a truck that the Public Health Service had loaned him, and the other was in a trailer that Dr. Garvin had gotten the commissioners of those four counties to go together and purchase and had fitted out with an X-ray machine.

Well, since one was a Public Health Service truck, I think he reasoned that my being in the Public Health Service, I should have that one. At any rate, my last six months there, I put on an X-ray drive in those four counties and took 10,000 chest X-rays myself, and kept him busier than he had ever been reading chest X-rays. I would drive the truck, and using industry largely as a base and that meant cotton mills in that part of the country, well, not just cotton mills, but there were brick plants and a few other kinds of industries.

Dr. Y.:

The mills, as a matter of fact, at least in the earlier days, were days in which the kind of cotton lint...

Dr. G.:

Oh, yes, a lot of lint in the air.

Dr. Y.:

So that it would be a...

Dr. G.:

Oh, yes. And they were available; the manager of the plant, you could talk with him and say, "Well, we want to bring the X-ray unit here, and it will only take a short period of time, and your workers will only be away from the job for a short period of time." I would drive the truck and hook it up to

the power source, the 220 lines, and take the X-rays myself.

Now I would have a...

Dr. Y.:

A one-man operation?

Dr. G.:

A one-man operation. I sometimes would have the help of a woman to supervise the filling out of the cards, but that was about as far as it went. I would stay and catch the second shift and the third shift. I would stay until after midnight in those larger plants to catch the third shift. Well, I not only took 10,000 in six months, I got very proficient at doing this, and I would get a line of people... I'm afraid I got over-enthusiastic and I would take as high as 60-70 in a minute. And I burned out the main transformer in this particular piece of equipment. I'm not quite sure how it happened. The people who had to repair it up in Washington in the Rockville shop said they'd never seen anything like it before either, but Dr. Garvin still shakes his head about how I managed to burn out that main transformer on that X-ray unit. This kind of experience was important because it was free enough and unstructured enough that you had to learn by your own method, learn to develop your own methods and you learned a lot of lessons

along the way. They could afford to let you make mistakes in that setting, and you made them, but they were valuable mistakes to learn by. I also first had a run-in with a major corporation when I was there, and it was Sealtest Dairies. They were attempting to dump some milk with high bacterial counts in North Carolina that couldn't get passed in other states, and we caught them bringing this milk into this four-county district, and Dr. Garvin let me handle it, and I met with the Sealtest regional man and told him the next time we caught one of his trucks in here and pulled a bacterial count that was in that range of 3 or 4 million per centimeter, as I recall, or even higher, we would just have the truck confiscated and dump the whole load. And that stopped that nonsense. I learned to do restaurant inspections; go out with sanitarians on restaurant inspections throughout the four-county area; school health work; do examinations of school children, the pre-school group in particular. I had to set up and organized those clinics. I had the nurses in the health department to help me, guide me on those things. You always learned a lot from the nurses and from the people in the structure, because they had been doing it. You are new to it. Now, on the other hand, you see things that they don't because they're inured to it. You bring a fresh viewpoint



to it, so you can sometimes innovate in ways that are apparent to you need to be done but not apparent to those who are there. That's one value of changing jobs occasionally. Sir William Osler, you know, believed very strongly that every five years an individual in this professional field should pack up and go someplace else, because he said that forces you to re-examine what you've been doing, and you see things afresh because you move to a new physical setting and are dealing with people who don't know you and whom you don't know.

Dr. Y.:

And that became a kind of doctrine that coincided with your own individual bent?

Dr. G.:

Yes. Yes, it did. And so, in my subsequent career, I never managed to stay anyplace more than three years, and some combination of circumstances would then force a move. I always committed myself to a five-year stay. Intellectually, I would say, "I am going to stay five years here." But it never was my privilege to have that happen.

Dr. Y.:

Now, did you, while you were in North Carolina, have any

contact with the Food and Drug Administration people on the local level?

Dr. G.:

No. We did the food work, by inspecting the food processing plants and the restaurants that operated there, but I never had any contact with the Food and Drug people on the local level.

Dr. Y.:

That just didn't happen?

Dr. G.:

That just didn't happen. No. The residency was, I thought, an extremely valuable fifteen months. I went then in September to Harvard School of Public Health.

Dr. Y.:

Now that had been a natural consequence of the residency?

Dr. G.:

That was one of the requirements of the residency training program, that in your second year, you would go to a school of public health and get a masters degree in public health. You were allowed to select which school of public health you would go to.

Dr. Y.:

How did you happen to pick Harvard?

Dr. G.:

Well, I read through the catalogs at the university library of the various schools of public health, and, of course, I think I had always been attracted to the idea of Harvard. Do you recall that I was living in North Carolina at the time and Thomas Wolfe, I had been a great admirer of his, and he, in turn, was fascinated by Harvard and had attended Harvard.

Dr. Y.:

So that quite possibly...

Dr. G.:

Yes, I felt an attraction to Harvard that I didn't to Hopkins, although I must say, that Hopkins was quite attractive to me because of all that Osler wrote and he had been at Hopkins. Do you want to stop and change that?

Dr. Y.:

Yes, I think we'd better turn it over.

Dr. G.:

Yes. Okay.

Dr. G.:

As I say, I was attracted to Hopkins because of Osler and having read Cushing's book about him. I thought Osler was one of the real giants. Of course, Cushing was a great neurosurgeon. Then I later read the book about Harvey Cushing which was sort of written in the same style as Cushing's book about Osler. And that covered then a span of medicine and public health, because Cushing was quite broadly concerned about health matters up through the era of Franklin Delano Roosevelt, and up through the early forties, the beginning of the war.

Dr. Y.:

Cushing, eh?

Dr. G.:

Yes. Cushing's daughter married a Roosevelt, as I recall.

Dr. Y.:

Right.

Dr. G.:

I've forgotten which one. Elliott, perhaps. I don't know.

Dr. Y.:

I've forgotten, too, but Cushing was one of the ones who kept pushing Roosevelt to get more interested in food and drug problems.

Dr. G.:

I didn't realize that. Yes. But I knew he was quite concerned about health matters in a general way, not just neurosurgery which was his particular specialty. Those kinds of writings...the history of medicine interested me. I've always enjoyed reading anything along that line. But those particular books covering that era of medicine, I found perhaps more interesting than any other, because that was a very explosive, dynamic period in American medicine. That was the period during which we shifted from dependence upon European training for our specialists and the development of our own specialty institutions. That, of course, embraced the period of the Flexner Report, the profound influence that had on medical education. It was the same period, of course, during which public health developed as a specialty in this country, and it was fascinating. Well, at any rate, I didn't choose Hopkins as much as I was attracted to it. Now, I approached it, this was graduate school. I didn't have to work. I was paid my salary, even though I was reduced one grade, to go to school. The children were young. We didn't particularly live in a high style. But I studied a great deal and enjoyed biostatistics. This was probably the best course I've ever had in any school.

Dr. Y.:

Who taught it?

Dr. G.:

Hugo "Hooks" Muench had a great department; Jane Wooster and Bob Reed and Jane Droulette were the principal people in the department at that time, although they had graduate students working there as instructors.

Dr. Y.:

Now that's the Department of Biostatistics within the school.

Dr. G.:

Yes. That was the department that I enjoyed the most and learned the most from. It was a very valuable experience because we studied sampling methods, design of studies, problems of this kind. I took advanced courses in the second half of the year beyond the basic course.

Dr. Y.:

Do you have any explanation as to why it was that this seemed to be the most interesting course?

Dr. G.:

Well, it was the most factual course. It was a mathematics-

based type of course, and I've always enjoyed mathematics. It has been a strong area in my education, one that I was fairly good at. So, it had those characteristics which made it attractive. It was well taught. The instructors obviously were concerned and made themselves available to a far greater degree than any of the members of the other departments. The other course that was extremely good was one in legal medicine, in Public Health law, by Bob Hamlin. Bob was my faculty advisor, interestingly enough, even though he was a year younger than I. He had just completed...receiving his law degree from Harvard Law School, which was very impressive and, as well, he had, during his last two years in law school, gone to Harvard School of Public Health and gotten his master's degree simultaneously, and held a job in the State Health Department in Massachusetts.

Dr. Y.:

Did you say Hamlin?

Dr. G.:

Bob Hamlin. H A M L I N, Robert Hamlin. He now has a private consulting firm. But Bob was, at that point in time, health officer in the City of Brookline and held a faculty appointment teaching Public Health law, this was a seminar course

in the second half of the year, with about eight students. It was held at 5:30 in the afternoon, because of Bob's work schedule. So you really had to want to participate to take this course, and it was a very good course in this sense, better than the others again because you did participate. You were stretched; you had to think; there wasn't any set answer. It wasn't spoon-feeding. The problem of most students in the School of Public Health was that professors wanted to tell you. It was more teaching than learning and so, this, of course, was an exception, as was biostatistics.

Dr. Y.:

Well, now the biostatistics: had the background in North Carolina, seeing the thing on the local level, made the relevance of biostatistics seem...?

Dr. G.:

Yes. And Public Health law, too, because you were up against...problems such as...for example, North Carolina had a law which permitted the sterilization of a married female whose children were mentally defective, or if she and her husband were borderline mentally defectives. Now, these kinds of issues are more than just legal issues. They become moral, societal issues. So, when this type



of issue would come up in Public Health law, I could relate back to problems I had dealt with in the real world. And North Carolina actually had that type of problem to contend with. Again, the relevance...those courses were not only relevant in view of what I had just experienced, but proved to be very relevant later on as we had the opportunity to turn these issues over in Public Health law and in biostatistics, too, to examine all different methods of getting at a problem, not just saying there is only one way, but looking at the variety of ways you could set up an experiment and what the virtues and the disadvantages of each method were. Well, those were extremely valuable courses, not that I didn't learn anything...It was interesting, I became exposed for the first time to what you might call sociology and the social sciences at Harvard. Now, this was through courses such as ecology where Dr. Benjamin Paul, Ph.D., taught the course in ecology. And I became aware of books and writings of sociologists that I never encountered before and never had a chance to read. I also realized that as far as a graduate school was concerned, the School of Public Health really wasn't. It was sort of a Mickey Mouse school kind of situation where you didn't have to work as hard as I was working. So the last half of the year, I did nothing but

read these books in the field of social science, and this really was something exciting to me. I hadn't been exposed to it, and I felt that I had learned a great deal on my own.

Dr. Y.:

As you look back, could you spotlight any of the books that were to be...?

Dr. G.:

Well, no particular one book. These were things, such as Lewin's "Theory of Inter-Personal Relationships" and "Group Behavior" and "Why People Are As They Are" type of thing, Kluckhohn. They were pretty standard things but I had never run into them. I think I learned a great deal in that year about myself.

Dr. Y.:

You mean that your ideas about yourself, about your career interests, got better formulated?

Dr. G.:

Not so much the idea about my career interests, but my ideas of self in terms of relationships with other people and a better understanding of self. A sort of self-analysis type of thing.

Dr. Y.:

Something much more basic really.

Dr. G.:

Yes, that became much more formulated during that...don't forget, I was, what?, 32 or 33 at the time. I had led really a fairly sheltered life up to that point, you might say. Mostly in an academic environment. Although this again was academic environment, I began to think for myself more, began to mature a great deal more then.

Dr. Y.:

Did you have any kind of thesis to do as a part of this?

Dr. G.:

No. This was the odd thing. This was why it wasn't a graduate school in my book. You didn't have a master's thesis to write. You had to write examinations. Now, you know, this didn't strike me as graduate school, and I was one of the ringleaders within the student group, by the way, demanding that the dean meet with us and he did, the new dean of the School of Public Health, Jack Snider, whom I've since gotten to know quite well. In fact, I'm on the Visiting Committee at that school now, but we met with him and explained to him and the faculty members that we were dissatisfied with the courses they were presenting; that it

was spoon-feeding; that they didn't stretch us enough; that we learned more from ourselves. We organized evening seminars...students from other countries or from other disciplines or people such as Joe Garland, the very great editor of the New England Journal of Medicine, would come in and meet with us. These were seminars we, as students, arranged, and we did this the last half of the year. We were an extremely active class. It was a lot of fun to be in that particular group.

Dr. Y.:

There was this international angle which, of course, was to be important when you got to CDC.

Dr. G.:

Yes. Yes. We had a fair number of students from overseas countries, Korea, Thailand, India, Sweden, to mention just a few.

Dr. Y.:

And so they were to bring their background to the kind of problems you talked about.

Dr. G.:

Right. And we had the evening seminars where we could discuss the health care systems in other countries. It gave

us a much broader exposure, and, as I say, we felt the students probably learned more from each other than we did from the faculty. That may not have been really true.

Dr. Y.:

That may generally be true.

Dr. G.:

Well, learning requires the active emotional involvement on the part of the individual for learning to occur. At least, I feel very strongly it does. And emotional involvement isn't something that you acquire in a passive situation. Sitting in a lecture room listening to someone talk doesn't exactly lend itself to an emotional involvement. But when an interchange develops, and ideas begin to be tested against reality structures and situations, when challenges are hurled out and you are forced to think through positions, then you begin to get emotional involvement and learning. And that's what we found so lacking and wanted so much and why we felt we learned so much from each other, because we could challenge each other as peers on ideas much more easily than we could faculty members, although most of us didn't hesitate to challenge faculty members when given the opportunity.

Dr. Y.:

The school wasn't too big for there to be discussion in courses.

Dr. G.:

No, it wasn't too big. There probably, as I recall, were somewhere around 100 students in the class, which then was broken down into your specialty areas. Some of the group were Air Force officers whom we seldom saw except in the required courses. They were there because of courses in aviation medicine. There were nurses who were there who were involved in Public Health Nursing and engineers who were studying Sanitary Engineering. So, in general, you worked in small groups, and it did afford an opportunity for back-and-forth if the professor were willing to do it.

Dr. Y.:

Were you confined pretty much to the curriculum at the school?

Dr. G.:

That was another major objection on our part that we met in the dean's office and tried to get some resolution on. We felt that although Harvard University was just across the river, we never got over there and never got a chance to get exposed to those people. This was all due to the curriculum being so rigid. Well, they did loosen it up after that, and provided in the subsequent years a little microbus to go back and forth and take students so

that they would have more interchange between the University and the graduate school. But the point being that I was not only involved in getting my master's degree, but I was also involved in the student affairs. For example, I helped on the yearbook...I wasn't the editor, but I was the manager, we put out a yearbook the first time any class had put out one with a hard cover, I managed that, put it together. Oh, all sorts of things going on. Ford Hall forum, I found that very exciting to go there on a Sunday evening. It was ten cents, as I recall. Fantastic...they would have great speakers. Judge Justine Pollier Wise on juvenile delinquency, and the next Sunday evening it might be the president of the American Medical Association debating with J. Howard Means and Walter Reuther on the "High Cost of Medical Care and What Can We Do About It?"

Dr. Y.:

Each of these episodes you told me about illustrates something that I certainly observed in the later time that I knew you. Somehow you got a lot more done with your time than lots of people manage to do.

Dr. G.:

That's funny you would make that remark. I think I'm very self-indulgent and waste a lot of time. I feel that I always have.

Dr. Y.:

Well, if you look at it that way, I look at it from a different perspective, I guess, but it seemed to me that here you were doing all of these things at Harvard and you were doing these extra programs at North Carolina. Is it because you got less sleep or...?

Dr. G.:

No. I never suffered from a lack of sleep. But one of the things I enjoy is innovation. I like to innovate. Now, really you do very little that's innovative. You apply what you've learned in one setting to a different setting and that then becomes innovative in that new setting, or you see things slightly differently than you did before or than someone else sees and that means you are innovative. It's rare that someone comes up with a truly new idea that has never emerged before. That's a rarity, but I derive great pleasure from developing new ideas at least quote "new" in those settings. Now, because I like that, I think I...and I don't mind making decisions. I'm a gambler and willing to take the risks of decision-making. You have to be willing to do that to be a good administrator in my book. I get more things done maybe because of those characteristics. I don't really spend more time at it, because I still indulge myself by reading a great deal. While I was Commissioner for Food and Drug, for example, I read more journals



during that two and a half years than I had ever read at any time in my life. They came across my desk, and I always found some new idea in them that made me think of something that we hadn't been doing. It was an intensive period of education for me, because, although I had dealt with drugs, I had to look at them now differently. I had never become deeply involved in the pesticide matters and the food additives matters, although I had an interest in them because of my work at the Communicable Disease Center. So, we are always harsher on ourselves than others. We know that there are three Jim Goddards, you see.

Dr. Y.:

Now what are they?

Dr. G.:

Well, this is true of any of us. First, is the person we want others to see, and second, is the person that others do perceive, and third, is ourselves as we know ourselves really to be. Now, at best in life you can get that down to two, as you mature: the person we want others to see and the person we know we really are can coalesce. It's difficult. And then the other person, that "you" as perceived by others, you have less control over. But at any rate, we do have those three persons, you see. Well, on the FDA job, it still was one of expanding, you saw me in a slightly different light than I saw myself.

Dr. Y.:

I'm sure that's true. It certainly did strike me that way, and you mentioned doing all of those things at Harvard, besides the studies and your reading, and so I just thought I'd bring it up. Well, let me ask one question that I thought of awhile ago.

Dr. G.:

Sure.

Dr. Y.:

With respect to the biostatistics, was this a period of rapid change within that field or broadening application of the knowledge in the field to different kinds of phenonema?

Dr. G.:

More of the latter certainly than the former. Mathematics and biostatistics as you know from your own experience isn't a highly volatile field. We are still using the theories that were developed with respect to probabilities of injuries on Prussian soldiers, aren't we? This field doesn't change all that rapidly, but the broadening application would be a fair comment, yes, during that period of time.

Dr. Y.:

And the hardware to handle it?

Dr. G.:

Oh, yes. Well, that was just beginning, you see, in '54 we had computers but they weren't commonplace as they are today.

Dr. Y.:

I was wondering if you learned things of this sort that would have been important both to CDC and the FDA?

Dr. G.:

Well, certainly, I learned through this particular part of the program about computers but only in general terms, only what they were capable of doing. That's extremely important though. That is as far as it went. We didn't have a computer available to us to work on at the School of Public Health. They were far too expensive for them to have had at that point. They do now, however, have computer capability. But biostatistics was well taught. I would stress that that was one of the things. You taught yourself. It was a problem-solving course. The faculty simply helped you and said, "Oh, you've been looking at it this way; look at it this way and if you were going to structure this, then here's how you...wouldn't you consider...and why don't you..?" You really taught yourself biostatistics under their guidance.

Dr. Y.:

Was a sort of a case method used in a simulated situation?

Dr. G.:

Yes. Yes. Very much so. Very much so. With problems that they would give you and you would turn in the reports on the problems. I spent many, many hours working up those reports and, in fact, I had had drafting at one time in my high school training, and so all of my graphs were done with India ink, using a drafting pen and French curves, whatever was necessary. I had the technique and all my work was typed.

Dr. Y.:

Had you had typing in high school?

Dr. G.:

No, I had to learn it on the job when I worked in the theater. I had to get a payroll out every week so I taught myself to type, but I recall Dr. Muench. I turned in the first section and it was returned marked "A"; turned in the second and it came back graded "A". And the third one, he appended a note to it and said, "I would appreciate it very much if you would not hand in the previous sections. I shudder to think of this getting lost some place in our department. You've taken such pains and it's so beautifully done. Please just turn in the appropriate section." Well, that tickled me, you know. They never had had anybody turn in one like that before. It was showmanship. I had not only done this work in high school; but working in the theater

you learned how to present things. That's an important thing in life: to learn how to present an idea.

Dr. Y.:

What do you mean that you learned this in the theater?

Dr. G.:

Well, we made displays. We made billboards. We had a workshop backstage, and the man I worked for was a very imaginative guy, Earl Bailey, and a very fine fellow. He would hire us high school students to work as ushers. Then, the first thing you knew, you were backstage working, making a sign that would go across the side of the theater. You learned how to do electrical wiring, or how to make a lobby display, or a trailer display to be driven around town to advertise a film that was currently showing or about to start showing. He took a liking to me and, during my senior year, I was doorman and after I graduated from high school, I was promoted to assistant manager. That paid twenty dollars a week, and I had to write the newspaper ads, the radio ads and take care of...you had to learn how to handle people, because you not only had twenty-two people working in the theater itself, but you had the crowds that you had to learn to handle. You talked them into taking seats in the front row which really weren't very good seats, but you wanted to fill all the seats in the theater. So you learned a wide variety of skills

and one of the things that you had to learn was how to present yourself and how to present ideas.

Dr. Y.:

You mentioned that in North Carolina, you presented, as it were, the films and also answered questions and spoke to women's clubs. Was this your introduction to public speaking or had...?

Dr. G.:

No. I took public speaking in high school and college. Because I worked in the theater and I was interested in it, I gravitated in that direction and took those courses as electives and, as a result, I have never been afraid of public speaking. That doesn't mean to say that I haven't been nervous, but I've never backed away from anything that required me to meet the public, large groups of people, 1500 or 2000 people, it doesn't matter, or just in Congressional testimony, I always felt comfortable. I enjoy that kind of activity, as a matter of fact. So, I look back and, talk about influences on your career, I would have to say that Earl Bailey, the manager of that theater, had a great influence on my life, because of the many things I learned from him, by observing him and working for him. I remember one evening, he came back from Pittsburg. Back in those days, Franklin Delano Roosevelt was our president, you recall. This was in '39, '40, '41. This happened to be, however, in '41. And I was assistant

manager of the theater, and it was a Monday, and Roosevelt had scheduled a Fireside Chat for that evening. Before Mr. Bailey went to the manager's meeting (this was a chain theater) in Pittsburgh that Sunday, he spoke to me and said, "Jim, don't forget there's a Fireside Chat," now the point being, that we always arranged the schedule on Monday so that the feature film ended just at the time the Fireside Chat came on, or the short subject, or the news or something, so that we had a natural break. And I said, "Fine." He said, "Take that into account in working out the schedule for tomorrow." And I said, "I will." And I did, and he came back from Pittsburgh late Monday afternoon, and we were chatting and he said, "Did you work the Fireside Chat into the schedule?" I said, "Sure, it's okay. It's at nine o'clock." And he looked stunned and he said, "But God dammit, the Fireside Chat tonight is at eight o'clock." And I said, "Well, he always gives them at nine." "Well", he said, "he's not giving this one at nine." He said, "And you're going out on that stage when we stop the movie in the middle and explain to those people why they're going to have to wait to see the last half of the film after President Roosevelt's Fireside Chat." Well, I had to do that. It was one of those kinds of things, you know. There was a situation you had to cope with. You had to handle people. You offered them the opportunity to have a refund, to come back, or anything to keep them satisfied.

Well, a digression of sorts, but...

Dr. Y.:

But an important digression, I think.

Dr. G.:

Well, you see, I did learn a lot from him. He gave me responsibilities. That was the point I was getting at. He gave me responsibilities. He also taught me that along with that responsibility, you have to pay some consequences once in a while, if you don't measure up properly. And I tried to use that throughout my career in handling the people that worked for me. I was quick to delegate. I don't think people expand and grow in their jobs unless you do delegate things to them, you see. But at the same time, I never hesitated to blister a guy because he didn't do his job right. My people knew that, in FDA or CDC. They knew that I would give them the responsibility but also expected them to produce and I would follow up and ask them about it. They liked this.

Dr. Y.:

The ones who would produce would like this?

Dr. G.:

Oh, yes. Most people want to do a good job. This is an interesting thing. Most people really want to do a good job, and



the reasons that they don't, quite often are related to the management philosophy that operates at a given point in time. I think that if you give people responsibility and encourage them, reward them, they'll measure up for you.

Dr. Y.:

How long into the Harvard year was it before you learned what you were going to do after you were through with your master's?

Dr. G.:

Again, Robert Leslie Smith came to see me about halfway through the year and said, "Well, where do you want to go next?" The third year you had to spend with a state health department to give you state level experience. Looking over and talking to people in classes who worked for state health departments and were knowledgeable about this and to a few friends I had made in the service by then, I decided New York State and California were the two best state health departments and I elected to go to New York State. Primarily because of Herman Hillabough. He was the commissioner of health, an outstanding public health administrator, and I asked that I be sent there provided I could work in his office. I was assigned to the New York State Department of Health after graduation, beginning July 1, 1955. Initially, I was given six months experience in the Albany Regional Office with Dr. Ralph Vincent, and subsequently I was

placed in the Office for Program Development and Evaluation. I was given my choice of two projects to work on. One was on a meat inspection program which didn't appeal to me. The other was in highway safety and that was of interest to me. So I developed for New York State a Driver Research and Testing Center in cooperation with the Bureau of Motor Vehicles and the Department of Mental Health. This was the first of its kind in the United States. During that six-month period, I attended meetings on safety held in various parts of the U. S.; I talked and met with officials of New York State trying to decide what New York State should do in approaching this problem of highway accidents. And the end result was the development of the Driver Research and Testing Center. Now, a choice, you see, played an important role in my subsequent career. I could have gone into the sanitation field and maybe become drawn more into environmental problems, if I had chosen to develop the meat inspection program; but I chose to go to the highway safety thing. Now, that has relevance for the rest of my career because in the spring of '56, I was asked, "Okay, what are you going to do now?"

Dr. Y.:

This was the end of your training?

Dr. G.:

That's right. I asked, "What's available?" And the Public Health

Service people that I met with said, "Well, all sorts of jobs are available. Look them over." So I did. One that nobody wanted interested me. They were talking about starting an Accident Prevention Program. That fit with what I had been doing in New York State. I was interviewed by Dr. Seward Miller who was then head of the Division of Special Health Services. He decided to take a chance on me. I was young for a program chief. I was thirty-three at that time. So, July 1 I went into Washington as Chief of the new Accident Prevention Program. Here again, I was involved in starting something new. That was fun. I had a small staff, a biostatistician, a nurse, and an engineer, a secretary and a statistical clerk. Five people and myself, and we got fifty thousand dollars which the Bureau Chief obtained by what we call "tapping" other programs or "tin cupping." And that was what we operated on the first year. Dr. Chapman a few months later became the director of the Division of Special Health Services, and he also had great influence on my subsequent activities. I have great respect for him. An imaginative man. He had more ideas in one day than most Public Health people have in a year. Three out of ten of them...four out of ten...might not be any good, but Ted Williams only batted .400, and Al was a very imaginative fellow, just could keep you busy all of the time with little notes: "What would you think of...", "Why don't we consider...",

Dr. Y.:

That was part of his administrative talent, wasn't it?

Dr. G.:

Right. Yes and I grew up during that period of time, having the responsibility of testifying before Congress, developing a new program, selecting research projects to be developed, etc.

Dr. Y.:

Now, you had to do that in order...at the budget hearings?

Dr. G.:

Yes. Right. And also the Highway Safety hearings which Representative Kenneth Roberts in the House was chairing then, I testified a number of times in the period '56 through '59 before Kenneth Roberts' committee.

Dr. Y.:

What had been the reason for starting your highway safety program which you came in to take over?

Dr. G.:

Well, it was the accident prevention program which meant home safety, recreational safety, and highway safety. My interest was keenest, admittedly, in highway safety. In fact, I proposed in 1957 that the Public Health Service develop a driving simulator. This was a technique that I became aware of and knew of its

being used in some fields, and I saw that, going back to my engineering training, possibly, you see, that this had applicability. This also involved motion pictures, too, oddly enough. I met with people in Hollywood to check the feasibility of doing this and made a proposal before Representative Fogarty's committee for a driving simulator. That unfortunately never was funded. It was unfortunate because I think many of the problems that we have in design could have been avoided had we had such a simulator available to crank them in and study them in advance, problems with signing, intersections, these kinds of things, as well as learning more about why drivers react the way they do under certain situations. Highway safety was a very high-level interest for me in the accident prevention field. It was more challenging because there was a relationship between design and injuries and accident patterns that soon became apparent. Hugh DeHaven did much of the early work in this field at Cornell and John Moore had succeeded Hugh and was doing this work at that time when I came on the scene. We, in fact, supported this project. I got funds into the research activities largely through NIH. I had an arrangement where I was an acting grants branch chief at NIE during that time period, to get accident research started. So we had monies available. I soon got to know everybody in that field. As a matter of fact, when I left New York and took over the

accident prevention program, I got a young man to take my place who was a Public Health Service officer and he was only to be there a year. The question then came, well, who would follow him? I had met a young doctor at the Harvard School of Public Health...named Dr. William Haddon. Bill was an interesting physician who had an MIT engineering degree and a Harvard Med School degree and was working in virology at the Harvard School of Public Health and wanted to take a master's in Public Health. But the Public Health Service wouldn't support this bright, young physician unless he would take a commission and come in and spend a couple of years on an Indian Reservation. "Then," they said, "we'll see whether we send him to the School of Public Health. After all, we just can't send him to a School of Public Health." So, I said, the heck with that. They wouldn't do it, so I got the New York State Department of Health to support him while he went to the School of Public Health with the understanding he would then work in the highway safety field. We put Bill on the payroll and he subsequently took that job over and really developed the Driver Research and Testing Center and carried out some of the most imaginative research in highway safety that anybody has ever done. Bill is an outstanding expert on study design, you see, and he wrote a book, in fact, on accident research methodology. Bill Haddon and I stayed in close touch and, as you probably know, he was the federal Highway

Safety Administrator until January of this year. Actually, February, I think he left. And I happened to have been involved in getting him into that job, too.

Dr. Y.:

Because you knew his whole background?

Dr. G.:

I knew his background and also this related to...I'm getting ahead of myself, but while I was at FAA, I worked a lot with the Civil Aeronautics Board, and Allen Boyd who was chairman of the Civil Aeronautics Board. Allen later became Secretary of the Transportation Department. When he became Secretary of the Transportation Department...or rather when he knew he was going to become Secretary, he asked me if I had any suggestions for someone who would make a good head of the highway safety activities, because he knew I had worked in the safety field both in aviation and highways. I recommended Dr. Bill Haddon and got them together for Bill to make a presentation. Bill and I used to do an "Ev and Charlie Show." We did that so many times, it became a routine. We did it for the President's Science Advisory Commission; we did it for the Department of Commerce; a Scientific Advisory Board; we did it for the Secretary of Commerce, and more importantly, Allen Boyd. Going through the whole business of highway safety and how the problem should be

tackled. As a result of that exposure, Bill was given the job of Federal Highway Safety Director. Well, that was great good fun, and I met lots of people in the accident prevention field and whose paths I keep crossing at different points in my career. Some of them when I was Civil Air Surgeon for the Federal Aviation Agency.

Dr. Y.:

How important is this in the success of a person, the network, the web, of human associations?

Dr. G.:

Very important, I think, very important, and you have to pay attention to it. Of course, you understand the web you're in, and you see some of the interlocking webs that others are in. I've always maintained a good Rolodex file of these people, and even though I may not see them for a number of years, I try to keep current and know where they are, because something will come up in a meeting or some situation will develop on a job, and you'll suddenly think of a fellow at Antioch College in Yellow Springs, Ohio, who, four years ago, did a project for you of this nature. You'll say to your secretary, "Get him on the phone. I want to talk to him."

Dr. Y.:

When did you start this as a formal method?



Dr. G.:

In accident prevention. I started then.

Dr. Y.:

Is it a name file or is it a subject matter file?

Dr. G.:

It's a name file, and I sort of keep the subject matter in my head and try to think, when I've got a problem, "Well, who have I ever worked with that has done something like this?"

Dr. Y.:

And then you did the same thing in connection with Public Health?

Dr. G.:

Oh, sure. The Public Health Service has only about 5,000 commissioned officers. There are many more civil servants, about 35,000 to be exact. You get to know a pretty sizeable number of the commissioned officers and know their capabilities.

Dr. Y.:

You'd see them so infrequently that you would want to have...

Dr. G.:

Yes. And they move, too, so it's interesting to keep...Well, just a personal aside here. One of the fellows who worked for Dunlap and Associates, a bright young mathematician, statistician and

research psychologist, Herb Jacobs. Herb and I took a liking to each other. I had great respect for him and I think he did for me. We just sort of kept in touch, not even letter-writing much, but through mutual friends. Now, oddly enough, Herb is president of Hallmark Greeting Card Company, and our oldest daughter is now at a commercial art institute in Denver and a year from now, a year from August, she'll finish. I saw her last week and I said, "What kind of a job do you think you can get?" And she said, "Oh, Dad, some of the kids went to work last year for Hallmark." I said, "Hallmark. That's interesting. Would you be interested in a job like that?" "Oh, yes," she said. I said, "Well, let me know when the time comes." Well, that's just a personal aside...

Dr. Y.:

But the thing worked...

Dr. G.:

Isn't it odd that the network works. And you encounter people at different stages of your career, who drop out of sight for awhile, and then pop back up again, and you are then in a different position, but you see they have some relevance to a problem that you have at hand.

Dr. Y.:

Right, and so that you were able to call on expert counsel,

whether formally or informally, hire a person or not, or just ask him questions.

Dr. G.:

Sure.

Dr. Y.:

When you needed it.

Dr. G.:

That's very important, too.

Dr. Y.:

Well, the Accident Prevention lasted how long?

Dr. G.:

Three years. Just three years and thirteen days. The reason I know it was thirteen days...and here again, the long arm of coincidence and circumstance. By that time, that time being Spring of '59, Bob Hamlin was a special assistant to the Secretary of Health, Education and Welfare, who was Marion B. Folsom, and Bob was working across the street in North Building and I was working in South Building. We didn't see much of each other. He operated with Congressmen on legislative matters and at a different level. But, we knew each other. We knew where we were, and he knew he could get in touch with me and one day, he did. He said, "Jim, would you do me a favor?" I said, "Of course, Bob. What do you

want?" He said, "Well, I've been asked by the FAA to sit in on a meeting and help advise them on a new job, the new medical director's position, "and," he said, "I promised them to do this, and now the Secretary wants me to go out of town and give a speech. Would you go for me?" I said, "Sure." I went to a meeting at the old Executive Office Building, and Ford Luikart, the director of personnel for this new agency, Dr. John Smith, who worked for the CAA and then for FAA as a physician, was there, and a Navy captain who later retired, and Dr. Bill Ashe, Professor of Preventive Medicine and head of aviation medicine at Ohio State, was there. Mr. Luikart started talking about this new job and we asked, "Who does this man report to?" He said, "Well, it works this way." We asked him another question, and it was obviously a very poor administrative arrangement. We made no bones in telling him this. And he said, "Gentlemen, let me tell you. General Quesada, the head of the agency, has decided that it's going to be this way. Now this isn't my view, but that's his." We said, "Well, there's no point in us writing the job description if you're going to have an administrative bastard of an arrangement that doesn't permit the man to work effectively. He has to have line authority and you've only given him staff authority." He said, "Would you like to have me get the general to come and talk to you?" We said, "Sure." So, Ford left the room. A few minutes later, he came

back with this man who wore glasses, stood very erect, and refused to sit down. He said, "I just have a few minutes I can spend with you, and I want to thank you for coming over here to help us with this problem, but I want you to know that where this man is in the administrative organization and how he operated is none of your business. It's our job. Now, if you can't write the job description, why then, we'll get another group that can." "But," he said, "that's our business." And I thought about what he had said and decided what have I got to lose if I tackle him direct? I looked directly at him and said, "General, you couldn't be more wrong if you tried." Well, that really started things. He said, "What do you mean?" I said "If you'll sit down, we'll tell you what we mean." Although he came in to spend five minutes, he wound up spending over an hour with us. And, at the end, he was very cordial and thanked us very much for having helped him with the problem. End of story. At least, I thought so. A few weeks later, this same Federal Aviation Agency called and said, "Would you come over and help us with a problem we have with respect to maximum age of pilots for airline flight status?" I said, "Why me?" And they said, "Well, General Quesada sort of took a liking to you. Besides, you're working in the safety field and this is a safety issue." I agreed and went over to meet with them. It was an all-day meeting, and again the general was there, a very impressive

man. After great debate, we finally agreed on age 60 as a maximum age for flight status and age 55 as a maximum age for transition to jets. During the meeting the general asked us a lot of tough questions and we put the answers back to him in a way that he seemed to like. Again, fine. It was a nice day, intellectually stimulating and fun, and I got back to my office late that afternoon and one of the participants, Dr. William Ashe, called me and said, "Dr. Goddard, you know we just spent the day together here and I met you one other time. I know what you're doing. You probably think it's very important, but I want to ask you would you consider taking over this new job as civil air surgeon over here? General Quesada has asked me to call you and find out if you'd be willing to take the job." I said, "Well, I am very flattered. I'm very impressed by the general. But the answer is 'no'. When I took this job as Chief of the Accident Prevention Program, I committed myself to five years, and I've only been on it three years and I've got a lot yet to accomplish." Period. End of story. At least I thought so. About a week later...I had taken the day off, but I had to come into town and decided to stop by the office and pick something up. So it was just happenstance that I was in the office. I was wearing a sport shirt, a pair of slacks, sandals, the way I am dressed today. And while I was in the office, my secretary came in and said, "The Surgeon-General wants"...well, I left one element out.

A week after that first phone call, I was in a staff meeting with the Bureau Chief and he said, "Come on outside. I want to talk to you." He said, "You know, you've been helping the FAA lately and the general has asked the Surgeon-General who has asked me to find out if you really will take that job?" And I said, "Dave, no. And I'll tell you why." And I told him why. So that was the second contact. Now, a week following that, I was in the office on my day off, without a tie and without a suit coat, and the Surgeon-General called and said he wanted to see me right away. So, I borrowed a necktie and a suit coat from one of my staff and went over to the Surgeon-General's office.

Dr. Y.:

Who was he at that time?

Dr. G.:

Leroy Burney, and Lee and I liked each other real well. I'll tell you why later on, but I went in to see him and he said, "Jim, General Quesada has been over here to see me about you." I said, "That's interesting." He said, "Do you know what about?" I said, "Yes. I've already told him 'no' twice; Dave asked me and the general had somebody else ask me." And so Lee started to talk to me and, the longer he talked, it became clearer and clearer that I was going to volunteer to go over there. So that's

how I became Civil Air Surgeon. Again, you see the chain of circumstances that often determines our careers. Bob Hamlin had to go out of town for the Secretary and so I subbed for him.

Dr. Y.:

That's right. But you would have the kind of background to be asked, too.

Dr. G.:

Well, Bob had respect for me and knew I would not let him down, nor the Department down, in participating, and so that's why he asked. It's fascinating how these little events subsequently seem to be important in how your career develops.

Dr. Y.:

So, it was in 1959 then that you...

Dr. G.:

July 13th, you see. I was transferred over there and that's how it started me on this. The general was superstitious and he wouldn't let them date my transfer on July 13th, but insisted that it be back-dated to July 12th. I actually went to the agency on July 13th.

Dr. Y.:

Well, while you were there, you had lots of opportunities to observe the general, no doubt.



Dr. G.:

He was a great man. One of the best decision-makers I ever saw. Let's take that up in the next session.

Dr. Y.:

All right, because the tape is just about to come to an end.

Dr. G.:

It's just an hour.

# History

of the

## U. S. Food and Drug Administration

Interviewee: Dr. James L. Goddard

Interviewer: Dr. James Harvey Young

Date: April 30 to June 19, 1969

Place: Atlanta, Ga.

Session 2

Pages 80-165

Dr. Y.:

This is a continuation of the conversation with Dr. James L. Goddard at his home in Atlanta. Today is May 23rd, 1969, and I am James Harvey Young. When we talked last, you had described some of your adventures while you were head of the Public Health Service's Accident Prevention Program, and you had indicated that it was in this role that you first began to run into some kinds of consumers' problems and into lobbies of industry, in this case, the automotive industry. Jim, would you say a bit about that?

Dr. G.:

Well, at that time, I remember this was in the period from July 20th of 1956 to July 13th of 1959, I went in to head up the Accident Prevention Program for the Public Health Service. It was a new program, and I was selected primarily because nobody else wanted the job. At that time, I believe I was thirty-three years old. And that was fairly young for a program chief in the Public Health Service, but it wasn't much of a program to start with either. There were five of us. Well, we looked at the accident data that was available, deaths, injuries: sources, types. It was very easy to discern the fact that--common sense would tell you--the highway deaths

and injuries were far the most important thing, contributing over 50 percent of the total number of accidental deaths each year in the United States, and generally striking at younger people, more than the home accident deaths or other kinds: work accidents. And so therefore, more man years lost and, also, by virtue of work that had been started by Hugh DeHaven back in the late forties at Cornell, it was also apparent that these were deaths that could be prevented. Primarily, we are talking about the problems of deceleration. Now, in looking at highway accidents, people literally refused to do much about them. In fact, the automotive industry consciously aided and abetted this attitude by establishing in 1936 the Automotive Safety Foundation. This came about because there was a writer who had a story published and it was reprinted in the Readers Digest, and it was called "And Sudden Death." It pointed up the problems of highway accidents, the poor design of the cars, as a source of contributing significantly to the deaths. This got the automotive manufacturers very upset, so they ponied up jointly enough money, and have continued to ever since, so that the budget of the Automotive Safety Foundation when I was familiar with it, was a little over a million dollars a year. This, I always thought, was conscience money that they were spending. It was interesting. The charter of that organization forbade that group to support

any research or to do any work on the vehicle; roads, driver, human factors, anything but the vehicle. Well, in 1947, '8, '9, Hugh DeHaven became very intrigued by the problems involved in deceleration. He had observed that people could sustain tremendous, or rather fall from tremendous heights, and survive under certain kinds of circumstances, and so, as any good epidemiologist would, he began to look at the circumstances surrounding those exceptions. People usually die when they fall from fifteen-floor heights, you know, but he found there were some that didn't, so, whenever one of those happened in the New York area, he would go out there and study all of the relevant factors, and, of course, he found what was known by Hippocrates. Hippocrates described the problem in his day in connection with skull fracture. Hippocrates noted that if you hit a hard, unyielding object with your head, a skull fracture is apt to occur and is apt to be fatal. DeHaven found that even a slight amount of energy absorption by virtue of a person landing on a recently plowed area, or on a car rooftop, would enable the human body to tolerate a fall from great heights. The more he looked into it, the more he was convinced that something then could be done, not only about aviation safety, which was one of his major interests, but about automotive safety, that you had to design then in such a way that would provide the added period of time for the body

to absorb the forces. That's what happens when you provide some means of cushioning, let's say. You see, if an object falls, if the human body falls a significant height and if a person were to land on his feet, then the total force of that impact is distributed over a very small area and the deceleration distance, if it's relatively short, results then in a transmission of forces throughout the body that can't be tolerated. If that same person falling from the same height were to fall lying completely flat on his back, you'd offer the maximum surface for distribution of the forces and if, at the same time, the object against which the body impacts is such that it yields even a couple of inches, will then, decrease the rate of onset, as we call it. Well, now, this is important and relevant to the automotive thing because this then was the beginning of an automotive crash injury research project that DeHaven got funded from the Public Health Service, and then John Moore succeeded him.

Dr. Y.:

This was up in New York State?

Dr. G.:

In New York State.

Dr. Y.:

Where you had been.

Dr. G.:

Well, it's where I went later on.

Dr. Y.:

I see.

Dr. G.:

They were working out of New York City. They were gathering data on motor vehicle accidents, and so they had been in operation four or five years when I first started the accident prevention program. And I visited them and I found that they were getting data from state highway patrols on speed of impact, and make of the car, and nature of the accident, whether it was head-on and what direction the impact was and the kinds and nature of the injury, and they were beginning to relate the injuries that caused death or were non-fatal to the design of the car such as the hinter bar over the front windshield, and put protuberances on the dashboard, and going through the windshield, or going out of the open doors that tended to fly open more in those days. And so they began to build a mass of data and they had a pretty good indication at that point in time, a very good one, in fact, that seat belts could reduce both the frequency and severity of injuries, all grades including death. Now the automotive manufacturers at this time were also putting small amounts of money into this project.

They were funding the research, but the results they were ignoring. So we had a situation where the scientific information was available in 1956, '7, '8, '9, in fact, from that point up until the Highway Safety Act of 1966. The scientific data existed that would permit designers to design a motor vehicle that would provide the maximum opportunity for survival in the event of a crash, but corporate policy prevented those designers from using the knowledge that was available, and vehicles, by and large, continued to be designed that didn't really affect the death rate. Now, I was exposed to their attitudes, the corporate attitudes in the form of people from the companies, high-level people, vice-presidents, etc., making speeches, such as the one Chrysler vice-president who in a meeting of scientists and legislators tried to tell us that the problem was the trees along the road. If we wanted to cut down on the highway death rate, we ought to see to it that all the trees were cut down alongside the highway. Well, this is the kind of utter nonsense that they engaged in throughout these years trying to avoid the basic issue. The basic issue is that they had a responsibility for building a product that could be used safely. Or put it perhaps more properly, that accidents are going to happen. Human nature is the hardest thing in the world to change, and you can study it from hell to breakfast and learn all you will, but when you go to the



job of trying to implement and change human nature, you're really up against something tough. Therefore, the only influence on highway death rate and injury rate, the thing to do is to take those actions that you have available that require no inter-action with the human being. And that meant better design of the vehicle, so the doors didn't fly open as much, so the windshield wouldn't amputate a person's head as it went through, so the dashboard didn't have protuberances all over it, and all these features. Now they resisted that mightily, and they were alerted to the responsibility in Congressional hearings held by Congressman Roberts, Kenneth Roberts of Alabama, who, by the way, has told me that he lost his Congressional seat in the election of 1964, I believe, or '2, I don't remember which one, because the Ford Motor Company poured a lot of funds in through dealerships in his district and saw to it that he got beaten.

Dr. Y.:

So that he was persuaded that had happened?

Dr. G.:

Oh, yes. Oh, yes. He made no bones about it.

Dr. Y.:

Well, now, I take it that the people who made these speeches

before Congressional committees, and so on, when your agency was set up this new agency in the Public Health Service, would be bound to come by and pay their respects to you. Is that true?

Dr. G.:

No. They didn't. They disregarded us. We were so small. It was so insignificant to them. They felt we couldn't have any influence. And then we began to testify as we got further information from studies we were supporting both through NIH and our own program, that we were able to point out to the Congressional committees changes that were needed. Then, and only then, did they begin to pay some attention to us. And even at best it wasn't too much. The highway safety field was a strange one to work in. The motor car manufacturers were most resistant to change on their own initiative even though it was pointed out that if they didn't, then there would be federal legislation.

Dr. Y.:

Was this a competitive thing that it was difficult to get the team all together to do the same thing at once so that one wouldn't gain a competitive advantage over the others?

Dr. G.:

Well, they claimed that, they claimed that. But since then,

it's been proven that this is not the case under the federal highway safety standards that the Department of Transportation administers. The Ford Motor Company, you know, claimed they tried to introduce safety in one year and that they badly got beaten in sales by Chevrolet that year. But what they failed to tell you, at the same time, to be fair they should, was that they didn't undertake a model change that year and Chevrolet did.

Dr. Y.:

So other variables enter in.

Dr. G.:

Many other variables. Let me make perfectly clear. I never felt at that point in time that people were interested in buying safety. But rather, they wanted an automobile or any other consumer product for other kinds of values rather than it being safe. It was a sex symbol, or whatever use...status symbol, who knows. Those were the kinds of things that apparently motivated people to buy objects of this kind in our society. Now, I always felt that safety should not be a feature that you tried to sell but you built it right into the product unobtrusively. In fact, if it didn't require anything on the part of the consumer, that was the optimum goal that you could arrive at. You see, seat belts had been a problem because they

require a conscious act, even though the evidence clearly supports that seat belts will, if worn, help protect the individual in the event of a crash. Now, there was another kind of interesting thing with the motor car manufacturers. In '56, '7 and '8, we tried to get them to introduce fastening points to their vehicles, so that a person could buy seat belts and simply snap them on, you know. "Oh," they said, "those would cost fifty cents per installation point." Well, that was a lie. It cost pennies when they finally got around to doing it, you see. But they would go to all of these elaborate kinds of self-deceptions and delusions, which for what reasons I have never understood, other than to avoid having to measure up to their responsibility. It may well have been that their lawyers advised them, and I'd like to find out some day, that by doing these kinds of things they would, in fact, be admitting culpability when accidents occurred and therefore, avoided it at all costs kind of an approach.

Dr. Y.:

But there might be some kind of a liability...

Dr. G.:

That is product liability and law suits followed. Well, since then we've seen law suits, and they now, as the courts have ruled, are held responsible for kinds of damages...I'm not

talking about monetary, but the principles have changed, and they are held responsible in ways that they had never dreamed of before.

Dr. Y.:

Well, what was your mission there? Was it research?

Dr. G.:

No. Our mission was, through whatever methods were available, to help reduce the number of injuries and deaths from accidents of all causes.

Dr. Y.:

So propaganda was part of your mission.

Dr. G.:

Propaganda was part of our mission; research was part of our mission; action programs. I spent a great deal of time and energy working on the highway safety aspects because that was the largest single factor to be coped with and was killing so many young people. It was quite interesting to brush against the motor car manufacturers, and to go to their meetings in Detroit. They were always very hospitable, lavish with their entertainment, and yet resistant to any change, and they would downright lie. I remember going to the proving grounds one day and watching with a Congressional committee some vehicle

crash demonstrations that they had arranged and that one of them was a longitudinal roll. The vehicle goes down the roadway, leaves at a slight angle, goes over a bank and rolls several times, like a barrel roll, but in the same direction axes they were traveling. I asked one of the principal engineers and safety men from General Motors who was there; I said, "Where is your evidence that the hardtop sedans provide as much safety as the former centerpost construction?" Well, first of all, he tried to put me off by saying, "Well, doctor, you don't believe in suspension bridges." I said, "Yes, I do. They are a fact of life; I can see them. That wasn't what I asked you about." He said, "Well, we use the suspension bridge principle." I said, "That's fine. I don't care what principle you use. Where is your evidence?" He never would--in spite of my making a formal request in writing--he would never show me any hard engineering data to show that that top would provide as much occupant protection. Now just within the past ten days, I've seen an article in a news magazine, in fact, I think it's the current issue of Time, where a woman has successfully sued a major manufacturer because that hardtop didn't afford the protection that she felt, as a buyer of a car, she required. Well, in fact, it was in the Time magazine of May 23rd, which is today's date, on page 66, in an article called "Torts" T O R T S "Expensive Lessons". The U. S. District Court Judge in Pennsylvania held that accidents are now so common that manufacturers are liable if their cars prove

unreasonably safe in a crash, and the suit that led to that decision was brought by a woman who was riding in a Buick hardtop that flipped over. The same kind of accident I had witnessed, you see. Her roof collapsed and the woman contended that it was defective and had added to her injuries. General Motors replied that accidents are not part of the normal and foreseeable use of the car. Now if that isn't a bunch of hogwash, you see. They occur with such an amazing frequency that I don't know how you could reasonably draw that conclusion, but they wanted it for legal reasons, and that's why they did it. The judge found the defense too narrow. While auto makers, he said, can not be required to build a crash-proof car, he said passengers must be provided with a reasonably safe container within which to make the journey. Now, that's an interesting conclusion he drew because all of the evidence in the Cornell crash research projects, Automotive Crash Research Project, said in fact that what was needed was that cars should be built as containers which provided the sort of the same kind of protection as an egg crate provides for eggs.

Dr. Y.:

Right.

Dr. G.:

So that we don't rattle around inside this vehicle.

Dr. Y.:

And that was the principle that you had come to in your own mind at the time you were part of this program?

Dr. G.:

Right. And this was what we were trying to promote, and we supported research projects to try to improve design. We supported the Cornell project. We engaged in meetings and symposia and papers published. We tried to get the National Safety Council involved. Now they astutely avoided getting involved in this issue, even on seat belts. They wouldn't support seat belts until, oh, I think it was 1964, as I recall. You see, it was quite a few years later before they finally capitulated on that issue, because the National Safety Council has always been a handmaiden of the automotive manufacturers. They are a captive group and this isn't just my opinion, but the opinion of everybody I have talked to who has worked in the safety field: Dr. William Haddon, the former director of the National Highway Safety Administration; Dr. Al Chapman, at one time in charge of accident prevention in the Public Health Service, innumerable persons.

Dr. Y.:

So that in Dr. Goddard's education, you learned something about the industries involved as a result of this experience that you were to carry on with you. How would you sum up what you learned?



Dr. G.:

That the industries, the large industries in this country, have a very extensive network of relationships. They have a very large capability and influence in Congress. They have the economic wherewithal to prevent rapid progress in the field. Those were the kinds of lessons I learned. It was very frustrating to see clearly from the scientific point of view what could be done, to have those principles enunciated at meetings time after time after time, and not see any action result.

Dr. Y.:

So that it would have to come in another decade after you were on another responsibility?

Dr. G.:

Right. It was very interesting to move from that field to the Federal Aviation Agency. It was a new agency that Congress had created. Again, they were responsive to disaster.

Dr. Y.:

Like Caesar, you were asked three times and the final time....

Dr. G.:

And the final time I said, "Yes, I'll go." And I joined this new agency which had been created by Congress because of the Grand Canyon crash. Now, there had been a lot of complaints about the

lack of coordination between the civilian and military and the splinter agencies in the aviation field, but only with the occasion of the Grand Canyon crash did Congress finally act and create a Federal Aviation Agency, the administration under President Eisenhower selected General Elwood R. Quesada, Pete Quesada he was known as, to head this up, and it was my good fortune to wind up, as I've told you before, as his Civil Air Surgeon. Well, to move from the field where you tried to persuade, cajole, convince on scientific and rational bases, to a field where there was a federal agency with a strong, statutory responsibility and therefore, could act decisively, that was quite an education. Now, I had been involved in enforcement work at the local level in health department work, but this was my first experience with an enforcement agency at the national level, and it was quite intriguing to see how it worked. We had all of the responsibility that one could...and authority...that one could ask for. In fact, Congress demanded performance, and measuring up to these responsibilities, and would have oversight periods periodically. Almost every airline crash was the occasion for convening a hearing on the part of one senator or representative, at least. So what we did was carefully reviewed. Now, we had the authority that Congress gave us to suspend licenses, to ground aircraft if necessary. These were strong economic authorities, you see, and I learned at that point in time that the use of

economic sanctions is perhaps one of the most powerful instruments. I don't mean an economic sanction of a fine of a hundred dollars a day to an airline, or a two thousand dollar fine, which would be a slap on the wrist to an airline for failing to meet some required Federal Aviation Agency standard. I'm talking about the actual grounding of aircraft where they can't earn revenue or where an airline pilot would lose his license because of disobedience of the civil air regulations, you see, for drinking within the proscribed period.

Dr. Y.:

Now was pilot health the main thing you were responsible for?

Dr. G.:

Yes. When I went there I was asked to set up this Bureau of Aviation Medicine to get at the problems of medical licensure, developing standards on aging, these kinds of problems. But it became quickly apparent there were other kinds of responsibilities that we should meet that hadn't been met in the past, particularly, for example, in civil air disasters, there was no policy that there would be medical participation in the very intensive investigation that followed each airline crash. And so I instituted a policy of providing a pathologist and medical team to assist in those investigations. That was met with some skepticism on the part of the agency. And I can understand that, but there was a crash at Kure

Beach, N. C., that soon changed the minds of the other persons in the agency about the values of this kind of investigation. There was a jet--this was shortly after the advent of the jets--due to leave New York for Miami. They had some mechanical failure with the jet, and so they off-loaded the passengers, put half of them in an Electra and the remainder in a DC 6 B, and sent them on their way. This means there was about a one-hour delay in getting out of what was then Idlewild, I believe. I'm not sure of the airport of origin, but, at any rate, they were one hour late in getting out of New York. The Electra went on and no problems. The DC6 B, however, just after it crossed the coastline of North Carolina at Kure Beach, something happened to it. There was an explosion on board, but that wasn't known until later. The side of the plane was blown off, and a hole made large enough at least for one or perhaps two men to walk through in an upright position. The pilot was able to keep that plane under control, even though he had crossed the...you know, he was flying out towards...on that route you fly over water from that point down to Miami. So that's why the delay was significant, you see. Because he had barely left the coastline, he was able to turn back and make a descent to within about 1500 feet of the ground before that aircraft broke up. That old 6B was a tough bird. Everybody on board was killed. All we knew was that the accident had occurred and the approximate time and our team went out on that crash. This

was, I believe, the first one, the first major crash we went out on.

Dr. Y.:

After the teams were organized?

Dr. G.:

That's right. And so, during the investigation, it was odd that one body was washed up on Kure Beach, the rest of them were all in the litter of the aircraft in the inland area. Our pathologist who was doing the autopsies for us commented--he had been in Korea during the war--he commented that this one body almost had the kinds of wounds that saddle mines would cause in Korea. Both legs were blown off in a funny way and this puzzled him. You know, in an aircraft crash, the expert teams just descend on that site, and they recover all the pieces they can, then take them to some place nearby and then begin to reassemble, and that means, in this case, they built a framework, put chicken wire over it, and they'd hang the pieces of fuselage on it, and try to fit it back together as much as possible. Well, they hadn't finished this. The pathologist by then, who had fairly well finished his work with the bodies, went and looked this thing over, and he noted in the area where this hole had been created that there was an air vent inside, part of the overhead rack, and it had some blood spots on it, and he asked that that be removed so

that he could see if he could match that blood with the blood from the body that had been washed ashore to try to establish the seating position, you see, for at least that one, because that was an anomaly. He got that back in the lab, and he noticed up inside a grayish, powdery residue, and he called the FBI, or called the senior investigator and they turned it over to the FBI, because they then suspected dynamite. Sure enough, it was residue of dynamite. Well, it turned out, of course, that a young man had taken out a considerable amount of flight insurance, loaded a satchel full of dynamite, put it under his seat, got on board the jet, the jet was delayed, he was off-loaded and put on the DC6-B, but the timer, he couldn't then adjust the timer, or forgot or something, and instead of that plane going down far out at sea, it went down as I've described. Well, after that, of course, we had no problems.

Dr. Y.:

Then the medical teams went out always and still do, I take it.

Dr. G.:

And still do. And they've been useful on other occasions since then. Now, I had some other interesting experiences there. One of the things that one of my staff said, and brought to my attention earlier on, was the desirability of installing a flight deck voice recorder. That made sense. This would be a tape recorder

that would record on a continuous loop basis what had been said and hold it only for the last thirty minutes' conversation. So, it would be constantly wiping out and only retaining that part that might be significant should a crash occur.

Dr. Y.:

Now, this was on the plane?

Dr. G.:

This would be on the plane, you see, because...

Dr. Y.:

Not necessarily broadcast...

Dr. G.:

Oh, it wouldn't be broadcast at all, because the FAA routinely records all of the broadcasts from the aircraft and holds those thirty days, but this would be for on-board, in-the-cockpit conversations, because I was convinced just as my staff were that when something goes wrong those pilots are talking to each other and they are too busy sometimes to switch on the hand mike and carry on their conversation so that it could be recorded even though they know that those conversations are recorded in the tower. But at any rate, I proposed this as Chief of the Bureau of Aviation Medicine to the General and the staff on a number of occasions, and they wouldn't buy it. Well, then General Quesada

retired when President Kennedy was elected and President Eisenhower left office, and Najeeb Halaby came in. I proposed it to him and he wouldn't listen until one day in May of 1965, there was a crash at O'Hare Field. As I recall, it was May 30th, Decoration Day, because I remember there was a regatta in the Washington area and I got caught in the traffic and missed catching the agency plane to go out on the accident because of that regatta traffic, and I had to ride jump seat on a commercial plane to Chicago, but I got there. It was an Electra that had gone down shortly after take-off just on the edge of O'Hare Field and all of us were up in the tower at O'Hare. We had just finished listening to the tapes of the conversations between the tower and the pilot. I turned to Halaby and I said, "You see, if we had a flight deck voice recorder, we would have, I think, good knowledge of what had happened in that cockpit over and above the conversations to the tower." And I guess maybe I finally got through to somebody just by being persistent, and he ordered the Director of the Bureau of Research to work on that project and caused it to bring into being. Don't you know it took about two and a half years to develop that and get it into the aircraft? No, I'm sorry. I said it was '65; that was July of '62. It took four years to get that in. It was in May of '62.

Dr. Y.:

Right. May of '62.



Dr. G.:

Because this was before I went to the Communicable Disease Center. It didn't become widely used until '66, as I recall.

Dr. Y.:

This was not so much technological problems as it was administrative red tape or...?

Dr. G.:

Well, they claimed it was technological problems. I couldn't believe that we could send a man around the earth and have all the hardware to do that and not be able to put a flight deck voice recorder aboard an aircraft in a fashion that would protect it against the forces of crash. Now, they finally did, however. The major point though is that sometimes you have to overcome obstacles within the government...

Dr. Y.:

Right.

Dr. G.:

That are just as tough as getting manufacturers to adopt a different approach to a problem.

Dr. Y.:

Well, there were two different situations as you indicated here,

because in the FAA lobbying would be quite a different sort. It would be...

Dr. G.:

Well, here is this resistance to change and the fact that it wasn't invented here...what we call the NIH factor, not invented here...that somebody other than the Bureau of Research came up with an idea. It wasn't my original idea. I want to make that clear. It was one of my staff; I don't even remember which one now. It was an idea that had been kicked around a long time. Well, since then, that's proved to be of great value in determining the cause of aircraft crashes on several occasions: one, an F27 in the Pacific Northwest, the other, a jet that crashed into a motel in New Orleans. In both of those accidents the flight deck recorder has been instrumental in detecting the cause of crash. Then we had other sorts of benefits. We were able to find that myocardial infarction occasionally occurred in the cockpit, in flight; you know, we changed the rules, requiring an EKG of pilots, once at age 35, once a year at age 40 and thereafter.

Dr. Y.:

That hadn't been done before?

Dr. G.:

No. That hadn't been done.

Dr. Y.:

There had been physical exams but not...

Dr. G.:

Oh, yes. Every six months an airline pilot had to have a physical. We made some changes in the standards; we, of course, implemented the age 60 rule that pilots had to retire at age 60. That was a court case, it went all the way to the Supreme Court who turned it down on a writ of certiorari. Well, Judge Learned Hand, by the way, heard that case in the New York District Court, U. S. District Court there, and ruled in favor of the agency. I've always been fortunate in my federal assignments. I have been involved in a number of...have been sued a number of times. I was sued along with General Quesada on the age 60 case and yet I have never had to appear in court.

Dr. Y.:

So you were a defendant?

Dr. G.:

Oh, on a number of occasions, at FDA as well as FAA and the Communicable Disease Center. I think I was sued for \$6,000,000 as Chief of the Communicable Disease Center on one suit alone.

Dr. Y.:

Well, let's hold that one off. I wanted to ask you to give a

kind of personality sketch and analysis of Quesada.

Dr. G.:

Oh, yes. Well, General Quesada had a great influence on my perception of how a federal official meets his responsibilities to the consumer. The General was a no-nonsense administrator to begin with. He would listen to reason if you had facts. He didn't like yes-men around him, but he wanted people who had the facts to back up their arguments. He wanted answers to questions; he didn't want a long discourse. I think I could illustrate both of these points perhaps by recounting a meeting in which we were involved with the discussion of the Electra crash at LaGuardia where one came over the end of the field and busted its landing gear on a dike, a temporary dike, crash landed and there were no fatalities, but the Electra by then had come under a considerable number of...had considerable problems and the General's neck was out a mile and, by the way, that was one of the toughest and best administrative decisions I have ever seen made in the government, the one to allow the Electras to keep flying. Najeeb Halaby would have grounded the Electras. You see, that would have been easy, and everybody would have said, "Well, he had no choice." But the General made a different kind of decision. Well, back to this meeting...at stake, at one point in the meeting, the discussion was what was the roll-out of an Electra? How far after touching down

did the plane roll out before it could be brought to a complete stop and turned around and gotten off the runway. He asked one of the men from flight standards who reached down and got a thick book, a manual, an Electra manual, out of his briefcase and looked in the index and found the appropriate pages and started saying something to the effect: "Well, General, of course, depending on the wind and the temperature" and going into all of these factors. The General said, "I asked you what the roll-out was?" And the fellow started over again, "Depending on the wind and..." And the General said, "Would you take that black book and your little bag and get the hell out of this meeting, and when you figure out what the roll-out of an Electra is, come back and let me know." Well, the man, of course, wasn't used to being talked to this way, and it shook him up badly, but he did get out. Now, the point is, that the General, when he asked you a question, wanted an answer. He knew that there was no single answer. Hell, he wasn't dumb; he'd been flying airplanes since Hector was a pup. And he knew all these operating conditions could vary, but what he wanted was a figure that gave him something that then he could crank in his own factors and say: "Now, in a high wind, it probably would be flying right into the teeth of it...would be short, much shorter, much shorter; no wind..." What he wanted was a maximum roll-out, you see. Zero wind conditions and that kind of a thing. So the General was right sticky about those kinds of things. Now, I've

already recounted my first fight with him and I had a number of others, but notwithstanding that, we were good friends. We would get together at the end of every day, his general counsel and myself and we would talk over some of the battles that the agency was then involved in. And as a result of this closeness to the General, during that hectic period of time when he put in all sorts of restrictions on the airlines and requirements for safety. He used to make the point, "Look, we are the representatives of the public. No one else is interested in protecting their interests. That's what Congress said we should do." In effect he was saying, "We are their advocates." You see. I can remember he used to say, "Now, when somebody buys a ticket, they're counting on us to make sure that that pilot is fit to be on that flight deck; fit in the sense of physically fit; fit in the sense of knowing the technical procedures and understanding and demonstrating how to fly that aircraft. That was our job", he said. "There is nobody else that will do that. That's our responsibility."

Dr. Y.:

So that no matter how much flak you might get and how many voices elsewhere might be raised, you had to keep thinking of that.

Dr. G.:

Right. That was the point. He was roundly criticized. The Air

Line Pilots Association was after him all the time for harassing the airlines pilots, making it unsafe for them because he was a threat to them. All he said was, "You guys are responsible for flying those planes. You damn well ought to stay up on the flight deck. Your job isn't public relations back in the rear end with the passengers, talking to them. That's not your job. You're to fly the airplane. And these are new aircraft. They are faster. They are far different from what we have been flying all of those years, and it's tricky. You stay up there, fellows." That was the flight deck rule. Then he put in a requirement that made the manufacturers install radar and DME, distance measuring equipment, steps which they wouldn't have taken on their own initiative. Now, I noticed, and I don't have that clipping here. It's at the office, I'm sorry to say. Recently, the Civil Aeronautics Board, in a hearing it was revealed that Pan Am and the other airlines had refused to install a piece of equipment that cost less than a hundred dollars, for safety. A piece of safety equipment. You see, it was held responsible for an aircraft crash. Well, you see, here again, it's an illustration of the failure of the private sector of our economy to move for public protection, and for some reason they are short-sighted on these things and then there has to be a regulatory agency, and I think that's unfortunate, but I've now grown to accept that as a necessity. Well, the General was tough. He didn't run in a

popularity contest. He wasn't there to win friends. He was fair though. He had an innate sense of fairness about him. He was just tougher than hell and demanding as hell. But I always thought fair and above all, he was the protector of the public. The public's advocate, in this setting.

Dr. Y.:

He wasn't mushy about it.

Dr. G.:

Oh, he was decisive. He had a great ability to sort the wheat from the chaff. Other administrators I've watched would bumble around with things and assign the job to a committee, but the General wanted all the facts that he could get his hands on. He would listen to those and he would mull it over, and then he would make a decision and he didn't have trouble making decisions. I can remember we went to a crash in Boston one time. He and I flew up one morning. The crash had occurred about 5:45 the evening before and we went up in a DC3. That's what the agency had to put up with in those days. They now have jets. But we had a DC3 and we flew up to Boston and we got there and we were met by some of the other personnel from the agency, and they had a car and we were about to drive off to see the site of the accident and talk to some other people when a man came running up to the car and Pete put his hand up to his brow and said, "Oh, God, do I have



to talk to Crocker?" And this man was Crocker Snow who was the assistant manager of the airport there in Massachusetts, the port authority at Boston and Crocker came to the car and stuck his head in and said, "General, there's something I think you ought to know." And the General said, "What is it, Crocker? I'm busy." Crocker said, "I know you're busy, General, but", he said, "out here on this active runway that was active last night when the flight took off and crashed, there are hundreds of dead birds." Well, the General's ears went up almost like antenna, you know. He was the kind of guy you could look at and he would react and you could see a sudden flash of interest. He said, "Show me." And so we went out to that active runway that had been the active runway at sundown when the Electra went off the evening before, and sure enough, there were hundreds of dead starlings. The General picked some up and looked at them and turned to me and said, "Doc, did all of these birds die at the same time?" I said, "General, I don't know, but I'll get somebody from Harvard, an entomologist, and we'll find out." He threw them down on the ground and said, "They all died at the same time, I know." And he walked around the runway and looked at the distribution pattern of the birds, asked a few questions about the time of day, established the facts again of the accident in his mind, asked me specifically to find out what time they died, if I could, and then we went inside. The reporters were all there, you see. They

hadn't been able to get to him and they got to him then. They had TV cameras and movie cameras, the whole business, and they started a press conference. The General said: "It appears to me that the aircraft was not at fault, that a large number of starlings flew up in front of the aircraft and may have gotten in the engine and caused the power failure." We were in the process then of trying to recover the aircraft from the bottom of the harbor at the same time. Well, the Chairman of the Civil Aeronautics Board was there, Allen Boyd, and he was just furious that Pete would make such a statement.

Dr. Y.:

Shoot from the hip that fast?

Dr. G.:

That's right, because it was the Civil Aeronautics Board's prerogative to say what the probable cause of an accident was. Now, Pete, on the other hand, said: "My responsibility is to the public in terms of making a decision whether this aircraft is unsafe or not and whether it would be permitted to continue flying and I, therefore, have to make such judgments. They are not final judgments; they are operating judgments for this point in time." And I mention that because this is how decisive he could be, and he was subsequently proven to be right. No question about it, the starlings did get into the air intakes, block

the air intakes, cause arcing across the busses which then made the aircraft uncontrollable because it was an electric boost assist on the controls of the Electra, and it caused the plane to crash. But this was the kind of decisiveness that we had from this man. He would go to the scene himself, which is another interesting thing, you see. He wanted to see for himself what had happened. He wasn't the greatest scientist I ever worked for by any means, but he had flown enough airplanes of different kinds and had seen enough accidents and had enough knowledge of the aviation field that a lot of that was cranked into his computer and he was just so close to right so many times, it hurt. A great guy though. But what I would stress about this man above all was his character, his decisiveness, his feel for his responsibility. It's interesting...from the Republican administration.

Dr. Y.:

Right. How did he differ as an administrator from his successor?

Dr. G.:

Well, his successor would vacillate. His successor couldn't make decisions and would refer things to committees, and yet Najeeb Halaby had been a test pilot. He was a lawyer; he was far more educated than Pete Quesada was in the sense of academic training, but, yet, he wasn't as good an administrator. He didn't have the

leadership qualities that Quesada had.

Dr. Y.:

The ability to quickly make at least a temporary decision is one of your key points in leadership, isn't it?

Dr. G.:

That's an important thing. You have to...now the decision may be no decision for this point in time. That's a valid decision to make, too. But, see, what people grow uncomfortable with is a situation where decisions don't get made at all. You see, it's a nice balance between moving too soon and waiting forever that you have to strike. I've always been accused of being like Pete and I don't mind that. That's quite a compliment. In shooting from the hip, you see. What do they mean "shooting from the hip?" That means you haven't waited until you got all the facts. Lots of time, you have facts cranked in from previous experience, from exposure over a long period of time to the field or other kinds of knowledge. It's difficult to substantiate by showing pieces of paper, so, therefore, you don't have facts and you're shooting from the hip. Instinct is still an important part of administration, but sure, in this day of technology, you have to have lots and lots of data and you have to rely on your people to give you good data and when they don't, you get in trouble. I got in trouble at FDA on a drug survey because I relied on the data

from a study that I asked to be carried out. My people carried it out and they really didn't think I was serious about it, and they gave me bad facts and I got hung up by those.

Dr. Y.:

Now which particular case was that?

Dr. G.:

Oh, this was early in office, I asked that each district laboratory go out into the market and buy x number of drugs and bring them into the laboratory and see how they measured up to standards. And the results were just horrendous and we asked questions. Mr. Rankin and I both asked questions of the district directors, "Are you sure about these results?" "Oh, yes. Oh, yes", they said. But in the long run, the percentage wasn't as high as I had stated, based on data they gave me.

Dr. Y.:

So, the manufacturers did their tests and found different, as I remember.

Dr. G.:

That's correct. Then they said, "You see, you're shooting from the hip. You were wrong." So, your agency people, your staff, whether you are in the government or not, they have to be with you. And you have to rely on them and they have to understand that.

Dr. Y.:

And they have to be competent to do what you want them to.

Dr. G.:

Oh, indeed, they have to be competent. Well, the General had a great impact, I thought, on aviation. We, all of us who fly, owe him a great deal, because literally the most important progress in the past decade was made under his leadership. You see, the important technological advances in terms of what is required in civil aviation, the main thrust was under General Quesada, not under Najeeb Halaby. Najeeb Halaby's handling unfortunately of the supersonic transport was so inefficient and wishy-washy that President Kennedy took that away from him and gave it to Vice-President Johnson to handle. We had a 144-man committee for supersonic transport at FAA under Najeeb Halaby. Now, he came in and he was going to have a "lean, clean, keen" administration. That's the way he described it. He was marvelous with words, very suave, smooth guy, and he, of course, was inferring that under Quesada, we didn't have a "lean, clean, keen" operation. Within six months, the size of that front office had more than doubled under Halaby. Committees proliferated; decisions didn't get made. Instead of delegating more to the field, which is what he said he was going to do, no decision got made until it got to his desk. It was amazing to watch and I learned a lot about administration from watching

that, too, and I decided if you ever have a job at the top of an agency, one thing you have to be willing to do is to delegate and mean it, because your people know whether you mean it or not doggone fast. Those regional administrators who thought they had had delegations of authority under Halaby found out that they hadn't, and so this was a valuable lesson in administration, too, although I stayed there but 18 months.

Dr. Y.:

I read in one of the trade periodicals a statement that you scared the agency, that you were so active that the agency got afraid that the Public Health Service was going to take over its whole medical set-up.

Dr. G.:

Yes, I think that was true when I first went there. But let me finish up on Quesada.

Dr. Y.:

Right.

Dr. G.:

He was attacked constantly, undeservedly so, by pressure groups. I learned some other things about pressure groups through him and through that experience. One of the pressure groups was the Aircraft Owners and Pilots Association, a self-serving group if I've

ever seen one, that is operated by a couple of characters out in Bethesda who really do so for their own profit, and they keep issues stirred up to keep readership in their magazine up and to convince the membership that they...Max Karant is the editor of the Aircraft Owners and Pilots Association.

Dr. Y.:

How is that spelled?

Dr. G.:

K A R A N T, and I've forgotten the president of AOPA, I've forgotten his name. But those two people kept the pot stirred all the time, and they were constantly attacking the agency in articles, stirring up trouble with Congress, and there were a couple of Congressmen who would listen to the AOPA. One of them was a senator from California who since has died, who used to give us a lot of difficulty. He was an AOPA man. Another was a senator from Indiana, and he didn't like the General because the General came from the military. Now, just before the General left, he went up on the Hill and almost, I would say, it was his valedictory; is that correct speech? He talked about the vested interest groups, and he said: "After this period of a year and a half, I have observed a pattern." He said, "First, they attack the rule."



Dr. Y.:

The rule?

Dr. G.:

Yes. Then they attack the way the rule is administered. If that fails, they attack the agency as being bureaucratic or spending the taxpayer's money frivolously. If that fails, they attack the man. He said, "I have now seen this happen." And sure enough that has, and I've watched that since then in my own experience, and that is a pattern that these kinds of organizations use, you see. AOPA, for example, got nowhere in attacking certain laws and rules which had the force and effect of laws, and then they would start complaining about the agency's uneven administration of these. They weren't fair in the way that they administered them differently in one region versus another. Then that didn't get them anyplace, so then they next attacked the agency itself in terms of having one employee for every two aircraft in the United States. True enough, they do, but what's that got to do with anything, you see? What they neglected to say then was: "What are all of those employees there for?" 16,000 of them to maintain navigational aids for the airlines, you see. 17,000 in air traffic control work.

Dr. Y.:

They made it sound as if...

Dr. G.:

They made it sound as if there was one inspector harassing a private pilot for every two aircraft in the United States, you see, and that was the common tactic that they employed. Then they attacked the General personally, on a personal basis, you see, in their editorials and in their dealings with Congress. Now, I've seen that same kind of thing later on in the drug industry when I went to FDA.

Dr. Y.:

Right.

Dr. G.:

Is that a good place to change tapes?

Dr. Y.:

Yes. I think we are about at the end of this one. Let me flip it over.

Dr. G.:

Okay.

Dr. G.:

Well, I left FAA September 1, 1962, to take over the Communicable Disease Center.

Dr. Y.:

Well, now in the leaving, this was positive from your point of

view? What about this reference in the trade press that there was some pressure behind it because the agency worried about the Public Health Service taking over?

Dr. G.:

No. I'm talking about leaving FAA.

Dr. Y.:

Well, that's what I'm talking about, too.

Dr. G.:

Oh. Well. At one time there was some fear on the part of the agency employees in the Bureau of Medicine that Public Health Service people were going to take over. This just wasn't so and I was able to reassure them. I brought some officers in from other services on assignment, including the Public Health Service, but that agency had been sort of ingrown, too, and I felt it was desirable to expand their horizons a little by different kinds of training and by different kinds of people on the staff, and so I sought to accomplish that. My leaving was an interesting thing in itself. I hadn't been getting along well with Najeeb Halaby, and I knew that I had to get out of there because we were starting to fight in staff meetings rather openly.

Dr. Y.:

What were the problems and issues?

Dr. G.:

Well, one of the problems was that Najeeb started interfering and making medical decisions that he wasn't competent to make on pilot licensing, overruling the Civil Air Surgeon, in effect. And if you can't work for a man and believe in what he does, you better get out. I can remember a sort of amusing episode in staff meeting. Najeeb had just come back from Texas where he had gotten into a fracas with a congressman from San Antonio of Mexican descent, a Mexican-American, Gonzalez, and Najeeb had made some remark that gave offense to the local people and so Gonzalez was mad at him. Now, at that particular staff meeting, Najeeb asked the staff, about twenty men in the room at the time, "How many of you are going to the dedication of the new air route traffic control center at Fort Collins, Colorado, next week?" And about fifteen people held their hands up, and he was horrified. He said, "My heavens, that's an awful number of people to go out to the a...uh...uh...," and he was searching for a word to describe Fort Collins, and I used the phrase that he had used in Texas. I said, "A hick town?" God, if looks could have killed you know, Najeeb would have had me dead on the spot.

Dr. Y.:

That was your impish puckishness.

Dr. G.:

That's right. I just couldn't resist putting it to him, because, by then, he and I were at each other's throats, and he had used this phrase and described this Texas town, and Gonzalez took offense, and it was in the paper and I knew about it, and so I just gave it back to him, and twisted the knife as I slid it in. Well, I knew I had to get out of there. I went over to the Public Health Service to see Dr. Kurlander who was Assistant Surgeon General, worked in the immediate office of the Surgeon General, a sort of a right hand man to Dr. Luther Terry at that time. I had known Arnie for a number of years, going back to when he was sick one time. He was more senior than I. I was a four-striper, you know, medical director is our title but it was four stripes. I remember taking care of him once when I was a very junior officer, in fact, I was interning and he was a two-striper, and so I had known Arnie for a number of years, and I went to see Arnie and told him I had to come back to the Service. There was some pressure being put on by the agency, interestingly enough, to get me a star as Civil Air Surgeon, because the job warranted a star. It was a bureau chief's job, and the military equivalent for bureau chief in an independent agency is two stars. Well, the Public Health Service didn't want to put any more stars out on officers on loan, so they indicated I should come over and talk to them. And I knew I had to get out of FAA, so I went out to

see Arnie and he said, "Jim, why do you think that you should get a star?" I said, "Do you mean over there or back here?" He said, "Either one." I told Arnie, I said, "Well, I've noticed some of the people you've put stars on lately, and I just happen to think I'm about as good as any of those are." Terrible thing to say, but we'd known each other a long time. He said, "Well, you're pretty damn cocky, aren't you?" I said, "No, Arnie, I just think I know what I can do and what these other guys are capable of, and I think I'm just as good." He said, "Well now, Jim, you're only thirty-eight years old--I was going on thirty-nine at the time--and he said, "You've got a long time to wait." I said, "Well, Arnie, you know. I think I merit it, I'm ready for a larger job, so here I am. Now you decide whether you want to give it to me over there or give it to me back here. I'd just as soon come back here." So he laughed and he said, "All right. We've got three star grade jobs open right now. One of these is the Director of the Hill-Burton activities." That's the program that for many years provided funds to communities on a one-third, one-third, one-third basis for hospital construction. And then he said, "That's a one-star job, but I sort of think that's a dead end. But there it is. It's available. The other is Indian Health Service, and you know what that program is." I said, "Yup." He said, "The third is the Communicable Disease Center." He said, "Now, I'll tell you what. You go

home tonight and think about those three and come back tomorrow and tell me which, in the order of your preference, and why you want it." I said, "Fine." I went back to see Arnie the next day and said, "Okay, I've thought about it and number one: I think I'm best qualified for the Indian Health Service, and I want that job." He said, "Well, why are you qualified for that?" I said, "Well, I've trained in local health work, I have a master's in public health administration, I've been out on the Indian reservations, I've seen some of the problems, I'm sympathetic with the need, and I think I'm better trained for that particular job than the other two." "Okay", he said. "What's number two?" I said, "Well, the hospitals, even though it's a dead end job. You know, I've worked in hospitals like all of us have. I could believe in that program. I think I'm reasonably well-fitted, not the best in the world, but I studied hospital administration while I was up at Harvard. I have a little...a few ideas about the field." "Okay," he said, "that means the Communicable Disease Center is number three." I said, "Yeah. I don't know anything about communicable disease other than what you get taught in medical school. And, you know, it's not my bag, Arnie." He said, "Congratulations. You're the new chief of the Communicable Disease Center." I said, "You bastard."

Dr. Y.:

He had known it...

Dr. G.:

He had known it the day before, you see. He and the Surgeon General had decided where they were going to put me. I said, "Well, if you don't mind telling me, now why is that? What's all this nonsense about?" "Well", he said, "Jim, we think you still got a little growing to do, and we think that's a good place for you to do your growing. So you go down there to Atlanta September 1." So, sure enough, I did.

Dr. Y.:

Well, now, you mentioned last time about Dr. Burney.

Dr. G.:

That was vis a vis my appointment to FAA.

Dr. Y.:

Right. I kind of wanted to get your view of him as Surgeon General and also Dr. Terry as Surgeon General if you knew them well enough.

Dr. G.:

Yeah. Well, I think that we all knew them well enough, whether we knew them personally. I knew them both fairly well, I think. I wasn't a day-by-day intimate of either one, but I saw enough of them in meetings, read enough of their pronouncements, talked to enough people who knew them. I felt I had a pretty good



understanding of them. Let me start out by saying that we really had...I worked under Len Scheele, too, you know, when I first came in and prior to that, of course, was Tom Parran. Now, Tom Parran was the last really good Surgeon General that we had.

Dr. Y.:

Is that your judgment?

Dr. G.:

Oh, yes.

Dr. Y.:

Well, now, explain this.

Dr. G.:

Parran was a forceful guy; after all, don't forget, he tackled the taboo on using the word "syphillis" on radio; he knew Roosevelt well enough that he could be reasonably tough and he was; he was a leader. Now, Len Scheele was my idea of nothing as a leader. He was a cold fish. No personal relationships with people that amounted to anything. He was afraid of issues. The birth control thing came up one time. Joe Dean under Len Scheele put up a proposal with the Surgeon General's office that birth control was a public health problem and we ought to get competent in the field. Now, don't forget, this was back in

'52. Yeah. Joe Dean got busted from a two-star to a four-striper.

Dr. Y.:

Just for bringing up that subject?

Dr. G.:

You bet he did. Yes, sir. Now, Scheele didn't want anybody rocking the boat, you see. Now, Burney was an old line...Scheele got in by his acquaintantship with Harry Truman, you know. Burney had been out in Indiana on loan as the state health officer, and I think Mary Lasker was responsible for Burney's appointment. Now Lee was an old-line V. D. man, old-line Public Health Service officer who came in, as I recall, in the early thirties. A good group of people came in then, the thirties. He was easier to relate to than Len, but I don't think provided the level of leadership that we should have had, nor did Luther Terry who got in because he was a close friend of Senator Lister Hill. In fact, Luther was named for Lister's daddy, Luther Hill.

Dr. Y.:

I didn't know that.

Dr. G.:

Yes.

Dr. Y:

And Hill had this chairmanship of the most important...

Dr. G.:

Oh, yes. And so he had a great deal to say, and Mary Lasker and the whole crew did. Now, it was unfortunate, from my point of view, that during this period of time there was one guy that I think should have been Surgeon General, and that was Jim Shannon.

Dr. Y.:

Who ran NIH?

Dr. G.:

Well, one of the major bureaus of the Public Health Service was and is today the National Institutes of Health, and Jim was the most imaginative, creative administrator in the Public Health Service and the most capable, bar none. You know, as much as I've fought with him, in staff meetings, on different occasions, over issues, I never lost my admiration for that man's capability. I think we would have had a far stronger Public Health Service had we had, instead of Len Scheele, Jim Shannon, or certainly instead of Lee Burney or Luther Terry, because NIH under Jim, they were able to fight the Surgeon General's office successfully. The Surgeons General, frankly, were afraid of Jim Shannon.

lots of pressure being generated by myself and supporters of Carruth Wagner, et cetera, et cetera.

Dr. Y.:

What kind of backing did you have and what kind of backing did Stewart have?

Dr. G.:

Well, I can't speak for what kind of backing Stewart had, other than he had Wilbur Cohen in his corner, the Under Secretary. Now, there is a funny thing. Don't forget that in early...in that year of '65, Luther Terry, we had a new...let's see, Johnson came in, elected in the fall of '64 and came into office on his own election in January of '65. Right?

Dr. Y.:

Right.

Dr. G.:

So, at that point in time, there was some talk that Luther Terry might be leaving. I went to see Luther in January of '65 and said, "Luther, I don't expect you to answer me, but if you would, it would be helpful, and I'm here to tell you what my plans are. I've heard that you might be leaving. Now, if you are and if you can tell me in confidence, fine. But whether you do or not, I want you to know I'm trying to try to get your job as Surgeon

General." And he laughed and he said, "Well, Jim, I appreciate your coming in to tell me." I was friendly with these people. I don't want the impression given that I was ungrateful to Luther, because he had appointed me as star grade officer, and chief of CDC and so on. But he wouldn't tell me, in fact, and so I did start to generate some support at that time with various groups.

Dr. Y.:

If and as he really retired?

Dr. G.:

Yes. Yes. And so right after seeing him, I'd given some thought, and I knew that Bill Stewart was then working in the office of the Secretary as a special assistant, so I went around the corner and saw Bill after seeing Luther, and I said, "Bill, I just talked to Luther. I'm going to try to make a run for it, and if I get it would you be my deputy?" He said, "Why, sure. I'd be happy to, Jim." And we left it at that.

Dr. Y.:

He didn't say he was making a run for it?

Dr. G.:

No. This was back in January. Now, as it turned out, Luther was reappointed and did stay on until September, October. The job

was then vacant and, at that point in time, we really started campaigning actively, and we really started trying to generate as much political support as we could. Now, by "political support," I mean two kinds: one, organizational support, AMA, American College of Surgeons, et cetera, et cetera; the other, support up on the Hill. Well, I went to see John Fogarty and I, for a number of years, had what I thought was a plan for an effective reorganization of the Public Health Service. This dated back to, oh, 1962 reorganization when I first proposed this plan. And so I had this in hand and I knew John would ask me that, and I went to see him about my candidacy as Surgeon General. Well, I told him what I would like to see done with the Public Health Service, namely, doing away with all the bureaus except the institutes and they have twelve or thirteen institutes of health, with each one of the institute directors reporting directly to the Surgeon General. Now, that's when Fogarty, who for years had worked with Shannon, you see, became concerned. He said, "What would you do with Dr. Shannon?" I said, "I would make him Deputy Surgeon General for planning, not for operations, but for planning, because," I said, "Jim is a master at looking for and seeing what the needs will be in a given area and developing new activities, and that's an area that is extremely important." Well, Fogarty wouldn't buy that, it was too much loss of prestige for Shannon with whom he had worked

so closely over the years. So he told me he wouldn't support my candidacy at all, but he didn't say he would fight me, which was equally important. Well, Luther Hill wouldn't commit himself one way or another, and I was asked if I wanted Mary Lasker's support. Friends of mine who knew what I was up to offered to act as intermediaries, and I said, "No, I wasn't about to be another one of Mary's little lambs." Well, apparently, that word got back to her, too, you see, so it wasn't very wise on my part. I think she, as a result, actively opposed by selection. Well, to wind up what could be a long story...

Dr. Y.:

What about the organizational side? Did you work at that, too?

Dr. G.:

Oh, yes. I worked at that. It was difficult to get commitments, or at least it was on the ground rules under which I would operate, because I wouldn't promise anybody anything. If they wanted to support me, I would welcome that support. So, John Gardner didn't know the cast of characters. He was getting all sorts of outside pressure and that's just the wrong thing to do with a guy like John Gardner, and he turned to Wilbur and told him, he said, "Wilbur, who do you think we ought to make Surgeon General?" Wilbur said, "I think Bill Stewart. He's worked up here and he knows the problems and I can work with him." What he was really

saying was that he could control Bill. He knew Bill was very passive and wouldn't fight, and all that subsequently has been proven to be true in my book, in my appraisal of what's happened to the Public Health Service, and Wilbur didn't want anybody up there that would fight him, because Wilbur doesn't like doctors.

Dr. Y.:

I see. Well, I wondered. There are some things about relationships involving you and him later on that I think we need to go into.

Dr. G.:

Well, this was how Bill Stewart came to be appointed, in my opinion. Well, that led then to...it was a funny thing. I was at CDC and I used to go and work out every day at Emory at noon at the gym, and I was over there tying my tennis shoes, when somebody came in, one of my staff who also worked out and said, "Hey, they just announced the new Surgeon General on the radio." I didn't dare look up and I said, "Who?" He said, "Bill Stewart." I thought, "Oh, for Christ sake." Well, I was disappointed as hell, which you might expect.

Dr. Y.:

Sure.

Dr. G.:

But...



Dr. Y.:

But, you learned to take these things...

Dr. G.:

Oh, yes. If you can't stand the gaff, you can't play in the ball game. So, when they had an exercise, that was, if I remember correctly, that was late in October, about mid-October probably. And so, I can remember clearly, Dave Sencer and I sitting around early in December, and Dave said, "Hey, I saw in the paper today that George Larrick retired." And I laughed and said, "With my luck, Dave, I'll get that job." Just joking, and a few days later, the Surgeon General called and said, "Jim, the Secretary would like to see you." "Well, fine, when? Does he want me to come up tomorrow?" Bill said, "Oh, no, just the next time you're in town, he'd just like to see you. Nothing urgent." I said, "What about, Bill?" He said, "Well, the Secretary didn't tell me." Okay. So, a week later I had to be in Washington, and I called the Secretary's office when I was there and I said, "Secretary Gardner indicated he would like to see me." "Oh, yes, Dr. Goddard. Could you come in tomorrow at such and such a time?" I said, "Yes, I'll be in town tomorrow and I'll come in." Well, I went in and met this Secretary Gardner.

Dr. Y.:

This was the first time you had met him?

Dr. G.:

The first time I had met him. A tall man, sort of a rugged face, a tanned individual, soft-spoken person and we talked around for a bit. He seemed right cold to me and he asked me some questions. He said what he was trying to do was to become acquainted with the major programs in the health area. He didn't have a feel for these and would I, therefore, tell him some of our major problems and high priority items, which I did. "Well," he said, as I enumerated the last one, "that last one's interesting. I think I need to know a little more about that. Would you send me a staff paper on that, outline?" "Fine." I left his office and on the way out, I remember saying to myself, "Well, he tested my verbal communicative skills. Now he wants to test my written communicative skills." So I went back to CDC and prepared what I had hoped would wind up as a one-page memorandum outlining the laboratory inspection problem, laboratory standards problem, and a seven or eight page attachment. Try as hard as I could, I couldn't get that memorandum down to but one and a third pages and seven or eight pages of an attachment, and I sent it up to him. Well, I knew he was sizing me up for something. The FDA job was still open. This was just around...getting close to Christmas and he called me and asked me when I would be in Washington next? I said, "Well, between Christmas and New Year." Right after New Year's, I have forgotten now which it was, but he

said, "I want to see you." He said, "I'd like to talk to you about that vacant job at FDA. You know, we've been looking for somebody, and your name keeps coming up to the top of the list." He said, "I would like to talk to you." He said, "I'm just alerting you to it now so that you can be thinking about it. Don't tell me yes or no right now." So, I went up to see him the first part of January or the last of December, the last of December, as I recall, 28th or '9th, and he told me that the Miles Committee had recommended some changes be made at FDA. There were certain problems and they had recommended a person with certain kinds of capabilities and I seemed to fill the bill. Would I take the job? I asked him what his expectations were if I took the job and what kind of support would I have. He reassured me on support and said he expected that the person who would take it, and if it were me that I would upgrade the competency of the agency, bring new kinds of talents in and get them accomplishing their mission, because he was quite concerned that they weren't really doing their job. So, I told him I would take the job.

Dr. Y.:

You told him right then and there?

Dr. G.:

I said: "I want to think about it, but will let you know in a day or two. I know you are anxious to move, but I think I will

say 'Yes.'" He said, "I hope you will." And so I left. I called him back then the next day, as I recall, from Atlanta, and told him I would.

Dr. Y.:

Did you talk to Boisfeuillet Jones at all during this period?

He was on this committee.

Dr. G.:

No, not at that point in time. An odd thing: when I first went to CDC, I hadn't been at CDC a month, and Boisfeuillet Jones was Assistant Secretary for Health at that time, and he called me and asked me to come up and see him in Washington or stop in the next time I was in Washington. Well, in those days, you got into Washington at least once a week as Chief of CDC, so I stopped and saw Bo, and he said he was looking for new Director of the Bureau of Medicine at FDA and would I take the job. And I begged off because at that time, our oldest daughter, Peggy, was being seen by a psychiatrist. We had just started in the family therapy at Emory with Dr. Alfred Messer, and Peggy had had some psychiatric problems, emotional adjustment kind of thing, family and social adjustment thing, for several years. We had had her at one time in a school in Pennsylvania, not the Deveraux, but Wilkes Barre Children's Social Center, it's called, and she had been seen by psychiatrists at Children's and so when we came here, we continued

and got under Dr. Messer's care, and she was making progress, and we had moved so often that the doctor thought this could be a factor, and here she was in the eleventh grade in high school and we had just moved and she had just enrolled in a new school and I said, "Bo, I've never said no to any request from the Public Health Service, but I would like to be let off the hook." And he thought my request was not unreasonable, and so he said, "Fine. I'll find somebody else." Well, as you know, it took him a long time to find somebody else.

Dr. Y.:

It certainly did.

Dr. G.:

Well, at any rate, that was a right interesting thing to look back on in retrospect, because when I went in as Commissioner of FDA, Joe Sadusk was the Medical Director.

Dr. Y.:

Had you known him before?

Dr. G.:

Yes. Joe had been an assistant professor of medicine, of clinical medicine, at George Washington University Medical School when I was a senior medical student, and we used to have him on service, as we said, out at what we called Gallinger, which is now D. C.

General Hospital. And so I had known Dr. Sadusk as one of my assistant professors in medical school, and I had run into him from time to time since then, in various capacities. You know, Joe worked in a number of places. So I knew him before. I also got to know him while I was chief at CDC, because I went to him once on a problem involving lab diagnostic tests that was bottled up in the FDA, and it was on Francis Kelsey's desk, and he threw his hands up and he said, "Jim, I can't get her to do anything." So, I had direct contact with Joe while I was at CDC.

Dr. Y.:

I think I would like to go on and get this business of your getting into the new office of Commissioner, and then we'll go on back before we talk about the tasks of that position and look at the CDC because it was important background, too.

Dr. G.:

After seeing the Secretary that time and calling him, then the Secretary called me back one day and said, "Jim, you know one thing that is most difficult to contend with in this town is a secret." He said, "I don't want any premature disclosure of this." I said, "I haven't told anybody, Mr. Secretary, except my wife, and she won't say anything to anyone." He said, "Well, what's your schedule like the next few days?" I told him it could be adjusted. He said, "Why don't you go someplace that

you're not too accessible?" And so, I went to Puerto Rico after he made the suggestion. We had a laboratory in Puerto Rico, so I had a perfectly reasonable basis for going down and visiting Fred Ferguson's laboratory. I quite often did this, once or twice a year, usually once a year. So, I just went down to Puerto Rico as a routine visit.

Dr. Y.:

I know. When it was announced, I called your home and was told you were in Puerto Rico.

Dr. G.:

That's right. In fact, I had a call within a day after the Secretary talked to me. I had a call from Morton Mintz in Washington, saying that he had heard this and this and this and I said, "Well, I'm sorry. You know something that I don't know." Now, it's just necessary to do this.

Dr. Y.:

Sure. You had promised the Secretary.

Dr. G.:

That's right, and I said, "You know something I don't know."

Dr. Y.:

So that your dealings...

Dr. G.:

I put him off successfully.

Dr. Y.:

Your dealings were entirely with Secretary Gardner?

Dr. G.:

Entirely. No one else.

Dr. Y.:

If the White House was involved in the decision-making process...

Dr. G.:

They were. Because one of the things that the Secretary indicated that he wanted to do, he didn't want any premature leak because this upset the White House a great deal.

Dr. Y.:

I understand that. I remember that...

Dr. G.:

That was the kiss of death with Mr. Johnson, was for this to be disclosed prematurely, and so the Secretary was doing something that was absolutely necessary in telling me to get out of town and protecting his own flank, because he felt that I could do the job, and he wanted me in it, we had agreed and so, therefore, it was important.



Dr. Y.:

What kind of checks had he made with the White House?

Dr. G.:

That was his business. I had no knowledge of that.

Dr. Y.:

Or with Congress?

Dr. G.:

Or with anybody on the Hill.

Dr. Y.:

Right.

Dr. G.:

I wouldn't know.

Dr. Y.:

This ad hoc committee that...

Dr. G.:

The Miles Committee?

Dr. Y.:

The Miles Committee had a number of people on it, and it received names from a great many sources, from industry, from within Food and Drug. They asked the members of this advisory council that

I was on and so on.

Dr. G.:

Who was on that committee? I've forgotten.

Dr. Y.:

Rufus Miles who was chairman as you suggested. Boisfeuillet Jones was on and Edward Dempsey who had held the same position right after Boisfeuillet. John Corson who was from Princeton and once had been a management consultant man, and an Atomic Energy Commission member named Dwight Ink, and then the staff work evidently was done by two aides in HEW, one of whom was Dean Coston.

Dr. G.:

Yes. I know Dean.

Dr. Y.:

Who was shortly, of course, to become Wilbur Cohen's deputy. Now that was the group which sorted the names out, not only, I take it, for this position but for a number of others.

Dr. G.:

I don't know about the latter. I knew that they were involved. I only knew two of those people, three, Rufus Miles, Dempsey and Bo Jones, of course. I knew none of the others. I had never heard of Dean Coston until I took the job and found him as

Wilbur's deputy.

Dr. Y.:

One of the other positions was an assistant HEW deputy secretaryship for environmental health that they were considering at the time. There wasn't any action as far as I know, and you weren't talked to about that? Did you talk at all to George Larrick during this process of consideration?

Dr. G.:

Never.

Dr. Y.:

Right.

Dr. G.:

I didn't see George. You see, I had dealt with FDA at Larrick's level too, on the egg problem.

Dr. Y.:

The incubator egg rejects?

Dr. G.:

No. We had a problem with an epidemic of salmonellosis that was traced back through our CDC efforts and joint efforts ultimately with FDA to a farming area in Pennsylvania, and I had dealt with him on a couple of other things. I had dealt with him earlier

when I was with accident prevention on the cranberry episode.

Dr. Y.:

Well, now how was accident prevention involved in that?

Dr. G.:

Well, we had the national clearing house for poison control centers and we were handling queries from all over the country, you see, the poison control centers were. And we had some competency in toxicological capabilities, and so the Secretary cast a wide net.

Dr. Y.:

That was Secretary Fleming.

Dr. G.:

Secretary Fleming. I can remember spending late evenings up in the Secretary's office on that task force on cranberries.

Dr. Y.:

What did you think of Secretary Fleming from the point of view of that episode? Do you remember he carried the ball himself in that episode, and did it not only right out in front of the troops but in a very active way, and industry was really jumping all over him.

Dr. G.:

Yes. But I thought that he did a right good job on this. I was sort of impressed by Secretary Fleming. I didn't have much of any other contact with him. It wouldn't be fair for me to make a judgment about him in general, other than the same kind I could make about him in contrast with Ribicoff, whom I had met while he was still governor and interested in highway safety, or I could make about the Secretary, the one from Rochester.

Dr. Y.:

Folsom.

Dr. G.:

Folsom. Marion B. Folsom, or indeed, anybody back through and including Ewing and Madam Butterfly from Texas.

Dr. Y.:

Mrs. Hobby.

Dr. G.:

Oveta Culp Hobby. I could make, you know, just general observations. Oveta Culp, she was something else again. She didn't want anybody to leave until she left, and poor Len Scheele spent many a night just sitting in his office waiting for a call that never came. Of course, the famous remark about the polio vaccine: "Who could have anticipated such a demand?" I didn't think she was

was very competent as a Secretary. I thought Folsom, at least among the people I spoke to and from what I could see from my lowly vantage point, had the respect of a great many people in the department. He was well thought of as a Secretary within the establishment. Fleming: there were strong admirers and haters. He evoked stronger emotions. Folsom didn't evoke strong emotions, you see. Ribicoff was viewed as being there as a political expediency. Celebrezze was sort of viewed as a joke by the people in the department. I had dealings with him directly, too. And you got the impression that Tony really had gotten one notch higher than he should have, if maybe not two. There's a book out now called "The Peter Principle" which elucidates that phenomenon. It points out that people tend to get one level above their level of competency because of the system. I had that feeling about Mr. Celebrezze.

Dr. Y.:

Well, now before you go up to the...

Dr. G.:

I went to Puerto Rico and I stayed out of sight down there. I ran into Frances Kelsey, oddly enough. She was there for a meeting. Of course, the announcement came out while I was in Puerto Rico, and it was in the New York Times. And one of my personal friends, Dr. Mort German was there with me, and I hadn't told

him even, and he came down and I was out by the swimming pool. It was the weekend, I don't remember the exact date. But at any rate, I was at the pool. I wasn't going to work whether it was a work day or not that particular day, and German came out with a newspaper under his arm and he said, "You son of a bitch. I rode down on the airplane with you, and you didn't even tell me that this was going to happen." He was all excited about it, of course, and so was I. And then the newspaper men got after me, and Time Magazine's local photographer came. My God, he took about twenty rolls of film in one afternoon. That's when he turned up with Frances Kelsey, and got a picture that ultimately showed up in Time Magazine. I had all sorts of telegrams and phone calls and most of them I disregarded because I felt it would be unfair to give any interviews. Now, Time, being a weekly, I knew that I had time to get back to the mainland and subject myself, make myself available, to the press, but I didn't think it was fair to give a telephone interview to one reporter and not to any others, so I didn't give any interviews. I did go back to Atlanta and then went to Washington for a press conference and swearing in. I was sworn in on the 17th by Secretary Gardner.

Dr. Y.:

Now, at that time, a good deal was revealed about what this committee had been about, because they had not only been picking a person, they had been laying down certain guidelines with respect to what

they believed the future of the agency should be.

Dr. G.:

What should be done. I had to, in effect, reassure the Secretary that I could, in general, agree to those guidelines. They were subject to modification, however, on further study.

Dr. Y.:

You had been given these to read?

Dr. G.:

I had been given the Miles Committee report to read.

Dr. Y.:

Was this before you accepted?

Dr. G.:

Before I was sworn in. Before I accepted it, in fact, as I recall.

Dr. Y.:

Right. Now did you get any idea from the Secretary at the time that you were being questioned and instructed by him about any kind of stipulations that came from President Johnson or from the White House that were higher than...?

Dr. G.:

No. The subject just didn't come up in that context.



Dr. Y.:

Right. So that even though the White House considered this so important as to announce it itself rather than let it be announced at the departmental level, you didn't have any kind of personal association prior to...?

Dr. G.:

None whatsoever. None whatsoever.

Dr. Y.:

Right. And it was only afterwards that you went down and saw the President?

Dr. G.:

That's correct.

Dr. Y.:

So that the contract that you signed, so to speak, with the Secretary was fairly simple. He didn't go over these points in this Miles report point by point.

Dr. G.:

Oh, no. He didn't say, "What would you do about this?" He was quite realistic about it. The Miles Committee report was one set of viewpoints that a committee had arrived at, and these had to be left open and flexible. He simply said, "These may be

helpful to you as a guide. But feel free to move away from any particular point in here." He said, "I think most of them are probably valid, but you're going to have to determine that as you go along. Whatever you want in the way of help and support, you'll get." Within reason obviously, you know; you can't take the whole budget.

Dr. Y.:

And I take it that...

Dr. G.:

He was always good about support. Just magnificent. I would rate him with General Quesada in terms of being a fine administrator who had a sense of public obligation and exercised the duties of high office with that always in mind. You see, he knew the constituency, plural, the constituencies that he had to represent, and I think he followed his obligations and devoted himself to them in a way that rarely is seen in the administration of high office.

Dr. Y.:

He had such a broad domain that he had to delegate, but he did have that ability?

Dr. G.:

And he had the remarkable ability, also as the General did, to sort the wheat from the chaff. I've found most great men do. They can

get right at the guts of an issue, you see, and John Gardner was no exception. You could go to him with a technical, fairly technical issue, as I did on a couple of occasions because they were politically sensitive issues, and informed him of what was about to happen. At the same time, I gave him an opportunity to overrule me if he so chose, but that wasn't why I went there, and I said, "Mr. Secretary, I bring this issue to you not because I haven't been able to make a decision, but because I've made a decision. I want you to be aware of the implications of that decision. And, of course, if you wish to change that and recommend that I take another course, that's another matter. But, here's what the issue is." Sometimes it would require technical briefing.

Dr. Y.:

Do you remember specifics on this?

Dr. G.:

Let's lay that aside for the time. There was one that was quite technical in nature that would fit nicely that description.

Dr. Y.:

Well, let's postpone that because we have leaped over the CDC and I would like to find out how it...

Dr. G.:

Well, CDC was an interesting three-year period. At that time,

Dr. Aaron Christensen was director of the Bureau of State Services under which CDC was one activity. Now all of the other activities were headquartered in Washington, and so his staff meetings were in Washington and I was expected to fly up once a week, just to start on this level and we will work on the other thing. Now Chris was a very conservative Republican, a mid-Westerner. He didn't like the boat rocked; he didn't like commotion; he didn't like argument; and it soon became clear to him that he wasn't going to have peace with me at his staff meetings. It soon became clear to me that it wasn't worth my while to fly up there once a week for his staff meetings. It was a complete waste of my time and the taxpayer's money for the airplane flight. So I convinced him that it would be good to have a speaker phone put in his office and I could have, then, because I had a speaker phone in my office, opportunity of listening to the staff meeting and make comments where I felt comments were appropriate from my office, and then I would save the money flying to Washington every week, which he agreed to and we did. So I used that hour every Thursday morning to go through mail, Dave Sence would be in there with me, and sotto voce we would handle other matters. Every once in a while, Christensen would say, "Do you hear that, Jim?" And I would say, "Oh, yes. I'm with you," and go on with my work. Well, the kind of bureaucracy that existed then is important to understand, because CDC got things done in spite of

that bureaucracy. For example, there was a character in the bureau office who was supposed to clear all printed material. One man. Now he was a bottleneck to us. We didn't send everything up, admittedly, but once in a while when we had to go outside on contract for printing jobs, we knew we had to get it cleared up there. We had our own print shop, you see. We didn't go through the bid procedure for many of these things, and this man would turn out to be a hell of a bottleneck. For example, the VD Branch had a comic book that they felt would be helpful with young kids--that's a format they knew as a means of disseminating information about VD. That sat in that man's office for about two and a half months, and I found out he wouldn't approve it because in one of the little boxes it showed some young people in a drug store booth and they were smiling and talking about VD, and he didn't think it was appropriate that people smile when they talk about VD. Now this is a kind of nonsense, you see. Well, I got fed up to the gills with that so one Thursday in advance of that, I had the executive officer of CDC pull every requisition for every bit of printing done in the previous fiscal year, get a copy of every film we had made the previous fiscal year, a copy of every training manual, of every brochure we'd printed, and assemble them all at one end of one room on a long table and pinned to the wall behind it. Then I had him get the photographer in and take a color photograph of

himself and this mass of printed material, stacks of cans of films, stacks of training manuals, notebooks, all of these aids, educational aids, that we had produced and we used in our work. And I had a blow-up made of that photograph that was about 24 by 16 inches. I took it up to Washington to the next staff meeting, and when Dr. Christensen got to the part about, "Does anybody have any new business?" I said, "Dr. Chris, I've got a little problem I want to bring up." So I told him what the current bureau of clearance procedures were. I reached down under the table and I said, "Now, Dr. Christensen, I'd like to show you what CDC produced in the last twelve months." I held it up so that everybody could see it. I said, "Now I come here with one single question: do you want us to clear this material or do you want us to get our job done? Because the two are mutually exclusive. If we are going to devote our energies to clearing the material with the man that you have up here, who is incompetent, technically and physically incapable of clearing this mass of material, then we'd do that. If, on the other hand, you want us to get the job done, let's cut out this goddamn nonsense." He didn't like this and he said, "Aw, Jim, come on. Now, you're making too much of it." I said, "No, I'm not now. I want a decision." He tried to laugh it off, you see, and Chris is just the finest guy I've ever known as a person, a comfortable, warm, friendly guy to be around, but again, not decisive; he

didn't want to stand up and belt it out; I had other problems as examples of that. Chris was non-combative in nature, you see. Well, he never did make a decision on that point.

Dr. Y.:

So, you just went ahead...

Dr. G.:

So I just went ahead and I told the people to disregard their clearance procedure altogether.

Dr. Y.:

It was just settled by lack of decision.

Dr. G.:

Indecision, and by my decision to handle it down at this level. So CDC, you see, as an organization was a fascinating one because... they started out as the malaria control in war areas. This was set up at the request of the old War Department, because prior to 1941 when war was declared...on December 8th, wasn't it?

Dr. Y.:

7th. Oh, war was declared on the 8th. Right.

Dr. G.:

Sunday was the 7th. Prior to that time, you remember, about a year and a half earlier, two years earlier, we started the draft, and

the young fellows were drafted for a year and then they could go back to their communities. Well, at that time, around the Southern training camps, and many of the camps were in the South because of the patronage system, and the committee appointment system was in effect then as it is today. And around those camps, a lot of malaria occurred. Well, the War Department got concerned about that because for the first time, large numbers of civilians were coming in; therefore, other politicians could get complaints and so they decided that that mess had better start to be cleared up and so they got the Public Health Service to start this malaria control in war areas. At that time, it was largely ditching and drainage and Paris green, but at the height of that operation during the war years they had 5,000 people employed, with headquarters here in Atlanta, and they were producing training films and manuals and everything that was aimed at malaria control in war. When the war ended, we had a very far-sighted guy in Washington, a guy named Joe Mountin in the Public Health Service, an Assistant Surgeon General, Director of the Bureau of State Services. It was Joe's idea that an organization that had been as successful as that one was, and that's an interesting judgment that we want to come back to later on, should not be lost, and that this perhaps could be the first of a series of centers that could be established, and this one could perhaps should be the Communicable Disease Center, and Joe was able to get that



established. That was the only one he was able to get established.  
He envisioned a center for chronic diseases, as well.

Dr. Y.:

Did this take, to get it settled...?

Dr. G.:

No Congressional action. No.

Dr. Y.:

Just decision within the Service?

Dr. G.:

That's right. Well, so this became the Communicable Disease Center and its mission was broadened. All through the war years, it was under the leadership of sanitary engineers. After it was converted, it became put under the leadership of MDs, and the leadership was good, bad, indifferent, you name it, they had a little of everything. But, generally, it was viewed as a place to put a guy to further develop him before he took over a bigger job in Washington. And so, most of the leadership of CDC was good.

Dr. Y:

But indeed it may be partly because of the leadership and partly because of the need for that kind of mission, it constantly grew in importance within the Service, didn't it?

Dr. G.:

It did, indeed, and the fact that they had been successful, or thought they were successful, in malaria control, gave them, as an organization, a good esprit to start with. I think that's extremely important in management of an organization. I started the accident prevention program with a small group, and I decided that we should pick something manageable as our first task, and it should be something that we could be successful at doing, because I felt that that would give us an esprit de corps, you see. I think that's a good principle to go by.

Dr. Y.:

And they believed that they were good.

Dr. G.:

They believed that they were good.

Dr. Y.:

Well, now, you say this is debatable.

Dr. G.:

Well, Dr. Langmuir, in later years looked back at the malaria control, and it's true that malaria was, for practical purposes, eradicated from the United States by about 1949, as I recall, but he maintains that in all probability it was the improvement in the standards of living that occurred in the Southern area more than

anything else. That people, because of jobs in defense plants and government work were able to afford better housing which meant screening and better standards of living, and he felt this more than anything brought it down to where the pool of susceptibles wasn't large enough to maintain the reservoir for infection, you see. And the Paris green and ditching and draining, sure, that helped some, but really he felt that the other... But the esprit and the belief was there and that became important in itself and so the organization has always had a feeling of success, that they were good, and NIH has had that same feeling, and that's an interesting parallel, so all through the years as new responsibilities were added, everybody accepted them in the spirit that, "Sure, we can do that. We're CDC."

Dr. Y.:

Right, so that made it an agency somewhat in line with your own mood, I think.

Dr. G.:

Yes. When I was told I was coming down here, I said, "Well, something's wrong," I told Arnie Kurlander, "because I've always been asked to take over the jobs that nobody else wanted or the organization was loused up. From everything I can learn this organization is in good shape. It isn't a new one." I was often asked to start new things, you see. "It isn't a new organization. It's

a large one, and it's got an established history in back of it, and they're successful. I can't figure why you're asking me to take it over, you see." He laughed and said, "Well, maybe you'll get something from it."

Dr. Y.:

What did you get from it that was particularly relevant and germane to the Food and Drug Commissionership later?

Dr. G.:

I think there would have to be a number of things that I could cite. I gained an understanding of certain kinds of problems in food-borne diseases that was important later on, in fact... the salmonellosis problem was rising while I was chief of CDC. And I used to read food journals as much as any other kind of journal when I was chief of the Communicable Disease Center, Food Technology, for example, publications of this kind that I would get from our library and read. So I gained an understanding of the food processing industry before I ever became part of FDA, and some of the dangers that existed, you see. Beyond that, I think I gained a great deal from the contact with both the laboratory people and the epidemiology branch at CDC, just on technical issues an assessment of their competence, and knowledge of what they could do, and I drew on that later on. I saw what kind of training course Dr. Langmuir ran for his EIS officers.

Dr. Y.:

What does EIS stand for?

Dr. G.:

Epidemic Intelligence Service, young officers that he brought in and trained for a couple of months and then assigned out to the states and communities to work on disease problems, outbreaks of communicable disease, epidemics, try to understand their origins, and institute corrective measures. And that became important later on because we had a comparable problem of training young men at FDA. I gained a lot more experience in testimony before Congress, because I had to carry...although I had carried a budget in an adversary kind of situation with Congressman Thomas at FAA who was a very tough examiner, knew your books better than most people in the agency knew them. I gained more experience with the committees, Fogarty and Hill committees, that I still had to deal with when I came up to FDA. So I had the Congressional experience of the contacts on the Hill. I think it considerably broadened my contacts with other organizations, the AMA, the American Colleges of Surgeons, American College of Pathologists, because we were involved with training activities. I initiated some kinds of programs at CDC that were of interest to them.

Dr. Y.:

Did you work with universities at CDC?

Dr. G.:

Oh, yes. Oh, heavens, yes. I spoke at meetings, symposia at universities. We sponsored research and so I had a great deal of contact with the university community.

Dr. Y.:

You mentioned making speeches. Certainly one of the things that you were to do at FDA was to immediately get yourself in front of your interested population, and was this a tradition with you from the point of view of the preceding positions you'd held?

Dr. G.:

Yes. In fact, I think it goes back to my work in the theater business where you tried to move people and lead them, you see, get them to do something. You had to get out in front of them and talk to them. You had to have some exposure. They had to know who you were. Well, at CDC I showed up in the Public Health Service uniform, you see. Now, that set me apart from any of the other chiefs they had ever had. I established a custom, while I was there, that at the awards ceremonies the officers would be in uniform and so would I, because it was a commissioned corps. I brought the band in from Fort McPherson to play at those ceremonies. We had flowers on the stage. I think we made it a more meaningful ceremony. It was interesting;

the civilian employees used to say, "You know, we like that. It makes us feel better. We're a part of an organization. We're proud to see you people wear the uniform. Why don't you make them wear the uniform all of the time?" Now I have always been a strong one on the Public Health Service needing an identity, and one of the ways of establishing an identity, I maintain, would be through the wearing of the uniform, because it always gives you an opportunity to acquaint people with the Public Health Service, because they'd say, "Oh, I see you're in the Navy." You'd say, "No, I'm in the Public Health Service. Here's the difference. You know how we used to provide medical care in the Navy back in 1795, '98, rather..." And that was the kind of exposure that got me in front of my people. Beyond that though, the exposure to the university community and other kinds of audiences as the leader of CDC was valuable, too. It sort of fit my pattern of operation.

Dr. Y.:

Were there industry relations in connection with CDC?

Dr. G.:

Yes, particularly in the laboratory reagent area. That was a significant area where we were evaluating the quality of the laboratory reagents and decided to go ahead and publish a list even though it could be viewed as a form of economic reprisal,

you see, because it would be very meaningful if the manufacturer's reagent didn't measure up and wasn't on the list that we then circulated to the state laboratories. He'd lose business. But we did it.

Dr. Y.:

And did you speak to their trade association?

Dr. G.:

Well, I don't recall. I spoke to representatives of their association. They came to see me very much concerned about this. But there were other kinds of innovations that I brought to CDC.

Dr. Y.:

I think I'm going to have to turn this off.

Dr. G.:

I think probably this would be a good place to end for today.

Dr. Y.:

Good, Jim.



# History

of the

## U. S. Food and Drug Administration

**Interviewee:** Dr. James L. Goddard

**Interviewer:** Dr. James Harvey Young

**Date:** April 30 to June 19, 1969

**Place:** Atlanta, Ga.

Session 3

Pages 166-251

Dr. Y.:

This is our third conversation, Jim, for the tape, a conversation being held on June 4, 1969, between Dr. James L. Goddard and James Harvey Young about Dr. Goddard's experiences as Commissioner of the Food and Drug Administration. We're sitting on the deck of his home, so that maybe that waterfall will get into the tape and I imagine certainly the airplanes will. When we last talked, we had reached the point at which you were sworn in as Commissioner on January 17, 1966. You moved up from Atlanta where you'd been Chief of the CDC into your new office which was then over on the Washington side of the Potomac, and you were faced with a pretty grave situation, with many eyes, Congressional eyes, drug trade eyes, food trade eyes, upon you. How did you go about familiarizing yourself with your job, with the staff that you'd inherited, with the kinds of problems that were left over? You spoke of some of these problems as "dead cats on my doorstep" once.

Dr. G.:

First of all, I met individually with members of the staff. For example, on January 19th, I notice, I met with Mr. Fred Delmore, Director of the Bureau of Education and Voluntary Compliance; Mr. J. Kenneth Kirk, Assistant Commissioner for Operations; Mr. James Cribbett, Acting Assistant Commissioner for Regulations;

Mr. Robert Roe, Director of Bureau of Scientific Standards and Evaluations; and Mr. Daniel Baner, Deputy Director of Bureau of Scientific Research.

Dr. Y.:

Now, just let me have you explain what it is you're looking at.

Dr. G.:

I'm looking at my daily calendar. I had a very efficient secretary, Mrs. Beulah Sink, and when I left she gave me the daily calendars that she had put on my desk every morning. And so I have two stacks of these about two inches thick each, and it helps me recall many of the events that occurred. But I did meet with the individual bureau chiefs, assistant commissioners, and tried to size them up as persons, and then, secondly, ask them to describe to me what their operations consisted of. Being a newcomer, I was completely free to ask the dumbest questions one could imagine, and these were the worst questions for them to handle, for I would ask them, "Well, why would you do that?" Sometimes the responses would be entirely inadequate and would ultimately have to come down to, "Well, because we've always done that."

Dr. Y.:

Right. Now, when you came in, as far as the previous staff was concerned, there had been a lot of key retirements and resignations.

Dr. G.:

Oh, yes. I was very fortunate in that. When Commissioner Larrick retired in December of 1965, shortly after his announcement of retirement, the deputy commissioner retired.

Dr. Y.:

Mr. Harvey.

Dr. G.:

Yes. John Harvey. And one or two others. So, I had, in effect, a fair number of vacancies. Well, that's an optimum opportunity, so to speak, for a new commissioner because he can then select at least a few people whose loyalties are directly to him. One of my first appointments, by the way, was Mr. Theodore Cron, the Assistant Commissioner for Information and Education.

Dr. Y.:

How did you come across Ted Cron?

Dr. G.:

Ted actually was with the Department of Health, Education and Welfare at the time I first met with him. He was at the Office of Education. He was referred to me by his boss in the Office of Education, the Director of the Office of Public Affairs, in effect, of OE. I met with Ted and I liked him immediately. He was a bright young man, thirty-four years old, as I recall,

at the time, and had the kind of background and experience that I felt would be valuable to me and to the agency in the months ahead, and so he was my first selection. Now, let me point out that I swore in a director of the Bureau of Veterinary Medicine prior to Ted's coming on board who had been selected actually by Dr. Clarkson, the previous Director of the Bureau of Veterinary Medicine. Dr. Clarkson selected Dr. Van Houweling as his replacement. Dr. Van Houweling came to us from the U. S. Department of Agriculture. I had no objection to him. In fact, he was quite capable and competent, but he wasn't my selection, but he was the first man I think I appointed as Bureau Chief after my swearing in as a Commissioner. But Ted Cron was the first person that I selected and put in a slot and he came from outside the agency.

Dr. Y.:

You made that decision very quickly after you came.

Dr. G.:

Yes, I did. Very quickly, in fact, and it was one that I never regretted. Because he came from outside the agency, he had no inside loyalties or ties, and I leaned very heavily on Ted in the early months, making certain that he was always with me in certain kinds of meetings. Some of them were with inside people, some with outside people, because he and I then could sit back

later on in the day and size up what had happened. We could get a fix on what was going on, and this was very valuable to us, to me, and Ted was my strong right arm throughout my tenure as Commissioner.

Dr. Y.:

What were his particular advantages? Did you see rather eye to eye, was that what it was?

Dr. G.:

Well, we saw eye to eye on issues, on approaches; he'd had broad experience in audiovisual public media fields. In addition, he was a Harvard masters in education, as well as a Harvard undergraduate, you see, and this told me that he had a fairly broad educational background. And so, I had every expectation of a man with great breadth of understanding of social issues, which he did prove to have, and he was very quick to perceive, much quicker than I, in fact, to perceive how what we were doing related to the problems of our society and how the societal problems, certain ones, were properly ones that we should tackle, too. And Ted and I saw eye to eye very early. In our first meeting we took a liking to each other which is very important. We could communicate easily with each other, which is extremely important, and he was always the one fellow who would look me in the eye and say, "Commissioner, that's a bunch of baloney."

And everybody has to have that kind of person on their staff.

Dr. Y.:

He became one of the key persons in writing the first drafts of your speeches, didn't he?

Dr. G.:

He did all of that and shaped and guided other writers who from time to time worked on speeches. We tried a number of speech writers, by the way.

Dr. Y.:

Tell me about that.

Dr. G.:

Well, Ted was so involved in a variety of activities and his time was so valuable. I kept after him. I said, "Ted, why don't you get a speech writer for me?" Because he had been doing this and it was quite a burden. I gave quite a few speeches during the two and a half years. And so, every six or eight months he'd turn up with a speech writer, and we would then sit down with the man, the both of us, and talk to him, and he would talk to the man and have him read speeches I'd given, have him listen to me in impromptu sessions where I had spoken with only notes, so he would understand how I talked, the phraseology I used. Ted had a great ear for that. He could write a speech as

if I had written it, you see.

Dr. Y.:

Right.

Dr. G.:

Because he understood my phraseology and how I put things together. And we never could find a man who could do this. So every time the job fell back on Ted's shoulders, The draft would come in and I would read it. I'd call Ted in and I'd say, "Ted, this guy isn't cutting the mustard on it." And he would look sheepish and say, "Well, all right, I'll write that one."

Dr. Y.:

You'd get some raw data you needed that way, but he had to put it into your...

Dr. G.:

Oh, yes. It had to be put together, because when you're trying to get an agency that has been very backward in a way, very reluctant to assume its proper responsibilities, when you're trying to move it ahead, trying to recruit new people, meeting with all those who thought they had to meet with the new Commissioner, do all the tasks involved in administrating an agency of 5,000 people, then, on top of that, to write your own speeches would just be ridiculous. You have to shape them, you have to



give the speech-writer the point of view that you want to make, but I was giving as many as three or four speeches a week.

Dr. Y.:

You, at the beginning, decided one way that you would make an impact for the agency and for your new approach to the agency would be through making public speeches.

Dr. G.:

In fact, I made a conscious decision that, in order to be fair, and in order to let people know what to expect, I would meet with all of the major associations and speak at their annual meetings. Now, Washington is filled with representatives of trade associations, and I really didn't perceive how many trade associations there were in this particular field of interest until after I had made that decision. And the invitations just kept coming in and in, and it took me a year literally to get around to all the major associations, but I felt this was necessary, that they should know the person they were dealing with and the philosophy that the agency would have as a result of new leadership. And so this was a conscious decision to move ahead in this fashion.

Dr. Y.:

You have spoken before about how making speeches wasn't a chore; in fact, it was almost a joy.

Dr. G.:

Well, yes. It was fun. I must say that those weeks where you had three or four speeches to give in one week and entailed a great deal of travel, at times, it became less of a joy than others.

Dr. Y.:

Right.

Dr. G.:

Getting back to the staff: now, there were some vacancies. I had to have a Director of the Bureau of Regulatory Compliance. I was very fortunate in that the man who had headed that particular bureau had retired.

Dr. Y.:

That was Allan Rayfield?

Dr. G.:

Yes. Now, Allan Rayfield was, in my opinion, and I never met the man, a brilliant man, but he ran the agency. In fact, he ran it; it wasn't George Larrick. Allan Rayfield ran FDA because he had absolute control over the field personnel. He decided who was transferred to which of the eighteen district offices; what the eighteen district offices would do; and, in fact, the eighteen district directors really made no significant decisions on their

own. Now, he retired in December, and went with a trade association, no, went with a pharmaceutical firm, as I recall, out in Cincinnati, Ohio, but, at any rate, his leaving really made it possible for us to convert the district operation from one of just blind obedience to orders from one individual to one where the administrative capabilities of district directors could be relied upon to perform the agency's missions. Now, unfortunately, this meant that a fair number of district directors who were so steeped in the old pattern had to go. Many of them were long-time FDAers; had been there, one man, I think had forty-six years of service. So, it wasn't a question of individuals being eligible for retirement. Most of them were past that point, and, in fact, a couple of them had been extended on age, even, which meant they were past seventy. In that first twelve-month period, I felt one of the major tasks was to reshape the field structure, both by replacing most of the district directors with new men and by making the district directors and their immediate staff responsible for the operation of that district, the use of the personnel, and accountable for what happened in their district, something that hadn't been done before.

Dr. Y.:

Now, first of all, how did you reach the decision about which men would work under your new system and which men would not?

Dr. G.:

Well, we had a district directors' meeting. First of all, I had the Personnel Office gather...work up a notebook which gave me the background and photographs of each of the district directors, so I knew what all of their past assignments had been, how long they had been with the agency, just the biographical data, and I had their photographs. Then I would talk to several people. Winton Rankin by then was my Deputy. I decided to keep Winton on. He was acting deputy, or acting commissioner actually, when I was sworn in. I then asked him to become acting deputy and then that was made final later on, within sixty days, as I recall. At any rate, I did that over the advice of people, such as Don Gray on Mr. Fountain's staff and one or two others in the Department of Health, Education and Welfare, who cautioned me that Mr. Rankin was an old-line FDAer and I shouldn't have him as my deputy. Well, I recognized that Mr. Rankin was a very strong person and a very knowledgeable person about FDA procedures. He knew all of the people, and I felt that I would take a calculated gamble on this one and use an old-liner because, at some point, you had to have an inter-face between a new person and the existing personnel of the agency, and if two of us were new in the head office, I felt it would be even more of a burden, and I would rather know a man's biases and use him accordingly, which is what I did with Mr. Rankin.

Dr. Y.:

So that you kept him acting until you found out whether or not you could work with him, whether or not this calculated gamble would work out.

Dr. G.:

Even after he was no longer acting but was the Deputy Commissioner, it was still a calculated gamble, because Winton can be a very devious kind of person who works behind your back. Every once in a while I would let him know that I knew what he was doing.

Dr. Y.:

What is an example of this kind of thing? Do you remember something specific?

Dr. G.:

Well, let me put it this way: There would be meetings in his office early in the morning, and some of the old-line FDAers would constantly go to Winton with things, and Winton would try to see to it that I appointed men that he had selected for certain jobs. He would make strong recommendations. In many instances, I did select those persons. Others, I did not. So, Mr. Rankin was a very important person in the two and a half year period. He's a very strong individual, and it takes a

strong person to work with him because of this. We were never personally close. We never met socially, for example. But we got along on the job.

Dr. Y.:

He was knowledgeable?

Dr. G.:

Indeed, so. In fact, Ken Kirk, whom we also held over and made Associate Commissioner for Compliance, probably was the most knowledgeable man in the agency about regulations, past history of cases, and Ken was extremely valuable to me during that two and a half year period. It was recognized that some of his philosophy was not, perhaps, the most desirable, his approach to certain problems, perhaps, could have been improved upon, but nonetheless, on balance, Ken was a real plus in that two and a half year period. I tried to mix up the appointments of people--the district directors, let me see, I think that within a year, we had replaced fourteen of the eighteen district directors.

Dr. Y.:

When they came in, then, I take it, to that first meeting, you sought to use the paper background you had to size them up personally.

Dr. G.:

I used that to size them up, coupled with my experience with them in the first meeting, meeting then with people like Rankin, Kirk, and others who knew them.

Dr. Y.:

You went out to the field some, didn't you?

Dr. G.:

I visited every one of the district offices within the first twelve months. In fact, most of them was within the first six months. Buffalo, I think, was the one that took the longest to get to. Who wants to go to Buffalo? At any rate, we did succeed in getting most of these people to retire. In some cases, it was in the nature of forcing them to retire. You can't force a man to retire against his wishes, but what we did do--what I did--was to offer them a transfer to Buffalo. Once that office was vacant, that became the ploy that was used; call a man up and tell him we needed him in Buffalo, anxious to restructure the district, I'd like him to think it over. We wanted him very much to make the move.

Dr. Y.:

He recognized this as a hint of demotion?

Dr. G.:

Well, it wasn't a hint of demotion. Buffalo...nobody really

wanted to live there. The damn winters are so terrible, and so, a couple of days later, generally, the individual would call up and say, "Well, look Dr. Goddard, I appreciate the opportunity, but I've decided I want to retire. I've got enough time in, I'm old enough, maximum retirement, so..." I said, "I'm sorry to hear that. We hate to lose you." And we would put on a nice farewell party, and I would either go or send a telegram and make sure it was handled in the best way we possibly could, but we had to open those districts up. The district directors at their first meeting sat there like bumps on logs. We would raise a question and ask for their opinion, and nobody would venture an opinion. Now, this went back to the experience of a few years earlier when Allan Rayfield had a meeting of district directors and convinced them that he really wanted their opinion on an issue. Well, they got together that evening and they, as a group, selected McCay McKinnon, who was Director of San Francisco region when I came in, to present their opinion the next morning at the meeting. McCay got up the next morning and presented the district directors' opinion on this particular issue, and Rayfield then proceeded to cut McCay's legs right out from under him. Well, this had apparently happened before, but Rayfield had conned them into thinking he wanted their opinion and maybe he thought he did, but when it didn't agree with his, he then carved McCay up. That, effectively, I am told, was the last



time anybody offered an opinion. They just sat there and listened. And this was what happened in our first meeting of the district directors. Well, I couldn't run an agency with eighteen people responsible for fifty percent of the agency's personnel utilization who didn't have an opinion and weren't willing to express it and use their administrative talents to help run the agency. So, it was very important to restructure the districts' operations and get different men in. Well, we picked younger men for the most part, men who were in the middle management group.

Dr. Y.:

They all came from within the agency. Is that true?

Dr. G.:

Yes, every one of them came from within the agency, in order to have acceptance; one of them came out of headquarters, Maurice Kinslow who was in charge of the Office of Congressional Liaison.

Dr. Y.:

That was rather late.

Dr. G.:

That didn't happen immediately. No. Most of them came from the districts themselves.

Dr. Y.:

At least one of the district chiefs, Al Barnard, from Kansas City, you moved up.

Dr. G.:

Yes. Moved him into Director of Bureau of Regulatory Compliance. We had this opening; it was a difficult one to fill; it was an important one, although the Bureau's role had been downgraded. We felt that some of the functions should be parceled out: the Bureau of Regulatory Compliance, in effect, ran FDA under Rayfield. We wanted to make sure that that wasn't going to happen. Voluntary Compliance was separated from it, for example. We needed a man who could run it, and Al Barnard looked like the person to do it. Subsequently, I regretted that appointment.

Dr. Y.:

Why was that?

Dr. G.:

Well, because Al never could get on top of the backlog and handle the problems effectively, and he came to me within a few months of my leaving, before my leaving was public knowledge, and told me if he hadn't made it by that July, meaning July '68, he was going to ask me to transfer him, but then subsequently, he found out I was leaving and that was a whole new ball game. Other men, I'm skipping around a little here, some of the other men had to

be disposed of: Cribbett was one; there was an associate commissioner for science.

Dr. Y.:

How do you spell his name?

Dr. G.:

Well, Cribbett was not associate commissioner for science. Let me see now what Cribbett's responsibility was at that time. He was acting assistant commissioner for regulations. C R I B B E T T. He was completely ineffective and had to be moved out. Fortunately, the Director of the Bureau of Science wanted him in his shop, and then I was able to move Kirk into the associate commissioner for regulations slot.

Dr. Y.:

When Ted Cron came in, he, of course, took the place of Wallace Janssen.

Dr. G.:

Well, he really took an upgraded job. We expanded that job over what Wally had been doing, and Ted was the assistant commissioner for education and information. We had to get rid of the man who was in charge of...he was associate commissioner for science, I can't think of his name.

Dr. Y.:

Was that Oral Kline?

Dr. G.:

Yes. Yes. It was Oral Kline.

Dr. Y.:

What was the problem there?

Dr. G.:

One major thing, we got into it on the vitamin, proposed vitamin and mineral regulations. He never informed me of the possible problem with the National Academy of Sciences-National Research Council, and yet he had met with them, he knew that they were upset, and yet he hadn't informed me of it. When it became apparent to him that I was about to find that out, plus one or two other things, he simply didn't show up in the office. He phoned in his resignation.

Dr. Y.:

I see. That had to do with the situation in which these long-standing regulations were going to be issued, and they were...

Dr. G.:

There were, in fact, issued. A notice was published in the Federal Register, and then certain members of the National Academy of Sciences expressed their displeasure. And it was at

that time that I'm talking about that Kline decided to leave the agency very precipitously.

Dr. Y.:

Because he had been aware of the displeasure but hadn't told you about it?

Dr. G.:

Hadn't told me about it at all. In fact, that was his responsibility, to carry out the liaison with the Academy and keep me advised. So that position became vacant very quickly, too.

Dr. Y.:

Well, one of the hold-overs which, of course, most interested the drug industry and the medical profession was...

Dr. G.:

Joe Sadusk.

Dr. Y.:

Right.

Dr. G.:

Well, Joe I had known as a medical student at George Washington University. Joe was an assistant clinical professor of medicine at G. W. in those days, and so I had known him, oh, fifteen, let's see, 1948, I had known him about eighteen years earlier

and intermittently had seen and talked to Joe over the years at meetings, sort of kept track of him and knew where he was. He'd taught again at G. W. later on, he was in charge of the out-patient clinics. So, he was not an unknown quantity to me when I came in, as Director of the Bureau of Medicine. It became apparent to me very quickly, though, that one of the major problems in the bureau was Joe himself. In this way: An issue would come up for my review from the Bureau of Medicine. I would review the material and call Joe in to discuss it, and in order to try to have a good feel for the situation, you have to put a lot of probing questions to a person, and Joe never really understood these were probes, and he would flipflop completely, and say, "Oh, well, it could be done the other way." And so very quickly I became aware that this was a man who really didn't have a strong position on any particular subject, and therefore, I couldn't rely on him, because I really would never know when something came forward as a recommendation whether this was a well-thought-through recommendation that could be battled in the courts, because that was part of what was involved.

Dr. Y.:

Right.

Dr. G.:

So, Joe saw, also, that he and I weren't getting along; he didn't like my style of operation, of moving things; he didn't like my separatism from the pharmaceutical industry; he wanted to meet with people and conciliate and compromise. That wasn't my way of doing it. I felt that we had gone that route long enough and that we had to have a marked change. And so Joe left. As I recall, in late February, he announced that he was leaving. He gave me a letter. He left, I know, on March 14<sup>th</sup>. We appointed Dr. Robert Robinson as Acting Director of the Bureau of Medicine.

Dr. Y.:

Well, it wasn't that you and Dr. Sadusk disagreed about the major role of the agency?

Dr. G.:

Oh, I think there was a philosophic difference there between us.

Dr. Y.:

Not only about method, but about substance?

Dr. G.:

I think about substance, too. There was a difference between us that was irreconcilable. Joe's basic concept was "Leave it up to the doctor, the practicing physician. Don't worry about

it. The individual physician knows best." My position was different. I thought the individual physician had to look to us as an unbiased source of information on drugs, because I was well aware that there was a lot of misinformation being deliberately peddled by the pharmaceutical industry in order to increase their sales, and that there was bad research being done. I had to play catch up when I went into this job, because most of the people there had lived with the problems. My wife and family did not move up from Atlanta, because our youngest daughter was in the midst of her senior year, no, junior year, in high school, and I felt it best to wait until the summer. And so I took an apartment, and this meant I was batching it for the first six--seven months. This was extremely useful, because I then could spend the entire evening reading, and I did.

Dr. Y.:

Now, what did you read in this catching-up process? What kinds of things?

Dr. G.:

My heavens! I read everything I could lay my hands on. Some of the trade journals, I had, oddly enough, been exposed to as Chief of CDC and had regularly read them, although I suspect from a different point of view than I read them as Commissioner of Food and Drug. So, I was fortunate in the area of food. I



had a fairly good feel for what was going on in part of that segment of the agency's responsibility, but it meant, in effect, for most of the other areas, and part of the food area, I had to read all of the trade journals. So I always kept a stack of them in the car, and this is one of the real values for having a driver, by the way, for an agency head, a little thing, but it's important. You can spend your time when you're being driven from one building to another for a meeting, you can spend your time, reading. You can get a lot of reading done that way.

Dr. Y.:

Especially because FDA was spread out.

Dr. G.:

Yes, and I had to travel around. Then I did a lot of reading in the evening, not only journals, but I actually reviewed new drug application material to get a feel for what the pharmaceutical industry was submitting.

Dr. Y.:

One of the very first things I remember that seemed a bit dramatic, that helped give you the kind of image that you quickly acquired, was your reversing a decision with respect to some new drug application which had been passed on to you from the Bureau of Medicine.

Dr. G.:

Well, that was based on my own reading of the new drug application. It was interesting. On the Bureau of Medicine activities, quite often, more often than not, in fact I would say about 90% of the time, in those early days, when Joe Sadusk was still there, a recommendation would come up to me for an action. I would look at it, and I wouldn't agree with what had been recommended, or I would want to question it. As I would dig into it, I would find that staff at the next level down had proposed something entirely different, and in the office of the Director of the Bureau of Medicine, their recommendation would be reversed. It would get up to me, and I would reverse it back to what the staff had recommended. That told me something, too, and that also made my job easier, by the way, with the Bureau of Medicine, because it meant that once Joe Sadusk left, and we replaced him, even on an acting basis with one of the people who had been on the next level down, we then got a harmony in the decision-making process that hadn't existed before, and it meant a lot of memo writing could stop, because people were documenting their positions for the record before, and this was a fascinating thing to see.

Dr. Y.:

Was this all wrapped up with the question of industry spokesmen seeking to find out about applications?

Dr. G.:

Oh, my. A very complex thing, Harvey. Industry spokesmen... industry came into the FDA Bureau of Medicine building at will. They would camp on people's doorsteps; they were distracting people from getting their job done. The drug industry representatives did spend too much time checking on the status of the application. Make no mistake, they were up against a situation where they perhaps could be excused, because the backlogs were excessive, they weren't getting decisions, and this was then understandable. But I didn't like it from the security point of view. If those applications are, as industry maintained, full of manufacturing secrets, then we certainly were derelict in meeting our responsibilities by the way we were handling them internally, because one could walk into that Bureau of Medicine building, up and down the halls, and there were applications stacked on desks and in rooms. People weren't even in the office. This was not too good. So we instituted a security system that required people to sign in and to indicate whom they were going to visit, and they have a definite appointment with the person before they could go into the building. I thought this was important to do in order to meet our responsibilities, preserving in secrecy that kind of information. Also, it made a more orderly operation out of it. God, anything we needed was a little more order in that

Bureau of Medicine. It was the most disorganized bureau of the agency.

Dr. Y.:

It had been that way for a long time, or was this a management problem or was it a workload problem?

Dr. G.:

It was a combination of both of them, a management and a workload problem. First of all, they hadn't been adequately staffed back in the pre-Kefauver-Harris days prior to '62. After '62, the agency had to give them more personnel, and then it became a problem of being able to hire good people. I can remember a flight surgeon we got rid of at FAA, poor old Benny Moxness, because Benny was getting a little senile, couldn't do his job in flight standards, and when I went over to FDA, my God, there was Benny. I said, "Oh, my God." I mention that because it is just typical of the kinds of people that FDA could hire.

Dr. Y.:

They couldn't even hire enough at that.

Dr. G.:

That's right. They still were short of staff in a major way at the time I became Commissioner. But it was that, and then we had a nest of homosexuals in the Bureau of Medicine who were in

charge of the administrative activities, and, boy, they were lousing things up with their little games. They would deny people supplies, just because they weren't nice to them, you know, and we had to clean that mess up. Fortunately, that didn't get much publicity and we were able to effectively get them out of there. There was both the workload and the lack of administrative capability. We got a good administrator in, Vaughn Choate, a very competent guy who understood what was needed. We got a Bureau of Medicine Director. Dr. Ley came in.

Dr. Y.:

Tell me about that.

Dr. G.:

All right. Dr. Ley, Herb Ley, I first met him when he was a lieutenant colonel in the Army. He was serving as a staff man on the Armed Forces Epidemiology Board. As I recall, General McNinch was in charge of the board at that time and Joe's now here in Atlanta, and a great guy. But Herb Ley I met because I was appointed as a member of the commission on accidental trauma when I was chief of the Accident Prevention Program. That was 1956. And I was very impressed by this young lieutenant colonel, his capabilities, and later on...

Dr. Y.:

Impressed in what way? What things did you notice?

Dr. G.:

By his professional competency, by the manner in which he handled difficult situations within the Board. Later on, I saw more of him. He became professor of preventive medicine at G. W., and while I was at Federal Aviation Agency, in fact, he resigned or rather reverted from an active duty status in the Army to a reserve status, and I tried to hire him as deputy civil air surgeon at FAA, so that he could take my place when I left, because I knew I would only stay there a few years. Unfortunately, Herb decided not to take that job. He decided it was too alien to his capabilities, which were epidemiology, virology and bacteriology. Herb was very competent both in the laboratory and in the establishment and direction of field studies. He did some rather significant work on chloramphenicol in its early days, at Walter Reed and later over in Korea and in Malay. So, he was a very competent scientist. Now, I next tried to hire him when I was chief of the Communicable Disease Center, and by that time Herb was disenchanted with the situation at G. W. University School of Medicine, and he moved from there to Harvard School of Public Health. So I didn't get him at CDC. When I was confronted with the fact that I had to find a Bureau of Medicine Director, because Sadusk resigned fortunately, and it was apparent that Robbie, Robert Robinson, although I could work with him, he wasn't going to be the man that would head up

the Bureau of Medicine on a long-term basis.

Dr. Y.:

Why was that?

Dr. G.:

Well, one of the problems was a security problem. It was a very messy situation with Robbie having at that time a record, at least. It appeared that he had been married twice and hadn't bothered to get a divorce, and then some question about validity of records pertaining to his education. It was just...even though...now Robbie is Negro, you know, and I probably could have bulled it through using that as a...

Dr. Y.:

Well, I can see part of the problem, if there was any suspicion. You were in the middle of a situation in which the credentials of the researchers who were doing background work on the applications was a matter of prime importance.

Dr. G.:

Well, indeed. And so I wanted a man, and I turned to Herb Ley again and fortunately for us, at that point in time, there were problems at Harvard School of Public Health, and so Herb was able to secure a leave of absence from Harvard School of Public Health and come with the agency. Herb did an extremely good job

in my opinion as Director of the Bureau of Medicine. Now, that doesn't mean there weren't problems that he couldn't solve, or that there weren't blind spots, because we all have those, and there are always problems that some of us don't see and others do, but on balance Herb just did an outstanding job. He got rid of the backlogs. He and I...I was able to borrow enough Public Health Service officers, something that had been available to Larrick before me and to my predecessors, but they had been unwilling to bring people into the agency on a loan basis. They were afraid of the Public Health Service. Hell, if there was anything I wasn't afraid of, it was the Public Health Service, because I grew up in that agency. So we borrowed a bunch of young, two-year men and brought them in to help get rid of the backlog. This worked.

Dr. Y.:

You said earlier that Ted Cron and you got along quite well together, partly because you had such similar styles. Now, certainly, you and Herb Ley don't have similar styles.

Dr. G.:

No, but one: we'd known each other and had respected each other for years, and we were friends, you see. So, we had that in our favor. Two: I respected his style, although it was different than mine, and he recognized what I was up to as Commissioner,



what I had to do. I had to break the ground for him, and he's now finding out that that's part of the Commissioner's job, to protect his people, to take the beating, but, at the same time, to break ground and to break the trail. So, you have to perform a little differently. I think Herb still has to grasp some of the fundamentals of those requirements, you see. You can't vacillate. It's like, I think back to General Quesada who was criticized because he was so positive in his actions. Why, hell, if you're going to inspire confidence in the people who work for you, you have to be positive, even at the price, at times, of knowing it's not quite scientifically accurate. Now, I could depend on Herb to back me up by being scientifically accurate, you see, and so that's an important function that the Commissioner fulfills of leadership, and you have to operate, in my opinion, in a little different style in that job than you would as Director of the Bureau of Medicine.

Dr. Y.:

You recommended him to succeed you?

Dr. G.:

I not only recommended him, I deliberately leaked to the press the fact that I'd made this recommendation in order to call the hand of the Johnson Administration--it was in its dying days, of course--on making sure that Herb was put into the job. That

was the only time that I deliberately went against the establishment and leaked something to the press. I was always a good team player up until then, but I felt that this was important. I didn't want Wilbur Cohen to dump Dr. Ley or not to take his recommendation and so I leaked it to the press on purpose.

Dr. Y.:

Right. We had gotten to this point beginning with the point of your own self-education as soon as you became Commissioner. You were talking about the things you read. I remember when we came down to Atlanta on a plane maybe at the end of your first or second week, you were talking a good deal about Morton Mintz's book, The Therapeutic Nightmare.

Dr. G.:

Yes, I read that. I read several books, in fact, at that point in time. Ted had gathered up a number of background materials for me. I relied on him to do that and I read them. Fortunately, I'm a fast reader, so I was able to read a great deal of background material. I was able to get studies out of the files that had been carried out by different groups. For example, the second Citizens Committee report.

Dr. Y.:

That seems to me to have been...to make...

Dr. G.:

The job was really easy, Harve, when you think about it. All the recommendations that had been made by different groups were just laying there. Congress had acted and spoken; they passed the Kefauver-Harris Amendment; they gave the agency the authority; they said, "Do this; thou shalt." And yet the agency hadn't. So all anybody had to do was to look at what had been studied, what had been recommended, and then pick and choose.

Dr. Y.:

The Second Citizens Advisory Committee report seems to me administratively to have been almost like a blueprint.

Dr. G.:

It was. It was. It wasn't difficult to step into that situation, as I say, because so many people had looked at it and said, "This should be done and that should be done," and then I just simply had to come along, and all you had to do is swallow hard and say, "Let's do it!" Now, that's what the agency was suffering from. Nobody was willing to take the bit in their teeth and get at doing the job.

Dr. Y.:

Now, Morton Mintz very early interviewed you, I take it.

Dr. G.:

Yes, he did. If I remember correctly, it was shortly after the first of February. We met one evening at Ted Cron's house and spent the entire evening, and then I drove Morton home that night. Morton never had a car, you know, and I got a little insight into Morton.

Dr. Y.:

What is the insight that you got into him?

Dr. G.:

Well, this is only a suspicion. First, fact: I know that the Mintz' have a daughter who is institutionalized. Suspicion: I suspect that she is institutionalized possibly because of being mentally defective, and Morton thinks this may have been due to a drug that his wife took during pregnancy. Now, that's a suspicion. I can't verify that, but it would be an interesting correlation with his attitude toward the drug industry which, at times, is excessive. Morton is an extremely competent investigative reporter; I must point out that in terms of digging up a story, he and Jon Spivak are two of the best I've ever seen, and Morton goes after it hammer and tong. Jonathan works very differently than Morton, but nonetheless just as effectively. Morton's more apt to break a sensational story than Spivak, but Spivak's more apt to have a story that, although it's not as

timely perhaps as Morton's, is more comprehensive and better balanced. So, that was part it. Then I began to appreciate Morton's very deep emotional involvement; whatever the reason, Morton had a very deep emotional involvement with the pharmaceutical industry and a very strong set of biases, and that evening made this clear to me. But I must say, Morton never violated his word or trust that was reposed in him. On a number of occasions, I would talk to Morton, did talk to him and say, "Now, Morton, this is coming along, and here's what I see at this point in time, but you can't say anything about it." He never did. He waited until the right time.

Dr. Y.:

But he, of all the drug reporters, was one who kept on top of what was happening as much as any?

Dr. G.:

I would say he kept on top as much as any, although as I've indicated, Jon Spivak knew what was going on. Morton had a preoccupation with the Pill which wasn't perhaps misplaced in view of what we've heard and seen since then. Morton was very disturbed by the data that apparently was used to support the approval of the NDA and the fact that good studies weren't being carried out by the agency.

Dr. Y.:

Speaking of reporters, what about the staff members from the F-D-C Report or the Pink Sheet?

Dr. G.:

We had some dillies from the Pink Sheet. There was one young man whose name I've forgotten who really was a pain in the ass from the Pink Sheet. He was an overbearing, officious, pompous S. O. B., and he would buttonhole everybody in the Bureau of Medicine. He had just come with the Pink Sheet shortly before we instituted the security program in the Bureau of Medicine building, and he was well hated by most of the people in the Bureau of Medicine, and he did something to me that I never forgave him for. I called a staff meeting in the Bureau of Medicine one day and he sat in on the staff meeting. It was a meeting of all of the physicians in the Bureau of Medicine. I wanted to meet with them to tell them what the job was, what it was we had to get done, where we were going. He sat in that meeting. Now, I know of no Washington reporter worth his salt, once he found out he was in a staff meeting, who wouldn't get up and get the hell out. Steve Rippey corroborated this and told me, in fact, that would be what he would have done, and said any reporter worth his salt would have got out of there because, after all, "We have to live and work with you people." But this fellow sat through the whole thing. Well, it was a

meeting of perhaps 150 people, and so he was unnoticed. He wrote his story.

Dr. Y.:

He wrote the story that told everything that had happened?

Dr. G.:

Yes. Yes. We protested.

Dr. Y.:

Was this editorial policy on their part?

Dr. G.:

I don't think so. No. No. I don't think so. This was just a new reporter and he didn't follow the usual rules.

Dr. Y.:

Well, this Pink Sheet kind of Bible, certainly among the trade part of the drug industry, as to finding out what's going on. What was your general impression of this, looking at it from the time you were Commissioner?

Dr. G.:

Well, I thought it was biased towards the drug industry point of view. I read it. Every week it came out and I read it. I must say we improved their circulation a great deal while I was Commissioner, but nonetheless there were enough inaccuracies

in it that I used to get many a chuckle over reading their stories, but I really think that there is an unconscious bias, or was then, towards the drug industry, towards that readership. Stories were slanted, perhaps not knowingly, but to that readership.

Dr. Y.:

Earlier you mentioned Donald Gray.

Dr. G.:

Don Gray on the staff of Fountain's Committee.

Dr. Y.:

As part of your education, I take it, you read the Fountain Committee hearings and conversed with...

Dr. G.:

I read the Fountain Committee hearings; I read the Kefauver Committee hearings in '62.

Dr. Y.:

That was a big stack.

Dr. G.:

Oh, my God, yes. Oh, my God.

Dr. Y.:

Did you go down and visit with Representative Fountain and his staff?



Dr. G.:

I had lunch with him and Del Goldberg and Don Gray. I had lunch with the Congressman and met with Gray and Goldberg. We sized each other up.

Dr. Y.:

I'd appreciate your impressions as you sized them up and as you had further experiences with them.

Dr. G.:

Well, I thought that...first of all, I was very hostile to Don Gray and Del Goldberg initially. I felt that they were unfair in their handling the agency. Now, as I went further along, I reversed my opinion of them. I felt that they perhaps were still somewhat unfair in the methods they used, but that they had reason to be concerned about the agency, this I agreed, and I really worked out a fairly good working relationship with them. They were good investigators. Let me point out that Don Gray, when he tackled a subject, he went into it very thoroughly, and I came to respect the suggestions that Don and Del would make. They were a channel of communication, an informal one, albeit, that was quite useful in that if something came up that was potentially a problem, they would be kind enough to call me even and say, "Well, you may not know it but such and such in the Bureau of Medicine...." Or, "Have you looked at this?"

Dr. Y.:

Where would they learn these things? From an investigation of the files or from outside?

Dr. G.:

They would learn them either from an investigation of the files, (in which case I was more apt to know because we kept track of what files they were looking at; they had to request them from us), but more commonly, people within the agency still, three or four echelons down, would call them.

Dr. Y.:

Oh, really?

Dr. G.:

And confide in them and then in turn, they would let me know.

Dr. Y.:

Was there very much of that, generally speaking? Were there leaks like that?

Dr. G.:

Oh, that agency was like a sieve. It was just like a sieve. It was almost impossible to keep something quiet or to keep it buried, you see. First of all, I decided that we should be as open as possible about the agency's business. We were a public agency and so there was a bunch of nonsense to try to hide

anything, and it really would have a salutary effect to open the agency up as much as possible. Ted did that. Ted Cron. But there are certain kinds of items that at times you want held very closely, because it's premature to expose what your plans are. If you're working on, for example, an investigation of a drug company, and you're going to take an action against them, you don't want that disclosed prematurely, because as the investigation proceeds, you may find you were in error, and it would be unfair, if nothing more. And so we found it extremely difficult to keep items away from the reporters. They all had their own channels, people that would open up to them and talk to them. The agency was like a sieve. But Don Gray and Del Goldberg ultimately--within, I would say, six months--we had reached a point where they felt it was no longer desirable to have the agency up on hearings. That was a vote of confidence that I thought was very significant.

Dr. Y.:

What about Representative Fountain himself?

Dr. G.:

Well, Representative Fountain is a gentleman. People have badly maligned him, in my opinion. He always treated me very courteously, even during testimony, testifying before him; he was interested in seeing the agency did a job; he was Chairman of the Oversight

Committee; that was his job, to look into it. So we got along quite well right from the first meeting. I had lived in North Carolina. I knew the district he was from, and we never had any problem between ourselves.

Dr. Y.:

You thought he was knowledgeable and sincere?

Dr. G.:

Oh, no question about his sincerity. His knowledge level was a reflection of what Goldberg and Gray were able to give him, and they did a good job of that.

Dr. Y.:

And he was capable of...

Dr. G.:

Oh, yes. He understood what was going on, indeed, much better than people like Frances Dwyer on his committee who was really a pawn of the pharmaceutical industry. Of course, she comes from New Jersey, and many companies were in her district, but it was so clear that she had no comprehension of what was going on in those hearings. It was just remarkable. She had been told what to say and ask. There it was.

Dr. Y.:

I think I'm going to have to turn this tape over.

Dr. Y.:

You hold in your hand there the first stack of the appointment cards which...

Dr. G.:

These were for 1966.

Dr. Y.:

We were talking about the different things that you did in order to plunge quickly into this new position to orient yourself as to what the responsibilities were. Now, one of the things that was stated by the Miles Committee in the report that was issued on the very day that you were sworn in related to these new management approaches that the committee felt was needed. We have talked about some angles here as they related to personnel, but it wasn't just a matter of personnel to work with you...

Dr. G.:

Oh, no.

Dr. Y.:

It was a much broader...

Dr. G.:

It had to be a different philosophy of management, the involvement of more people in managing the agency. This was why it

became important to turn the districts around, and why it became important that the bureau chiefs, who had been dominated by Rayfield also, had to become independent and run their own bureaus. You see, Rayfield really, by controlling the districts and the manpower in the field which was where each of the other bureaus had to turn to get jobs done, really controlled the entire agency. Now, he must have been an extremely brilliant guy to have done as well as he did. For one man to keep all of this under control, he had to be very capable, but nonetheless, it was bad because they weren't using...they weren't getting what they were paying for in terms of leadership from the second echelon staff, the district directors and the bureau chiefs. And so we had to instill and install a different management philosophy, and that was perhaps the hardest thing to do. Now, one of the things we did to help us with this was to hire Booz, Allen and Hamilton to come in and study the field organization, how the field staff were being used and to make recommendations to the agency as to what changes should be made. Now, this was an extremely expensive undertaking, about \$800,000 by the time we were through, and Mr. Rankin, myself and the key staff members recognized that, in effect, we were paying Booz, Allen and Hamilton to do a study which would come out with conclusions that we knew in advance, and we knew what the recommendations would be. In

fact, I don't think they came up with very many recommendations that we hadn't foreseen.

Dr. Y.:

Even the Second Citizens Advisory Committee had had a number of the same recommendations.

Dr. G.:

Sure. Of course. They were obvious ones, but we were willing to pay that price because the way Booz, Allen and Hamilton went at the job was to involve the district people to a great degree and make them feel that this was their study and that what was being recommended was in the interest of the field personnel and, therefore, it had a better chance of being adopted than if we decreed it from headquarters. And this to me was extremely important and, therefore, worth spending that large an amount of taxpayers' dollars on it. And, in fact, I think that's the way it did work out.

Dr. Y.:

Right. Now what about the way the lines of authority ran in the new system in comparison with the old system?

Dr. G.:

In the old system, of course, everything had to go through Rayfield. If the Washington Bureau Director wanted something

done in San Francisco, it had to be done through Rayfield's office and with Rayfield's approval and he could block everything. From the other end, Rayfield was like the constriction in an hourglass. Everything had to flow through his office, whether you were in the district, in the field or in headquarters.

Dr. Y.:

Oh, even in headquarters?

Dr. G.:

Oh, sure. The bureau chief in headquarters, if he wanted something done by field personnel, a study. Let's say the Bureau of Veterinary Medicine wanted to have something done in terms of finding out the incidence of contamination of meat with antibiotics. Then they had to get Rayfield's approval and get him to direct the district staff to spend inspection time on collecting samples and lab time on analyzing the samples, you see. So, everything was a bottleneck. Now, in contrast, the style we adopted and promoted was that there were parallel lines going up within the bureaus to the bureau chiefs and then from the bureau chiefs to myself, or within the districts through the district directors to me. And so I had a span of authority that looked as if it was 35, there were that many people reporting directly to me, bureau chiefs, district directors, assistant



commissioners. Now, we ultimately wound up with seventeen districts. If you have seventeen district directors reporting to you, I submit that's not the same as the span of control of seventeen, because their functions by and large are very comparable, and so the span of control is maybe more like three, you see, and that would mean your span of control is much less than thirty-five, more like twenty-one. Now, there has been a lot of argument in the management field about how broad a span of control a manager exercises. I think we've underestimated at least, in my opinion, the span of control that one can effectively work with. I never felt particularly bothered by the fact that thirty-five people were supposed to be reporting to me. Now, it worked this way, too. Mr. Rankin handled a great many of the direct communications with the staff, but I kept myself in reserve for problems they chose to bring to me, and we would resolve those problems on the occasions of those meetings or discussions.

Dr. Y.:

Did Mr. Rankin always report to you about the reports that were made to him, whether or not they were problems, so that you were aware of what had been brought up and said? Or was this at his discretion?

Dr. G.:

It was largely at his discretion but generally he did. Now we

had some checks and balances in the system. Remember I told you I wasn't exactly unaware of some of Winton's propensities. He could be pretty slippery on some things, you see. If he didn't want you to know about something, he could sort of bury it away from you, but I asked each district director to report to me by TWX. We installed a system.

Dr. Y.:

That was a speed device?

Dr. G.:

Yes, a communications device. We installed a system within a month after my assuming the Commissionship which linked all of our district offices with headquarters by TWX, and every Friday I asked the district directors to TWX to me outstanding problems, things they wanted brought to my attention. Mr. Rankin and I both personally reviewed those TWX's, and then referred them for action to the appropriate bureau chief or assistant commissioner, you see. And so there was another mechanism of bringing problems to the attention of the Commissioner, and in fact one of the district directors, I in effect forced him out--fired him--because he failed to bring a problem to my attention. That was the Seattle District which had a significant problem with canned salmon. Now, it was in the warehouses, bad seals, and they sat on it for a number of months. It was a

fantastically large problem. It ultimately consumed a great many hours of inspectors' time. It was an industry type of problem. It represented a potential hazard in view of the botulism problem of a few years earlier that just couldn't be countenanced. And yet, the district director sat on this problem and never reported it to me. In fact, in spite of the fact that he was submitting every Friday a telegram telling me nothing was wrong in Seattle, here he had this damn problem he was sitting on. So, it didn't always work, but at least they had a channel directly to my desk once a week, plus the telephone.

Dr. Y.:

The TWX system is an example of an innovation of the hardware of communications and planning, it seems to me, that was part of your new regime. Do you want to talk about that? You've been interested in this kind of problem all through your career, it seems to me.

Dr. G.:

Yes. You have to take advantage of the hardware as a means of facilitating communication. It's nothing more than a device to assist in communication, to speed it. It's one more way of opening a channel; it's a different channel. Perhaps, each type of channel of communication has its own virtues, the telephone, the TWX, the written letter, the in-person confrontation

and discussion, the conference, these all have advantages, and I simply wanted a range of these available to the key staff to use.

Dr. Y.:

I take it with regard to automation all over, that the Food and Drug Administration previously wasn't an agency that was at the cutting edge of...

Dr. G.:

No. My God, no. They weren't using a computer, not that you need a computer for everything; certainly, with the masses of data that the agency had to and does have to cope with, it just became...and their inability to retrieve any information when you wanted it, which was the really significant thing. Hell, you could have information from hell to breakfast, that's fine, but if you can't retrieve it, it's not worth a damn. And so, it became apparent, early on, that we had to have some kind of automation in order to retrieve data. The sheer volume of information on inspections of various firms throughout the nation was such that we needed it, and so we did form a task force to study the problem, and they recommended that we acquire a computer. We did acquire a computer. Part of the Booz, Allen and Hamilton study was to look at the inspection system; the report forms, the information that was gathered, how it was stored and utilized

and fit this in. And that has been done, you see.

Dr. Y.:

And once you acquired that capability, there were other angles you could push it into. What are...

Dr. G.:

Well, you could begin to develop an information system for management of the agency so that you were consciously making decisions based on information from the district offices, from the inspectors' reports and you weren't managing as much on an exception basis, or you wouldn't be when it was fully implemented, or at least, you had a fuller range of information available. You could do more critical analyses and show where the productive man hours or man years of effort were derived from; you could then redirect the use of personnel. There were all sorts of added benefits. Ed Tuerk came with the agency from the Communicable Disease Center, by the way, and I shouldn't omit talking about Ed Tuerk, an unusual person. Ed worked with the VD program. In fact, many say Ed ran the VD program at CDC. A very strong individual, an extremely intelligent guy. And an abrasive sort of a person. He rubbed people the wrong way, because Ed made them aware of their own deficiencies.

Dr. Y.:

He always seemed very quiet and shy to me.

Dr. G.:

Well, he has that appearance initially, but in a meeting or in a discussion with him, Ed would begin to ask questions that soon get on people's nerves. And I had many problems even with the FDA staff that came about as a result of Ed having come there, but, on the other hand, Ed did so much for the agency that those are the kinds of problems that an administrator is happy to put up with. It was Ed who devised a different method of reporting, who, in essence, worked out within FDA what turned out to be the first significant program within the department of Health, Education and Welfare collection of agencies on PPBS.

Dr. Y.:

Now, that is...

Dr. G.:

The plant performance budgeting system.

Dr. Y.:

Right. The same thing that had been used in Defense?

Dr. G.:

Yes. It was the Hitch-McNamara type of system. Ed was responsible for this in FDA, and we were the first agency in HEW to get off the ground with it and probably did it a better way than any other agency. Some agencies maintained they couldn't

do it, but be that as it may, Ed Tuerk was the assistant commissioner for planning.

Dr. Y.:

And, of course, this sort of analysis of the past was related to...

Dr. G.:

Extremely important, you see, and one thing that Ted Cron and I soon perceived as the major problem in FDA at every turn in the road was "There's no data base." It got to be so common that it became almost a joke between Ted and I. We'd just look at each other and say "data base," whenever this problem came up throughout our stay at FDA, because, no matter what the question was..."How many drug companies are there?" I would ask, did ask, early on. "Well, we think there are 900," I said, "What do you mean 'think'? Aren't you required to inspect them once a year by act of Congress?" "Yes." Then I'd say, "Why don't you know?" "Well, as near as we can tell, there are 900." And after Ed came, I said, "Ed, how many drug companies are there?" He said, "Doctor, as far as I can find out, there are 714, but," he said, "let me point out: don't attach any significance to that having a high degree of accuracy." And a few months later, I said, "Ed, how many drug companies are there?" He laughed and he said, "I think there are 650."

And before I left, I think it was down to around 572. It was interesting that we didn't have a good data basis in almost any part of our work in FDA. How many food companies are there? Well, nobody really knew, you see. And so it became extremely important to have people such as Ed Tuerk. Ed is fiercely independent and, again, was extremely valuable to me because of his independence. Now, the FDAers, the old-liners, hated Ed's guts, and many of them hated my guts, too. I knew this.

Dr. Y.:

This was because it upset the familiar applecart?

Dr. G.:

Of course. Of course. And because Ed was very demanding of them, and, you know, he took them to the wood shed. They would give him garbage, and where garbage might have gotten by at one time, it didn't go with Ed Tuerk, because Ed, on the other hand, knew that I would question him, and even if I hadn't, Ed would have gotten good information.

Dr. Y.:

What kind of background training did he have to make him this sort of person?

Dr. G.:

Well, Ed, as I recall, started as a VD rep, and worked up in



the management field. Now, he had worked for a little more than a year at Emory on his doctorate, just before coming to join FDA.

Dr. Y.:

He talked with me about his dissertation...

Dr. G.:

Uh huh.

Dr. Y.:

About being on his committee, but I imagine that he just got so busy that he just hasn't had...

Dr. G.:

I hope he's followed up on it because...

Dr. Y.:

He's got a whole, new political science department.

Dr. G.:

Yes.

Dr. Y.:

Well, one other area in which this data base problem and the computer to help acquire a data base was of great significance, I guess, was in the adverse reaction reports, wasn't it?

Dr. G.:

Oh, my God. That was a mess and it still is, I'm afraid. The adverse reaction reporting system theoretically was being managed in the Bureau of Medicine by a Dr. Donald Lovett there. Well, it turned out that this was entirely unreliable. So was Dr. Lovett, and we had to get rid of him, and we fortunately did, but Dr. Lovett was one of Joe Sadusk's favorites, and he was a right engaging kind of a guy, but he was in private practice at the same time that he was working at FDA. A number of the physicians were and I tried to eliminate that. I was never completely successful.

Dr. Y.:

Just a question: This, I imagine was a financial situation. Was one of the reasons you weren't able to do it the old old problem of inadequate salaries?

Dr. G.:

Well, by the time I left, I didn't feel that that really was the problem, because we got the salary levels up during my tenure as Commissioner. We were paying pretty respectable salaries to these people, and I didn't feel there was justification for them remaining in private practice, and so we tried to...Don was particularly active in practice and was often away from his desk, and we made book on him and just before we were about to

throw the book at him, he resigned, but the whole time he was there, that adverse reaction reporting system was a mess. The practicing physicians were not reporting to either us or the AMA. The AMA, during the latter part of say, '67, early '68, they dropped their adverse reaction reporting system because it was totally unsuccessful. We were paying from FDA money to residents in hospitals five dollars a report to submit a report. Reports we were getting were highly repetitive, penicillin reactions, sulfa reactions, et cetera, and I didn't think worthwhile. I asked Herb to dig into this one. Of course, he had so many other things to do and, in truth, nobody has come up with a good method of gathering adverse reaction data.

Dr. Y.:

Did the Dakota experimental system work or was it the same...?

Dr. G.:

It never was set up.

Dr. Y.:

It never was?

Dr. G.:

No.

Dr. Y.:

I thought that was...it was on the planning board, I guess, at

the time I talked with you, but it never did get set up?

Dr. G.:

No. The Public Health Service wouldn't fund it.

Dr. Y.:

I see.

Dr. G.:

Yes. So the adverse reaction reporting system never functioned properly and I don't know the answer to it. I tried to get the Bureau of Medicine in late '67, early '68, to work out a system where a physician could phone in an adverse reaction and in exchange get information on drugs involved in the treatment of adverse reaction or on any drugs he wished, and not necessarily a quid pro quo. I worked out with the telephone company and met with AT&T officials to discuss the possibility, and they were interested in the program. It would have involved the use of inbound watts from all over the United States, and we felt the way to go at it was to start in the District of Columbia and have the phones manned from 8 in the morning until 11 at night, using medical students from the medical school in the evening, or physicians who were on our staff. I never could get the Bureau of Medicine staff to actively go after this. They could be quite successful in resisting you. Again, it was something that Dr. Ley, being so busy getting rid of the new drug backlog,

couldn't give much personal attention to. He thought the idea was worthwhile. If the District of Columbia experiment was successful, we were going to open it up to New England physicians as a group and then, region by region, extend it. Now the philosophy behind that was that physicians are quite leary of making a written record of an adverse reaction because of possible medical-legal problems. But if they could telephone free of charge and provide the information, thus help other physicians, and at the same time, get any information they wanted on drugs, not advice on treatment, but information on drugs, I felt that it might work more successfully than the current adverse reaction system. But I never could get Arthur Ruskin, who was in charge of this project, to get off his ass and get the D. C. Medical Society moving on it. So he just sat there. Now those are the kinds of things that are frustrating because you see the possibility, you have the idea, and you then turn it over to a staff person and he doesn't follow through. Well, your time is occupied by many, many activities and responsibilities, and so you can't yourself do everything personally, and I never believed in that as an operating philosophy anyway. I always believed in delegating and then seeing to it that the person got it done, and Arthur just wouldn't do it, and Herb couldn't spend enough time following it up, and I couldn't either.

Dr. Y.:

But the data base in this field is indispensable to the...

Dr. G.:

Terrible. We need it badly, and yet it doesn't exist, and there doesn't seem to be, at this point in time, a good method of siphoning that information off from the routine information that's collected in hospitals. I think it can be done when we get computer-based hospital information systems.

Dr. Y.:

Right. You even were looking into the possibility of having the Food and Drug Administration be responsible for adverse reaction reporting from the whole world, weren't you?

Dr. G.:

Well, we did work out a contract with the World Health Organization where we would provide facilities and let them use our computer on the WHO adverse reaction reporting from member nations, and we simply were providing housekeeping assistance, some funding of the project, and they were calling the shots with respect to what information they wanted, the format of the reports, et cetera.

Dr. Y.:

Did that go ahead?

Dr. G.:

Yes, that's operative.

Dr. Y.:

That's operative.

Dr. G.:

But it has the same limitations as the U. S. system.

Dr. Y.:

One of the other segments that was very important right at the start, of course, was the confrontation with the drug industry. Would you talk a little bit about how you assessed what had been the status of the relationship of the drug industry to the agency before you came and how you sought to apprise yourself of what the drug industry was about and tell of the contacts that you had, especially with representatives of the Pharmaceutical Manufacturers Association.

Dr. G.:

First of all, my feeling was that the agency had gotten too close to the drug industry. Now, in part this was substantiated by Morton Mintz's book where he talked about that molecule, the PMA, the FDA and the AMA. And, indeed, it was interesting if you looked at the hearings, and I used that in a speech one time. The PMA said this, the AMA said this, and the

FDA said this, and they were all talking the same party line. Well, that didn't seem right. Not that there necessarily has to be a difference, but it seemed a remarkable coincidence. So I decided that there was too close an alignment there, that Dr. Sadusk had been unwilling to step on people's toes, his philosophy was that the practicing physician knows best. So, in looking at the drug industry, I first began by looking at NDAs, the new drug applications, and reading those in the evenings. I had a stack of them on my conference table in the office. And the more I read, the more I began to appreciate the very complex and subtle problem that the drug industry was posing, and yet the very serious problem it was posing, by virtue of its wordsmanship in using Madison Avenue agencies to distort the factual data in order to induce physicians to prescribe drugs. So, I had the strong feeling that they were involved in that kind of an activity; secondly, that their research really wasn't as good as it should be or as good as it needed to be. These conclusions were formed well enough by April 6th, I believe it was, when I spoke to PMA in Boca Raton that I really laid out the agency's position at that time and somewhat shocked the pharmaceutical industry. They were watching with great interest, of course, They had sent many delegations to see me, and I had made a practice of meeting with the medical directors and some of their staff in the evenings



during the early months. Perhaps once a week, I would meet at the Madison Hotel and have dinner with them. "Them" being the medical director of Smith, Kline, and French, for example.

Dr. Y.:

You mean one at a time?

Dr. G.:

Yes, individually. And I felt I was fair game for that. They wanted to know me, talk to me and be able to have an understanding of how I looked at their world, so I tried to make myself available in that fashion and did. So I was getting a lot of input from different sources. I had those kinds of meetings where I could probe the individuals.

Dr. Y.:

Did you feel these were valuable or did you feel there was a kind of conspiracy to give you the same kind of point of view all the time?

Dr. G.:

Well, there was a remarkable similarity in point of view, but it was helpful to get to know the kinds of people who were employed by the pharmaceutical industry, to know what I was up against. I don't think there was any conspiracy. I'm certain they shared information.

Dr. Y.:

Well, that's all I meant.

Dr. G.:

I know that because it soon became apparent that my drink was bourbon and ginger ale, and I would go to their suite for the meeting in the evening, and, sure enough, there would be bourbon and ginger ale.

Dr. Y.:

So that you didn't even need to ask.

Dr. G.:

I didn't even need to ask. The first couple of sessions I had, there wasn't any ginger ale, and I had to ask, and they would have it brought up, but it became apparent that the word got around very fast, and I assume that if that word got around, other kinds of information were shared by the medical directors that I met with.

Dr. Y.:

Well, in these sessions, did you mostly listen or did you in your turn seek to present to these individuals the same point of view you were later to present to the industry in your speech?

Dr. G.:

I did both. I tried, first of all, to find out what it was they

thought the problems of the FDA were. This part was very useful to me, because they, after all, were dealing with the Bureau of Medicine on a day-by-day basis, and this gave me a good fix on what the internal problems of the Bureau of Medicine were. And many of them were willing and responsible enough to be very open and above board, very forthright, in their discussions of the problems, naming individuals who they thought were blocking, like Frances Kelsey whom we had to move aside to get at the IND problem in an effective way. They were willing to name individuals. Well, this was useful. Then, secondly, I could explain to them what my concept of the agency's responsibilities in their particular field of interest were, and I think that was helpful to them.

Dr. Y.:

A part of this, too, was speaking with the head man, I suppose, in the pharmaceutical industry insofar as it was pulled together in the trade association, Joseph Stetler?

Dr. G.:

Joseph Stetler, yes indeed. I had known Joe when he was counsel for the AMA. I was working in the field of highway safety, and I was on the AMA's committee on traffic safety which Fletcher Woodward, Dr. Fletcher Woodward, was chairman of. Joe attended occasionally those meetings and talked about the legal aspects,

and so I got to know him and I thought he was a very effective AMA counsel. Now, when I went into FDA, not immediately after my appointment or swearing in, but within a reasonable period of time, Joe invited me to have lunch with him, or perhaps it was dinner, I don't recall now, but he then tried and did explain to me what he thought the role of PMA was, offered assistance and willingness to work together.

Dr. Y.:

What kind of a person is he, and how does he operate in his position?

Dr. G.:

Well, Joe is an interesting man to watch at work. First of all, Joe will dedicate himself completely to the interest of his employers, totally, in a way that I never could. I could never work for AMA and do the kind of jobs that Joe does, or PMA, because inherently there are some things wrong about those organizations. Joe is able to accept those, throw himself wholeheartedly into their work, and I just couldn't do that. So, he is an interesting person from that point of view. Even though he may personally have reservations about the way they operate, an organization operates, he apparently can subjugate those to his sense of responsibility for the job and not make any effort to change them. I may be misjudging him on that last

point, but certainly he knows what the problems of PMA are. He knows it's a lowest common denominator organization. Joe is extremely intelligent. He's a shrewd operator; he's a good infighter. Joe knows how to handle Congressional liaison functions. He knows who to lean on to get something done. Now, what people often fail to perceive is that within the establishment Joe can come to people like Wilbur Cohen and sit down and tell him openly--and to me--when we had a bill pending: "We have x number of votes and you have x number and we have you beat on this one." I sat there and listened to this kind of discussion. There was no hiding of information on that basis. When the battle lines were drawn, he knew what the issues were, he knew who to go after, and he was very realistic and open about dealing with you on that. I never found Joe to go back on his word. He was a very direct person in dealing with me.

Dr. Y.:

How was he from the point of view of compromise, because lots of the issues that there were between you and PMA, particularly I think of the big issue of advertising regulations, were issues that neither one of you wanted to get into the courts if you could help it.

Dr. G.:

Well, Joe, being a lawyer by training, you see, Joe was very

effective in the battling for position in a compromise. He was much better than I at this. Now, the thing that bothered me most about Joe in those dealings, when I was willing to compromise, when there was room to compromise and not give away the public's interest, where we would state a position in excess of what we really thought was needed to do the job and thus had room to retreat, Joe would, far too often, fall back on legalities. Now, that was his major shortcoming, in my book. He would say, "Well, of course, that won't stand up in court," or "If necessary we can go to court on this," and that got my dander up at times. I learned to keep my cool and not get into a fight with him about it, but it became apparent that this was a stumbling block for us and we could have more effectively compromised a number of issues had Joe not been so legalistic in his thinking.

Dr. Y.:

At least by bringing the cases, whether or not he would have won as he thought, he could have put off any sort of enforcement for years.

Dr. G.:

Yes. Well, provided there wasn't an imminent danger to the public health. Now, one of the things that Joe had to contend with that I didn't have, Joe had a board of directors at PMA, and that may

well have hampered him in his dealings with us, you see. Because, then it did come down to the lowest common denominator type of decision that he could get from the board on how to go at a problem like advertising regulations, you see. So, to be fair, I didn't have that constraint that Joe had to work under.

Dr. Y.:

You had a certain eye over your shoulder on what Congressional committees might do.

Dr. G.:

Oh, of course. I had, more importantly than that, I had the basic authorizations and responsibilities that Congress had afforded the agency. This meant that you had a public trust that you had to meet. You couldn't give that away.

Dr. Y.:

Well, I didn't mean that.

Dr. G.:

No, I know you weren't suggesting that, but always...I never really worried about Mr. Fountain and his Oversight Committee. I thought that if the agency met its responsibilities and I met mine with respect to the public trust that Congress had given us, then Mr. Fountain wouldn't have any complaints. Sure enough, that's the way it worked out, too, as you know. But

another interesting thing with the pharmaceutical industry, not only did we have the dealings with Mr. Stetler and the PMA which were very difficult, for the reasons I've cited, but also we had the direct confrontations. This is an innovation that Mr. Goodrich has commented on (Mr. Goodrich was and is the General Counsel for FDA). For the first time I required the president and/or the chairman of the board to come into the Commissioner's office, on faulty advertising and misleading advertising, and sat them down and went over it with them. Billy Goodrich always felt this was an extremely significant departure from what had been. First of all, almost nothing had been done in the past, but he felt that for the first time the corporate head was beginning to feel the weight and pressure of a public agency, and he felt this was an extremely important venture that we undertook, as a change.

Dr. Y.:

Well, now, one of the first examples of this might very well have been Peritrate.

Dr. G.:

That was when we got Dr. Len Scheele in. Len and Bob Clark. Bob Clark was the president of Warner-Chilcott which was part of...in that corporate structure he worked with Len Scheele, who in turn worked for the former governor of New Jersey who was



chairman of the board of Warner-Lambert at the time, Alfred Driscoll. Now, I got Governor Driscoll, Len Scheele, who had been Surgeon General of the Public Health Service when I first came on duty as a commissioned officer, you see, and Bob Clark in on the Peritrate.

Dr. Y.:

This was the first seizure under the Kefauver-Harris advertising provision.

Dr. G.:

That's right, for misleading advertising. They were using animal data and presenting it as if it were data on humans. They had ignored the results of certain studies that had been carried out that did not show Peritrate to be of value, the way other studies did, which weren't as carefully controlled, which they did present. In their advertising message, they had an eight-page color ad, a series of them, that they ran in different medical journals which were misleading, and so we did seize the drug. Now, I learned a very valuable lesson from that, and, unfortunately, you have to make certain mistakes in order to learn, and I perhaps should have perceived that this could have happened, but the mistake was this: The seizure of the drug was not understood either by the public or the practicing physician. Our laws that we operate under go back to old

admiralty laws, and this seizure was indeed a token seizure. You seize an amount of the drug to provide a basis of issue to bring before the courts in a speedy fashion, you see.

Dr. Y.:

Right.

Dr. G.:

You don't seize the entire drug. You don't withdraw it, order it from the market, but you engage in the seizure in order to get the issue before the courts, and that was deemed in the old days as the fairest way of handling this matter. Now, what happened, and this happened in spite of accurate reporting on the part of the press, the public press, it created great consternation on the part of the patients who were receiving this drug, because they hadn't read the story carefully, they didn't realize the safety of the drug was not in question, and they besieged their physicians with phone calls, and it resulted in physicians calling us and great consternation.

Dr. Y.:

Your attack, so to speak, was aimed at the advertising which made the drug sound as if it was useful for heart problems other than angina?

Dr. G.:

Well, not only that, but that it was misleading with respect to how useful it was in regard to angina.

Dr. Y.:

Is that right?

Dr. G.:

Oh, yes. And that the data submitted..., for example, they used pigs for certain kinds of studies and didn't clearly indicate to the reader of the advertising that this data was derived from pigs.

Dr. Y.:

Did this seizure occur before or after your confrontation with the officers of the company?

Dr. G.:

It occurred at the same time, as I recall.

Dr. Y.:

I see.

Dr. G.:

The seizure really is under the control of the U. S. Marshal. It probably, thinking back, was just before. Now we seized subsequently a drug. It happened with Upjohn and that seizure took

place at the same time as my meeting with Mr. Ray Parfet, the head of Upjohn, and his staff. So, I think the Warner-Chilcott was just before.

Dr. Y.:

Do you want to talk about that particular meeting since this was the first major case, as an example.

Dr. G.:

Let me finish up on the other, and then we'll talk about the meeting. The lesson learned was that it's bad to seize a drug unless there is a matter of safety and you wish the drug off the marketplace, because neither the public, who you can't expect to be totally informed, nor the physicians clearly read the stories and understood them. So the press wasn't at fault, but it created such alarm on the part of patients who, by the way, in that instance, shouldn't have been alarmed--you don't want to alarm cardiac patients--that we decided after the episode not to seize any more but to use a different method. Now, the meeting itself was quite interesting. Len Scheele never said a word, to my recollection. He just sat and listened. Bob Clark who was the president of that particular part of the Warner-Lambert corporation, Warner-Chilcott Labs, I think it's called, had to bear the brunt of it. He was very direct and open in his dealings with us, very frank, and he was quick to admit

after questioning some of his own people that the information was not properly presented and that he did promise to remedy it.

Dr. Y.:

So that you had a feeling that he was unaware of the fault as of the time of the meeting?

Dr. G.:

In fact, I found that very commonly the president of the company wasn't aware of what was going on, and this was one of the reasons that it was significant to bring them in, to force them to become aware of what their advertising people were claiming about their drugs, and to begin to view drugs in a little different way. As you know, ultimately we brought some 24 companies before the Commissioner in that two-year period, some 24 instances, rather, because some of the companies repeated. They had to be brought in twice for misleading advertising. So, this was a departure, to bring the president and/or chairman of the board into the Commissioner's office, let him see his medical director being questioned and have to yield to the agency people on the lack of validity of claims and let him see his advertising people. At times you could just see the president begin to get mad, at his own people, not at us, that they had been so stupid. In fact, let me say that, almost without exception, there was, in

almost every instance, agreement between the corporate president and myself on the company objectives and how their advertising should be pursued and what the ethics of the situation were. Henry Gadsden of Merck Sharp and Dohme; Barney Mattia of Hoffmann-LaRoche, all of these individuals, pharmaceutical company presidents, were not in disagreement with me, and I felt that their agreement was a genuine one, not one that was contrived to fit the situation. That was reassuring. It was upsetting, too, because it also meant that they weren't paying attention to what their people were doing.

Dr. Y.:

Well, if they did reach agreement with you in these individual cases and...

Dr. G.:

We began to see some change. I think the advertising, even in that short period of time, two and a half years, we began to see more honest advertising. It became tougher to find in the printed journals examples of advertising as grossly misleading as it was in the early days.

Dr. Y.:

Well, now, why was it, then, that you had so much opposition toward getting the kind of guidelines that you drew up?

Dr. G.:

Well, they...

Dr. Y.:

Is that the lowest common denominator problem?

Dr. G.:

I think it's the lowest common denominator thing, and then, secondly, they know that the regulations have the force and effect of law, and they didn't want the guidelines to go into regulations. They wanted the situation left as it was, so their common plea was a lack of understanding of the regulations. In every meeting we had, they said, "Well, we didn't understand that that was what the regulations really meant. That wasn't clear." And we set about to make the regulations more clear and more explicit. Now, then you see, they feared getting their hands tied by these regulations and they would then have no defense. So they didn't want this degree of explicitness to occur.

Dr. Y.:

They didn't want them to be either too vague they couldn't understand...

Dr. G.:

Oh, I think they much preferred them to be too vague, because then they had an easy out if they got caught. Now, keep in mind that

we had only six people working at the peak on misleading advertising in FDA. Now, in contrast, the pharmaceutical industry spent that last year I was Commissioner about \$800,000,000 on advertising. So there were literally hundreds and probably thousands of people involved industry-wide in advertising activities. So it was a sort of David and Goliath proposition as far as we were concerned. We couldn't begin to review all of the advertising, and we simply wanted to make them aware that, by causing a "Dear Doctor" letter to be issued...Now, that cost them \$40,000, just the mailing costs and the cost of changing the ads; altogether the penalty probably was a hundred thousand dollars. Now, that's insignificant, because the risk was relatively slight in getting caught, and they really depended on not getting caught, and if they did, by that time they would have gained enough of the marketplace that a hundred thousand dollars really was a tap on the wrist. This was one of the problems with FDA. It needs stronger penalties to invoke against manufacturers. The most effective thing we did, the one that really got a manufacturer's attention the quickest, was when Bristol-Myers had negotiated over labeling for a new penicillin called "Dynapen" for months, quibbling over words in the final printed labeling, bringing to us their advertising for pre-clearance because we perceived problems, and, after all this was done, a week before the NDA was formally approved, in other words, when they had received notice that the



NDA was going to be approved and began developing their advertising campaign, they came out within a week before the formal approval and marketing of the drug with a letter to all physicians that was misleading as hell. In spite of all this negotiation and good faith. Well, it was an antibiotic, don't you know. So I called the president on Friday and said, "We are decertifying all the stocks of "Dynapen" that you have sitting in warehouses. Now, first of all, I said, "We are having some problems with the advertising. Would you like to come here Monday and discuss that?" "Oh, no", he said, "I don't think I could get there Monday. I have something else. Perhaps, later in the week." I said, "Oh, I just wondered, because we are decertifying all of the 'Dynapen.'" He said, "Could we meet tomorrow?" This was a very effective thing. This, of course, was why I think the pharmaceutical manufacturers fear registration, because if the agency could withdraw registration, their drugs would then be illegal in the marketplace.

Dr. Y.:

The whole shebang.

Dr. G.:

The whole shebang. Everything. And this is the kind of penalty, I think, that the agency is ultimately going to have to have available to get at the problem and control it.

Dr. Y.:

Well, now, some of these decisions in the small number of cases that your small staff was able to check out, some of these were really your own from reading?

Dr. G.:

A few. Many of them came from doctors who wrote to the agency who had worked on the drug during its IND stage, and some of them were agency personnel getting mailing pieces at home because they practiced medicine, and they'd bring them in and say to Dr. McCleery, "Dr. McCleery, look this one over. I have reason to think..."

Dr. Y.:

I was getting around to him. Would you speak about him a minute?

Dr. G.:

Well, Bob was an interesting person. He had been a surgeon at one time. He worked for a Madison Avenue advertising agency that handled pharmaceutical accounts, so he knew that end of the business, and he was in charge of medical advertising review. My first encounter with Bob, he asked for the opportunity to see me, and he rode to Dulles Airport with me because my schedule was so jammed that was the only time I could see him that week. And enroute to Dulles Airport, he told me the problems in medical advertising. I was very suspicious of Bob McCleery at that point in time. I

asked him, in fact, point blank, I said, "Are you an iconoclast?"  
And he said, "No, I don't believe so."

Dr. Y.:

You mean you thought he was so far out he was in the next county?

Dr. G.:

Yes, I did, and only later I came to have great respect and trust for his capabilities. He was a methodical workman, analyzing a pharmaceutical ad. He could take it to pieces and dissect it beautifully and did so. When Bob came to you with something... at first, I was very leary, as you might suspect, and I would dig into it myself and look at the references and read the ad and study the literature. I insisted on all of the background literature being brought to my office so that I could personally review it, and I did that for quite a few of them, and I never caught Bob out on it. As I came to understand this very complex individual, who has since left the agency unfortunately, I respected his capabilities and never found him to be wrong in the analysis of an ad. When he had it down, it was well documented.

Dr. Y.:

Do you believe that it was he who was important in getting your attention to this in the full degree that it...

Dr. G.:

Yes, I think Bob should be given credit for that, and I tried to give him credit at the time of his retirement. He and Billy Goodrich. Of course, Billy right from the start, as well as Bob, said, "Doctor, this advertising is terrible and something's got to be done with it." Old Billy is an extremely shrewd guy. He knows what's wrong, where the bodies are buried. I relied...in fact, I should mention Billy Goodrich. I gave serious consideration to using Billy as a deputy.

Dr. Y.:

Is that so?

Dr. G.:

Yes. At one point in time, when I was weighing Billy Goodrich versus Winton Rankin. Now, the reason I finally didn't was because I felt I couldn't afford to lose Billy in his other capacity.

Dr. Y.:

Exactly.

Dr. G.:

Not that I didn't think he wouldn't make a good deputy, but I then said, "Gee, who would handle this other?" And as we went further and further down the road, I said, "Boy, I may have some problems with Winton, but I'm so glad I left Billy where he is because he

was such a pillar of strength for the agency and for me." It would have been a great loss to have had him...he would have been a good deputy, I'm sure.

Dr. Y.:

Sure. He always had such an imaginative way of seeing what was inherent in the law.

Dr. G.:

He was my idea of a good lawyer, because Billy would say, "Doctor, we can do anything you want to do. The law says this. Now, if you want to do that, I'll guarantee you we can do that." But he could very subtly suggest to you the ways he thought you ought to go. I learned to listen to Billy very carefully. Not that we didn't disagree.

Dr. Y.:

What did you disagree about particularly?

Dr. G.:

Well, let me think a minute. There weren't very many things that we disagreed on. I'd have to give some thought back to dredge up the one or two occasions where we disagreed.

Dr. Y.:

Well, let me put that down as a question for the future.

Dr. G.:

Okay. Now, on the advertising, Bob McCleery was very important. I relied on him. He then worked up the material, and it took about ten man days to work up one ad. Then we would get the president of the company. He almost always brought his lawyer, his medical director, his vice-president for advertising, whatever title he may have had, along with him, and he would be met in my office by myself and Mr. Goodrich, Dr. McCleery, Dr. Ley, or Dr. Robinson prior to that time, and Mr. Cron. Ted had a good feel for these things, too, very quick to perceive, and a good understanding of words, which is why I had him there.

Dr. Y.:

And probably no great sense of awe either.

Dr. G.:

Oh, none at all. And we would then discuss the ad. Dr. McCleery would have prepared a brief that I would use, and I would make copies available to the pharmaceutical company people, so that they had everything except the recommended course of action available. We would then tell them, after discussing what was wrong, getting their agreement, we would then say, "Alright, we think a 'Dear Doctor' letter is indicated. Why don't you go write one?" Now, it was funny. They would try to weasel out from under that "Dear Doctor" letter and write it as if...In fact,

most of them turned out on the first draft to be more promotional than apologetic. I guess that's a natural tendency, but, at any rate, we then had to hold their feet to the fire and force them to do it in a responsible way. This really wasn't a strong enough penalty for them, as I've mentioned before, but another effective one we got at was forcing on "Dynapen," not only forcing them to write a second letter to all doctors, but also corrective ads. That was a different thing. That was just before I left. We forced them to run in the same medical journals that they had run the misleading ad, corrective ads.

Dr. Y.:

Well, it looks as if we are going to have to take up the next topic the next time. Thank you, Jim.

# History

of the

## U. S. Food and Drug Administration

Interviewee: Dr. James L. Goddard

Interviewer: Dr. James Harvey Young

Date: April 30 to June 19, 1969

Place: Atlanta, Ga.

Session 4

Pages 252-341



Dr. Y.:

This is one more in a series of conversations with James L. Goddard, and I am James Harvey Young, this one being held in Dr. Goddard's home on June 11, 1969. Jim, I happened to be with you on the day that you turned in your resignation, or rather your retirement, to the Secretary of Health, Education and Welfare last May, a year ago May, and you told me right after that that one of the reasons you felt free to take this step was that you had kept a little list from the very beginning of your experience as Commissioner, and on that list you had the things that you needed to get done. Now, what was this list? Is it a document that exists?

Dr. G.:

Unfortunately, it's not a document that still exists. This was a habit that I had acquired over the years in a variety of jobs. I would make a list of items that I could foresee as being needed in the next six months, twelve months, one, two years, three years. And I would keep that in the bottom, right hand drawer of my desk, and periodically I would in an idle moment pull it out and check off whatever had been accomplished, maybe add one or two, and over a period of a year or so it would require being redone, and then I would throw the original one away. Well, I made such a list up shortly after getting into the FDA job, and it expanded as I went along and began to learn more about the agency and what might be

needed. The first list had on it such things as an improved communications system; a computer center for record-keeping purposes, a data processing center for FDA. They were without one at that time, a computer-based one. And these were the kinds of things that would be on that list. They were sort of objectives that I would set, an improved professional recruitment program, this type of item. Now when I told you that I'd completed the list, I meant I had fairly well completed what I had visualized at the time I took the job, when Dr. Gardner requested me to take over. It shouldn't certainly be suggested that everything was finished that needed to be finished. There are still many unfinished things at FDA.

Dr. Y.:

You told me at the time that you had "gotten them rolling."

That was the way you put it.

Dr. G.:

That's right.

Dr. Y.:

Well, as one just begins to run down the calendar after you had first come in, one finds this Peritrate case, about which we talked some last time, looming into view. Now, as you look back upon that experience, which was the first major case as far as you were concerned involving pharmaceutical advertising, how does

this case and what arose from it look in retrospect?

Dr. G.:

Looking back on it, it was an important landmark for the FDA because, as Mr. Goodrich has pointed out, this was the first time we involved the chairman of the board of a company in discussion with the commissioner. It was the first time the agency really became the aggressor in trying to get the industry to live up to what the law required. It wasn't the absence of good law that prevented the agency from acting in the years following passage of the 1962 Act, but they simply didn't take the initiative. So I would view that as a turning point in terms of the agency now taking the initiative, getting at the industry, making known to the industry what the agency would and would not countenance in advertising. They had really never done this, other than in the spelling out in the regulations, which they then proceeded not to enforce. Now, we clearly demonstrated we were going to enforce them. Of course, I mentioned the last time we met the lesson learned in terms of not upsetting the general public by virtue of newspaper stories not being clearly read even though they were accurately written reflecting the seizure as only being a mechanism of getting the issue before the courts for discussion. We learned that lesson. And from then on we moved rather promptly against the firms that we could find. I mentioned also earlier the lack of adequate staff to police this area, but I'm satisfied

and was satisfied at the conclusion of my thirty months as commissioner that we had followed the spirit and the letter of the Kefauver-Harris Amendments. The drug companies then, in July of 1968, knew far better than they did prior to that time, prior to 1966, at least, what was required and what was expected of them.

Dr. Y.:

Right. With regard to the Peritrate situation, shortly after that had come to a head, you took a step with regard to that whole type of product, the nitrates and the nitrites, and decided on what could be said in advertising, and in this case, you decided to notify the doctors first before there was a release that hit public opinion.

Dr. G.:

That's right. We were criticized and quite properly in retrospect for not advising the medical community first in order that they could allay their patients' fears, because, as was pointed out and talked about, these are not the kind of patients that you want to deliberately upset or upset in any way.

Dr. Y.:

But yet, the way of notifying the doctors that you tried this time, at any rate, by sending each of them a letter...

Dr. G.:

It was a very costly way. It cost about \$40,000 in postage to do

that, and we recognized that because of our budget limitations we couldn't pursue that course on every occasion, so then we turned to using professional channels of communications. We worked that out with the AMA and other media representatives--Medical World News--and they indicated a willingness to carry this kind of information on a timely basis.

Dr. Y.:

So that that worked out as far as the quick response from different kinds of journals to printing the things...,

Dr. G.:

Yes.

Dr. Y.:

...since communications with doctors as fully and honestly and frankly as could be devised was part and parcel of your whole method. Now with regard to the advertising as such, certainly the Peritrate case was only the first salvo in what came to be a war. You've indicated how it ended up in '68 in midstream, so to speak, but it took a while to get to that point. One of the major steps, it seems to me, in reaching that point was the speech that you gave when you went down in April, April 6th, into Florida and met at the Pharmaceutical Manufacturers Association convention with the leaders of this trade and spoke to them in about as hard a hitting speech, I suspect, as you may have made while you were commissioner.

Dr. G.:

Well, it certainly was the hardest hitting speech they'd ever had delivered to their annual meeting. They literally were stunned at the end of the speech. They were quite polite, but nonetheless, the reaction was obvious. No one had ever spoken to them before in those terms. I told them that their work was bad, it was shoddy, and their advertising was misleading. The new drug applications were not in order. They had to bear a large part of the blame, and if they were going to profess to be part of the health industries in the United States, which they certainly had made many claims of being a part of, then they had to begin to behave as if they were, because of the law. At the end of that long chain of research, back in the laboratory stage, the animal stage, and then in humans, through the FDA clearance procedure into marketing, there were human lives involved. I think in fact that that's the phraseology or close to it that I used in that speech.

Dr. Y.:

You aimed at the management side, the lay people, for the most part?

Dr. G.:

Yes. This was absolutely essential. I was convinced even at that early stage that the medical directors literally were powerless, the professional people within the pharmaceutical firms, and my

suspicious were corroborated, because I had a number of them after that speech, at that same meeting, come up to me and mention very quickly--and these were the professional people who were also in attendance--: "That was needed." Now, in other words, they couldn't do the job although they perceived what needed to be done. I had a good friend, Dr. Cortez Enloe, who had been in the...

Dr. Y.:

Spell that, will you?

Dr. G.:

E N L O E, Cortez. Well, Dr. Enloe had run a Madison Avenue advertising firm which largely handled pharmaceutical agency accounts, although it also had some food accounts, Campbell Soups, to mention one, but most of his business was with the pharmaceutical industry. Cort had told me shortly after I took office and just, by the way, after he sold his advertising agency, which he did within a matter of two to three months after my taking office...

Dr. Y.:

Was this happenstance?

Dr. G.:

I don't think so. At any rate, he told me after he had gotten out of that business that the only way that we could really stop the pharmaceutical industry from misleading advertising was to have one

or more of the corporate officials arrested, convicted after trial, and thrown in jail. He said, "This is about what it will take to get these people to get in line and begin to tell the truth about their drugs."

Dr. Y.:

He thought they were terribly hard-headed?

Dr. G.:

And dishonest.

Dr. Y.:

Well, shortly after the speech, you yourself told the press that there were some of the drug presidents who had let you know that it was about time something like that had been said.

Dr. G.:

That's correct. At least one or two of them had that feeling and expressed it to me.

Dr. Y.:

Do you remember any particular...?

Dr. G.:

No, I can't...here again, some of them simply on different occasions came up and made the remark, "You know, I agreed with what you said at Boca Raton."



Dr. Y.:

Not making a big thing out of it...

Dr. G.:

No. No. Just in passing at a cocktail party or at some meeting.

Dr. Y.:

Now, you had had the Peritrate case. Supposedly a certain message should have been read by the industry from the case. Why did you feel it was necessary to go on down and hit so hard?

Dr. G.:

Because they obviously didn't read the message. They continued to pursue the same course. In fact, some firms, after we had them in once, made them write a "Dear Doctor" letter, within months, six or eight months later, they repeated the same kind of mistake, and we had to get them back in and go through the whole thing again. That was the most discouraging thing of all.

Dr. Y.:

That was, of course, after this speech so that...

Dr. G.:

Oh, indeed, they had had ample warning, and I think it basically came down to this: here was an industry that had gone unfettered in general, some minor annoyances from the federal government and the FDA, but generally had their own way from the very beginning,

and now they couldn't believe what was happening. They just couldn't react. Dr. Mattia's firm, Dr. Barney Mattia, M A T T I A, of Hoffmann-LaRoche, although we had made them do one corrective letter, he perceived the climate and read it more carefully and properly than anyone else, and his principal officers in that company, they read him clearly. He didn't want any nonsense.

Dr. Y.:

He said, "Let's don't get caught this way." That's what you mean?

Dr. G.:

Yes.

Dr. Y.:

You indicated in the speech that there were almost a third of the firms which were members of the PMA which your checking showed were falling short of the law.

Dr. G.:

On their advertising.

Dr. Y.:

Right. Now, where did you get this data?

Dr. G.:

From perusal of the ads in the journals, discussion with my staff members, principally Dr. Robert McCleery, Mr. William Goodrich.

Dr. Y.:

Had they deliberately set out on a kind of special campaign beginning with your commissionership or beginning with the Peritrate case or at some point?

Dr. G.:

Yes.

Dr. Y.:

To make a survey?

Dr. G.:

Not a survey but to get the problem corrected. Now as part of it, I had to know how large was the problem, and so there was no formal survey carried out, but it was an estimate based on experience of the people who knew this field.

Dr. Y.:

And McCleery and one other man, I take it, were all there were engaged in...

Dr. G.:

That's right...on the staff in the Bureau of Medicine looking at misleading advertising.

Dr. Y.:

How big did that finally get?

Dr. G.:

Six people.

Dr. Y.:

That was as big as it ever got?

Dr. G.:

As big as it ever got. Six people aligning themselves against the giants in the industry who were spending some \$850,000,000 a year on the promotion of pharmaceutical products, several hundred million on direct mail and journal advertising, and, of course, it was in this field that they concentrated because little could be done about the detail man. And so, I think that they compiled an enviable record in that thirty months' period of time. We had twenty-four firms that we brought in and made write letters to physicians. Now keep in mind there were 140 firms in the PMA. And so when I spoke to them about one-third I was talking about forty-three firms perhaps. Now we had twenty-four that we uncovered with six people in thirty months, after they had been warned. I think that's an indication of how bad it was prior to that period of time.

Dr. Y.:

Right.

Dr. G.:

Frankly, there were some cases that we didn't follow up on just because of lack of staff time and the amount of difficulty and the priorities. Some of them were a lesser level of violation, but still nonetheless misleading. And we just didn't have adequate staff time.

Dr. Y.:

Would you say that it would be a fair statement, that if one of these ads that you seem to think was violative in a major way appeared in the Journal of the American Medical Association...

Dr. G.:

Every one of them did.

Dr. Y.:

That made it a high prime target.

Dr. G.:

Yes. In every one of these, as I recall from Dr. McCleery's statement, all of these had been accepted by the Journal of the American Medical Association, which indicates that their at one time effective program, when the advertising was the responsibility of the Council on Drugs, was no longer an effective program after the Council had lost the responsibility and the JAMA or the AMA itself had a small professional staff that was supposedly taking

care of that function. Now it's interesting their revenues increased very markedly after the Council on Drugs was no longer involved to where in 1967 their revenues from medical advertising in the JAMA, as I recall, were eleven and a half million dollars. So, they obviously weren't doing the job of screening these ads and that was understandable. After I met with Dr. Blasingame and with some of the trustees, and in that meeting I heard Dr. Blasingame say, "Well, Jim, advertising's just advertising. It isn't education. It doesn't have any impact on the physician," I knew why the AMA wasn't doing a good job of taking care of the advertising, as far as its accuracy and truthfulness was concerned.

Dr. Y.:

Now, you met with AMA people in order to try to get your point across in an informal way, in a way hopefully to get voluntary compliance?

Dr. G.:

Yes. I wanted their backing, but as Dr. Dale Console, former medical director of Squibb, recently testified before the Nelson Committee...He submitted a statement, to be more accurate, because Dale has had a heart attack. Dale made the point very clearly that now the FDA has acted on the antibiotic combination products, which are not rational, as a result of the National Academy of Sciences-NRC review which I established when I was commissioner.

He said, "Now that that action's been taken and the battle has been joined, let's see the AMA throw it's weight behind FDA and show that they're really interested in the good practice of medicine." He said, "They won't do it because they are too closely aligned with the interests of the pharmaceutical industry." I'm afraid he's right. Of course, I was trying to get at them back in those days in hopes that I could get their leadership to see that they should change.

Dr. Y.:

Where did your meeting with him occur?

Dr. G.:

In Chicago in AMA headquarters in the Board Room.

Dr. Y.:

Was this the time that you came out to that quackery congress or was this an earlier time?

Dr. G.:

This was another time.

Dr. Y.:

That time when you came out, you had obviously spent part of the day with the Council on Drugs of the AMA.

Dr. G.:

That's correct. That was a different meeting then.

Dr. Y.:

Now, did this in some measure involve the advertising problem?

Dr. G.:

No. It was more involved with the compendium issue.

Dr. Y.:

I see.

Dr. G.:

Whether or not AMA was going to publish a compendium, what the Council on Drugs' position would be with respect to a federal compendium, and those kinds of issues.

Dr. Y.:

Obviously, the Council on Drugs, or at least some members of it, since that time have been at odds with the management's policy.

Dr. G.:

Well, John Adriani, the Chairman of the Council, recently took a strong stand against the advertising policies of JAMA and against the pharmaceutical industry in terms calling for use of generic drugs only.

Dr. Y.:

But certainly, some of them felt the same, I think, at that earlier time.



Dr. G.:

Yes. But they hadn't evoked or stated their position clearly. There tends to be some value in causing polarization to occur. People do have to take a stand. They can pretend up until that point in time that, well, it's not really so bad, but there comes a time when they're pushed and they must take a stand and defend it. And I think that's valuable.

Dr. Y.:

One of the very early reactions after your PMA speech that came from one of the members of the Pharmaceutical Manufacturers Association was that you hadn't been specific enough in telling the drug companies what it was that they had to do.

Dr. G.:

So we set about to remedy that lack of specificity by proposing amendments to the advertising regulations which then would spell out book, chapter and verse, and we did this, and we proposed it. Then the industry very quickly said, "Oh, that would hamstring us if those went into effect. You can't...that wouldn't be proper; you have to give us some latitude." Which really tells you the whole story.

Dr. Y.:

Who was it who worked those out? Was that Dr. McCleery?

Dr. G.:

And Mr. Goodrich.

Dr. Y.:

Mr. Goodrich.

Dr. G.:

Ah, yes. Mr. Goodrich. Don't underestimate the role that Billy Goodrich had in that administration and still continues to have. He's an extremely knowledgeable person. He has lived with the problems for 28 years. He can look at a pharmaceutical ad and, although he's not a physician, he can look at it, and he can very quickly come close to telling you what's wrong with that ad and, after careful study by the medical staff, sure enough, that's what comes up.

Dr. Y.:

Now, you drew these up and decided among yourselves what would be the proper kinds of specifics, some of which would be mandatory and some of which would be discretionary, and you hoped that you could get these new regulations about the ads into effect comparatively easily.

Dr. G.:

That wasn't to be. We published them and then we were criticized by PMA because we had published them without conferring with them

in advance. We followed the Administrative Procedures Act, which is an interesting point that kept coming up during my tenure as commissioner. Perhaps it's worth just spending a moment on. The Administrative Procedures Act was passed by Congress, applies to regulatory agencies of the federal government, and it spells out how one conducts the affairs of a regulatory agency with respect to the promulgation of regulations, in that it requires, first, that the agency publish a notice of intent to regulate, provide those affected a period of time to comment. The period of time is discretionary but usually a minimum of thirty days is specified, unless the health of the public is being jeopardized. And then once those comments have been reviewed, the agency is required to make a determination of whether or not hearings may be needed in order to serve the public interest prior to the implementation of the regulations. Then under the hearings portion of that act, where it's spelled out how the hearings will be conducted; the hearing examiner is appointed by the head of the agency; review of the hearing findings is specified and spelled out, how that will be conducted, the conduct of the agency employees while those hearings are being carried out, vis a vis public statements, et cetera. All this is spelled out. It's clear that Congress had studied very carefully problems relating to regulatory agencies and drew these rules in the interest of promoting fairness with respect to the affected parties and the interests of

the public. Now, my comment is that, having worked in two regulatory agencies, I've noticed that the business community, in general, does not like the Administrative Procedures Act. They criticize it time and time again because they claim that the agency becomes the judge, jury and the prosecutor under this act. The pharmaceutical industry in particular has fought to discredit this procedure, and this time was no exception. They immediately, instead of coming in, as I had hoped Mr. Stetler would, with a series of items over which we were in disagreement and could reach some compromise that would still provide the public the protection that we felt was needed and at the same time accommodate some of their points of view.

Dr. Y.:

Just a minute. Can I ask...

Dr. G.:

Sure.

Dr. Y.:

Did you build in compromising features?

Dr. G.:

Yes, I think there were compromising features; it would be fair to say that we didn't expect to get everything in that proposal. But, instead, Mr. Stetler came in and challenged our authority to

promulgate such regulations on a legal basis saying that we did not have the authority, and he had an obscure kind of rationale behind his statement and threatening to take us to court. Now this, I think, typifies the kinds of problems I had with the PMA and the reason that the PMA, in my judgment, is an ineffective organization, because they concentrate on legal issues rather than the substantive issues. They don't wish to face up to the substantive issues may be the reason that they do that.

Dr. Y.:

Well, certainly the Administrative Procedures Act was an act which, if they didn't like, they were able to convert into Fabian tactics of considerable delay.

Dr. G.:

Indeed.

Dr. Y.:

There are several examples of that, it seems to me, that were true from your commissionership, things that aren't anywhere near settled yet.

Dr. G.:

Well, the vitamin and mineral hearings, of course, where there is so much quackery involved and fraud, are still being fought; hearings are still being held, and yet there's ample evidence now, as

the nutrition surveys as carried out by Dr. Schaefer show. Food is adequate. The people who need and who are under-nourished and who may have vitamin deficiencies are the very ones that can't afford those kinds of foods that are sold in health stores or the vitamins that the pharmaceutical manufacturers promote on television. So, they are trying to discredit the hearing procedure, they are involved in these delaying tactics, and it looks very clearly as if Dr. Ley, the present commissioner, is really up against a series of such legal battles based on the initial reaction to the proposed regulations on combination antibiotics which grew out of the NAS-NRC studies, and it doesn't seem that they've changed.

Dr. Y.:

And the advertising regulations that you sought to put into effect are still pending and the effort to secure compromise has been, it seems to me,...

Dr. G.:

Unsuccessful.

Dr. Y.:

Unsuccessful...but kept open for months and months.

Dr. G.:

Oh, yes. Months and months.

Dr. Y.:

Several times into the conversation has come this extremely intriguing and significant episode of another segment of the Kefauver-Harris Act of 1962, the requirement that new drugs be proved efficacious prior to their going upon the market and that, in addition to that, the backlog of drugs that went back to the 1938 law also be resurveyed so that their efficacy might be established or shown not to exist. Now, here was a tremendous task, and there was all kinds of wonder about how it could ever be done. Maybe there was hope that it might never be done.

Dr. G.:

I think that latter is closer to the truth with respect to the manufacturers.

Dr. Y.:

Because you had so much trouble even keeping up with the going business.

Dr. G.:

Yes, it was a serious backlog with current business, let alone not being able to handle what Congress had instructed the agency to do. Now there was another reason that isn't immediately obvious. Dr. Joe Sadusk, who was the Director of the Bureau of Medicine when I joined the agency, didn't believe in having that efficacy review carried out, because philosophically he felt the practising

physician was the person that should determine whether or not a drug is effective. He felt the physician was capable of doing that, and this was such a fundamental difference that although the mechanism that was finally adopted was available during his administration as chief of the Bureau of Medicine and during a predecessor's administration, George Larrick as commissioner of FDA, it wasn't taken up. They did not seek the assistance we did, even though the mechanism was available to them because, I think, Sadusk didn't believe in it.

Dr. Y.:

Well, just a little point, that may help explain something--does it?--that was a little puzzling to me. After Dr. Sadusk resigned, he had a certain lame duck period that he was to serve before he got out...

Dr. G.:

That's right.

Dr. Y.:

And you indicated that it was this very responsibility, trying to figure out what to do about this effectiveness review of the pre-1962 drugs that he was to have. But then, as soon as he heard about that, he said, "I'm going to quit right today."

Dr. G.:

That's correct.



Dr. Y.:

Were you sort of mean to put that particular task in his lap or what was...?

Dr. G.:

No, I felt that it would afford Joe the..., don't forget I knew and had liked Joe,...

Dr. Y.:

Right.

Dr. G.:

I felt it would afford him an opportunity to serve the agency, leave with having accomplished something that was meaningful and that he couldn't be criticized for. In fact, it would be a very positive contribution if he had worked out the arrangements with the NAS-NRC. To do so I felt would be a feather in his cap. It would help the agency and it would make him look better than he was going to look when he departed without that.

Dr. Y.:

So you were surprised then when he said he would quit immediately?

Dr. G.:

Well, I was disappointed more than surprised.

Dr. Y.:

I see. At any rate, this was considered to be a tremendous coup

at the time it was announced, the way you were going to achieve this.

Dr. G.:

Well, let me point out this: although some may have considered it a coup, really the charter of the Academy, if one reads it, says in effect that it exists in order to assist federal agencies in the conduct of their affairs. It was established under President Abraham Lincoln over a hundred years ago, about one hundred and five years ago right now, as I recall, 1864, and a friend of mine who was a very trusted advisor behind the scenes, Dr. H. D. Estes, dug up the charter of the Academy for me. He pinned it down in that fashion before I ever went to see the head of the Academy and then formally followed up by writing. I knew that we could get them on the hook to do this, in other words.

Dr. Y.:

Well, how did the idea originate? Was this your idea?

Dr. G.:

No, I honestly don't know. As I recall, it was my idea and I asked Don to look into it.

Dr. Y.:

Right.

Dr. G.:

Because it's such an obvious thing. It doesn't take any great brain to figure it out, because the Academy had assisted the agency, keep in mind, on DDT, on food additives, other kinds of problems in the past. As I recall, one of them, the coal tar issue, was handled by the Academy. So there was a history of the agency having referred problems to the Academy. I simply looked at a much more massive problem that the agency had and thought, "Why couldn't it work with them on this one?"

Dr. Y.:

It was obvious that it couldn't be an onboard handling since you were so far behind in more urgent matters. Did you consider any other possibility? Some of the trade press suggested, for example, that you might have been considering the National Institutes of Health or even a private research agency like the Research Triangle down in North Carolina.

Dr. G.:

Well, we did consider, and I really racked my brains trying to figure out how to do this job, first, as you suggest, by looking at internal resources. That was immediately clear as an impossibility. Secondly, by looking at NIH because I had come from the Public Health Service. I had worked at NIH. I began to explore that and ran into resistance on the part of NIH officials who

might discuss the issue in a preliminary fashion.

Dr. Y.:

Now, with whom would you...

Dr. G.:

In the director's office, Dr. Shannon's office, Stu Sessoms, Bo Mider. I then thought about...

Dr. Y.:

What kind of resistance? Why? Not their mission type of thing?

Dr. G.:

That's specifically it, yes. They didn't want to become involved in regulatory kinds of activity. That was Dr. Shannon's attitude throughout my tenure as Commissioner of Food and Drug. It happened to be his last two and a half years with NIH as well. He consistently rejected any collaborative arrangements with FDA on the basis that we were a regulatory agency, and he didn't want to get NIH tarred with that brush. I then thought of the university community. It became obvious that using even segments of that really offered no overall umbrella under which the project administratively could be carried out. And I did indeed think of research institutes, non-governmental, Battelle Memorial Institute, Stanford Research Institute, these places, but...

Dr. Y.:

Did you ever check with them?

Dr. G.:

No, I didn't check with them because I became a little worried, having known some people who worked in them, worried because I knew from time to time they had among their clients members of the pharmaceutical industry, and that was a little worrisome. I also had to look at the fact that Congress had said, "You shall do this," and "you", I interpreted to mean the federal government. The NAS-NRC is a quasi-governmental agency, it's a federal charter agency, as I recall, like the National Red Cross and, therefore, that became my instrument of choice.

Dr. Y.:

Right. Now, it was more appropriate for this kind of a task in this year in which you turned to it than it would have been several years before because there was a Drug Research Board...

Dr. G.:

There still is. There was when I turned that task over to him.

Dr. Y.:

Right. But this was set up just a couple of years before as a result of a big study that Dr. Coggeshall, is it?...

Dr. G.:

Yes, Lowell Coggeshall.

Dr. Y.:

...that he was the chairman of, and one advantage that seemed quite apparent to this was that if the Drug Research Board within the NAS-NRC took over the planning then all segments of society ought to be happy because all segments of the drug world were represented on this board.

Dr. G.:

They were part of, I called it "the drug establishment" in an article I had in Esquire magazine in February of this year, and it's true that the interest groups are all represented in that Drug Research Board membership which has existed now for four or five years.

Dr. Y.:

So when this was decided and announced in late April of 1966, Joe Stetler of the PMA called the plan excellent.

Dr. G.:

Yes. The pharmaceutical industry felt very good about it according to their statements at that time. They were thus given, they felt, an opportunity to be heard in the planning of how the study would be conducted. This they wanted and felt was very important.

There was some uneasiness on the part of people such as Don Gray and Del Goldberg on Mr. Fountain's staff, and some of the long-time observers of the scene felt a little uneasy because of the very fact that PMA did have representation on the Drug Research Board, and therefore the study might be done in less than an appropriate way. I didn't have that fear at all. Right from the very start I wasn't worried because this was such a massive undertaking and there would be such a strong requirement laid upon those who did the evaluation for documentation of their point of view that I felt that it would be indeed difficult, if not impossible, for any shenanigans to occur. And, in fact, that's what did evolve and turn out. Now Don Gray was most critical of the fact that the study panels, 28 panels, their membership was not to be made public until after the results of the study had all been released by FDA. That was felt necessary by the Academy itself and the Drug Research Board in order to protect panel members from potential pressure from industry, so only the chairmen were named, you see. Here again, the fact that we at FDA didn't know those panel members didn't really bother me because again I had faith and confidence in the mechanism of the Academy, that it would bring together scientists of sufficient stature that there wouldn't be any nonsense. And there wasn't in my opinion.

Dr. Y.:

What's the behind-the-scenes story in your personal contacts in

connection with getting this established?

Dr. G.:

Well, I went to see Keith Seitz after I had a good fix on the charter, knew what they were required to do. I'd talked to several of my own staff about it. Of course, Don Estes was the key person in this.

Dr. Y.:

Now, explain Don Estes.

Dr. G.:

Well, Don Estes was a friend of mine dating back to the time we both went to Harvard School of Public Health. He had been in the Air Force in World War II as a bomber pilot, test pilot, at Wright Patterson, had worked in industrial medicine, and then wound up going to Harvard School of Public Health the same time that I did. We had had similar interests. I had done industrial medical work; I had been in the Air Force in World War II, although as an enlisted man. I was interested in aviation. Don and I got along personally very well, and our wives got along, and so our friendship grew over the years. I ultimately hired him when I was at Federal Aviation Agency to head the FAA Civil Aeromedical Research Institute in Norman, Oklahoma, later in Oklahoma City, which he did. I got him commissioned in the Public Health Service in order to bring him on board in that job, and he subsequently



succeeded me as Civil Air Surgeon at FAA, and then had two heart attacks and retired. After he had retired, it was at this time I became Commissioner. He had nothing to do, and so I brought him on board as a consultant. I should say he was working as a consultant to NASA at the same time, but he had lots of time available is the point.

Dr. Y.:

And he was a close friend in whose judgment you trusted.

Dr. G.:

Yes, I trusted his integrity and his judgment, and he could "bird dog" something for me. He later worked for me very closely with the USAN Council.

Dr. Y.:

The what?

Dr. G.:

USAN...U-S-A-N, Council. This is the group that names the drugs, the generic names, you see, and that's another interesting fight about the lengthy names of generic drugs which pharmaceutical manufacturers proposed, the generic names, to the Council, and the Council generally just accepted them. Well, of course, I think the pharmaceutical firms proposed unwieldy names deliberately. Sure, they fit the general scheme that was required

of naming, but I think they went out of their way to make sure that there was a wide margin between their simple trade name and the generic name. Don worked for me on getting that USAN Council to work in a more meaningful way for simplified generic names. So we were involved with the Academy study. I went to Keith Seitz...

Dr. Y.:

How is Seitz spelled.

Dr. G.:

S E I T Z, not Keith, it's Frederick Seitz, and Seitz allowed as how he would look at the issue and let me know. I let him know I had read the charter. I made it clear in our discussion that this looked to me as if it was something that fell within the charter of the Academy. He then subsequently agreed it was and that they would do the job. There were details to be worked out. The Academy felt, the Drug Research Board felt, that it was an important task to be undertaken, it was in the nation's interest, and, although it would be a monumental task, one of the largest they had ever undertaken, they would be glad to do so. And they did, and they did a magnificent job. I have no quarrel about the way in which they handled it, the way in which they organized the meetings, the policy-making group, et cetera. Beautifully done.

Dr. Y.:

Now, once the contract was signed that they would provide you with these reports...

Dr. G.:

I stepped out. The FDA stepped back from that except in this way: they had a manpower problem, too, and by that time we had secured the assignment of young Public Health Service officers to FDA to help get rid of the drug backlog, the new drug application backlog. Well, this was something else that my predecessors had available to them, but they were fearful of the Public Health Service. I wasn't, so I got these young physicians assigned, and they indeed proved to be, most of them, immensely valuable. Well, it was at that time that the Academy study was to start. The Academy study started, as I recall, the first of July of '66 and...

Dr. Y.:

I'm not sure.

Dr. G.:

Yes. And that was the reporting date for these young physicians. So we gave Dr. Gilmer of the Drug Research Board the opportunity to interview, after he had screened the records of these young physicians, sixty-eight of them, as I recall. He then interviewed a group of them and selected ten who were the best ten, we thought, of the whole group. These men were then detailed from FDA to the

Academy to work as executive secretaries of the various specialty study groups that the Academy set up. And they were the continuing liaison and that was their entire job for two years.

Dr. Y.:

So they didn't really work in FDA at all?

Dr. G.:

No, they worked on the drug efficacy review. It was an extremely valuable experience, because they got to know some of the top people in U. S. medicine. Every one of them were offered residencies in leading institutions as a result of that exposure and, I think, nine of them did take such residencies. One fellow, bless him, said, "To hell with it. I'm going out into general practice." But that had been his intent when he joined this group and he stuck to it. Nonetheless, we did provide that staff. We also provided Dr. Smith who...

Dr. Y.:

Ralph Smith?

Dr. G.:

Ralph Smith who was very difficult at times to get along with, who was in the Bureau of Medicine. He was high enough up in the Civil Service structure that he could not be pushed aside in terms of unblocking, and so this offered Dr. Ley...offered us in

the Bureau of Medicine an opportunity to put Dr. Smith full-time on this job which was just about as important as the division chief's job he had been heading up and permitted a new appointment there and again, unblocking, just as we did to Frances Kelsey.

Dr. Y.:

Right. I want to talk about that.

Dr. G.:

We'll talk about that later. That was the substance of getting the Academy thing on the road.

Dr. Y.:

Dr. Smith was liaison.

Dr. G.:

And he did a good job on this. Yes. Ralph was respected; he had come from the university community; he was a good teacher and a good scientist; and he handled the job nicely and earned the respect of the people at the Academy and the members of the various study groups, various chairmen that he had contact with, and he had an enormous job of coordination to carry out, getting all of the material from the files that these groups wanted to see from FDA, because that was part of the accepted plan, that the group could call upon the material that would be normally secret to FDA and would be provided them in such a way to protect trade secrets but nonetheless make the scientific data available to

them, because during the period of their actual use by the Academy, although they were non-government scientists, they then became government employees.

Dr. Y.:

So that they had the legal right under the law...

Dr. G.:

Legally, we had an interpretation of that there was no problem.

Dr. Y.:

To see new drug applications and things of that sort.

Dr. G.:

Yes. That's right.

Dr. Y.:

Did any of this begin to come back before you retired?

Dr. G.:

Just a bare trickle started in January, as I recall, of '68, and it began to increase during the last six months of my tenure, and I deliberately buried some of those in the safe. We had to handle them in a very secure way because keep in mind that in some of these products there are millions of dollars involved, and if it became public information it could be used to someone's advantage to sell short in the stock market. Now this

was particularly true with some of the compounds which were over-the-counter drugs, and because I felt that we should tackle and have a good record behind us with respect to prescription drugs, I deliberately put those over-the-counter drugs, many of them toothpastes and mouth washes, in the safe and instructed the staff, "Don't do the remaining staff work on these until we get a backlog of experience in prescription drugs."

Dr. Y.:

I guess they are mostly still there.

Dr. G.:

They're still there. Things like Lavoris.

Dr. Y.:

Right.

Dr. G.:

Wow. Terrible reports on those items.

Dr. Y.:

Well, we'll be hearing about that in due course, I guess.

Dr. G.:

I really didn't see too many. What I did see in the way of reports from the Academy did convince me, however, they had done (a) a very thorough job, (b) an impartial job, (c) a scientifically

supportable job, and that there was no hint in any way, and I saw, oh, I would say a couple of hundred of these reports, no hint of any bowing to the drug industry pressure. So, I was enormously pleased by what emerged.

Dr. Y.:

Right. Now I take it that out of all the reports that have been put into the action sphere so far, there's only maybe one judgment that the Food and Drug Administration has that is different from the committee, and there may be only one legal action on the part of industry, as yet, at any rate.

Dr. G.:

I think there'll be many more than one on the part of industry. So far, the agency's judgment has been corroborated almost one hundred percent, as you point out. Well, there was an interesting corollary to this business that I think is extremely important. That's one of the main failures of my administration and that relates to the drug compendium. I felt that the Academy, in undertaking this review, was doing a great service to the nation. I characterized it in the opening speech of the organization meeting where, for the first time, the drug industry, FDA, interested parties, came together under Academy auspices, as being as significant in terms of today's practice of medicine. Now there were some who thought that was an excessive type of remark,



that it was over-generous. I think in retrospect it may well not be. I think it may still hold up to be almost of that same magnitude of significance. But in order for it to become that significant there was a corollary step that was needed and that would be the development of a single drug compendium. A single source for the practicing physician to turn to for reliable information about drugs. No such source exists today, and here, when the Academy picked up the responsibility, it was obvious that a unique opportunity was going to emerge because they would have timely information having just completed the review of some thirty-four hundred drugs as it ultimately turned out. That combined with what had gone through the new drug mill subsequently could be the 90% level of a drug compendium.

Dr. Y.:

The raw data was right there.

Dr. G.:

It was right there, you see. And so I began pushing for a drug compendium. Now let me point out that this, have we talked about this?

Dr. Y.:

No.

Dr. G.:

This issue originally came up on April 6 after the speech. Joe

Stetler got me aside to talk about the drug amendment. I'm sorry. It was before the speech. At any rate, he pointed out that my predecessor had been unwilling to exchange with PMA or compromise with them, to put it more properly, on the drug compendium. I said, "Tell me what you mean by drug compendium." He said, "Well, our membership, our organization, would underwrite the cost of publication of the compendium if the agency, in turn, would excuse us from the package insert requirement." You know that the present regulations call for every drug shipped in interstate commerce to have accompany it a package insert. This package insert consists of what is technically known as the final printed labeling and that is worked out just prior to marketing a new drug by a series of discussions between the pharmaceutical firm involved and the agency personnel. Now, it originally has as its intent the provision of information for the practicing physician. And that was fine. But in today's "system" of drug usage, it almost never gets to the physician; biological products that he uses in his office, it does. But with most drugs, it gets shortstopped in the pharmacy of either the hospital or the corner drug store and thrown away. Now true enough, he can call the pharmacist and get that information. He can even have one copy sent to him or get it from the drug company. But he seldom bothers, and that's not a handy way, because the insert is overburdened with details, it's too fine print, and it's not the kind of information he

really wants to practice medicine. So Mr. Stetler said, "What I would propose, Dr. Goddard, is you allow us to publish the compendium and stop the package insert program at the same time. Your predecessor was only willing to stop the package insert requirement a year after the compendium had been published in order to evaluate it." Well, I decided right on the spot that that was unreasonable and burdensome. Mr. Stetler told me the package insert program was costing the industry \$6,000,000 a year. I didn't debate his figure; I accepted it. Used it many times after that and told him, yes, we would permit this to occur; if they would publish a compendium they could stop the package insert program. He was very pleased. That really was the beginning of the compendium.

Dr. Y.:

So that the compendium...

Dr. G.:

Wasn't my idea. The Drug Research Board had talked about its necessity and the desirability for three years prior to that. The Council on Drugs of AMA under Harry Dowling and then under Adriani for ten years had recommended such a compendium, so it certainly wasn't my idea. But once Mr. Stetler and I reached that agreement, there began an extraordinary series of backslidings on the part of the PMA, particularly because they found out

that, to be approved by the FDA, the compendium would have to have the drugs listed under the generic names, even though the cross-indexing would be by trade name and the access thus in the customary fashion that the physician looked up drugs. They would have no part of any system that described reserpine as the generic name, described the drug, its actions, and then listed the brand names underneath, the manufacturers and the dosage forms. Now this was absolutely essential in the view of our experts in the agency in order to prevent a compendium from being ten volumes long and unusable, and it certainly made sense scientifically, and all the physicians I talked to thought it made sense, but the drug manufacturers, once they found out this would be the format and not the format to which they had become accustomed as in PDR, where each drug is written up as if it was a different product even though it's the same generic name, then they began to backwater, tread water, and back off from the proposal, and since then they have done nothing but drag their feet and fight it openly and actively, because we then submitted a bill to Congress, an administration bill, and it never got out of Harley Staggers' committee. It never had a hearing by the sub-committee on health. PMA effectively blocked that. I must say that they did a good job of work on the Hill on that particular issue. Now, there is no compendium today, and it's unfortunate because again it's timely. It could still take advantage of the wonderful work done by the

Academy. PMA doesn't want it for another reason. They are fearful that if doctors ever start looking at drugs and seeing that there are 42 brands of rauwolfia, they might begin to prescribe on a more rational basis. That's why they don't want it.

Dr. Y.:

Well, I always had the wonder about, if you managed to have such trouble with advertising which was supposed to reflect the basic package insert in fair balance, how could you have an abbreviated story...?

Dr. G.:

The only way you could do it is again to use a group such as the Academy of scientists. This was an issue that Billy Goodrich and I disagreed on. I'm glad that this came up, because Billy and I differed; we were poles apart on it. Billy was standing firm and advising me to insist in all my discussions on the compendium that we would hold the firm to the final printed labeling. I said it would not work; it would be too lengthy. Billy pointed out that it could lead to problems in advertising if we yielded on this. I said, "It's not a question of yielding. We must actively promote a telegraphed version of the final printed labeling. You have to advise me legally on how we do it, but that's what it's going to be, because otherwise, it will be of no use to the physician. It will be a waste of money."

Dr. Y.:

But your idea was not to leave that up to industry.

Dr. G.:

No, but to get a group like the Academy.

Dr. Y.:

Or not to do it yourself...

Dr. G.:

No. No. I wouldn't have done it within FDA. A lot of people refused to understand this; Walter Modell of Cornell refused to understand the whole compendium issue and went around the country shooting off his mouth about the FDA and bureaucracy never being able to do this. He never was willing to understand that I wanted it done by the best experts in the United States on a given class of drugs. I wanted it kept up to date. He said it couldn't be kept up to date which revealed a total ignorance of modern methodology. With computer-based books now being used one can edit and revise very easily, and we could publish a quarterly supplement and indeed we planned to. And it was unfortunate that the industry was able to get people like Dr. Modell and use them. Dr. Modell is well-meaning, but he sure as hell has been steered nicely by PMA. On this and a number of other things.

Dr. Y.:

It looks like I'd better turn the tape over, Jim.

Dr. G.:

It became interesting with respect to the compendium issue to also see the shenanigans that went on with respect to other groups. The Drug Research Board, for example, never was willing to get the Academy firmly behind this bill that was pending before Congress. Nor were the members of the Drug Research Board non-industry representatives ever willing to push for it.

Dr. Y.:

Not even the non-industry people?

Dr. G.:

The non-industry people. That's right. They said that they were for it, that it was good, but Gilman, for example, never was convinced that this was the right approach, Alfred Gilman.

Dr. G.:

Finland...wasn't he on it?

Dr. G.:

Max Finland, the little Napoleon.

Dr. Y.:

Yeah.

Dr. G.:

Yeah. He, of course, does an awful lot of drug testing in the

antibiotic field for the pharmaceutical industry. I'm not suggesting that Max isn't honest. Let me make that clear. The little Napoleon, the little dictator that he was and is, he just wasn't willing to push this concept, even though the Drug Research Board endorsed the idea for four years prior to that, they didn't get behind it. Now this was why in my article in Esquire in February of this year, I mentioned this, you see. Dr. Seitz didn't realize, he said, in a letter to me, that I was unhappy with the Drug Research Board and with the Academy, Well, I wrote back to him and pointed out that yes, I was, and that was the reason, because they hadn't fought for the compendium. They weren't capitalizing on a unique opportunity in American medicine. Now the AMA similarly, the AMA claimed, of course, it was going to publish its own compendium, and they still say they are. However, when asked, Dr. Hussey or any other representative of AMA, they wouldn't say or couldn't say whether or not it would be distributed free to all members. Now, as you know, they have published for a number of years a volume called New Drugs, an excellent book, but it's not complete. It only covers new drugs, meaning drugs that have been marketed within the past ten years, single entity drugs; it doesn't cover combinations. And it's used...I think sales run about, the maximum sales..., last year 32,000 volumes were sold. That's a little better than ten percent of practicing physicians. On the other hand, what we envisioned,



and I envisioned, was something that went automatically, just as PDR now does, the most widely used book in American medicine, Physicians Desk Reference. It goes free.

Dr. Y.:

It's advertising.

Dr. G.:

It's a compilation of paid advertising. It turns up on every physician's desk in January of each year. I wanted, in fact, PDR to have the job of publishing the compendium. I wanted the same name to be used because it would provide instant acceptance. All I wanted was a change in format. This again was something people refused to accept and understand. I didn't want to put Bill Chapman out of business. I wanted to capitalize on his know-how and the fact that physicians accepted it and they would just see a minor change in format. But that hasn't come about. So the AMA has not been helpful at all.

Dr. Y.:

Dr. Hussey was on that Drug Research Board also, wasn't he?

Dr. G.:

Yes, and privately Hugh Hussey would say to me periodically, "Keep up the good work." He said, "I can't say anything publicly, but keep up the good work." He was in favor of what I was doing

at FDA even though AMA wasn't, and I think that tells you as much as one can. It speaks volumes about the AMA and their pernicious attitude towards this problem which is an extremely important problem in American medicine, the overprescribing, the lack of good information, the misleading advertising. And the AMA, the principal professional organization, doesn't tackle that problem because it derives so much revenue from the pharmaceutical industry. It's iniquitous.

Dr. Y.:

Well, with regard to the compendium, the major support you had came from certain members of Congress, didn't it?

Dr. G.:

Yes.

Dr. Y.:

Not enough, I gather.

Dr. G.:

Not enough, because the bill never got out of committee. Mr. Hill, Senator Lister Hill, wouldn't take a position on it. Mr. Staggers wouldn't push his sub-committee. Mr. Rogers of Florida, a friend of the drug industry, certainly didn't do anything to help the bill. And so the idea, although I think it soundly conceived, feasible, and I felt it should be financed,...by the way,

and that's another interesting point. I wanted the book to turn up free each year on the physician's desk, not to be sold to him and therefore, it was a financing problem. We estimated the cost, Ted Cron had estimates made that showed it would cost about six million dollars, just about what the package insert program was costing. Well, in order to be fair, I proposed to Mr. Stetler and to anybody that would listen, that we, instead of just asking PMA to pick up the tab, which is what I originally had asked them to do since they manufactured the drugs that account for 95% of the prescriptions sold, and I felt they could carry the other five percent in view of their small but steady profits... small!...number one in the nation on return on investment. But, nonetheless, I felt they could do it. But they weren't willing for the reasons I've cited. I then felt that the bill should require or provide the secretary with the authority to charge a registration fee to the pharmaceutical firms. And the fee would be a function of the number of drugs they marketed and the number of units of each sold which then would put it on a sliding scale, and I think be quite fair, and that would be in effect how the volume would be paid for. Now, this shouldn't have increased the price of drugs any, which some contended it would, because they would be excused from the six million dollars with respect to the package insert program. And so it would be a straight trade-off. It would distribute it perhaps differently, but

nonetheless it shouldn't result in an increase in the price of drugs. All told, I thought it was a sound proposition, one that was entirely feasible both from the publishing point of view in terms of mechanics, using their computer-based system, and one that certainly would fulfill a need that had been bespoken many years by the AMA and later the Drug Research Board, but it's an example, in my mind, a prime example, of why the pharmaceutical industry is not a part of the health industry in the United States, because they are not willing to take a leadership position. They're working actually in a way that's derogatory to patients' health by confusing physicians about drugs deliberately and not being willing to provide them a single source of scientifically valid information about drugs. End of story about the compendium.

Dr. Y.:

One of the other speeches, to shift rather sharply, that you made in the early days of being commissioner was to the American Association of Advertising Agencies. This was April 30.

Dr. G.:

AAAS in Phoenix.

Dr. Y.:

Scotsdale.

Dr. G.:

Scotsdale, oh yes, outside of Phoenix, isn't it? And Tucson?

Dr. Y.:

Arizona.

Dr. G.:

Arizona. Barry Goldwater's home.

Dr. Y.:

And in this particular address, among other things, you changed your aim from prescription drug advertising in order to have a little bit to say about over-the-counter drug or proprietary advertising which you treated very sharply. Now, you recognized that the Federal Trade Commission had charge of this advertising.

Dr. G.:

And still do.

Dr. Y.:

And still are in charge of it. Now what about the relationship between FDA and FTC? How did you begin to develop or strengthen the already existing liaison that there was. What was your appraisal of Paul Rand Dixon who was the chairman of the Federal Trade Commission?

Dr. G.:

Paul Rand Dixon, to begin with the latter, is a political creature, and I perceived him as such and dealt with him as such. We met... Paul and I met on several occasions, and it was quite clear that

if there was to be any work done, it would be done by our staffs and not by ourselves. We simply had to set the climate so that our staff people could get together and then get at the business.

Dr. Y.:

Did you take the initiative?

Dr. G.:

As I recall, I asked that the meeting be set up. We had an informal working relationship with the Federal Trade Commission, but it in effect had become inactive. Now behind the scenes, you see, here again, going back to the Kefauver-Harris thing, Rand Dixon had been a member of Kefauver's staff. There was a woman physician at the Federal Trade Commission.

Dr. Y.:

Barbara Moulton.

Dr. G.:

Barbara Moulton that called me shortly after I became commissioner and said she wanted to talk to me.

Dr. Y.:

I noticed her name on your appointment list.

Dr. G.:

I spent an evening at her house, had dinner with her and her

husband. She told me all the problems as she saw them from having worked at FDA. I think she really was asking to be rehired by FDA; I know she was. I appreciated her comments, but I didn't, after checking, I didn't want her rehired.

Dr. Y.:

Why was that?

Dr. G.:

I thought that there was a good possibility of trouble developing if Barbara came back. Now, Frances Kelsey was frankly enough trouble on the staff without bringing Barbara back. Now, it did set me to thinking, however, about the Federal Trade Commission, and I talked to Mr. Rankin and Mr. Kirk and I found that there was some sort of an agreement, but it wasn't really an active one, so we set out to make it an active one. Charles Sweeney, "Chuck" Sweeney, of the FTC staff was the key person from there. A marvelous person, a very fine man, now dead, but a real public servant in my book. Chuck set up the meetings and represented the FTC. It was because of he and Ken Kirk and a few people on our staff that we were able to get a few things done for the first time in a cooperative way. The FTC is a creaky mechanism. I think it was characterized in that fashion in a Saturday Evening Post article, and I don't imagine if you set about to create an ineffective mechanism of government, you could do much better

than set up an FTC kind of operation. It takes years for them to get at and act on a problem. At least, it has in our field. It took them eleven years to get the "liver" out of Carter's Little Liver Pills, and the only impact was greater sales, and they have fought Geritol and Hadacol and not very successfully. Now, my reason for striking at, by the way, the over-the-counter drugs was not just because I was speaking to the AAAS, but I was finding as I went to meetings that one question physicians always raised was, "You said something about the drug companies and their ethical drug advertising, but we think the over-the-counter television drug ads are far worse." And they were right. So that was why I decided to say something about that. Now, FTC, subsequently, we did work out to provide them better information from FDA. I thought I saw some improvement in their actions, but it's still not a good mechanism.

Dr. Y.:

Well, you had a tighter handle after 1962 even though...

Dr. G.:

Yes.

Dr. Y.:

...even though they still kept control of that advertising because...

Dr. G.:

Yes.



Dr. Y.:

...you had control of the definition of what efficacy meant.

Dr. G.:

That's correct and also the final printed labeling, you see, which even for over-the-counter drugs had to be approved by FDA, and so FDA had a better hold after '62, there's no question. But if you look at most of the over-the-counter drugs today, they are pre-'62 drugs, a goodly number of them, you see. And most of the advertising goes in to trying to expand the sale of aspirin and aspirin-containing compound. I will say, I think the over-the-counter drug advertising has for the most part improved in the past three or four years. I recently sat and recorded television drug sales pitches on tape and listened to them carefully time and time again. Now, Geritol is still a lying commercial. They give on the one hand...they say, "Of course, you should see your doctor, if you think you have anemia," but then they take it away with the other hand by telling you how great their product is and how fast you'll feel better if you take it. Now they don't say, you know, they don't say that you need their product, they simply say, "If you do need it, if your doctor says..." but they describe anemia in the process in such a way that it encourages self-diagnosis. Anemia is not a condition that one can self-diagnose with any degree of confidence, and, therefore, it's still an example of people being willing

to delude the American public. "Responsible firms" engage in this kind of nonsense all the time.

Dr. Y.:

A lot of the drugs that are over-the-counter are made by the very same companies that...

Dr. G.:

Of course, or a different division of the same company.

Dr. Y.:

Right.

Dr. G.:

American Home Products is a good example, that has ethical and over-the-counter divisions.

Dr. Y.:

So you were trying to buck up the backbone.

Dr. G.:

That's right.

Dr. Y.:

Offer the promise of more scientific help.

Dr. G.:

That's exactly right.

Dr. Y.:

What did you mean when you said that Dixon is a political creature?

Dr. G.:

Well, Dixon, I think, was more responsive to political realities than I was. Dixon, aside from the Ralph Nader thing, he's never gotten whacked the way I did publicly, because Dixon was too shrewd to ever take a position publicly, you see.

Dr. Y.:

I see.

It's my feeling. Now Nader got to him. I mean, Nader really stung Rand Dixon, but apart from that Dixon never got really taken over the coals publicly. He was a much more savvy person than I was in the political arena. Not that I don't know how to handle myself in testifying before Congress, but in terms of being candid and discussing very frankly with the press, I think I may have set a record in Washington for candor. Now, that was really in the long run what hurt me, but I think I would rather go that way than to go another way. That's just my nature.

Dr. Y.:

I see.

Dr. G.:

Dixon will survive a long period of time in the political jungles,

much longer than I could or a person like me could. And that's unfortunate when you're dealing with a technical area such as the Food and Drug Administration.

Dr. Y.:

Several times you referred to the problem of Frances Kelsey or to her as a problem. Now, she was a great heroine because of the thalidomide episode.

Dr. G.:

Yes.

Dr. Y.:

Then one of the things that you undertook as soon as you arrived was the reorganization of the Bureau of Medicine, and I take it that what you mean by...

Dr. G.:

Frances was a lovely woman, a kind person. Frances couldn't run an organization, and she was in charge of investigative new drugs when I joined FDA.

Dr. Y.:

Now, she had been elevated probably as a result of...

Dr. G.:

Without question. Frances became a hero on the thalidomide disaster. Now, I wasn't at the agency, so anything I would say is

only hearsay, and it came from the principal staff people at FDA. It is an interesting little story though about how it occurred. In retrospect, one would have to say Frances became a Presidential Gold Medal award winner and a heroine because she procrastinated. There had been an IND pending on thalidomide, and Frances couldn't make her mind up and just sat on the material. Two young physicians on her staff recommended that it not be approved, and reports began to get to Frances and some of her staff about some of the problems, and still nothing got done about it. Morton Mintz started poking around and wrote the story that broke in the Washington press, and Frances became the heroine because of this. She had, in effect, held up the approval of this drug. Now, her husband, Ellis, who subsequently died, he died about a year and a half ago, recognized the significance of what Frances was involved with in the thalidomide thing before she did. She had taken some of these papers home one night, I'm told, and Ellis insisted that she leak or report this problem even though she had a working arrangement with the two young men who were working on this particular IND that they would jointly issue a statement on this. He said it was far too important and these other two men were out of town and not to wait. And so apparently she discussed it with Morton Mintz, and the story broke and the President, President Kennedy at that time, asked the Secretary of HEW, Celebrezze, to have a bill before

Congress, an administration bill, within 24 hours, the FDA staff stayed up all night, threw everything but the kitchen sink into what became the Kefauver-Harris bill. Now, also President Kennedy wanted to pin a medal on somebody and that somebody happened to be Frances Kelsey. So that was basically how Frances came to become a sacred cow in FDA. You couldn't do anything about Frances, and when I came she was director of the Investigative Drug Division, chief of it. Now, there was serious backlog in that division. Frances could not move people and get things done. Frances couldn't make a decision. My appraisal of her is that if it were raining, she'd drown before she could make her mind up that she ought to go indoors. Indecisive. Now, in order to get that division moving, Frances had to be given a different job. Here again you had the problem of Civil Service, so we created a job for Frances, looking at the qualifications of scientific investigators and actually investigating any suspicious cases where drug work had been carried on, and Frances did get a couple of cases developed for us in that field, so she became a useful person. And that was much more her speed than the IND which was a backbreaking job. So that's basically what I've been referring to as far as Frances Kelsey is concerned.

Dr. Y.:

Right. Well, about the backbreaking nature of the job, you thought that a better organization of the Bureau would help

and that, of course, these new young Public Health Service doctors would help. But I take it that this might have been the problem you had about which there was the most pressure being brought on you. Wasn't this one that President Johnson himself got...

Dr. G.:

Yes, and Secretary Gardner certainly was involved with it. Everybody recognized the seriousness, because, first of all, the agency was vulnerable to any charge the drug industry chose to level as long as we were sitting on a lot of new drug applications. You see, the drug industry could claim that the bureaucratic practices of FDA were such and such and doing this to American medicine. It doesn't matter what charge they levied, then all they would have to do to prove it is to say, "At the present time the FDA has 150 drugs in backlog status depriving the physicians and the patients of these wonder-cures that the industry has developed." Well, that's a bunch of hogwash and always was and still is when they try to say anything about it, because most of those weren't new drugs as we've talked about before. Eighty-five percent of them are new combinations of old products or molecular manipulations, so the American public wasn't being deprived of wonder drugs. In fact, just in fear there might be some important ones in there, I asked Dr. Ley when he came on board and accepted the charge of getting rid

of the backlogs, if he would have somebody and, preferably, he himself become involved, take a cut at what was pending, and if anything looked promising, take it out of order, take it out of sequence, if it was something really new and remarkable, because we didn't want to have those that were more than six months old have anything significant bottled up. He did. There wasn't anything really significant in there. Now, the most important thing of all was to bring in some new management techniques, and to do this I turned again to somebody who had worked with me in the past, Vaughn Choate. Vaughn had worked at one time with the National Institutes of Health, later on at the Federal Aviation Agency as Don Estes' executive officer, and Vaughn had reached a stage where he had made all the promotions he could in the medical organization of FAA, and if he were interested in moving ahead he had to move to a larger organization. I knew him to be a capable, conscientious guy who understood management principles, offered him the job, and fortunately, he accepted. This would be just before Dr. Ley came. I then was confronted with the problem of bringing on a new director of the Bureau of Medicine although I had already hired his executive officer. I mention that in order to show you how much confidence I had in Vaughn Choate, and he did work very well subsequently with Dr. Ley, and Dr. Ley expressed on several occasions pleasure that Vaughn had been brought on board and he said, "Although it's



not the best way to do something, after I got to know him, I understood why you were willing to take that risk." So, Vaughn did come in, oh, about May or April of '66, May, and, during the subsequent period of two years and three months that I was there, Vaughn was the executive officer to the Bureau of Medicine, and he did make many changes and did make many improvements. He brought some order out of chaos there, working, of course, with Dr. Ley and Dr. Minchew and people in those particular positions, the division chiefs, and I think it was probably one of the most significant things that happened to the Bureau of Medicine was to get some real professional management capability in there.

Dr. Y.:

Well, was he the one then who, among the things that he might have done, looked at what the new drug application was as a kind of document and decided what might be done that would speed things up if it were modified?

Dr. G.:

Yes, he looked not from the standpoint of subsequent modification; he looked more at the procedural aspects. He was part of Herb Ley's task force on modifying the procedures, and he did put into effect a record tracking system that...hell, when I first went there, nobody knew how many new drug applications even were pending.

Dr. Y.:

They were just stacked up everywhere.

Dr. G.:

They were stacked in corners and bunks and rooms. My God, it was terrible. The manufacturers weren't required to paginate. They weren't required to submit an index. They weren't required to have precis of the significant subjects. Now, we did change that. Vaughn came in, and he and Herb and I got together and decided that was absolutely essential. It was nonsense not to require that and we did it and we did get current. Before I left FDA, we were current, which means that we had all the drugs that had been submitted in the previous 180 days either approved or rejected. Now, there was some, but I think very, very little, returning in order to avoid the 180-day clause. I'm sure with people being involved there was a small percentage of them. A lot of them were returned to the manufacturers because they were inadequate, yes. But not to avoid the 180-day time clause, you see. All told, I thought Dr. Ley did a magnificent job in getting rid of those backlogs. Now the IND backlog was a tough one, too, and that hadn't been eliminated, although it was being whittled down when I left to where it was in a reasonable...

Dr. Y.:

Well, that was the newer problem since it had been so redefined by the 1962 law.

Dr. G.:

That's correct. It was a newer one and a less critical one in many ways, because the law, as you recall, only required that they submit how they were going to carry out the investigative new drug work, and then they could proceed. It wasn't as if anything were being held up. This was a post hoc review of what was going on, in other words.

Dr. Y.:

Your problems here were problems of finding out occasionally that something wasn't reported that should have been...

Dr. G.:

That's correct.

Dr. Y.:

...that was potentially hazardous.

Dr. G.:

Yes, or some danger was being perpetrated that shouldn't have been.

Dr. Y.:

Right. What was that, the MK665?

Dr. G.:

That was one. The MER29, of course, took place before I got there.

Dr. Y.:

Right.

Dr. G.:

But that's the kind of thing the IND work was designed to preclude from occurring.

Dr. Y.:

And the DMSO, that was one of the...

Dr. G.:

DMSO. That, of course, had happened just before I got there.

Dr. Y.:

And so you had the aftermath?

Dr. G.:

Oh, yes. I had the brunt of the problem.

Dr. Y.:

Right.

Dr. G.:

Now, it might be worthwhile mentioning that DMSO. This was an industrial chemical that a Dr. Stanley Jacob in Oregon felt was advantageous in the practice of medicine. This chemical primarily was a by-product of the wood industry in the Pacific Northwest, and a wood processing company was in fact the IND sponsor. Dr.

Jacob was the principal investigator. But Dr. Jacob became convinced that this was a wonder drug, and he was going to win the Nobel Prize, and he was promoting its usage for every thing that one could imagine. He was shipping it illegally directly to patients, to unqualified investigators all over the United States, and there grew to be a tremendous trafficking in DMSO which was illegal, and the agency was forced to act.

Dr. Y.:

There were a lot of very reputable pharmaceutical firms that had it too, weren't there?

Dr. G.:

Yes. Oh, yes. There were a number of them. Now, just before I joined FDA, the commissioner, Commissioner Larrick, had cut back and had taken action on DMSO. Well, this led, during my tenure to an acrimonious exchange between the proponents of DMSO and the agency on a number of occasions. Unfortunately, Dr. Jacob was able to get Congressman Wendell Wyatt on his side, and I say "unfortunately" because the Congressman doesn't know that much about drug work. He has made some very naive proposals in Congress. He was able to get Hatfield. He enlisted him on his side, and generally kept things stirred up. Now, if Jacob had devoted the same amount of energy to seeing to it that qualified investigators did carefully controlled studies, DMSO

could have, by now, secured a rightful place. It's an extremely interesting compound. I'm sure it will have some use, but its value has been beclouded by the claims of miracles by the promotional efforts of one Dr. Stanley Jacob, and it's been used to make political hay unfortunately by some of the senators and representatives. Now, I think it's symptomatic of what's going on in American medicine and on the scene in America today with respect to politicians that so many bills were introduced to require the agency to approve DMSO.

Dr. Y.:

It was just like Krebiozen.

Dr. G.:

That's just exactly the point I wanted to get to. It was put then in the same category as Krebiozen, the Rand vaccine, and these other kinds of quack cures. And that's most unfortunate, because when the day comes that Congress votes and requires FDA to approve a drug or to permit a drug to be sold in the marketplace, then you have in effect, in my opinion, lost the consumer protection that the agency was designed to provide.

Dr. Y.:

Right. I think that may be a long time, and it may not happen.

Dr. G.:

Well, I hope it doesn't happen ever.

Dr. Y.:

After the Krebiozen trial, the names of the senators who sponsored bills along with Senator Douglas read like a Who's Who of some of the most...

Dr. G.:

Oh, that grand old man of American politics, Everett McKinley Dirksen, that iniquitous bastard, was among them. And he's always among them. He is one of the real friends of the drug industry. It's shocking.

Dr. Y.:

Yes, it really is, some of the names that are listed. Of course, with DMSO, it wasn't just a matter of making claims that would elevate it into a miracle drug status. There were really hazards with this one, weren't there?

Dr. G.:

Well, that's still being debated. We felt that there was sufficient potential for risk that we had to be cautious. There was some evidence, in work with experimental animals, namely, beagle hounds, that it did cause lenticular opacities, therefore, could have some serious repercussions with respect to visual problems if this were true in humans. Now, keep in mind that we had already been up against it with MER29 which caused cataracts in humans, an investigative new drug. In fact, the law suits

are still going on with respect to MER29. And so, the agency was being cautious, but I think we are supposed to be. Congress instructed us in the legislative history to be cautious about these kinds of problems. Now, how much toxicity a product like DMSO represents is difficult to estimate. First of all, you know, it's commercially available.

Dr. Y.:

That was one of the problems?

Dr. G.:

That was one of the problems, that everybody could lay their hands on it and still do.

Dr. Y.:

And a commercial grade was a different grade?

Dr. G.:

Yes, it was a different grade. And that's still the problem with a couple of other drugs, lithium carbonate can be obtained from chemical supply houses. It's being used by psychiatrists in the treatment of the mentally ill, and it hasn't ever been well documented.

Dr. Y.:

And there's no new drug application?



Dr. G.:

And it is a dangerous one. And now, the NIMH is sponsoring some new drug work, IND work, on lithium carbonate, but this is a dangerous situation, because it can be purchased over the counter, and yet it is one which you literally can't do much about. You don't want to get involved with prosecuting practicing physicians, you see.

Dr. Y.:

No.

Dr. G.:

That's not the agency's mission. We did have one or two cases though where we had to take action against physicians who were doing investigative drug work. Dr. Cass in Boston was one. He was guilty of supplying the agency with data on patients who had died before the drug studies had ever started, therefore, it was just phony data with lab results that were inaccurate. They were sink tests, what we call sink tests, meaning the lab work had never been done. Dr. Cass, we put him out of business. This also happened with an investigator in Philadelphia, although he subsequently was allowed to resume drug testing. It was under tighter controls and stricter supervision.

Dr. Y.:

Was there anything behind the scenes in these situations with

respect to the amount of research that these people proved to have done?

Dr. G.:

They were doing so many studies that this is what drew Dr. Kelsey's attention to them, and her staff.

Dr. Y.:

They showed up so often?

Dr. G.:

They showed up on so many investigative new drug work applications, you see, or NDAs, that it became a serious question as to whether or not any one individual could do this volume of work and do it well. And so this was how the matter came to the attention of FDA. They subsequently began investigations. We put trained investigators into the field, documented our case, called the individual in, presented him with the evidence before any action was publicly announced of any kind, and notified the university in both cases ahead of time that we were going to take the action and then took the action.

Dr. Y.:

And this must have thrown tremors throughout the drug industry because there must have been a good deal of research on all these other cases you were speaking of that would be put in

jeopardy or uncertainty.

Dr. G.:

Well, again, it was symptomatic of what the drug industry had been doing, you see. Every drug company has a list of investigators that they know--I am told this by people who work for the drug industry--that they can get results from to fit their needs. And they all have a black list, too, of investigators who aren't any good at all, who you'll get in trouble with. Now, they won't share that information with the FDA. Again, they're not really members of the health community. They're not concerned about anything but making profits.

Dr. Y.:

But there is this lore about the researchers, you say.

Dr. G.:

Yes. Yes. The drug companies themselves like to help perpetrate the myth that they had done this outstanding research, and that it's only through their efforts that the American public has a continuing supply of new drugs. They never mention the very sizeable amounts of money spent by the National Institutes of Health on drug research. The fact that they in effect by having studies carried out in medical centers are being subsidized by public monies, by medical schools, et cetera, this they don't mention. They really don't spend...they talk about a five

hundred million dollar a year research budget. Well, they don't really expend as much as they'd like to have people give them credit for. And their work, certainly I found it to be shoddy in many instances. Now look, nothing is an all or none principle. Some of the finest work that's done in American medicine has been done by people in the drug industry. Some of them...Dr. Maurice Heilman, the virologist, for example, at Merck, Sharp and Dohme, an outstanding person. He may well some day receive a Nobel Prize, and I certainly, if I were on the committee that selected Nobel Prize winners in medicine, I would give Maurice Heilman serious consideration. There are people at Merck, Sharp and Dohme who have done some exquisite work in DNA, and, in fact, have been recognized for their scientific contribution. So, some very important and basic work has been done. But, on the other hand, there is some of the lousiest clinical research that one could imagine supported by the drug industry. Let me say, as an interesting sidelight, I have visited facilities that are used by drug companies for research, both their own facilities and public facilities where drug research is carried out, and it's interesting the discrepancy between the research carried out on laboratory animals, which is very sophisticated, which they do beautifully, which is instrumented to a tee, direct linkage between the sensor mechanisms and the analogue digital converter right into the computer, on line, you see, and then

you go into their clinical facility, and you find the good old doctor with the stethoscope, his sphygmanometer, and the urine tests, you see, not well instrumented, not the modern technology, and there's the difference.

Dr. Y.:

What lies behind that?

Dr. G.:

First of all, of course, it's easier to do research on animals. I'm not that naive. I know that you can't instrument humans. But secondly, what lies behind is, I think, they take the path of least resistance. They often don't want to know, in my opinion, all there is to know about a drug before it's marketed. If they know too much, then they might have too much trouble perhaps. That may be their reasoning. I can't imagine their reasoning, I just have to guess at it. But it is true as Billy Goodrich has pointed out that for every drug that is marketed, you can look at the claims at the time of marketing and three years later you're going to find those claims substantially modified, qualified, because the research that has been conducted is limited, and as the base of experience grows, so does our uneasiness with the drug because we do encounter more problems with it.

Dr. Y.:

It is adverse reactions more than it is lack of efficacy or...?

Dr. G.:

Both. Both occur. Now with Talwin, for example, it was marketed with great fanfare.

Dr. Y.:

With what?

Dr. G.:

Talwin. T A L W I N. And a former director of the Bureau of Medicine of the FDA is the medical director for that corporation. And it was marketed with great fanfare as being a non-addictive narcotic, or non-addictive pain killer. I should have known better than that. We as an agency should have known better than that, but we let them go ahead, because the evidence on hand did not show it to be addictive. Now, they are having to admit in their advertising and it's known that it is an addictive substance. Doctors, many doctors all over the country are now addicted and using it as a drug, just the way Demoral, which was also hailed as being a remarkable breakthrough, is being used. And this is just an example. Now efficacy. I think Merck, Sharp and Dohme's product for the treatment of arthritis was hailed by the...

Dr. Y.:

Indocin?

Dr. G.:

Indomethacin. Indocin's their trade name. It was hailed by them in their advertising as just a fantastic discovery. Now, a few years later, it isn't as good as they claimed, and, in fact, the efficacy...some physicians who have studied it say it isn't any better than aspirin, you see, double blind experiments. Well, that's basically the way I see the problem of the research in the drug industry, not as well carried out as it should be. Now, I am sympathetic with some of their problems. Part of their problem is related to the physicians who do the work, who often don't keep the proper records and aren't timely in submitting their reports and...

Dr. Y.:

They're not skilled...

Dr. G.:

They're not skilled and properly trained, but the drug industry, one could say, maybe consciously uses these kinds of people. That's an accusation I can't back up, or a suggestion, at least, but you begin to wonder about it after so many times when you find that they've lied, aren't willing to take a responsible public position, and their only interest does seem to be money.

You begin to have these cynical attitudes.

Dr. Y.:

On the rest of this tape let's talk about another thing that had been created the year before you arrived, but for which you had to assume the major responsibility, for its youth, at any rate, and that was the situation stemming from the 1965 law that related to dangerous drugs.

Dr. G.:

Right. I'll take full responsibility for the implementation of that. It's true that Congress did pass the Dangerous Drug Act of 1965, the Drug Abuse Control Amendments as they were called, DACA, but it was my responsibility in '66 to implement them, and so I was fortunate in getting Mr. John Finlator to join the agency. He had been with GSA and prior to that with security in the State Department. John was a very attractive person, an experienced administrator. I put him in charge of this activity and then we started off in May of '66. A year later, we had over three hundred qualified agents working all over the United States. We had a good record behind us in terms of arrests, in terms of meeting the responsibilities that Congress had laid out for us, and we then came into a very interesting chapter which I would have to entitle "The Transfer to Justice of Dangerous Drugs."



Dr. Y.:

What lies behind that that would be hard to find in the printed record?

Dr. G.:

That's an interesting story. In 1962 the Prettyman Commission reported to President John Kennedy and recommended that the Bureau of Narcotics be transferred from the Justice Department and that Dangerous Drug Work be assumed by them, too. It would be a single agency within government that would handle this. This recommendation was not adopted. In late 1967 and early '68, or beginning first in late '67, I recommended to Secretary Gardner that we transfer...no...I want to check the dates on that...at any rate we took the initiative. I recommended to Secretary Gardner that we transfer the Bureau of Dangerous Drugs from FDA to the Department of Justice, that this really was not the kind of operation we should have in the Department of Health, Education and Welfare and in FDA, that the Department of Justice was more capable of coping with the problem, they were dealing with criminal elements...the same people all of the time...and more importantly that the Bureau of Narcotics in the Department of the Treasury and our agents were often working unknown to each other on the same case, same people, and on some arrests we would make we would find marijuana which was under their jurisdiction as a hallucinogen, even though it was

classified by them as a narcotic and their agents would find hallucinogens, LSD or amphetamines, when they were working on a narcotics case, and it didn't make any sense at all. Now Henry Giordano was director of the Bureau of Narcotics, and I met with him early in the development of our Bureau of Dangerous Drugs, because we were recruiting agents and, to get a quick start on a problem, we did turn to agencies that had trained agents, and the Bureau of Narcotics was one of them, and so we recruited some of their people. We recruited some from the Department of Justice, the FBI, and other agencies, Army Intelligence, et cetera. But Giordano complained, and so I met with him and had lunch and talked with him on a couple of occasions and said, "All right, we won't recruit any more of your people." We discussed at one luncheon that we had philosophical problems of drug abuse and marijuana, and he assured me that they were not arresting young people, making felons out of them, which was a lie, and Henry was a dangerous man, in my opinion, in our society. But he ran the Bureau of Narcotics in the same style that he'd been trained. He was Harry Anslinger's boy. So I recommended to the Secretary that we give up the Bureau of Dangerous Drugs provided that the Bureau of Narcotics was pulled out of Treasury and the two brought together in Justice. Now, behind that was more than just the matter of rationale--it made sense because of what I've already explained. But behind that

also was the suspicion that there was some hanky-panky going on in the Bureau of Narcotics. The hippies in the Haight-Asbury section of San Francisco and in the Village in New York had told me on a number of occasions when I met with them that the Narks, they called them Narks N A R K S, the Narks are on the take, they would say. The Narks are peddling drugs. Now you hear this once, you discount it, because the hippies tended to be a little paranoid anyway about the Narks, but when you start hearing it on both coasts and every time you encounter hippies you begin to wonder, and then as you have an operation develop under your guidance and you see how the opportunity certainly exists by virtue of the up-front money that's used in these kinds of things, you begin to wonder. And also that the Bureau of Narcotics is in the Department of Treasury, really not an enforcement agency in general terms, you see, left alone, run as a domain by Anslinger and now Giordano. So I insisted that that would be part of it, and indeed it did become part of it. Now Giordano fought politically very hard to prevent this from occurring. The reorganization bill, Congress must act within thirty days or what the president proposes becomes law and the reorganization takes place. That bill was within five votes of being defeated.

Dr. Y.:

Well, it seems to me that it was not only Narcotics, but, at

least to go by the trade press, there were lots of people who were more or less adherents of the Food and Drug Administration who didn't want this to happen also.

Dr. G.:

Well...

Dr. Y.:

But within the agency you wanted to get rid of it?

Dr. G.:

Oh, yes.

Dr. Y.:

This is unusual for an agency to give away a big chunk of power.

Dr. G.:

Yeah. Well, I thought it was wise to do it, and I went to see Ramsey Clark a week before we turned it over to him, and I told him about the organization we were turning over to him, what I thought of the principal people, and I thought we had a good organization. I asked him to do one thing. I said, "Look very carefully at what you get from the Department of Treasury. I have reason to believe there is something going on in the Bureau of Narcotics." Now, within six months, thirty-two agents in the New York office alone were indicted for selling drugs. That's just the New York office. That was ten percent of their total

national work force. So, I think there was good reason for the suspicions that I had based on what the kids had told me. And I think that as a result we have a stronger organization. Now keep in mind the Bureau of Narcotics for years reported that the heroin problem was stable. Well, their agents were selling heroin, you see. This is a terrible situation. It's awfully ugly work. Make no mistake.

Dr. Y.:

And it was a different kettle of fish from the kind of work that traditionally the Food and Drug agents had done.

Dr. G.:

Yes, undercover agents, wearing guns, using surveillance, wire-taps, Kell units. This was dirty, vicious work.

Dr. Y.:

You even set up a completely separate outfit.

Dr. G.:

Set up a completely separate operation and that again was one of the justifications.

Dr. Y.:

It was one of the rumors in the years before you came, within the Food and Drug Administration, that some time narcotics and dangerous drugs--this was when the amphetamines and barbiturates

began to be a problem more than before--that these two kinds of regulations would be fused, but the hope was that it would be fused within the Food and Drug Administration.

Dr. G.:

Well, if you stop and think it really makes sense to do that work in the Justice Department, because increasingly the same criminal elements, the Mafia, were involved. They'd been involved in the heroin trade, that's been one of their bulwarks, of course, for 10, these many years, and since Justice, the FBI, has the capability and has been working on the Mafia and the criminal problem in general in the United States, it made good sense to get this responsibility under them, too.

Dr. Y.:

Well, now I take it that Secretary Gardner went along.

Dr. G.:

He enthusiastically endorsed it. He thought it was good, and Jim Kelly, who is the real power in HEW, he thought it was great. He was just tickled pink that I would not fight to keep that, because he'd long wanted to see it go over there.

Dr. Y.:

And then the Secretary had got the President to make it one of his administrative recommendations?

Dr. G.:

Right. I remember very clearly the last time I saw Giordano was a meeting that took place in Assistant Secretary Lee's office, where the Assistant Secretary of the Treasury came over, Giordano, and one or two of their people, met with Assistant Secretary Lee, myself, Mr. Goodrich, Mr. Kelly. And it wasn't a very successful meeting, and Giordano apparently felt very happy about it, because I happened to walk out in the hall after the meeting was over and Giordano was doing a little dance of glee with a big smile on his face which he instantly erased as soon as he saw me, and I've often thought...

Dr. Y.:

It wasn't successful, so he was happy, that is what you mean?

Dr. G.:

It wasn't successful in the sense that the two department representatives couldn't agree to the merger, and that Giordano felt that his point of view was going to win out. And I've often thought, since Giordano has been pushed out by Ingersoll, the new head of this Bureau of Dangerous Drugs in Treasury, and has now retired, I've often wondered what it would be like if we encountered each other again. Some merit and truth in that old statement, "He who laughs last, laughs best," you know.

Dr. Y.:

What about the residual problem of the location of the decision of what should be a dangerous drug?

Dr. G.:

Well, I felt confident that, if people were of good faith, that could be worked out between Justice and FDA. But that really wasn't as great a problem as people were making it out to be.

Dr. Y.:

But it seems to be a highly controversial thing.

Dr. G.:

It seems to be one point that people are stuck on now. But I think that can be solved.

Dr. Y.:

I hadn't realized that...

Dr. G.:

Justice would be in bad shape if FDA ever recommended, like Talwin, that something go on that list, and the Justice Department wouldn't put in on the list. They'd be in bad shape to explain why they wouldn't. They'd have to have good documentation.

Dr. Y.:

Right. Well, that's just a kind of a twist because I...



Dr. G.:

Well, it's not the usual bureaucratic practice, I'll admit.

Dr. Y.:

It certainly isn't.

Dr. G.:

It was fun to see that transfer take place. It made good sense administratively.

Dr. Y.:

Even though all of your ideas and Finlator's ideas--and Garfield must have been a kind of important fellow in that outfit.

Dr. G.:

Yes, he was. Fred did a good job. He's still with them now.

Dr. Y.:

Your ideas had gone into creating and building...

Dr. G.:

Right.

Dr. Y:

...the sort of structure that it was.

Dr. G.:

But even so it was well worth it because we delivered a good

organization to Justice, and I think they are doing an important job.

Dr. Y.:

Well, good. Maybe this is a good place to stop.

Dr. G.:

I think this is a good place to break for the day.

Dr. Y.:

Okay, Jim. Thanks so much.

# History

of the

## U. S. Food and Drug Administration

Interviewee: Dr. James L. Goddard

Interviewer: Dr. James Harvey Young

Date: April 30 to June 19, 1969

Place: Atlanta, Ga.

Session 5

Pages 342-411

Dr. Y.:

Well, this is the fifth conversation, Jim, between you, James Lee Goddard, and me, James Harvey Young about your experiences in life leading up to your position as Commissioner of the Food and Drug Administration. This like the others, is being held in your home, and today is June 13, 1969. As I was going over transcripts of our first two conversations, it occurred to me that I had talked with you something about your background. We had gotten back as far as the job you had at the movie theater in Ohio when you were in high school. But I hadn't gone back before that, and I wondered if a historian ought not to be interested somewhat in heredity and what you might like to say about heredity and your relationship to your parents and your family and so on, as this may have helped make you the man you became.

Dr. G.:

Of course, Harvey, as far as heredity is concerned I think the immediate environment in the formative years is even more important than what genes you start with, although they are important. They may be most important with respect to longevity. They certainly have a bearing on intelligence, some of the other facets of our character. My family came originally to this country from England on my father's side, back in the 1600s,

and the original Goddard to emigrate from England was a cabinet maker who settled in Rhode Island. He came over actually to track down a man who owed him some money and liked the New World and decided to go back and get his wife and sons who were in England and brought them over on another ship and settled in Rhode Island. He did very fine cabinet work. I've had the pleasure of seeing one of those pieces he created, and he was extremely successful. From that beginning the family...the sons, as they matured and married, moved westward, some of them... one of them at least up into Connecticut. That's the branch of the family my grandfather and his father were descended from. My grandfather Goddard, to get down to the more immediate family, was in business; he was a painter and decorator, as were all of his sons. He had four sons and one daughter and one daughter by his second marriage. His first wife died, my grandmother, whom I never knew, on my father's side. C. V. Goddard, Clifford Virgil, was his name. He was an interesting person. I remember him well, as a child. He was a rather stern, forbidding type of man, to me at least, and yet, later in life, I came to know of him. He died when I was about ten years old. I came to know of him through my aunts and uncles. He really wasn't as stern as he had seemed, according to them. My father, Frederick Oscar Goddard, was born in 1892 in Alliance, Ohio, and married my mother who lived across the street from him. Her maiden name was Calhoun. C A L H O U N. Beryl Calhoun B E R Y L. They

had grown up, at least in high school days, living across the street from each other. They were married in 1917 at an Army camp outside of Chillicothe, Ohio. My father was in the service at that time, the time of World War I. I was born in 1923. We lived in Alliance, Ohio. I was born at home on Geiger Street. I was two months premature. We lived in Alliance until I was five years of age and then moved to Warren, Ohio. My father went into business for himself, painting and decorating, in Warren, in 1928. Now, of course, in 1929 we had the crash and from then on it was very difficult. He was unemployed, except for finishing up a few painting jobs, from 1929, the winter of '29, to 1933. At that time he obtained employment with the Republic Steel Company as a mill policeman, and we were able to move to...we had been living in a small cottage in the east end of Warren, Ohio, at that time after a series of furnished rooms and apartments...and we were able to move to a larger house which cost at that time fifteen dollars a month, as I recall it, for rent. And I grew up...well, we lived in that house until 1940, at which time my parents were separated and subsequently divorced. At that time we moved. My mother and sister and I took a furnished apartment again in the downtown area where we lived...perhaps two or three different furnished apartments between that time and the time I graduated from high school. During those formative years, I was interested a great deal, as

I've mentioned earlier, in reading. I was encouraged a lot to read and to apply myself to my studies by my mother. My father wasn't too interested in my activities. I had always felt that he was somewhat disappointed in me because I was a very scrawny, thin, non-athletic type, although I enjoyed and engaged a great deal in sand lot baseball and football, not organized. We didn't have little leagues and those activities. I had an uncle, Eugene Calhoun, who was married. He and his wife had no children. I was one of two nephews in the family, on he and his wife's side of the family; naturally they were quite nice and quite good to me and encouraged me also a great deal with presents of books and games. Subsequently he proved to be an even more decisive factor in my life, because he encouraged my mother...and me... to help me go to college. Now, in order to do this, I worked for a year after graduating from high school in the theater as assistant manager and had been able to save two hundred and fifty or three hundred dollars. Now, with that money and with the assurance of a job, he lived...Mr. Calhoun lived in Alliance, Ohio...ran a restaurant. He owned a restaurant, I should say, just off the college campus, Mount Union College. With the assurance of a job waiting table which would provide my room and board and spending money, a dollar a week, I was able then to enter college. The tuition was a hundred and twenty-five dollars each semester. So I had enough for one year when I started, and

he and my Aunt Gladys were very kind to me and looked after me and saw to it that I...

Dr. Y.:

Were you or your sister the older?

Dr. G.:

My sister is five years older. She was born in 1918. Although five years different in age, we've always enjoyed each other's company. She and I have been very close. We were the only two children.

Dr. Y.:

Right. Were your interests...this reading which seems sort of unusual to me, that you should develop both the breadth and the speed of reading which you have...was this kind of on your own and from the encouragement of your mother and uncle or was there some other influence?

Dr. G.:

It seems largely on my own. There was no program of any kind at that time.

Dr. Y.:

There weren't any teachers who had tremendous impact?

Dr. G.:

I can remember some of the teachers in grade school who were



very encouraging and in junior high school. We were fortunate, more fortunate perhaps than children are today. I do think we had more dedicated teachers in the public schools at that time than we have today. Of course, unfortunately, fewer children were able to stay in school throughout the twelve years at that time, so the burdens weren't as great on society.

Dr. Y.:

So you really knew what the depression was.

Dr. G.:

I remember it quite vividly, not only because my father was out of work. We lived in a town that depended upon the steel mills by and large for employment. Work was...the mills were closed down and so money was extremely scarce. Everyone who had any land available to them grew their own vegetables during the summer months and canned them in order to have food for the winter months. The grocers carried everybody on credit. I don't know how people would have survived had it not been for the fact that the grocers...how they got the money to pay the wholesalers...the wholesalers must have been carrying the grocers. It was an amazing set of circumstances. There was very little money. Ten cents was a highly respected sum, you see.

Dr. Y.:

That's right.

Dr. G.:

You remember that well, too.

Dr. Y.:

I do. I can remember things of the same sort.

Dr. G.:

And you see, that again relates to my reading, my love of reading. We didn't have a radio, in fact, until 1933 or 1934, the summer of '33, and so, reading was...that was my pleasure. I had very few toys, but books were free. You could go to the East End Library, walk to the library, get the books and return them in a week. I always had a stack of books around the house. And so I was able to occupy myself between that and the usual games of childhood. Thinking of childhood reminds me of that book, "Where Did You Go? Out. What Did You Do? Nothing." Because that was typical of the kind of childhood I had, and remember, at least.

Dr. Y.:

Now, you spent the one year with your uncle. You went to school at Mount Union the one year and worked at your uncle's restaurant and so on. As I remember, you joined the service at the end of that year.

Dr. G.:

That's right.

Dr. Y.:

Was this because that money ran out or were you moved by patriotism?

Dr. G.:

Oh, a combination of factors. I wasn't satisfied with what I was doing in college. Patriotism was running high at that point in our history, if you remember correctly. That was January of '43 and I got itchy feet and I decided to volunteer and so I went back to Warren, Ohio, at the end of the term, after midterms, the end of the semester, I should say, and went to the draft board and asked them could they take me. They said, "Well, how about next Friday?" The following Friday, I went to Camp Perry, Ohio, first to Cleveland, then to Camp Perry, Ohio, and I wasn't there more than about a week before I came down with pneumonia and was very ill. But fortunately, they had sulfonamides available, treated me with those. I was in the hospital for some six or seven weeks, eight weeks, and then I was shipped to the Air Corps, to Florida for basic training.

Dr. Y.:

And that's where you took the tests that got you back into the pre-medical work in Philadelphia?

Dr. G.:

No.

Dr. Y.:

No?

Dr. G.:

That's where I was...I had finished basic training. I had had another siege in the hospital again during that basic training period, but I had finished basic training and was working at pulling targets. They sent a jeep out, took me back to town... this was St. Petersburg, Florida, and the sergeant said that I was being assigned to ASTP. I'd never heard of it and didn't have any idea what it was. But he told me it was a program where the army sent people to college. I was being assigned because a young man who was supposed to go that same day as one of a group had come down with appendicitis and they needed somebody to take his place, so they simply went through their records to look for somebody who had been in college before the War, and my name being in the Gs, I came up fairly early, or he may have started at random, I don't know. They simply said I was going. I wasn't given a choice, I was told. I got on a train that same evening and went to what they called the Star Center at Savannah, Georgia, at the Citadel, took some examinations there and was sent to Washington and Lee University in the engineering program. While I was attending the engineering course, after about two terms, the early part of the third term, they did give this medical aptitude test. All three hundred of us had

to take it. I was one of the six that scored the highest, and we were then sent to pre-med at Temple University in Philadelphia.

Dr. Y.:

Right. That kind of brings us up to what we talked about before. One of the other things that I put on the list to come back to was this: at one point, we postponed a discussion of Secretary John Gardner in action, when you would take him, as you said, fairly highly technical issues that you had already decided, but that had such potential political repercussions that you wanted him to be aware of them, and this would give a picture of what you thought were issues of this kind and of how he operated under such circumstances.

Dr. G.:

One of these issues that I remember vividly was the one that surrounds the present hearing on vitamins and minerals and, let me see, what else is involved?

Dr. Y.:

Special dietary foods.

Dr. G.:

Special dietary foods, the labeling, low calorie, those issues. These were not new issues when I took over as commissioner. Most of them had been put out in the previous administration as a proposed set of regulations.

Dr. Y.:

In 1962...

Dr. G.:

In 1962 for the first time. But they were withdrawn very quickly because the storm clouds gathered very quickly, and the Administration decided to pull in its horns. Well, Mr. Goodrich and other staff members briefed me on those proposed regulations. They certainly seemed to be needed in terms of what was going on in the marketplace. The irrational combination of vitamin products, the deceptive packaging and labeling on dietary foods, particularly the low calorie items, and so I decided to reinstitute these regulations as proposals. They were up-dated and they were about ready to be issued and I decided this was the type of thing the Secretary should know about because there had been such a furor before. And so I went to him, accompanied by Mr. Goodrich, and we briefed the Secretary. Now, you know, from your own work, Dr. Young, that in this particular field of quackery, and certainly the nutritional quacks are numerous in our society, you know from working on those kinds of issues that some of this is fairly complicated.

Dr. Y.:

That's one way it's so successful.

Dr. G.:

That's why...its very complexity. But the Secretary listens... Secretary Gardner's good at listening to what was being said, and he grasped very quickly what the issues were and was able to sort out the really significant parts of what we were doing. I was amazed, because it was an involved set of proposed regulations, very complex, and yet within a matter of thirty minutes he had a good grasp of them, was asking the kinds of questions that it had taken me much longer to arrive at in preparing to brief him, and at the conclusion of the briefing and the questioning, he leaned back in his chair and looked at Mr. Goodrich and myself and he said, "Well, batten down the hatches and let it go, boys."

Dr. Y.:

So he was all for it.

Dr. G.:

He was all for it.

Dr. Y.:

His quick lines were one thing that impressed you.

Dr. G.:

Wonderful to work with a man like Secretary Gardner. There were other kinds of complex issues that I watched him grasp in briefings just as readily as this so it wasn't a one-time performance.

He had a good understanding and a good appreciation for fairness in our society and the need to promote it. Of course, his books speak for themselves.

Dr. Y.:

He supposedly backed you up in almost everything.

Dr. G.:

Without exception. Without exception. One good example was in the case of the furor that surrounded the marijuana flap. I remember I had been misquoted by a Miss Judy Vick...

Dr. Y.:

Let's just go into that since you have mentioned it.

Dr. G.:

...in Minneapolis. I was there to speak on some issue related to industry and the public.

Dr. Y.:

Can you remember when this is. I've kind of forgotten.

Dr. G.:

Oh, let's see.

Dr. Y.:

'66?



Dr. G.:

Hold on just a second. I've got it right here. There was the other day a clipping here, my son was bringing out something... it doesn't have a date on it. Isn't that a shame?

Dr. Y.:

Well, I can pin it down. I just didn't happen to have a note on it.

Dr. G.:

October 17th in Minneapolis.

Dr. Y.:

I see, of 1967?

Dr. G.:

Yes. A Miss Vick was the stringer for the UP. She worked at the University.

Dr. Y.:

Was she a student or was she a staff person?

Dr. G.:

A staff person, as I recall, at the University. She filed the story with the UP to the effect that I would not object to my daughter's smoking marijuana any more than her taking a drink. In fact, I would rather she smoked marijuana than drink a cocktail, was, I believe, the way the story was written. Now,

fortunately for me, in one sense, although it was a minor consolation, there was an experienced science writer at that press conference. Had I made such a statement, I'm sure that this particular science writer, Vic...I can't think of Vic's last name right now. He's now the staff writer for the Washington Post on medical sciences. I'm sure Vic would have filed the story, because he knew a good story when he saw one without a question, but he didn't, and so the UP had to back off and had to issue a retraction and wrote me a personal letter, the Washington bureau chief, apologizing for any trouble the misreporting may have caused me. Well, the trouble was simply this: I had to appear before a number of Congressional committees within a very short period, within a week thereafter. In fact, one of the problems was that Secretary Gardner and Under Secretary Cohen and I had to work out which committee would have the first crack at me, because a number of them wanted jurisdiction and wanted to get me before them and to...

Dr. Y.:

It certainly did mean headlines.

Dr. G.:

Oh, all over the United States. All our newspapers carried it. Now we did work out that Representative Staggers of the House, inasmuch as his committee was the substantive committee for HEW,

would have the first chance. Then, as I recall, the Senate committee was next; then the third committee was Mr. Fountain's committee, as I recall, and then there was a fourth committee, in the Senate, Senator Dodd's committee. So they all had a chance at me. Four of them within a five-day period.

Dr. Y.:

You say Secretary Gardner was very understanding.

Dr. G.:

Secretary Gardner was extremely understanding. He called me one evening at home, and he was an extremely busy man with many other important issues, more important issues, in fact, and he said, "Jim, don't let this get you down." He said, "I'm with you and we can ride it out. Don't let it bother you." At that point, the public press was...things were being fanned to a peak by statements such as Representative Dan Kuykendall, Republican of Tennessee, said, "Because of Dr. Goddard's sick and utterly intolerable advice, he should be summoned immediately before the House Commerce Committee and explain himself." And this was seconded by Representative Clarence J. Brown, Jr., a Republican of Ohio, an idiot if I ever knew one.

Dr. Y.:

Well, this gave your enemies a kind of handhold, a presumptive one, at any rate...

Dr. G.:

Yes.

Dr. Y.:

...to try to attack you. In fact, there were lots of calls for your resignation.

Dr. G.:

Oh, a number of calls by Congressmen and others for my resignation, but it was at that point indeed that Secretary Gardner said, "Don't worry about it." He said, "We can ride this out." And we did. That proved not to be the major issue...a major issue...although it's something that every place I go, whenever I go to speak at a university or on campus, particularly in Georgia, the issue comes up again.

Dr. Y.:

Did you ever hear from the young woman who made the mistake?

Dr. G.:

Never.

Dr. Y.:

How did she ever make such a mistake?

Dr. G.:

I don't know.

Dr. Y.:

She just cooked it up?

Dr. G.:

No way of knowing, no way of knowing. But it was interesting. During the Congressional hearings, three of the Congressmen took their allotted five minutes, because this was the full committee and Mr. Staggers had to give every committee member a chance to question me and so he had to ration the time and allowed each of them five minutes. Three of them took their five minutes asking me how I got an apology from the United Press, complaining that they had been misquoted by the UP on a number of occasions and they had never gotten an apology. So, the fact that I did get a written retraction from UP was a very significant thing, it was clear. Now, it was an important issue for other reasons. It got the whole issue out in the open. It made the public and the Congress begin to think and talk about this set of laws which was so unrealistic, that classified marijuana as a narcotic.

Dr. Y.:

They haven't done anything yet though, have they?

Dr. G.:

It also got others interested in the subject. The furor dragged the National Institute of Mental Health into the whole field,

because one of the points I made very strongly was that there had been no good research, and Dr. Stan Yolles had to go before Congress and admit that there was none and that they would see to it that there would be some good research conducted. In the long run, I think it helped topple that Bureau of Narcotics empire in the Department of Treasury and hasten the day of its transfer to the Department of Justice. And so, I don't feel badly, in fact, I noted with some interest last week that Philip Handler, the new president of the National Academy of Sciences--NRC, who takes office July 1, testified before Congress and said that he didn't think marijuana was as dangerous as alcohol, and he cited practically the same...made practically the same statements that I had and cited some of the same reports that I had used.

Dr. Y.:

In briefing yourself on the background of this issue, from whom did you draw evidence?

Dr. G.:

I read all of the world's literature that the staff could assemble, going back to the Indian Hemp Commission Report of 1868 or...I've forgotten the exact date on that.

Dr. Y.:

In other words, you said:...

Dr. G.:

I personally read the literature.

Dr. Y.:

"I want to make a speech on this, and I..."

Dr. G.:

I knew I had to make a number of statements to Congressional committees and so I had to be well-briefed. I found the LaGuardia Commission's report probably the best that had been done in this country. That was back in the mid-40s, around 1945, '44.

Dr. Y.:

Just a technical point: You would do something like tell Ted Cron or somebody, "I want..."

Dr. G.:

In that instance, I told John Finlator, the Director of the Bureau of Dangerous Drugs, of BDAC, that I wanted the literature on marijuana, the world's literature without exception. I wanted it as far back as they could get it together, and I gave him a time period and they delivered it, Verifaxes or Thermofaxes or whatever you wish to call them.

Dr. Y.:

So you had the vast stack of...

all of the available data was of help.

Dr. Y.:

But you had done this reading before you made your speech or was this in between?

Dr. G.:

This was between. I had done some of it before, but the intensive part came between the misquote and the Congressional hearings.

Dr. Y.:

So it was a rapid proposition?

Dr. G.:

Oh, it was a pressure proposition. Fortunately, the National Institute of Mental Health had the references fairly well assembled for other reasons, and I was able then to tackle those and read them in the evenings and get at the business of a statement over the weekend. So the whole issue now is being studied.

There is some good research going on and, as I've mentioned, Dr. Handler also now has said basically the same thing that I said before the House Committee and before the Senate Committee. I can't find his statement right now, but we can get a copy of it.

Dr. Y.:

Right. When you were talking a while ago in connection with



the vitamin and mineral and special dietary food matter as you brought it before Secretary Gardner...

Dr. G.:

Let me give you another example...

Dr. Y.:

All right.

Dr. G.:

...of the Secretary's ability to absorb the technical details. There was an item pending before I went to FDA surrounding the use of trash fish. These are fish that normally don't find their way into commercial markets, except sometimes in the form of fertilizers, to create a product known as "fish meal" or "fish protein concentrate," whose advocates suggested could help a great deal in alleviating hunger on a global basis, but the FDA up until that point in time had been unwilling to approve the product for marketing in the United States. Now, let me make clear that the law at no time precluded the product from being developed and sold overseas, but because of political necessities it was felt best to have it approved for marketing in the United States before ever exporting it to India.

Dr. Y.:

Diplomatic.

Dr. G.:

That is correct. For diplomatic reasons. Now, there was a promoter whose name was Ezra Levin. He had a process that produced a whole fish protein concentrate which he called Viobin, and who was his friend but Senator Paul Douglas? Senator Douglas used to get me up to the Hill, as did Senator Teddy Kennedy and one or two others, quite often, to inquire about the progress on whole fish protein concentrate.

Dr. Y.:

Back in Larrick's regime, the reason that they had kept this off the market was...

Dr. G.:

George Larrick felt that to process the entire fish would result in a filthy product because the intestinal tract and all would be processed into a flour or meal that could be used as a protein base for other foods. You see, primarily, this would be a high protein food and could be used in soups, a small percentage in bread and biscuits and baked goods, or eaten as a supplement on rice and in whatever fashion, in a paste, fish paste. So there were a variety of possible uses and the major purpose was to get more protein into the undernourished countries, countries with malnutrition problems. But Commissioner Larrick felt that this could not be marketed in the United States, even though he was sympathetic with the problem with respect to other nations.

Dr. Y.:

He thought the law flatly forbade it.

Dr. G.:

He felt indeed that the law forbade it. Now, on the other hand, if you examine the feeding habits of fish, you see that the deep water fish, their intestinal tracts are practically clean, practically no bacteria at all. And if you look at the fact that we permit sardines to be marketed which are intact and eaten by the American public, you begin to wonder about the rationale, even though sardines are held for a period of time, you see, in the water, in nets, before they are brought aboard and processed. Nonetheless, they are processed with the entire intestinal tract. Well, this was the issue. Now, I felt strongly that that kind of thinking could no longer be tolerated and that, therefore, we would approve the U. S. Department of Interior's request which would permit them to market whole fish protein concentrate in the United States but limit it to one pound bags in order to prevent consumer deception. If it went out in 1500 pound bags, you might find some millers or some bakers mixing it with other higher priced items in order to deceive the public. And we felt that if it were sold as a consumer item, directly to the consumer, and properly labeled, "Whole Fish Protein Concentrate," then the consumer would know and have a choice. If they chose to exercise that choice in favor of the product, just as they do

sardines, then there really wasn't any problem. Now this was basically what we presented to Secretary Gardner. Mr. Goodrich, to help, played the devil's advocate and pointed up the classical arguments about filth in the marketplace, the fact that the fish with bones, scales, heads, eyeballs, intestines, everything, would be included. The Secretary listened very attentively and after Mr. Goodrich finished, he said, "I guess you don't believe that cities downstream on the Ohio River from Pittsburgh should use the water that Pittsburgh has used, because we recycle, and filth isn't really a relevant issue. It's a technological problem today. Can the product, Dr. Goddard, be marketed in such a way that it's clean, it's wholesome, it doesn't have any potential for infecting anybody?" I said, "Yes." He said, "Bless you."

Dr. Y.:

There was a problem of some sort of alcoholic residue.

Dr. G.:

Ah. Now we did find out that the Department of the Interior hadn't done their homework properly, and, in fact, there was a problem with a too high concentration, as a result of the particular process the Interior Department was going to use, of flourine, flouride residue in whole fish protein concentrate which could cause mottling of the teeth. Now, we were able

to work out with them, however, a change in methodology that would remove the headbone, the head of the fish, and decrease the flouride, and then they were able to go ahead, and they are now building the pilot plant, as I understand.

Dr. Y.:

Oh, is that what's happening?

Dr. G.:

Yes, I understand...

Dr. Y.:

I remember the big argument one day at the Advisory Council in which you presented this issue and Tex Cook of General Foods was all upset about this one pound package business.

Dr. G.:

Yes.

Dr. Y.:

Is this still the situation?

Dr. G.:

That's still the situation, and I don't think that's a bad thing. As the experience grows with it, that can be changed, but I don't think he should start off with no holds barred. Really, the people backing this they were telling us the truth. They

said, "Well, Doctor, we don't expect there ever to be a U. S. market. It's only a political necessity to have approval, FDA approval, in order to send it overseas."

Dr. Y.:

Because India couldn't accept it if Americans were too high and mighty to eat it.

Dr. G.:

So if they never foresaw a market in the United States, why was it such a problem when we put a one-pound limitation on it, you see? But at any rate, they now are going ahead.

Dr. Y.:

But that was another point of interest.

Dr. G.:

Secretary Gardner saw the technical issues very quickly. Again, I had made the decision. Of course, if he had said, "Well, don't do that," I would have respected it. But I didn't take this issue to him to ask him to decide it. I didn't think that was fair.

Dr. Y.:

You had worked it out ahead of time...

Dr. G.:

Right. I wanted to alert him to the political sensitivities involved, because every congressman and senator from every coastal state was interested in this particular process and in seeing this approved, because it had been blocked for so many years.

Dr. Y.:

And they even thought you were dragging your heels.

Dr. G.:

Oh, yes. They thought I was dragging my heels because of the flouride problem.

Dr. Y.:

And on this conference, you and Billy Goodrich had figured out ahead of time you were going to present it this way in order to make the thing sparkling clear.

Dr. G.:

Yes.

Dr. Y.:

Well, you were talking about the vitamin and mineral proposed regulations as an example of an issue which Secretary Gardner grasped. I had some things about this down to raise questions about. The Federal Register did carry the first draft of your

new revised set of regulations on June 18, 1966.

Dr. G.:

It was unfortunate that we had some errors that we hadn't caught.

Dr. Y.:

I wanted to raise a question about how you got acquainted with this question and who brought it up, who was responsible for taking the 1962 version and converting it into what became the 1966 version, and how it...

Dr. G.:

Billy Goodrich and Ken Kirk.

Dr. Y.:

They were the two?

Dr. G.:

Were the two. This was again in the category of pending business... something that had been left hanging fire for a considerable period of time, and so Billy had brought it up, and Ken Kirk took it over, and McLaughlin, as I recall, on his staff, did a considerable rewrite on this, and in spite of going over it a number of times and asking as many questions as I could think of, we still made some mistakes in that original draft that went out. On portion size for infants...it was most embarrassing to find the portion sizes for infants were ridiculously off, which



meant that we just hadn't done our staff work even though it had been looked at by, I would judge, eight people, at that point in time.

Dr. Y.:

Well, one of the biggest black eyes that you got, of course, came from rather a protesting voice that was raised by the chairman of the Food and Nutrition Board of the National Research Council. A fellow whose name was...

Dr. G.:

Henry Sebrell.

Dr. Y.:

Dr. W. Henry Sebrell.

Dr. G.:

That's right. Public Health Service Officer, retired.

Dr. Y.:

At Columbia.

Dr. G.:

At Columbia, former NIH director.

Dr. Y.:

And his sub-committee, at any rate, was in charge of the recommended daily allowances and what they should be.

Dr. G.:

Minimum daily requirements, until that point in time. Only subsequently to then did they shift to "recommends dietary allowances", RDAs.

Dr. Y.:

Well, I thought that it was only the food and drug that had the minimum.

Dr. G.:

We followed their recommendations, and because the minimum was such a problem in terms of misleading people, because the people engaged in this business would say, "You don't want just the minimum daily requirements. You want three times the minimum." So, in order to avoid this, the Academy went to recommended dietary allowances. But they were responsible for setting the RDAs which the agency then followed.

Dr. Y.:

Right. The trouble was, somehow, that in the transfer, the agency had gotten more precise than the somewhat flexible system that the committee had had, and at any rate...

Dr. G.:

There were a couple of problems.

Dr. G.:

I had a stack of them, but being able to read rapidly was of great help.

Dr. Y.:

And so you drew your own judgment.

Dr. G.:

That's right. There was a series of sessions with Mr. Goodrich and Mr. Cron and the people from BDAC again were involved and then the Congressional statements were drafted, based on my discussions with them, what I had read in the literature, and what we thought we should say to the Congressional committees.

Dr. Y.:

This wasn't to say to the committee about this report. This was general policy statement or judgment?

Dr. G.:

I felt I had to make a defense before the Committee. One, that I had not said what I was attributed by Miss Vickas having said. Two, however, there was reason for Congress to be concerned because the penalties were indeed excessive, so, three, Congress should seriously consider reducing the penalty from a felony for possession to a misdemeanor. Now, in order to make those recommendations, I had to have some justification and that was where having read the world's literature and having looked at

Dr. Y.:

...he jumped on the Food and Drug Administration pretty hard for that and for quoting them, as it were, in the so-called crepe label that you were...

Dr. G.:

That's right.

Dr. Y.:

...saying should be on every package.

Dr. G.:

That's right. Well, unfortunately, this was the issue that Kline, remember, we talked about Dr. Kline...

Dr. Y.:

Right.

Dr. G.:

Dr. Kline. This was one he was supposed to be gum-shoeing and he didn't. He didn't do the coordinating work that was expected of him, and one would have to reason to think he was capable of, and that fell between the cracks, and Sebrell was mad and, unfortunately, he criticized us publicly without ever giving us a chance to smooth over the difficulties and get our house in order. Dr. Seitz, Frederick Seitz, the head of the Academy, I went to him and complained about that. Now this is relevant

at a later point in history, because of my article in Esquire. Dr. Seitz wrote me and said he had no reason to think that I'd ever been unhappy with the Academy. He'd forgotten all about that problem that Sebrell had caused for FDA and for me personally, you see. So, it's interesting how these work in cycles.

Dr. Y.:

You did get it straightened out and get back in liaison?

Dr. G.:

Yes, we did. We got back in liaison, so I personally attended conferences that the nutrition group at the Academy held, spoke at a luncheon meeting they had and worked much more closely with them. That need never have happened had Kline done his job, and if I had been checking on Kline, but that was in the early, extremely hectic days, and I gave Kline an assignment and had no reason to doubt that he wouldn't follow through on it.

Dr. Y.:

One of the problems with this is that it was so complicated, and another obviously is that it hit so many segments of industry.

Dr. G.:

Oh, yes, this brought together all sorts of unholy alliances. It was complicated to begin with, as you point out. For example,

the diet food store operators, who also tend to sell vitamins, mounted the campaign again which was comparable to the one of 1962, but they misinformed their followers, their clientele, by telling them the FDA was going to prevent vitamins from being sold over the counter. That was not true. We were going to prevent the sale of vitamins in therapeutic dosage forms as over-the-counter items, but the "one-a-day" type vitamin, we were not going to take that off of the market place, so it was a complex set of issues.

Dr. Y.:

So that the ones that were wild and had seventy-five different ingredients in, they were going to be badly hit, no question.

Dr. G.:

They were going to have to come into conformance with the recommended dietary allowances. We put the crepe label statement in as a give-away, as a trade item. We never had any thoughts of keeping that in.

Dr. Y.:

Oh, I didn't know that.

Dr. G.:

Oh, yes. That was a straight trade. Billy Goodrich and I agreed ahead of time when push came to shove we would have that deleted

in order to get the rest of the package through, and that may not have been good judgment in retrospect, but at least that was why it was put in there.

Dr. Y.:

Well, one-a-day- brand people were also upset. That is, the makers, the pharmaceutical manufacturers.

Dr. G.:

Oh, of course, because they have a multi-million-dollar, hundreds of millions of dollars a year, vitamin business selling these to people who don't need them. And, of course, they don't want to lose that business. What we were going to do though, was, and we were realistic enough to know not to have unreasonable expectations of the public, we knew that the public would continue buying these products. We, therefore, wanted to make sure that, at least they had some basis, rationale in science, and that a firm wasn't bilking the public by suggesting that their product was one-a-day when, in fact, it was deficient in some of the major elements and had too much of some of the less important elements in the formula. In fact, that was a quite common thing. The more expensive items would be cut short. The inexpensive ones, they would put three and four times the recommended dietary allowance in. And so it was a hodge podge.

Dr. Y.:

Well now, why should the biggest pharmaceutical manufacturers who made these on the side have been upset at a proposal that would have curbed their competition from the more quackish operators?

Dr. G.:

They were afraid of the label restriction, that their sales might fall off. That's a very profitable field. The margin is extremely high on these products. They simply didn't want any restrictions. It goes back to their lack of foresight. But, you are right. There were many other groups involved: the National Canners Association was upset, the Grocery Manufacturers Association was upset.

Dr. Y.:

Millers?

Dr. G.:

Millers. You name them and there was somebody. About the only people who weren't upset were the Pepsi and Coca Cola companies, because they had Diet Coke and Diet Cola. Those would have been low calorie foods, and they weren't badly labeled at that time.

Dr. Y.:

One of the things that was done was an effort on the part of



the Pharmaceutical Manufacturers Association to stop things...

Dr. G.:

Again, on a legalistic, procedural basis. They weren't successful. This again, was typical of Joe Stetler and his whole approach to the Food and Drug Administration when I was commissioner. He said that we had no right to do this, the fact that this had been published once in 1962, then made it...

Dr. Y.:

It had to do with a particular section of the law.

Dr. G.:

That's correct. We could no longer do it the way we proposed. Well, we did.

Dr. Y.:

One of the big questions that was only in a minor sense present at the beginning but that has grown larger as there has been more attention to the poverty problem and to a recognition of how much poverty there is and how much malnutrition was this question about malnutrition. You say that this crepe label was put there in order to have a kind of a bargaining give-away.

Dr. G.:

Uh huh.

Dr. Y.:

Well, it said rather straightforwardly that the foods a person had available had the vitamins within them which he should take.

Dr. G.:

That his body needed.

Dr. Y.:

That his body needed. Now,...

Dr. G.:

And that's true still.

Dr. Y.:

Right. But the tremendous argument that has arisen since, a great crescendo, against the continuing hearings which are still going on, has been made that no such statement as this crepe label statement should be made because malnutrition is a bigger thing, so obviously people aren't getting from their food the vitamins that they need.

Dr. G.:

Well, that's a statement, not a fact.

Dr. Y.:

Right.

Dr. G.:

There are generally not good facts yet. Dr. Schaefer's group had been doing a survey. There is suggested data from that survey to show that some of the vitamin levels, Vitamin C levels in particular, some of the Vitamin A levels, in serum obtained from children, show some level of deficiency. Frank malnutrition has been extremely rare. It has been surprising, however, that five percent of the population examined in one area showed evidence of thyroid goiter. Now, we thought this problem was pretty well solved by the introduction of iodized salt. But many of the food companies, such as Campbell Soup, do not use iodized salt in the preparation of their food, because it's a cent or two per pound more expensive than non-iodized salt. Now, whether or not if Campbell's Soup had iodized salt it would prevent the goiter, no one can say. I didn't use that as one example. Frankly, I'm skeptical that malnutrition is as widespread as some would have you believe. Even if it were, vitamin and mineral tablets aren't within the pocketbook reach of that section of the population. What they need is the opportunity to have a sufficient number of calories in the major categories of food stuffs, then you won't have to worry about their malnutrition or their vitamin levels. That's the major problem. The major problem is getting a good school feeding program in the South which is where much of this exists. Another major

problem is proper education of the low-income population as to how to use their food dollar properly, rather than some of the ways people on welfare unfortunately now spend their dollars. Another problem is to see to it that the super markets in the low-income areas don't bilk the people by shooting the prices up the day before the welfare checks come out, and that's been observed, you see. So, there are all sorts of problems to be solved, but certainly the sale of vitamin and mineral tablets isn't one of them related to malnutrition.

Dr. Y.:

It isn't an answer to the question.

Dr. G.:

Of course not. It's ridiculous.

Dr. Y.:

In fact, insofar as people who should use the money to buy food, buy these, it's a waste, it's a risk.

Dr. G.:

Yes.

Dr. Y.:

But this argument has been made and that...

Dr. G.:

Well, the people involved in the hearings from industry, there's no question in my mind that the health food store operators as a lobby are the most disreputable, dishonest group in the American society today. They will use any tactic available to them. They will lie and it has been documented that they have lied. So, the fact that some of the people involved in this hearing say that this is justification doesn't sway me at all. Now, unfortunately, some of the other trade associations will engage in some of these same tactics. The National Canners Association, I think, has had the worst leadership of any major trade association in Washington. It's been terrible.

Dr. Y.:

Well, do you want to be specific? Can you recite an instance where you ran into this?

Dr. G.:

Yes, they lied on the canned salmon problem in Seattle. They said they were doing one thing and they were deliberately concealing the problem even after they had reached agreement with our agency on what procedure would be followed.

Dr. Y.:

That was where they had self-inspection, wasn't it?

Dr. G.:

Yes. And I told them they were jeopardizing the existence of the program. But it went beyond that. The leadership of the association, the individual involved just was afraid of his own shadow. He was an Aunt Nellie. He couldn't see what the future held or holds and was unwilling to make any change. On labeling on the Fair Packaging Act, he had the greatest dog-in-the-manger attitude I have ever seen. He just said it was impossible for them to do this job. It wasn't. We worked out through the GMA the procedures that could be followed. His attitude was always, "It can't be done; it can't be done. I don't want any change. Let's just leave things the way they are. The industry's comfortable." Well, they're comfortable alright. So these hearings...I'm not surprised that several of those groups whose financial interests are threatened want this to be the outcome.

Dr. Y.:

Well, obviously here it's more than seven years and nothing finally done. Partly, the procedural issue, the complex method of coming to grips with the problem...

Dr. G.:

We do need a different mechanism, I will agree. Our society deserves and merits a better mechanism than we now have for

these very complex and sophisticated problems which involve to a large measure science and public policy. We do not have a good mechanism today. I certainly agree and I was hard put... I can't think of a better mechanism. No one seems to be able to.

Dr. Y.:

There was no way to speed this up.

Dr. G.:

No. You have to use the Administrative Procedures Act and that means that lawyers get in. There are all sorts of tactics used. In fact, one of the things the industry occasionally does is to try to discredit the whole Administrative Procedures Act, the mechanisms involved, by making the hearing a laughing stock. Now, that doesn't do anybody a service.

Dr. Y.:

It has been suggested that maybe the peanut butter hearings is an example.

Dr. G.:

Indeed, I think they were. Indeed they were. The hearings on that, as you know, went on for about nine months as I recall. The bread hearings, another example. But, it's unfortunate.

Dr. Y.:

Okay. I think I'll turn over the tape.

Dr. G.:

Okay.

Dr. Y.:

One case that looked to me as if there must have been something behind the scenes was the case that involved Measurin...

M E A S U R I N...which was a timed-release aspirin which was being put out by Cheseborough-Pond. When this case surfaced, it appeared as if maybe you were running into your first trouble in what up to that time had been a relatively smooth relationships with the staff of Representative Fountain's committee. This began because this aspirin compound had been tested clinically by the Cass Research Associates Laboratory in Massachusetts and you found out that this was one example of clinical research that supposedly had been done but hadn't been done or hadn't been done adequately, and so there was a decision you had to make as to what you were going to do about the product. At the time you decided to leave the product, which had gotten on to the market through an NDA, on the market, giving the company time to try to bring in some new clinical evidence. But later on, the Fountain Committee wondered why you hadn't eliminated the product immediately by revoking the NDA. I notice



that you talked to the company officials on March 16th, and you handled a prescription analgesic somewhat differently, taking it off of the market rather peremptorily, and you didn't do that with this. There was also some feeling that maybe one reason the Fountain Committee got upset was deliberately in order to take a crack at Winton Rankin who signed one of the orders instead of you yourself signing the order. Yet, you yourself, when you were asked about it took full responsibility for the decision.

Dr. G.:

Well, no question about the decision, it was mine.

Dr. Y.:

Right. Well, now what was all this about? I have given you a kind of trade press view of the situation.

Dr. G.:

This was sort of a tempest in a teapot situation really. Now, legally, I think Don Gray and Del Goldberg were right. I should have acted and withdrawn the product from the market place. It was an over-the-counter drug. It was a timed-release aspirin. It did seem to serve a useful purpose for some people. It wasn't any more dangerous in my book than the other aspirins on the market place. It was more expensive, yes, but not more dangerous. Therefore, I couldn't get upset about it. In fact,

I think in testifying I said, "Why, it's only aspirin, Mr. Fountain." Not knowing at that point in time, as I later learned, about the sophistications of aspirin with respect to the research that we ourselves supported at Georgetown University. It was a very complex subject, but nonetheless, at that point in time I viewed it as only aspirin. Keep in mind in over-the-counter drugs we require a margin of safety about five times greater than for prescription drugs. So I felt safety wasn't really an issue. Therefore, I didn't see much reason for disrupting the market place. I refused to take it out of the market place and gave them time to do more studies. Now, they really didn't do good studies even though we gave them more time and Chesebrough-Pond lost several million dollars on that product. He ultimately got out of that business.

Dr. Y.:

Well, ultimately you did in August of '66 revoke the NDA, on grounds of both safety, because too much of it was being absorbed within a certain period of time...

Dr. G.:

That's right. By the studies we had then. But, you see, I didn't have that data available at the time the decision was initially made, and, as I say, I was surprised by the sophistication that was involved in an issue like aspirin. So, I was

wrong, as I said, but again, it seemed like the right thing to do at the time.

Dr. Y.:

But a good deal more was made out of it in the press...

Dr. G.:

Oh, yes. As you said I think that Gray was trying to get Winton. He never liked Mr. Rankin. He hated his guts. He didn't want me to take him as my deputy commissioner, and he thought he had something he could pin on Winton, but it wasn't Winton's fault. It was mine.

Dr. Y.:

So that was all there was about that.

Dr. G.:

There wasn't anything...no, there wasn't any hanky panky going on, really. What was the other analgesic, "Norgesic"?

Dr. Y.:

Right. Riker's "Norgesic."

Dr. G.:

Yeah.

Dr. Y.:

Well, one of the other big things has to do with the whole

internal reorganization in connection with the Department of Health, Education and Welfare on the health side. There had been stirrings of this, I suppose, almost from the beginning. President Johnson had sent a message to Congress in April of 1966 that dealt with the reorganization of health agencies within the Public Health Service, and there evidently had been a committee headed by John Gorson of Princeton...

Dr. G.:

Corson. C O R S O N.

Dr. Y.:

...who had made certain recommendations to Stewart who was then Surgeon General, and one angle of this that came up at the end of your first six months, about, was that you rather publicly hinted that you'd be glad to take over the pre-marketing approval of biologics into FDA from the Division of Biologics Control.

Dr. G.:

Yes.

Dr. Y.:

You said indeed that Secretary Gardner had this under consideration.

Dr. G.:

He did.

Dr. Y.:

And you told a House Interstate Sub-Committee this and later on Representative Rogers recommended in a report that he issued that this occur. So, what about this particular thing? This obviously shows rivalry for a certain power function within agencies, both of which are part of the health part of HEW. What about this matter?

Dr. G.:

I never viewed it as rivalry or as empire-building. I didn't think DBS was doing its enforcement job, and that they were too close to industry. That was their modus operandi, was work right with industry. And I felt that logically...We always got left in FDA with cleaning up the mess that grew out of DBS' unwillingness to take any action. For example, the Rand vaccine. They delayed and were dilatory in that. They were dilatory on Krebiozen, if that's the right word. They certainly piddled around, is what I am trying to say, and couldn't come to a decision about prosecution. But, you see, once they decide to go after somebody, then they turn the enforcement over to FDA, but they have to make the basic decision. They never really wanted me to take a tough line. So I felt it made sense, and I recommended it, and, in fact, Secretary Gardner and Assistant Secretary Lee were kindly disposed to the idea. Now, Rod Murray and I weren't old friends. Let's make that perfectly clear.

Dr. Y.:

Who was this?

Dr. G.:

Rod Murray, the Director of DBS. We fought on different sides of issues in the past, when I was Chief of the Communicable Disease Center, in fact. But there wasn't any personal animosity involved in this. But Rod made it perfectly clear that he would leave before he would work for me. And Rod's a good man. So, there was that to be considered. Frankly, also it wasn't a major issue with us because we had enough to say grace over. We had our own house to clean up and that was a job, an Augean stable as it turned out. And so I really wasn't looking for more for the agency to do. This was more in the sense of it was a logical kind of thing. NIH is not an enforcement agency, not a regulatory agency, and yet they had a regulatory function housed there. It didn't make any sense to Dr. Lee. It didn't make any sense to Secretary Gardner, and it logically belonged in FDA, so that was what that was about.

Dr. Y.:

Why did it get stifled?

Dr. G.:

Well, it got stifled because of politics between NIH and Public Health Service and the Office of the Assistant Secretary for

Health, and I really wasn't all that actively interested in pursuing it to make a big issue over it. So, it just sort of died.

Dr. Y.:

Another recommendation that came from HEW, this was early in 1967, related to the up-grading of the post of Assistant for Health to the Secretary of HEW. I remember when Boisfeuillet Jones had it, it was a statutory position, but it really wasn't called an Assistant Secretaryship.

Dr. G.:

That's right.

Dr. Y.:

It had been defined the way it was by Congress.

Dr. G.:

Well, there was a more basic issue. What turned out to be Assistant Secretary for Health or what had been Assistant to the Secretary for Health, really what was involved was should it be a line or a staff function.

Dr. Y.:

I see.

Dr. G.:

And as it turned out, it became a line function, and the power thus moved from the Surgeon General's office to the Assistant

Secretary, Dr. Lee's office, and this meant that staff had to be developed at his level, it meant that decision-making shifted, the power base changed. I would say it was the beginning of chaos. Let me make it clear, I liked and enjoyed Phil Lee's friendship, but I don't think Phil was a capable administrator. He would be swayed by the last person to see him on an issue and change his decisions. Let me give you an example: at issue was the question of whether budget people and the Assistant Secretary for Health and his staff would work under his supervision or under Mr. Kelly, the comptroller's supervision. Dr. Shannon and I argued almost vehemently, certainly vigorously, in Dr. Lee's staff meeting with him to retain control over those twenty-six positions, not to have those people work in Mr. Kelly's shop, because we had had experience with Mr. Kelly. The remainder of the staff watched interestedly but didn't get into the fight. Shannon and I fought with Lee, and Lee reassured us that this could be done without losing any control, which is utter nonsense, because if you give Jim Kelly twenty-six positions, those people are going to work for Jim, even though they technically are on your staff. If they report to him day by day, they're going to be under his supervision. Well, this was the kind of decision that Phil made that upset many of us so much. I also think that he made some poor selections. I've made some from time to time, and I know how they can occur, but



I thought that he made a higher percentage. Joe English, for example, C. C. Johnson, and a few people like this, aren't really strong administrators.

Dr. Y.:

Now, this proposal was made to up-grade the job under the President's authority, or was this a special...it wasn't a Congressional act?

Dr. G.:

It wasn't a Congressional act.

Dr. Y.:

And, at the time it was rumored that perhaps you might be given this job.

Dr. G.:

No. I wasn't even interested in it. That was strictly a rumor. There was no interest on my part and never any consideration on the part of the Secretary that that job would become mine.

Dr. Y.:

Well, one of the most intriguing, behind-the-scenes stories that seems to me that needs to be taken account of in our conversation is this story that came out just this last January and I'd kind of like to read it into the record.

Dr. G.:

You go ahead and I'll get another can of beer.

Dr. Y.:

All right, and then let you comment on upon what is said. Now, this story was written by one of the deans of the Washington drug reporters named Stephens Rippey who was the Washington editor of Drug Trade News and it appeared on the front page of the issue of Drug Trade News for January 13, 1969. /A photo-duplicated copy of this article follows on the succeeding page./

Dr. G.:

Finished reading?

Dr. Y.:

No, I've just gotten started. It starts off.../the article is read/...and that's the end of the article, and there's plenty in there to comment on.

Dr. G.:

God, yes. Let me have it.

Dr. Y.:

You just take it and take off.

Dr. G.:

Well, Steve Rippey normally was pretty accurate. He was off base

# Dr. Goddard's Dream Fades Away

DN 44 (Jan 13 69)

BY STEPHENS RIPPEY  
Washington Editor

WASHINGTON—The Consumer Protection and Environmental Health Service of the Department of Health, Education and Welfare is all that remains of a dream of former Commissioner of Food and Drugs James L. Goddard of a Cabinet-level Department of Health with—who but?—James L. Goddard, M.D., as Secretary.

The idea of a separate Department of Health did not, of course, originate with Dr. Goddard. It has been around Washington for many years. But, signs of germination appeared in his mind and in the hyper-active brain of Theodore O. Cron, his

alter ego and assistant commissioner for education and information, within a few months after Dr. Goddard became commissioner in January 1966.

It seemed logical to gather under a single department the vast health activities and facilities of HEW, plus the bound-to-grow environmental health activities. This still may happen at some time in the hazy future, but Dr. Goddard's idea really never got off the ground despite some rather strenuous efforts to launch it.

The dream was presented to Secretary John W. Gardner by Dr. Goddard and he was given the signal to go ahead with a plan. This was done, beginning in December 1966 with a formal

memo to Mr. Gardner, followed by briefings, replete with charts and other more or less sophisticated "presentations" to other HEW officials whose approval was needed.

They were not impressed, despite the charm and eloquence of Dr. Goddard. Nor was Donald F. Hornig, President Johnson's science advisor, who had a dream of his own which is still afloat—a Department of Science, which would encompass not only the health activities of the government, but its scientific activities as well.

Mr. Gardner didn't push the movement himself and there was definite coolness on the part of then Under Secretary Wilbur J. Cohen; the assistant secretary for health and scientific affairs, Dr. Philip R. Lee; the assistant secretary comptroller, James F. Kelly, and other key officials whose support would be needed for such a major upheaval. The matter never was presented to the chairmen of key Congressional committees.  
*(Continued on page 43, column 1)*

## Dr. Goddard's Dream Disappears

*(Continued from page 1, Col. 4)*  
al committees without whose support nothing could have been done.

By the time Mr. Gardner left HEW in July 1968, the Goddard dream had shrunk to an intra-departmental reshuffling which would put all HEW activities relating to the "ecology of man," including the Food and Drug Administration, under a single administrator. Mr. Gardner and Dr. Goddard understood that the latter would be appointed.

However, with Mr. Gardner's decision to leave HEW, Dr. Goddard lost his strong friend and supporter who wasn't perturbed by Dr. Goddard's other-world sorties, such as his misquoted marijuana remarks, and his not misquoted remarks about closing down drugstores. Mr. Cohen and Dr. Lee were not wave-makers, and let it be known they considered Dr. Goddard a liability, who might be permitted to continue as FDA commissioner but wouldn't be considered for a higher job.

Some of those who know Dr. Goddard well believe he might have swallowed his ego and remained as commissioner of FDA

if the new job for which he was bypassed had gone to an outstanding, nationally known scientist-administrator under whose shadow Dr. Goddard's pride would permit him to work.

But, this was not to be and Dr. Goddard had few illusions that it could be. For one thing, he had searched the country, even calling on the National Academy of Sciences for help, for an outstanding scientist-administrator to become FDA's associate commissioner for science. No such man was found who was willing to take that job, and there was little chance that any would be interested in becoming administrator of CPEHS. Secondly, Mr. Cohen and Dr. Lee weren't looking for a wave-maker. They wanted a solid man who wouldn't rock the boat.

They looked inward and found Charles C. Johnson Jr., a sanitary engineer with 20 years of engineering and administrative responsibilities in the U. S. Public Health Service, but for the preceding year New York City's assistant commissioner for health and environmental health. A personable man, and apparently a capable administrator, Mr. Johnson has let it be known that he wants to stay on in his job and demonstrate his ability to provide stronger and more cohesive all-around protection for American consumers.

on this one, though, with respect to the following. First of all, I never proposed to Secretary Gardner the assemblage of all the government health activities into one agency. What I did present in formal presentation to Secretary Gardner in the presence of Wilbur Cohen, Phil Lee and Jim Kelly, however, was a proposal that went back to 1962 when the Public Health Service was being reorganized. I proposed at that time to the then Director, Bureau of State Services, Dave Price, that the Public Health Service be reorganized into twelve institutes of health and that the bureaus be eliminated. It was very clear in 1962 that Jim Shannon was stronger than the Surgeon General, that the NIH had captured the imagination of Congress and the public. My reasoning, therefore, was to build on that strength, eliminate the Bureau of Medical Services and the Bureau of State Services, and have twelve institutes with each institute director having under him a man responsible for research programs and the implementation of community action programs. Now, on this, I had one ally, Dr. Bob Felix, who was then director of the National Institute of Mental Health, who always maintained control as director of one of the institutes over his extramural community action programs. There was never a division in mental health, of the kind we had in cancer, heart disease, et cetera. I thought that Bob was right on this point. However, I could not get support within the Public Health Service. They were unwilling at that

time. Dr. James Hundley was Chairman of the Surgeon General's Committee on Reorganization. That committee would not take a stand on a bold, imaginative reorganization proposal, because it would have meant a showdown with Jim Shannon. Either he would have moved up and become Surgeon General, which I felt would have been good, or he would have been Deputy Surgeon General. But the Institute Directors would have reported directly to the Surgeon General, each one accountable and responsible for both his research and his action program. I felt this was still a valid reorganization plan in 1967, when Secretary Gardner, in the winter of '66, spring of '67 and all of this period of time, when we were talking about reorganization up until the time that he left in 1968. And so I presented that late...it was in December or January...December of '67 or January '68...to the Secretary and the people I've mentioned. I also presented it to John Corson and one or two others. At no time did I present it to Dr. Hornig. I want to make that perfectly clear. If he heard about it, he heard about it from sources other than myself. My plan was not acceptable to Secretary Gardner, Mr. Cohen, Phil Lee or Jim Kelly. Mr. Cohen did not want a strong Surgeon General, in my opinion. I think the record will show that he wanted a weak Surgeon General, that he influenced Secretary Gardner to select Dr. Bill Stewart who was a very weak Surgeon General, in order that he, Wilbur, could dominate the

health activities of the department. And so, to that extent, Steve Rippey is entirely wrong. I never visualized all of the federal...First of all, Wilbur was the one who visualized all of the health activities being brought together under HEW. He got a very grandiose idea, and he proposed something and, for a while it looked like he had Mr. Johnson sold on it, and the Veterans Administration and the military agencies, the health people of the military agencies, really rose up in unison and smote him down, deserted him. Now, I was never naive enough...I was naive about some things...I never believed that you could bring together those things. I made the point in discussions with people from time to time that ideally we should have a single Department of Health, yes, idealistically. That would be fine. It would make great, good sense...use a single hospital system. You would always have then enough physicians at the ready state by taking care of veterans, merchant seamen, military dependents on civilian bases, etc., to handle the needs in case of war, you see. You could do it. But, I also recognized that one could not do this, that the Veterans Administration power block with Congress was so strong that you couldn't possibly do it. So in that, Steve was wrong. I aimed my presentation exclusively at the idea of twelve or fourteen institutes of health. Now, in fact, when I was trying to become Surgeon General, I discussed this same proposal with John

Fogarty which was before John's death. John asked me very pointedly what would become of Jim Shannon if I were named Surgeon General and put this plan into effect. I said Jim would have to take a position until his retirement two years hence as Deputy Surgeon General in charge of plans, and Jim is great on plans and development of new activities. He's just great on that activity. Fogarty then said that he would not support me in my quest for the Surgeon General's post, because he had been friends with Jim Shannon for many years, and he would not stand by and allow Jim to be downgraded. That was the word he used. In fact, it wasn't, because the deputy surgeon general for plans, if this had been implemented, was a higher level job than director of NIH. But Fogarty nevertheless did feel that it would be a downgrade. So that didn't occur. I mention this only to show there was a consistency. I first presented the plan in 1962, and presented it to Fogarty in the late fall of '65, when I was trying to become Surgeon General. And it wasn't anything new.

Dr. Y.:

Well, when you presented it again in late '66 or '67...

Dr. G.:

Well, it was late '67 to Secretary Gardner.

Dr. Y.:

Yes. If it had come into effect, did you have any ambition, within the structure, of your own?

Dr. G.:

I think one always has ambitions. I knew Phil Lee was in there as Assistant to the Secretary at that time, that he had strong political backing. I wasn't unaware of what his power source was, and if some of the...

Dr. Y.:

What was it?

Dr. G.:

California based. Some time in the future I thought that perhaps I could go beyond the commissionership of FDA, yes. No question about it. But I was still interested in the possibility of becoming Surgeon General, don't forget.

Dr. Y.:

Sure.

Dr. G.:

Even though I was Commissioner of Food and Drugs.

Dr. Y.:

Right.



Dr. G.:

This reorganization then would have in mind the idea in the future of still being Surgeon General. Now...

Dr. Y.:

And the Surgeon General's position under the plan have been made more...

Dr. G.:

Strong operating position, yes, not...it wasn't a weak Surgeon General's position. Now, Wilbur didn't want a strong Surgeon General.

Dr. Y.:

Right.

Dr. G.:

Let me go on and tell you the other side of this.

Dr. Y.:

Right.

Dr. G.:

Rippey's right about the difficulty finding an associate commissioner for science. I did find a good man. Dr. Daniel Banes is in that post now. He was within FDA, and I think a good scientist.

Dr. Y.:

Did you find Dr. Summerson, or had he come in before?

Dr. G.:

He had come before. He was brought in by Larrick. Now Dr. Charles Johnson, I think the record will have to show whether or not C. C. is going to do a good job as head of CPEHS, or whatever it is.

Dr. Y.:

Well, whose idea was it to create this present system?

Dr. G.:

Well, after Gardner turned me down, then I had to throw my shoulder behind an organization of CPEHS, which was, as I recall, largely Kelly and Lee's baby. I either had to support it or get out. Well, I did both. I supported it and then I got out, but it wasn't my idea even though at one time I was considered, even told, in fact, that I was going to head it up.

Dr. Y.:

What was the problem on that?

Dr. G.:

The problem really came up with respect to Willard Simmons, the head of National Association of Retail Drug Stores, who got to Vice-President Humphrey.

Dr. Y.:

And Simmons was upset because of what you had said about the drug stores?

Dr. G.:

Yes, I said that twenty years from now the corner drug stores ought to be closed down. Well, Simmons didn't have any issue to keep his position a lively one before his trade association. He seized on this as an issue and said that I had to be gotten rid of. Well, he went to the Vice-President. The Vice-President, although he recognized he couldn't get rid of me as Commissioner of FDA, he could see to it that I was blocked, and he told Wilbur he was not to appoint me to any other job.

Dr. Y.:

So you say, you had been told that you were to get the job?

Dr. G.:

Oh, yes. It was clear and...

Dr. Y.:

Who had told you that?

Dr. G.:

Phil Lee and Wilbur Cohen.

Dr. Y.:

And they told you why you couldn't, then, later?

Dr. G.:

Yes, and Phil kept saying, "Jim, we'll work it out. We're working with the White House." And I kept telling Phil, "Look, if it takes this long, forget it. There's a problem." And at one point in time, Mrs. Goddard was sick, she was in Walter Reed Hospital. They thought she had a brain tumor, which was in early February, of '68, and that was when this came up, and Wilbur was trying to reassure me. You know, he got me one day, and said, "I'm having some problems." I said, "If I'm one of them, that's easy, I'll quit today. I've got twenty-one years in." "Oh, no, no, no," he said, "we can take care of that. We'll handle that. We'll get the White House to agree." So I agreed. I don't know why I agreed to stay on until August, the first of September. I said, "I'll stay on until one September." Then a couple of months later, I said, "One August." Then I changed it to the thirtieth of June.

Dr. Y.:

Was there any reason for your pulling back the time?

Dr. G.:

Only that the "lame duck" is in an awfully poor position to be in in Washington. I had selected my successor, Dr. Herbert Ley. I had leaked the story to the press. He had been named as my successor, and therefore, quite reasonably, people started

going to see Dr. Ley, and if you'll look at my appointment calendar those last few weeks, you'll find that there is almost nothing on it. Well, that's reasonable. So there wasn't any point in my staying, and then I wanted to get started with this new firm.

Dr. Y.:

Sure, and you told me that day that you went to see Mr. Cohen that you also were reading the political calendar.

Dr. G.:

Oh, yes. I felt very clearly that Mr. Humphrey was going to lose, and the Republicans would be coming in, and there wasn't any point in my staying around.

Dr. Y.:

Would you pull together your relationships with Mr. Cohen? And give a judgment of him?

Dr. G.:

Wilbur Cohen is one of the greatest tactitians in Washington in getting a piece of legislation through. I don't see him as a good leader. As Secretary, he wasn't a good leader, in my book, nor, in fact, with my confreres with whom I discussed this, the heads of other agencies. The staff meetings were quite different under Wilbur than they were under the Secretary, in the sense

that one left without any feeling that they'd been exposed to a leader. When you met with John Gardner, you came away inspired. You really felt great about working for this man. With Wilbur, no. We didn't. Now Wilbur, as I mentioned was an extremely capable and shrewd politician. I give him credit. He engineered par excellence the social security legislation, medicare, et cetera.

Dr. Y.:

Was he more interested in that aspect of things than he was in health?

Dr. G.:

Well, I think Wilbur has a basic mistrust and dislike of physicians. Why, I don't know. I only observed his dealings with them, and his facial expressions, and I've watched him pretty carefully at times, and this is my conclusion, that he doesn't like physicians. Now, I can understand some of the reasons he doesn't.

Dr. Y.:

Because of the power structure, you mean, that he had to fight?

Dr. G.:

Yes. He had to fight, and his basic beliefs about society, and some of this I don't disagree with, but I found that Wilbur dealt

in political expediencies. The thing that really made me decide to get out fast was I found that Wilbur had committed the Food and Drug Administration to a position on an issue with a senator without consulting me ahead of time, and that was when I decided that if politics were going to have that much to say, I couldn't stay on.

Dr. Y.:

What kind of an issue was it?

Dr. G.:

It wasn't a major issue, but that isn't the point.

Dr. Y.:

Right.

Dr. G.:

The point was that John Gardner would never have done that.

Dr. Y.:

I understand that.

Dr. G.:

I ran the Food and Drug Administration.

Dr. Y.:

Exactly.

Dr. G.:

And then all of a sudden, Wilbur made a decision and then advised me he had made that. Now, that was his prerogative. I understand that, but it's poor leadership in that situation, as it was a technical issue. It happened to be a technical thing, and he wasn't competent to make that kind of judgment.

Dr. Y.:

Then it was made for not the right reasons.

Dr. G.:

It was made for political reasons only, and solely on the basis of political expediency. So, that was when I decided I had to get out. I could have swallowed my pride and stayed on as Commissioner of the Food and Drug and even worked for C. C. Johnson. Maybe not too long from what I learned afterwards from some of my friends who did stay on, but once I saw that happen, I really had to get out. So my problem basically was with Wilbur. But there's never one single issue. It was a culmination of circumstances. I had spent twenty-one years. I had done those things that I felt John Gardner asked me to do. He had left; the political party change was coming; I knew I would be a dead duck with the Republicans. I had an opportunity to join a company, the president of which was a friend of mine, and it looked interesting. My wife wasn't well. There were all of these factors



weighing on us at once, and the crowning blow or the straw that broke the camel's back was that little political thing that Wilbur pulled on me. So I said, "To hell with it. I am getting out." And that's when I told him I would leave, and then I just kept moving the date up. That's all there was. Mr. Johnson...I never had any problems, the President and I. Now, Humphrey quit speaking to me after the thing with Wilbur Simmons. That was pretty childish, but he's purely a politician and a drug store man himself.

Dr. Y.:

Had you had...

Dr. G.:

Although I must say I understand that he got his diploma in pharmacy from a diploma mill in Denver, Colorado.

Dr. Y.:

Had you had very close relationships since he was so interested in drugs prior to then?

Dr. G.:

No, not close, but we had spoken at these dinner functions and things the Vice-President always had to attend. He always made a point to speak to me and he was quite nice. Julie Cahn of his staff would call me on the issues but no, we weren't close.

Dr. Y.:

Did you have much association with Cahn?

Dr. G.:

Oh, no, telephone, seeing him at cocktail parties. Vic Cahn, by the way, was that writer's name for the Washington Post, who was in Minneapolis that day I had the problem.

Dr. Y.:

Well, it looks as if most of the points...

Dr. G.:

Well, I think maybe it's four-thirty and we ought to quit for the afternoon. What do you think? We can do the rest up the next time.

Dr. Y.:

Well, okay. That's good. Well, thank you very much.

# History

of the

## U. S. Food and Drug Administration

Interviewee: Dr. James L. Goddard

Interviewer: Dr. James Harvey Young

Date: April 30 to June 19, 1969

Place: Atlanta, Ga.

Session 6

Pages 412-493

Dr. Y.:

Well, this is the sixth conversation that we've had of an afternoon at the home of James L. Goddard. I am James Harvey Young and today is June 19, 1969. I've gone through a few records, mostly published records so far, to cover those eventful years and months, and I've got some more questions that I'd like to ask, some that have to do with the evaluation and appraisal of persons and groups, and some that have to do with decisions and projects. So how about my just running down my list?

Dr. G.:

Fire away.

Dr. Y.:

First of all, the Toilet Goods Association. In January of '66, you said that "the cosmetics industry was not without its problems." That was a quoted phrase, and in September of that year you warned the cosmetics manufacturers to clean house. Yet, despite the fact that TGA was engaged in earnest litigation with the Food and Drug Administration about color additive regulations, which FDA eventually lost in January '68, you began, at the initiative of the trade association, a series of conversations with their leaders that ran from July, 1966, virtually up until the time you retired. Now, in midstream you termed these discussions good, and you spoke in a very conciliatory vein to the 1967 TGA

convention. I've got some questions about this general situation. Who was there for the Food and Drug Administration and who was there for TGA, and would you evaluate the TGA people, the key people, as to their leadership?

Dr. G.:

Well, Food and Drug was always Billy Goodrich, Ken Kirk and myself. We were the principal ones involved. Occasionally Dr. Summerson because some of the issues got down to technical questions having to be discussed or at least how we would approach the solution of technical problems. TGA...I might have difficulty recalling the names, it's been some time now...

Dr. Y.:

Their general counsel was named...

Dr. G.:

Leiberman.

Dr. Y.:

Fuller Holloway?

Dr. G.:

Fuller Holloway, yes. Fuller would come most of the time, but in later months generally Fuller did not continue to be involved. Leiberman of Toni Company; the president of TGA in '67 who was...

Dr. Y.:

Breck?

Dr. G.:

Breck at that time. I can't recall the others.

Dr. Y.:

Did James Merritt ever get involved in this?

Dr. G.:

Oh, yes. Jim came in after...Jim came on board with TGA in '67, as I recall, and so Jim was characteristically or usually involved in these meetings. Now, one or two others came and went. The purpose of the meetings was to try to resolve some problems between TGA and Food and Drug, quite apart from the color additives suit that was in the courts at the time, that were of long standing duration. It was my hope and the hope of Leiberman, Breck, Merritt, Fuller Holloway, and the others, Billy Goodrich, Ken Kirk, that we might reach agreement on what could be called the GRAS list--generally recognized as safe. At least, the scientific people could do that, and if that were done we could perhaps come to some understanding of a method by which toilet goods manufacturers could market a new product, and if it were completely constituted of GRAS elements, they could be assured, reasonably assured, that they would have no problems with the Food and Drug Administration. They wanted to

avoid a pre-market clearance system like the new drug system. We recognized some of the problems inherent in a field that moved as quickly as toilet goods does, because fashion becomes involved, and we're sympathetic to their point of view. At the same time, we felt that we just couldn't let them bring anything into the marketplace. Some mechanism had to be established. And so our discussions throughout that time period were centered on what kinds of mechanisms would be acceptable. We finally got down to a list of nine points, and of those nine we were in agreement, as I recall, on seven of the nine, which, if you think of it, is not too bad between an association and a regulatory agency. Now, the last two we never could come to an agreement on, so I suggested that the TGA take the proposal to Congress and let the committee then be the arbiters, the substantive committee of Congress, that would be the Interstate and Foreign Commerce Committee, and decide which point of view on these two issues had merit. That, after all, would really constitute a substantial achievement. The TGA was somewhat fearful of doing that and never did go before Congress, and so when I left they were still wrestling with the agency over two issues.

Dr. Y.:

Do you remember what they were?

Dr. G.:

I can't remember now what they were. One, as I recall indeed came down to, let's see, what appeal mechanism would be provided. They weren't too happy with the Administrative Procedures Act. As I recall the other issue was again related to a matter of approval of sorts, that the agency had to act within a specified period and, if they did not, then the product could be marketed. That was what TGA wanted.

Dr. Y.:

I had some feeling that they had come up with the proposal that they would be willing to tell you all the ingredients, except possibly the fragrance, and that there was some sort of worry on the part of some of them about letting even the Food and Drug Administration know what fragrances were in, granted that there was a generally recognized as safe list of fragrances.

Dr. G.:

Yes. There was some concern on fragrances. That particular portion of the industry is perhaps the most difficult to compromise with. They feel very keenly the need for secretism and much of their work is based on secret formulas. So we didn't reach any agreement.

Dr. Y.:

Did they pretty much have a united front throughout the discussions?



Dr. G.:

Well, I would characterize them as...yes, they had not only a united front, but I thought a realistic approach to the problems, and they were not unmindful of the consumer protection aspect involved. So, I felt they were a responsible group. Mr. Breck was a fine gentleman to deal with, Mr. Lieberman also.

Dr. Y.:

Were they the ones who took the major roles?

Dr. G.:

They had the major role to play. And, of course, Jim Merritt. In terms of association secretaries, I think Jim Merritt is about as good as any that I've ever dealt with. So, for this reason, we were perhaps somewhat more tolerant and patient of the long time elapse between initiation of discussions and reaching agreement even on minor points. We worked in good faith with them and they with us. I felt that it was worthwhile to continue.

Dr. Y.:

Now, this was an approach that was different from some possible approaches to settling issues between industry and government. Did the Booz-Allen report that came in about this time bolster your own natural bent on this approach toward regulation?

Dr. G.:

No, I wouldn't say that it bolstered it. The Booz-Allen report really contained nothing that we did not suggest to them for inclusion.

Dr. Y.:

Well, I wondered about that. There was some sort of indication that you got the report. There must have been something you didn't like because quite a while went by and you made suggestions and then a new version came in and finally it was publicly announced. What was going on behind the scenes then?

Dr. G.:

Well, they were doing their homework. We didn't think they'd given us \$450,000 worth in their report; we didn't feel that it measured up to what we had a right to expect. Keep in mind now that we were consciously using this as a mechanism to gain acceptance from our field personnel. It wasn't that Booz-Allen had discovered any magic formula, but rather that we felt that we needed to bring most of the agency personnel on board with a different approach, and that the best possible way of doing it was to get them involved through using Booz, Allen and Hamilton to help them, the field people, formulate new approaches to regulatory matters. Now this particular report really had no relationship to the problems of the

cosmetic industry per se. It was more aimed at the field use of inspection time, the more optimum use of personnel than had been possible in the past.

Dr. Y.:

Now, I guess you've answered this question about how close to agreeing with them you were on the terms of what might be a possible new law.

Dr. G.:

Well, to comment further, we were very close and yet very far apart. Because the major point really was the point relating to how products got into the marketplace, whether or not there had to be any form of approval by FDA or not. On this point, Mr. Goodrich and I and Mr. Kirk were together. Mr. Goodrich felt very strongly, for example, that we must have some mechanism. That point prevailed in our meetings, and so therefore, we were quite far apart. But, yet, it was a substantial gain over what previously had existed between the industry and FDA, and I really felt strongly that the industry should go to the Congressional committee. That was the point of view that I advocated to trade associations consistently throughout my tenure, that they should take the initiative in seeking good legislation. They should help frame it. They shouldn't

wait and react in response to a presidential or executive department proposal for legislation, which meant that they quite often would be in opposition to whatever was proposed, but rather a responsible association would see the need for legislation and work to help it become a fact, and in so doing could help steer the development of the legislative package in such a way that it would represent legislation they could live with and still provide the protection that was needed.

Dr. Y.:

Right. And so to some extent these conversations, the hope was, would limn out the outline and to some extent maybe settle issues that then wouldn't even need to be put into the form of legislation at all.

Dr. G.:

Or if they were put into the form of legislation, we could feel certain there would not be points of controversy.

Dr. Y.:

In connection with another one of the trade associations, the Proprietary Association, there was the possibility of a law in connection with children's aspirin, and then conversations evidently reached a point at which that issue was at least sufficiently settled so that no legislation could come whether

or not it was still desirable. Is there any background on this particular episode that the documents might not reveal?

Dr. G.:

Howard Prentice of the Proprietary Association who has since retired worked very closely with us. Their medical director was a former FDA Bureau of Medicine deputy chief under Sadusk, Joe Pisano. He also was involved in these discussions, although Joe never had much to say, I must admit. He was the most silent physician I've ever seen. We held a series of meetings involving outstanding pediatricians, Harry Shirkey then of the University of Alabama, Allan Deane of the University of Utah, Jay Arena of Duke University, industry representatives, particularly from firms who marketed aspirin as a major product, St. Joseph's aspirin. These meetings were aimed at trying to pinpoint what was the exact nature of the childhood aspirin poisoning problem. As I recall, it became very clear that a major part of the childhood aspirin poisoning problem was related to the ingestion of adult size aspirin and not just flavored children's aspirin. The industry, however, recognized that there was enough accidental poisoning occurring that they should assist in the prevention efforts through better investigations on closures, safety closures, and so they did agree that they would sponsor more research and become more active. Now, as far as legislation, this was not a major

proposal for the agency. We were simply anxious to get at the problem and I think we accomplished our objectives.

Dr. Y.:

As I remember, you had a minimum number of children's aspirin you wanted in a container, and your own witnesses didn't seem to feel that small a minimum was necessary, so that it came out a bit of a compromise, a bit bigger than that.

Dr. G.:

Yes, based on the evidence that people like Doane, Shirkey, Coleman of Washington, D. C., Children's Hospital, et cetera, were able to make available, we recognized that a compromise was indicated. We compromised at the level they suggested.

Dr. Y.:

Now, how would you say the feel was between you and these Proprietary Association people? As you look on back to the '30s, let's say, it was really chilly between the commissioners and the high proprietary presidents who were members of the Proprietary Association board and even the former FDA man who was their executive man at the time, it was really arm's length. It took a long time for any kind of warmth to develop, and then there wasn't too much. Now, how would you say the climate was with them while you were there?

Dr. G.:

Well, my feeling was that any regulatory agency should deal at arm's length, generally, with those who are regulated. As far as their feeling towards us, you would have to interpret what was said, the attitudes displayed. Howard Prentice certainly was friendly enough. He dropped by occasionally to see me when I was commissioner and was interested in working on the poison prevention project, the medicine chest project, as a Proprietary Association activity. He always seemed interested at least in gaining suggestions with respect to what the Association could do to assist in this particular field. The leaders from the companies I had relatively little contact with, aside from one or two of the medical directors, whom I would see occasionally and not too often than.

Dr. Y.:

This was really a very side issue as to amount of time?

Dr. G.:

They posed relatively few problems for us. They gave Rand Dixon many problems. One of the most difficult problems was with respect to the advertising of aspirin products on television, and the television industry itself, their code people, came to my office one time and informed us that they were having difficulty with the aspirin manufacturers, specifically

with one company at that point in time, who proposed to advertise on television, "Don't wait for the headache to strike. Take the aspirin now." This, they thought, was quite ridiculous, and I certainly agreed. We did suggest privately to the various companies through the Association that they had better reduce their emphasis on using aspirin as a tranquilizer. That was as far as we could go.

Dr. Y.:

Did you get any reaction from these trade association people to your efforts with Dixon to try to tie together the advertising controls and the labeling controls, so that whenever you made decisions about what could be said on the labeling, advertising might rather quickly have to get into line?

Dr. G.:

No, I got no overt reaction from them. I would have to guess again, and I feel very confident that industry wasn't too happy with the idea of FTC and FDA working together.

Dr. Y.:

But you didn't get any...

Dr. G.:

No, I got no flack.



Dr. Y.:

Now a couple of members of Congress. Your first testimony before a committee after you became Commissioner, relatively soon after, was before Congressman Fogarty's committee. He gave you advice on that occasion, if I remember rightly, to set out to make FDA very visible to the public. You must have seen him several times before his death. What kind of an appraisal and evaluation would you make of him?

Dr. G.:

John Fogarty was the key person as far as public health in this country was concerned, throughout his tenure as chairman of the sub-committee for health appropriations in the House. I had known him first, testified before him, in 1957 when I was Chief of the Accident Prevention Program, and through the years subsequent to that, I had seen John in the course of business quite frequently. However, I didn't begin to know him socially until after becoming commissioner. I had at one time sought his assistance when I was trying to become Surgeon General, as you'll recall, and he refused to give me that assistance because I would not promise to leave Jim Shannon alone. After becoming commissioner, I began to see Mr. Fogarty more, socially at cocktail parties, overseas meetings, particularly at WHO in Geneva, meetings in Puerto Rico. I became more aware of the fact that he had a serious drinking problem.

He had, by that time, of course, had a rather serious heart attack. He had a myocardial infarction. He had recovered very well but hadn't followed his physician's advice with respect to losing weight or cutting back on his drinking or modifying his style of life. John would stay up until all hours of the night and ask that you stay with him. He could drink a prodigious amount of whisky, starting early in the morning and just going all day and all evening and all night. For example, we were at the World Health Assembly meeting in Geneva, and at the end of the first day's session I went back to the hotel. We happened to be staying at the same hotel. I believe all of the American officials were there. I ran into Mr. Fogarty in the bar along with Dr. Murdoch Head and we started drinking at that point in time. We continued until suppertime, went out to eat as a group, four of us, then went to a night club after supper, and went back to the hotel at 2 o'clock. He insisted that we come to his suite for a nightcap. I checked out about 3 o'clock in the morning, and he and the others went on until 5. And yet at 8 o'clock the next morning, he was at the meeting in Ambassador Tubby's office, bright, shaven, looked fine, ready to go. Now at 10 o'clock that morning, he ducked out of the general session, and at the coffee break I ran into him and Dr. Head and one or two others, and they were sitting around having a drink. And that

would continue all day long, and that evening he asked me to join him again. I refused because I just couldn't keep pace with John. So he had that problem. Nonetheless, he was a very effective man in the health field. He was interested in what FDA was trying to do. He privately suggested that I could build FDA to a size equal to that of NIH. This horrified me, and I told John that I saw nothing in the future that would lead me to believe that that would be feasible. He was somewhat disgusted with this and made plain to me that he thought I wasn't taking advantage of the opportunity.

Dr. Y.:

What kinds of expansion did he have in mind?

Dr. G.:

Through research grants, programs in pharmacology at the medical schools, through the construction of additional facilities through hiring more people. Just a repetition of the NIH pattern.

Dr. Y.:

But not necessarily enlarging your sphere of action?

Dr. G.:

No. I didn't feel that it would be a worthwhile use of the tax dollar. So I refused to engage in that, and John would chide me privately from time to time up until his death for my failure

to really come to his committee with substantial requests.

Dr. Y.:

He was a layman.

Dr. G.:

He had been a brick layer, by the way, was always very proud of it.

Dr. Y.:

Do you think this suggestion that he made to you about expansion was indicative of the kind of understanding he had of medical problems? Was he thinking of it...

Dr. G.:

I don't think John had a good understanding of what FDA was, what it was supposed to do. He simply saw it as an opportunity for his committee and for himself to assist in another area.

Dr. Y.:

Because he got a sense of fulfillment from seeing things grow that he had responsibility for.

Dr. G.:

Of course.

Dr. Y.:

So it was a quantitative rather than a qualitative judgment?

Is that what you're saying?

Dr. G.:

I'm saying that it was just a poor judgment on John's part. This wasn't what was really needed.

Dr. Y.:

But his scale of values had the quantitative angle, you're thinking?

Dr. G.:

Yes. But John died, as you know, in fact the very morning that he and others were to be sworn in for the 90th Congress. He dropped dead in his office shortly before 10 o'clock that morning. We lost a really fine leader in the health field as far as Congress is concerned.

Dr. Y.:

Regardless of his sensitivity toward the detailed problems, he would work hard?

Dr. G.:

If it hadn't been for John Fogarty and Lister Hill, much of what has been accomplished in the health field in the past two decades I don't believe would have been accomplished. John was instrumental in the House. You had to have that kind of leadership. He had enough seniority that he could effectively

go around what the party leadership wanted...get around it by taking a bill to the floor and getting additional funds directly from his confreres, which he was known to do.

Dr. Y.:

You mentioned earlier the group or power structure of a certain sort that was centered around Mary Lasker. I take it that she was one of the outside bases of support for Fogarty.

Dr. G.:

Yes, she supported his political campaigns. She worked closely, her man in Washington worked closely with Mr. Fogarty and his staff on getting legislation drafted, on having it introduced, helping secure support for it, making certain that the budgetary requests were large enough. Mary then was able to work directly with the White House, with President Kennedy and later with President Johnson, to get programs initiated. She used people such as Mike DeBakey of Texas with President Johnson very effectively. Mary Lasker was a king maker in those days. I believe that no longer exists, but during the years from 1954, '53, along in there, '55, beginning there, until this past year, Mary Lasker was indeed a king maker.

Dr. Y.:

So that this wasn't a myth?

Dr. G.:

No. No. Indeed it was no myth. It was an actuality. In fact, when I was trying to become Surgeon General of the Public Health Service, a friend of mine, Herman Hilleboe, asked me if I wanted Mary Lasker's support. Herman knew that this would be important. He was a Public Health Service officer who had been on loan to New York State for many years prior to his retirement. I knew of the problems that her support brought with it.

Dr. Y.:

Now what do you mean by that?

Dr. G.:

Well, the Surgeon Generals that she assisted really couldn't call the shots, and I told Herman that I didn't want to be another one of Mary's little lambs, and that remark got back to her eventually. Because of that Mrs. Lasker never was very prone to support anything that I was involved with.

Dr. Y.:

Well, what kind of a person was she?

Dr. G.:

Very friendly. I think Mary would like to buy immortality through support of research. She's very afraid of death.

She's an intelligent person. She had used a relatively small amount of money to wield a great deal of influence. The Lasker fortune is not very large by contrast with, say, the Rockefeller or other family moneys that are engaged in support of the health field. But she has used her influence politically to multiply the Lasker investment in health.

Dr. Y.:

Do you remember any incident where you were involved with her that serves to reveal her personality or her mode of action?

Dr. G.:

No, I had very limited personal contact with her. I had lunch with her at one time in New York City. I attended a luncheon on another occasion, the Lasker Awards luncheon, to be a guest and sit at the head table. But apart from these and occasional cocktail parties in Washington, something like Senator Lister Hill's retirement party, where I would encounter Mary Lasker, but apart from those I had relatively no...

Dr. Y.:

No business dealings?

Dr. G.:

No dealings with her because I wasn't in her camp.



Dr. Y.:

Right. Surely. Did she support Lister Hill?

Dr. G.:

Indeed she did.

Dr. Y.:

How did he compare with Fogarty as a man acting in this field?

Dr. G.:

Senator Hill operated quite differently than John Fogarty. You would have to characterize Senator Hill as a Southern senator of the old school, full of charm, grace, and courtesy, with a great deal of effectiveness in getting legislation through the Senate because of his long tenure, his seniority as chairman of the committee, the fact that his fellow senators respected him for his work in the health field, and looked up to him for it. He was a most affable person to deal with, a very courteous individual, a fine person.

Dr. Y.:

Toward the close of your commissionership, Senator Nelson of Wisconsin began to get deeply involved in making investigations in the general area of drugs, and you testified and must have become acquainted with him. How would you characterize him and his motivations and mode of operation?

Dr. G.:

Gaylord was well-motivated in this field. He really wants to do a job, but at times he doesn't do his homework properly, nor does Ben Gordon on his staff, and that's unfortunate because it is such an important area. Generally, though, if you are given time to work with him, he can do a very effective job. I found by going up to his office and sitting down with him in advance of a hearing, I could get him to understand the issues involved in a way that would permit us to have a much more effective hearing than we otherwise might have.

Dr. Y.:

Otherwise, he might go off on some kind of a tangent?

Dr. G.:

He really wouldn't understand the issues, if you didn't do this. Some of them were right difficult, of course.

Dr. Y.:

Do you anticipate that he has the sort of staff work and sort of drive himself that might lead to legislation? There's something similar to what he's interested in and what Estes Kefauver was interested in. Do you see him in the same mode as...

Dr. G.:

No, I don't see him in the same mode as Estes Kefauver, because Kefauver really had a very effective staff, Rand Dixon, wasn't Sonofsky on it?

Dr. Y.:

I've forgotten. I'm just not sure. There was an economist named Blair, I know.

Dr. G.:

But he had a very effective staff. Now, I don't think that Nelson has a staff that is that strong. Furthermore, he's got some competition. Senator Phil Hart is nibbling away at some of these areas; Magnuson would like to but hasn't gotten into this area very much.

Dr. Y.:

Senator Long, to some degree.

Dr. G.:

Russell Long on drugs. Yes. He doesn't have the clear field that Estes Kefauver had.

Dr. Y.:

That makes a good deal of difference.

Dr. G.:

Nelson felt very strongly that the PMA had used money to

influence the outcome of the campaign in his district, in his state, on the last election. He said he couldn't prove it, but there was evidence that they had spent substantial sums. There were signs, I should say, that they had spent substantial sums in trying to prevent his reelection.

Dr. Y.:

That would probably tend to keep him interested in the subject.

Dr. G.:

It was the wrong thing for PMA to do, again, but that doesn't surprise me.

Dr. Y.:

Okay. How about the American Pharmaceutical Association and Dr. William Apple.

Dr. G.:

Well, Bill is a very hard working executive, an easy man to work with, very perceptive. He understood the issues. I had no problems with Bill right from the very beginning.

Dr. Y.:

Now, generally speaking, their policy was a good deal more in accord with what you had in mind, I take it, than would be true of NARD.

Dr. G.:

Yes, it happened to fit much more closely than PMA or any other group.

Dr. Y.:

Right.

Dr. G.:

Or NARD. William Simmons of NARD was a far different person than Bill Apple. Bill, I would classify, as a professional. Simmons simply was a politician. Now, Simmons did get after me on that closing the corner drug store issue, of course, and stirred his membership up because he had no other issue to fight at that time or to justify his existence, so he carried that as a major issue and it really was a minor one, as far as, I think, any objective appraisal of it is concerned.

Dr. Y.:

But it did have certain political moxey.

Dr. G.:

Oh, yes. He had good ability in terms of getting to Vice-President Humphrey, and he did on that particular issue.

Dr. Y.:

You mentioned Dr. Harry Shirkey in connection with the aspirin hearing. He also was an official advisor to the NAS-NRC

efficacy review project.

Dr. G.:

Well, he was also used a great deal by FDA for other things, too. He sat in on a number of Bureau of Medicine committee meetings of various kinds. Harry was both a pharmacist and an M.D., with a lively interest in pharmacology and therapeutics, with particular emphasis on the need for special studies for establishing proper childhood drug dosage, something he felt the pharmaceutical industry was most remiss in not doing and that they oftentimes simply would scale down adult dosage without showing any understanding of pediatric physiology.

Dr. Y.:

Or else they would say it shouldn't be used for children...

Dr. G.:

Yes, denying children an appropriate drug that might have been helpful. They weren't willing to spend the money on research with little probability of any financial gain, again, illustrating that they are not members of the health team and that they didn't understand the health professions.

Dr. Y.:

A person that perhaps had a considerably different stamp was Mrs. Margaret Kreig who wrote the book called Black Market Medicine.

Dr. G.:

She was sick. She was a problem for us.

Dr. Y.:

I understand. In what way?

Dr. G.:

She was emotionally ill. She was a mental case by the time I saw her.

Dr. Y.:

She had been given permission, evidently under the previous regime, to go along with inspectors when they went on raids.

Dr. G.:

Yes, in the New York District, and I think it caused enough trouble that the agency hopefully learned that you don't give somebody carte blanche of that type. She was not an accurate reporter of the scene, to begin with. She tended to see plots where none existed, in my opinion. All told, before she was done, she was a great deal of trouble for the agency.

Dr. Y.:

She had testified before Representative Foscell's Government Operations Sub-committee that you really didn't know what was going on in the area of black market drugs.

Dr. G.:

Well, did she mean me personally or the agency?

Dr. Y.:

I'm not really sure. You, at any rate, personally replied by testifying before the committee.

Dr. G.:

Yes, and we, I think, demonstrated that we did know what was going on.

Dr. Y.:

Wilbur Cohen, once again. You told me that he went over your head to make a decision that was really yours to make at the request of some senator and that this episode influenced you, at least in the timing of your retirement.

Dr. G.:

He didn't go over my head. He simply made the decision and informed me after the fact.

Dr. Y.:

Right. Now I should have asked you if you'd be willing to tell me what was the issue and who was the senator.

Dr. G.:

I'd be happy to but I really can't even recall now. It wasn't



of great significance in terms of its own merits, but it was simply the fact that he made it and told me, and I remember talking to Mr. Goodrich and telling him about it, and he was sympathetic. He wasn't unmindful that such an event could take place.

Dr. Y.:

Right, so that you remember your feel and reactions to something that wasn't that important to remember the facts.

Dr. G.:

That's correct, at least it wasn't to me at the time.

Dr. Y.:

Now, one further thing...in the trade press there was the suggestion that Secretary Cohen may have let you down somewhat by not backing you up sufficiently at the time that Simmons of NARD did let loose his blast at you for your comment about the drug stores. Is there any truth to that?

Dr. G.:

I think there is. Keep in mind that Mr. Humphrey was running. Mr. Cohen was anxious to help Mr. Humphrey. In fact, Mr. Cohen made political speeches even though the President had asked that none of the cabinet members do so. Mr. Cohen made it quite clear that he was actively and strongly supporting Mr.

Humphrey. Therefore, it is not unreasonable to assume that if Mr. Humphrey had been influenced by Mr. Simmons that Mr. Cohen wouldn't strongly plead a case before him on my behalf. Quite to the contrary. Mr. Cohen, being a politician above all, would be happy to see me leave. That was my feeling.

Dr. Y.:

He didn't say anything to you about this speech, scold you or anything?

Dr. G.:

Oh, no. Well, wait a minute. Yes, I'll take that back. He did call me in and said he was very unhappy about it. I take that back. I'd forgotten. He called me in and said he was most unhappy, and he used a phrase. He said, "That was a shitty thing." I told him what was involved, I was talking about something twenty years off.

Dr. Y.:

It was more or less a symbolic thing in any case, wasn't it?

Dr. G.:

That's right. But he had asked me during this transition period earlier not to get into any flaps, you see.

Dr. Y.:

Oh, he had.

Dr. G.:

Yes. And he felt I had let him down, so, of course, he was justified in chewing me out. Now, I didn't feel that this was all that important, but it proved to be because of Mr. Simmons' involvement with Mr. Humphrey, and thus it had an influence on Wilbur.

Dr. Y.:

What do you mean by this transition period...the one between Secretary Gardner's going and presumably a new president being elected?

Dr. G.:

That is correct.

Dr. Y.:

And he said that because of the trouble in connection with the marijuana business or even before?

Dr. G.:

No, don't forget the marijuana business took place earlier while Secretary Gardner was still there.

Dr. Y.:

Right.

Dr. G.:

I'm now talking about the period of time after Secretary Gardner had departed and in advance of the nomination of Humphrey.

Dr. Y.:

I see. Right. While that contest was going on and presumably things like that might have hurt Humphrey at the convention. I take it that's what he had in mind.

Dr. G.:

Well, I don't know what he had in mind. I only know he was unhappy.

Dr. T.:

Did you ever talk to Secretary Gardner about why he made his resignation in such a quick and precipitous fashion?

Dr. G.:

No, I didn't and I didn't think it was my place to. The staff... the principal staff was very unhappy to see John Gardner leave. We were dejected by his departure, as we all respected him so much. But I don't believe any of us would have felt it would have been proper for us to have asked the Secretary. He was a man of deep feeling, high motivation, and we assumed whether properly or not that it was related to an argument that supposedly took place between him and President Johnson down on

the ranch when Secretary Gardner was trying to get President Johnson to restore moneys that the Director of the Bureau of Budget had taken out of HEW's budget, and Secretary Gardner was pushing for restoration of the Great Society programs which had been effectively handicapped by the budget cuts. Apparently, the story we heard was that he and the President got into quite an argument and that that was when he decided to leave. Now, perhaps Mr. Gardner will validate that at a later date.

Dr. Y.:

Right. Now, as to the President, you saw him at least twice officially.

Dr. G.:

I saw him more than that...at signing bills...at cocktail parties that would be given or dinners at the White House. I went on one occasion to a dinner, these kinds of affairs. If you are talking about going to his office to see him, yes, I saw him twice in his office.

Dr. Y.:

Now, I think that I ought to ask you what were your reactions, what impressions did you get about how he looked at the Food and Drug Administration and its problems, how seriously he had it in mind?

Dr. G.:

I don't think that Mr. Johnson had the food and drug problems seriously in mind or firmly in mind. He was aware there were some problems. He was very much interested in the possibility of collusion and price-fixing in the drug industry. He brought that up of his own initiative in one meeting, and I pointed out that that wasn't any area for Food and Drug, and we weren't competent, and I therefore knew nothing about it. He snorted and said, "Well, I do and I have the Justice Department looking into it right now." My impression was that this was a very hard working individual who every conscious moment of the day was trying to be a good president. As I said, I saw him on a number of occasions under different circumstances and at different times of the day. He was preoccupied every moment of the day with accomplishing some objective that he had in mind at that moment. He wasn't one for idle chatter. I think the most painful thing for him was to stand in a receiving line and shake those hundreds and hundreds of hands. How he ever did it, I don't know, or how any president does it, I don't know. At other occasions, a cocktail party, for example, he would move from person to person, and you could see he would do so with great purposiveness in mind. He had something he wanted to accomplish, and he would buttonhole a senator or representative and talk to him about some issue

that was bothering him at that point in time. I was very impressed by this aspect of Mr. Johnson's personality. You know, he gave up smoking, he gave up drinking, he lost weight, he did everything that one can think of to make sure that he was fit, physically fit, to do the job. Beyond that, just as a personal observation, I would say he tried hard to be a good president of this country. He was badly maligned. Now, he made one serious mistake that Ted Cron and I discussed at the time that was right interesting to both of us. In the 89th Congress, the President, President Johnson, was able to get what will probably be judged to be a record amount of social legislation passed. He pushed the Congress hard. They were tired. He kept them on through the summer. At that point in time, Ted Cron and I talked about it, and he said, "You know, he would be smart if he would call the Congress together at this point, ask them to allow him to speak to them, compliment them for what they had done, remind them there was more to be done in January and send them home." Instead, he kept them until the last moment, pushed, cajoled, bullied, used every tactic in the book to get more legislation passed, and they did pass it, but when they came back in January, that was it. Congress was a different Congress. He no longer could get what he wanted from them. That was a critical decision that he must have made and I often wondered if he's regretted it

since then.

Dr. Y.:

That's an interesting observation.

Dr. G.:

To be specific on Food and Drug. He kept in touch through Joe Califano, Marvin Watson, Doug Cater. He didn't have a strong personal interest in it.

Dr. Y.:

Were you in more or less frequent touch with these White House staff men or did that come through the Department?

Dr. G.:

That came more through the Department, but occasionally, I would say no more than once every six weeks, I would get a call from Doug Cater or Califano or Marvin Watson on some specific question or a request to see a person. This would be about the extent of it.

Dr. Y.:

They didn't make themselves particular specialists in this area, they were just...

Dr. G.:

No. If anybody had the assignment to handle that, it was



Doug Cater, and Doug was a very sensitive, fine writer, an interesting person to work with.

Dr. Y.:

Well, now, I've got some questions listed here as I came to them that are related to decisions and projects within the agency. First, as to the big policy decisions that were made, how were these made? With whom did you talk? What kind of records did you keep of them? Were there minutes of staff conferences?

Dr. G.:

Big policy decisions were seldom made in staff meetings. An issue might come up in a staff meeting that would ultimately lead to a policy decision, but in general, the individual bureau chief would be asked to work up a background paper and be prepared to discuss it, on a potential policy issue. After that was done, and I had digested the paper and listened to his discussion, questioned him, along with, generally, Mr. Rankin, and if it were in an appropriate area, Mr. Kirk and/or Mr. Goodrich. Quite often, Ted Cron, whom I had great trust in, would sit in on these kinds of presentations. In addition, I would ask the opinion occasionally of somebody in the field, occasionally of somebody in HEW, Dr. Lee, to sound him out, occasionally, not often. But more often, I would discuss the

issue with Ted Cron, Winton Rankin, Ken Kirk; if there were any Congressional implications, I'd talk it over with Congressional liaison, Maurice Kinslow at first, get their feeling for it, try to get as many inputs as I could, then I would simply make the decision. Now, there were no records kept of that decision-making process, of those individual discussions.

Dr. Y.:

What about those position papers?

Dr. G.:

Those would be in the files.

Dr. Y.:

Probably according to the theme.

Dr. G.:

Subject matter involved, and probably in the bureau files and/or in, as well, the commissioner's office files. I took no papers of that kind from the office when I left. I didn't feel that that was appropriate. I took only those personal files that were personal correspondence of mine. It was limited to that.

Dr. Y.:

Right. So that somewhere some of that material would be there but not necessarily reflecting what it was...

Dr. G.:

No. Unfortunately I'm not much of a person for creating a written record of my actions. I felt it was more important to get the job done than to have the written verification, and we were moving at a very rapid pace...

Dr. Y.:

I understand.

Dr. G.:

...for those two and a half years, and I felt that someone was putting something in the paper but it wasn't going to be me.

Dr. Y.:

Right. Well, I understand that. I'm a guy who, to some extent, has to come along afterwards and try through the paper to find out what was going on.

Dr. G.:

It makes it hard. On major policy issues, if the timing was right, we also talked it over with the advisory council, but many times there wasn't an opportunity to, but we did get a fair number to them.

Dr. Y.:

Right. Well, in due time, things will probably show up for

me that will be blank and then I'll have more concrete, sharply aimed questions than I can at this moment. One thing that interested me in the reporting was what might be called the problem of the consistency of your posture. The trade press was rather fond of contrasting what they believed to be your two alternating faces toward industry. Sometimes, especially early in your tenure, you were mean and tough. You took the low road, as they were fond of saying. And at other times, especially later, you were, in their language, more statesmanlike, more diplomatic. You took the high road. There was even speculation that you were being pushed into a more docile role by your superiors so that you'd fit better into LBJ's consensus pattern of rule.

Dr. G.:

That wasn't the case at all. It's interesting to read what's in the press when you know what the case, what the background, really is. It's often amusing. The New York Times, which I have revered for 10 these many years, was as prone as the rest to make those kinds of errors and that was somewhat dismaying to find out that they had feet of clay as well. But what happened more than anything...there certainly was no interference from on high, let me make that clear to begin with. But, as you move along in a job, you don't have to keep beating people over the head. They know that you have that capability and

that you're not unwilling to use that method if necessary, and so they become more susceptible to the conciliatory methods than they would otherwise have been, and you can thus afford to adopt a different approach and accomplish the same objective. There's no point in creating friction where none is needed.

Dr. Y.:

You did deliberately, as I think you said, stir things up when you came.

Dr. G.:

Absolutely. It was essential. We had no credibility as an agency at that point in time. Who believed FDA? They were patsies for industry. There had been a long series of good examples of how FDA had failed. The Congressional committees were beating them over the head and bloodying them badly. I felt it was necessary to instigate a series of changes, to create a change in the agency's image, public image, to myself provide the image of a strong, forceful leader in order that the employees would have someone they could identify with, and so I set about very deliberately to do this.

Dr. Y.:

And then when you changed, with respect to different segments

of industry, this wasn't a blueprinted thing, this was a pragmatic feel as to whether or not the new approach was now proper and fitting.

Dr. G.:

Exactly. That's right.

Dr. Y.:

And indeed sometimes you'd revert a little.

Dr. G.:

At the slightest sign of backsliding on their part, I was perfectly willing to revert to the original approach and whack them again.

Dr. Y.:

Right. Well, that is rather the way I felt about it, and I wanted you to comment on what was, in some of the trade press, especially in drug trade press, a kind of picture that emerges as you read through. Now we've talked about some of the problems of internal reorganization. There doubtless were many that I'm unaware of, but I ran across a few that surfaced into print that I would like just to see whether you have anything to say that might not be in the records or might be hard to dig out. In the Bureau of Medicine reorganization, it was reported that John Nestor was upset. Now, what about him?

He had been...

Dr. G.:

John was a very controversial figure. It was felt by many that he was the source of leaks to the Fountain committee. I don't know. He may well have been. John was a pediatric surgeon, as I recall, of very strong opinions. I occasionally had breakfast with John Nestor, particularly after we moved to Crystal Plaza. He had no significant influence on the operation of the Bureau of Medicine during my tenure. He was a thorn in the flesh of some of the bureau staff during that period of time, but he really wasn't a major problem for us.

Dr. Y.:

Now, in a way, one might have guessed that the kind of vigor that you would bring would have been something that would have pleased him. His role earlier had been to give testimony to Congressional Committees that was critical of the agency, but critical because it wasn't vigorous enough. I can't remember... I think it was the Humphrey committee, particularly.

Dr. G.:

Yes.

Dr. Y.:

And so...

Dr. G.:

That criticism no longer could be valid, you see.

Dr. Y.:

But yet he was reported to be upset. There wasn't any deliberate action...

Dr. G.:

I think John will be upset until the day he dies. He's almost Don Quixotic in his nature, and John will find something to be upset about all of the days of his life. That's my appraisal of him as an individual. He's almost like The Last Angry Man, if you recall that book.

Dr. Y.:

I see. So it was a temperamental thing as well as a principle thing.

Dr. G.:

A very strong set of personality factors at work in this individual.

Dr. Y.:

Also, there was some stir during the Bureau of Medicine re-organization, and members of the staff were allegedly upset, when Julian Hauser was moved from the Bureau of Medicine into...



Dr. G.:

Ken Kirk's office.

Dr. Y.:

Ken Kirk's compliance office.

Dr. G.:

That was absolutely essential. Keep in mind that we were trying to reorder the administrative activities of that bureau. Julian had been the crown prince of the bureau, so to speak, under Joe Sadusk. Now unfortunately, we had some practices develop that were poor administrative practices. These were apparent. We didn't know how many NDAs were pending. We didn't know their status, who had them. We had no sign-out system that would work. There just wasn't any administrative order and so we had to change that. To facilitate that, I asked Julian to transfer to Kirk's office. I felt that Julian could do a good deal in a positive way for the agency working in Kirk's office. At the same time, he wouldn't handicap the new team of Ley and Vaughn Choate. Certainly, if he were to stay in the Bureau of Medicine, there could be a power struggle develop. Now, that was the last thing we needed. So I had to move Julian, had to do it in such a way that he had a meaningful job, and fortunately Ken had enough things for him to do that were meaningful, and Julian

did a good job to his credit in that set-up.

Dr. Y.:

This was blamed on Rankin. It was one of the efforts to show that there were people within the agency who didn't like the way he operated. But, as you said, you did this.

Dr. G.:

Yes. Winton and I did it together. There are always people willing to cast blame, find reasons, other than the actual reasons that the Administration may have had at that point in time.

Dr. Y.:

Right. That was why I asked it...to find out whether there was fire behind this thing or not.

Dr. G.:

No. We knew that Julian could cause trouble. Winton and I talked about it and we agreed. He had to be moved. But we weren't trying to get rid of him.

Dr. Y.:

And he certainly did rather a major job after he did get moved.

Dr. G.:

Yes he did.

Dr. Y.:

Also, in connection with the sudden shake-up in the antibiotics and insulin division in October, 1967, in which the leadership, especially William Jester, the head of it, was ousted, there was some secrecy about this, at least before the public, and this was attributed either to the fact that the situation was so terrible that the men had to be fired to protect the whole agency and your reputation, or the fact that the situation was not especially bad but it was sort of bumbled and again Rankin was blamed. Of course, either interpretation damned you.

Dr. G.:

Rankin was wrongly blamed. Rankin, on these kinds of occasions, would be the man who would actually carry out the orders, but he didn't initiate them. The Jester thing, the whole business of the antibiotics certification activities and the problems related thereto, I was intimately involved with that. I was horrified to find what a mess we had in that activity and hard put to understand, except that if one thinks back he finds that it goes back really to the days when that particular division was riding fairly high, and sort of had a free rein within the agency, and there was never any strong administrative review or control placed over that group, and it became apparent that there were shortcomings that could hurt the

agency badly.

Dr. Y.:

Do you mean just administrative snafus or inadequate...

Dr. G.:

Administrative snafus. There was some suggestion of illegal activities. We, in fact, had a prisoner interviewed in a federal prison to try to pin down any tie between...it wasn't Jester...it was one of his staff. And there was a suggestion that some money had changed hands for the approval of certain batches of antibiotics, chloramphenical, in fact, as I recall. We never could get corroborative evidence, but we knew that this was a powder keg, and it was clear that Jester wasn't running the organization the way he should. Now, Jester was sort of a hopeless pawn in this, or helpless, I should say. He was sort of hopeless, too. (That was just a psychological lapse.) He hadn't been running the organization. He hadn't been doing his job, and yet he had been a loyal, faithful employee. We didn't want to force this to a hearing. We wanted to protect Jester and, at the same time, clean up the mess, and that was why it was basically handled that way. But it wasn't Rankin's fault, again. Heavens, I sweat that one through along with Winton and Ted Cron.

Dr. Y.:

So that there was a potentially terrible situation in this case...

Dr. G.:

Yes.

Dr. Y.:

...that would have been embarrassing to some degree.

Dr. G.:

There were actions and things that had taken place before my ever coming on the scene, but nonetheless, it would have just helped feed ammunition to those who were opposed to the agency, and I felt we had to handle it properly and yet do so to protect some of the ones who were innocently involved and get at the person that we really could never prove of being guilty.

Dr. Y.:

There was never any...

Dr. G.:

There was no evidence of misfeasance or malfeasance ever uncovered in our investigations, and we did have a very comprehensive investigation carried out in this.

Dr. Y.:

This was the same division that had come under a cloud before, and so I suppose that made it even more urgent that you check things out.

Dr. G.:

Yes, it did. Art Davis, our security man, worked for a considerable period of time on that investigation. It was he who interviewed the man in prison, and, as I recall, it was in Detroit, and we also had asked for additional, outside investigation assistance from one of the other federal agencies which we had received, but we, as I said before, could not pin down any evidence of misfeasance or malfeasance.

Dr. Y.:

Right. In 1967, you made a speech placing great emphasis on trade association voluntary advertising codes, seeming to urge PMA really to mean business with their code, which soon was expected then and did indeed come out several months later, a code that had a sort of built-in mechanism for self-regulation that the Justice Department had approved. Then you made another speech in which you seemed to express disappointment with the poor results of the Proprietary Association code revision which was then a year old. How about these codes?

Dr. G.:

After careful study, I have to conclude that they really aren't worth a damn, that they come down to the lowest common denominator level, that they are unenforceable by and large, and if you really have public issues involved, then a voluntary code isn't going to solve the problem.

Dr. Y.:

At one point I believe it was you who used the phrase, "self-protecting pious documents."

Dr. G.:

Yeah. All too often that's what they were. I'm an eternal optimist. It would be great to see an association adopt a meaningful code, enforce it, and relieve our society of the necessity of creating a governmental organization to carry out that function.

Dr. Y.:

It would be interesting to draw a graph of the revisions of the codes...

Dr. G.:

...and relate them to the level of activity of the agency charged with surveillance and enforcement in that field, wouldn't it?

Dr. Y.:

It would be, and I think it would probably show...

Dr. G.:

...a close correlation, I would suspect.

Dr. Y.:

Okay. Now another question, about LSD. In February, 1968, an AP story suggested that President Johnson tried to block your testifying before the Dodd Committee on LSD, since you could be expected to disagree with the recommendation of his recent crime message to Congress that mere possession of LSD be made a misdemeanor. It was also suggested that the White House later changed its mind, albeit reluctantly, and gave you permission to testify. You gave fairly moderate testimony both before a House committee and the Dodd committee, giving your own opinion, but saying also that the new agency had a right to have a different view, and to Dodd you denied that you had, in fact, been muzzled.

Dr. G.:

Well, the fact that I testified showed that I wasn't muzzled. There was a problem about the timing of when I should go before Dodd, and the administration didn't want me to go in response to the first request and asked that I hold that up. I did. Now, what Mr. Cohen, who was actively involved in this,



wanted done was, he wanted me to work out a position that would permit me to support the legislation that the White House had proposed. Well, I felt strongly enough that I...I just said that I could not in good conscience give wholehearted support. I had to qualify my testimony, and so I was then permitted to establish a date and testify on that basis.

Dr. Y.:

There was a little heel-dragging and a little pulling and hauling.

Dr. G.:

Oh, yes, a fair amount of heel-dragging on that, and consternation. There were many meetings at 5:30, 6:30, 7:00 o'clock in the evening, trying to figure out--not many but several--trying to figure out what position I could take. And I would simply, in these meetings, say, "It's easy. I know where I stand and that's where I'm going to be."

Dr. Y.:

And so you came out of it saying what you really believed, but at the same time, not seeming to make the...

Dr. G.:

Well, the President wasn't very happy about that. The White

House staff weren't too happy about the whole thing, but there wasn't much they could do about it.

Dr. Y.:

As to a device control bill, this was a matter that certainly one way and another had been before Congress long before your commissionership, and soon after Dr. Ley came he worked out a set of categories which formed the basis of the bill that President Johnson recommended to Congress at the start of 1967. Nothing happened. But then, when 1968 came, it was rather suspected that he would suggest a device bill once again, but he didn't do so. What was the matter here? What was the snag?

Dr. G.:

The problem was at the department level. There were just so many issues that could be placed in the legislative package that this didn't come out on the priority list high enough to permit it to be included. It was just that simple.

Dr. Y.:

I see.

Dr. G.:

There wasn't anything on the part of the White House having lost favor, or it certainly wasn't due to any intervention

that I was ever made aware of. I'm not saying that it couldn't have occurred. But I wasn't aware of it. Now, it's unfortunate that that device bill never had a hearing in its original introduction, or that it didn't become reintroduced, in a way, and I think industry now regrets that did not take place, because since then the Supreme Court has ruled on the Difco case and on the AMP case, both. And, in effect, FDA now has control over devices as a result of those decisions, and it's the sort of back-door interpretation that industry doesn't care for. They're now thinking about going to Congress and asking for legislation. It's obvious they want legislation to limit FDA's powers, because the Supreme Court decisions were such that there was almost no limit on FDA.

Dr. Y.:

Do you think that these court decisions give FDA the kind of power over quackish-type devices that they got from the Ke-fauver-Harris Bill over quackish-type cancer drugs?

Dr. G.:

I think it gives them more than the quackish devices. It gives them the authority over the ethical devices.

Dr. Y.:

I realize that.

Dr. G.:

This was one of the bones of contention between the ethical devices manufacturers and FDA. They didn't want to get thrown into the same bag of tricks along with the quack devices, and we were really never too successful in sorting that out for them.

Dr. Y.:

Even despite all the efforts that Herb Ley made?

Dr. G.:

Right. I thought Herb had accomplished that objective, but that there was still some unhappiness. Now, I believe the industry is even unhappier that they didn't go along with the idea of legislation. Now they feel they're going to have to.

Dr. Y.:

Right. Okay. We talked some time ago about the problem of data storage and retrieval. This was a modern management technique that you stood for. There was an Arthur D. Little report that came after three years of study that recommended a very complicated system, and this report arrived in Washington at FDA about the time you did. What were the hang-ups in getting such a system? Later one high Food and Drug official was quoted as saying that there'd been a number of false starts. Was the trouble leadership, was it manpower,

was it dictionaries to be used in coding? What was it?

Dr. G.:

All of those, and then a few more. First of all, we didn't have the manpower. It wasn't a line item in the budget. We had to secure funding, and we had to identify personnel, and they are not easy to find. It took a considerable time to find the appropriate kinds of people. Then there was the matter, as you suggested, of coding: working out the coding alone was a formidable task. The drug code directory which came out late last year was the first attempt at this. And that still has some problems that have to be resolved. The Arthur D. Little report was a very complex system proposal. We didn't buy it. I didn't personally buy it in toto, so we wound up with a modification of that. We encountered the usual problem internally as to who was going to run the computer center, whether it would be run by the management people or by the scientific people, and we had, as every agency or every organization does, the not insignificant problem of educating the staff as to what the computer would do or couldn't do, how it would be operated, what their relationship would be with the facility, and we had to gain support. This was essential. That's a time-consuming process. So, these were the reasons. Now, I'm convinced that Henry Kissman who came to us to work on the professional aspects of the data bank is a capable

individual. He is doing a good job. The management people who were operating it for the computer center also, I think, have been doing a good job. Kottler who I at one time thought we would have to fire, we gave another chance to, and he squared around. I give Ray Landon credit for that.

Dr. Y.:

What was his position?

Dr. G.:

Well, Kottler was in this data management division, and a source of trouble when I first went with the agency, and thanks to Ray Landon we got this man squared around where he's doing a good job. Before I left, it was my pleasure to reward Kottler for his performance, but within a month after I took office he was one of the sore thorns in the management team's side that I had to take care of.

Dr. Y.:

And this, to some degree, is just that complex?

Dr. G.:

Oh, yes. Oh, yes. The problem was not limited to FDA alone. We got involved with the question of the National Toxicology Data Bank, who would operate that, the environmental health people, FDA, NIH? It got very involved, as these issues can.

We, fortunately, however, were able to keep working at the problem. We didn't suspend work waiting for decisions on those matters, and a fair amount was accomplished.

Dr. Y.:

The drug potency study. You mentioned earlier how, with respect to this study, you were let down by inaccuracy of analysis and reporting from the field. I neglected to ask how this hurt. What were the short-and long-range repercussions that were harmful to the agency?

Dr. G.:

That hurt us in terms of credibility in the pharmaceutical industry. The field people viewed this just as one more demand that Washington was putting on their backs, and that this new administration was no different than the previous, and they really didn't turn to and do a good job on this. They didn't validate their results. So, as a result, we got some bad figures. I used those figures, and the companies were quite concerned, and they demanded--and quite properly--to know whose drugs were involved. We did in every instance let them know when their drugs were involved, but the outcome in my book was that the industry felt that there was lack of scientific competency at FDA and this was just one more example.

Dr. Y:

They might have even thought that there was worse, that there was some deliberate effort to hit them, I suppose.

Dr. G.:

Yes. It wasn't a deliberate effort. I won't say that Mr. Rankin and I weren't pleased when we originally got the results, but that pleasure was...

Dr. Y.:

So you just backed away from it as gently as you could.

Dr. G.:

I had to.

Dr. Y.:

There wasn't much to be done.

Dr. G.:

You couldn't do anything about it.

Dr. Y.:

The salmonella problem of 1966 and after in dried milk, drugs, coloring agents, other places. Anything about this that should be said from an overview on which the records might be silent?



Dr. G.:

One thing that the records should show is that we consistently had a policy of allowing the firm whose product was involved to make the announcement. Borden would not make an announcement on Starlac. In retrospect, I think they probably regret not having done so, because we were forced to make the announcement. It was our position that this was a public agency. These were public matters. One couldn't keep a secret of this kind, nor should one. Borden didn't want the story released. They didn't want to release it themselves and didn't feel that we should, but we felt we had to.

Dr. Y.:

You mean even while they were withdrawing all of it from the market?

Dr. G.:

Yes. I didn't feel that you could withdraw from that many sources in the market that large a supply of Starlac and not have a story break. Totally unreasonable and, furthermore, I think that the public had a right to know about it. Now, if Borden had released the story, I suspect it would have been buried in the inside fourth page of the newspaper, but since we released it, it was front page. Borden felt we killed their product, a twelve million dollar loss. I feel that

they killed their own product by not perceiving that they should have told the public of the dangers. Now, we consistently permitted the company, encouraged any company involved, to notify the public of the problem in order to get the product returned, to get it out of circulation, and to minimize the hazard. So I feel that that point should be made. Secondly, the Grocery Manufacturers Association became concerned about this, and George Cook, their executive director, worked very closely with me and set up a number of meetings where this problem could be discussed, first of all, with the heads of corporations, technical meetings. The GMA since then has put money into the problem trying to help solve it, trying to educate people in the various segments of their membership so that the problem can be minimized through better sanitation in the household as a part of breaking this chain of infection. All told, again, I feel that they took a responsible position and that was characteristic of that association.

Dr. Y.:

Was it with a group from this association that you held a series of continuing conferences?

Dr. G.:

Yes. I met periodically with men such as Tex Cook, chairman of the board of General Foods, Ted Gamble of Pet Milk Company, the

president of Hershey, the president of Mueller macaroni, the president of Pillsbury.

Dr. Y.:

Was it just the salmonella problem or was it...

Dr. G.:

No. We talked about general issues, packaging and labeling... fair packaging was a major point at many of the meetings, and we were able to work out some of the problems that I wasn't aware of and I'm sure the legislators didn't anticipate when that bill was passed. Specifically, one of the problems that came up was the timing, the time period in which the agency would require all labels to conform. We had originally one set of expectations. It became apparent, though, very soon that there was a major bottleneck. The bottleneck was in getting the labels printed. The reason there was a bottleneck was because in the process one particular type of employee called a "spotter" is very critical. Now, keep in mind that these labels are gang printed on large presses. They are colored labels, and once a run is started they will stop the machine at a given point, let's say after 150,000 impressions. This gang press, you see, prints maybe six different kinds of labels, ten kinds of labels, simultaneously. So, after 150,000, then they stop and take the peach label off and replace it with

one for pears or pizza or noodles, who knows? And start the presses and run it again for a period of time. Well, that job of replacing that portion of the plate is called "spotting." "Spotters" are in short supply, and the labor union laws are such that, although one could be trained realistically in a few months, the union requires a year as an apprentice. And so it came down to a practical matter of union regulations thwarting the intent of Congress in the transition on fair packaging and labeling. This was the kind of thing that we were able to sit down and discuss.

Dr. Y.:

This was while you were in the process of making the regulations under the law?

Dr. G.:

Yes, it was, indeed, and we were able to resolve many kinds of problems. We made some errors again in our proposed regulations, failing to take into account certain of the problems within the industry. And through this mechanism, those errors were brought quickly to our attention. They would raise questions that we hadn't thought of and I think in toto made the whole program work much more effectively and reduced the need for enforcement.

Dr. Y.:

In connection with this food industry group, what did you call it incidently? Do you know? Did it have a name?

Dr. G.:

Food Processors Council, I believe it was called.

Dr. Y.:

Did you talk about the self-certification program at this group?

Dr. G.:

Yes, this came up with this group. It had its origins in my having been with the Federal Aviation Agency. In the aviation field, the airline companies themselves, who are certified carriers, carry out a program of determining that their pilots are capable of flying the equipment they're scheduled on. They do this by pulling a competent pilot off of the line for a six-month period, and then he, in turn, inspects his fellow pilots, puts them through check rides and observes their capabilities, and this, at one stage in FAA, led to the discussion of self-certification, and so it was a carry-over from my experience in the aviation field.

Dr. Y.:

So you introduced it into the discussions of this committee?

Dr. G.:

Yes. It also was related to the fact that the food industry was becoming quite different. It no longer was as visible to the naked eye in the inspection process as to what was taking place. If you were to go into the Sara Lee plant in Chicago, you would see that very modern equipment out of sight of the human eye mixes all of the cakes and the various products that Sara Lee markets, causes them to be baked, carried through on a conveyor belt, packaged, and emerge from the other end, completely invisible in the sense of not being able to observe the process of mixing, et cetera. Well, this is typical today of the food industry. It's a highly automated industry, because they work on such large volumes. And so FDA's inspection process is no longer as meaningful as it once was, and I felt that if the industry could be placed in a position of taking a greater responsibility, an individual company, for example, by reporting to us their use of certain additives and any problems they encountered, we, as an agency, would further the public's interest. Keep in mind that in the food industry, although approval had to be obtained for a food additive to be originally used, once that approval was granted, the company no longer had to divulge at any time or in any way how much of the food additive was being used, which is an anomalous situation, you see. If it's potentially

dangerous enough to require animal feeding studies, toxicity data, et cetera, then why should the company be given free rein and use it without disclosing the extent to which they use the product. Well, these were some of the factors. And so the idea was discussed at food processing council meetings. Mr. Cook of General Foods liked the idea, the possibilities inherent in it, and volunteered that they would be the first. And so their Dover, Delaware, plant was the first involved. And it was quite an educational experience for Mr. Cook, his people, myself, and our people. We found that there were many kinds of problems that we hadn't anticipated in terms of the reporting. It led to a general tightening of their quality control, which was already a very good QC program in industry, to help further reduce the possibility of contamination of their products.

Dr. Y.:

Now, quality control must be automated too, then?

Dr. G.:

Yes. We were mainly interested in concentrating initially on high risk items in the product line, anything with dairy ingredients, eggs, milk, butter, et cetera, because the possibility of salmonella infection contamination was greater.

Dr. Y.:

Is that what was done at the Dover plant?

Dr. G.:

Yes, we worked out a reporting system between the Baltimore district office and the Dover plant where the Dover plant would routinely provide certain information to the Baltimore office which they hadn't been receiving before, and would enable them to look at what kind of quality control was being maintained and spot any possible problems.

Dr. Y.:

Was a contract drawn?

Dr. G.:

A letter of agreement...

Dr. Y.:

So that the record...

Dr. G.:

...that I signed. Yes, it's in the record.

Dr. Y.:

The records will have this letter of agreement?

Dr. G.:

Oh, yes, indeed.



Dr. Y.:

And the technical points that were involved. Right.

Dr. G.:

Yes.

Dr. Y.:

"Written consent," this phrase under the 1962 drug amendments. Early in your administration you suggested a rather strict interpretation that academics and industry protested against, saying it was too strict. You evidently had conversations then with PMA, AMA, university researchers and later on...

Dr. G.:

A few others, too.

Dr. Y.:

A few others?

Dr. G.:

Well, a few other professional associations and those individuals involved in pharmacological research. A number of professional associations called on me and Representative Paul Rogers of Florida, who I would have to say was a friend of the pharmaceutical industry, sponsored a meeting of interested parties which I attended to present our point of view. It was quite obvious that a number of the people involved had not clearly

read the proposed regulations, because, to cite an example, at a meeting which Mr. Rogers had sponsored, seated at the table on my left was an internist from the Cleveland Clinic. He made a statement that made it perfectly obvious that he had not read the proposed regulations. He said, "Why, Jim, this requirement would mean that we couldn't even administer a dose of digitalis without getting the formal consent." I said, "Now, Doctor, you haven't read the regulations, have you?" Well, he was man enough to admit, well, no, he really hadn't, and therein lay much of the problem. There was a great deal of talk but very little careful reading of what was proposed. As a result, we had not only that meeting, we had a meeting at PMA headquarters of all interested parties, the clinical pharmacologists, the AMA, the PMA, the Pediatrics Society, you name it. Everybody was sending representatives. And what it all boiled down to, we modified a couple of phrases which Mr. Goodrich assured me did not in any way weaken the proposed regulations. In fact, he thought that the doctors had put themselves in a somewhat worse position than they realized, and we then went ahead and published the regulations. But, again, it was a good illustration of how a lot of sound and fury and really not much light was cast on the matter because the individuals had all shouted before they had carefully read what the proposal was. Now,

the Congress intended that this be done. The agency hadn't done anything about it. Here again, this was something that was just sitting there waiting to be picked up, and the Public Health Service, in fact, even in advance of our getting our regulation out--because we were delayed due to the interest on the part of the Congress, Mr. Rogers; and Dr. Lee's office further delayed the publication of the final notice--PHS just got theirs out earlier. Theirs simply shifted the burden to the research institution where the grant was held, but nonetheless, HEW collectively through PHS and FDA now required that the individual involved in experimental procedure be notified, it be discussed with him, that he be given an option, which certainly wasn't happening up until that point in time.

Dr. Y.:

Right. So that you think that it did shake down pretty well?

Dr. G.:

Yes. We subsequently tried to find out how it was working, and we found relatively few problems in spite of all the fuss that went on about the proposed regulations when it was in the proposal stage. After all, what we were proposing was what had been adopted in the Helsinki declaration, which was basically what the AMA had proposed itself, and we were simply putting it in as a requirement. I think the physicians and

the groups involved became fearful that we would try to enforce this, and it gave credence to the belief that Congress had in incorporating it in the bill that the patients weren't being notified, that they were being used as experimental subjects. But we, of course, would not be able to enforce it. We couldn't go into a physician's office and ask his patients were they notified. This is just not practical. It serves as a reminder to the physician that he has a professional responsibility.

Dr. Y.:

And if there should be tales circulated of gross violations, then it would give a way to dig back into the situation before.

Dr. G.:

Yes indeed.

Dr. Y.:

At several times, especially after the FDA Obstetrics and Gynecology Advisory Committee would report, you would see reporters or go on television and make fairly bullish statements about oral contraceptives.

Dr. G.:

Oh, my, yes. Unfortunately.

Dr. Y.:

Are you now satisfied that FDA followed the proper policies on oral contraceptives?

Dr. G.:

I'm not satisfied that the original approval was an appropriate one, but by the time I assumed the office approximately five million women in the United States were using the oral contraceptive. I would have been hard put to remove the product from the marketplace with no more evidence than there was then available. The committees that studied the problem I thought were objective as far as they possibly could be. Their reports to the commissioner I felt were a fair reflection of what they perceived and learned in their travels and at interviews and in studies of literature. But it's again a good illustration of...we have a serious dilemma in our society of marketing products and then subsequently finding out that the products have more problems than originally had been perceived and that changes have to be made. Now, the oral contraceptive, of course, is unique in that it was the first time a medication was designed to be taken by a well person basically. Its proponents are almost fanatic about the desirability of the product, it's opponents almost equally fanatic about its dangers, and we're now finding that the truth seems to be somewhat in between. It's not entirely

safe; it's not as dangerous as some would have had us believe, but it certainly is more dangerous that I suspected at the time following those committee meetings. Now, Roy Hertz was a member of one of those committees, and Roy constantly made the point that this, The Pill, as it was called, had a potential for carcinogenesis because of the estrogen component. There is still debate on this point. Some of the studies that have been carried out do suggest that possibility. However, those studies aren't clear-cut either, and we still have no final answer. I felt compelled following those meetings to report in a meaningful way to the American public, and that meant that one had to swallow hard and say the Pill is safe or it's not safe, or, at best, on one occasion, you remember I said a yellow light. I used that as an analogy but you have to get down to terms that people can understand. You can't equivocate all over the place in discussing something of this nature.

Dr. Y.:

But making a speech now, was there...

Dr. G.:

I'm more cautious than I would have been then, because the evidence certainly is different today than what we had available at that point in time.

Dr. Y.:

Right. Generic equivalency versus clinical equivalency.

Dr. G.:

Or physiologic equivalency.

Dr. Y.:

Right. Did your view change here as a result of new evidence?

Dr. G.:

Not so far. You know, Gilman suggests, Alfred Gilman of NAS-NRC, suggests that FDA now have to require proof of equivalency, clinical equivalency, on all so-called generic drugs. Gilman does this still on the basis of a very limited number of cases where equivalency has not been demonstrated, therapeutic or physiological equivalency, to be exact.

Dr. Y.:

That's blood levels?

Dr. G.:

Blood levels mostly. This emerged as a result of Parke Davis trying to protect its own interests on chloramphenicol, to begin with, where they came in in advance of the expiration of the chloramphenicol patents and pointed out that we should require the companies that tried to enter this marketplace to

submit clinical data, which they had been required to do on two occasions when they made substantial changes in their process for the formulation of chloramphenicol. I rejected that. I said enough was probably known by now that these other firms could enter the field. This did not prove to be a case. We found later, or Parke Davis found later, after several of these firms were in the marketplace that blood levels were not sent up to required standards on certain products made by competitors.

Dr. Y.:

This was more than just the excipient?

Dr. G.:

We never really found out what the problem was, a very complex problem, particle size, excipient. We dissolved the product in a liter of water and had subjects drink that, and they got an adequate blood level, so it wasn't the fact that the chloramphenicol wasn't present in adequate amounts. It certainly was present. It was something delaying in the absorption; the absorption patterns were wrong. Now this strengthened Gilman's belief apparently that this was a more widespread problem than had been suspected, and he had gotten the Academy apparently to produce a white paper which I as yet have not seen. This white paper purportedly recommends



to FDA that clinical studies be required. I think this would be unfortunate. The FDA is doing some studies of physiologic availability of certain drugs, because they happened to be more critical drugs. Those studies haven't shown the problems to be all that significant.

Dr. Y.:

First of all, there was the chloramphenicol. Then there were certain other antibiotics.

Dr. G.:

Yes. That's true.

Dr. Y.:

And then, did you go on?

Dr. G.:

Oh, yes. Went on...they were doing some studies on Dilantin when I was with FDA.

Dr. Y.:

Was this done out in the St. Louis...

Dr. G.:

Georgetown, originally.

Dr. Y.:

The clinical thing that was done at Georgetown?

Dr. G.:

Then the St. Louis group was doing the laboratory studies.

Dr. Y.:

Right.

Dr. G.:

Now, I think it would be unfortunate to reach a decision now with no more evidence than is in hand that every drug to enter the marketplace had to have clinical data. I'm talking now about generic drugs that are "me, toos" and have been in the marketplace for some time. I, of course, would not feel--on new drugs you have to have clinical data. And it may ultimately be proven that you should have at least physiologic availability data on all marketed drugs, but I say that's a substantial cost factor that would be involved and that judgment should be reserved on that issue for a while.

Dr. Y.:

You tend to feel that the chloramphenicol was unusual and is not going to be generally typical?

Dr. G.:

I don't feel that that problem is as widespread as Gilman suggests. I have asked him where is the evidence that the problem is that widespread?

Dr. Y.:

Right.

Dr. G.:

Of course, PMA loves this because it helps their members maintain their position in the marketplace.

Dr. Y.:

Right, and if they say it's true or likely to be true of every drug, then that blots out generic production.

Dr. G.:

Yes. Yes.

Dr. Y.:

In connection with this, in December of 1966, you and other Public Health Service people went up to the Defense Personnel Support Center, and I kind of got the idea that that conversation might have alerted you to this problem initially.

Dr. G.:

Well, the Defense Support Center handled the purchasing of drugs for the military services, and we met with the staff which was responsible for that activity, and it was quite an education for me. I wanted to find out what procedures they went through. They, in fact, carry out factory inspections, pre-award factory inspections, what their criteria for

selection were, how they ruled bidders out of consideration, how often did they have to rule out bidders that FDA had permitted in the marketplace, and so it was felt very worthwhile.

Dr. Y.:

And they had done some kind of tests that involved equivalency?

Dr. G.:

Yes, they had had some problems with equivalency on a couple of products, Griseofulvin and Dilantin, as I recall, were the two they brought up as examples. They had switched their supplier of Dilantin from Parke Davis to a generic equivalent. The clinic physicians noted a more frequent rate of epileptic seizures, complained, this complaint was dismissed as nonsense, but when they actually went out in the field and investigated it, they found that there was substance to the complaint, and they then switched back to the old source of supply. They had some problems with some antibiotic too, as I recall.

Dr. Y.:

So that you went back from Philadelphia to Washington somewhat more alert than you had been?

Dr. G.:

Yes. I was somewhat more conditioned. This convinced me we

had to do more work in our Georgetown facility. I then asked Dr. Ley for a priority list of drugs that he would have Georgetown tackle, and they did produce such a list and Georgetown started on that task. Now, unfortunately the Georgetown activity has not worked out well. Dr. Chris Martin has never been sympathetic with the idea of doing work on demand for the agency, and the medical school hasn't really backed the FDA's hand on this, and I understand the contract is now being terminated.

Dr. Y.:

Well, the agency needs something like this.

Dr. G.:

I felt that they did. And so it's unfortunate that it hasn't worked out.

Dr. Y.:

Well, that's about all the questions I've got now. Certainly, the high priority ones.