History

of the

U. S. Food and Drug Administration

Interviewee: Paul A. Pumpian

Interviewer: Robert A. Tucker

Date: January 22, 1996

Place: Washington, D. C.

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Paul A. Pumpian

As a conditional gift under section 2301 of the Public Health Service Act (42 U.S.C. § 300 cc), and subject to the terms, conditions, and restrictions set forth in this agreement, I, Paul A. Pumpian of [redacted] do hereby give, donate and convey to the National Library of Medicine, acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at my home (above address) on January 22, 1996 and prepared for deposit with the National Library of Medicine in the form of recording tape and transcript. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

Title to the tapes and transcripts shall pass to the National Library of Medicine upon their delivery and the acceptance of this Deed of Gift by the Chief, History of Medicine Division, National Library of Medicine. The Chief, History of Medicine Division shall accept by signing below.

I place no restrictions upon the use of these tapes and transcripts by the National Library of Medicine.

The National Library of Medicine may, subject only to restrictions placed upon it by law or regulation, provide for the preservation, arrangement, repair and rehabilitation, duplication, reproduction, publication, description, exhibition, display and servicing of the tapes and transcripts as may be needful and appropriate.

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

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

Date: April 2, 1996 Signed: Paul A. Pumpian

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

Date: _____ Signed: _____

Chief, History of Medicine Division
National Library of Medicine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 1, 2 & 3

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

DATE: January 22, 1996 PLACE: Washington, D. C. LENGTH: 150 minutes

INTERVIEWEE	INTERVIEWER
NAME: Paul A. Pumpian	NAME: Robert A. Tucker
ADDRESS: [redacted]	ADDRESS: U.S. Food & Drug Administration Rockville, MD 20857

FDA SERVICE DATES: FROM: 2/14/66 TO: 11/30/69

TITLE: Director, Office of Legislative & Governmental Affairs
(Last FDA position)

INDEX

PUMPIAN INTERVIEW

INDEX

PUMPIAN INTERVIEW INDEX

Appendices:

RT: This is another of the interviews in the FDA Oral History Program. Today, January 22, 1996, Paul A. Pumpian, former director of the FDA's Office of Legislative and Governmental Services (OLGS), is being interviewed in his home in Washington, D.C. Robert Tucker is interviewing Mr. Pumpian.

Paul, as we start these interviews, we usually like to begin with a bit of brief early history as to your birthplace, your education, and perhaps interim employment prior to the time you joined the Food and Drug Administration.

PP: OK, Bob. Thank you for the opportunity to speak about a little bit of history.

I was born and raised in Baltimore, Maryland, and graduated from high school, which was known as the Baltimore City College, in February 1943. I went right out to College Park, University of Maryland, where I was a pre-medical student and also took two years of army ROTC while I was there, which has a bearing on my next statement.

My eighteenth birthday was in December of 1944, and the government was drafting people because of World War II; after having completed two years of army ROTC under a speed-up course situation, I knew I didn't want to go into the army. So before I was eighteen, I enlisted in the navy and was able to get into the U. S. Navy Hospital Corps.

While serving in the Naval Hospital Corps I was exposed to autopsies being performed by physicians, and discovered at that time I did not want to go into medicine as a result of my exposure to the autopsies. I was a pharmacist mate third class, and I was working in a pharmacy dispensary, and at that time got very interested in pharmacy. So when I was discharged from the navy in '46, I applied to pharmacy school in Baltimore, the University of Maryland Pharmacy School. Unfortunately, I got out in July, and the class had been filled several months previously, so I went back to College Park, and again applied to pharmacy school and was accepted with advanced standing the following September. I graduated from pharmacy school in 1950, and then I went to law school.

In law school, from '53 to '56, I became very friendly with some people in my law school class, and wound up being elected second vice president of the Young Democratic Clubs of the Schools of Law. Ultimately, I became president of that group, and I became president of the Fifth District Young Democrats. I mention this for purposes of explaining some later matters. I was also a vice president of the Queensbury Democratic Club in Baltimore City, whose secretary at the time was a young man named Marvin Mandell, who years later became governor of Maryland. I later became secretary of the Young Democratic Clubs of Maryland and served as chairman of the Jefferson-Jackson Dinner of Maryland, which is the big Democratic fund raiser. That was in 1955. From 1953-1956 I served as the first chairman of the Department of Pharmacy Administration at the University of Maryland School of Pharmacy with the rank of assistant professor.

I left Maryland in 1956 to go to New Jersey as a patent attorney for E. R. Squibb & Sons. During the summer of 1955, I had worked in the U.S. Patent Office as a patent examiner and felt that I would like to go into the patent field working for a pharmaceutical company.

I was with Squibb in New Jersey until 1958, when I was told that the Wisconsin State Board of Pharmacy was looking for a pharmacist lawyer to serve as their executive secretary. I really wasn't interested, but I was talked into it as an opportunity to further my interest in pharmacy law. I accepted the position and went there in November of 1958.

The position was rather unique, because it was one of five states in the country where the secretary of the Board of Pharmacy was also responsible for the enforcement of the state dangerous drug and narcotic laws. So in effect I became the state narcotic officer, as well as the chief enforcer for its dangerous drug laws.

I might mention that my appointment was strictly nonpartisan. My appointment was approved by a Republican governor, and two days after I got to Wisconsin, a Democrat was elected governor. That Democrat was Gaylord Nelson,

who later became Senator Nelson, with jurisdiction over the Food and Drug Administration.

In Wisconsin, because of a program I initiated, I became acquainted and friendly with the governors under whom I served, the attorneys general, and the state's U. S. Senators.

In 1965, I was in Florida on a program sponsored by the International Narcotics Enforcement Officers Association. On the program discussing the 1965 drug control amendments to the Food and Drug Act, were Winton Rankin, who was then deputy commissioner; Harry Anslinger, who was a retired commissioner of narcotics and U.S. representative to the United Nations Security Council that dealt with narcotic control; as well as Congressman Paul Rogers, and a representative of Smith, Kline & French, who funded the program.

I was there as the chairman of the Committee on Legislation of the National Association of Boards of Pharmacy (NABP). At a breakfast of the speakers the morning before the panel discussion, I mentioned to Anslinger that I had been contacted by the United Nations Security Council representative about accepting a position as director of narcotic control for the United Nations in Geneva, Switzerland.

When I mentioned that to Anslinger, Rankin says, "What do you want to go to Switzerland for? We're setting up a Bureau of Drug Abuse Control in Washington. Why don't you join us?" And that's how I got to the Food and Drug Administration. I followed through on Rankin's suggestion and met with Fred Garfield, and I was eventually appointed deputy director of the Division of Case Assistance in the Bureau of Drug Abuse Control. John Finlator was the bureau director, and on a trip he and I had made to Dallas, Texas, to address the National Association of Boards of Pharmacy, he said to me that he wanted to move me into his director's office.

What had happened is that before we were fully established, all inquiries that were coming in by phone and by letter from the pharmacy groups around the country

were primarily directed to me, because as secretary of the Wisconsin Board of Pharmacy and one who had engaged in some pioneering efforts in Wisconsin, I was invited to speak around the country and knew, I guess, every Board of Pharmacy secretary in the country and every state pharmacy association secretary, as well as most of the deans of the schools of pharmacy. So it was only natural for them to contact somebody they knew for information concerning the Drug Abuse Control Amendments of 1965.

On the way back from Dallas, Finlator said that he was going to move me into his office. When we got back to Washington, he made me his assistant--this would have been about April or May of 1966--my having come to Washington and started in the Division of Case Assistance in February of '66. That, of course, made me very happy, because it promoted me to a GS-15, which I can't complain about.

I worked with Finlator and was his liaison with the press, with the professional communities, with local law enforcement officials, including Boards of Pharmacy, and he used me as the lecturer on drugs for the investigators school we were operating in Berkeley, California. I was fortunate enough to have retained my interest in the field of pharmacy as secretary of the Wisconsin Board of Pharmacy, and my knowledge of dangerous drugs was perpetuated by my activities in enforcing the dangerous drug and narcotic laws in Wisconsin.

Late in 1966, one of the members of the staff of the Bureau of Drug Abuse Control showed me an announcement put out by the FDA Office of Personnel that they were creating an Office of Legislative and Governmental Services in the Food and Drug Administration, which would combine the Office of Federal-State Relations with the Office of Legislative Affairs. I read that, and that individual said, "Look. Here's something that you ought to be interested in." Because this individual knew about my past political background he felt that I would be a good fit for that job. Knowing that Maurice Kinslow was occupying the position of legislative affairs director at the time, I went to see him to ask him exactly what he did and was he interested in the position, and he said, "No."

I then talked to Ted Cron, who was the assistant commissioner for public affairs or public communications for Dr. Goddard, the commissioner, and asked him about it, and he said he thought that that would be a good spot for me. Ted and I were good friends; we were neighbors, so we knew each other fairly well. He says, "Why don't you go talk to Dr. Goddard?"

Well, by the time I got to see Dr. Goddard, Ted had already spoken to him, and he said he would be very interested in having me apply for the job. I said I wasn't sure that I wanted it, because I enjoyed working with Finlator, and John Finlator was out of town at the time. He says, "Well, why don't you wait until Monday when John comes back and you talk to him." So Monday morning, when Finlator came in, I told him about my conversation with Goddard, and he says, "Well, I don't want to lose you. But if you want to do it, I won't stop you." I said, "Well, I still haven't made up my mind."

About an hour later, he called me. He said, "You know you've got that congressional job." I said, "No." He said, "Rankin just called me and told me you got the job and who your replacement is going to be." I said, "Really?" About twenty minutes later, Rankin called me. He says, "I haven't gotten a piece of paper from you yet about the congressional job." I said, "Well, I'm not sure that I want it." He says, "Oh, no. You've got to take it. It's already been decided."

So that's how I became director of the Office of Legislative and Governmental Affairs. The appointment would have been made earlier, but in January of 1967, Fred Garfield and I had scheduled a series of speeches around the country at schools of pharmacy to talk about the drug abuse control amendments and the Bureau of Drug Abuse Control. So the official appointment to the position at OLGS came after my return from this nationwide tour.

RT: Well, Paul, maybe that was a little later. Wasn't the Office of International Affairs combined with that group somewhere along that line?

PP: In December of '67, which was like nine or ten months later. The commissioner called me in and said he was thinking that he would put the Office of International Affairs into OLGS, and I said, "Fine." Well it took some time to get the paperwork done, and here's a table of organization, dated April 1968, which shows both the Office of International Affairs with me as acting director and the Office of Legislative and Governmental Services with me as director. But ultimately the two offices were merged.

RT: Perhaps we could add that organizational chart as an appendix to the transcript.

PP: Fine. Take it with you.

One of the reasons that I think I was picked for the director of the Office of Legislative and Governmental Services goes back to what I explained before about my days in law school.

Two of the people I was very friendly with while active in Young Democrats were Joseph Tydings and Danny Brewster, both of who were members of the United States Senate at the time I was appointed director of OLGS. The two senators from Wisconsin, Senators Nelson and Proxmire, were two people I had befriended when I was secretary to the Wisconsin Board of Pharmacy and in my official capacity had contact with them and then later became personal friends, which meant I had four members of the United States Senate that I was on a first-name basis with, as well as the vice president of the United States, Hubert Humphrey, whom I had befriended in 1959 and continued a relationship with through his Senate term when he became vice president and even during his presidential campaign.

RT: I see one of the things you have here is a picture of you and Senator Humphrey. What was the occasion of this particular photograph?

PP: In 1959, Senator Humphrey came to Milwaukee, Wisconsin, to address the annual convention of the Wisconsin Pharmaceutical Association. At that time, I was promoting the program throughout the state to get all the pharmacies to post a sign: "Indiscriminate use of drugs is dangerous; consult your pharmacist." Because I was concerned about the abuse of over-the-counter drugs, I was doing this as part of an educational program to let the public know that they should consult their pharmacist before using over-the-counter drugs for the first time.

This was mentioned to Senator Humphrey at the time of his appearance, and he thought it was a good idea. He was convinced by the officials of the Wisconsin Pharmaceutical Association to don a white jacket, because, as you know, Senator Humphrey was a pharmacist. So he and I were displaying this sign, and the photograph was taken of us in a model pharmacy that was at the convention. This particular photograph was published in the drug trade magazines throughout the country at that time, which would have been the beginning of 1960. The same photograph was republished when Humphrey ran for President in 1968, and I was serving as director of the Office of Legislative and Governmental Services at the Food and Drug Administration.

Of course, you know Richard Nixon beat Vice President Humphrey. Upon Nixon's succession to office, I was told by some of my Republican friends that I had a problem because of the notoriety of my relationship with Hubert Humphrey. I might add that I was very pleased to receive a beautiful Christmas present from Vice President Humphrey in 1967. It was a cut-glass ash tray with his initials and the vice presidential seal enclosed. Bob, I can show you the ash tray, but you can't take it with you.

RT: OK. (Laughter)

PP: Well, while working for Commissioner Goddard, I was exposed to a great deal of activity on the Hill. Commissioner Goddard, as you know, did not hesitate to

speak his mind and often, as was quoted, "shot from the hip." On two occasions that I recall, he made one comment about he'd rather have his daughter smoke marijuana than drink two martinis. And another comment he made was that corner drug store as we know it today will not be existing in the future.

RT: That probably did not endear him to Mr. Humphrey too much.

PP: No. As a matter of fact, it probably was the reason that he did not become the administrator of CPEHS, the Consumer Protection and Environmental Health Service. I had a personal relationship with Wilbur Cohen, who was then secretary of the Department of Health, Education and Welfare, and when we were having dinner one evening together, I said to him or I asked him about Goddard's leaving. And he says, "Well," he said, "the vice president said to me, 'What are you trying to do, close my brother's drug store?'" I said, "And you took that to mean that the vice president was not happy with him?" He says, "Well, what would you do?"

What happened is that the National Association of Retail Druggists (NARD) took Dr. Goddard's remarks about the drug stores meaning he wanted to close the neighborhood drug store, which was not the situation at all. He was merely saying that the evolution would be that the pharmacy as we knew it in 1967 would not be existing in the future, and he was absolutely right, because the practice of pharmacy today is much different than it was in 1967.

RT: Was he looking at that issue as one wherein pharmacists would become more advisors on medication rather that just dispensers?

PP: Right. They would become advisors, clinical advisors. Their pharmacies would be more prescription-type pharmacies. Now, if you look at the big chains, in 1967 and before that, when I worked in retail pharmacy, the pharmacist was the manager. He not only filled prescriptions, but he had to manage the store. Well, the

prescription volume has increased such over the years that now the pharmacist in most chain operations only fills prescriptions. He doesn't have time to manage other parts of the pharmacy. You see this in the supermarket chains; you see this in the traditional chain operations; and Goddard was right. He was looking upon the pharmacist as becoming more of a clinical advisor than he was in the early sixties.

But the National Association of Retail Druggists took this on as a crusade, and they, of course, were very close to Vice President Humphrey. I was somewhat involved in this because I was very friendly with the executive vice president of the NARD and the head of their Washington office. But they saw it as an issue that they were not going to let go of.

RT: Now, when Dr. Goddard came in, he instituted a number of organizational changes, among which was more autonomy for field managers. As to the responsibilities you had in legislation and federal-state relations and so on, did you have any particular charge or direction from Dr. Goddard on changes he desired in these areas?

PP: Well, I know that for a while he believed in decentralizing authority. I'm trying to remember whether or not he brought that back to Washington. But he really let the district directors control the policies for their areas, which resulted in some confusion, because each district director looked at matters differently. I remember Fred Garfield was one who felt that it should be centralized. As far as my personal charge, he, knowing about my friends on the Hill and my contacts at the state level, really gave me a free hand.

Just as one example, he had asked me to resolve a problem with a certain congressman, and evidently the problem had been present for several months. So I went over to see the congressman who was from Kansas. While talking with the congressman, I asked him if he knew Clara Miller, who was the secretary of the Kansas Pharmaceutical Association. And his response was, "Know her! When I was

in the state legislature, she used to sew the buttons on my jacket for me." Needless to say, I was fortunate enough to be able resolve the problem.

When I went back and told the commissioner that the problem was resolved, I told him how it was resolved. He says, "Well, gee, we recommended that months ago, and the congressman wouldn't buy it. How did you do it?" I very flippantly said to the commissioner, "I can't tell you that. Just tell me when you have a problem on the Hill, and I'll take care of it. Don't ask me how."

So that began a very wonderful relationship with the commissioner, and it worked out well with some of the problems we had. Unfortunately, I was not able to overcome his corner drug store remark; the marijuana remark led to several hearings on the Hill, one of which was held by Senator Nelson, and I remember the commissioner having me at the table with him, and I responded to some of the questions.

We had a number of hearings during my tenure, mainly dealing with a specific drug problem. I don't recall all of them; some I do. That was during Commissioner Goddard's reign. Dr. Ley had some hearings. Dr. Goddard left in 1968. I guess his resignation was effective as of July 1, which is the date that the Consumer Protection and Environmental Health Service came into being.

RT: While Dr. Goddard was commissioner, were there many oversight hearings? The Fountain Committee was an active oversight group on the Hill. Did that result in many hearings during Dr. Goddard's tenure?

PP: Well, now, the first year Dr. Goddard was there, Kinslow was still in legislative services, and I guess they had a number of them, but I wasn't following that, because I was in drug abuse control. We didn't have too much with Fountain after I got there. We had a couple, but I was fortunate enough to establish a good working relationship with Don Gray, who was the chief investigator for the Fountain

Committee, and Jim Naughton, who was the counsel for the committee. Most of the things were worked out without hearings.

Whenever the committee needed something in the past I was told they had to have a hearing to get it. I was able to provide the information they needed when they wanted it, so there was not much demand for a hearing, although there were some. But Dr. Goddard and I met on occasion--frequently, I guess I should say--with Gray and Fountain so that there was really no need to have oversight hearings because problems were resolved.

RT: How about Senator Kennedy? Was he active in his committee oversight during Dr. Goddard's time?

PP: I don't think so. It seemed to me that Kennedy was not the chairman then. In the Senate it was Harrison Williams, if I remember correctly.

RT: And, of course, Mr. Fountain was in the House of Representatives, wasn't he?

PP: He was Government Operations Committee chairman. We did have hearings with Paul Rogers, who was acting chairman of the Health Subcommittee of the Interstate and Foreign Commerce (Committee). I remember we had a hearing when Harley Staggers was chairman of Interstate and Foreign Commerce. I don't remember the subject matter, but I do remember preparing the testimony.

After going through the normal routine of getting testimony prepared, this had to be cleared by the secretary, and I remember working Saturday and Sunday with Dr. Phillip Lee, who was then assistant secretary of health in the Department of Health, Education and Welfare, finishing up a handwritten correction of a typewritten draft on Sunday and going up early Monday morning to Dr. Lee's office and having the final testimony typed. I took one copy of the testimony with me to hand to the committee, and the rest of them were being run off while I was telling the

committee that we were going to have it for them shortly. Dr. Goddard had already started his statement when the other copies of the testimony arrived. But I can't really remember the subject matter.

(Interruption)

RT: All right, Paul.

PP: During the first six months that FDA was under the Consumer Protection and Environmental Health Services, which would have been from June or July in 1968 through December, things continued, as far as I was concerned, to operate smoothly. The Office of Legislative and Governmental Services had, I thought, been fine tuned, had an excellent deputy in Bob Wetherell. My legislative services group was functioning well. I had created a congressional services group and brought Mort Schneider from New York to head it.

And I was creating a legislative services group to handle not only pending legislation on the Hill, but legislation that states were interested in, since one of my responsibilities was federal-state relations. Bob Tucker, who is the gentleman interviewing me, was active in the legislative group, because he had done work on state legislation, and I wanted him to head up the legislative group, which would handle both state and federal legislation. Glenn Kilpatrick headed up federal-state relations. International affairs, which was another of my responsibilities, was being headed up by Harold O'Keefe, who had been in charge of international affairs.

I thought things were running very smoothly. I spent a lot of time on the Hill, because I had the feeling that you're always better off getting to know the Hill people before you need to answer questions, before you have to take action on matters.

I remember one situation when Hervey Machen, a congressman from Prince George's County in Maryland, which is where Beltsville is located, and the location

in which Dr. Goddard wanted to build the Food and Drug Administration building. At an appropriations subcommittee hearing, Dr. Goddard was told that a provision had been adopted by the committee that no FDA building could be built within fifty miles of Washington. It turned out that the proposal was to build the building in Wisconsin because of that provision.

But the congressman from Prince George's County, Hervey Machen, called Dr. Goddard and says he wanted to see him about this building; he wanted to discuss it. As was Dr. Goddard's practice, he called me, and we went over together. I must say this about Commissioner Goddard, he was very good about not going on the Hill without me. Any time a congressman came to visit him, he let me know, and I was usually present. And, all mail that went to the Hill was over my signature, a suggestion that was made to enable my name to become known to the people on the Hill so that when I went up there I wouldn't be a stranger.

We went over to see Congressman Machen. We walked into his office, and I told the receptionist that Dr. Goddard and Paul Pumpian are here to see the congressman. The congressman's administrative assistant looks up, and runs over to me, and she throws her arms around me and kisses me. It turns out that she was the executive secretary of the Young Democrats when I was the secretary, so we were old friends. She goes into the office and says to the congressman, "There's an old friend of yours here." Hervey Machen and I had been buddies in Young Democrats years before. Needless to say, we had a good meeting.

I spent a lot of time on the Hill getting to know staff members, and thanks to one of my Senate friends, I became a member of the Senate Staff Club and used that as a vehicle to meet many Senate staff members. So the first six months that CPEHS existed, my job continued as if there had been no change, other than my reporting not only to the commissioner, but to the gentleman who was put in charge of legislation, a very fine gentleman whose name I don't remember at this time. He was the CPEHS legislative person. He preceded Meyers. He was a very quiet guy, but he was only there for six months.

RT: I'm trying to recall who he is in the Public Health Service.

PP: Right. He retired to Marco Island in Florida, I remember. He was a fine fellow.

During that six months, the commissioner continued to attend the secretary's staff meetings, and there was no problem in communications between the commissioner and the secretary. But in November of 1968, there was an election, and Richard Nixon was elected president, and it was obvious that Secretary Cohen would no longer be around. Shortly after the election, the commissioner was told he would no longer be attending the secretary's staff meetings. Not too long thereafter, the commissioner had to provide the secretary with some information and sent a memorandum directly to the secretary.

RT: Now the secretary at that time was . . . ?

PP: Finch. It might have been somebody acting by then. No, I guess Finch was already in. Bob Finch from California. He had been lieutenant governor to Ronald Reagan.

Dr. Herb Ley had a different management style than Dr. Goddard. Dr. Goddard once a week had all the bureau chiefs and all the assistant commissioners and the directors of offices to a large meeting that probably had thirty people in the conference room. Goddard would individually talk with these unit heads when a particular problem came up. And, of course, whenever there was a hearing or there was testimony, the people involved in the testimony would get together in Goddard's office.

Herb Ley continued that practice, but he added one additional practice. At 8:00 or 8:30 every morning, he had a meeting with the deputy commissioner, the associate commissioner for compliance, who was Ken Kirk . . . It was Rankin and Kirk; Danny Banes, who was the associate commissioner for science; the assistant

commissioner for public communications, who replaced Ted Cron, and I don't remember his name. He worked with Bob in legislation for a while, but I've forgotten his name. I remember he had been on Congressman Gil Conte's staff. Mickey Moure, was the assistant commissioner for administration, and myself. I think that's seven, because I remember we considered we were the top seven every morning. We discussed what had happened the day before, and what was anticipated for that day, and this kept Dr. Ley as commissioner on top of everything.

Dr. Ley announced at one of these meetings--this would have been the beginning of '69--that he had been criticized for sending a memo to the secretary without notifying CPEHS. It was suggested that he carbon copy CPEHS in the future. The next time he did that he was told that anything going to the secretary should go through CPEHS, through Administrator C. C. (Charles) Johnson. The original thought behind the creation of CPEHS was as a coordinating body for various parts of the Public Health Service: air control, water control, product safety, and the Food and Drug Administration.

RT: In the earlier formation stages of CPEHS, wasn't Dr. Goddard supportive of the development of that organization?

PP: Dr. Goddard was the motivating force behind it. I think his original idea was a little more expansive than what resulted in CPEHS, but he was pushing CPEHS. And we had discussed before he left, when we thought he was going to be the administrator of CPEHS, what some of his plans were. It was strictly to be coordinating. After the Republicans came in, C. C. Johnson decided to make it a line operation, and that's where the trouble started. The line operation concept related to this correspondence situation, which I'm describing. He was to send memos to Johnson . . . He was to send memos to the secretary through Johnson, which would mean that Johnson had to sign off on it before it got to the secretary.

One such memo dealt with a drug product recall. I believe Upjohn was the company; I don't remember the product. That memo followed the path that I understand C. C. Johnson followed constantly. Anything that came to him, he referred to a committee to look at and then get back to him. That memo was out to a committee when representatives of the Upjohn company who knew about the recall and possibly seizure--I'm not sure if it was one or both--but the information was conveyed to them through the district office. Whether it was formal or informal, I don't remember. But they went to see secretary Finch. Secretary Finch, not having been given the whole story, said there would be no recall.

This hit the newspapers, and there was a hearing called by Ben Rosenthal, who was chairman of the House Consumer Committee of, I guess, Government Ops (Consumer Subcommittee of the Committee on Government Operations). His staff director was a fellow named Peter Barash, who by this time I had gotten to know quite well.

During the hearing when Dr. Ley laid out this chronology of events of his memo to the secretary through the administrator and what evidently happened to it. Because the memo never got to the secretary, Ben Rosenthal said to Dr. Ley and the group at the hearing, "Maybe we should take the Food and Drug Administration out from under CPEHS. I was sitting directly behind Dr. Ley, who was at the witness table. I was in the first row of chairs sitting on the end. Behind me were seven or eight people from CPEHS Administrator Johnson's office.

When the hearing was over, Congressman Rosenthal left the table--this was a small hearing room, not one of the ornate hearing rooms--came walking down the aisle past the seat where I was sitting, he put his hand on my shoulder and said, "I guess I told them the right way, didn't I, Paul?" And he continued out of the room. All of the CPEHS people sitting behind me heard that. Of course, I was blamed for setting this up.

Another incident came up with the administrator, C. C. Johnson. The Kinslow Report, which I know you have heard about, appeared on the Hill. I was at a

luncheon for my secretary. This was when Mary was retiring if you recall, Bob, and we had a luncheon over at the . . . Was it the Black Steer?

RT: This was Mary Wright.

PP: For Mary Wright. That's right. When Mary Wright retired, we were at a luncheon, and I got a phone call from the commissioner's office that I was wanted immediately in C. C. Johnson's office. When I asked who else would be there, she said the commissioner, the assistant commissioner for public communications, and possibly Rankin and Kirk. I don't remember now.

When I got there, we went in. The first thing C. C. Johnson said, "How did this report get on the Hill?" My response was, "I gave it to them." I got a telephone call from Peter Barash, who was with Congressman Rosenthal when somebody from UPI asked him about the Kinslow Report, which had not been released because it was only a draft. Peter said that Rosenthal told him, "Call the secretary and get me a copy of that report," and I (Peter) said, "I'll call Paul Pumpian. He should be able to get it for us." Rosenthal said, "Fine." Peter called me, and I gave him a copy.

That, of course, did not sit well with C. C. Johnson. That, plus a couple of personal problems I had beginning in January and February of 1969, with the gentleman who was brought in to head the legislative unit in CPEHS . . . His name was Meyer. I've forgotten his first name, but he was a retired colonel, as I understood it had an honorary doctorate from a school that he got the air force to fund, and I think the school was in Chicago.

When Colonel Meyer first became legislative director, I, of course, went over to meet him, and he said he wanted me to take him up on the Hill and introduce him to all of my contacts. I said, "Fine," but I just never got around to doing it.

Then one day he called my counterparts from all the units that were under the CPEHS umbrella, and when we went to the meeting, he said he was setting up sort of a legislative council, and he made me the secretary of the council, which I

understood to be a ploy to get to know my contacts. Bob, you may remember that I attended the first meeting, but I sent you to the subsequent meetings. Because of my responsibilities for federal-state relations and international affairs, I was just really too busy to attend the subsequent meetings that CPEHS held.

What CPEHS was doing then was replacing what had been occurring under the Johnson Administration when the assistant secretary for legislation, Ralph Huett, used to have all the congressional people within his department come together. CPEHS, of course, was just having those within the Public Health Service come together.

Dr. Meyers later said to me, "I want you to let me know when you go up on the Hill," which was perfectly OK. And I used to tell him I was going up for this or going up for that. One day, I forgot to tell him. I was in Paul Rogers' office, and I remembered I forgot to tell him. So I called him, and I said, "I'm going to be talking to Paul Rogers," and he said to me, "Well, fine. Stop by, and we'll go up together." I said, "Well, gee, I'm already up here." And he hung up.

Later in my office I got a call. He says, "I don't want you to leave your office to go up on the Hill without telling me." I said, "OK." Not too long thereafter, Senator Nelson's office called, and he wanted something that was rather bulky, and the call was like five minutes to 5:00, and I was getting ready to leave. So I said rather than going to the expense of sending a messenger, I would take it up.

So I took it up to Senator Nelson's office. I didn't see him. I just dropped the package off and left. When I got on the elevator, I ran into Creed Black, who was then assistant secretary for legislation for the Department of Health, Education and Welfare. With him was a person he introduced me to as a dentist who was going to become the deputy assistant secretary for legislation for health matters. Creed Black and I were friendly. We had some mutual friends, and I'd met with him on several occasions.

About a week later I got a phone call from Colonel Meyer. "How come you're going up on the Hill when I told you to call me before you go up there?" It

turns out that he said to the dentist he wanted to introduce him to me, and the dentist says, "Well, I already met him. Creed Black introduced us on an elevator at the Senate Office Building." Well, of course, Meyers didn't know I had been over at the Senate Office Building, so this caused some problems.

RT: Who was this dentist now that was . . . ?

PP: He was a young dentist who was going to be deputy assistant secretary of legislation for health matters.

RT: I wondered if you recall his name?

PP: No, I don't. You'll have to go back and look in early '69. Do you want to stop?

RT: Just a minute.

(Interruption)

PP: This was all going on at the beginning of '69, in addition to which I was getting requests for information, for the same information, from the CPEHS legislative staff, from the CPEHS Federal-State Relations staff, from the CPEHS International Affairs staff.

Now it's true, I understood why, but when I would say . . . I would do the original . . . The first inquiry I would complete, and then I would say to the second and third, refer to so-and-so. Well, I caught holy hell for that. They wanted me to complete all three inquiries. I said, "Well, maybe I'll just xerox one and send it . . ." But that didn't work either.

To make a long story short, I was getting pretty fed up with CPEHS, and at the same, I was being pressured to come back to Milwaukee to accept a position with a company that was furnishing prescription drugs to nursing homes, which at the time was very much of a pioneering effort and something in which I had some experience as secretary of the Wisconsin Board of Pharmacy.

With all of this as a background, when I addressed the Food and Drug Law Bar at their luncheon at the American Bar Association in Dallas in 1969, I made up my mind to blast CPEHS and tell everybody what's actually going on, which I did.

RT: I think Mr. Rankin made a very critical speech about the CPEHS too?

PP: He did that months before at the Food and Drug Law Institute. But his speech was a visionary-type thing. He was predicting what he thought was going to be because of the structure. My speech was what had been going on, which was really confirming what Rankin had visualized as a possibility. Because the first six months--when Rankin gave his speech in '68, it was in November or December--things were still fairly good because Secretary Cohen was still there. He hadn't left yet. C. C. Johnson hadn't really grabbed hold of things yet. He was still on the learning curve. And because Cohen and the Democrats were still in, they didn't really change the commissioner's relationship with the secretary.

But it changed rapidly after Nixon was inaugurated. Because of all of the problems that I have heretofore recited with Colonel Meyers, with C. C. Johnson, and with what was turning out to be one crappy operation, I decided to give that address at the American Bar Association.

RT: Now your description of it being a crappy operation . . . Are you suggesting that it was getting more and more difficult for the Food and Drug Administration to reach the secretary or to take actions independent of a lot of interference?

PP: Right. Well, CPEHS was making itself a line operation instead of a coordinating operation, which meant that everything the Food and Drug Administration wanted to do had to go through CPEHS, and everything they'd ever take to Johnson, he'd refer to a committee. So it added literally weeks and possibly months to any action FDA had to take. And, as you know, FDA had to act immediately. You know, when you've got a seizure or when you've got a recall, you can't wait around for a dozen committees to study the situation.

I laid all of this out in my speech. I remember Tommy Austern from Covington & Burlington getting up and saying, "Please keep this confidential. If it gets out, Mr. Pumpian's job will be in jeopardy." Well, it did get out. It was published in the Pink Sheet, and I think I can give you a citation.

RT: Maybe that would again be a good appendix to your statement if you would make it available for copying.

PP: All right. Here it is. "FDA's Pumpian Attacks Submerging Under CPEHS in Speech to Lawyers."

RT: And that was Pink Sheet of what date, Paul?

PP: August 18, 1969. And I gave the speech on August 13. It says, "Departing from his prepared text, Pumpian voiced strong criticism of FDA's being submerges in the Consumer Protection and Environment Health Services." OK, I'll get a photocopy of that for you.

RT: That would be great.

PP: Maybe we ought to stop there.

RT: I think we should perhaps for the moment.

PP: I can continue later on subsequent events to this. But this is a good place to break.

RT: Agreed.

(Interruption)

RT: OK. We're resuming now, Paul.

PP: I came back to Washington after that Dallas speech and found on my desk a memo from Rankin saying, "What did you say and why did you say it?" And, basically--and I don't have a copy of the memo--what I wrote was that I was sick and tired of the Food and Drug Administration being blamed for matters that were not their fault; that the fault was with CPEHS.

About a week later, I was scheduled to address the Federal Bar Association on medical device legislation which was one of my primary responsibilities, getting some medical device legislation through Congress. Up until this point, I was merely working with the industry trying to develop support.

Anyway, you might recall that you picked me up here, because you were going to take me to the airport. But we stopped by the office, and I had my suitcases in your car, and I went up to the office for about an hour, because I had an 11:30 plane to catch to go to Florida for the Federal Bar Association meeting.

While I'm in my office, Herb Ley came in and said he just left the administrator's office, and I am not to make any more speeches on behalf of the Food and Drug Administration. So I said to Ley, "Well, maybe I should go at my own expense." He said, "Well, that's your business." "Well, then maybe I should call

them and tell them why I'm not coming." So my decision was I called Ed Byerly. I don't know if you remember him.

RT: Yes, I do.

PP: But he was the chairman of the program, and he had been present in Dallas when I made the speech. He was in Florida. I told him that I was not going to be permitted to make the speech, even though all I was going to talk about was medical device legislation; I wasn't going to say anything about CPEHS. And he says, "What can we do for you?" I said, "Well, just don't say anything until I'm supposed to appear on the program."

(Interruption)

RT: All right, Paul. I think it's ready to continue.

PP: I'm refreshing my memory as to dates. *Food Chemical News* of September 8, 1969, indicates or reported about my being muzzled, that I can no longer speak for FDA. As the article said, I would be unable to speak for FDA until my remarks to the American Bar Association were explained more fully to CPEHS administrator Johnson.

Shortly after that, Herb Ley came in, and it seemed that whenever he had meetings over at the administrator's office, one of the first places he headed for when he got back was my office to tell me that he was conveying a message from Johnson about something. This time he came, and he told me that he had been ordered to take me out of the legislative position.

We talked about what I might do. He mentioned possibly going to Chicago as a district director, and I didn't think that was right, because it wouldn't be fair to

the people up there--or the regional director rather--if I was only going to be there for a short while. Because I told him that I thought I was going to leave. I had been offered an opportunity in Milwaukee that I had been considering for several months, and decided after this flap with CPEHS, which I was sure could not get any better, that I would leave. So Ley asked me for a suggestion, and I said let me look at the way that the FDA can work with the National Association of Boards of Pharmacy, because one of the things I had been involved with in the recent past at FDA was trying to obtain for the Boards of Pharmacy the same financial support that the state health departments and agriculture departments were getting for doing inspections that were FDA's responsibilities.

RT: You're speaking then of the state contract program?

PP: Right, right. And I felt that should be expanded to the Boards of Pharmacy. I thought that the time was very good for such expansion, because the president of the National Association of Boards of Pharmacy was Redfield Bryant from Louisiana, who was very close to Russell Long. Russell Long at the time was chairman of the Senate Finance Committee. That was another story, but we were looking into that.

So my assignment for my remaining days at FDA was to develop that program, which I did, only I did it much faster than I expected to and found that I was finished about October 10.

I left . . . I took some accumulated leave and left in October to go back to Milwaukee, and the date of my resignation was November 30, and on December 10 it was announced that CPEHS would be abolished. So I left ten days too soon.

(Interruption)

PP: Should I make reference to the fact that I read this?

RT: Yes.

PP: When I read the transcript of Maurice Kinslow's comments where he said when the agency thought about the drug abuse control amendments passed in 1965, he mentioned that Mr. Larrick proposed the setting up of a separate bureau, because he recognized the fact that the area of responsibility could be taken away from Food and Drug. And I think that was a very, very astute observation, because what happened when I was handling legislation, Dr. Goddard said to me one day, "You know, I'd like to get rid of the Bureau of Drug Abuse Control." He was very concerned about the reaction to agents being killed. He was also concerned that the Food and Drug Administration should be more of a scientific agency, rather than one going on the street and fighting drug abuse.

So I mentioned to him that I had been a participant in President Kennedy's White House Conference on Narcotic and Drug Abuse and was later a consultant to Dean Markham, who at the time was special assistant to President Kennedy for drug abuse, and that we had recommended that these functions be in the Justice Department.

Commissioner Goddard asked me to write a memo to that effect. He passed the memo up to Assistant Secretary Ralph Huitt, who was assistant secretary for legislation. He passed it on to the White House, and a reorganization plan came from the president merging the Bureau of Drug Abuse Control (BDAC) and the Bureau of Narcotics to form the Bureau of Narcotics and Dangerous Drugs (BNDD). That responsibility moved from the Food and Drug Administration to the Justice Department when this merger or reorganization plan was completed.

Ramsey Clark, who was then attorney general, appointed later a director of the Bureau of Narcotics and Dangerous Drugs. This was a forerunner to the Drug Enforcement Administration, which currently exists.

RT: What happened to John Finlator at that point?

PP: John Finlator became an associate director of the Bureau of Narcotics and Dangerous Drugs, and Commissioner Henry Giordamo became the other associate director. One was for Dangerous Drugs; one was for Narcotics. They were still operating or functioning as two separate entities for all intents and purposes until a bureau director was appointed. Then they started merging functions. But if I recall correctly, the BDAC (Bureau of Drug Abuse Control) portion of BNDD was still housed in the FDA building until Ingersoll was named as director of the BNDD. Then they moved to Fourteenth and "I" in the district. But I'm not sure of the exact dates, but it was sometime in '68.

RT: Most of the FDA BDAC personnel, of course, went over to the new organization.

PP: Right, right. There were a lot of FDAers, but many of the BDAC personnel had come from the FBI, from the Bureau of Narcotics, and from the Labor Department investigators force.

RT: My point was to mention that some of those people then returned to the FDA, a few people did.

PP: Yes, I think a few people did come back to FDA. And if I recall, one of them even went down to EPA--a fellow by the name of Russell, if I remember correctly.

RT: I think some of those that returned apparently felt that some of the other more police-oriented personnel were probably better equipped.

PP: They were better equipped to handle it. That's true.

There was a very interesting mix of people. I know our district directors, some were former FBI people, some were state narcotic people, some were from

Labor, and we had some Food and Drug people who were . . . Charley Karadimos out in California was a Food and Drug person.

RT: And you're speaking now of the people that staffed the BDAC.

PP: BDAC, right.

A fellow in Chicago was an FBI person. Baltimore was a Justice Department person, Jack Bologna. He had investigated labor unions.

RT: And John Finlator, who headed up BDAC, had come from was it GSA?

PP: He came from GSA. He was a manager. He taught executive management at I think George Washington or Georgetown University. He was a "cracker jack" manager. He told me, "I don't know anything about drugs, and I don't know anything about the law, but I'll learn; but I'm a manager." We organized on February 14, which was when I came on board, and Finlator came on just about the same time. By June, I think we had nine district BDAC offices operating, with automobiles and guns and radios and making cases, and that was unheard of in the federal government for anybody to move that fast. He was a "cracker jack," a fine gentleman, and a good manager.

Bill Coon, who was his executive officer, who had come with him from GSA, was very good, too. They both were able to get things done. I remember that probably the worst thing that happened in the time I was involved with FDA was when one of the agents got shot, and this was one of the things that convinced Goddard that he wanted to move out BDAC. Since it was already a self-contained unit, it became a very easy thing to do, and President Johnson's reorganization plan just merged BDAC and the Bureau of Narcotics.

A very interesting sideline was that the commissioner of Narcotics did not want the merger, because he in effect was losing stature. He had worked with Hale

Boggs in the House as a staff person on one of the committees that Hale Boggs was on. So Boggs introduced a resolution to the Congress to overturn the reorganization order.

RT: Now, Boggs, was he in the House of Representatives?

PP: The House of Representatives, yes. If the president introduces a reorganization order, it can be rejected by majority vote in either house, either the Senate or the House. I remember being in the gallery the day that this was voted on in the House, a vote that was considered to be extremely close. I may be mistaken, but my recollection of the vote was something like 200 to 211. The resolution failed; therefore, the reorganization went through.

Then, of course, I was really not privy to what was going on subsequent to that. There was no director appointed for months. Both Finlator and Giordamo went to the attorney general's staff meetings until an appointment was made in April or May of '68. The word was that Attorney General Ramsey Clark was going to let the BNDD continue to function under Finlator and Giordamo.

As I told you, Ramsey Clark had given a story out to the press in which three potential directors or three people were being considered for the director's position, and I was one of the three he named. Dr. Goddard, in response to a request from Ramsey Clark for the name of a young, scientifically-trained person with law enforcement and investigative experience was what he was looking for to head up BNDD, and Goddard asked me if I was interested because I fit those qualifications. And I said, "Yes." So he submitted my name, and Ramsey Clark mentioned to me one night that I was one of the three being considered. He had given this story out to Les Whitten, who was at the time writing for the Hearst papers, and later or I think prior to that had been working with Jack Anderson.

I might mention that I knew Ramsey Clark because I was president of the Wisconsin Chapter of the Federal Bar Association when Ramsey Clark was national president, and I knew him through the Federal Bar connection.

Anyway, he did not appoint a director for a while, and then when he said he was not going to appoint one, it looked like there was not going to be a director appointed, and naturally, I was disappointed. But, ultimately, he appointed Ingersoll, who was a graduate of the University of California at Berkeley College of Criminology, and was a police captain I think in Charlotte, South Carolina, but I'm not sure. But he was a street cop. He had street cop training and had been brought to Washington initially to work on the Law Enforcement Assistance Administration legislation. But when the White House wanted that position filled, Ramsey Clark offered it to him.

Ultimately BNDD it went through several modifications, but it's now part of the Drug Enforcement Administration. From what I currently read in the papers, it looks like the DEA is really being taken over and controlled by the FBI which was something they did not want to have back in the sixties. They wanted the drug component to be separate from the FBI, because it was a different type of operation. It was an undercover type of operation, as opposed to an investigative operation. But now I guess they're kind of merging their functions. But I'm really not equipped to speak on it now, because I've been away from it for so long.

But I thought you might be interested in that history of getting BDAC into FDA then out of FDA, and it had been mentioned by Maurice Kinslow.

RT: Now, perhaps this would be a perfect time to fall back a little bit with regard to some of the functions and activities of other components of the Office of Legislative and Governmental Services. With regard to the International Affairs Unit, were there any particular international food and drug problems?

PP: Yes. There was a very interesting situation. When I took over, which I think was December of '67 or January of '68, the first problem I had to confront was a problem with the Swiss. The president I think of Geigy, but I'm not sure, had visited with President Johnson and said he was having trouble shipping or sending to the United States bulk drugs to be encapsulated at their plant here in the United States and sold to the consumer here in the U.S. The trouble was that the Food and Drug laws stated that no drugs should be imported into the U.S. unless the plant had been inspected by FDA inspectors, which I think is still the law. I'm not sure, but I think it is.

In most countries, it was no problem, because the FDA inspectors would visit the foreign plants and make an inspection. In Switzerland, the cantons, which are their states, are very independent, and it's a very strong canton-rights government there. As a result, the cantons would not permit the federal government to inspect their plants. In order to be able to produce drugs there, the plants had to be inspected; each canton employed a professor of chemistry, I believe he was, from one of the universities to do the inspections. But he did all the inspections. He inspected each canton. It was not a different inspector for each canton.

RT: You mentioned that the federal government was not permitted to inspect them. Do you mean the federal government of Switzerland?

PP: Right, of Switzerland. And since the federal government of Switzerland couldn't do it, the federal government of the U.S. wasn't going to be permitted to do so. This was all explained to me in a number of meetings that I had with the Swiss embassy people. Basically, the economic attaché and the general counsel, who was a very intelligent woman, who had been involved in the Nuremberg trials as a prosecutor for the allies. She was now in this country as the general counsel for the Swiss Embassy.

In order for the Swiss company to ship drugs to the United States, there had to be a way developed to permit FDA inspectors to visit those plants. Since the cantons would not permit Swiss federal inspectors in, they were not going to permit U.S. inspectors in.

So I suggested to the commissioner a way that I thought could correct the situation as far as we were concerned. The suggestion was that a Food and Drug inspector go along with the professor just to see what he was doing and to evaluate his inspection. Not to inspect the plant, but to evaluate the inspection by this professor. And as I said to the commissioner, if he sees what he's doing, and he's there, he's not going to blindfold himself to what he sees. He's also going to be inspecting. He won't write reports. When he leaves, he can say everything is OK. But our problem at this point in time was just the Geigy plant, because that's what the White House was interested in resolving.

So the commissioner said it sounded OK to him; I should bounce it off the general counsel, Billy Goodrich. He wasn't against it, but he didn't come out fully for it. He says, "See what you can do with the Swiss government." So I went to meet with the general counsel of the Swiss embassy, and I laid this out for her, and she thought it had merit. So we drafted an agreement which took a month or so, because it had to go back to the Swiss government and come back and so forth.

Then the final agreement had to be sent to the State Department. After it cleared FDA, including Billy Goodrich and everybody else, I sent it to the State Department, and six months later it came back with one word changed, and that's how Ciba or Geigy of Switzerland was able to ship bulk supplies of drugs into the U.S. and have them put into dosage forms here.

Of course, the same principle applied to every plant that the FDA inspector examined. I think I suggested they change the name, take it from inspector to representative, who was evaluating it. Whether that is still the situation or not over there I don't know, but it worked, at least to resolve that particular problem. As a result of that experience, I realized that there's a lot that Food and Drug people do

not know about these foreign governments, and certainly the foreign governments do not know about the Food and Drug Administration.

So I proposed a program, a seminar for . . . I called it the "FDA Embassy Diplomatic Corps Briefing," and it was held on Wednesday, April 17, 1968, in the east auditorium of the Department of State. That program admitted only accredited representatives of the various embassies, plus, of course, the Food and Drug officials. We even had a pass issued for the briefing, which I was pleased to assign or authorize as director of the Office of International Affairs.

At this briefing, we had a morning and an afternoon session. The objective was to acquaint foreign embassy personnel with the organization, jurisdiction, and function of the U.S. Food and Drug Administration. I was presiding as acting director of the Office of International Affairs and the director of the Office of Legislative and Governmental Services. I made the introduction; Joe Greenwald, the deputy assistant secretary of state welcomed the participants; and what I considered as a coup personally, remarks were made by the secretary to the Department of Health, Education and Welfare, Wilbur Cohen. We convinced him that this was important enough for him to participate in the program. Dr. Goddard gave an overview of FDA. Harold O'Keefe, who was the assistant director in the Office of International Affairs, discussed the U.S. Food, Drug and Cosmetic Act. In the afternoon, we had district operations discussed.

Here's the program. You can look at it. Excuse me a minute.

(Interruption)

PP: In the afternoon, we had FDA district operations discussed by Harris Kenyon, who was the assistant commissioner for field coordination. We had sanitation discussed by William Eisenberg, who was chief of the Microanalytical Branch, in the Division of Microbiology, in the Bureau of Science. We had bacterial contamination discussed by Joe Olson, who was director of the Division of Microbiology in the

Bureau of Science. We had Walter Moses, chief of the Food Case Branch and the Bureau of Regulatory Compliance, discuss import foods. And Ted Byers, director of the Division of Case Guidance in the Bureau of Regulatory Compliance, discussed import drugs. We also had the Ken Taylor, who was in the Office of International Affairs, discuss how FDA can help you, meaning the embassy personnel who were interested in getting drugs into the United States.

This program was so successful that the embassy people asked that additional programs be put on for their consulate offices around the country, and the first one was put on in New York City. I think there were others, but I don't recall exactly where. But I do remember New York City putting on the program, because I got calls from the consulate people in New York who were very happy about the fact that such a program would be given.

(Interruption)

PP: Food and Drug officials of Central America and Panama had a meeting in San Salvador in the country of El Salvador. I was invited to speak about the Food and Drug Administration, because at that particular time there were some problems with importing meat from South America, primarily Argentina, because of pesticide residues. I remember having to deal with Argentina officials on that issue. This was a very interesting opportunity for me to go down and talk about the Food and Drug Administration. I had a member of my staff who spoke Spanish translate an English speech that I had prepared to talk about FDA. He translated it from English into Spanish, and then he had it typed up in Spanish phonetically for me. I forgot the name of the gentleman, but he was a Ph.D. He was a tall, thin fellow. You may remember, Bob.

RT: Doctor Muriel Morris.

(Interruption)

PP: So I went down. I flew down, and I was giving this speech phonetically. And I have given a number of speeches in my lifetime prior to that point and subsequently also, and I can usually tell when the speech is a dud, and it was a dud. I wasn't coming through. But I wasn't speaking in English. I was pronouncing the words phonetically in Spanish. There was with me a Food and Drug official who spent time in South America. I've forgotten his name. He said, "Paul, I think you're killing these guys." I said, "Well, do they understand English?" He says, "They don't speak English too well, but they understand it." So I stopped. I was through maybe the first page of the speech, and I apologized to them for my aborted attempt to address them in their language. I said, "So now I'm going to start over and try it in English." Well, that went over much better. They did understand it.

It went over so well, and we had such nice conversations afterward, although I found it very difficult to understand them, there were translations, that they invited me to go out to dinner with them that night. So I joined them, and the fellow from Food and Drug was with us, and all of these foreign officials. We went out eating and drinking that night. Now, I'm not a heavy drinker, but I had a few of whatever the native drinks were. We went back to the hotel. About 1:00 or 2:00 in the morning, I woke up and I saw the chandelier swinging. I was a little concerned about what I had eaten or had to drink. The next morning I was actually relieved to learn that we had an earthquake that night, and that's what caused the chandeliers to swing.

But it was an interesting trip. I enjoyed meeting those officials. It was interesting seeing the population, the very rich and the very poor and nobody in between, which reminded me of the week I had spent in Havana some years before. I didn't get to make any other trips for the international side of my activities. I had lots of embassy activity. As I mentioned before, the Food and Drug Administration stopped the shipment of beef from Argentina because of a . . . I'm not sure if it was

a pesticide or an antibiotic residue. But, anyway, we had to use a gas chromatograph to determine this residue. Then the beef was detained at the docks. This led to a delegation from Argentina of ranchers, government officials, meat packers, which is very interesting. We had luncheon at the Argentine embassy and then had a party at the embassy that night. But the sum and substance of it was that we recommended that the world health organizations make available to these countries gas chromatography so that they could determine before they shipped the beef whether it would be acceptable into the U.S.

So the Argentine situation, and the Swiss situation, and the speech in Central America were my big international activities that I can remember. I met with many, many embassy officials over the period of time and attended lots of embassy receptions.

But I will say this, attendance at the embassy receptions was very helpful, because many congressmen and staff attended those receptions, and it gave me an additional opportunity to socialize with the people from the Hill in a non-advocacy position, because we didn't talk business; we were just socializing. So that was one of the reasons I thought . . . And I do consider that I was successful with the legislative activity at Food and Drug, because when I retired, the Pink Sheet said that FDA had never had better congressional relations than they had during the time that I was there. And that can be found in the Pink Sheets.

RT: Now, I think in recalling the earlier remarks during our interview, the impression seemed to be that during the Goddard era, the Hill, Congress didn't call the agency over as frequently for oversight hearings as had occurred earlier or perhaps occurred later during Dr. Ley's tenure as a commissioner. If that be the case, what would you attribute to the increase in the hearings under the Ley administration as compared to the Goddard years?

PP: Well, I can only speak to the second half of the Goddard years. He came in January or February of '66, about the same time that I got there, but I was in BDAC and he, of course, was the commissioner. So I had very little to do . . . In fact, I had nothing to do with his Hill appearances and activities. The second half of his tenure, actually the second year and a half, I was involved in legislation. He had hearings basically as a result of comments that he made, like preferring his daughter to smoke marijuana rather than drink martinis and the drug store issue. There were a couple of drug hearings on the effects of marijuana. Senator Nelson had hearings. And I forgot the name of the Parke-Davis drug which caused blood dyscrasia when used for arthritis. But there were rather extensive hearings on that.

One thing I personally, very personally, got involved in was a hearing on whole fish protein concentrate, which was a product authorized or approved or permitted to be marketed by the Food and Drug Administration under Commissioner Larrick. What it provided was that the concentrate could not be sold in packages larger than one pound in size, the purpose being that it would discourage commercial bakeries or the use of this in bread commercially. Somehow that got up to the Hill, and they wanted to look into it.

Goddard was not familiar with the subject. Both Kirk and Rankin had both been personally involved in it and didn't feel it would be appropriate for them to be testifying. So the three of them turned to me and said, "You're it." So I had to become an expert on whole fish protein concentrate in a very short period of time and went before the committee, which was a House Subcommittee of Interstate and Foreign Commerce, and the subcommittee was chaired by John Dingell.

It was a very interesting experience, and I'm pleased to say I survived it. I, of course, had with me a technical person from the Bureau of Foods, but my recollection is they didn't get to questioning him, because I was being questioned quite severely when a vote was called. So John Dingell asked the committee members, "If there were no more questions of Mr. Pumpian, we shall adjourn the hearing." So I got the brunt of it, but it wasn't too bad. I remember a congressman

from Minneapolis, Frazier, who later became mayor of Minneapolis, was the one who was questioning me most closely. But that might be because Pillsbury is out there.

Some of the hearings you're asking for . . . We had hearings on DMSO, as I recall. There were oversight hearings on it, and then there was legislation introduced by a congressman from Oregon, whose name I can't recall. Are you familiar with DMSO? DMSO is a byproduct of paint or something, but it's a product that can be absorbed into the system if you rub it on the skin. There was a possibility of it being used as a vehicle for drugs. I remember when I was in BDAC, there was great concern that they were going to mix LSD with DMSO and try to introduce it into people unknowingly.

But as far as any big issues . . . The Parke-Davis drug for arthritis, the DMSO . . . Many issues that could have resulted in a hearing did not, because we were able to resolve them.

I remember once getting a call from a congressional office that a constituent suffering from Parkinson's wanted to get hold of L-Dopa. Evidently the patient was in pretty bad shape, and the individual was very close to the congressman's staff. I was able to contact the medical director of the pharmaceutical company who was manufacturing it and put him in touch with the patient's doctor, and they arranged for qualifying the physician for clinical evaluations who was able to get the drug to the patient, for which the congressman's office was most thankful. But I found it easier to do that than to tell them it can't be done. And you make a lot of points that way.

I had another situation where a clinical evaluator was found by the FDA inspector to not be properly recording data for an investigation. The Bureau of Medicine or Drugs or whatever it was called at the time advised the physician he was going to be suspended as an investigator. I then got a call from a congressman that wanted me to come to discuss this matter with him. When I got there, there was the physician, his attorney, and the congressman. It turned out that he was an evaluator for a medical school who was working under a very substantial grant from the

pharmaceutical company whose product was being evaluated, and this was like in March or April. If this man had been disqualified, the school would not have received the grant for the following academic year which could have disastrous results for the medical school.

But I was under orders: under no way could this man be continued as an investigator. That was the position that I took. We argued back and forth listening to the physician say, well, he dropped the notes in a puddle of water and smeared the notes, and he tried to recreate them. What had happened is that one of the dates that he'd put in as evaluating a patient, the inspector knew that he was giving a speech out of the city, and that's what caused the whole investigation.

To make a long story short, the news of dropping the investigator went out thirty days later, but after the company had agreed to give the grant to the college for the forthcoming year. So the school benefitted, I think the company benefitted, and the doctor did not benefit. Again, it was a situation of trying to apply common sense to a situation rather than using a hard-and-fast rule, and I think everybody came out of that OK.

A very funny situation happened once. In New York City, Weems Clevenger, who was then district director of the New York office, initiated a telephone . . . I don't know if it could be called a hotline, but an information line. People could call this number in New York and get a message about what was going on with Food and Drug. One message had to do with pulling a drug off the market which was not ready . . . I think it was a cardiac medication and there was some part, some batches that I guess had to be recalled. But the message was all-encompassing, and many, many people thought that they were having a problem with the drug, and if they were taking it, they were concerned.

And it even reached Philadelphia. Well, the pharmacists in Philadelphia were trying to get information, and they found out that people should not stop taking the drug, because it was dangerous to do so, and they complained to the secretary of the Philadelphia Pharmaceutical Association that patients were being frightened

needlessly. That secretary contacted his congressman, who was a close personal friend of his. That congressman wrote to the commissioner.

Of course, I got the letter as head of OLGS, because all correspondence from the Hill and the White House came from my office to be handled on behalf of the commissioner. Of course, if anything was so important that I felt the commissioner should know about, I would advise him. But, generally, we handled most of these matters without going through the commissioner since the letters went out over my signature.

So I checked into this matter and straightened it out, and I called the congressman and told him it had all been taken care of. So he said, "Fine. Send me a letter to that effect." I said, "Fine. I'll have one prepared." He says, "Well, I'd like to have it tomorrow, because I'm going back to Philadelphia," and tomorrow was Thursday. So in this particular case, I dictated the letter myself, because I was familiar with the facts. I put a paragraph in the letter to the congressman that I could understand the problem being a pharmacist myself and being involved with the public, and I sent the letter over to him to take to Philadelphia with him. I had even offered to call the secretary of the pharmaceutical association, but he said no, he wanted the letter, because the secretary was a friend of his.

The next day I got a telephone call from the Hill from somebody not remotely associated with the congressman who said, "I didn't know you were a pharmacist." I said, "Well, what made you call me now?" He said, "Well, it's in the congressional record." The congressman published my letter in the congressional record, and, of course, that paragraph about being a pharmacist. So I then decided I would never put into a letter to the Hill anything that I did not want to see in the congressional record.

RT: That was probably very prudent.

PP: It was a great experience. I really enjoyed it up until the beginning of 1969 when the CPEHS people decided they wanted to take over everything.

RT: Now, keeping in line with what I most recently asked you, as far as the federal-state relations segment of this combined OLGS unit, were there any particular things other than the contracts, state contracts, that you wanted to mention?

PP: We had state inspector schools which had been functioning. I mean, I didn't originate that.

RT: Yes, those really began way back in about 1965.

PP: Right. Which I felt were very good, because I participated in a couple of them as faculty.

I tried to expand the activity of Food and Drug with the National Association of Boards of Pharmacy. I was a firm believer that the community pharmacy should be off bounds to Food and Drug inspectors, because I felt that was a state operation and that only state inspectors, state Board of Pharmacy inspectors, should go into the pharmacies. Both commissioners I worked for, Goddard and Ley, agreed that there would be very little reason to go into pharmacies on a routine basis. Now, if there was an urgent recall of a product, and they wanted to go into the pharmacies and make sure that the prescription product was recalled, that would be different. But as a routine matter, they were not going into pharmacies.

RT: Well, there was a time in the history of the agency where inspectors frequently went into, or tried to buy, or to see if the pharmacist would sell restricted drugs or controlled drugs without prescriptions.

PP: That was before the creation of BDAC.

RT: That was a prior period.

PP: That's one of the things that led to BDAC, because they were selling drugs, and it was a proper function, but state boards did it too. I remember when I was in Wisconsin. I had my own inspectors, and I used the narcotics squad or the Milwaukee Police Department on occasion for things like that. I guess I was responsible in Wisconsin for the creation of the Narcotic Division of the Milwaukee County Sheriff's Department, because I used Milwaukee city police to go into the county with me on various drug investigations until the chief of police found out about it and told me that they can't do that because of insurance problems since Milwaukee Police Department has no insurance outside the city line. So I went to the sheriff, who had countywide jurisdiction, and he was helpful.

I might indicate there that I used to do a lot of lecturing in high schools about drug abuse, and I found out that the Milwaukee Police Department officers who were lecturing at the high schools really didn't know anything about drugs. They were referring to the amphetamines as narcotics, among other things, and seconal . . . Everything was a narcotic to them. I happened to mention it to the people in the narcotics squad that I worked with, and I found out that most of these talks were being given by the local policemen, not by the narcotics squad. People knew them; they asked them; they thought it was good community relations, which I agree with.

So, anyway, the word got to the police chief about this. So he called me in one day, and Chief Brier was a very gruff guy, and I didn't know what kind of a reaming out he was going to give me. He says, "I hear you're criticizing the lectures my people are giving." I said, "Well, I think there's a lot more about drugs that they need to know." He says, "How about you going on the faculty of the police training school and talk about drugs?" And I thought that was a great idea, so I did.

In 1964 I put on a seminar for Wisconsin police chiefs and sheriffs on Dangerous and Narcotic Drugs and had somebody from the White House, Dean Markham, scheduled to speak. Unfortunately, he didn't make it, so Sam Levine from the Bureau of Narcotics replaced him. But I had speakers from the Bureau of Narcotics, the Chicago regional office, from my office, and we put on the first seminar ever held in the United States for police chiefs and sheriffs on narcotics and dangerous drugs.

This became the prototype for BDAC's sessions around the country. After I came to Washington, I showed the program to Finlator, and he liked it, and we used it. I used to speak to a lot of local enforcement officers on behalf of BDAC when they had, I guess, orientation seminars for the local police around the country. I remember speaking in Hartford, Connecticut, Boston, and Indianapolis, plus I used to lecture the agents in California.

But I had an enjoyable time in my, I guess, three and a half years at the Food and Drug Administration in some very interesting positions and very interesting situations.

RT: Now, of course, we've pretty well covered your Food and Drug career I think at this point. After leaving FDA, I'm aware that you still served in both state and federal government for a time.

PP: Well, I left the FDA and went to Milwaukee in the private sector, and I was in that for a couple of years. I left to become vice president and counsel to Medical Health Industries which was supplying prescription drugs to nursing homes, which was at the time an infant industry; today, it's very, very big. I was with that for a while, then I had an opportunity to start my own business, and I started with a partner, the Langer Medical Supply Company in Milwaukee which provided hospitals, nursing homes and doctors' offices with disposable equipment, plus things like wheelchairs and canes and so forth.

RT: Didn't you go to another board of pharmacy?

PP: Well, that's what I'm about to say. But it was slow taking off, this business, and I happened to be talking to some friends from New Jersey who told me that there was a problem in New Jersey, and they were looking for a Board of Pharmacy secretary, and the people that they talked to all suggested me, because I had known many of these people. When I was working for Squibb in New Jersey, I got to know them, because I was active on the legislative committee of the New Jersey Pharmacists Association. Then when I went to Wisconsin, they were following my career in the trade press. So I thought that since at the time I was negotiating the sale of my business to a company out in New York, I would be much better off being in New Jersey trying to negotiate the sale than I would be in Milwaukee trying to negotiate with the people in New York.

So I took the job with the attorney general's office in New Jersey. In New Jersey, the Board of Pharmacy was part of the Department of Consumer Affairs which was in the attorney general's office, and my immediate boss was Millicent Fenwick, who later became a congresswoman, and then she ran for the Senate and lost to Senator Bill Bradley, and then she was appointed by the president to the . . . Is it OAC, Organization of Agricultural Countries?

RT: Yes. It's a part of the WHO (World Health Organization) organization.

PP: Well, anyway, she was the ambassador to that for a while, and then she later passed away.

RT: Well, how long did you serve in New Jersey before you returned to Washington?

PP: Well, in New Jersey, I was secretary of the Board of Pharmacy from July 1971 to February 1976.

RT: And then you returned . . .

PP: No. In November 1995 I was invited to join Ketchum & Company which was at the time the third largest wholesale drug distributor in the country behind Bergen Brunswick and McKesson & Robbins.

Ketchum & Company had four subsidiaries. They had Ketchum Distributors which was the wholesale operation; they had Ketchum Laboratories which manufactured generic drugs; they had a proprietary division which marketed Propa-pH, which was an acne preparation; and a fourth subsidiary was called Ketchum Marketing Services which provided management and financial services to community and hospital pharmacies. I was asked to join that group as vice president, which I did in February of '76, not knowing that the president had terminal cancer. He died in June, and I was named president in July of '76.

Now, in effect, I was providing services to pharmacies similar to that the Small Business Administration (SBA) provided to small businesses. I was named to the Advisory Council of the Small Business Administration in the New York area and became knowledgeable about the Small Business Administration because of that activity. In 1978 I discovered that SBA was creating an Office of Advocacy, and it intrigued me. I wanted to get back to Washington, especially since at that time I was also made a vice president of Ketchum Distributors for credit management and was sent to Ohio for ten weeks to collect a half million dollars in outstanding receivables.

I decided I didn't want to do that for the rest of my life and made a few phone calls to my friends in Washington and wound up as the assistant chief counsel for environment and health at the Small Business Administration with responsibility for a number of agencies, including the Food and Drug Administration. That responsibility entailed representing small business before those agencies and

monitoring the regulations of those agencies to be sure they complied with the Regulatory Flexibility Act of 1977 or '76, I'm not sure which.

So I got back in contact with the Food and Drug Administration people. One of the things I was pushing, not only FDA but all the agencies, was to appoint individuals as a small business contact within the agency. The Food and Drug Administration, I'm happy to say, had four or five set up. I worked with Minna Golden at FDA, who was kind of coordinating FDA's efforts. I also worked with Bob Wetherell on that, and he told me that he would see what he could do. FDA now has a number of small business contacts spread around the country. Many other agencies do also. EPA was one of my client agencies, and they set up the small business contacts.

What I did was to review all the regulations from the agencies which were in my responsibility to see what kind of an impact they would have on small businesses. One of the things that FDA started to do was their user fees, and I remember filing a brief recommending a reduced user fee for businesses under a certain level, much the same that the patent office had done for small businesses. I guess individual inventors and small businesses were able to get reduced user fees. The generic drug manufacturers opposed the user fees, but the compromise was the smaller amount. I guess that's still in effect, I don't know.

I used to communicate with Nat Geary on a fairly regular basis. He was the industry liaison, I guess, for a while. I went out to FDA a couple of times.

In addition to reviewing regulations, I could assist a small business person having trouble with an agency. We would represent them to get the matter straightened out.

(Interruption)

PP: One case was that of an individual who had a home diagnostic kit for AIDS that he wanted to market. FDA would not consider even evaluating home diagnostic

kits at that time. I made a number of phone calls to FDA but they wouldn't accept his application. They said they wouldn't . . . Well, finally they got to the point of saying they would accept the application and evaluate it, and I guess ultimately they did.

Another case was a manufacturer of generic drugs had a contract to supply government hospitals through GSA. But he couldn't get an FDA inspection that was required before the GSA would approve the contract. I made a couple of phone calls to FDA, and they were very cooperative. It was a matter of scheduling, and nobody knew how important it was. I find that if you explain things to people, that you can usually accomplish what you're trying to accomplish. It's when you bulldoze that you have problems.

I had a situation with EPA where a fellow had developed a paint to keep barnacles off of a boat hull, and, of course, there's a pesticide involved in it, and in order to market that paint, he needed EPA approval. To get EPA approval, he needed documentation from the manufacturer regarding the pesticide or barnaclecide that was in the paint, and the manufacturer of that product, even though he sold it to the paint manufacturer, would not give him the justification unless he paid for it. There was some provision that they could not charge them for it, and that was all in the application.

So when it came to me, the application had been accepted but not reviewed by EPA. It came to me through a regional SBA person out in California. The painter or manufacturer had a representative in Washington, and he came to see me. He told me that EPA told him it would take two months to handle that application, and that his client would lose the GSA contract if he didn't have it in a couple of weeks, because a lot of time had elapsed, and EPA was giving the guy a hard time and so forth.

To make a long story short, I called the EPA and talked to the examiner, and I said that I was somewhat familiar with these types of applications, because we once

had pesticide jurisdiction at FDA. Was it Federal Fungicide and Pesticide Act? FIFRA.

RT: FIFRA.

PP: Federal Insecticide, Fungicide (and Rodenticide) Act.

RT: And Rodenticide Act.

PP: Rodenticide. Anyway, we talked, and I got a call from California the following week that the guy had gotten approval of his application, and I was somewhat surprised. I said, "Well, how come you called me?" He says, "Well, I called to tell you that I called the EPA, and I spoke to the guy handling the application and said I was very pleasantly surprised to have it approved. How come?" He said, "Well, Pumpian said it shouldn't take any more than two weeks."

So that made me feel good, because here was a resolution to a problem that could have gotten very big. When I was at FDA in the congressional office, I had a similar request from a pesticide manufacturer in West Virginia, Elmer Fike. I don't know if that name means anything to you. But I talked to Kenneth Kirk about it, and he was very familiar with Fike. Fike was a manufacturer and had an application pending for a long time at FDA. I went to Kirk, and I said, "What's the procedure on these applications?" So he told me.

So I went down to the unit that was handling it and walked through it to see what happened to the application. And I found, much to my dismay, that when the applications were brought in to the examiner's desk, they were put into his in-basket, and then everything else that came in went on top of it in the in-basket. So there was really no chronological evaluations going on. Well, I raised a little hell about that, and Ken Kirk made known to everybody that they've got to set up a system so that this didn't continue to happen.

Now, why was Elmer Fike so important? Because he was Stanley Fike's brother, and Stanley Fike was the chief of staff to Senator Stuart Symington, and Symington had a lot to do with the Food and Drug Administration in St. Louis, Missouri, because at the time we were talking about closing the district office there. It ultimately became the lab, but both Mrs. Lenore Sullivan and Senator Symington were involved in that little controversy. So I thought it was very important to keep Stanley Fike happy.

The funny part about it is when I went to the Small Business Administration, I was handling Food and Drug matters. What should come across my desk but something from Elmer Fike, and he was well known to the people there, because he used to go to all the small business meetings and raise hell about what the Food and Drug Administration was doing. So I revisited with Elmer Fike on that issue.

There were other matters . . . Let's see . . . I got somewhat involved with the patient package insert (PPI) at the Food and Drug Administration, as it was originally proposed under Jere Goyan's commissionership. The economic analysis done on the impact of using patient package inserts at the wholesaler and retail level, the community pharmacy level, was way, way out of line. They had no concept of the economic impact that requirement would have had on the community pharmacy or even on the drug wholesaler.

One thing I was able to bring to that SBA job was experience with a wholesaler which was Ketchum, because I had been president of one of their divisions, and I was thoroughly familiar with their wholesale distribution system, and I certainly knew retail pharmacy distribution having been a pharmacist working in a pharmacy, and I knew that it would be impossible for either the wholesaler or the practicing pharmacist to handle his patient package inserts in a economically . . . *Feasible* is the word I want . . . It's not really the right word, but it would cost them a fortune. That can be done today like this (snaps fingers) with computers. But in those days, and I'm talking 1979, I guess it is . . .

So I wrote the brief and got the Office of Management and Budget (OMB) to concur with the concept that this was not a practical regulation to impose. There were lots of others against the PPIs. I mean, I was not the only one. The industry was against it, the wholesalers, the manufacturers. Everybody was opposed to it. But I was fortunate enough to be able to get the person at OMB handling this, whose name I've forgotten, to sit down and listen. I described to him how the wholesaler is set up, how the retail pharmacy, the community pharmacy is set up, how the wholesaler can only sell at the prices he sells because of the automation, which would be destroyed if they needed to distribute these patient package inserts which is the only way the pharmacist could get it.

I had some experience with computers in New Jersey, because I instituted the regulation that required the patient profile maintenance in pharmacies in New Jersey. I guess, about a dozen other states are now requiring it. But when I did it, I consulted with a lot of computer people, because they were talking about the possibility of computerizing the pharmacy operations, which you see today in Giant, Safeway, and every other chain pharmacy operation. Because the information that was going to be required on the patient profile would be similar to information on the prescription label and on the prescription itself, and most importantly, on the paper submitted to third-party health programs which paid for the prescription. If you would like a photocopy of an interview I gave to *American Druggists* on this topic, I'll be glad to give it to you.

RT: Well, that might be useful as an appendix.

PP: I was invited all over the country to speak about the patient profile, primarily because thirteen drug chains took me to court to stop the issuance of the regulation requiring it. I talked two of the drug chains into dropping out of the lawsuit, but the other eleven remained in. I proposed that regulation either late '71 or early '72. It

was not approved by the Wisconsin Supreme Court till the middle of '73. Both the governor and the attorney general, as well as Millicent Fenwick, considered it a great consumer victory, and I considered it a great Pumpian victory.

It was something whose time had come, and the people needed it, and frankly, we got the support of the attorney general. He swears that his son's life was saved by his pharmacy having a patient profile and having known that his infant son was allergic to a penicillin preparation. The pharmacist called the doctor, got a new prescription, and told the attorney general's wife. The word I got from the deputy attorney general was, "The boss says we're going to take this up to the Supreme Court, because it saved my son's life." And when he made that statement, I looked into it to see what happened and found out. Many things that the pharmacist does are not relayed to the public, so they don't know about it. But this guy was smart enough to tell the attorney general's wife, and she, of course, told her husband. That patient profile has saved many lives, because it records all the medication, and the pharmacist determines if there are any possible drug-drug interactions.

Now, because of that, the Federal Trade Commission investigated me. They wanted to know from an anti-trust point of view if I was compelling people to go to a particular pharmacy. Well, if the profile is going to work, you should get all your drugs at one pharmacy. If you don't, then you're at risk. But there was no compulsion. All my requirement was that the pharmacy keep the record. Not that the patient go to one pharmacy. I remember spending a half a day with two people from the Federal Trade Commission back in '74 or '75 on this issue. They went to a couple of drug stores first; then they came to see me. Why that ever came up, I don't know. But it was very interesting.

RT: Well, Paul, we certainly have covered a broad spectrum of your experience, your career contributions, in the arena of Food and Drug regulation and consumer protection. As to Food and Drug, your experience was with the two commissioners covered, Doctors Goddard and Ley. Do you have, in summation, any commentary

you'd like to make about the Food and Drug Administration as you view it in retrospect, or as to where it's moving?

PP: Well, I think there were a lot of dedicated public servants there who took a lot of heat from the regulated industries which was totally undeserved. They tried to do a good job. I think that Commissioner Goddard marked a change in the type of leader that the agency had. He was more outgoing, more forceful, and had plenty of guts, because I think he took on the industry, where former commissioners had not.

I think he made a great impact, and it's a shame that he used to shoot from the hip, which caused him not to become administrator of CPEHS, because it could have worked, and I'm sure he would have made it work. He saw it strictly as a coordinator. I guess it would have been looked at as a lower-level assistant secretary of health if you want, which is a coordinator. He would have done a good job, and he would have appreciated FDA's problems, because he had been commissioner of FDA.

Herb Ley was a different type. He was a very quiet, plodding type. He was a good director of the Bureau of Medicine, which he served in before he became commissioner. I think he was more of a detail man than Commissioner Goddard was. He was not as prone to shoot from the hip. In fact, I don't ever recall him shooting from the hip. He was very prone to bend to bureaucratic pressures, which Goddard was not. But I think they were both men of great integrity, and both people who wanted to do a good job. They just had different ways of trying to do the job. I don't think you can say either was right or wrong. You know, it depends on a person's style.

But it was a great experience, and I enjoyed it. I wish I could have stayed longer, but with the heat I was getting from the CPEHS operation and this opportunity to go to Milwaukee to be vice president and counsel of this company was just a little too much. I guess knowing that I had this opportunity to leave to do

something which I knew would be interesting may have prompted my remarks at the American Bar Association in Dallas in an attempt to do something for people who I thought a lot of, and that was Commissioner Ley, and Kirk, and Rankin, because those poor guys were being brow-beaten, and they couldn't fight back. They had long-term investments in their careers, and I didn't, and I had something to go to, which I don't know whether they did or not.

But I remember Roger Egeberg was the assistant secretary for health of HEW at the time Edwards was brought in as his assistant, as his deputy. When I came back to Washington in the Small Business Administration, another of my agency responsibilities was HCFA, Health Care Financing Administration. I not only represented some small businesses before HCFA, but acted on their regulations and was very critical of some of their activities. This resulted in my being detailed to the office of Senator Donald Stewart of Alabama to put on a hearing on the impact of HCFA's policies on the small business health care provider.

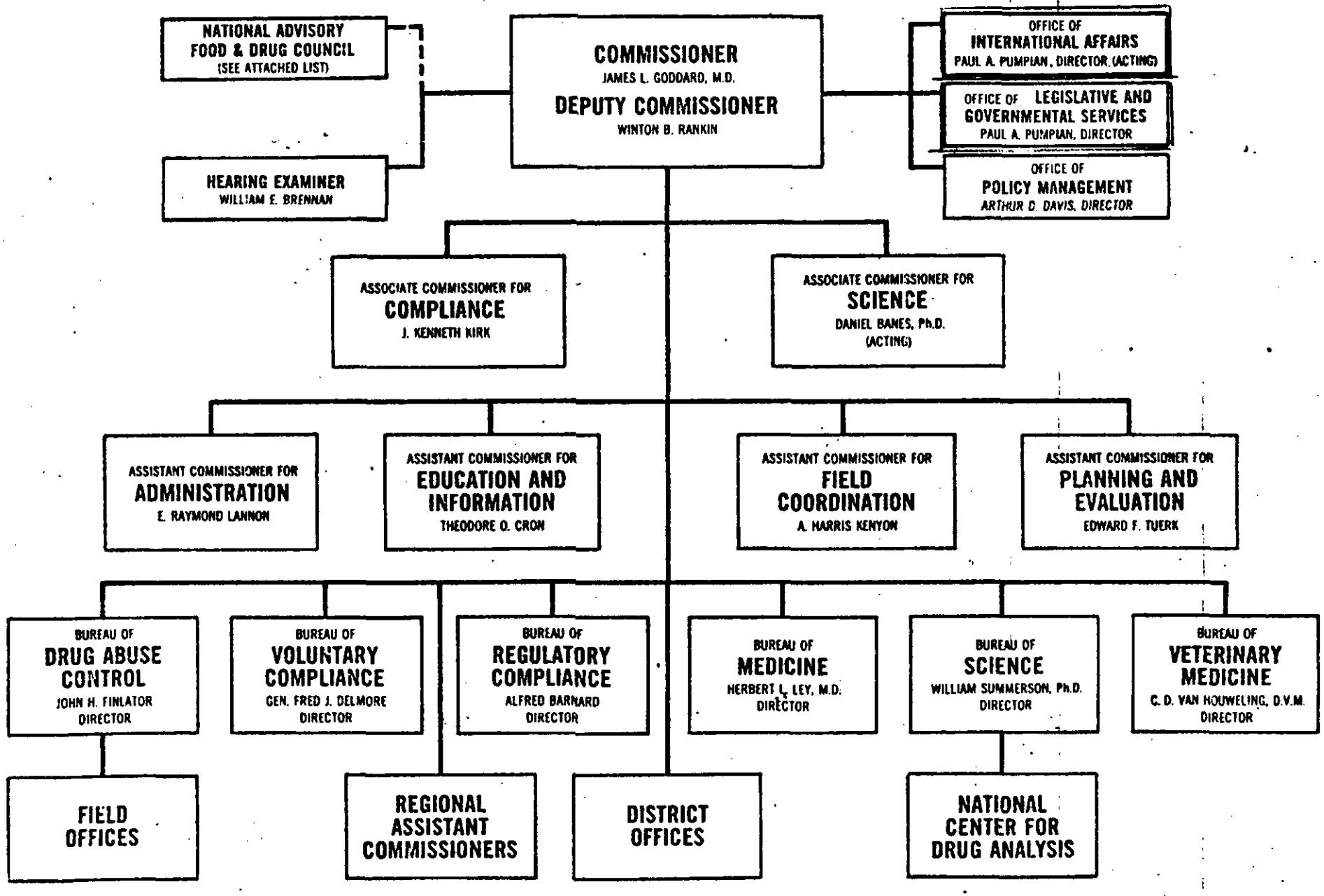
I mention this because at a meeting in Senator Stewart's office with the administrator of HCFA, their congressional liaison, and their medical director, I spoke with the medical director who was Dr. Roger Egeberg, who had been the assistant secretary for health at the time CPEHS was abolished. He and I chatted, and he mentioned how unhappy he was that he had to do what he did with the Food and Drug Administration, but he said, "We had to get rid of CPEHS." And Edwards was there, and it seemed that the problem with CPEHS and Food and Drug is what gave rise to bringing Edwards in.

But he thought a lot of Ley. He really did. He liked Dr. Ley. He says he wished Ley had accepted the job as his deputy.

But it was a good experience. I enjoyed it.

RT: Very good. Well, Paul, we appreciate very much your granting us this interview.

FOOD AND DRUG ADMINISTRATION ORGANIZATION



APRIL 1968

Except for a mere mention that the Aug. 12 memorandum was concerned with "the need to keep top management informed of news developments," no other reference was made in the Sept. 4 memo to the original notice to report "policy conversations" to Zatman. FDA-ers were still unclear about this request, although most considered it patently ridiculous.

The memo had also been called to Finch's attention by Samuel J. Archibald, chief of the Washington Office of the Freedom of Information Center of the University of Missouri.

"I hope you will immediately order the memorandum withdrawn and will clarify the question of press access to FDA information," Archibald wrote.

Noting that "information officers . . . contend" that the purpose of the memo "is merely to help them keep on top of news breaks," Archibald wrote that "the true purpose of the order is to block press access to unauthorized information which might embarrass the FDA."

"An initial investigation indicates that the information blackout was ordered by the Consumer Protection and Environmental Health Service," the letter said, adding: "The . . . memorandum, as originally drafted by FDA, would have required a report on all conversations between FDA employees and the press, but CPEHS officials modified the order to cover 'policy conversations.'" Archibald said, "A CPEHS official said the phrase was changed to 'policy conversations' to warn FDA employees that they should not talk to reporters about things the employees do not know all about."

As "further proof . . . that the purpose of the memorandum is to block reporters' access to FDA information," Archibald noted that the official title of the memo was "Unauthorized Release of Information." He noted that previous attempts by the Departments of State and Defense to require reports on conversations with the press were cancelled.

Saying that "FDA's restrictive memorandum certainly does not match the Freedom-of-information policies enunciated by President Nixon," Archibald added that, "I am confident that it will not be supported by Baxter Omohundro, the HEW Department's new Director of Information who, as a reporter himself, fought hard for the public's right to know the facts of government."

Pumpian Is Muzzled, Cannot Speak for FDA

Meanwhile, Ley ordered Paul A. Pumpian, chief of FDA's Office of Legislative and Governmental Service, to remain in Washington, and forbade his scheduled speaking appearance in Miami Beach to the Federal Bar Association (See story, Page 5).

Ley said Pumpian would be unable to speak for FDA until Pumpian's remarks to the American Bar Association were explained more fully to CPEHS Administrator Johnson (See FOOD CHEMICAL NEWS, Aug. 25, Page 2). Pumpian

departed from his prepared text to take some digs at the CPEHS operational controls over FDA. Pumpian reportedly is leaving Federal service.

PRD WANTS PROGRESS REPORTS BY NOV. 1 ON NO-RESIDUE REGISTRATIONS

The Department of Agriculture's Pesticides Regulation Division has notified manufacturers that unless progress reports are received by Nov. 1, the Division will cancel extensions it has already granted for testing necessary to establish negligible residue tolerances for pesticides previously registered on a no-residue basis.

The notification will be necessary for those studies which will not be completed prior to Jan. 1, 1970, and require further limited extensions.

PRD has extended the use of a large number of pesticides registered on a no-residue basis for which the Food and Drug Administration has no tolerances or zero tolerances, pending the outcome of studies to allow establishment of negligible residue tolerances. PRD, in a notice (PR 69-12) issued Aug. 1, pointed out that these extensions expire on Jan. 1.

More than 150 registrations were cancelled officially last year by PRD (See FOOD CHEMICAL NEWS, May 13, 1968, Page 2) as a result of implementation of the no-residue agreement worked out by FDA and USDA (See FOOD CHEMICAL NEWS, April 11, 1966, Page 14), which requires establishment of negligible residue tolerances for all food use of pesticides by Dec. 31, 1970.

Final Deadline for Negligible Residue Tolerances Is Dec. 31, 1970

In the new notice, which reiterates that no extensions will be granted on the basis of progress reports beyond Dec. 31, 1970, PRD advised manufacturers and formulators that if the studies "have not been initiated in an effort to obtain the data to support the necessary tolerances or exemptions, it will be necessary to cancel the registrations involved."

PRD noted that if FDA takes action before 1970, the Department's registrations will remain in effect, and it pointed out that if "a petition(s) for the necessary tolerances or exemptions is submitted to this Division and 'filed' by the FDA prior to Jan. 1, 1970, such registrations will be extended to permit time for processing the petition(s)."

Meanwhile, in Albany, N.Y., industry representatives met behind closed doors with a Committee on Environmental Health of the State Assembly to defend the use of DDT, and oppose curbs recommended by the State Pesticide Control Board, which has proposed that DDT be banned by 1971. The closed session was scheduled to insure a frank exchange of views.

Rather, he explained, a hearing is held because FDA disagrees with the objections and the aim is to "provide a public record of the positions of the FDA and the objecting parties and a record which will constitute the four corners of any order resulting from the hearing... (A hearing) provides any party who disagrees with the agency an opportunity to force the agency to establish a record of such clarity and completeness that a Court of Appeals can properly review the agency's action."

The cmte. limited recommendations to those that FDA could adopt without having to go to Congress for additional authority. "The situation... with many hearings scheduled and more in the offing, compelled us to take this expedient course of action," Pendergast said.

- Defining an FDA hearing as an "adjudicatory" one "where 'trial-type' procedures can play a role," Pendergast said the examiner should be given greater authority and control over the pre-hearing conferences and over use of discovery mechanisms. The cmte. also suggested greater use of depositions prior to a hearing.

"Any regs providing for such depositions would have to be drawn with care so that they are not abused and the examiner must have control at all times," Pendergast said. "But, if they are properly controlled, the intelligent use of depositions can go far toward eliminating unnecessary contentiousness at the actual hearing. But the use of depositions is of no value unless the examiner has the power to enforce his orders regarding such discoveries...

"The cmte. has concluded that the only way the examiner can control depositions or discoveries and make them work is to give him the authority to exclude from the actual hearing any witness who refuses to appear for a deposition the examiner has ordered."

FDA's Pumpian Attacks Submergence Under CP&EHS In Speech To Lawyers (over)

Pendergast defined the cmte.'s other recommendations as:

● Examiners should apply greater effort to pre-hearing conferences, and FDA, by regulation, should encourage them to do so. The examiner should be given the opportunity to review all the relevant material before the pre-hearing conference so "he will be able to make the parties sit down, head-to-head, and discuss the factual issues, hopefully with candor.... The examiner can then enter a pre-hearing order which would narrow the issues and rule on many peripheral issues... shortening the conduct of the hearing itself."

● All direct testimony should be submitted in written form before appearance of the witness for cross-examination. Pendergast noted this has been tried in the vitamin-mineral hearings, and "while it had many problems there, I think most of those problems were the result of a failure to initiate the procedure soon enough."

● All witnesses "should be required to produce the relevant portions of their prior written statements, as well as other documentary material specifically relied upon by them... Appropriate safeguards (should) be promulgated to insure that trade secrets and confidential govt. documents, if any, are adequately protected."

● No H-E-W or FDA employee who participates in the investigation or conduct of the hearing should be allowed to participate in the decision-making process. "We think this is just elemental fairness which is more and more the rule today, and that a reg or announcement from FDA that it accepts these principles is essential."

● Current regs governing ex-parte contact should be revised "to make it clear that all ex-parte communications to employees of H-E-W or FDA concerning the issues raised at such a hearing are prohibited unless made a part of the public record... This prohibition includes all communications made by employees of FDA or H-E-W when made to any official of FDA or H-E-W who is or may reasonably be expected to be participating in the decision

process. This proposal would permit FDA employees to discuss the hearing proceedings freely among themselves, so long as they do not discuss them with the commissioner or (his) office."

Paul Pumpian, FDA's legislative liaison chief, also addressed the food and drug lawyers Aug. 13. Departing from his prepared text, Pumpian voiced strong criticism of FDA's submergence in the Consumer Protection & Environmental Health Service.

- 0 -

LEY GETS KID-GLOVE TREATMENT FROM NELSON, AVOIDS STAND ON DRUG TESTING BILL; PLUGS "PEER REVIEW" OF INVESTIGATORS; DOLE SAYS NELSON MONOPOLIZES SUBCMTE.

FDA Com. Ley got the anticipated kid-glove treatment from Sen. Nelson (D-Wis.) at the Monopoly Subcmte.'s Aug. 12 drug testing hearing. Ley expounded on his "peer group review" proposal for increased surveillance of clinical investigators and endorsed Dr. Austin Stough's IND work while avoiding a clear-cut stand on Nelson's new drug testing legislation.

The only harsh words at the two-hour hearing came in an exchange between Nelson and Sen. Dole (R-Kan.), who exploded with the comment that "this subcmte. is aptly named. The chairman (Nelson) monopolizes not only the witness but the time for questioning. It is unfortunate that 99% of the time is devoted to the chairman."

Ley told the subcmte. FDA has "under development a proposed reg that would require that all investigational studies conducted in an institutional setting be subjected to the same type of peer review and evaluation that is currently required for research work funded by PHS. FDA disclosed earlier it was considering the "peer review" concept in connection with Stough's controversial drug studies in Alabama prisons ("The Pink Sheet" Aug. 11, page &). The U.S. attorney in Montgomery, Ala., has launched an investigation into Stough's work (see page T&G-7).

At the Aug. 12 hearing, Ley elaborated on the "peer" proposal at some length, and every time Nelson alluded to his "Natl. Drug Testing & Evaluation Center" bill ("The Pink Sheet" Aug. 4, page 15), the exchange would go something like this:

Nelson: — "Why shouldn't we just follow a system in which the sponsor has nothing to do with the IND?"

Ley: — "There are other answers in between the present system and what you... propose. Our proposed Federal Register statement will make all investigational studies in Phases 1, 2 and 3 subject to review by a peer group cmte.... on a continuing basis to insure that the results are scientifically sound and justified. This would be a very important factor of protection... Investigational drug testing in man is the only area in which we do not have a requirement for peer group review. I think it's time such a requirement be established."

Nelson quoted from Ley's speech last Dec. 3 to the Food & Drug Law Institute, his maiden address to industry after assuming the post of commissioner ("The Pink Sheet" Dec. 9, page 20) where Ley said FDA had "not seen the degree of improvement in the quality of clinical data... that we would like." *"Are you saying," Nelson asked him,* "that the peer group system is going to resolve all of these problems?"

"No sir," Ley responded, adding that "there has been an improvement in the quality of information flowing into our files" from drug mfrs. and that he had recently "spoken to several pharmaceutical industry leaders," telling them "the major problem today... is the poor quality of data coming into our files on investigational drugs." Earlier he referred to "two major firms voluntarily coming forward to me presenting adverse data on their products" and he said that since enactment of the 1962 Kefauver-Harris FD&C Act

by Stanley Siegelman
Editor-In-Chief

PATIENT PROFILE: WHAT IT MEANS

NEW Jersey's regulation requiring all pharmacies to maintain medication profiles of their prescription customers is a landmark in the evolution of pharmacy as it is practiced in the U.S. It appears certain that other states will follow New Jersey's lead.

Paul A. Pumpian, secretary of the N.J. pharmacy board, has received numerous inquiries about the regulation from pharmacy officials elsewhere. Their interest is, of course, more than academic.

As the man largely responsible for implementing mandatory profiles, Mr. Pumpian says vigorous enforcement will begin on Oct. 1. By then, he believes, the state's pharmacists will have had sufficient time to make the necessary adjustments in their prescription department procedures.

Although he spearheaded the drive for profiles, he disclaims credit: "I did not initiate the concept. It was 'in the air,' so to speak, when I assumed the post of secretary in August, 1971. It was one of the first assignments given to me by the pharmacy board. I was simply carrying out the board's wishes.

"I do believe, though, that profiles offer pharmacists the biggest public relations opportunity they have had in a long time. In the next year or so, I estimate that at least a half-dozen states will adopt the idea."

Because of its potentially national implications, I discussed the matter at some length with Mr. Pumpian. Following are some of my questions, and his replies:

Q *Maintaining patient profile records will add to pharmacists' costs. These costs will be passed along to the consumer. Doesn't it follow that Rx prices in New Jersey will rise?*

A "Prescription prices won't rise by any appreciable amount. In some cases, perhaps, they might be increased by 10¢ per Rx. But I don't think the majority of independent drug stores will hike prices. Over 50% of the independent drug stores in the state have been using the profile system for some time, anyway. Those which charge on the basis of a professional fee already took into consideration, as a cost factor, the maintenance of these records. Some drug chains, however, might find it necessary to increase prices."

Q *Do you expect, then, that Rx prices in chain drug stores will tend to become equalized with those in independent drug stores?*

A "Well, actually, there's very little difference at present between prices charged by conventional drug chains and by independent pharmacies. But supermarkets with prescription departments have been using those departments as loss-leader operations. I think they'll continue to do so."

Q *Please clarify the question of pharmacist liability. If a pharmacist, for example, fails to maintain a medication record accurately, or fails to alert the*

(Continued on Page 27)

PATIENT PROFILE

(Continued from page 21)

patient—or physician—about a known allergy or idiosyncracy, and injury to the patient results, then what? Do you foresee more lawsuits against pharmacists?

A "Once the new system becomes standard practice, liability suits will be no more numerous than before. Actually, progress towards standardization had already been largely achieved—even before our regulation was passed. Most liability claims are settled before they get to court anyway. In the majority of cases, the insurance company takes care of matters.

PAUL PUMPIAN

The number of hospitalizations due to drug interactions will assuredly decline, as pharmacists make active use of profile records."

Q *There are admitted flaws in the medication profile concept. For example, the patient will patronize more than one pharmacy—or use more than one physician—with a consequent "blurring" of the uniformity of data necessary for a meaningful profile. What's your comment?*

A "It's our hope the pharmacist will ultimately convince the consumer that there's only one way the system will work: namely, if the consumer buys all his medications at the same pharmacy. When a pharmacist fills a prescription, he should always ask 'Are you taking any other medicines?' When the consumer asks why this information is necessary, the pharmacist has a great opportunity to explain the benefits of profile records. A clerk, by the way, simply cannot do such a job. Speaking about flaws . . . we discovered one in our own regulation. It fails to require taking down the patient's phone number. We plan to correct this deficiency. At some future date, we'll require the pharmacist to include this information on the record."

Q *Will the new regulation really tie individual patients more firmly to individual pharmacies?*

A "Yes. It will have this effect eventually. The important word is 'eventually.' It will take pharmacists some time to convince patrons they'll be better served if they confine their prescription purchases to one drug store."

Q *Is there a possibility that physicians might become less sensitive to the possibilities of unfavorable drug interaction—knowing that the pharmacist has now been "officially" charged with this responsibility by the state of New Jersey? Might they not "pass the buck" to the pharmacist?*

A "I don't see how doctors could become less aware of the drug interaction problem, because their awareness is so minimal as it is! Most of them don't even consider the matter, sad to say. Here again, the patient who goes to several doctors, but gets his Rxs filled at a single pharmacy, stands to benefit when the pharmacist scrutinizes his medication record to spot possibly harmful interactions."

Q *Now that the principle of medication profiles has been established, what do you think of the idea—sometime in the future, perhaps—of using centrally located computers to perform this chore, rather than have it done on the premises of individual drug stores?*

A "The idea is sound . . . and its time will come. Some chains have already talked to me about using a sys-

(Continued)

PATIENT PROFILE

(Continued from page 27)

tem that is common to all their stores. In a city the size of New York, for example, I can visualize a neighborhood-by-neighborhood arrangement."

Q *Is it possible that OTCs might eventually be listed on profile records, via computers?*

A "Yes . . . but first it'll be necessary to limit the sale of OTCs to pharmacies. The increase in 3rd party pay programs is hastening the day when OTCs will be included on profiles. Because they are paying the bills, the 3rd parties are seeking better ways of handling claims. They have resorted to the computer, which yields other possibilities as by-products. The computer has the capability of including OTCs."

Q *Some people oppose the medication profile system on grounds that it invades privacy. Do you have any qualms in this regard? Does a patient have the right to refuse to participate in the system? How does the pharmacist handle a case of this kind?*

A "You have to balance benefits against so-called invasion of privacy. Now it's true that we have had complaints from consumers on this score. But we usually find, in these instances, that the pharmacist used poor judgment. For example, Mrs. Smith would bring in a prescription for herself, and the pharmacist would proceed to ask questions about her entire family. That's poor timing and poor psychology. But nobody is compelling the patron to participate. She has a perfect right to refuse. The regulation clearly says that the pharmacist shall *attempt* to ascertain and record the patient's allergies and idiosyncrasies. If the patient declines, all the pharmacist has to do is make a notation—'information refused'—on the record."

Q *Have you had any reactions from consumer groups thus far?*

A "Yes—all favorable. The president of the Consumer Federation of America praised the concept. The Governor of New Jersey described the medication profile requirement as one of the greatest consumerist victories of his administration. Many individual consumers have expressed admiration and support. Public health nurses have said they like the approach, because so many of the patients they serve tend to be over-medicated."

Q *Will the board of pharmacy issue a standardized or "official" form to be used in maintaining medication profiles?*

A "No. Many forms are on the market. The board did not feel it should dictate any specific format."

Q *How about operators of mail order prescription businesses in New Jersey? Will they, too, have to maintain profile records?*

A "Yes. Probably they will have to resort to questionnaires to get the required information. But they are not exempt from the regulation. Personally, I feel that mail order prescriptions are not in the best interests of public health."

Revco Now Operates More Units Than Any Drug Chain

Revco has just become the biggest drug chain in the country—so far as number of stores is concerned.

As this issue went to press, Cleveland-based Revco opened store No. 602, in Martinsville, W. Va. The long-time leader, Walgreen, has 567 drug stores, plus 25 Globe junior department stores, all with pharmacies—for a total of 592 units.

In dollar volume, Revco has a long way to go to catch up with Walgreen. For the 1973 fiscal year, ended June 2, Revco's volume was $300,482,474. In Walgreen's latest fiscal year, ended September 30, 1972, the Chicago-headquartered chain did $863,334,299.

Over the mark: What put Revco over the 600-store mark, in addition to the opening of several new units during the past few weeks, was completion in mid-August of the purchase of the Jacobs Drug Store chain of Atlanta, which operates 25 units in Georgia, Alabama, South Carolina, and Mississippi.

Combination: Founded 17 years ago, Revco has grown by a combination of acquiring existing drug chains and opening new units, primarily in the areas where the acquired chains are located.

Within the past year, in addition to Jacobs, acquisitions included 12 Parkview-Gem stores in the Kansas City area. Just over a year ago, in July 1972, Revco made its biggest purchase yet—the 168-store White Cross chain of California. Revco now operates in 19 states.

Sidney Dworkin, president and chief executive officer, noted that, in the fiscal year just ended, Revco "opened three times as many new stores on an individual lease basis than in any previous year." He was referring to the opening of 83 stores, more than half of them in the south and southeast.

Revco's $300,482,474 volume in fiscal 1973 represented a 16.1% increase over 1972.

Net earnings were $10,184,197, up 12.2%.

At Walgreen, sales in the first three quarters of the current fiscal year were $705,488,433, up 9.2%. Earnings were $9,682,504.

before the UNCED. It expresses the sense of the Congress that the United States should place the highest priority on the success of the conference by participating actively, particularly through the personal participation of President Bush. The President's presence at the conference would signal U.S. commitment to lead the international movement to protect the environment. His absence would represent a serious setback to United States should place the highest priority on the success of the conference by participating actively, particularly through the personal participation of President Bush. The President's presence at the conference would signal U.S. commitment to lead the international movement to protect the environment. His absence would represent a serious setback to United States and global efforts to protect the environment.

My resolution also calls for the United States to work with its neighbors in Latin American and the Caribbean to address environmental concerns in the Western Hemisphere. In such a small world, the environmental problems of our neighbors are our problems, and demand our attention. The resolution also states that the United States should evaluate its assistance programs in the region to ensure that they reflect our national security interests by apportioning sufficient funding to environmental concerns.

In addition, the resolution I am introducing today expresses the sense of Congress that the United States should:

Negotiate with other parties to the conference international agreements that effectively reduce the threats of climate change and biological diversity loss;

Propose a financing initiative for the global environment that takes into account the concerns of developing countries and increases the accountability of the funds provided for environmental purposes;

Support programs aimed at encouraging a global transition to environmentally sustainable energy systems;

Support new programs to help developing countries become more energy efficient;

Support global goals of slowing deforestation increasing worldwide forest cover, and preserving mature forests;

Support the development of a new international agreement to eliminate land-based sources of marine pollution: and

Promote public participation in environmental and development decisions at all levels—local, national, and international.

In the coming months, the Subcommittee on Western Hemisphere Affairs, which I chair, will conduct hearings on this resolution and on other important environmental issues in our hemisphere and with respect to the UNCED.

The health of our planet is in the balance at the United Nations conference in June. The Congress must take an active role in setting the conference's agenda and ensuring that the interests of the American people are represented at the highest level. I urge my colleagues to support this resolution.

OUTRAGEOUS PAY FOR AUTO INDUSTRY MANAGEMENT

HON. DOUG BEREUTER

OF NEBRASKA

IN THE HOUSE OF REPRESENTATIVES

Friday, January 3, 1992

Mr. BEREUTER. Mr. Speaker, this Member wishes to call the attention of his colleagues to excerpts from a Lincoln, NE, Star editorial of January 2, 1992, entitled "Outrageous Pay Is Societal Problem." The editorial contains the following comments about corporate leadership salaries that is particularly relevant to the management of the American automotive industry:

OUTRAGEOUS PAY FOR AUTO INDUSTRY MANAGEMENT

As President Bush heads to Japan, the Japanese are making noise about this modern American propensity to pay top executives incomprehensibly enormous salaries.

The 21 businessmen going along on the Bush trip include 12 chief executives of major U.S. corporations. Their combined annual compensation last year was $25 million, according to the Wall Street Journal—an average of more than $2 million each.

By comparison Japanese chief executives are paid $300,000 to $400,000 a year, pay higher taxes and are expected to take voluntary pay cuts when a company gets in trouble. In Japan, top executive salaries get cut before any layoffs.

Nebraskans may rage over their tax money going to pay for $100,000-plus salaries. But their hard-earned dollars also help pay for Roger Smith's $1.2 million annual pension when they buy a Chevrolet, or Donald Petersen's $6.5 million salary when they buy a Ford.

The typical chief executive of an American company makes 160 times what an average American worker earns. In Germany, the figure is 21; in Japan it's less than 20, according to Graef S. Crystal, a business professor at Berkeley.

If American automobile manufacturers' leadership like those at General Motors want their blue collar workers and the American public to believe they are serious they might well follow the Japanese example and cap all combined salaries, benefits and bonuses to no more than $250,000 for top executives in 1992, with an appropriate lower cap for middle management. No doubt such a principle ought to also apply to many corporations and institutions—including Congress, Governors, and the White House—that cannot get their fiscal or competitive houses in order.

A TRIBUTE TO PAUL A. PUMPIAN

HON. ANDY IRELAND

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

Friday, January 3, 1992

Mr. IRELAND. Mr. Speaker, I rise in recognition and appreciation of a true small business champion, Mr. Paul A. Pumpian. Mr. Pumpian joined the U.S. Small Business Administration in 1978 as the assistant chief counsel for environment and health, office of the Chief Counsel for Advocacy, and since 1980 has served as consumer affairs officer. The invaluable skills and knowledge Mr. Pumpian has offered to the Administration have been acquired through years of distinguished experience in both the public and private sectors.

Mr. Speaker, too often we paint civil servants in one color, but the achievements of Paul Pumpian, in a variety of professional positions, throughout his career serve as proof that such a perception is an unfair one.

A 1950 graduate of the University of Maryland School of Pharmacy, Mr. Pumpian went on to receive his J.D. degree from the University of Maryland School of Law in 1953. He continued the excellence of his academic career as he embarked on his professional career in the pharmaceutical field. He started as an assistant professor and chairman of the department of pharmacy administration at the University of Maryland. He went on to become a patent attorney for E.R. Squibb & Sons, Inc., and later became the executive secretary of the Wisconsin State Board of Pharmacy.

Mr. Pumpian's Government service began in 1966 when he accepted a position at the U.S. Food and Drug Administration. For 3 years he offered his already impressive experience to the Federal Government, serving as deputy director of the Division of Case Assistance, as assistant to the director at the Bureau of Drug Abuse Control, and then as Director of the Office of Legislative and Governmental Services in the Office of the Commissioner.

Mr. Pumpian returned to the private sector in 1969 where he continued to contribute to the betterment of society, holding such notable positions as vice president and general counsel for Medical Health Industries, and later president of Langer Medical Supply Co., Inc., both in Milwaukee.

Paul Pumpian became, in 1971, the first person to have served as executive secretary for two State boards of pharmacy when he took over that position in New Jersey—a true indication of Mr. Pumpian's eminent accomplishments throughout his career.

The lifelong achievements of Paul Pumpian and his success have not gone unnoticed nor unappreciated. In 1963, he received the Achievement Medal of the Alpha Zeta Omega International Pharmaceutical Fraternity, and in 1976 he was chosen hospital pharmacist of the year by the New Jersey Society of Hospital Pharmacists. More recently, in 1991, the Alumni Association of the University of Maryland presented Mr. Pumpian their highest honor, the Honored Alumnus Award.

Mr. Speaker, I bring the attention of my fellow colleagues in the House of Representatives to this fine American because he is soon to end his career. On January 10, 1992, Paul A. Pumpian will retire. His absence from the administration will be felt and regretted, but his contributions to the small business, and other communities, has resulted in improvements which will endure. I congratulate and commend Paul Pumpian on a lifetime of achievement and extend my best wishes for happiness in the future.