# History

of the

# U.S. Food and Drug Administration

Interviewee: Robert P. Fischelis (1891-1981)

Interviewer: James Harvey Young/Richard G. Hopkins

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Place:

Ada, Ohio

Robert P. Fischelis

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The U. S. Food and Drug Administration History Office edited this transcript. The tapes and transcript ribbon copy from the interview were deposited in the National Library of Medicine, History of Medicine Division, July 1990.

(Side 1, tape 0000)

# Dr. Y.:

This is an interview with Dr. Robert P. Fischelis at his office at Ohio Northern University in Ada, Ohio. The interview is being begun on September 17, 1968. I am James Harvey Young of Emory University and with me is Richard Hopkins of the University of Wisconsin in Milwaukee. Dr. Fischelis, you certainly have had a career that touched base at every possible part of pharmacy. You've been a teacher, you've been in industry in your early career, you've been an editor, you've been an administrator, a dean, a bureaucrat. There's hardly any aspect, I think, that one could imagine that you haven't had experience with during your career. Would you mind beginning our conversation by reminiscing about your career and indicating some of the key positions that you've held and responsibilities that you've undertaken?

# Dr. F.:

Well, Dr. Young, I was born in Philadelphia and after graduating from the Northeast High School in 1908, which was a depression year, I was looking for a position, and I saw in the Philadelphia press a want ad: "Boy wanted to learn drug business." I had never expected to go into the drug business, although my father was a physician. I had no particular interest, at the time, in going into medical affairs. I went to see Mr. James Houston who placed the advertisement and, this was on a Sunday, he asked me to come in on Monday morning at 8 o'clock. The hours were from 8 in the morning until 10 at night, Wednesday afternoon off and every other Sunday off, and the salary was four dollars a week. That night, I looked up my chemistry notes in the high school chemistry that I had had,

so as to brush up a little bit on things I thought that I might need when I got into the drug store. On Monday morning he greeted me with "Good morning, Robert. You'll find the broom over in this corner here," and then he proceeded to tell me how to sweep the store. After that had been done, he said, "Now Mondays, we start to clean the shelf (tape 0034)

bottles, and we put the bottles from the lower shelf on the table and then we lower the bottles from each shelf to the one below and clean the shelf and then each bottle. Now, one way in which you'll learn things is by looking at the bottle and perhaps even smelling it and reading the label and trying to memorize the names on the labels.

Well, this became routine procedure from week to week, and gradually I was permitted to wait on customers. One of the big troubles I had, although this was an old-time community pharmacy which did more prescription work and sold more drugs than anything else, it did have a small soda fountain and it did also carry a lot of things which I didn't know a drug store carried in those days, because I caught myself telling people we didn't have mucilage or we didn't have writing paper, only to be told by the boss that "Why sure we have those things. You must learn to look for them." I found that this was a very interesting job, although it did keep me until ten o'clock at night, but when business slowed up a little bit after 8 o'clock, there was a book called Remington's Practice of

(tape 0052)

Pharmacy which was then the text in most pharmacy schools, and I could sit and read about the things that I had been working with during the

day, the bottles that I'd been cleaning and the labels that I had been trying to memorize. And so, it happened that after a little while, I began to find out what it took to become a registered pharmacist in the state of Pennsylvania, and one of the prerequisites was graduation from a college of pharmacy. There were two colleges of pharmacy in Philadelphia at that time, the Philadelphia College of Pharmacy and the Medico-Chirurgical College which was a medical, dental and pharmacy school combined, with hospitals attached to it. My father, being a physician, was on the faculty of the Medico-Chirurgical College, and he was able to arrange for a scholarship for me in the Pharmacy School. So, I went there, working in the drug store three days a week from 7 a. m. until 11 p. m. and every other Sunday and going to college from 9 to 6 on the other three days of the week. The pharmacy where I started to work was unable to arrange for my part-time work while going to college, so I obtained experience in a downtown drug store at 19th and Chestnut Streets in Philadelphia

(tape 0073)

which was an entirely different kind of a setup. But I found that they were very much in need of the kind of help that I had been trained to give as an apprentice in the James Houston neighborhood-type drug store. The vacation period I spent in a drug store in New Jersey, in Palmyra, New Jersey, and there, the preceptor again was a neighborhood-type, in fact a country store-type of a pharmacist, and the experience there became varied and rather helpful in sizing up the kind of work a pharmacist was expected to do.

I completed the first year of the two-year course at the head of the class and into the second year, also working three days a week and going

to school three days a week, and came out at the top of the class, in fact, winning four out of the five prizes which were given at the time. This led the people I had been working for to urge me to take additional courses. I graduated with the old Ph. G. (graduate in pharmacy) degree, and this college, because the Food and Drug Act had passed in 1906, started a course in pharmaceutical chemistry to prepare inspectors and chemists for examination of drugs. This was an intensive course which took from 9 to 6, six days a week. The mornings were devoted (tape 0098)

largely to lectures in food and drug chemistry, mineralogy, metallurgy and clinical chemistry, as well as biology and some pharmacology. The afternoons were intensive laboratory work. So, the Dean of the Pharmacy College, Dr. Ivy S. Stanislaus, took an interest in me and urged that I go ahead with this course and perhaps go into teaching.

#### Dr. Y.:

Did you ever have temptation to go into the Bureau of Chemistry and use this course as the basis for being a chemist or an inspector?

#### Dr. F.:

Yes, in fact, I took a civil service examination to qualify, a laboratory course, but I did this before I had finished the college course, in preparation, and I don't think that I passed the examination. I had no occasion later to go into it except as a consultant and helping the local Food and Drug Administration office in some of their work.

# (tape 0115)

# Dr. Y.:

But at the very beginning of your career, this law was passed and so your career and the history of the law are simultaneous, in that sense.

# Dr. F.:

Exactly. Dr. Wiley was then the champion of better foods and drugs, and he had succeeded in convincing Congress, along with others, of course, that such a law should be put on the statute books. This was talked about considerably at the time, and the very fact that this intensive course was inaugurated indicates how much it was in the public eye or at least in the eye of the people who were going to train persons for regulatory work.

#### Dr. Y.:

Did you ever see Dr. Wiley or hear him give an address?

# Dr. F.:

Yes, I met Dr. Wiley and was greatly impressed by him. I remember one story that he told to illustrate how much psychology is a part of curing various types of ailments or imaginary ailments. He was from Indiana, and he told

#### (tape 0132)

about the <u>yarb</u> doctor in Indiana who came to see a patient and looked him over and said, "Give me two glasses of water, half full of water . . . two glasses each one half full of water." And he went down into his black bag and picked up a root, or something that looked like a root, one of his so-called yarbs, and he scraped it with a knife and then dipped it into the first half-glass of water for about two or three minutes, then took it out and then he scraped it again and put it in the second glass and held it there for a few minutes, and then he said, to the patient, "now you take a tablespoonful out of this glass on the even hour and a tablespoonful out of that glass on the odd hour." "But, doctor," said the patient, "they are the same medicine, aren't they?" "Oh, no, they're

not the same medicine," he said. "Did you watch me make it?" "Why, yes, I watched you." "If you watched me carefully, you noticed that when I took the yarb the first time, I scraped down with the knife and then dipped it in the water, and then I took it and again scraped it, but I scraped it up with the knife, and I put it in the water. Now, this is the one that I scraped down and that's Low Calcalorum, and the one that I (Tape 0151)

scraped up is High Calcalorum."

Dr. Y.:

So it was two different medicines, but both potent.

Dr. F.:

According to the Yarb Doctor. Well, Dr. Wiley was quite a man, and he impressed me as one who was a crusader for something that needed attention. I followed his career even after he left the regulatory work of the Department of Agriculture; it was then not called the Food and Drug Administration. I think it was the Bureau of Foods and Drugs.

Dr. Y.:

Bureau of Chemistry.

Dr. F.:

Bureau of Chemistry. That was it. Then he wrote for <u>Good Housekeeping</u>. Of course, he did an amount of good in many ways. I also knew Mrs. Wiley.

Dr. Y.:

Would you say that knowing the Wileys and what they stood for was an important influence

(tape 0164)

in the way you arrived at your own posture toward what government should

do in the public interest as far as drugs were concerned?

Dr. F.:

I don't think I was far enough advanced at that time in my own studies to know what I learned later of the importance of the regulatory processes. As a matter of fact, although I was a law enforcement officer for eighteen years in New Jersey, I had never been in a courtroom until I started as Secretary of the Board of Pharmacy. And so, the <a href="Legal">Legal</a> side of things had not impressed me nearly as much as the thought that people just did the right thing regardless of law, that anyone who would adulterate or sell adulterated drugs was just so far out of the social area that it was a rare thing. I didn't realize, until Dr. Wiley's exposures, how serious this was.

# Dr. Y.:

In the pharmacies in which you worked before you went to school and while you were going to school was the general position very strongly against the idea of adulteration? Was there any sort of palpable ethical level that you imbibed, so to speak, as an employee there?

(tape 0184)

#### Dr. F.:

Well, there were two things that I noticed—one, in the first pharmacy where I worked. This was a time when some of the synthetic, organic drugs first came to the market, and they were all of German origin. A man would come around with a little black bag, and he would sell packages of drugs which were supposed to be the equivalent of drugs that were then on the market, and under proprietary titles. Now, I had no idea as to the possibility of the drug not being what it was labeled, and the question has often arisen in my mind whether in those days we were putting up

prescriptions with some drugs that were sold as the equivalent of the branded drugs or not. It didn't enter into my mind. I felt that Mr. Houston was an honorable man, and he wouldn't buy anything that wasn't absolutely okay.

#### Dr. Y.:

These were supposed to be cheaper substitutes for the very high-priced German patent-protected drugs that were imported?

(tape 0204)

#### Dr. F.:

That's right. Very likely other German concerns which were imitating or perhaps just selling the same thing because their patent laws only cover processes. The German patent law did not patent the product. And so, where the Bayer Company, for example, could sell aspirin as their brand of acetylsalicylic acid, another firm could very well make the aspirin by another process and perfectly, lawfully sell it, but they couldn't call it aspirin, of course. Now this antedated the American chemical industry, which, of course, didn't come into prominence until after World War I.

#### Dr. Y.:

During this period, do you remember reading the exposures of patent medicines that Samuel Hopkins Adams made that preceded the law by a year or so? Was this part of your background?

#### Dr. F.:

I didn't read those . . . didn't get into that until I almost had finished my pharmacy course. I didn't recognize the importance of it. The second that I was going (tape 0221)

to refer to was that salesmen would come into the drug store and tell Mr. Houston about some new remedy that they were producing, a new liniment, for example. His answer would be, "When there's some demand for it, if I get a call for it, I'll be glad to put it in. I'll get it from the wholesaler." He would never stock up a new product just on a salesman's say-so. "When we get a demand for it." And as a result of advertising these demands would come and, of course, he would put it in. But the thing that I didn't realize at the time, but that I thought about later when all these exposes of the patent medicine industry and quack remedies were made, was that, after all, if the product was sold in the pharmacy, the customer had a right to believe that the pharmacist felt that it was a good product. They had that much confidence in him. And yet, the pharmacist never paid any attention to the composition. He didn't ask what the composition was. The composition didn't have to be revealed. All that the literature said was that it was better than any other remedy and praised it to the skies and talked about

(tape 0241)

its safety, and so forth, and all the different ailments it was good for, but we never questioned anybody who came in for it. The one thing that Mr. Houston was careful about in those days was Bromo-Seltzer, because there were people who would come to the soda fountain and ask for a dose of Bromo-Seltzer practically every day and sometimes two or three times a day. Well, at that time, Bromo-Seltzer was largely, as far as its therapeutic action was concerned, an acetanilide product. And some of these people who took Bromo-Seltzer continuously would have blue lips, and Mr. Houston would remark: "We oughtn't to sell this fellow anymore of this unless he sees a doctor." But I don't know whether he ever told the

man to go see a doctor or refused to sell him the Bromo-Seltzer. I was building up an experience in the retail drug business, but I did not recognize, as an apprentice, the significance of some of the things that I, of course, learned later when I began to think about them and when I went to college, and some of the professors in the school would talk about the harmfulness of certain remedies; that they covered up symptoms by allaying pain, or they would make a person feel that just because (tape 0264)

they were taking something that this was helpful. I did, however, get into that a little later.

Now, the dean who urged me to take this course in pharmaceutical chemistry which led to the Ph. G. degree, also told me that he thought that I had the making of a teacher and that he would like to see me become an instructor, but that in order to do that, you would have to have a Bachelor of Science degree, he said. And, he said, "I don't know whether you could do it or not, but Temple University in Philadelphia has a night school, and some of their teachers in the night school are better than the professors who teach in the day school, because they are the University of Pennsylvania people and others who just want to earn some extra money, and they give these night courses. I think you'd find it very interesting." So I went to see the Dean of the College of Liberal Arts at Temple University, and he said, "Well, what would you like to do?" I said, "What do you have in the way of curriculum supplements at night school that I could supplement the credits that I would get for my intensive pharmacy and biology and physiology and pharmacology and the rest that that I was taking there?" And he became

(tape 0283)

interested and worked out a schedule which took me from 7 until 10, five nights a week and covered Sociology, Ethics, History of Education and Method, English, German, and Psychology, and if I were to survive those courses, they would credit me . . . I would have more than the required credits for a Bachelor of Science degree numerically, but I would also meet their curriculum requirements for Bachelor of Science in Chemistry. So I decided to try it, and I did and came through and got the the Ph. D. and the B. Sc. the same year from the two institutions. I was then ready to take the teaching position. They needed an instructor in Pharmacy, the dean's assistant, and I went into that for . . . the summer came along and the deans of the Dentistry, Pharmacy and Medicine usually went on vacation, and in those days we didn't have a registrar. We had a bursar who did some work the registrar did, but the colleges pretty much took care of their own student records, and so on. The deans needed to have someone around in the summertime to take care of inquiries from prospective students and take students around the building, and so forth, and they offered

(tape 0309)

me the position of registrar for the three schools during the summer which worked out very nicely. Then I went right into the teaching and I taught pharmacy not only to pharmacy students, but also to medical students. This was quite an experience because the medical students, of course, had their courses in therapeutics and pharmacology, but they had no idea of pharmacy, and in those days, when the physicians were still prescribing a number of drugs in combination, they needed to know what incompatibilities there might be, physical and chemical and so on, and a

basic pharmacy course was very valuable, and this kind of a school which had a pharmacy college could teach it. I taught a laboratory course for two hours and lectured one hour to medical students, at the same time when I taught pharmacy students. And this also gave me an opportunity to do some graduate work under Professor Wood, Horatio C Wood, was a noted pharmacologist and was a member of the medical faculty, and Dr. Meeker who was head of the Chemistry Department, and I was able to get a Doctor of Pharmacy Degree in another two years.

#### Dr. Y.:

Did you do a dissertation?

(tape 0331)

Yes. The dissertation was on a drug called Combretum sundaicum which was offered as a remedy for the opium habit. Wood got interested in it because it had been used, and he got Stanislaus, the professor of pharmacy, interested in the composition. My thesis was on the composition, endeavoring to find an alkaloid or glucoside or some principle in the drug which might be isolated and used as a contra-narcotic agent to help those who were acquiring the opium or morphine habit.

# Dr. Y.:

I'd like to ask you two questions at this point: first of all, would you describe Dr. Wood as a person, as a teacher, just briefly; give a little vignette of him.

#### Dr. F.:

Yes. Horatio C. Wood, Jr., was a very dynamic person. His father was a noted pharmacologist, and Horatio C Wood, Sr., was the professor at the University of Pennsylvania and Junior was at Pennsylvania for a while,

then came over to the full professorship at Medico-Chirurgical. He was noted for his very interesting lectures. He was a good lecturer, and he also was a deeply

(tape 0354)

religious person and frequently spoke in churches as a lay preacher, not as a minister. He was a man who had very strong beliefs and expressed himself very forcibly on them, and sometimes became a controversial person about certain types of drugs. I recall that when he lectured in the Philadelphia College of Pharmacy, where he later lectured again, the students all flocked to his lecture on certain vegetable drugs, one of the principal ones of which was sarsaparilla, because he went on to expound the alleged virtues of sarsaparilla at considerable length and told all about the folklore connected with its use and how it had been used in patent medicines of various kinds and teas, and so forth. And then, wound up the lecture by saying, "But this drug is absolutely worthless."

Dr. Y.:

So this was one of his very popular performances.

Dr. F.:

Yes.

Dr. Y.:

Now, the other question that I wanted to ask came out of your dissertation topic.

(tape 0378)

As I understand it, this was the period—the period when you were first going into the drug store—that medicine was coming to realize what the true danger of narcotics was. Up to this point, there had been

recognition of the danger, but the real overall perception of how really risky these were came about this period . . . maybe a little earlier . . . but about this period. Can you set yourself in this story in the way you came to realize the danger of narcotics? Did you realize this immediately or was this gradual?

#### Dr. F.:

Yes. I'll go back again to my first drug store. I was warned, of course, when I learned how to fill prescriptions, that there were certain doctors who were writing prescriptions for addicts, and there were also certain doctors who were buying some of the narcotics because they had become addicted. And I was not to fill any of these prescriptions; they were all to be referred to Mr. Houston. And, of course, we had our system there. We had two registered pharmacists, in addition to myself, and I was allowed to mix drugs after a while in a mortar and to pack capsules. Capsules were a very popular way of medication at that time. (tape 0405)

The extemporaneous prescriptions that were powders came from the day when they used to take powders, headache powders, for example, and they transferred the powder from a paper. You had to learn how to fold powders into papers so that the powder would not come out. Then, when people undid the paper, they put this powder on their tongue and swallowed with the aid of some water. Well, this was a distasteful way of taking medicine to a lot of people, even though the powders usually contained considerable sugar so that there would be no obnoxious taste. But capsules then came into play, and the business of mixing the ingredients, four or five ingredients usually in a powder, and then putting it out on paper and taking capsules and learning how to pack

those capsules, the pharmacist got so proficient at packing the capsules that he would be able to pack them all pretty evenly, but I observed that sometimes if a prescription called for twelve capsules, by the time you got the tenth capsule filled, there would be no powder left, and then he'd have to open them up

(tape 0424)

and put the powder back so that he could take care of the other two, and I questioned this: "Shouldn't these be weighed?" "Yes, they should be weighed; an empty capsule on one side of the balance, and then when you get your capsule packed, put it on the scale to weigh it." Of course, when I got to college, that was the way they taught it. The professors warned against the possibility of not giving the correct dose. In those days, strychnine and arsenic were prescribed considerably, and it would be pretty bad if you got a little more than the required amount of strychnine into a dose. So, the filling of capsules came along at that time, and you got to be pretty proficient at it; maybe toss every second or third one, but the only safe way to do it, of course, was to make sure that each one weighed properly. And compressed tablets had come into play also, but there were a good many compressed tablets in those days that passes through the alimentary tract without being disintegrated, because they were packed, pounded so hard, and the mix wasn't one that disintegrated readily. Well, all of these things I had learned about empirically, and then

(tape 0449)

when I got to college and got the background for all of this from really trained people, I began to find out how dangerous it really was to give a pharmacist a prescription if you weren't sure that he was the kind of a

person who would take all the care that was really necessary. Now, on the narcotic side of it . . . I started in 1908. The Harrison Narcotic Act wasn't passed until 1914, and there used to be in the poison closet a bottle with morphine cubes. Morphine is a fluffy substance, and it was usually furnished in cubes, and it was nothing unusual to have a person come in and want a couple of cubes of morphine. Now, of course, there was no law to keep you from selling it, and there were undoubtedly places that sold it to addicts without a prescription. Of course, men like Dr. Wood told you about the dangers of narcotic addiction. Heroin, of course, was used in those days and could be purchased, and it was a peculiarly habit-forming alkaloid of morphine, more so than morphine. As I look back on it now, I am surprised there wasn't a greater amount of addiction. What we are hearing now about school children using drugs of (tape 0479)

various kinds: if what was going on now had been going on with narcotics it would have been a really serious thing. But neither as a student in the high school nor as a student at college nor in my experience in the drug stores did I run across many incidents where anybody that you knew became addicted to drugs or was a drug addict.

# Dr. Y.:

Some of the patent medicines, too, were equally loaded.

#### Dr. F.:

Exactly. Paregoric . . . well, we did have paregoric fiends, they called them. That was a nice-tasting product, and it did have some opium in it and it was nice tasting to some people. It was like the anise flavor.

# Dr. Y.:

But you came to this gradually. There was no dramatic moment in which

you suddenly realized that narcotics were . . .

Dr. F.:

No. And I never could understand the Hearst newspapers who took up this narcotic

(tape 0498)

crusade. Their statistics were so unbelievable to me because of my contacts, since they would publish statistics that indicate that every sixth or seventh person that you would meet would be a drug addict. Well, I have known very, very few people who were addicted to drugs and encountered very few in the drug stores.

Dr. Y.:

How long was it that you taught at, what you call it, Medico-Chi?

Dr. F.:

Medico-Chi, we call it, for short. I taught there in, let's see, began teaching in 1913 and continued until about '16 full-time. And then I had been writing occasional letters to the <u>Druogists' Circular</u> in New York on some topics, and the editor asked me to come to New York to see him and offered me a position as assistant editor and I decided to take that. He had offered it to me one time and I decided I wouldn't go, because I wanted to continue with the teaching a little while longer, and then they repeated the offer in a year and then I went over and became assistant editor which was a great experience.

(tape 0530)

And there, again, Dr. H. V. Arny, who was Professor of Chemistry in the College of Pharmacy at Columbia University, was the editor of the journal at that time. He succeeded a man by the name of Hayes whose sight began to fail, and Hayes stayed on, and I really learned the rudiments of

journalism from Hayes and from a man by the name of Snively who had been an editor of a newspaper in Tennessee but came up to New York and joined the Allison organization which published Oil, Paint and Drug Reporter, Druggists' Circular, and Painter's Magazine. He really was the preceptor of Mr. Hayes, and so I got my editorial experience under Hayes and also under his preceptor which took us pretty far back in journalism, and that's where I learned to be particular about proofreading and punctuation and all this sort of thing which modern editors don't pay too much attention to.

### Dr. Y.:

Do you attribute this early experience in journalism with lifting your sights from practicing pharmacy and pedagogical pharmacy to the broader, national kinds of problems that pharmacy had?

(tape 0557)

Dr. F.:

Yes, indeed.

Dr. Y.:

Including the regulatory aspects?

#### Dr. F.:

With the three-day-a-week course in pharmacy as it was at that time--it was a two-year course and the junior year (they called it the junior and senior) the juniors went to college Tuesdays, Thursdays and Saturdays, and the seniors, Monday, Wednesday and Friday. So when I went to the Druggists' Circular, I still kept up my teaching by going back to Philadelphia on Saturdays, and I taught a freshman course there and this kept me in the teaching level while I was in New York on the Druggists' Circular and also got me home every weekend which wasn't too bad. Now,

about the influence of the editorial work, this, of course, put me in contact with all of the many organizations. There were something like 17 pharmaceutical associations in greater New York. Brooklyn, Queens, they all had their separate organizations, their county organizations, and then there was the German Apothecary Society and the (tape 0580)

Italian Apothecary Society, and then there was a branch of the American Pharmaceutical Association. By being a reporter for the paper, it put me in touch with all of the leading people. I had to interview them and, of course, when they gave a paper or were elected to an office, they were glad to see their names in the paper, and I learned then what a reporter, a newspaperman, can do to help make or unmake people which, of course, put me in very close touch with the leaders of the American Pharmaceutical Association. I became a member of the American Pharmaceutical Association in 1912 as a result of having won the chemistry prize in the chemistry course, which was a year's membership in the American Pharmaceutical Association, five dollars. And this, of course, made me a very early member, and it just happens that the year in which I joined, Dr. James H. Beal became the editor of the <u>Journal</u>. He was the first full-time secretary and editor of the American Pharmaceutical Association. My thesis for the Doctor of Pharmacy degree was published in the 1912 issue which was the first issue of that <u>Journal</u> and, of course, Dr. Beal knew me. As an individual, he was, of course, a man well along then.

(tape 0614)

He had graduated in law as well as pharmacy and had been Dean of the Scio College of Pharmacy which also had a law department, and they merged with

the University of Pittsburgh. Apparently with his legal knowledge and his pharmaceutical knowledge and connections he had a broad view of the whole situation. I mean he was a very good writer and a clear thinker and he could, no doubt as a result of his legal training as well as his pharmaceutical training, and his own keen intellect and mind, expound on things in a very lucid and logical way that took the issues of the day directly to the practicing pharmacist who maybe never went to conventions, who was stuck in his store, but who could read Beal's dissertations and editorials and articles. He undoubtedly also was a very great help to the drug industry, particularly the patent medicine industry for whom he wrote labels and literature and did it within the legal limits of what could be said.

#### Dr. Y.:

While he was editor, was he also a consultant on the side? Is that what you mean?

(tape 0646)

#### Dr. F.:

This I don't know from actual fact, but I'm sure that because of the . . . I'm quite sure from the relations between these people that he was consulted. Now, he may not have been consulted privately as a paid consultant of a particular firm, but, as far as the Association and its attorneys were concerned, he, I'm sure, was able to transmit their views to the more professional groups and to do it in such a way as to make the professional group very often come along and close an eye to some things they might not have done without him. At the same time, he gave some very strong points of view to committees of Congress which were not always in line with what I what learned to consider as the strictly ethical and

public health-minded views that we like to feel our professions represent and work on.

Dr. Y.:

When did you first meet Mr. Beal ? At the time you wrote your dissertation?

Dr. F.:

No. I met him at the first convention of the American Pharmaceutical Association I attended. I had correspondence with him as a result of papers and that sort of thing, and I admired his very logical presentations.

(tape 0694)

Dr. Y.:

What did he look like?

Dr. F.:

I would say he was about five foot eight. Well, he looked somewhat like Harry Truman, about that build and also that general facial expression. He had a lot of wit and he could be very sharp in his characterization of things and always clear in his enunciation. He was a good speaker, and he had been a member of the Ohio legislature. In fact, I think he had something to do with the local option law that . . . there was a certain bill . . . I never went into it enough to get the details, but there was the Beal Bill that was spoken of, and I'm quite sure that it had to do with local option. Now, whether it had anything to do with keeping liquor out of certain sales emporia or not, I don't know. I don't go back that far, but I know that he was written up from time to time on what he did in the Ohio legislature.

Dr. Y.:

You indicate that his position might be closer to manufacturing than would be

(tape 0733)

true of some people who played an important role in administration and editing over on the professional side of pharmacy. What specific things do you think of when you think of that generalization with respect to him?

# Dr. F.:

Well, Dr. Beal was really an unusual person in that I think he had the respect of all branches of pharmacy. He had the respect of the medical profession. But I don't think that he ever was very close to anybody. He was not the kind of bosom friend that people talk about. As I saw his intercourse with other people, in conventions and so on—he was very friendly with a man by the name of Welpley, Dr. Henry M. Welpley, who was treasurer of the American Pharmaceutical Association. Dr. Welpley, the treasurer, and Dr. Beal, the general secretary and editor, they were the leaders in the American Pharmaceutical Association and everybody respected them, so that the drug manufacturers and the pharmacists, the practicing pharmacists, the retailers and wholesalers, whenever they had anything that seemed controversial, or when there was a session of the Association or any of its sections

(tape 0778)

where controversial matters were discussed, Dr. Beal would sit there and listen to all of it and then, at the right moment, he would come up with a kind of summarization of discussions and a way of meeting the crisis that might have arisen. It was always in the nature of a compromise type of thing. Later on, as I became active in the Association work and in

law-enforcement work and so forth, I began to see or feel that the leadership there was not always in the direction that I thought it should be. Now, Dr. Beal when it came to the narcotic situation, for example, in 1914 or prior to 1914, when the law was passed, the Harrison Law was passed, there was great difference of opinion on the part of not only the people in the various phases of pharmacy but in medicine also as to how they should be regulated. Obviously, the doctors didn't want to be regulated with regard to prescribing narcotics, the manufacturers and the wholesalers didn't want to be regulated too much with respect to what they put into their proprietary over-the-counter preparations, nor did they want to be regulated too much with regard to record-keeping and responsibility for custody of narcotics. But the thing that (tape 0823)

had gotten so far in the public area was that all of them knew that they were going to be regulated, that they had to be regulated in some way. When it was decided that in order to get Federal regulation of narcotic distribution that the only way to do it was to tie it up with Internal Revenue, which gave the Federal government the right to go across state borders, then these different groups felt that they ought to get together instead of hanging separately, hang together. This is where Dr. Beal then proposed the National Drug Trade Conference, and that's what brought it into being.

#### Dr. Y.:

It came out of the narcotic situation.

# Dr. F.:

Out of the narcotic situation. This was the first time that the wholesalers, manufacturers, retailers and the rest sat around the table

together to get up something which would put them in a position where they were not opposing something which was certainly in the interest of the public health and welfare, and I think Beale (tape 0854)

worked with whoever it was that developed what was called the Harrison Act. This was somebody else . . . anyway the Harrison . . .

Dr. Y.:

But this was a major crisis in the drug industry, and that precipitated this group, which still exists, as far as I know . . .

Dr. F.:

Yes.

Dr. Y.:

To get what kind of meeting of minds there could be. What fights there'd be would be in private, and, if possible then, when the public face was given it would be as unified as could be. That was the point to it?

Dr. F.:

Yea. It was organized on the basis that no action can be taken by this conference that is not unanimous. Any one organization would have veto power. This has been one of the criticisms. It was an early criticism that I made of it, that the Drug Trade Conference met annually but never accomplished anything because they couldn't get together well enough to be unanimous on any one thing.

(Side 2, tape 0000)

Dr. Y.:

Well, Dr. Fischelis, before we went out to dinner, you had been talking about the National Drug Trade Conference which you said had been initiated mainly by Dr. Beale in connection with seeking an agreement of

the various elements of the drug trade and professions at the time that some national legislation was in prospect in connection with control of narcotics. This began, I think, back in 1914. Why don't you run through your recollections that relate to this National Drug Trade Conference and tell us what you recall about it.

# Dr. F.:

The fact that the various groups in the drug industry and the profession of pharmacy were able to get together on working out a suitable type of legislation for the control of distribution of narcotic drugs led to the feeling on the

(tape 0015)

part of the conferees who were called together to form this National Trade Conference that they might have a medium at last for getting together and ironing out differences on other matters. The fact that the by-laws called for unanimous action and gave a veto power to each one of the organizations represented was an indication that this was to be what its name indicated, a conference or a common meeting ground for the exchange of views, rather than an action body which, if it were to become such, would obviously replace the voice of the individual organizations that made up the conference. So, annual meetings have been held ever since this 1914 initial meeting and numerous matters of interest have been discussed. Each group has from time to time introduced a discussion of subjects in which they were particularly interested. Such matters as price maintenance on a legal basis, fair trade, and matters of legislation which seemed to affect all of the groups--such as the anti-trust laws and legislation introduced from time to time to restrict certain activities having to do

(tape 0039)

with health matters-have all been suggested, but perhaps the one outstanding matter on which agreement was reached and which resulted in the formation of another permanent body was the discussion of financing of pharmacy colleges. This eventually led to the formation of the American Foundation for Pharmaceutical Education in which the same groups that are represented in the National Drug Trade Conference are represented and which has built up a considerable sum of money for scholarships, fellowships, promotion of graduate education, and award of fellowships for both those who are expected to go into industry in research work and for teachers. Obviously, the supply of teachers has become very important, and the creation of fellowships to enable competent persons to carry on graduate work in various phases of pharmacy has been helped considerably. This foundation, incidentally, makes an annual solicitation of drug manufacturers, wholesalers and others in the industry, and collects in the neighborhood of \$200,000 a year which is awarded then to properly-selected fellows or students, undergraduate students. Now the Conference is made up of three delegates from each of the

(tape 0064)

presently nine, but formerly ten, organizations: the National Wholesale Druggists Association, the Federal Wholesale Druggist Association, the American Pharmaceutical Association, the National Association of Retail Druggists, the American Pharmaceutical Manufacturers Association and the American Drug Manufacturers Association which have now been merged into one and which caused the reduction from ten to nine, the American Association of Colleges of Pharmacy, the National Association of Boards

of Pharmacy, and the National Association of Chain Drug Stores. This, as you will note, is representative of all phases of production and distribution of drugs, as well as education and regulation as far as the boards of pharmacy are concerned. The annual meetings have been productive in the sense that they have exposed the attitudes of the different groups one to another by expressions either in favor of or against certain measures and actions which reflect the viewpoints of the drug industry and the pharmaceutical profession to the public.

Dr. Y.:

Are these secret meetings?

(tape 0084)

Dr. F.:

The meetings have been opened to the pharmaceutical press, except at special times when executive sessions have been held, but, generally speaking, there has been very little that has not been open to the pharmaceutical press.

Dr. Y.:

Or reported in the annual reports after the meetings have been over.

Dr. F.:

Yes.

Dr. Y.:

Now, were you a representative from the American Pharmaceutical Association at this conference?

Dr. F.:

Yes. The year I was president of the Association and also previously and subsequently I was a delegate from the American Pharmaceutical Association, but from the start, Dr. Beale, Dr. James H. Beale, was the

leader of the delegation. In the year that I was president, the food and drug legislation had been a matter of considerable controversy starting with the Tugwell Bill and subsequent versions

and then the Copeland Bill. I found myself in disagreement with some of the things that Dr. Beale had said in hearings before Congressional committees.

Dr. Y.:

(tape 0099)

Let me just interrupt a minute. The bill was introduced in 1933. I don't know if you were a delegate to the National Drug Trade Conference in that particular year.

Dr. F.:

I believe I was.

Dr. Y.:

At any rate, in that year, the Conference did get unanimity. As I recall, it favored the fact that new legislation was necessary, but it came out very strongly against the features of the Tugwell Bill which seemed to give, as the members saw it, unduly arbitrary power to the Secretary of Agriculture. Do you remember this? Was there any debate about this particular point?

Dr. F.:

There was considerable debate, but as I recall it, the main features on which there was a difference of opinion were, first, the so-called variation clause which gave a manufacturer the right to use an official name, that is, a name that was used

(tape 0117)

on a drug preparation in the United States Pharmacopoeia or National

Formulary without having the product meet the standards of the National Formulary and the United States Pharmacopoeia as long as the difference from the official standard was mentioned on the label.

#### Dr. Y.:

Now, that had been the situation under the 1906 law. It had been a variation clause. It had been legal. In 1933, those who were proposing the bill from the government's side wanted to end the variation clause, and you say that this issue came up for debate?

# Dr. F.:

Yea and I was in favor of abolishing the variation clause because drug manufacturers had been using the official titles in large print and then in very fine print stating the difference from the official standard which, to the average pharmacist, meant that the product, if it was labeled by an official name was the official product. And, actually, it was not in some cases. Now, this was one place (tape 0131)

where Dr. James H. Beale and I differed considerably. Then too, there was the matter of formula disclosure. I was in favor of complete formula disclosure. The manufacturers wanted to limit it as it had been limited in the 1906 act when I think there were something like eight or ten drugs that had to be declared and the others need not be declared. Then there were some other things, such as advertising and the control of advertising by the Food and Drug Administration, what is now the Food and Drug Administration, and the idea of giving it to the Federal Trade Commission under what later became the Wheeler . . .

# Dr. Y.:

Lea.

Dr. F.:

Wheeler-Lea Act. So, when it came time to appoint the delegates to the National Drug Trade Conference from the American Pharmaceutical Association, I wrote to Dr. Beale and said that I thought that he had not represented the Association's views on food and drug legislation correctly before the committees of Congress, and I said that I thought that anybody who was sent to the Drug Trade Conference (tape 0149)

from the American Pharmaceutical Association ought to speak for the American Pharmaceutical Association. And I asked him, in a letter, I said that I would like to reappoint him as a delegate to the Conference, but before doing so, I would like to know whether, in the capacity of a delegate, he would speak for the Association, based on the recorded action by resolution at conventions of the Association or whether he was going to express his own personal opinions. He replied that he would express his personal opinions, and I then said I was sorry, but under those circumstances I could not reappoint him as a delegate to the Conference.

Dr. Y.:

This was in the year of your presidency?

Dr. F.:

That's right.

Dr. Y.:

When you had the responsibility of appointing the three members.

(tape 0160)

Dr. F.:

That's right.

Dr. Y.: And this would therefore be in 1934? Dr. F.: Yes. Dr. Y: And you were . . . Dr. F.: Yes. I took office . . . Yes, that's right, it would be in December '34. Dr.Y.: You took office in December '34? Dr. F.: I took office in May of 1934 and the Drug Trade Conference always met in December. Dr. Y .: Yes. And so, it was your responsibility to make these appointments, and the evidence that you had that he was speaking in a different voice from that as represented by resolutions of the American Pharmaceutical Association had come to you on the basis (tape 0168) of the testimony that he had given before the Senate committee on the first version of the food and drug legislation. Dr. F: Right. Dr. Y.: How did he respond to this? Dr. F.: Well, he, of course, accepted the fact that I didn't reappoint him, but

he attended the meeting of the Conference because he was, I believe, an officer, and I then appointed . . . in addition, the secretary of the American Pharmaceutical Association, Dr. Kelly, was also previously a delegate. The way the delegations were appointed was usually with the president, the current president of the Association, and Dr. Beale and Dr. Kelly, Dr. Beale, of course, was no longer secretary of the APhA, but the outstanding figure in the Association, and Dr. Kelly, of course, was general secretary. I appointed two other people.

### Dr. Y.:

Because Dr. Kelly shared Dr. Beale's point of view? (tape 0181)

### Dr. F.:

Yes. Dr. Kelly would go along with Dr. Beale on whatever he felt was the proper thing to say, and we got to the Drug Trade Conference meeting and before the meeting was called, the president of the Conference came to me and asked me to reconsider the appointment of my delegation, that Dr. Beale was such an important factor in the National Drug Trade Conference, he had started it and was, of course, considered one of the most outstanding, if not the most outstanding, persons in there. I had to say to the president that I was sorry but Dr. Beale and I were in disagreement on how the American Pharmaceutical Association was to be represented and I didn't feel that it was the business of any other member of the Conference or any officers of the Conference to ask me to make any changes. I wouldn't have made the change if I hadn't had good reason for it. They delayed the opening of the meeting and had different ones come to talk to me about what a terrible thing I was doing in not reappointing Dr. Beale. At any rate, the Conference met finally, and the

atmosphere was quite strained because of

(tape 0200)

the fact that Dr. Beale was not spokesman for the American Pharmaceutical Association. No other organization appointed him and they all had their delegates appointed, of course.

Dr. Y:

This was the first time presumably that he wasn't a spokesman since it had been begun twenty years before.

Dr. F.:

That's right. That's right. But I felt that the issue was of such great importance because it meant that whoever was going to . . . whatever action the Drug Trade Conference was going to take would have to be guided, as far as the American Pharmaceutical Association was concerned, by what we had felt was the way to strengthen this Food, Drug and Cosmetic Act.

Dr. Y.:

Now, the issues that divided you and Dr. Beale and that, as you saw it, divided him from the prevailing sentiment in the American Pharmaceutical Association were the ones you mentioned: the variation clause. Had there been a resolution by the APhA to

(tape 0214)

oppose, to abolish it in the new law?

Dr. F.:

Yes.

Dr. Y.:

Right. And the APhA also had made a resolution in connection with open labeling?

Yes.

Dr. Y.:

And with respect to . . .

Dr. F.:

Complete formula disclosure.

Dr. Y.:

And with respect to advertising, too?

Dr. F.:

That's right.

Dr. Y.:

And so that if you have this position and other groups in the Conference continued to hold the kind of position that Dr. Beale had held, what was the nature of the discussion after you finally got around to it in this 1934 session? Was it tense?

(tape 0223)

How could you reach unanimity?

Dr. F.:

Yes. Well, we didn't.

Dr. Y.:

You didn't.

Dr. F.:

So the Drug Trade Conference didn't take any action, and this is exactly what I anticipated. They would either have taken action endorsing the variation clause and only partial formula disclosure and these other matters on which we differed, or they would have taken no action, and I preferred no action to taking the previous action which, to my mind,

contributed nothing to strengthening the law.

Dr. Y.:

So that, as individuals, if they wanted to go before the committees and testify about the bill, they could do so.

Dr. F:

Oh, yes.

Dr. Y.:

But they couldn't say, when they went, "We speak for the National Drug
Trade Conference."

(tape 0232)

Dr. F.:

That's right. And, therefore, for all of its constituents including the American Pharmaceutical Association.

Dr. Y.:

so that it was your deliberate intention to do this so that it didn't appear as if the American Pharmaceutical Association was party to what the other groups, presumably the rest of the groups, the groups that were in manufacturing and distribution, tended to favor the variation clause and to want only restricted disclosure of ingredients?

Dr. F.:

Perhaps I should say that I was, of course, at that time, secretary and chief chemist of the new Jersey State Board of Pharmacy and, in that capacity, I was a, I'm trying to think of the correct name, a cooperating official of the Bureau of Chemistry or Food and Drug Administration or whatever it was called at the time.

Dr. Y.:

In 1927, I think it changed from the Bureau.

(tape 0249)

Dr. F.:

Yes. And I didn't feel that, and neither did the people that I represented feel that, we should not support the Administration on this very important matter.

Dr. Y.:

Now, at the time that these events were taking place, were you in any sort of close liaison with the leadership of the Food and Drug Administration?

Dr. F:

Yes. I was in rather close touch with Mr. Campbell, who was then the Chief of the Administration, and, of course, I knew quite a number of his associates and the man who worked most closely with me and with other Board of Pharmacy officials was Walter Frisbie, who was the state relations director of the Bureau and, of course, he would make visits to the various boards from time to time, and we had a chance to discuss these different matters and the progress of the legislation and so on and I had indicated how we felt about it.

Dr. Y.:

And he was a vigorous spokesman for the bill that the Food and Drug Administration had

(tape 0269)

put forth, the Tugwell Bill.

Dr. F.:

Yes. Yes. Of course, I also later had some contact with Dr. Copeland and principally with Ole Sathe who was the man who really worked on the bill and also with Mr. Crawford who later became Commissioner, but who

was, at that time, an assistant commissioner of . . . in fact, he was Mr. Campbell's right hand man with regard to the details of the law, the language of the law, and so on. A very able person.

# Dr. Y.:

When did you first begin to get acquainted with Bureau of Chemistry and later Food and Drug Administration people? Was this when you were in New York on the staff of the <u>Druggists' Circular</u>?

#### Dr. F.:

The acquaintance then was rather casual. It was more in the nature of being a reporter, but an interesting thing developed there. Dr. W. A. Puckner who was Secretary of the Council on Pharmacy and Chemistry of the American Medical Association

# (tape 0284)

had always had a good deal of respect for the <u>Druogists' Circular</u> because of all the pharmaceutical publications, it championed the cause of better and stricter drug regulations. There were a number of patent medicine companies in New York City, and in his work as secretary of the Council where they passed on prescription products and other drugs that were offered to the medical profession, and also he had some connection with the agency of the AMA that handled proprietary medicines, Dr. Cramp, I think was . . .

### Dr. Y:

Dr. Arthur Cramp. It's name varied from time to time.

## Dr. F.:

Yes. Well, Puckner wrote to me about some of these concerns and had asked me on one or two occasions to visit them, to see whether they were really a manufacturing outfit or just a loft somewhere or an office and

that they had their products made by other people. Very often, it was found that they were just sales offices or business offices and that the products were manufactured by some of the very reputable drug manufacturing houses. There was no doubt the products were competently (tape 0305)

prepared and up to standard, but the advertising and the literature and the labeling, that was . . . the manufacturer assumed no responsibility. That was the responsibility of the distributor. So I had . . .

Dr. Y.:

You were sort of a private eye for him, in some cases.

Dr. F.:

Yes. Yes. And this brought me in contact with the Food and Drug Administration to some extent also, because I would explore with them what the situation was. But I really didn't get into a strong, cooperative position with the Food and Drug Administration until after 1926 when I became Secretary and Chief Chemist for the State Board of Pharmacy.

Dr. Y.:

In New Jersey.

Dr. F:

In New Jersey.

Dr. Y .:

And then you were appointed as a cooperating . . .

Dr. F.:

Cooperating official.

(tape 0317)

Dr. Y.:

With the Food and Drug Administration.

Dr. F.:

Yes.

Dr. Y.:

So that that gave you a kind of capacity. With whom did you work initially?

Dr. F.:

Well, I worked with, of course, directly through Frisbie with the people in the Washington office. Mr. Larrick was then, I believe, chief inspector; he was on the policing side of things, and Dunbar was the scientific man. He later became a commissioner also, and Crawford was an assistant to Campbell, but Campbell kept a pretty close connection with all of us and would address the annual meetings of the local and regional Food and Drug Officials to which we, of course, were invited, and of which we were actually members. Now, as an example of the kind of thing that would go on there, there were several cities like Newark and Jersey City which had their own health department and a food and drug division. And one day, a fire occurred in one of the buildings (tape 0337)

of the S. B. Pennick Company. Pennick sold crude drugs, that is, vegetable drugs largely, which went into most of the patent medicine extracts, vegetable extracts, and so on. And this fire occurred in their storage house where they had all of these crude drugs. So, the Jersey City inspector called me to let me know about the fire because he understood that the insurance company had been called in to evaluate the losses and to make restitution, of course, as much as the insurance carried, and he got wind of the fact that they were going to reconstitute

these drugs as much as they could, to take the burned part away. Of course, there had been water damage and water damage to vegetable dried drugs would, of course, extract some of them and leave them substandard, even though they had once passed the import regulations and also the local regulations. So he advised me about this. I went up to look the thing over and saw it was quite a problem and immediately got in touch with the Philadelphia branch of the Food and Drug Administration which had jurisdiction over that area, and they, in turn, got in touch with the Washington people, and they asked me to represent them in this whole thing and see that

(tape 0358)

none of this material got out into commerce. We then took over and we negotiated with the manufacturer. First of all, we threatened to confiscate or destroy their entire lot of stuff, but there were some valuable drugs there, such as golden seal, which was a drug used in a good many patent medicines and a rather expensive thing. We permitted them to, and got this on record, that they would not sell any of this material but that they would be permitted to extract the vegetable drugs and get the active constituents which they could sell, if they were properly purified and passed the food and drug regulations and control analysis, and so forth. Well, this involved considerable sums of money, as I recall it, something like \$100,000 was involved in these stocks, and not by any prosecuting procedure at all, but just by working with the manufacturer and finally getting him to see that it was in the public interest not to repackage any of this material. The insurance company, of course, was the one that was pushing it, mostly because they wanted to have to pay as little as possible for the damaged material, but this

thing all worked out. It involved considerable negotiation (tape 0382)

and so on, but this is an example of the kind of cooperative work that was done.

Dr. Y.:

Now, in this, you did have occasion to meet Mr. Campbell from time to time, and then when you were in Washington where you were geographically closer, you probably met him on a number of occasions.

Dr. F.:

Well, Mr. Campbell. . . . I don't know when his term was up . . . but I didn't move to Washington until 1945.

Dr. Y.:

Well that was after . . .

Dr. F.:

I was in and out of Washington, but the Administrators had changed because of his retirement.

Dr. Y.:

Do you retain quite a vivid image of Mr. Campbell from the occasions . .

Dr. F.:

Yes, I do. I think he was a very outstanding person. He was a quiet and deliberate

(tape 0396)

worker. He was, of course, a lawyer by profession. I've often wondered whether the person in charge of food and drug regulation should be a physician or a lawyer. If the physician has the help and right-hand support of a good, competent attorney who also understands something

about the drug business, I would favor the physician as the top man in the Food and Drug Administration. I think Dr. Wiley was a good example of that kind of an administrator. Dr. Alsberg was more of a scientist, not the campaigner and the man who could get headlines.

Dr. Y.:

Did you know him?

Dr. F.:

I knew him, but not as well as I knew Campbell. I never had . . . Dr. Alsberg didn't encourage very much in the way of meeting with groups. He didn't do much speaking such as Wiley, of course, did, and such as Campbell also did . . . not as much as Wiley in his case, but he encouraged the idea of speaking before gatherings which were important in helping the Department.

(tape 0421)

Dr. Y.:

What did he look like?

Dr. F.:

Campbell?

Dr. Y.:

Well, I was thinking of Alsberg. We can go back to Campbell in a minute. You mentioned Dr. Alsberg.

Dr. F.:

He was a man of, oh, I would say, medium stature, and he impressed you very much as the scientist and physician, not so much as a general practitioner as one who was more active in the scientific area, and I think his coming in at the time he did was a good move because all of our medicine was gradually getting more scientific and the standardization of

drug products had become more complete and involved other procedures than chemical analysis. I never thought that he was the crusading type of administrator.

Dr. Y.:

What about his temperament? Did you have a chance to observe him enough to

(tape 0444)

make a comment about that?

Dr. F.:

Not a very great comment except to say that he impressed you as someone who was very deliberate in his arriving at conclusions, but very strong in supporting those conclusions after they had been arrived at, and he demanded first-class evidence.

Dr. Y.:

Now to go back to Mr. Campbell. What about his personality and temperament?

Dr. F.:

I would say it was a judicial temperament. He would have made a good judge, and he was incisive in his characterizations of situations. He would do some questioning, very active and in depth questioning, and he would make up his mind, not at the spur-of-the-moment but upon deliberation. I found that he was always more than fair to the other side of a question. He wanted to get both sides, and then I think he also contemplated the consequences, and if it was a matter that might be considered trivial, I don't think he would pursue it too strenuously, but if it was a matter that dealt with principles and policies, he was always, in my judgment,

(tape 0477)

looking toward what effect a certain set of circumstances would have on the basic policy of the agency that he headed, and once that was decided, he would hew to the line.

Dr.Y:

Now, can you think of an episode in your association with him that helps pin him down as a person in action in his role?

Dr. F:

Well, his appearance before some of the associations and particularly his appearance before the United States Pharmacopeoeial Convention, which is held every ten years for the selection of a revision committee of the Pharmacopoeia. Also, it lays down policies with regard to drug standardization and admission of drugs to the book, which gives the drugs the blessing of the combined medical and pharmaceutical group that makes the Pharmacopoeia. Now, appearing before that decennial convention . . .

Dr. Y.:

When would this be?

Dr. F.:

This would be on 1940, 1950, 1930. It's always on the decennial year. (tape 0503)

Dr. Y:

Right. But when Campbell would have appeared, it would have been 1940?

Dr. F.:

'40. I imagine also in '30. I'm not sure.

Dr. Y.:

'30. You observed both of them?

Dr. F.:

Yes. He laid down the policy which the Food and Drug Administration felt was in line with the law as it was at the time that he spoke, and he, in no uncertain terms, suggested to the convention that, if it wanted the Pharmacopoeia to remain the book of official standards recognized under the Food and Drug Act, it would be necessary to supply standards that were enforceable and just. He probably—I don't recall the examples that he would have given—but this was the thing that stands out in my mind as a place where he showed up as the bureaucrat, let's say. I don't use that in a derogatory sense, but as a person who was in charge of the enforcement of the Act. He didn't want his hands tied, and if there was any way

(tape 0532)

in which the Pharmacopoeia could help those who wanted to circumvent the law and the standards and the enforcement procedures, he didn't want the Pharmacopoeia to be a party to that. This was implied in his . . . otherwise the Pharmacopoeia might find itself removed as the . . .

### Dr. Y.:

The implication was very clear in what he said.

### Dr. F.:

Whether he said it in so many words or not, but this showed him to be a person with considerable courage, because even though the representatives to the convention were supposed to be representatives of medical societies and pharmaceutical societies, medical colleges and pharmacy colleges, there were always representatives of industry who crept in as substitutes for some of the people who couldn't afford to go to the meetings or didn't have the expense paid or what not. And always there were certain numbers of drug manufacturers' representatives put on the

Revision Committee which, of course, had the . . . for instance, the chairman of the committee on organic chemicals or (tape 0555)

the chairman of the committee on inorganic chemicals. He might be a scientist or control chemist in one of the industries, and he could influence the rigidity of the standards that were laid down for a product.

### Dr.Y:

Is there any evidence that this actually had happened from time to time in the revisions of the U. S. P.?

# Dr. F.:

Well, I had one thing that came to my personal notice. I was working with a professor of chemistry at Princeton University on a product of creosote. Now, creosote was a drug in the Pharmacopoeia, and creosote consisted of guaiacol and creosol, and the U. S. P. standard didn't say that it was such and such a percentage of guaiacol and such and such a percentage of creosol, but it simply mentioned the two items as constituents. Under that kind of a definition, the guaiacol could be extracted from the creosote and the creosote could still meet the standard of the Pharmacopoeia, because the product was still chiefly guaiacol and creosol, but it was predominately creosol in that kind of situation. And

(tape 0586)

it happened that the chairman of the committee on organic chemicals under which this comes made that standard and his firm was chief producer of creosote.

### Dr. Y .:

So that they were able to get a by-product out and sell it separately and still meet the standard.

Dr. F.:

This was the only thing that came to my personal attention, because we were working on that. When we got the creosote meeting U. S. P. standards and tried to get guaiacol out of it and there was very little in there.

Dr. Y.:

Now, can you tell me the date of this episode?

Dr. F.:

This must have been around 1926, I think.

Dr. Y.:

While you were working on . . . there was a revision that was published that year, if I remember.

Dr. F.:

Yes.

(tape 0603)

Dr. Y.:

And it was for that revision.

Dr. F:

Well, I wasn't working on the revision. I was working on something else and it came up incidentally, because we had to do the testing.

Dr. Y.:

And this gave you insight into this particular . . .

Dr. F:

Now, I may be very unjust to this person by citing such an incident, but it is possible to juggle standards in such a way that they still will do

no harm to the individual who gets the drug, but there's a profit to be made by doing something that doesn't quite meet the standard.

Dr. Y.:

And whether or not he had this particular example in mind, you have the feeling that it was something in this category that Mr. Campbell was speaking about when he gave his address to the revision committee. (tape 0622)

Dr. F.:

Well, that, in part, but I don't think that Campbell was interested so much in the standards of an individual product as he was in the standing of the Pharmacopoeia as the official standard for drugs under the Food and Drug Act, which is what he was enforcing. And he wanted that Pharmacopoeia to be so completely above suspicion in every respect that he called attention to the possibility that if it did not meet the highest standards that it was in danger of being withdrawn as the official standard.

Dr. Y.:

And also he wanted the tests in it to be such that they could be made and support the law so that they would be clear and full rather than fuzzy and therefore legally difficult to enforce.

Dr. F.:

And I think he accomplished that in the 1938 Act when it was provided in the Act that if the U. S. P. and N. F. could not give a standard that was satisfactory to the Food and Drug Administration, they could, in turn, make their own standard.

(tape 0647)

Dr. Y.:

Right. Now, let me go back to the '20s again. One of the reasons that underlay the effort of the Food and Drug Administration to get the new law was the feeling that better protection was needed. One of the reasons that Senator Copeland was so willing to undertake the leadership in Congress to get this law was that he had become persuaded that the Food and Drug Administration was a reputable agency as a result of a hearing that had been held in 1930 by a Senate committee to investigate many phases of the Food and Drug Administration, but particularly charges against it that its operation in the field of certain drugs, certain anesthetics, ether, and ergot particularly, had not been what it should have been. Now, the charges with regard to ergot had been made against the Food and Drug Administration by a man named Ambruster who, two or three years before, seemingly, had sought to corner the market in ergot. He raised such a hew and cry that much criticism was launched against the Food and Drug Administration, so much so, that finally this Senatorial hearing was held. Now, I'd like to know how close were you to this particular episode?

(tape 0684)

### Dr. F.:

Well, Ambruster was in New Jersey, of course, and Dr. Rusby who apparently was on his side, also lived in New Jersey but he was Dean of the College of Pharmacy at Columbia University, and I knew about the situation and at various times, I was urged to get into the thing, editorially or otherwise; I'm not certain that I ever did. I may have in the New Jersey Journal of Pharmacy. I could look it up. But, I never felt that there was much merit to Ambruster's case, and I don't think the Food and Drug Administration did.

Dr. Y.:

No, and I don't think that, as a result of the hearing, Senator Copeland thought there was. Did you ever meet Ambruster or see him?

Dr. F.:

Yes. I believe he came to see me and . . .

Dr. Y.:

Do you remember him as a person at all?

Dr. F.:

Yes, I remember him as a person. He impressed me as rather of a (tape 0712)

mountebank type.

Dr. Y.:

You mean on first blush from one visit, you got that impression?

Dr. F.:

Well, and from previous reading, of course. I knew he came to get us involved in the situation. I'm not sure whether I was then a member of this New Jersey State Board of Health or not. I was there for eight years during my 18 years of service. I'm pretty sure he tried to get us involved in the thing in some way. But from all the tests and from what the Food and Drug Administration . . . I think I had a discussion about it with Mr. Campbell at one time. I just felt that it wasn't anything that we wanted to be involved in because the ergot that was on the market—the fluid extract which was the only thing that was used (the ergot itself was never used) . . . and if there was any contamination the crude drug could be cleaned up and the extraction of it was for the active principle that was in it, and this had to be subject to biological assay and it couldn't be marketed without meeting the biological assay

standard. I never thought that Rusby was much of a (tape 0745)

pharmacologist. He was an M. D. who, I'm sure, did very little practicing of medicine. He got into pharmacy and then became administrator of that college of pharmacy.

Dr. Y.:

I've often wondered about his motivation in this episode. He had been an employee of the Bureau of Chemistry who had examined crude drugs at the New York Port of Entry.

Dr. F.:

He was a pharmacognosist really.

Dr. Y.:

For many years. Right. He had done this. Eventually, he had resigned in the late teens, but then, several years later, after having been an employee, as it were, of the Bureau of Chemistry, he takes a position that is quite contrary to it and, as you suggest, is in a position that seems to be quite scientifically unsound. What sort of a man was he and why do you think that he would boost Ambruster so much through these years, a man who was dean of a school of pharmacy? Do you have any (tape 0775)

impressions about this?

Dr. F.:

Well, Rusby was a very opinionated person, and he impressed you as a very discriminating type of scientist who would go to no ends to establish truth, and I think that probably in the examination of ergot, which he did physically and microscopically, if it was infested, he would abhor that and undoubtedly get the feeling that no decent product could be made

from it. Now, whether the ergot that Ambruster got was completely free of this sort of thing or not, I wouldn't know, but I'm sure that Rusby would not have taken up with Ambruster if he didn't sincerely believe that he was right in his own findings about it.

Dr. Y.:

So you think he was a sincere man.

Dr. F.:

Yes.

Dr. Y.:

You don't think there was any hanky-panky?

Dr. F.:

He had some very peculiar habits and reactions to things. I had a difficulty with him because the New York schools of pharmacy, about the time of the Prohibition era, they were running two shifts of courses so as to

(tape 0819)

accommodate all the people that were getting into the retail drug business by way of a college of pharmacy. And, in a way, it amazed me, as far as Rusby was concerned. I thought that he would—if there were a thousand applicants and you could only take three hundred—take three hundred and not go ahead and make professors lecture double time in order to take another three hundred, which is what the lecture room held, and work them in two shifts, adjusting hours and that sort of thing and even adding to the physical space in the building that they had so that they could do this. But he did, and it was just about at that time (this was in 1920) that the New Jersey legislature passed the law requiring college graduation for pharmacists who were to be licensed. Well, many of the

pharmacists licensed in New Jersey had been going to the Philadelphia College of Pharmacy if they lived in the south and to Columbia, Fordham and even Brooklyn if they lived in the north, but there was a New Jersey College of Pharmacy which was run largely by a wholesale drug company.

Mr. Keebler who was president of Rober and Keebler Wholesale Drug Company was the president of the New Jersey College of (tape 0858)

Pharmacy, and they gave a course, but they had part-time teachers, no full-time teachers at all, and they gave a degree and it wasn't necessary to be a college graduate to become registered, so a lot of these people took the easy course. I remember—I was still with the <a href="mailto:Druogist">Druogist'</a>
Circular—and he asked me to come over and give the commencement address and then spoke to me about the possibility of taking a deanship of the school because the prerequisite law was going into effect in 1920, and they would then, of course, have to meet standards of the New Jersey Board of Pharmacy, and if their graduates would be recognized in New York, the school would have to be recognized there and also in Pennsylvania by the Pennsylvania Board. So, I looked the situation over and I decided that I would take it, but it was just a low salary. (Side 4, tape 0000; Side 3 was silent)

### Dr. F.:

Well, at that time I was managing editor of the news edition of <u>Chemical</u> and <u>Engineering News</u>, a chemical engineering magazine which was published by the American Chemical Society, and I took this on along with keeping the editorship of this publication. This was the only way in which I could afford to take it, but I thought of the possibility of making something out of the New Jersey College of Pharmacy in view of the

passage of the state act, and so I went in there in the fall of 1921, and we had an influx of students because of the same situation had brought them into New York, but I discriminated considerably. We had the facilities for about 100 students, and I had no trouble in filling that number, and I then, of course, proceeded immediately to get some faculty. They had a small building, and we had to, of course, get some additional space. We built up, in the first year, quite a group of first year students, and in the second year, we had both classes right to the top, and some New York students began to come in and some Pennsylvania students. They didn't like that

(tape 0021)

in New York, so I have good reason to know that Rusby and Dr. Diner who was dean of the Fordham University School of Pharmacy got to the Education Department in New York and warned them against this upstart school here in New Jersey, and the Commissioner of Education, the Associate Commissioner of Education there for professional education, was a Dr. Downing, and when I was there the second year, there were some people who asked whether when they graduated they would be allowed to take the New York Board of Pharmacy examination. So I wrote to Dr. Downing and told him what our situation was, and he said, "Well, I understand you are a standard school, and we would have to investigate you." I said "Send down an investigator any time." "Well," he said, "this will take some time. We are very busy and it will be some time . . .." "Well," I said, "Can I come up to see you?" Well, that was all right. I could come up to see him, and so I took the entrance qualifications files of all of my students to Albany with me, and I said, "Now, Dr. Downing, what is the reason you suspect our not being able to

give a course?" "Well, he said, "in the (tape 0038)

first place, you admit anybody." "Well," I said, "I thought you might say that so I brought the credentials of all of my people up." It happened that the first name on the list was Baker. Baker was a Yale graduate who was in a manufacturing business in New Jersey and registered for the course in pharmacy so that he would know more about drugs and so on. course, this opened Downing's eye. Then he went on through the rest. Some of them were . . . most all of them were high school graduates, and some of them had one or two years in college, and another one was a Harvard graduate who was with the same company. "Well," he said, "this isn't what I heard about your school." I said, "Well, I think that maybe the things you're hearing are coming from biased sources, and I really would like you to send down your inspector." Well, "he said, "I will." And shortly after that, one morning I was just going in to give my lecture in pharmacy, when this fellow comes in and sits down in the back, and I recognized him as one of the New York inspectors. I just went right on with my lecture, and after I got through, I spoke to him, of course. He introduced himself--I had met him before. Then I showed him over the place and

(tape 0055)

showed him all our records and, to make a long story short, after a month or so, we got a letter from the New York Department of Education that the graduates of the school would be permitted to take the Board of Pharmacy examination. Well, Dr. Rusby raised a big fuss about that.

Dr. Y.:

Openly now?

Yes. He didn't see how the New York Department of Education could recognize an institution that had the reputation that we had. Well, on top of that, I tried to get one of his pharmacognosy teacher's assistance, and he came over to see me and he decided finally not to come because he knew that Rusby was very much incensed about it. Then they contacted the officers of the American, it was then called the American Conference of Pharmaceutical Faculties, which was the Association of Colleges of Pharmacy, about our institution and tried to keep us from becoming members. I applied for membership and just about that (tape 0070)

time, there was a great agitation for a three-year course, and the New York schools were against it. They couldn't see this 600 new students every year, you know, in two shifts, stopping their source of income there, you know. But I came out for the three-year course and very strongly, wrote about it, went to the county pharmaceutical associations and sold the idea of a three-year course to the practicing pharmacists so that the New Jersey Pharmaceutical Association was with me on it, although the secretary of the Association was on the faculty of Columbia University College of Pharmacy. And we made our application, and they sent inspectors, the Dean of North Carolina, the Dean of the Medical College of Virginia, and the Dean of the University of West Virginia School of Pharmacy. They came up and visited us, looked us over. They came in unannounced also, just about the time that I was lecturing, and we passed muster there. Then came the meetings of the conference, the first meeting, and the New York schools refused at this meeting to go along with the conference on a three-year program.

(tape 0088)

So the conference said, "Well, if you don't like it, you'll have to withdraw as a member." And they did withdraw thinking that this would be of terrific damage to the conference, and I was sitting in the rear at this meeting, and the nominating committee made its report and I almost fell over. They nominated me for vice-president. So, of course this was a little bit of Association politics. I wasn't a party to it. I knew nothing about it, but they figured it that the New York schools were going, but here's the New Jersey College of Pharmacy . . . we'll make this boy vice-president. I was, let's see, twenty-six. No, I was about thirty, I guess, a little over thirty. And, so this made Rusby still madder. . . . Columbia University College of Pharmacy never was very close to Columbia — even isn't today, as far as the pharmacy school is concerned; Columbia contributes nothing except the diploma. It doesn't contribute any finances to the College of Pharmacy at all.) And they then found themselves out in the cold. Everybody else was going to the three-year course. I think they stood it for about two years, then they came

(tape 0105)

back in.

Dr. Y .:

Well, now, tell me what kind of a person Rusby is. It's easy to see some of his characteristics from these episodes. What did he look like?

Dr. F.:

He was very near-sighted; always had a watchmaker's glass when he was reading, in his eye; he didn't wear glasses, but he was very near-sighted. He was a delightful person to be with as far as

conversation was concerned, and he would make an excellent talk, and I guess he was a good pharmacognosist, although as an M. D. That was his training. I guess he got an M. D. in the days when that wasn't a very difficult thing to do, if you were a person that was of college caliber. I would say that, in general, he was quite friendly, but he hated Remington, Joseph P. Remington, who was dean of the Philadelphia College of Pharmacy, and Remington's Practice of Pharmacy, of course, was the publication, and they had a Dispensatory which was gotten out by Wood, Remington and Sadtler: Wood, the

(tape 0123)

pharmacologist, Remington, the pharmacist and Sadtler, the chemist. Ther they had a Dispensatory gotten out by Rusby and Caspari. I think it was called the National Standard Dispensatory, and they were rival publications, of course, and Rusby always was very snide in his remarks about Remington. Remington was a much more polished person and not the kind that hated as I think, Rusby did, when he did hate.

Dr. Y.:

You mean to say that Rusby was unpolished? Or you just mean to say that he bore a . . .

Dr. F.:

Not very suave, let's say. Remington was very suave. Rusby didn't care whom he offended. Remington, on the other hand, would get his ideas across without offense.

Dr. Y.:

Was Rusby a big man?

Dr. F.:

He was stout and I would say about five ten.

(tape 0137)

## Dr. Y.:

It helps to try to get these people vivid as persons from those of you who observed them in action; so that he seems to have had a life that was marked by a good deal of controversy.

# Dr. F.:

Yes. Well, a couple of days ago I was looking through some things, and I saw a place in one of the drug journals of the time that said that Dr. Rusby was arrested, I believe, for shooting and wounding a boy with a shotgun who was stealing some of his peaches at his home there just outside of Newark. So, you see, he was a sort of person who flared up quickly and wanted to punish people for things. And yet, as I say, he could make a talk, and he could be in a group and fascinate the group with some of his conversations. He made these trips to South America, you know, for Parke, Davis and Company and for the purpose of discovering new drugs, and there was one of the people who went with him on the latest expedition. There were, I think, at least two and the last one he went to, a fellow wrote a book. If I could think of the name . . . (tape 0157)

region with nobody but the natives around, and there were three people in the party, and they had had their dinner, and the director was busy with his mimeograph machine grinding out the mimeograph notice to the staff for the next day's activities. He couldn't get them into a conference and talk to them about it. He had to . . .

#### Dr. Y.:

He had to have a mimeograph machine put out in the jungle?

This is one thing I remembered.

Dr. Y.:

He would make an interesting biographical study.

Dr. F.:

Yes, he would. I guess he was meticulous about a lot of things, and I don't know how he behaved with the natives, but I imagine the word that would characterize him at times was irrascible.

Dr. Y.:

You didn't cross swords with him about the Ambruster affair as such? (tape 0171)

Dr. F.:

No no, I kept out of that.

Dr. Y.:

Right. And so you were a kind of an oberver but not . . .

Dr. F.:

They, I'm sure that Ambruster and Rusby would have characterized me as a supporter of the Food and Drug Administration in this thing.

Ambruster . . . I wish I could find the correspondence, if it's still around . . . he wrote me numbers of letters and always they were couched in moderate language for him, and he did try to get us to do something about the quality of ergot.

Dr. Y.:

Didn't he get the New Jersey Pharmaceutical Association to support him?

Dr. F.:

I don't think so.

Dr. Y.:

There was a doctor whose surname was Ill, I-L-L, who was, I think, an obstetrician and gynecologist, who was made the chairman of a committee of the national body of obstetricians to look into this matter. Of course, ergot being extremely

(tape 0188)

important to a speciality group of this kind, and the Ill committee came out in behalf of the Ambruster side. As I recall, Dr. Ill was a New Jersey physician. Did you know him?

Dr. F.:

I knew him, not in any personal way. I met him and knew him as an active person in the medical society. There was a son also. I think Edward Ill, Sr., was the one that was connected with this, and I believe, now that I think of it, that they manufactured a Fluid Extract of Ergot-Rusby. I think finally Ambruster got to the point where . . .

Dr. Y.:

Yes, they did.

Dr. F.:

And then they put Rusby's name on it so as to carry weight with . . .

Dr. Y.:

He tried to break the market with the ergot he had. But then, ergot was brought in from another country, and so he couldn't break the market. His own, of course, was deteriorating, and so he did make fluid extract, and Rusby's name was put on it as (tape 0203)

a kind of advertising slogan. Now Ill's committee supported the Ambruster-Rusby side as against Campbell and his Food and Drug Administration.

I think where Ill came into the picture was that he was using Rusby's fluid extract of the Ambruster . . . and this is as I recall it.

Dr. Y:

It seemed a peculiar and somewhat irrational thing, just looking at it as I have slightly, for the Ill committee to have reached this particular position, and I just wondered, if having been in New Jersey at that time, you had any explanation . . .

Dr. F.:

I don't have very much recollection of that, except that it didn't really amount to much in medical and pharmaceutical circles in New Jersey at the time. They knew it was going on and there was some kind of a controversy, but they were getting their ergot and they were using other drugs anyway for the same purpose and . . .

Dr. Y.:

Well, there was enough of a storm kicked up about it that it put the Food and Drug Administration under great pressure, especially after Senator Wheeler published an

(tape 0219)

article which bought the Ambruster case wholeheartedly and completely, and so then the 1930 hearing occurred in which Copeland sat in and gained admiration for the Food and Drug Administration. Had you known Copeland when he was in New York before he went to the Senate?

Dr. F.:

As Commissioner of Health?

Dr. Y.:

Yes.

I have met him.

Dr. Y.: Have you met Ole Salthe?

Dr. F.:

Yes, I met him, too.

Dr. Y.:

So that, during the thirties, while the law was under consideration, you had some association with Salthe?

Dr. F.:

Yes.

(tape 0229)

What was the nature of this association?

Dr. F.:

Well, Salthe was an expert in foods rather than in drugs, and he would consult me from time to time about some of the drug phases of the bill, and he and Crawford worked rather closely together. They were at Copeland's beck and call all of the time on revisions, and so forth. I think Copeland was never a person to concern himself much with detail. He saw the big issue and, if that was something that he wanted to support, he did, and then got others to do the actual work, which was the case here.

Dr. Y.:

Now, we might, I think, end our evening's conversation. If you would do for the three men that you've just mentioned what I've asked you to do for some other persons who have come into the story, that is, try to make them vivid for me as people: Senator Copeland, his aide, Ole Salthe, and Mr. Crawford of the Food and Drug Administration.

We'll start with Mr. Crawford. His background was chemistry, analytical chemistry,

(tape 0247)

I believe, but he had an uncanny way of phrasing language to cover loopholes in any statement that would require living up to by those who were regulated. I think that his great service to Mr. Campbell and to the whole food and drug movement was getting statements into language which could not be distorted or circumvented by lawyers with whom he, of course, had plenty of contact in his work as a food and drug law administrator or prosecutor of violations. Now, he wasn't a prosecutor himself but I'm sure that he was the one in the administration who did the hard work of determining what the violation actually consisted of and bringing the essential evidence to prove the case. I consider him one of the best wordsmiths as far as the preparation of legislation and regulatory phases of enforcement is concerned, and he, of course, attended all the sessions of Congress where this discussion took place and was able, I think, to provide Copeland with the necessary answers to questions that had been raised or arguments that had been prepared.

Dr. Y.:

How would you compare him with Campbell as a person? (tape 0280)

Dr. F.:

Well, I think they made an excellent team. I think Campbell, in addition to being very astute about legal language, interpretation, and regulatory phraseology, was a better communicator to the public and to the <u>publics</u> that came in contact with the Food and Drug Administration. Crawford

would be the right-hand man who would sit and say very little, but take in all of the, not only language but the atmosphere and the innuendo and conclusions that could be drawn from certain words and phrases. Now, I found him later when he became Assistant Commissioner and then Commissioner rather hard on the drug industry. I wasn't concerned so much about the drug industry, as I was for the retail druggists, in that he would not distinguish between those who were violators and didn't care whether they violated or not and those who were conscientious and perhaps erred because of incompetence at times. I found this particularly in connection with barbiturates, and I had numbers of discussions with him, some of them somewhat heated about writing up the annual report of the Food and Drug Administration in which a few violations of the barbiturate phase of the law, for

(tape 0311)

example, would cause him to tell about the broken homes and the harmfulness and the heartbreaks that had been caused by people taking barbiturates when, as a matter of fact, the use under medical supervision of barbiturates is a very helpful thing. And these tremendous aberrations that occur in so-called addicts have been the results of ten and twenty and thirty times the average maximum dose of the barbiturates. And we tried to bring that out in some of our conferences with them, but just because a fellow renewed a prescription for barbiturates without having gotten a physician's order, or a new prescription for it, this, in Crawford's language made the pharmacist a criminal who broke homes and caused mental anguish and all of this sort of thing, when that sort of thing is really very rare in connection with the common use of barbiturates.

Dr. Y.:

So that you thought the way he was reporting it was false and misleading. (tape 0332)

Dr. F.:..

It was exaggerated, greatly exaggerated, in order to get a law. Now, I wanted the law as badly as he did, but I wouldn't give those reasons for it. He became melodramatic about the thing.

Dr. Y.:

I see. When you got into a heated argument, as you call it, with him, what do you mean by that? Did he have a temper?

Dr. F.:

Well, our past relations in connection with getting the legislation were so friendly that it bothered me to have him characterize the people that I represented as the type that would for a mess of pottage go and break homes and cause people the moral and mental anguish that he said they caused.

Dr. Y.:

When you made these representations to him, did you get anywhere?

Dr. F.:

Just a kind of a disdain in looks and so forth. We didn't come to blows or anything like that.

(tape 0350)

Dr. Y.:

But you really make your point. You didn't think you persuaded him?

Dr. F.:

No. He was doing it, I'm sure, to get headlines and I objected to using our group to make headlines because it reflected on the 100,000

pharmacists when there were about 100 culprits, let's say, at the most. And I felt that that should have been taken into consideration, and we went so far as one time to get it before . . . I wanted to get it before the Commissioner, and he delegated somebody to hear us out and when we got through, the Commissioner's deputy took my part and . . .

Dr. Y.:

Who was that? Do you remember?

Dr. F.:

I've forgotten his name, but I think it was Ewing's deputy. And the reports moderated from that time on, because I still say that it's not fair to stigmatize an entire profession for the acts of a few whom you wouldn't defend under any circumstances.

(tape 0367)

Dr. Y.:

Sure. Now, how do you compare Campbell and Crawford from the point of view of appearance and demeanor and character?

Dr. F.:

I think Campbell would be more impressive than Crawford. Crawford was more retiring. From approach and appearance, he acted more like a deputy than the main operator. It's a little bit like the Johnson and Humphrey situation. Not that I'm comparing the methods and the attitudes, but he was a second man in the administration and he became the first man, but I don't think he was as impressive a first man by any matter of means that Campbell was.

Dr. Y.:

Can you think of any other episode in connection with Crawford that makes him vivid as a person?

Dr. F.:

Well, my recollection is of his great ability along the lines I've mentioned, his faithfulness to the cause and to his chief and his commitment to high standards for foods and drugs and for an earnestness of enforcement of those standards.

(tape 0394)

Dr. Y.:

Do you want to go on? it's 9:30 now. Or shall we leave Ole Salthe and Dr. Campbell until tomorrow?

Dr. F.:

Suppose we leave them.

Dr. Y.:

All right. Fine. So then we'll resume in the morning.

Dr. Y.:

Now it's the morning of September 18, Dr. Fischelis, and after a night's sleep, we're gathered again to continue talking about your experiences. First of all this morning, Dick Hopkins is going to ask you questions about the background of the Durham-Humphrey Law of 1951. Dick.

Mr. H.:

Thank you, Dr. Young. One of the first things I wanted to ask you about were some reports in the business press in the 1940s, the late 1940s, about what appeared to be some concern, or considerable concern in some quarters, on the parts of pharmacy associations about the supposed decline in the

(tape 0411)

professional status of pharmacists. Was this, in fact, something that was of real concern?

## Dr. F.:

I think to give you a picture of that as I saw it, I'd have to give you a little bit of the philosophy of the people who are in the practice of pharmacy or who were in the practice of pharmacy at that time and a little bit of the tradition that has been handed down by those who were the leading practitioners in the profession and who, more or less, through the state and national pharmaceutical organizations, laid out the programs of the profession. I'll start by saying that as one gets into the practice of pharmacy as a young person who has had no previous familiarity with the drug business or the profession of pharmacy or the profession of medicine, for that matter, you, of course, think of the drug store, referred to earlier as the apothecary shop and also the pharmacy, and the development of the drug store in the United States particularly. The profession in America was started by pharmacists who came here from various sources. The German apothecaries had one type of (tape 0447)

establishment in mind when they began to set themselves up as prescription compounders and dealers in drugs and medicines. The English pharmacists had another type of background, the French and Scandinavians, still another, and they settled in different parts of the country, of course. And there were no laws on the statute books prior to the Civil War, let's say, which made it necessary for anyone who wanted to set himself up in the drug business to meet any requirements. All that he had to do was to open a shop and put a sign on the door that he was an apothecary or a pharmacist or a druggist and go ahead and accept physicians' prescriptions for compounding or selling drugs, medicines, and poisons, as the pharmacy laws refer to these items. The public

simply accepted them, because they took the qualifications that the man or men who opened these emporia gave out as possessing. So even the idea of having a physician write a prescription, give it to the patient, and have the patient seek out a pharmacy in which to have the prescription filled, was a matter of custom. It was not a matter of regulation nor law of any kind. It just was the way in which things were done and in many cases, of

(tape 0484)

course, the physician carried the drugs and gave the patient drugs himself. A good many of the earlier physicians started as pharmacists, and it was not unusual in the city of Philadelphia, for example, to have physicians have their office over the drug store or even in the drug store, and they would diagnose and prescribe and then fill their own prescriptions. So that one has to understand that everything dealing with the manufacture and distribution of drugs grew up on the basis of custom and not on the basis of law. Then we began to have laws because of the gross adulteration of drugs, some of which were imported and some indigenous to the United States. Complaints came from physicians and from others who used these drugs and chemicals and poisons for various purposes, that they weren't getting the expected therapeutic action, then there began to be some investigation. This resulted, of course, in the development of laws. This is how the patent medicine industry got its start really. In the first case in the Minnesota courts, the so-called Donaldson Case, the judge said that there was no purpose in restricting the sale of drugs to pharmacists because the pharmacists (tape 0516)

didn't know anymore about the composition of these patent or proprietary

medicines than the laymen, since their contents were not revealed on the label. The only person who was competent to talk about the product and to recommend it for whatever purpose it was prepared for was the manufacturer. Therefore, the judge saw no reason why the sale of packaged remedies should be restricted to pharmacies, because as far as the public was concerned, it wasn't getting any more protection when it bought them from a pharmacist than if bought from a general storekeeper. Now, this is fundamental to a whole idea about drugs, and I happened to grow up in an atmosphere in pharmacy, and it was confirmed later in my experiences in drug manufacturing houses and in preparation of literature for physicians and advertisements for prepared remedies, that actually in order to be fair to the public, the people who produced and distributed the drugs should be properly trained. When you say "properly trained," and follow that to its logical conclusion, it goes directly to the medical profession. So the ideal situation with respect to the use of drugs, whether they be prescribed or purchased for self-(tape 0548)

medication, is that they should be distributed under the supervision of a physician, prepared under the supervision of a physician, and used by the public only after a physician had diagnosed the disease or ailment and decided that this or that drug was the proper remedy. Now, if you use as the basis of the logical method of using any therapeutic agent, that is, on the advice of a physician, then you have to look upon the apothecary or the pharmacist or the pharmaceutical manufacturer as practicing a speciality of medicine as a whole. Now, those of us who looked upon the practice of pharmacy as a specialty of medicine wanted the people who were going into pharmacy to be properly educated. The ideal thing would

be for certain people who took a course in medicine to specialize in pharmacy just as they would in orthopedics or pediatrics or some other branch of the medical art. And when you begin to understand that you can understand why those who were brought up with that idea in mind, and who felt that that was the best thing for the public welfare and public health, why they wanted to restrict the production, sale, and distribution of drugs to persons who were qualified in the specialty (tape 0585)

of pharmacy which, in turn, required some knowledge of medicine. So the course in pharmacy developed and we had three major areas. We had materia medica which covered the great area of all kinds of drugs, whether from vegetable, animal or mineral sources or synthetically prepared, and knowledge of the constituents of the drugs, their action, their counter-effect, and some knowledge of the idiosyncrasy of patients towards the drugs that were being used. And, of course, this, in turn, led to great effort to caution against the misuse of drugs as much as to teach the use of the drugs. Then there was the department of chemistry and the department of pharmacy. Now, materia medica was made to include testing of the drug as to action on animals which, of course, brought them into pharmacology, and also whatever reaction there was on the part of patients to drugs, and this certainly bordered on the practice of medicine. If a customer came into a drug store and said "I want some Doan's Pills"--in those days, they were called Doan's Kidney Pills--and the pharmacist wanted to be of the type that we thought he should be (namely, one who knew all about the possible (tape 0620)

side effects and unfavorable effects of drugs), he would say, "Well, now,

of course, Doan's Kidney Pills don't tell you what's in them, but I believe it contains such and such a drug. Have you been taking anything like this? If you have, then, by taking this remedy, you'll get a double dose of the same drug and you might find that that's going to hurt you rather than help you." Well, you would find very few pharmacists who would go to that length to protect their patient. But to us who viewed the pharmacist as a truly professional person and a member of the medical profession in the sense that he practiced a phase of medicine, we wanted these people to be, not only highly trained, but to have a social conscience and not to put the dollar as the goal, but rather the welfare of the individual. And here you have a cleavage, because there undoubtedly are people who have done this very conscientiously, but they haven't been able to make a living to the extent that some others have. The latter were more interested in just simply passing out what the customer asked for, and taking the money and, of course, profiting from the sale. They had no hesitancy

(tape 0656)

about taking on any proprietary product. Of course, the manufacturers seized upon that and would say in their advertising, "Obtainable at so-and-so's drug store," and they would mention one or more places where they could be obtained and then go to the druggist and say, "See, we are bringing this business into your store. So stock up and be ready for it." In this way, they helped their promotion. Well, now, this commercial attitude toward the distribution of drugs and the professional attitude becomes a part of the function and makeup of the individual who goes into the drug business. We had in the earlier days, we may have even now, teachers in schools of pharmacy who go over the unfavorable

effects of drugs very lightly, as far as impressing the student is concerned, and urge the business side. And in the forties that you speak of, this kind of thing came to the fore. In fact, it did before that, because I remember an editor of one of the drug journals that was published in Detroit under the auspices of Parke, Davis and Company, Harry B. Mason was his name. In the days when I first began in the retail pharmacy,

(tape 0695)

he was urging the pharmacist, the drug store owner, to take these shelf bottles--fancy bottles--off the shelf: "They clutter up; they make some kind of an impression as far as the professional is concerned, but look at the valuable space you're wasting when you could be displaying things there that sell and that the customer would buy and therefore, increase your business." I recall this kind of literature very early in my career. It began to be promoted, especially when people who got into the drug business through the chain store operations and through the manufacturing organizations gave way to ordinary business management people, bankers and others who put their money into things and who looked upon drugs as merchandise, rather than something that was used in the treatment of disease. So we had these attitudes and desires on the part of people who went into pharmacy and who had to play a dual role, because they had to make a living and they also had to give a professional service. Now, some of them found a way out of this dilemma by filling prescriptions

(tape 0746)

and being very exacting and ethical in carrying out that function, but using the store in which they were practicing their profession as a place

where many other things could be sold. Now, I could never quarrel very much with the idea of a drug store, since it was in a corner location very often, handling related and even unrelated products, as long as the prescription department and the drug phase of the business was kept on a professional level. And I don't think that today there is any, great objection to the American drug store. In fact, the public has grown up with it. The present generation doesn't know anything about an apothecary shop. They admire it when they see it; they may take their prescriptions there to be filled; but it doesn't bother them to have things sold in the place, and it does bother the people who feel that, as a profession, pharmacy should not be practiced in a store. Well, I made a survey in New Jersey to determine how many prescriptions were filled by the pharmacists there when I became secretary of the State Board of Pharmacy, and I found that less than 100 out of (tape 0792)

1800 pharmacies were filling 100 prescriptions or more a day. The average was around thirty prescriptions a day. Well, now thirty prescriptions a day would keep one pharmacist fairly busy. In the days when there was a good deal of compounding, it was a full day's work, but when ready-made products came on and the pharmacist didn't have to pack capsules anymore, or mix liquids to any great extent, he could fill these prescriptions in a very short, relatively short, time. Now, I was confronted, as a law enforcement office., with the difficulty of demanding high standards of performance, the allotment of space, and the presence of equipment in places where maybe five or six prescriptions were filled a day, some country places. And I had a hard time convincing the pharmacists of the state that, regardless of how few or how many

prescriptions were filled in a pharmacy, it needed to be prepared for any kind of prescription service. It needed to have a clean and sanitary prescription department. You couldn't use the prescription counter for the receiving of merchandise and checking and pushing it out of the way when a prescription came in so as to have room

(tape 0842)

enough to fill it, or, if they had a soda fountain and a food department, of bringing the food dishes back to the prescription laboratory sink to wash. So, we just framed some regulations along that line, and I went around the state to the county pharmaceutical societies and others and I said, "Now you people, if you want to keep up the image of this profession before the public, your professional service has to be of the highest standard so that we can say to the public, 'Yes, these establishments are meeting the requirements of the State Pharmacy Act,' and so that you see a registered pharmacist certificate (we began to require his picture on it so that those who displayed the certificates of registration of deceased pharmacists, and who were using unqualified people to do the pharmaceutical work, wouldn't have the same advantage that the fellow had who was a legitimate pharmacist and a registered pharmacist)."

(Side 5, tape 0000)

#### Dr. F.:

Now this idea of permitting a professional function to be carried on in a business establishment, provided the professional work is properly done and properly supervised and is of the highest quality, is something that has to be kept in mind whenever we think about the development of the practice of pharmacy. So that when the chain store efficiency experts

begin to talk about the proper use of space because the prescription work might only bring in ten percent of the revenue, and, therefore, should occupy only ten percent of the space—this kind of thing just has to be worked out with the people who go into the drug business and who hire a pharmacist because they need to have a certificate of registration in view. They do not care about prescription work, that is, the compounding. If a person comes into a pharmacy with a batch of suppositories to make up, for example, they just say, "We're sorry we are out of this one ingredient. Why don't you take this to some other place, because we just don't have it." They'll take all of the quick-filling type of prescription and

(tape 0020)

the things that move fast, but they just won't give a 100% service.

Well, this isn't the idea. When you license a pharmacy, you license it to give full-service. Then, of course, came the open-view merchandising idea which the supermarkets and others provide, and here you run into the danger of the individual picking his own packages and not reading labels and not being familiar with different types of products and their contents, and never even bothering to check what the product contains because that doesn't mean anything to them. I had a judge condemn a pharmacist one time because he hadn't told the judge, who was a customer of the drug store and was buying Alka-Seltzer and giving it to his youngsters for indigestion or pain or something, what Alka-Seltzer was. When the pharmacist one day mentioned, "Do you know that Alka-Seltzer is chiefly aspirin?" "Why no. Why didn't you tell me that. I didn't want my kids to become addicted to aspirin." Well, he didn't read the label. Of course, the label doesn't exactly say that Alka-Seltzer turns into a

compound of aspirin, but that's what happens. So, this guidance just isn't there when the individual starts to respond to advertising and to brands of products which might contain drugs (tape 0040)

that I had as an enforcement officer—that it is not in the public interest for non-pharmacists to be dealing in drugs and medicine and that it is the function of a pharmacist to protect the people who buy drugs from him, whether they be prescriptions or ready—made products, to do enough questioning to be able to give guidance—then you're talking about a type of pharmacy practice which is really professional and which is in the public interest, and you're not talking about a business. What else goes on in the establishment, as far as the sale of merchandise is concerned, doesn't bother you as long as you can guarantee to the public as an enforcement officer that the professional function of the pharmacist is being available. Now, will you repeat your question so that I can . . .

### Mr. H.:

One thing you have touched on I'd like you to talk about a little further. In what the periodical literature in the late forties called the decline in the professional status of pharmacy there was involved the so-called therapeutic

(tape 0060)

revolution and the growth of the ethical drug houses and their practice of manufacturing drugs so that all the pharmacist had to do was to put up a prescription by taking pills out of a bottle. In effect, he became something of a "pill roller." What sort of effect did this have on the

pharmacist's professional self-image, for example?
Dr. F.:

Well, there was a seeming paradox. As the education of the pharmacist was enlarged and improved so that he would understand the chemical and pharmacological background of the drugs which were being used, his use of the education apparently diminished because he was no longer either making or compounding the drugs about which he was being taught. Some people thought that this was reducing the pharmacist's professional function and, therefore, his professional image, but I doubt whether the public generally lost any of its respect for the pharmacist as a professional person if he accepted and then delivered the prescription in person or had a registered pharmacist to do that. The people who talked about pharmacy losing its professional

(tape 0082)

image were those who looked only on the development of the modern drug store as a merchandising emporium, and they would talk about the sandwiches that they sold at the soda fountain, or garden hose was a common thing that was talked about, and magazines and newspapers. Well, actually, the pharmacy was so arranged that in most cases, the professional area was still pretty generally not only visible but impressive. Now, there were of course, chain organizations who, because they minimized their interest in prescription work, set off just a very small section in the drug store as a prescription and drug area, and moved more and more of the packaged remedies into a merchandising area. This, of course, called for questions on the part of people who were in the practice of pharmacy, and they ridiculed the idea of a merchandising organization trading on the term "drug store" or "pharmacy" when the drug organization trading on the term "drug store" or "pharmacy" when the drug

and pharmacy service was kept at a minimum. I'm not sure that anybody who gave real thought to the situation, especially in the practice of pharmacy and in the industry, could really find too much fault with the professional image of the pharmacist. I have personally checked that (tape 0107)

with people in various areas, professional and otherwise, and I never got the reaction that pharmacy was losing its professional image. They might have commented and even joked about the unrelated side-lines that were being sold, but when it came to the professional area, I could discern very little in the way of loss of respect. In fact, I thought that with the educational program being enlarged and especially since the medical care program was being advocated (which began about the same time—in fact, it was already underway), and as the national health programs were being discussed, nobody in any prominent place felt that pharmacy wasn't a part of the general medical care program.

Mr. H.:

So, what you're saying then is that the great increase in the number of prepared medicines for prescription use did not affect the public image of pharmacy as a profession.

Dr. F.:

I couldn't find any evidence.

(tape 0127)

Mr. H.:

And neither did it affect the pharmacist's own self-image of himself as a professional?

Dr. F.:

Well, I think that the pharmacists who were forced to compete with

chain-store organizations saw these organizations and especially the supermarket type of establishment taking over the sale of packaged remedies. They were unable to meet the competition effectively, and they began to lament the fact that the profession was, well, in their extreme terms, "on the way out." Actually, what this demonstrated was merely that they were not in a position to compete with this new type of drug distribution, and they had the choice of either closing up and moving into an area where their kind of service and their kind of shop could make out, or becoming a part of the system, such as taking on sales jobs with drug manufacturers and detail jobs where they expounded the virtues of these brand preparations to physicians. Now, I think that's the source of that kind of a feeling and, on the other hand, there were some pharmacists who took full advantage of the situation.

(tape 0151)

They got rid of their soda fountains and lunch counters and just concentrated on the prescription and other drug business, doing it with the help of the medical profession, in many cases, by locating where there was that type of . . .

# Mr. H.:

In doctors' buildings. It seems to me that what you've been describing here is a sort of built-in Dr. Jekyll and Mr. Hyde character which the pharmacist had to cope with. That is, on the one hand, he was a professional. On the other hand, he was also in business, or at least, many of them were in business, those who were independent drug store owners. It also appears that it was this Dr. Jekyll and Mr. Hyde character which the two national pharmacy or druggists trade associations, professional associations, appealed to, that is, the

American Pharmaceutical Association, of which you were Executive Secretary, was concerned primarily with the professional aspects of the nation's pharmacies or pharmacists. The National (tape 0167)

Association of Retail Druggists was concerned to a fairly large extent with the business aspects of the independent drug store owners. Does this account for some of the strained relations between the two organizations over the years?

### Dr. F.:

Well, it's difficult to know just what the "strained relations," if any, are, or just how much the associations were able to do for their members in solving the individual member's problems. Now, the American Pharmaceutical Association was organized in 1852 as a result of the complaint of physicians about the quality of drugs that were available, and I believe the American Medical Association was organized in 1847. There had, of course, been local and state organizations, but the national associations organized really to get rid of those who were incompetent or, put in another way, to put a badge of distinction on those who were actually trained to do the medical or pharmaceutical work. Now, when the American Pharmaceutical Association was organized, one of the first things it

(tape 0192)

did was to develop a code of ethics—I think they adopted a code of ethics at their first meeting—which was for the purpose of showing the public that there was a group of people who were qualified in this field and there were others who were impostors. How much attention the public paid to membership in the American Pharmaceutical Association or in the

American Medical Association at that time, I don't know. But, at least, that was the basis of organization, and then, of course, they began to develop an educational program and they asked for legislation to overcome these difficulties that were encountered because of unprofessional conduct and so on. Early in the American Pharmaceutical Association's history, there was attention paid to the business side of the drug service and pharmaceutical service, and a number of attempts were made to organize so-called commercial sections. I myself was secretary and later chairman of the commercial section and wrote some commercial-interest articles for the Journal of the American Pharmaceutical Association, always tending to show that in the commercial aspects of the calling, one had to be just as ethical and

(tape 0216)

professional, if you will, as in the discharge of the so-called professional duties. But there were price-cutting evils, and there were efforts on the part of some to monopolize business by the usual merchandising methods of bringing people in on a basis of low-cost of one or two items and then making it up on higher charges for other items. These so-called unfair practices were what led some of the members who were in areas, usually in areas where there was keen competition on the merchandising level, to ask for action by the association, legislative action, to correct this or to protect the small operator. It was this type of activity that led to the formation of the National Association of Retail Druggists. They were all members of the American Pharmaceutical Association who really formed it, and they started one organization and it disbanded after a number of years, and then they started off again and people said, "Well, now, if you're in the retail drug business, you have

certain problems; if you're in the wholesale drug business, you have certain problems; and if you're in the manufacturing business, you have certain problems that deal with your own peculiar interests and are (tape 0240)

not of interest to the Association as a whole. So we've got to have a wholesalers association, we've got to have a manufacturers association." Even the colleges felt that the education section in the American Pharmaceutical Association wasn't sufficient for concentration on their interest, so you had to have an association of colleges of pharmacy. The same was true in medicine, the Association of American Medical Colleges, and then you had the enforcement agencies, the boards of pharmacy. They felt that they had certain problems they wanted to discuss and work on for themselves, and so you have the National Association of Boards of Pharmacy. Well, this was a rather logical development, and the National Association of Retail Druggists limited its membership to owners of pharmacies. There was no reason why they shouldn't belong to the American Pharmaceutical Association. In fact, every professional in pharmacy ought to belong to the American Pharmaceutical Association according to the feeling of those who are association-minded, and then belong to their special trade association to (tape 0256)

protect their trade interests. So, I got into the American

Pharmaceutical Association in 1912, and these different ideas were

expressed at their convention, they were expressed in the journals, but

there was never any feeling generated about this sort of thing. You

belonged to the American Pharmaceutical Association, and you also

belonged to the trade association which was particularly helpful. If you

weren't in trade or in the retail field, or if you didn't have any retail problems that you felt could be solved better by association effort than by your own personal efforts, you just didn't join the National Association of Retail Druggists. But, obviously the people who get into the trade interests are trade and business-minded and then they begin to build up membership, and you get executive secretaries or people who run the associations who put on membership campaigns. In those days membership dues in the American Pharmaceutical Association were five dollars, and the dues were the same in the National Association of Retail Druggists. You wouldn't

(tape 0276)

think that five dollars would keep anybody out of the National Association of Retail Druggists if he felt that they could be of help to him, or that by joining for five dollars that they would give up the five dollar membership in the American Pharmaceutical Association. But, actually, that's how some of this worked out, and the promoters of the National Association of Retail Druggists were more active in the promotion field than the American Pharmaceutical Association. The APhA had the feeling that "Well, if you're a professional pharmacist, you will want to belong to your professional society, and so we invite you to membership, but we are not going out and try to solicit you for membership." Actually, of course, membership campaigns went on in both organizations. My own attitude was, "Fine. Let the retail drug store owner and the American Pharmaceutical Association support the NARD." I don't think I ever made a speech before any local group of pharmacists where I didn't say, "If you're the owner of a retail pharmacy, you ought to belong to the National Association of Retail Druggists.

(tape 0293)

And we're glad to work for your professional welfare and to expound the quality of your services to the public, but, by all means, when it comes to matters such as legislation that affects price-cutting or price-fixing or fair trade, we'd rather not be the advocates of that because it's business. We have a national association with a lobby in Washington that will help you on that. Go ahead and join it." And, of course, the thing that appealed to the retail druggists was the fact that NARD was an association with a full-time secretary, which the American Pharmaceutical Association didn't have at the time; it was in Chicago, which was central; and it had a Washington representative, a lawyer in Washington, who would do the usual lobby work that associations do. It wasn't that the American Pharmaceutical Association didn't appeal, but the average retailer didn't attend national meetings, and here was an association that was going to help his business. And so he joined. Now, the best illustration I have of the pharmacist's attitude was when the American Pharmaceutical Association decided to put up a building in Washington, there were 14,000 people in pharmacy who contributed to the building (tape 0319)

fund. The idea of pharmacy being represented with a building in Washington and, eventually, with a full-time secretary, appealed to these people. Less than 3,000 of those 14,000 belonged to the American Pharmaceutical Association and yet they were contributing to this building, so the image of pharmacy as a professional group had its appeal. But when it came to getting things done, as far as national legislation was concerned and as far as trade matters were concerned, fighting the manufacturers for better discounts and the wholesalers for

more services, appealed to their business instinct and they, of course, paid their dues there. Now, I found that situation when I became secretary, and it's a matter of record now that in the time I was there, the membership increased from less than 5,000 to 32,000, simply because we were hitting constantly on the idea that well, professional representation is one thing but business representation is another, and you ought to belong to both. Of course, then when it came to matters of legislation, like food and drug and the maintenance of the (tape 0344)

professional activities, we naturally, in the American Pharmaceutical Association, presented a somewhat different point of view than the National Association of Retail Druggists, not that we didn't go along with the general idea. But we felt that, as is exemplified in the Durham-Humphrey legislation, drugs shouldn't be divided into prescription drugs and non-prescription drugs; that drugs were drugs, and the protection that people need in the use and the purchase of drugs should be the same whether it's something bought for self-medication or whether it's something supplied on a prescription. And this is, of course, where differences developed, and we got into the matter of refills and the matter of protection. Implicit in all this was, of course, the fact that if you established the idea that drugs were more than merchandise and that they should be supplied only by pharmacists, there was an economic area there, too, and you were accused of wanting to prevent the sale of proprietary products, or medicines, or simple remedies.

(tape 0370)

You wanted to have them sold only in pharmacies and by pharmacists, and you didn't want them sold just anywhere. Well, the National Association

of Retail Druggists would go along with the idea that they ought to be sold just in one place, but they wouldn't go along with the idea of supplying services, such as questioning the customer for a proprietary medicine as to what they were going to do with it, whether they knew what the contents were, and so forth. In other words, the professional service didn't seem to them to be of much significance, and a product which is already packaged and directions for use given on the label to them became just an article of merchandise. They wouldn't go to the lengths that the American Pharmaceutical Association would go to extend the protection. In this way, they followed the Proprietary Association's program and were allied with the Proprietary Association much more than the American Pharmaceutical Association was. The American Pharmaceutical Association recognized the Proprietary Association by giving it a delegate in the House of Delegates, but it

(tape 0392)

did not go along with the idea of general sale by anybody. We had the idea that in the pharmacy itself all drugs should be sold under the immediate supervision of a registered pharmacist. NARD's idea was a little more lax in that respect. Anybody in the store should be able to sell it as long as it was an over-the-counter product labeled with the food and drug law. This is where I had a little difficulty with the Food and Drug Administration, because I felt that they should, in view of the support that the American Pharmaceutical Association and the professional pharmacists were giving the Food and Drug Administration in its enforcement program, that they should go to the extent of advocating the sale of drugs under professional supervision. But they shied away from that completely. They would not get into the area of the sale . . . of

where the drug was sold or by whom it was sold, as long as it was properly labeled with regard to regulations and the Food and Drug Act.

And my quarrel with the Food and Drug Administration, at that time, and almost continuously, was that they would not extend themselves into (tape 0415)

the area of the consumer's interest sufficiently to feel that it required a pharmacist to dispense a pharmaceutical, and they were very frank about that and said, "We have no concern about who sells it or where it's sold, as long as it meets the Food and Drug Law requirements, as to labeling and quality of content.

Mr. H.:

Dr. Dunbar, Paul B. Dunbar, who was the Commissioner of Food and Drugs in the late forties and retired, I think, in 1951 . . .

Dr. F.:

He died recently.

Mr. H.:

... chose a NARD convention for making the announcement about the Food and Drug Administration's opinion, which was a new opinion apparently, on refilling of prescriptions. This was in October 1948. The Food and Drug Administration, due to what it considered to be some abuses in refilling of prescriptions for dangerous drugs, had come to the conclusion that a prescription,

(tape 0436)

as Dr. Dunbar later said, was a check, and once it had been canceled, then it no longer was valid. Therefore, a refill for a prescription would have again to be another check from the prescribing physician. The American Pharmaceutical Association and the National Association of

Retail Druggists appeared after the convention to be uniting in much the same way that you described last night in the National Drug Trade

Conference for a united front in opposition to the Food and Drug

Administration. There was a joint meeting of the executive committees, I think, in December 1948, where it was agreed by the officers of both associations that a bill should be drawn up and introduced into Congress to prohibit such an interpretation of the Food and Drug Act by the Food and Drug Administration. In other words, that refills should be exempted from the provisions of the Food and Drug Act, in effect.

Dr. Y.:

All prescriptions by physicians should be exempted.

(tape 0455)

Mr. H.:

Yes. All prescriptions by physicians should be exempted.

Dr. F.:

Exempted from what?

Dr. Y.:

Control by the Food and Drug Law.

Mr. H.:

This united front didn't seem to last too long. In 1949, the NARD was taking credit for the first Durham Bill which was announced in March, I think, which would have exempted all prescriptions from the provisions of the Food and Drug Act. And then the American Pharmaceutical Association announced the formation of a joint conference committee on Food, Drug and Cosmetic Law problems and you wrote in editorials in the <u>Journal</u> of the APhA to the effect of this multi-representational body. You invited the NARD and various of the professional organizations which were affiliated

with the APhA as well as yourself, and other officers of the APhA. This group would meet with Food and Drug officials in an effort to try to negotiate some sort of what you said was a satisfactory conclusion, without

(tape 0474)

going through the need of passing the first Durham Bill which seemed to arouse quite a good deal of opposition in the first place.

Dr. F.:

Let me get the timing correctly. Was the exemption of prescriptions from the . . .

Mr. H.:

In other words, what had happened in the first six months after Dr. Dunbar's speech was that the NARD had introduced a bill to exempt prescription practice from the Food and Drug Law. The APhA, on the other hand, was trying to negotiate, or it seemed it was trying to lead to a negotiation of a settlement with the FDA, over how prescriptions should be handled, through this joint conference committee. By early 1950, late 1949 and early 1950, it was quite apparent that the two associations were heading toward conflicting opinions of the problem. What I'm driving at here is, why was there this divergence in the policies of the two associations when they had begun by completely opposing FDA authority? (tape 0502)

Dr. F.:

Well, I think it can be attributed to the fact that the National
Association of Retail Druggists is an organization to protect the
commercial interests of the pharmacists, and the American Pharmaceutical
Association has endeavored to put the professional service and the

professional activity first and the business interest second. The American Pharmaceutical Association is not unmindful of the importance of the business interest or the economic aspects of the distribution of drugs. It is interested in that, but, its primary function, it has felt, was to uphold high standards of practice for pharmacists and to keep the professional role of the pharmacist foremost in the minds of those who have anything to do with drug production and distribution and regulation. Now, as I have indicated, the Food and Drug Administration felt that the commercial interests of those engaged in the production and distribution of drugs was none of their concern. They were interested in the protection of the public far enough to believe and advocate the handling (tape 0537)

of all drugs by registered pharmacists. They felt and still do feel, I believe, that the state pharmacy laws have been passed to protect the public, and if it were not necessary to restrict the sale of drugs and medicines to registered pharmacists, the state would not have such a law on its statute books. One can argue that some so-called harmless drugs should be made available anywhere and the public wouldn't be hurt by it, but we have felt that in the law and regulations, either one thing or the other, that is, full protection or partial protection which very frequently becomes no protection at all. Now, based on that premise, the idea of labeling a product to be used as directed by the physician placed that product in a prescription category. If another manufacturer wanted to put adequate direction for use on the label of the same product, according to the Food and Drug Administration, this product was no longer their concern as far as its distribution was concerned. It was of great concern to the profession of pharmacy, because if a manufacturer chose

(tape 0575)

to label his product as a prescription product and wanted his product to be sold only on the prescription of a physician, we felt that he had a right to that option. We felt that the Food and Drug Law was not passed to compel manufacturers of prescription products, some of which products might be labeled with adequate directions for use, to become commercial products in that way, to be available in any place without the supervision of a pharmacist. I think the distinction is clear that the American Pharmaceutical Association was interested not only in correct labeling of products, but in the restriction of as many products to prescription status as possible, because only in that status would the full protection against misuse and unfavorable reactions become the responsibility of the physician. Now the Food and Drug Administration felt that this was perhaps an economic question as far as the pharmacist was concerned, that it was to his advantage to have as many products put on a prescription basis as possible so as to keep them out of general stores for sale and thus make the product competitive, not between pharmacies, but between pharmacies and general stores.

(tape 0613)

#### Dr. Y.:

Also it seems to me that the Food and Drug Administration had to read the law, whatever the people may have felt was ideal, they had to operate their policy under the terms of the law as they thought it was written. And it seems to me that this shows the difference between you and the Food and Drug Administration in this issue. Don't you think it would be a good idea, Dick, if Dr. Fischelis mentioned the precise occasions that he remembers when this debate occurred between him as a representative of

APhA and people at the Food and Drug Administration? Did you face them and have conversations over this particular issue you've just been outlining?

Dr. F.:

Yes, I had conversations even with Mr. Campbell about this situation.
Mr. Campbell was very sympathetic with the idea, but felt that if the
Food and Drug Administration got into the commercial aspects, as the Food
and Drug Administration interprets it, that they would weaken their
position with regard to protection of

(tape 0638)

the public. Mr. Murray who is one of the active people in the Food and Drug Administration under Mr. Campbell, said to me on one occasion, "Well, look, if I want to get some antiseptic or even tincture of iodine, and I'm out in the country somewhere, I don't see why I can't but it from the local merchant if there's no drug store around." Well, of course, this is taking extreme cases and, as in all legislation, you just can't provide for every individual case. We had that in our State pharmacy Act, for example, where the law provided that drugs, medicines and poisons shall be sold only under the suprevision of a registered pharmacist. The law didn't define the term "drug," it didn't define the term "medicine," it didn't define the term "poison," and I welcomed this lack of definition as an enforcement agent because of a pharmacy or by a non-pharmacist, and it got to the point of prosecution, I had to prove, in each case, that the item sold was a drug, or a medicine or a poison. I could do that, whereas,

(tape 0671)

if an item was defined, there was always some kind of a loophole where a

certain type of labeling or something would take it out of the category of a drug, or medicine, or poison. Now, of course, the Food and Drug Administration did have a definition for drugs, medicines and posion, but it did exempt prescriptions, and it was felt by us that exemption of prescriptions placed the responsibility for prescriptions on the physician and the pharmacist, and this is where the professional function of the pharmacist came in, as far as compounding and delivering was concerned. The Food and Drug Administration did have authority over the content of a prescription, if it could be proven by analysis that the prescription was incorrectly filled, or the State Board of Pharmacy, or the State Department of Health, and eventually the Food and Drug Administration, if interstate commerce could be shown in some way, were able to control adulteration and misbranding. And I believe they did have authority for adulteration nationwide under the act.

(tape 0700)

Dr. Y.:

If it moved in interstate commerce.

Dr. F:

If it moved in interstate commerce. Now, this was, of course, also the reason then for having state laws in conformity with the federal act. That's another question which I suppose we'll come to again. But this difference between the American Pharmaceutical Association and the professional pharmacists and the Food and Drug Administration was what led Dunbar, in my judgment to go to the National Association of Retail Druggists convention and talk about the prescription. The National Association of Retail Druggists had been confronted with violations on the part of their members, store owners who had been selling

over-the-counter some of the products which which were restricted to prescription because adequate directions for use could not be written on the label. And we had cases where drugs, such as the sulfa drugs, were sold over-the- counter with nothing more than a label giving the name of the product and the

(tape 0730)

strength of the tablet. This led to the Sullivan case, and we were perfectly content to have the Food and Drug Administration supervise anything that went over-the-counter, but the more things that were restricted to prescriptions were, of course, to the advantage of the pharmacist as a professional and as one who earned his living by doing that kind of work.

Mr. H:

So the issue then of protection of the public becomes tied up with the issue of protection of professionalism.

Dr. F:

That's right.

Mr. H:

And there could be cases, as the NARD, I think, was trying to point out, where protection of the public, under existing food and drug legislation, was not an issue but what was an issue, in the labeling, that is, a company like Eli Lilly which used this phrase "to be used as directed by a physician," which legally was not the prescription legend. It was a "half-way house," so to speak, between the prescription legend and (tape 0755)

adequate directions for use.

Dr. F:

Well, the prescription legend wasn't effective then, was it?
Mr. H.

Yes. I think, to some extent that it was, by regulation.

Dr. Y:

By regulation. Not by the terms of the law. Right. The Food and Drug Administration was trying to separate sheep and goats and clear out the fuzzy zone in between by regulation.

Dr. F:

Well, I started to say that the NARD was confronted with this over-the-counter sale by some of its members and then had to provide legal service for them to get them out of their difficulty with the Food and Drug Administration. We didn't approve of this over-the-counter sale of these drugs at all, and neither did the NARD, as far as that's concerned. But when their members called for protection and enough of them were violating the law, some of them gave as an excuse that one manufacturer's product was labeled "to be used only under the direction of a

(tape 0784)

physician." In the case of other products with adequate directions for use, they said, "Well, one time, we get one manufacturer's product from the wholesaler, and another time we get another one, and we're accustomed to selling it over-the-counter, and "wer're being stopped from selling it over-the-counter, so where do we stand?" That's when the NARD took the position that, "Well, we're going to compel the Food and Drug Administration to say what can and what cannot be sold without a prescription." And this, of course, led to the Durham-Humphrey legislation. But we felt that pharmacy would lose some of its

professional status if we got to the point where the drugs were classified just into two classifications, which would confine prescription compounding and selling to pharmacists but lay the other area of drugs open to sale anywhere.

## Dr. Y.:

That makes it, it seems to me, very clear as to what the basic position was. Let me, if I may, Dick, just insert another question. This point you just made does differentiate your policy from that of NARD and does show that there was a

# (tape 0824)

sort of schism here. I'd just like to ask a kind of provocative question on this point. Do you have any feeling that the deviation of policy on the part of NARD could in any way have had membership-building potential in a kind of a competitive way as against you, so to speak? You painted a pretty rosy picture about your relationship and the proper role, adequate role, of both of these organizations, and this is certainly true, but there was a certain competition for membership. Do you think that their effort to take a sort of leadership in this case, as they saw it, and to try to get a resolution with the Food and Drug Administration, even one that would differ from your position, was in any way a sort of public relations gesture from the point of view of pharmacy owners to try to build membership and kind of up-stage you, to some extent? Was there any of that kind of rivalry, organizational, and maybe even between the executive director

## (tape 0870)

of their organization and you, as a person, that might, as you see it, thinking back honestly, be an element in this kind of divergence of policy that came to exist at this point?
(Side 6, tape 0000)

Dr. F.:

I might point out that, having given you the American Pharmaceutical Association's point of view and the basis for its action and effort and interpretation of the Food and Drug Law, it seemed to me, and I'm sure to others (certainly to the governing board of the American Pharmaceutical Association) that the Food and Drug Administration took advantage of this difference in viewpoint and their disinterest in the place or by whom drugs were distributed. They worked with the National Association of Retail Druggists, rather than with the American Pharmaceutical Association in getting across legislation that would just give us the two classes of drugs, and selecting the NARD as the medium (tape 0020)

for making policy announcements in this particular area. Now, when it comes to the other matters, will you just mention the first of those?

Dr. Y.:

Well, one of them was the possibility that part of the rivalry between the two organizations related to a conflict in personalities between you and Mr. Dargavel. And another, and allied to that, was that the difference in views that NARD took was deliberately exploited by them in an effort to build up their status with pharmacists, especially owners throughout the country, at your expense in a competitive drive to build their membership and allegiance to them for fighting their battles, supposedly, for fighting battles of pharmacists on the national level. Now, how true is this?

Dr. F.:

Well, let's consider this: there are roughly 100,000 registered pharmacists in the United States, and there are roughly 50,000 independent retail drug stores, so the possibility of membership in the American Pharmaceutical Association which accepted for membership anyone who is engaged in any phase of pharmacy . . . This has later been (tape 0042)

restricted to graduates of colleges of pharmacy, but at that time, I was for those who were interested in the advancement and development of pharmacy. The potential then was 100,000. At the time I took over, the membership was less than 5,000. The potential membership of the National Association of Retail Druggists was the 50,000 retail drug store owners. And, of course, to do the kind of work it did, maintain a Washington lobby and also its Chicago office, it necessarily had to have members and obviously, to get members, it had to show that it was doing something for the commercial interest of the retail drug store owner. We had no quarrel with that, and we felt that the two organizations should go along separately as far as membership solicitation was concerned; the only overlap was in the drug store owner being a member of both. We welcomed the drug store owner, of course, and we urged the drug store owner to join the National Association of Retail Druggists. We wanted him also as a member, as a professional, and appealed to his professional pride ttical Association. Now, as far as we were concerned, we were trying to (tape 0063)

get more members, because one of the things that you are up against when you appear before a committee of Congress is to indicate whom you represent. And obviously, if you go to a committee of Congress, I never had to do it just this way, but Dr. Kelly, my predecessor, had to go

Pharmaceutical Association, representing the professional pharmacists of the United States. Well, the question would be asked: "How many pharmacists are there in the United States?" And he would say, "100,000," and then as to "How many members of your association?," and he would have to say, "Less than 5,000." "Well, then, you really don't represent the 100,000 pharmacists?" I overcame that difficulty in a way by, of course, endeavoring to increase the membership to start with, but when I was asked: "How many registered pharmacists are there in the United States," I would say, "100,000." "How many active members are there in your association?" Well, it was growing and, of course, I would say 10, 15, 20,000, whatever the number was at the time. But, I would indicate then that while our individual membership was low, we had an affiliation with every state pharmaceutical

(tape 0084)

pharmaceutical association was represented by two delegates, and the state pharmaceutical associations, in combination, had over 50,000 members, so that we were representative of the opinion and feelings of the professional pharmacists of the United States, because the House of Delegates was where our business was transacted. This was where our policies were formulated, and they were formulated by representatives of the state pharmaceutical associations, and also all of the national pharmaceutical associations who had delegates there. They all had a voice in it. So when I was speaking for the pharmacists of the United States, I was speaking through our House of Delegates. Now, Mr. Dargavel, when he appeared before the committees, he would say, "We have

let's say, 30,000 members, and there are 50,000 pharmacies, so we represent the majority of the retail drug stores of the United States."

Now, I felt that I was in just as strong, if not stronger, a position in my representation of the profession of pharmacy than he was in the representation of the retail

(tape 0101)

druggists. Of course, Mr. Dargavel wanted to impress the committees of Congress with the fact that the voice of pharmacy was the voice of the National Association of Retail Druggists, and he would say that he had 30,000 members and they were all retail drug store owners, so he spoke for the retail drug store owners. I never disputed that, because I wasn't asking for legislation in behalf of the retail drug stores of the United States. I was asking for legislation in the interest of the public who were being served by this profession and, in order to enable the profession to serve as we felt it should, professionally, we were speaking for the House of Delegates of our association which, in turn, spoke for the profession.

Mr. H.:

Do you feel then that the professional interests of pharmacy and the public interests were identical?

Dr. F.:

We felt so.

(tape 0118)

Mr. H.:

Which obviously was contrary to the point of view of the Food and Drug Administration on some matters.

Dr. F.:

Yes. They didn't feel that the protection of the public extended, had to be extended, to having all drugs supplied by or under the supervision of registered pharmacists.

Dr. Y.:

You said that you argued this point with Mr. Campbell and Mr. Murray in the earlier period. Did you argue this point during the more heated period when these things were up for perhaps legislative resolution, with representatives of the Food and Drug Administration?

Dr. F.:

I don't know that we had any necessity to argue it, because we understood each other's viewpoint so well that I ceased to ask the Food and Drug Administration for anything which had to do with the confining of the sale of drugs to pharmacists

(tape 0131)

or pharmacies.

Dr. Y.:

You didn't talk to Dunbar or Crawford about this issue?

Dr. F.:

Well, I probably alluded to it, but I knew in advance what their position was and that they wouldn't or perhaps even couldn't, adopt any other position. I think they could have if they had wanted to, but I don't think they were . . . I mean, they could have in a limited way indicated that . . . and they have since, in quite a number of instances, spoken of the distribution of drugs through pharmacists, but it has always been in connection with dangerous drugs. It doesn't help the professional prestige of pharmacy to have the Food and Drug Administration prefer to have the barbiturates supplied on prescription only through registered

pharmacists in pharmacies, rather than have them sold at filling stations by people who get the stuff in underhanded ways. I felt that the Food and Drug Administration could go a little farther than they did in letting the public feel that the proper (tape 0148)

place to buy drugs and be assured of proper warning, even though the warning was on the label, was through people who were trained to give that kind of information and professional service.

## Mr. H.:

Well, if this is so—this desire for restricting more and more drugs, from the professional viewpoint of the American Pharmaceutical Association—why did the APhA, why did you and why did Dr. Schaefer, Dr. Hugo Schaefer, who was then Dean of the Brooklyn College of Pharmacy, oppose the administrative listing provision in the Durham—Humphrey Bill? This would have empowered the administrator of the Food and Drug Act to list those drugs which could only be sold on the direction of a physician, and all of the rest would then obviously become over—the—counter drugs. The question is becoming involved, but, in the hearings, Oscar Ewing (the administrator of the act as the head of Federal Security Agency) replied to a question from one of the Congressmen about whether aspirin could ever be listed as a (tape 0165)

prescription drug under the provisions of the bill as it was then written, that it was quite possible, because it would depend upon who was the administrator. Now, wouldn't it seem . . .

### Dr. F.:

I'm not sure that I get that. Would you remind repeating?

# Mr. H.:

Well, the administrative listing provision would have provided, had it been enacted, the power for the administrator of the Food and Drug Act to survey all drugs and to say, after appropriate administrative procedures, which drugs could only be sold on a prescription basis.

#### Dr. F.:

You say that we opposed that?

## Mr. H.:

You opposed that very strongly. That was one of the main points in your opposition to the entire bill. This power of listing drugs for prescription could have been much more effectively turned around to your benefit under the argument that you're using here, you see.

(tape 0177)

#### Dr. F.:

I don't think so, because if it was up to the administrator, the pressures from the proprietary medicine and over-the-counter medicine people would have been so great that they would have the names of their products off the list, and the list of those which could be supplied only under professional supervision would be so small that it wouldn't really help the situation as far as the pharmacist is concerned.

## Dr. Y.:

Did you have the feeling that these professional manufacturing trade associations had that much power with the Food and Drug Administration?

Dr. F.:

Oh, yes. They were very much impressed with their arguments and here again, their desire to stay out of the commercial phase of any of this was so strong that they would lean over backwards not to be accused by

the manufacturers of in any way restricting the sale of their products. (tape 0194)

Dr. Y.:

So I take it that your major fear was not that the Ewing point of view which scared the manufacturers would prevail, that is, that aspirin and most everything would come under prescription so that there'd only be a small area of self-dosage drugs, but it was rather your fear that the influence of the manufacturers would be so strong with the Food and Drug Administration that most everything would come off of prescription and be for sale anywhere, and there'd only be a small zone of prescription medications left that the pharmacists would be in control of.

Dr. F.:

That's the general . . .

Mr. H.:

Taking this against the background of increasing FDA regulation of prescription practice and drug labeling, that is, in the forties after World War II, there were several squabbles between the drug trade and the Food and Drug Administration over what proper labeling on a drug should be. The FDA said,

(tape 0205)

that is, on prescriptions for certain drugs, there should be warning labeling to protect the user from himself really, in the use of dangerous drugs, and yet the drug trade even opposed this sort of thing. So, what I'm saying is, was yours a realistic fear taken against the context of ever-increasing FDA control over drug labeling and the dispensing of drugs?

Dr. F.:

Well, as far as we were concerned, we offered no objection to strong, protective labeling, warning "may be habit-forming," for example, even a laxative warning. We encouraged that sort of thing, and we provided pharmacists with cards to put up in their pharmacies warning against the indiscriminate use of laxatives because of possible appendicitis complications, and that sort of thing. We were always for strong labeling, but we had the feeling that if strong warnings are needed with regard to the use of any drug, the public should be protected to the ultimate, namely, to have the drug supplied first of all—prescribed and supplied—only through

(tape 0225)

professional channels. Now this is the <u>basic</u> difference, and I don't call it a difference of interest in the public welfare. It's just in the difference of degree of protection that the Food and Drug Administration felt was necessary. They felt they discharged their duty when they compelled a manufacturer to put a warning on the label. Now, knowing the relations between the public and the vendor of a drug and medicine, we were convinced, and still are convinced, that the mere placing of a warning on the label, especially with the wording of some of the warnings, does not afford the public protection that is essential. And you come down to the warning now against possible misuse by children. As far as a child is concerned, a warning on an aspirin label doesn't mean anything because he can concerned, a warning on an aspirin label doesn't mean anything because he can't read.

# Dr. Y.:

So, your argument was with, in a certain sense, the basic theory of the 1938 law, which, I think it is probably fair to say, the Proprietary

Association had a lot to do with getting in there. Time after time, Congressmen would say on the floor,

(tape 0246)

"The purpose of the bill is not to end self-medication, but to make self-medication safe," and safety was defined purely and solely from the point of view of the law (and the way the Food and Drug Administration had to read the law in enforcing it) as what was said on the label. The law didn't say a thing, as you suggest, about where the medicine should be sold, as far as the FDA was concerned. So, it's easy to see how you could make your arguments very persuasively and with genuine belief in them, but the Food and Drug Administration, even if they agreed with your arguments, would have to say, "Well, the law doesn't let us work in that way."

#### Mr. H.:

There also was the irony in the Durham-Humphrey Amendment, taking the arguments of the American Pharmaceutical Association, or the fears, that the law, especially the listing provision, would have the effect of exempting more drugs. The way it worked out was that the American Pharmaceutical Association became, in effect, allied with the Proprietary Association which had exactly the opposite fear, that the listing provision would drive

(tape 0263)

proprietary businesses right out of business. And so, in effect, the American Pharmaceutical Association joined forces with the Proprietary Association on Capitol Hill in working to defeat the bill altogether, along with the American Medical Association.

## Dr. Y.:

In <u>effect</u>, joined forces.

Mr. H.:

Right.

Dr. Y.:

I take it you didn't have any agreements about that?

Dr. F.:

But after the law was passed, Mr. Hogue, the lawyer for the Proprietary Association, and I had a conversation about it, and he said to me, "Well, we got a lot more than we expected because now there are only two classes of drugs: a) prescriptions, and b) non-prescriptions. The first can be sold only by pharmacists or under the supervision of pharmacists; the second can be sold anywhere." So, as far as the American Pharmaceutical Association's point of view was concerned, of protecting the public by having the

(tape 0277)

drugs sold through professional channels and under professional supervision, that protective measure was lost.

Dr. Y.:

And the manufacturer decided, rather than this earlier version we've been talking about, the listing provision, that when he put his drug on the market, he decided which category it was going to be in. If Mr. Hogue considered this a victory, did you and your associates at APhA consider the passage of the measure a defeat?

Dr. F.:

Well, we considered it a defeat for the point of view, the philosophy, that drugs of any kind should be sold and supplied only through professional sources, that is, under the supervision of a pharmacist, and

in a pharmacy. The pharmacy being registered by the state, and the pharmacist being registered by the state, you could always trace whatever might happen after the drug was purchased to a source which could be held responsible. We accept that responsibility. Now, if the product is sold in a filling station or in a general store or any other place, there's (tape 0297)

no registration, nobody knows who the owner is, where he got his supply, and so on, and this becomes a matter then of the prosecutor's job, detective work.

#### Mr. H.:

There also was a provision in the first Durham-Humphrey Bill which was introduced in 1950 by Carl Durham, the Representative, which stated that all prescriptions had to be cleared with the prescribing physician before they could be refilled, even if the prescription called for a drug which could legally be sold over-the counter. And the APhA worked to defeat this provision, to get it taken out of the bill, largely, I think, because the APhA felt that the pharmacist, the person who had put up the prescription, was competent to judge whether or not any prescription could be refilled. You talked in this period, you wrote in your pieces, all the time of pharmacy and medicine being a joint profession really, I think as you were describing before. This brings to mind questions, first of all about the public interest, and second of all, about the extent to which you

(tape 0316)

think the professionalism of the pharmacist can carry him in prescribing drugs or refilling prescriptions for drugs, vis-a-vis the physician.

#### Dr. F.:

Well, we were not urging that the pharmacist was competent in all instances to determine whether or not a prescription should be renewed, but our argument was that, "Yes, he had that competency up to a certain point, and he had the professionalism and ethics to inquire of the physician who wrote the prescription whether or not it should be filled without being compelled to do so by law." In other words, here's a professional who has the education, he's licensed by the state and the refilling of a prescription could or could not be harmful to a patient. The pharmacist could be trusted because of his professional status to determine whether the prescription should be refilled without calling the doctor, or whether the doctor would have to be called. And, of course, the patient would be questioned. Now, of course, as far as narcotics are concerned, he couldn't refill them anyway unless they were exempt narcotics. But as

(tape 0338)

far as the rest of it was concerned, it was felt that if we were a profession, we certainly needed to be trusted to that extent.

## Mr. H.:

Which to me, in my own mind, raises the question, was this a viable sort of a situation? That is, were the pharmacists in the country really that professional if the Food and Drug Administration could come up with provocatively, the number of cases that it did of the abuse of prescription-refills, as well as the abuse of selling drugs over-the-counter in violation of the prescription legend?

#### Dr. F.:

Well, there's no question that some pharmacists refilled prescriptions indiscriminately, and this is something that the profession feels very

badly about, and all it can say about it is that in every profession you have malpractitioners,

(tape 0355)

and you have some in pharmacy. We did not concur with the Food and Drug Administration's lamentation about the terrific amount of refilling that was going on, because of the very fact that the cases that they brought and cited were relatively few considering the number of drug stores and the number of pharmacists. I don't think their prosecution ever amounted to more than half a dozen or a dozen a year, and as far as the pleading of guilty was concerned, I don't think there were, as nearly as I can recollect, a hundred or so a year, and this in 50,000 drug stores. Now, this is the objection that I voiced before, that some of the commissioners condemned the whole profession for what a few were doing, and they would have, had they been members of the American Pharmaceutical Association, been called to account under the Code of Ethics.

## Mr. H.:

Had they been discovered.

Dr. F.:

Had they been discovered.

(tape 0381)

#### Mr. H.:

That brings up another question, too. Was there any sort of machinery in the pharmacy profession for regulating its members as to professional ethics without some governmental agency first turning up abuses on their part? In other words, I think the AMA has a council on quackery, or something which has to do with medical ethics, is that correct?

## Dr. Y.:

Yes, they have machinery to oust from membership people who oppose the standards that they set, not used too often, but they do have such machinery.

## Dr. F.:

Well, they have machinery, it's the judicial council that determines whether or not evidence that's presented to them of malpractice warrants action. And if it warrants action, then the County Medical Society, of which the physician must be a member before he can join the American Medical Association, is asked to act.

# Dr. Y.:

Right. And if it's malpractice that's of a sufficient degree, they can call it to the attention of the state authorities and get the license taken

(tape 0399)

away. Is there kindred machinery in pharmacy?

## Dr. F.:

Yes. The difficulty, of course, is that the machinery only works with members of the association, and members of the association very rarely have been the people who were culprits in these instances. Of course, I don't know whether the NARD has any machinery for the drug store owner to expel the drug store owner. I've never heard of anyone being expelled.

# Dr. Y.:

The state boards have machinery.

## Dr. F.:

The state boards have machinery for taking away the license, and, of course, if the license were taken away, the American Pharmaceutical Association would undoubtedly also cite the member, at least, for

appearance before the House of Delegates to show cause why he should not be expelled from membership.

Mr. H.:

But as far as machinery for professional regulation of its own body without government. State

(tape 0415)

boards are a governmental agency. Is that correct?

Dr. F.:

Well, the state boards are a governmental agency, but the American Pharmaceutical Association does have machinery for expelling a member for cause. It doesn't send out detectives or inspectors or anything of that sort.

Mr. H.:

That wouldn't, after all, be consistent with professionalism.

Dr. F.:

No.

Dr. Y.:

There's one loose end that I'd like to go back to, if I might. When I asked a double question, you answered one part of it, and I'd like to go back to the other part. There still is this human situation that certainly was referred to in the trade papers of your relationships with Mr. Dargavel and his ambitions and goals. I realize that this is a personal thing, but it was so mentioned in the trade press that I think it's very useful to have for the record your reflective judgment upon it. (tape 0432)

Dr. F.:

Why, I think what was mentioned in such publications as the Pink Sheet

and the Green Sheet with regard to relations between John Dargavel and myself was often just practically false and certainly exaggerated, and John Dargavel and I frequently smiled about it. We met and talked about things. John Dargavel was the secretary of the Minnesota State Board of Pharmacy when I was secretary of the New Jersey Board of Pharmacy, and we both had ideas about law enforcement that we discussed at various times. We met at the annual meetings of the National Association of Boards of Pharmacy, and then when he became secretary of the National Association of Retail Druggists, I worked with him on a number of matters. In fact, he asked me one time to be chairman of the Resolutions Committee at one of their conventions, even though I was only an associate member of the NARD. I joined the NARD, although I wasn't a store owner. They have an associate membership, and he always appreciated that, and when I became secretary of the New Jersey Pharmaceutical Association, we, of course, had delegates in the

(tape 0456)

APhA, but there also was some kind of affiliation between the state associations and the NARD which was the reason why I went to the NARD conventions. Now, when he became secretary of the NARD, as I say, I worked with him building up his membership just as much as I worked with Kelly in building up the American Pharmaceutical Association membership. I wasn't active in his association because I wasn't a drug store owner. I was active in the American Pharmaceutical Association because it was my professional society. Then, when I became secretary, he and Dr. Kelly had had various differences of opinion, but Dr. Kelly was a man who never became controversial about anything. And this is one of the things that the American Pharmaceutical Association felt was lacking in its activity.

Cases weren't presented as forcefully as they could have been, and they were always presented with trembling and a fear of treading on other people's toes. But Dr. Kelly was just naturally that kind of a person. I don't tread on people's toes unnecessarily, but when you're the executive head of an association and the association has a policy or a viewpoint or

(tape 0481)

a resolution which it has passed requiring certain action, you act on that. You don't just forget about it, and I took action on the various resolutions which were passed. Some of those overlapped functions of the NARD. So I asked Dargavel if we couldn't have a joint meeting of the two executive committees, our council and their executive committee, once a year to go over the resolutions that had been passed at both associations and, where they overlapped, have an understanding about who was going to take the initiative in the promotion of a certain thing and then have the other association cooperate. We got along on that basis for a number of years and then, when it came to some of these situations, like the Food and Drug Law, I didn't feel that we could reconcile the different viewpoints. I saw no reason why the different viewpoints shouldn't be presented to the committees of Congress, and that they should then make a decision with regard to what was in the best public interest. Now, John Dargavel never appeared as far as I can recollect before committees of Congress. He always had some one else, his attorney or somebody, appear. He might appear for a

(tape 0507)

statement, but he never, as I recall it, I don't know whether you ran across any . . .

Mr. H.:

I think he did appear at hearings.

Dr. F.:

Was he questioned?

Mr. H.:

I really don't remember how extensively.

Dr. Y.:

I'd like to have your personal appraisal of him as an individual the way you have done with others. Is this not appearing for questioning related to his personality or just his choice?

Dr. F.:

No, I think he always felt that he ought to be the final authority on things in his own organization. He was a very strong character, the kind of leader on the order of Mayor Daley of Chicago. He was the one who made the decisions. Well, I was brought up differently. I really believed that members of an association should express themselves, and the viewpoint that comes out of a meeting ought to

(tape 0529)

be the basis for actions of the administrator. This is why I took the stand that I did with Dr. Beale, and when I became secretary of the association, I recognized that my point of view might not always be that of the association members. I gave every opportunity; I never tried to be a dictator in any sense of the word. I gave my views, and if I couldn't be persuasive enough and bring them around to give good enough reasons for this way of doing it, I was content to carry out the instructions as they were given me, and I think this is where the difference came in. I appeared before Congressional meetings, and I

appeared before other groups and expressed the viewpoint as closely as I could, representing what the American Pharmaceutical Association had decided in its House of Delegates. Where there had been no decision and where emergencies arose and I had to act, I acted on my own, always, of course, contacting the president and some members of the council, the executive committee of the council, to be sure that I wasn't going overboard. I had no difficulty in adjusting to that sort of situation. John, on

(tape 0559)

the other hand, was a person who, once he had made up his mind to do things, he would feel that it had to be that or nothing else.

Dr. Y.:

Did that contain any sense of frustration or peevishness when somebody disagreed with him and was prosecuting an alternate course, as sometimes you felt you had to do?

Dr. F.:

Yes, he became pretty abusive sometimes in his writings about people, and I don't think he wrote it always, but he directed his editor to say the things that he wanted to say. I could have gotten very emotional about some things that he said about me, wrote in his journal about me, and some things he wrote in letters about me. But I felt that you just couldn't win with that kind of an attitude against you, so you'd better just go ahead and do the things as you saw they ought to be done and take the consequences.

Dr. Y.:

It didn't bring a coldness in your personal relationships, or did it? (tape 0583)

No. People used to be surprised to see us off in a corner talking about things, not necessarily the controversial issues that we were engaged in, but meeting at conventions or other places where we were speakers. I'll save this for later, but I liked John Dargavel as a person. There were many things about him that were very attractive.

Dr. Y.:

What sort of a person was he as far as his appearance, manner, demeanor?

Dr. F.:

Well, he was a very stout, short person, and he, well, people commented on his big belly, but I knew that he was deeply interested in the welfare of the drug store owner, and if his way of fighting for him was, in his judgment, the most successful way of doing it, I couldn't quarrel with that. I didn't like some of the things, and I didn't hesitate to say so. But I had my own way of presenting things. If there was a difference with a government official, state or federal, I preferred to talk with the individual and see just how far we were apart, rather (tape 0619)

than attack him publicly and demand his resignation or something of that sort. I just don't think that sort of thing gets you very far.

Dr. Y.:

Mr. Dargavel's approach was more in that somewhat more tempestuous fashion?

Dr. F:

Yes. He was somewhat of a bully.

Mr. H.:

Was he very quick and hot-tempered?

Dr. F.:

Yes. And yet he could be just as considerate as possible of other people, if he liked them.

# Mr. H.:

I was going to ask how he and Herman Waller, who was the general counsel, got along. From the printed record, it doesn't appear that Mr. Waller was that sort of a personality at all; it appears that he was quite level and even.

### Dr. F.:

Well, Herman had a certain influence over John Dargavel; being an attorney, Dargavel would say to him, "Now, look, this is what we want. Now you write the bill

# (tape 0642)

the way we want it and give me all the arguments in favor of it." Well, Waller would carry out his orders, but he and John were very close personally, I think, and I often discussed it with Waller, and Waller said, "Well, you have to understand John." Of course, you had to understand him, and that meant, as far as I could see, that you just let him get it off his chest and then do the best you could with what he wanted done, and write the speech for him that he needed to support the particular argument. I can recall only one time when John and I appeared at the same convention and he attacked me personally.

# Dr. Y.:

Which one was that?

## Dr. F.:

It was in South Carolina. I can't remember the exact date, but when I got there and saw the program, they had John Dargavel on at 10:30 and they had me on at 11:30, I think. That was in connection with discussion

of the Durham Bill, I believe. Yes. I think that was it. The secretary,

(tape 0675)

who was a friend of both of us, got me off to one side and said, "Now, doctor, you know we'd like to hear both sides of this situation, but we'd like to have it done in a friendly way." I said, "Don't you worry about me. I'm going to tell my story just as straightforward as I can, and there'll be no personalities in it." "Well," he said, "I appreciate that very much." Now, I don't know whether he said the same thing to Dargavel, but, at any rate, the convention was then about . . . well, they started late . . . and it got to be eleven o'clock before they introduced Dargavel. Somebody had written a speech for him that went into the Russian situation, the Kremlin, and all this sort of thing, which had nothing whatever to do with our program, but he was expounding on the national situation since he came from the NARD, and, of course, all of the national affairs were being considered in their legislative approach to things and so forth. He had been going on about that for about a half an hour, and it got to be around a quarter until twelve and I was looking at my watch. The secretary was sitting (tape 0712)

next to me. I said, "What time are you adjourning for lunch? "Oh," he said, "I don't know. But don't get worried about this time here, because you'll be on before lunch." Well, John kept on going and I got the impression that he purposely was doing this so as to kill off any possibility of my talking after he did and have the interval between, and then the secretary told me that he had invited the both of us to lunch after the meeting. Well, he finally got around to the Durham-Humphrey

Bill, and then he mentioned me by name, that I was not . . . that what the American Pharmaceutical Association and I particularly in my appearance before the committee was telling the committee was not in the best interest of the retail drug store owner. Finally, about quarter after twelve, he sat down, and as I expected, everybody made a beeline for the Coca-Cola fountain which was set up, and I said to the secretary, "Well, I guess I'm on for this afternoon." "No," he said, "just wait a minute." And with that a fellow announced "Everybody back to their (tape 0747)

meeting room. In five minutes we will have the prize drawings." They had some merchandising prizes that wholesalers always give to these conventions, and, of course, everybody flocked back and when they finally got around to it, the room was filled to capacity which hadn't been the case when John spoke. So, then I was introduced, and I told my story. I indicated that this was a matter for the profession to be definitely interested in and to want to work toward a recognition of the professional prerogatives of the pharmacist regardless of whether he was a drug store owner or not. In addition, I said that I had always felt every drug store owner ought to be a member of the National Association of Retail Druggists and I felt that, as a pharmacist, they ought to be members of the American Pharmaceutical Association, but I wasn't here to solicit membership. I was here to tell them what this legislation meant to them and what the outcome would finally be, and I stressed, of course, the business of the competition that they would have in the future in the sale of these over-the-counter products now that all restrictions would be removed, except where they were prescription items. And, I got a good hand, and then we . . . the secretary rushed up to me afterwards and he

said, "Doctor, may I say to you that you gave us a very fine talk, and you carried yourself as a gentleman all the way through, and may I say as a <u>Southern</u> gentleman." That was the greatest compliment you could have given me. But John didn't appear for lunch.

## Dr. Y.:

This time he just wouldn't face . . .

## Dr. F.:

Because he didn't have that crowd sold. At least, that's the way I felt. Of course, the comment that I got afterwards was to the same effect. But, I say again, that I think that his heart and soul was with the practicing pharmacist, having owned a drug store himself, and I think his brother was running this store that he gave up when he became secretary of the NARD. And, of course, he was very close to the problems of the retail operator and I respected that.

(tape 0816)

#### Dr. Y.:

Dick, we've got a little tape here. Are there other questions about this general area and time and theme that you have?

#### Mr. H.:

Well, I did want to ask briefly about the attempt by the APhA leadership to force the Food and Drug Administration, to force, Oscar Ewing who was administrator of the Food and Drug Act, to issue a regulation which would have embodied what the FDA officials had announced at the NARD convention regarding prescription refills. You, in particular, had strongly criticized the FDA officialdom because there never had been a regulation stating exactly what the refill situation was. And you were pressing for an administrative ruling at the same time that the Durham-Humphrey Bill

was headed for committee hearings; there was a good deal of conflict. This is where Dargavel started name-calling, and it seems to me, from reading the printed record, that you replied, not in kind, but in a sense in your own editorials. I wonder if this really was a sincere attempt, on the part of the APhA to find a solution, or whether this was, in fact, (tape 0854)

as Dr. Young has asked before, some sort of competition between personalities, between associations, between philosophies.

#### Dr. F.:

Oh, I think, if any competitive factor entered into it, it was philosophies rather than . . . certainly on our part, we didn't feel that this was . . . we weren't motivated by any personal aggrandisement or Association victory over the National Association of Retail Druggists. We just were sorry that we weren't united in the point of view on this, but we could understand that the National Association of Retail Druggists was trying to make it easy for its members, but in doing so we felt it was sacrificing some of the professional prestige which we felt belonged to pharmacy. We disliked very much seeing the retail drug store operator lowered in . . . being represented as of a lower professional status. (Side 7, tape 0000)

## Dr. Y.:

Dr. Fischelis, you and I have just been looking over a bound volume which was given to you when you ended your Secretaryship of the American Pharmaceutical Association which brought together your editorial column that you had published in the <u>Journal</u>, the practical pharmacy edition, under the heading, "Straight from Headquarters." In connection with what you have been saying about the Durham-Humphrey Bill period, I think it

might be well to point out that your columns for December 1949, August 1950, February 1951, and March 1951, are very pertinent material for anyone interested in studying the relationship of APhA to the background of this particular law. We also went ahead and found a column of July 1953, a couple of years later, when a bill was up before Congress that had passed the House but not yet passed the Senate, seeking to restore certain factory inspection authority which a Supreme Court decision had eliminated from the Food and Drug Administration. At this time, you evidenced the same kind of criticism of the Food and Drug (tape 0017)

Administration and its publicity policies that you evidenced in the editorials that you were writing at the Durham-Humphrey period. When a couple of years later, in July 1955, you wrote a column assessing the Citizens Advisory Committee report, once again there are elements of criticism of the position that the Food and Drug Administration takes in its press relationships. I take it, throughout the years that you were director of APhA, especially from the Durham-Humphrey years on, you had a feeling that whatever good the Food and Drug Administration might be doing, and you were certainly saying over and over again that it was doing a vast amount of good, you had certain caveats about its publicity policies, its use of publicity in order to try to get new legislative authority, and things of that sort, which you were quite frank in expressing at the time. Now, in connection with this episode—this series of episodes, this general view that you continued to hold—is there anything that you'd like to say in retrospect?

(tape 0034)

Dr. F:

Well, having been in law enforcement work myself, I can appreciate the necessity for publicizing some of the work that goes on in an agency, and it's unfortunate that a straight report of the activities is not as acceptable to publishers as something that is dramatized or contains the element that goes into headline-making. So, the administrator of an agency finds it necessary to go into dramatics to some extent in order to gain recognition for the ordinary activities of his agency, since it's in competition with many other agencies that do produce information that lends itself to dramatization perhaps better than the routine of watching the supply and quality and effectiveness of drugs or the quality and freedom from adulteration of foods. I have no quarrel with trying to find headline material, but I like to feel that the material that makes headlines does not necessarily reflect on an industry or a profession which is trying to do the right thing and, of course,

which has, like every other walk of life, elements in it that deviate from the straight and narrow path. Now, it's quite obvious that these deviations are considered news—and livelier news, let us say, than the proper discharge of routine duties. My quarrel about this simply amounts to a disappointment that the heads of the bureaus sometimes cannot find ways of making headlines or issuing effective press releases without resorting to the tactics of journalists who don't seem to care very much what they do to a respectable group as long as what they have to report gets into print.

#### Dr. Y.:

(tape 0062)

Now from reading with you these columns, "Straight from Headquarters," one gets the impression that you had the feeling that the Food and Drug

Administration, as its leadership was then structured, had difficulty understanding the kind of perspective that represented the best thought in pharmacy (partly because the men weren't pharmacists), couldn't look at it from within pharmacy,

(tape 0086)

and had no one of a high administrative level who was a pharmacist who could give them this perspective. Indeed, you kept reiterating that there should be in the Food and Drug Administration, which had so much to do with drugs, a high-level pharmacist. So I take it that because of these episodes in which you had had disagreement and because there wasn't a pharmacist there, you had a feeling that you had to watch each new step, each new proposed policy, each new suggested legislation, with a certain amount of suspicion, to be sure that it wasn't something that might injure what you thought to be the best interests of pharmacy and the general public served by pharmacy. Is that right?

# Dr. F.:

Well, I had the feeling from private conversations with some of the people in the administration that they did not have a very high respect for the average pharmacist. I think this was due, to some extent, to their knowledge of the

(tape 0101)

composition of some drug products and the cost of the ingredients that went into these products and the cost to the consumer by the time it emerged as a finished product on a drug counter. And, repeatedly, they would cite examples of their own experience in paying so much for a finished product and they knew what was in it and how little that ingredient that was active really cost. So, there was a personal feeling

that drug products dressed up in the form of proprietaries or prescriptions were costing them as individuals too much, and, therefore, there was a certain degree of, not exactly fraud, but over-emphasis on the money-making phase of dispensing drugs. Now, I think they carried that into their thinking . . .

#### Dr. Y.:

Who gave you this impression? Do you remember particularly?

Dr. F.:

Why, I think it was, except for such people as Mr. Campbell, it was pretty general.

Dr. Y.:

You don't believe he held it, but you believe his successors . . . ? (tape 0122)

Dr. F.:

No, I think Mr. Campbell had a very broad view of business. He was a lawyer, to start with, and he had an appreciation of the skills and the necessity for paying for the intermediate steps in the production of a drug or the distribution of a drug from a source to the buyer. Some of these other people had no such appreciation probably because of lack of experience and probably because, also, of the quackery that they were engaged in discovering and correcting.

## Dr. Y.:

You mentioned getting this impression from conversations, and, if not with Campbell, do you mean with Dr. Dunbar, Mr. Crawford, Mr. Larrick, or do you mean others around the Food and Drug Administration?

## Dr. F.:

I think others that I had occasion to talk to. I think Mr. Murray was

one who felt that drugs were too high-priced and gave very little consideration to the training and the business and economic factors involved.

(tape 0146)

Dr. Y.:

Dr. F.:

(tape 0165)

You almost give the impression in one of these columns that dealt with the factory inspection law that the Food and Drug Administration, in wanting to have authority to see all prescription files in the hands of pharmacists, didn't trust the pharmacists and that you were resentful of this fact, as if this was an undue presumption on their part against the profession which you held to be largely, as you've already suggested, honorable. You felt miffed about this, that they wouldn't have taken such a position presumably if there had been a pharmacist in the higher echelon of the Food and Drug Administration. Is this correct?

Well, my constant reiteration of the importance of having a pharmaceutically trained person in the policy-making echelon of the Food and Drug Administration was based on the fact that they were quite theoretical in their approach to many problems of the pharmacist. It wasn't so much the distrust of the

pharmacist or the feeling that he was not an honorable person as it was the failure to rely on state agencies, particularly the state boards of pharmacy, to be of service. Now, of course, as a cooperating official in New Jersey, I knew that I was giving the Food and Drug Administration as good service as they could get from their own inspectors if they brought them into the state. And I could see no reason why the Food and Drug

Administration should not, if they had a problem involving a prescription, simply get in touch with the State Board of Pharmacy and the cooperating official and ask for what they want. The State Board of Pharmacy was authorized by the state to inspect pharmacies and could inspect prescription files. The pharmacist would neither resent nor oppose the inspection of his prescription files by a representative of the Board of Pharmacy, whereas the inspection by a federal agent was considered unnecessary and certainly it was not as sympathetic as the inspection of a Board of Pharmacy representative would be. In the latter case, the pharmacist felt that here's an individual who understands my business and knows, if I

(tape 0191)

there, why I do that; he wouldn't be questioning me about it as if I were a criminal or had done something that was wrong, much less report that. And the state inspector would protect me with regard to the physician and the patient if any question was ever raised as to where information was obtained about someone using a certain drug under the physician's direction. I don't think the physicians like to have federal inspectors checking up on their prescription-writing. In the first place, these inspectors are not pharmacists. They are policemen, and there are many reasons why a certain type of confidence needs to be maintained with regard to prescription files, both from the standpoint of the physician and the patient. This is not understood by the federal inspector who is simply ordered to go in and get a copy of a prescription or to question the pharmacist about how many times it was dispensed and to whom, and so forth.

Dr. Y.:

The commissioners, at this time however, didn't want to rely on the state board

(tape 0212)

people, but evidently did want the federal right to examine prescriptions?

Dr. F.:

And we considered that unnecessary because, if there is an inspecting authority that has supervision over this, the pharmacist ought not to be subjected to more than one authority with regard to that.

Dr. Y.:

And the reason that the commissioners wanted the authority must have been an implied indication that the job wasn't being done satisfactorily by the state people and you, perhaps, disagreed?

Dr. F.:

No, I didn't disagree that in some cases, they couldn't get that kind of cooperation, but I did feel that in places where they could get it, they ought to use that avenue, and where they couldn't get it they ought to establish the liaison that was necessary to obtain it. They would always tell me, "Well, if they were all like New Jersey, we wouldn't have any question about this, but here's the Montana State Board of Pharmacy—it doesn't even have an inspector or has a part-time

(tape 0229)

inspector. We write to them for information about a certain pharmacy and, well, the fact that they are acquainted with them would tend to make them be soft in their inspection procedure and they'd find some excuse for not giving the information that we wanted. So we can do it a lot

better ourselves." Well, my point was that here is a profession, and the state has recognized that there should be a board made up of members of the profession to supervise it, and they are sworn to do their duty according to law, and if they do carry out their duties as they should, they could get all the information that the Food and Drug Administration would want. I can understand if there were a bad actor somewhere who covered up his actions in some way, that they would prefer to use police methods. But here again it's the individual case which doesn't occur very often and, in such a case, they had subpoena power and could use that. Where there's a real violator who continuously violates the law, they have enough power by way of subpoena to get the information directly, and, even at that, they should cooperate with the local enforcement agency, whether

# (tape 0255)

the State Department of Health or the State Department of Agriculture has supervision over state health matters, such as the Food and Drug Administration has in interstate commerce. It seems that they ought to use them, unless there was a very good reason to mistrust the agency, and then, as I say, they have the subpoena power anyway.

#### Dr. Y.:

Well, now, during these years, Dr. Dunbar, Mr. Crawford, Mr. Larrick were the commissioners. Yesterday we talked about your impressions of Mr. Campbell and Mr. Crawford as people, as individuals, with whom you had dealings. I think, at this point, it might be a good idea for me to ask you about your impressions of Dr. Dunbar and then of Mr. Larrick as people: what they looked like, how they behaved, what kind of man-to-man relationships there were when you had official dealings with them, and so

on.

Dr. F.:

Well, my meetings with Dr. Dunbar were usually in connection with meetings with

(tape 0273)

Mr. Campbell when Dunbar was the assistant commissioner. If there was a question that involved the scientific and professional areas of administration, rather than just the legal and regulatory, he would call in Dunbar and we would talk about those. This didn't happen very frequently. But when Dunbar became the commissioner, he took such a cold attitude toward the problems of the pharmacist that I never felt that he understood too well the point of view that we were trying to get across, and I know he was completely unsympathetic with the idea of channeling the drugs from their source to the consumer through the pharmacy. He felt that they could be supplied anywhere, if they were properly labeled, and I think probably of all the commissioners he was less inclined to feel that, outside of prescription service, the pharmacist was any better as a dispenser of drugs than any merchant would be. I'm talking about packaged drugs now.

Dr. Y.:

Did he tell you this face-to-face in conversation? (tape 0299)

Dr. F.:

I don't think as baldly as I have stated it, but certainly the impression was to that effect, and when it came to a case that involved restriction of any particular product to dispensing by pharmacists or under the supervision of pharmacists, he didn't open . . . He might have agreed

that the knowledge of the products and that sort of thing was important, but he didn't feel that pharmacists, as a general class, were giving that much attention to sales of drugs—packaged drugs—and that it was largely a commercial transaction with them just as it would be with a general merchant. At least that's the impression that I got.

# Dr. Y.:

What kind of a person was he when you sat across the table from him and engaged in a conversation?

# Dr. F.:

He was very affable and, I think, knowledgeable, but I always felt that he was more of a food man than a drug man, and, of course, their food problems were plenty. I think that he was a little annoyed with minor drug problems, especially when

(tape 0324)

they involved commercial transactions.

#### Dr. Y.:

Dr. F.:

How do you think Mr. Larrick fit into this sequence of commissioners who grew up within the agency and became heirs to the commissionership?

Well, Mr. Larrick, as far as I know, was not a college graduate. He attended some college. I'm not sure whether it was Wittenberg. I believe it was, in Ohio, but he never graduated as far as I know, and he came into the Food and Drug Administration neither as a scientist nor as a lawyer, but strictly as an inspector, and he was a good policeman.

Now, I had already expressed myself on the qualifications for commissioner to the effect that I thought it ought to be either a physician who would get the legal and other support through subordinates,

or a lawyer who would get the support through medical and other associates. Now, in the case of Mr. Farrick, he was pretty much of a layman to this whole field, although he acquired an immense knowledge of it and was a very able inspector.

(tape 0350)

Campbell thought very highly of him. I don't think Campbell ever would feel that he ought to be a commissioner. I think this was a matter of length-of-service, and there was a great deal of question at the time that Mr. Crawford went out as to whether the assistant commissioner who was Larrick should move into that place or whether it should be somebody outstanding in the professional or legal field or administrative field. So Larrick went into the position pretty much with the background of policing. And then, of course, he had to begin to make judgments on medical questions and chemical questions, and he undoubtedly had to rely on others for those judgments. They became more and more medical and more scientific and more legal as the drug field changed and the administration of medicines and the sources of medicines changed. I have no particular knowledge about his competence in the food field. I don't think he was any more of a food chemist or food man than he was a drug man, except that he was a very keen student, of course, of his law, of his regulations. I think he would be subject

(tape 0377)

to influences from industry and from the professions more than an individual who could make up his mind from his own knowledge and his own judgment of the importance of details that developed in these various areas. Now, I had a high regard for Mr. Larrick's integrity, but, again, he showed no interest in the economic problems of the distributors. I

think he was subject to a great deal of pressure from numerous sources, and I think that he usually sought the easiest and softest and best way out of a situation with as little friction from anybody as possible.

Now, this might be a very good trait in some administrative areas, but, I think you have to be pretty positive in a health area about all kinds of possibilities arising, such as variety of reactions, idiosyncracies of patients to drugs, the possibilities of deterioration under certain types of conditions, the necessity for causing extra expense on the part of producers in order to maintain certain high standards of preservation of drugs, and things that might happen in their transmission. I think (tape 0410)

that Larrick could be relied upon to do the very best for the public, but I don't think his capacity for making the best judgments was as good as, well, as Campbell's or Crawford's.

## Dr. Y.:

What particular personal relationships did you have with him?
What kinds of issues or occasions brought you into business
conversations, and so on?

## Dr. F.:

Well, legislative matters, of course, principally. I didn't have to plead a case for any violators. I didn't have to ask for any favors of any kind. I did stress the importance of the pharmacist.

#### Dr. Y.:

You did go to see him and talk with him about this as you had with his predecessors?

#### Dr. F.:

Oh, yes, from time to time. He was always receptive to any suggestions

and was willing to give information up to a certain point, but I noticed that when I was writing these editorials about having a person with pharmaceutical background

(tape 0437)

in the higher echelons, he didn't accept that too well, although they had Mr. Rankin, a pharmacist by profession and a very able person, too, whom they brought along. As time went on, they could then point to Rankin as someone who was pharmaceutically trained. And we got some pretty good results because of Rankin's position there eventually. He recognized the pharmacist's peculiar position in this whole situation and, I think, while all of us recognized the fact that there is the opportunity for commercial gain by pushing certain types of remedies—and some of us are not every much impressed with that—we don't think that drugs ought to be advertised like merchandise. I once made an investigation to determine to what extent the ratio of illness in the population of the United States had a bearing on the drug business and found to my surprise that the ups and downs of the economic scale, the financial scale, depressions or good times, had more of an effect on the sales volume of drugs than did the epidemics and extent of illness.

(tape 0477)

When I found that out, I stopped trying to figure the amount of business in drugs on the basis of the reports of reportable diseases, and others have borne that out, of course. And so, if people spend more money for medicines when they have more money, and less when they don't have it, that's an indication that there's a basis for trying to get their free dollars to be spent for, what might be termed "luxuries" in hard times, in the form of drugs.

## Dr. Y.:

That's certainly true. Again, with respect to the cast of characters of this vast, complicated story, let's go back a little in time and get to the two important individuals on Capitol Hill during the thirties, Senator Royal Copeland and his executive assistant, Ole Salthe. Last night we stopped just before you talked about them as people and about your impressions of them and your contacts with them as the effort was being made to secure what became the 1938 law. Would you return to them and talk about them a little while, please?

(tape 0505)

#### Dr. F.:

I didn't know Dr. Copeland personally very much. I met him and, of course, on occasions, discussed the legislation, but I never really got close enough to him to know very much about him as an individual. He had, of course, been health commissioner in the city of New York, and it was his prominence in that position that undoubtedly helped him to become a senator. Then when he got into the Senate, and this Food and Drug regulation issue came up, it just naturally drifted his way. I got the impression that the other members of the Senate deferred to him in his capacity as a physician on matters of this kind rather than on his capacity of a senator from New York. The medical profession, on the other hand, as I got the impression from the things that were dropped by different people in the American Medical Association, weren't so deeply impressed with Dr. Copeland because he was a homeopath, and they just took a good deal of his interest in

(tape 0542)

the drug legislation as part of his publicity effort. Now, I don't want

to be unjust, but the Food and Drug Administration, I guess, felt it was fortunate in finding a man in the Senate with his background and an M. D., (I guess he was an M. D. all right), to feed this information to; there was a mutual helpfulness there. The Senator had something that kept him in the public eye, and the Food and Drug Administration had someone who could really sponsor this legislation. Now, I never felt that Copeland was a real crusader in this effort, but he was a medium. I don't recall this too well, but I got the impression, I have the impression, that some others could have done better in handling this legislation than he did. Now, he did have with him Ole Salthe who was not a drug man, he was a food man primarily, but he was interested in this whole regulatory problem, and this resulted in contact with him through correspondence and occasional meetings, because he seemed to feel that (tape 0578)

I had a viewpoint on the drug phase of the legislation that was valuable and could bring to it some information through my contacts in pharmacy and my interest in the public welfare and not being in the drug business, that gave them a basis for negotiation with industry and otherwise.

## Dr. Y.:

So he would take certain propositions that were in the law and alternate propositions that were in bills that industry may have written, including the bill that Dr. Beale supposedly wrote, and bring this kind of thing to you and say, "What do you think about it?"

# Dr. F.:

Yes. He would contact me about that.

## Dr. Y.:

Using you as kind of the spokesman for the reaction of pharmacists?

Dr. F.:

No, not so much as a spokesman, but as someone that perhaps could be trusted to give a point of view that wasn't biased along industry lines. (tape 0602)

Dr. Y.:

And you had the chance then to have your personal say about the variation clause?

Dr. F.:

That's right.

Dr. Y.:

One that you didn't happen to win. And other elements of the bill as it underwent all of those many changes and moved toward passage? In fact, it seems to me he was more important in the final stages than he was in the early stages of this.

Dr. F.:

Yes.

Dr. Y.:

Copeland was very much criticized by Consumers Research people and others of that persuasion because he was giving radio broadcasts that were sponsored by patent medicines or at least products that were sold with what were considered to be exaggerated health claims. I take it that products of this sort dispensed in this particular way were something that you, too, opposed. You've talked a

(tape 0622)

good deal about that. Did you see Copeland through this particular filter? Do you remember that?

Dr. F.:

I don't recall that, but I did have somehow, in the development of the legislative procedures, the impression that, while Copeland got a great deal of credit for the legislation, he actually was ready to compromise on many things that a true crusader in the field wouldn't have.

Now, in a sense, the whole effort started in 1933 with a person who had some elements of the true crusader about him, I think, and that was Rexford Tugwell. The first reaction of the National Drug Trade Conference, and, indeed, the first reaction of the American Pharmaceutical Association, was a criticism of this bill on the basis of the amount of authority, which they considered to be arbitrary, which was placed by the bill into the hands of the Secretary of Agriculture. Now, as I recall, the American Pharmaceutical Association resolution didn't lay

(tape 0652)

Dr. Y.:

this blame at any given place. It just criticized this concept in the bill. But most everybody else criticized Tugwell, and certainly he took the rap for trying to make a "dictator" out of the Secretary of Agriculture in this particular field. What do you remember about your feelings toward Tugwell during this period?

## Dr. F.:

Well, I had no contact with Tugwell. I personally admired his effort to do something about this situation, but, of course, the industry and even people in the profession like Beale, felt that he was just somebody who had an idea that he could make the world over, that he could wipe out all of the quackery in medicine by just having a law on the subject, without any recognition of what it involved as far as the vested interests were

concerned. I know the drug industry was very critical of him and ridiculed a good deal of his activity as they did other things in the New Deal. The drug industry has always been on the conservative side of things, and, of

(tape 0693)

course, the medical profession wasn't too keen about him because he had expressed himself pretty frankly about certain types of medical practice. When was this? Wasn't it around 193--

Dr. Y.:

Three.

Dr. F.:

Nineteen thirty-three. Well, this was just about the time I was finishing up the study with the Committee on the Cost of Medical Care, and those of us who were on the staff there rather welcomed the idea because he was approaching the remedying of the things that we had been complaining about, especially in the proprietary medicine field, and so forth.

Dr. Y.:

In the literature that there is, some of the writing that has been done about this, by Tugwell himself and a student of his career during this period, and in some other places, the very strong inference is given (tape 0721)

that there was a real conspiracy deliberately created to overwhelm this bill. Different elements of industry objected to this bill so much, that it was a conspiracy with a deliberate strategy, and that strategy was to make Tugwell a devil and call him a dictator and speak of him in terms of the bad Russians and so give him such a terrible public image that he and

that the inspiration for this conspiracy and the leadership in bringing it about lay within the drug industry. Now, this charge, as I say, has been made by historians and there are hints about it, suggesting that there was such, at the time. And I think that Tugwell and his associates believed that this was so. Now, do you think, or know, if there was such a conspiracy or something that approximated it, and, if so, was the machinery of the National Drug Trade Conference employed, maybe not in its formal meaning sense but in a kind of informal meaning sense to do this hatchet job, if such it was?

(tape 0759)

## Dr. F.:

Well, I never gained the impression that the drug industry was the leader in it. But I had the definite impression that anything that bore the name of "Tugwell" was anothema to the drug industry, and this was, of course, fostered by all manufacturing areas. Then, of course, they had their representatives, not formal representation, but people who expressed their point of view in meetings and helped to give the impression that the Tugwell influence was something that was out to kill the drug business as such and to substitute a socialistic-type of control in the medical and other fields.

# Dr. Y.:

Before you, in a sense, made a break with the National Drug Trade

Conference, or, at any rate, challenged them on this issue, did you know

of any secret meetings that were called to plot strategy as to how to go

about to smear Tugwell?

# Dr. F.:

No, I didn't.

Dr. Y.:

You didn't? My memory may play me false on this, but I think that I have seen

(tape 0800)

it alleged that Dr. Beale may have been a prime mover in this. You weren't ever contacted to try to use your power and voice in an effort to just smash this bill?

Dr. F.:

No, my position and feelings about the drug industry as a part of the practice of medicine were pretty well known, and I don't think they would have approached me.

Dr. Y.:

Well, conspiracies are hard to prove. They are much easier to allege than to prove, and so anyone trying to rethink the record and seeing these charges is always bound to try to find evidence. Of course, the Proprietary Association was alleged to be a prime mover in this as well. Did you know Dr. Cullen?

Dr. F.:

Yes.

Dr. Y.:

He had been with the Food and Drug Administration and had come to the Proprietary Association where he seems to have played a role of both trying to improve things

(tape 0836)

within the industry by voluntary action, but at the same time, taking this very hard-nosed view towards the need for any change in the law as far as 1933 was concerned. Did you and he confer about the law? What were your relations with the Proprietary Association?

# Dr. F.:

Well, I became cognizant of the Proprietary Association largely through the National Drug Trade Conference, and I realized from the way their representatives approached everything that was discussed in the National Drug Trade Conference that they were very much for very free enterprise in the medicine business.

# Dr. Y.:

That included sales wherever they could be sold, unlike your position of restricting drugs for sale under the direction of the pharmacist.

#### Dr. F.:

I recall one meeting at which the representative of the Proprietary
Association gave a long talk about what the Proprietary Association had
done to clean up the industry,

# (Side 8, tape 0000)

and it wound up with a statement that, of all of the members of the National Drug Trade Conference, it is our judgment that we have come farther up the ladder towards good public relations with regard to health matters than any other member of the conference. I said, "I want to congratulate the Proprietary Association on the great progress they had made, but since they said that they had made more progress than any other association I want to remind them that they had much farther to come than all of the others in reaching the stage of protecting the public interest." This was, of course, considered a dirty crack. But it was the truth.

## Dr. Y.:

Sure. Was there fencing back and forth, because this was an odd gathering if you look at it one way. Everybody concerned with drugs, but with so many different elements and so many different perspectives, and competing and conflicting

(tape 0017)

interests, so that it would seem to me that it would have been a kind of strained situation almost everytime that you met. Was there a lot of fencing?

#### Dr. F.:

Yes, there were some strained moments when people would discuss a project at one time or another and when criticism was made, for example, of the Proprietary Association's lack of its members feeling of responsibility with regard to formula disclosure and truth in advertising and so on. But things generally wound up with people shaking hands and saying, "Well, Rome wasn't built in a day. You have to move slowly, and don't push us too hard because if you do we won't be able to bring our membership along, as we would like to do." And I found that the people who were really leaders in the Association, as far as that industry was concerned, must have had a feeling deep down that there were some pretty rotten eggs in that business. The less the better ones were associated with them the better, but they don't want to exclude

(tape 0036)

them from the Association because they felt they had more power to bring them along than if they were outside of the fold.

## Dr. Y.:

So they went on back to them and said, "We've just been with our drug brethren and here's what they say, so you'd better improve." That's an

interesting exercise in industrial diplomacy.

## Dr. F.:

And here the pharmaceutical manufacturers have adopted a code of ethics which says so and so, now, by implication, if we don't say something close to that or the same thing, we're going to be branded as a lower class of producers, so we'd better look things over. Gradually the influence was helpful. But their attorneys, in order to earn their fees, would make a big play about these terrible government bureaus that were trying to crush the business and stifle free enterprise and so forth, when what they were asking was simple justice for the consumer. (tape 0051)

## , -

Dr. Y.:

As a matter of fact, whatever the reasons, and this putative drug conspiracy may have been part of the reason, they certainly got drastic revisions in the nature of the bill between 1933, when the first bill was introduced, and when it was finally passed. Was this atmosphere of well, we've got to talk these things over no matter how controversial they are, and we'll do better next time, and all of that: Did it follow the confrontation that you made about the bill when you refused to go along with the variation clause and, therefore, didn't permit the Drug Trade Conference to have a unanimous report as required, in 1934, or were things a little more tense after that?

# Dr. F.:

I think that for a time they were tense, but when it was found that for once the profession was standing pat on a certain degree of regulation, that maybe pharmacy could get enough allies in other areas to make the industry look rather bad to the public, and grudgingly confessions were

made. As the thing developed, there were (tape 0071)

suggestions that, "Well, this is the best we can get and we'd better go along with this." But if there hadn't been a stand on the other side, and the Conference had been unanimous on easy regulations or the restriction of powers of the Food and Drug Administration, this could have been a factor in the outcome of the legislation.

## Dr. Y.:

If there was a conspiracy as I'm suggesting the scholars have indicated, and if many of the major elements in the National Drug Trade Conference were parts of that conspiracy, although it didn't use the machinery of it, the formal machinery of it, then it must have been a bit of a jolt to the conspirators in 1934 to find you standing so adamant against some of the things that they had agreed to. So I was hunting for evidences of dismay, of alarm, of anger on the part of those whom you opposed there, in some measure, wondering if you could read these emotions back to the fact that they were very hopeful about what they were going to do, being involved in this conspiracy, and then very upset by the kind of (tape 0091)

roadblock you seemed to throw. I grant you that this is all pretty speculative, but that was sort of what I had in mind when I asked the question.

# Dr. F.:

Well, I don't know whether this will be helpful in illuminating the situation a little more, but by the time the act was passed, there was, of course, agitation immediately for revision of state laws to conform to the federal act, because, without that, much of the benefit of the

federal act would not have been available, especially in states where the drug manufacturers are located. When it came to the National Drug Trade Conference meeting at which a uniform state law was proposed, to my surprise, I was asked to be chairman of a committee on uniform state legislation, and before the next Conference rolled around, I had worked with some of the other people to get a draft of a state uniform act, and I circulated it to the members of the Conference prior to the meeting. When they came to the meeting and I reported on it, they were rather profuse in their compliments on the general agreement that could be reached among them in favor

(tape 0114)

of this particular draft. A few things were changed, minor in my judgment, and the Drug Trade Conference uniform state law was adopted by the conference, and the members were asked to work for it in their respective states. Now, the Association of Federal Enforcement Officers also set up a bill and some of the things in their bill were not looked upon as favorably and efforts were made to get together with them and have one uniform act. I felt that that was quite an accomplishment.

Dr. Y.:

Surely.

Dr. F.:

And it showed how once the issues were settled, that we were again working together as we did in the Harrison Act.

Dr. Y.:

Yes. They didn't need to be mad with you in 1939, because, if conspiracy there was, it won its major point in defeating the rigorous 1933 draft and getting a kind of bill that the manufacturers, the big manufacturers

particularly, and

(tape 0130)

indeed, even the proprietary manufacturers, thought they could live with by 1938. So, in terms of this speculative picture that I've been suggesting, they didn't need to be mad at you after that, and, indeed, it was to their advantage to get the state laws as quickly as they could in harmony with the '38 law, so that they wouldn't have different practices on interstate and intrastate propositions. Along with many of the other things that you did, for some years, you held a responsibility for an offshoot of the National Drug Trade Conference, is that not so? Would you tell me about the Drug Trade Bureau of Public Information, and how it got started and what you did in that field?

## Dr. F.:

Well, Dr. Army with whom I was associated on the <u>Druggists' Circular</u>, was rather critical of the poor publicity that pharmacy was getting. There would always be publicity about drug addiction and law violations, but there never would be very much in the way of acquainting the public with the educational advancements

(tape 0150)

in pharmacy, with the legislative advancements which pharmacists were promoting to curtail illicit activities in their own field so that the public would benefit in the long run. He made the suggestion that some kind of publicity agency be created in the field. The American Pharmaceutical Association at that time, of course, did not have a full-time secretary, and it wasn't apparently prepared to issue bulletins. The National Association of Retail Druggists issued some bulletins, but they were largely in the direction of price-maintenance

and against discounting and fair-trade and, of course, the newspapers weren't too keen to take up that sort of thing, because that was not in the best interest of their advertisers. So it was suggested that maybe an organization similar to the National Drug Trade Conference should be created with an assessment for each organization and the establishment of a central bureau for preparing and disseminating bulletins about progress of pharmacy, National Pharmacy Week, and things of that kind.

(tape 0173)

# Dr. Y.:

Now pharmacy in the broadest sense to include drug manufacturing as well as distribution, the business as well as the professional side.

## Dr. F:

That's right. Since the National Drug Trade Conference was that kind of an organization, at one of the meetings of the Conference it was suggested that the representatives meet to organize what came to be called the Drug Trade Bureau of Public Information. The National Drug Trade Conference was a name that the American Association of Colleges of Pharmacy never liked. The National Association of Boards of Pharmacy never liked it. The American Pharmaceutical Association never liked it because of that "Drug Trade." And yet, when you had the trade association in there, there wasn't a real good substitute for the name of Drug Trade Conference. It could be called the Drug Conference, but that wouldn't indicate associations or the all-inclusiveness of the organization, so the Drug Trade Bureau of Public Information was selected as the name and even

(tape 0188)

though people didn't like it, that was it.

Dr. Y.:

Now, let me just try to get this as clarified as possible. The National Drug Trade Conference was the creator, is that Right?

Dr. F.:

In this sense, that they were already together at a meeting, and the proposition of a publicity bureau, let us say, could be made. But they didn't want to make it a part of the National Drug Trade Conference's activities because, here again, you were tied down by this unanimous consent thing, and if the director of the bureau would prepare a bulletin and had to circulate it to the membership and get vetoes of a sentence or two here and there, the thing would never get off the ground. So they said, "Well, let's have, since we're all together, let's have a meeting and establish the National Trade Bureau of Public Information." (tape 0201)

Dr. Y.:

They took of one coat and put on another coat.

Dr. F:

Right. But it was the same group.

Dr. Y.:

And this was when?

Dr. F.:

I'm sorry I don't recall the date exactly, but I can supply it.

Dr. Y.:

Well, just say about when for the moment. 1920?

Dr. F.:

In the early 1920s.

Dr. Y.:

Right. And you stayed with it, how long? About a decade?

Dr. F.:

Yes. Its demise came when I no longer was able to give the free service.

Dr. Y.:

Now what was this responsibility that you undertook?

(tape 0211)

Dr. F.:

They decided to issue bulletins which would reflect favorably on all groups. In other words, the subject matter would have to be such that it would not refer to any one of the groups unfavorably, nor lend itself to an interpretation by the newspapers and other media that received it to be critical of any group. It was to be a public information program which enhanced the public relations of the entire group.

Dr. Y.:

So you had a kind of ten-power veto just to start with then, in general terms.

Dr. F.:

The Drug Trade Conference, but the bureau trusted the director and secretary. I think the secretary was the secretary of the Proprietary Association.

Dr. Y.:

Who was that at that time?

Dr. F.:

At that time, Kemp was his name.

(tape 0226)

Dr. Y.:

Irving Kemp.

## Dr. F.:

Yes, I think that was the man, and he was a very congenial person to work with and somebody who could be consulted that was at the far end. One far end would meet at the other far end, so that if I was in doubt about the possible reception of a bulletin, I could check with him. If he found it was not objectionable, why, it gave me that much backing, and I felt safe, although I must say that in the time that I ran the bureau, I had no complaints that I can recall from any one of the constituents. The reason the thing got off the ground in the first place was that everybody was willing to try something constructive. Nobody was willing to put very much money into it, and I believe that contributions started with a hundred dollars or maybe even with fifty dollars a year and then went up to a hundred and then two hundred, and the bulletins weren't too frequent. They were maybe one a month, sometimes (tape 0245)

more than one, depending on what was breaking in the news. But we hired a clipping bureau, and I later got the support of a trained publicity man, James G. Grady, who was publicity director for Nicholas Murray Butler at Columbia University, and he had good contacts with the New York news media and some of the major city newspapers. He would never get out a mimeographed bulletin; it was always a carbon copy, so that it looked as though it was going to just a few and it was more or less exclusive. And I must say that the New York Times and Tribune, and the Philadelphia and Chicago papers very frequently printed some of the material.

## Dr. Y.:

Who was responsible for <u>your</u> selection when you became director of the news service as your title was? The members of the national association

. . .

# Dr. F.:

I think they were just looking for a goat, and I was willing to undertake it

(tape 0262)

without any salary or anything and just do it along with my other work. It was quite clear that there was no salary attached, although from time to time at the annual meetings it was pointed out that I shouldn't be working for nothing. I said, "Well, if that's the way you feel, give me some money so that I can hire a public relations man that can write some of these things. I'll give him ideas and let him do the circulating." This is how the thing really developed. Grady was the only person who was really compensated, and my secretary.

## Dr. Y.:

Was the choice of the subjects that would be written about in these monthly releases pretty well left up to you or were you given counsel from various trade associations?

#### Dr. F.:

It was pretty well left up to me, but I was constantly asking the constituent bodies to send me things that they thought ought to be publicized.

# (tape 0277)

Well, of course, each one of them, especially the industry people, had their own publicity service, and so the things that I would get were usually not too newsworthy. Once I got with Grady, he indicated to us what kind of thing could get across into the papers, and I would feed him some information or some happenings in the industry or prospective

meetings and that sort of thing, and then he would work up a readable publicity bulletin.

Dr. Y.:

Sometimes propaganda from an industry has been charged with being a sort of whitewash. Do you get any feeling that you were directed to do this? It's hard to believe that you would have done it—you wouldn't have done it—but did you have the feeling that industry was anxious to present its best face before the public. It was already getting certain bad publicity and that this was a kind of a counterweight effort?

Dr. F.:

I'm sure that some of them thought about that when they entered into it and were

(tape 0297)

willing to see what would happen once we got started, but we kept the news away from propaganda . . . completely.

Dr. Y.:

Right. What kinds of things did you handle? You say you have a file of the bulletins that you issued.

Dr. F:

I'm pretty sure I still have a file.

Dr. Y.:

Right. And what were some of the kinds of stories that you got written and released?

Dr. F:

Well, if there was some prominent speaker at one of the national conventions who said something that wasn't already covered at the time of the convention, we would pick out of that certain things which would be of interest to the public and which had a news value and also were favorable to the activities of the industry. I'll have to say that the educational and regulatory activities

(tape 0314)

probably were emphasized much more than anything that could be emphasized in the way of the development of a new drug, for example. We stayed away from that.

# Dr. Y.:

When you say "regulatory," did you write articles that dealt with the issues of regulatory activities?

## Dr. F.:

Largely the boards of pharmacies. The National Association of Boards of Pharmacy was a member, and if some board of pharmacy adopted a new internship program, or if they made some changes in examination procedures, or licensing requirements, this is the kind of thing that we would circulate for general information, whereas they may already have circulated their own state for the information of the practitioner.

#### Dr. Y.:

Now, not much about the Food and Drug Law on the national level with respect to drugs. Was this part of your beat in this . . . (tape 0328)

## Dr. F.:

I imagine that we did refer from time to time to food and drug legislation but only in the sense of showing the compliance of the pharmaceutical profession and the industry with the regulations.

## Dr. Y:

The years of the twenties were years of considerable closeness between

the Bureau of Chemistry (and then the Food and Drug Administration) on one hand and the Pharmaceutical Manufacturers Association on the other—not quite so close to the Proprietary Association. This was a period in which there was a good deal of cooperative effort, you'll remember, in connection with developing drug problems, about standardization of ampules, and what kinds of tests ought there to be that would constitute adequate tests, and a respectable level of good manufacturing procedures, as it's called now. A joint contact committee, indeed, was set up, with members from the two manufacturing trade associations that confronted these problems and dealt with the Food and Drug Administration with respect to them. Were you involved with this? You might have reported this. This might

(tape 0350)

have been a newsworthy thing.

# Dr. F.:

I would have to refresh my memory on that by looking at the bulletin files. I haven't looked at them for a long, long time, but I would like to do that.

## Dr. Y.:

You didn't have any connection, being with a board of pharmacy and not with industry, with the joint contact committees during the twenties.

They continued after that.

## Dr. F.:

Yes. I never was a member of the contact committee because that was . . really, the contact committee was formed because there were two manufacturers associations.

## Dr. Y.:

What was the difference between them? As you, sitting in pharmacy, looked at them, there was the American Drug Manufacturers Association, and there was the American Pharmaceutical Manufacturers Association. How did you differentiate these?

(tape 0363)

Were they Tweedle Dum and Tweedle Dee, or did they have, in some way, a separate image and indentity?

## Dr. F.:

This is interesting, because the American Drug Manufacturers Association was first known, I believe, as the American Association of Manufacturers of Medicinal Products, and they confined their membership pretty much to manufacturers of prescription products. They may have been making other things, but such concerns as Parke, Davis and Company, Eli Lilly, Sharpe and Dohme, Upjohn, and companies of that kind, organized the American Drug Manufacturers Association. Now there were a great many small manufacturers who manufactured one, two, three, or maybe a dozen or more different products for the dispensing doctors, and their sales were almost completely to dispensing doctors. The only reason a pharmacist would ever buy anything from them is when a dispensing doctor would write a prescription for the product of the company. They dealt largely in combinations of drugs in tablet form or capsule form or liquid (tape 0386)

form which the physician would ordinarily prescribe and give a prescription for. But for dispensing in his own office, he carried a line of tablets and liquids if he was a dispensing doctor, which many of them were, of course, at the time. Well, now this group, when the 1906 act was passed, found themselves in difficulties because they didn't have

lawyers. They weren't big enough to have lawyers or to have control laboratories. They manufactured on a formula basis, and I would say that few of them checked or tested the original drugs that went into a combination. They bought it on the basis of the standard that was proclaimed by the chemical manufacturer or the crude drug producer, and they had no control laboratories to test the finished product. Now comes the 1906 Food and Drug Act, and adulteration and misbranding became a very important factor to them, so they got together for the purpose of perhaps working out control laboratories which they could use jointly, and for the employment of legal counsel to help them in the interpretation of label requirements and that sort of thing. That's (tape 0411)

where Charles Wesley Dunn came into the picture. I think he was a young attorney and came into practice just about the time of the 1906 act, and he grew up with the act. He was a food and drug counselor, and became the attorney for the American Pharmaceutical Manufacturers Association which was the name given to this small group that got together. Well, as they developed, there were such organizations as Abbott Laboratories in there, for example. Dr. Abbott was an M. D., and his first line of products were pretty largely for the dispensing doctors. But they grew rapidly and became competitors of the prescription product manufacturers, so they felt that they ought to be members of the American Drug Manufacturers Association, and they were admitted to such membership because it was good for the Association to have them in, rather than out, I suppose, under the circumstances. There were others in this smaller group that grew to the point where they felt that membership in the American Drug Manufacturers would give them prestige. They still relied

on Charles Wesley

(tape 0433)

Dunn for their legal advice, and he was not only the lawyer for the Association, but also the lawyer for many of the individual companies. Then, of course, others got big enough so that they could hire personnel, and they developed control laboratories and did their testing of the crude materials and the finished product, and so forth, and one by one they began to apply for membership in the American Drug Manufacturers Association. Well, they took in some, but they didn't take all that applied, and so, for a time, the two associations kept on having meetings. Charles Wesley Dunn was a good promoter, and he established a certain medal to present to outstanding organizations and individuals for contributions to the public health and the development of better drugs and so on. Some very high class people got these and accepted these medals. The Food and Drug Administration was given a medal at one time, and the Public Health Service at another time. And by the promotion that this man did and his appearance before Congressional committees when legislation was

(tape 0459)

up, he was given a good deal more recognition than the old American Drug Manufacturers Association at various times. Mr. Campbell and I used to joke about Charles Wesley Dunn's appearance before a committee. When Charles Wesley Dunn entered the room, you knew it. He had wavy white hair. He was an impressive personality and a good speaker and very positive in everything he said, and few of the Congressmen dared to interrogate him very much because he always gave the impression as though whatever he said was the last word. He did get into some altercations,

of course, but he brought this Association along prestige-wise to such an extent that they began to overshadow the American Drug Manufacturers

Association as far as publicity and public relations were concerned. So, some of them were beginning to pay dues. You see, the dues payment in these associations is on a basis of their volume of business, and when Abbott Laboratories, for example, and some of the others that were in the Pharmaceutical Manufacturers Association began to pay dues on the basis of volume of business to two

(tape 0487)

associations, they began to talk: "Why do we have the two? Why don't we just have one and do a bigger job?" But the question was, you could never have two associations as long as Charles Wesley Dunn was not the top dog in the association which he had fostered, and, of course, the American Drug Manufacturers would have none of Charles Wesley Dunn.

Dr. Y:

Oh, is that so?

Dr. F.:

As the leader of that group. Not that they didn't think that he was a competent person, but the kind of domination that he demanded just was not for Parke, Davis and Company or for Upjohn. They had attorneys as good as Charles Wesley Dunn, as far as legal knowledge and ability were concerned, but they didn't have the public image that he had and provided. So, when Charles Wesley Dunn got ready to retire, that's when the two associations merged into

(tape 0507)

the Pharmaceutical Manufacturers Association.

Dr. Y.:

And it was delayed that long because of this strong personality factor?

Dr. F.:

I'm sure that was it.

Dr. Y.:

Well, of course, he had grocery interests, a food side as well as a drug side.

Dr. F:

Oh yes, food. A much greater thing and he brought them along just as he did . . . I forget what the food manufacturers' name is, but they were a very powerful group, and he was able to dominate the legislative . . .

Dr. Y.:

He certainly did get many changes from the draft bill that he wrote through Copeland into the evolving law, changes that blocked out things that had been in the 1933 Tugwell version.

Dr. F.:

And Ole Salthe was a sort of go-between there too, (tape 0524)

because of his connection with food, and Dunn thought very highly of Salthe.

Dr.Y.:

In retrospect, talking with people and reading, especially in something like the <u>Food Drug Cosmetic Law Journal</u>, one has almost a deified portrait of Charles Wesley Dunn and of his responsible role as a responsible business leader. Your story makes him more competitive in his lifetime than the impression I've got in some of the retrospective references to him, that is to say, that the American Drug Manufacturers view Association wouldn't merge in your, because they didn't want to be

dominated by the powerful personality that he was, and you say he did exercise this role of very strong leadership over the American Pharmaceutical Manufacturers Association.

Dr. F.:

And this, of course, couldn't help but influence the attitude toward drug manufacturers, in general. There were times when his thinking was not exactly in line with

(tape 0548)

the thinking of the ADMA, as it was called at that time (American Drug Manufacturers Association). They had their own lawyer, of course, and counsel, and . . .

Dr. Y.:

So they disagreed about some major policy matters?

Dr. F.:

Yes.

Dr. Y.:

Even if they did cooperate on something like the contact committee with the Food and Drug Administration.

Dr. F.:

But Dunn was usually able to smooth things over sufficiently so that they did show a united front. He didn't bother with the Proprietary

Association. He and Jim Hogue were not of one mind on many things.

Dr. Y.:

He was in favor of the variation clause, and, I take it, that his association was

(tape 0567)

interested in continuing that, and so that meant that in 1934 when you

opposed it, you were opposing him. Was he a member of the National Drug
Trade Conference?

Dr. F.:

He never came to the Drug Trade Conference, as far as I know. I don't remember his ever coming.

Dr. Y.:

But at any rate, he was a spokesman in the legislative hearings for the variation clause and so yours and his policy on that point certainly deviated.

Dr. F.:

I shouldn't say that he never came to these meetings, because I'm not completely sure, but I know he was not a delegate and didn't get into the discussions there, as far as I can recall.

Dr. Y.:

What kind of lawyer was Mr. Hogue, is Mr. Hogue?

Dr. F.:

I think he's a very astute lawyer and has done a great deal of good to his clients, the Proprietary Association, and has brought them along on many things,

(tape 0586)

but of course he's been opposed to the things that the proprietary manufacturers have generally opposed.

Dr. Y.:

Have you and he had policy arguments and debates?

Dr. F.:

Principally on the matter of the sale of products outside of pharmacies and not under the supervision of registered pharmacists. He never could

see . . . well, he, undoubtedly could see my point of view, but his clients just simply were people who wanted to sell everywhere, and while he was willing to have <u>some</u> products sold only under supervision, he was not for having a very large number of them restricted in that way.

# Dr. Y.:

Sure. One other thing that I had on my mind that I thought of at the time we were talking about the publicity in connection with the broad drug and pharmacy industry and profession. Right after the 1938 law was passed, a kind of

(tape 0614)

new journalistic venture began, rather an imitation of some of the private industry newsletters like the Kiplinger Newsletter, that concerned itself with regulation in this field and with economic trends in this field. This was Wallace Werble's FDC Reports called the Pink Sheet which was followed by a number of sheets of other colors. This is a major source of information and has been since its beginning within industry, government, and retrospectively, within the field of scholarship. Would you mind giving me an appraisal of this as a source insofar as you have observed it?

## Dr. F.:

This is a venture that has undoubtedly been a very profitable one to the sponsor and a very valuable one to the industry to which it is directed and, in my judgment, it would be even more valuable if the editorial content were limited to factual presentations of the news and information which becomes available through governmental and other sources. I think the kind of information that is supplied

(tape 0650)

is essential to people in the drug industry and also in the profession, especially those who are directing organizations or projects of various kinds. Its drawback as I see it is the editorializing and king-making activities of the editor, which, in many cases, detract from the value of the publication as a source of instant information on what is in the mind of regulatory agencies and what is actually promulgated by them. It has entered other fields, such as the information about the financial status of the drug industry, stock values and so on.

## Dr. Y.:

What do you mean by "king-making"? Could you just define the phrase as you use it in this context?

## Dr. F.:

Well, it goes into . . . the editor often goes into the business of speculating who is to succeed people in various types of jobs. This isn't confined entirely to governmental positions, but branches out into the internal affairs of

# (tape 0694)

drug manufacturers and colleges of pharmacy, boards of pharmacy, and pharmaceutical associations, and it's sometimes difficult to distinguish between a factual presentation and a speculative, trial-balloon type of presentation. It endeavors to give what Kiplinger gives to the general business fraternity, but fails in that Kiplinger does adhere pretty much to facts and sources of information without speculating on the future of individuals or the filling of positions of various kinds or resignations.

## Dr. Y.:

Or trends of policy?

## Dr. F.:

Trends of policy. Some of the industry people have, from time to time, expressed dissatisfaction with this phase of the recording and writing. In other words, there's a of the industry people have, from time to time, expressed dissatisfaction with this phase of the recording and writing. In other words, there's a good deal of editorializing along with the writing. Kiplinger supplies you with information on which you can base your own judgment, but Werble's supplies the information and then implies that certain things will happen or that certain (tape 0738)

things can be expected or should be done. It's more on the order of the Drew Pearson type of editorial work than strictly Kiplinger.

## Dr. Y.:

When you were with the American Pharmaceutical Association as its director, were you a source of news for the Pink Sheet?

## Dr. F.:

We gave them news along with every other publication, in other words, our news releases were sent there, but we did not contact this Pink Sheet with the idea of giving them a beat, a news beat, on other publications. The fact that they come out every week is, of course, an advantage to them over the monthly and semi-monthly publications, and we didn't feel that we ought to make them a sort of special type of medium to give information to. This does not seem to be the case at the present time, because there is a complaint from the National Association of Retail Druggists and some of the state pharmaceutical associations that news from the American Pharmaceutical Association gets into the Pink Sheet before it gets to them in the way of a news release. Of course, this is the business

(tape 0779)

of the editor and publishers, but there is this desire to be the first to tell, and it's very much like the television people who want to be the first to give a flash about something that is happening. It's a natural desire of a newspaper or news medium, but it annoys a good many people because some of the things, some of the speculation, just doesn't work out, and it does get into the hair of those who are running organizations or firms. There is also the feeling that maybe those who might be disgruntled or who have an axe to grind will supply certain information which can be the basis of a story or a speculation which isn't too desirable in certain circumstances.

## Dr. Y.:

From the point of view of drug trade journalism, if you were going back over the years, going to journalistic enterprise in this field to refresh your memory about certain things, what sources would you go to and which would you trust the most from your entrance into pharmacy on up to date information?

(tape 0823)

Naturally, you'd go the the <u>Journal of the American Pharmaceutical</u>

<u>Association</u>, but especially if you were interested in going into the trade and industry side a little more, what journalism would you consider the most authentic, the most helpful?

# Dr. F.:

Well, there was a publication called <u>Drug News Weekly</u> which was published by the Fairchild people for quite some time, which gave <u>news</u> without too much interpretation and, where there was interpretation, it was quite clear that the interpretation was not by an editor with a pharmaceutical background. We have the <u>Drug Topics</u> which is issued semi-monthly, but I think the most reliable of all of these publications is the <u>American Druggist</u> which comes out semi-monthly, and it, of course, couldn't possibly give news as quickly as the Pink Sheets, but if I were looking back and trying to get information and saw one issue of the Pink Sheet with a certain statement about a certain happening,

(tape 0864)

I would want to check with a publication, another publication, or with later issues of the Pink Sheet to see if there had been any retraction or any modification of the news.

Dr. Y.:

Would you feel for the earlier period that the <u>Druggists' Circular</u>, on which you worked, would be a good source?

Dr. F.:

Oh, yes. Everything was checked and rechecked before it was published.

Dr. Y.:

When did it stop?

Dr. F.:

It merged with the <u>Drug Topics</u>. I don't exactly recall the year, but <u>Drug Topics</u> bought the <u>Druggists' Circular</u> and the <u>Redbook</u>. They bought it principally for the <u>Redbook</u>, which is a price list that the <u>Druggists'Circular</u> originated and fostered for many years.

(Side 9, tape 0000)

Dr. Y.:

Dr. Fischelis, as we start this tape, I'd like to ask you about two people who are on my list about whom I believe I haven't asked you before. One was J. J. Durrett who became the chief medical officer of

the Food and Drug Administration sometime around 1930 and held this office for an important period of years. Maybe it was slightly before 1930. You were acquainted with him, were you not?

Dr. F.:

Yes, I knew him very well.

Dr. Y.:

Now, what kind of a man was he in his role as the main Food and Drug man with respect to drugs?

Dr. F.:

Well, he headed up the medical division. I'm not sure that that's the title, but he was the chief medical officer who, as far as the Food and Drug Administration was concerned, passed on medical questions which, of course, brought him into the

(tape 0015)

literature and labeling area. He was a very able person, in my judgment, for this kind of activity. He, of course, was alert to various types of fraud that were being perpetrated in the medical field, and he knew the law very well; I think he utilized the law to the utmost degree in running down improper labeling and claims that were extravagant. He had a very good delivery when he spoke to groups and was invited to a great many meetings of industry and professional people in the medical field and also to public meetings, because he developed his subject in a very interesting way and handled much of the scientific matter and the medical matter in terms the average person would understand.

Dr. Y.:

What were the things that brought you together as people?

Dr. F.:

I think that in my cooperative work with the Food and Drug Administration, I

(tape 0038)

met him, of course, and then, since I supported the views of the Food and Drug Administration on the broad principles that were involved in enforcement, we had opportunity to exchange many experiences on the federal and local level. I called on him very frequently for advice in handling important problems in New Jersey, and I also arranged for his invitation to meetings of pharmacists so that they would get first-hand information from one who could talk to professional groups, not only as an enforcement official but as one who had an interest in the practice of pharmacy on a high, professional level.

Dr. Y.:

What kind of a man was he in appearance and in demeanor?

Dr. F.:

His appearance was that of a medical man. You would recognize him as a doctor of medicine.

Dr. Y:

I didn't know that you could just see a man walking along and recognize him as a

(tape 0057)

doctor. What characteristics do you have in mind?

Dr. F.:

Well, first of all, what I might call a demeanor that reflected thought and interest in individuals, and something that is acquired as one digs into scientific problems; one generally can tell a businessman who is of the salesman type, from one who is, let's say, deeply interested in finance or in the production end of an operation. I don't mean that the label shows up plainly, but let's put it on the basis that he looked like a professional person, but also, in some respects, like an individual who had a sense of humor and could give and take in an argument and was quite alert to what was going on.

## Dr. Y.:

He was very serious about his job, wasn't he? I would take it from correspondence that he was a man very much in earnest. Your mention of a sense of humor even surprises me a little bit from what I've read, but you did detect this?

(tape 0081)

## Dr. F.:

He gave the impression of someone who knew his own field very well and who made decisions in the black and white area rather than in the gray area.

## Dr. Y.:

Right. Very full of dispatch and certitude.

#### Dr. F.:

That's right. A thing with him was either right or wrong, and while he recognized deviations from standards that were due to no deliberate action on the part of a producer, he didn't let that be the excuse for failure to meet standards that were high.

## Dr. Y.:

Was he a large man or a small man?

## Dr. F.

He was of medium size, inclined to be a bit heavy, but the impression that he made on you was favorable right from the start, and then when he got started on his message, or if he was being asked to make some concessions on something, you rather quickly learned that he didn't accept flimsy excuses for anything, that

(tape 0100)

he expected honest and direct action from those over whom he had any control as an enforcement person. And he was very deliberate in his talks and delivery of addresses to groups of manufacturers. For example, he made it very plain what the agency expected and made no bones about what the consequences would be if they didn't come through as expected.

Dr. Y.:

Was there any indication of his Alabama accent?

Dr. F.:

Some. Yes. Yes.

Dr. Y.:

That stayed with him.

Dr. F.:

Yes.

Dr. Y.:

To some degree.

Dr. F.

Now, after he had been with the Food and Drug Administration for a while, (tape 0111)

I was very much surprised to learn that he had joined the Squibb staff as medical director, and he was there for a couple of years. It has always been a question in my mind whether he took that job with the idea of finding out how the medical department of a drug manufacturing house was operated and what kind of domination there was by the business interests

over the scientific and medical personnel, or whether he took it with the intention of staying with that job. But he only stayed there for a couple of years and then went back to the Food and Drug, and, of course, had the benefit of knowing everything that went on inside. I never discussed this with anybody very much at the time, and I never discussed it with him, although I did indicate at one time to him that I was surprised that he went into industry. He just laughed that off and said that he thought that maybe he could do a good job for a house like Squibb, which would then be an example to the rest as to what could be done. And it settled his mind, perhaps, on whether the requirements that he had been active in promoting were too severe or (tape 0131)

impractical, as it was very often stated by the drug manufacturers representatives, or whether this was just an excuse for not complying with something that he thought was in the public interest. I never pictured him as a manufacturer's representative. I pictured him always as one who felt that the way to serve the public was in a regulatory capacity. And, of course, after he left the Food and Drug Administration, I don't know what the difference was, but there was some difference of opinion; he went with the Federal Trade Commission. I talked with him very frequently there, because he was controlling advertising there. I had a sort of feeling that Durrett's interest was in the improvement and abolishment of any fakery in the drug industry for the benefit of the public. He was testing out, for himself, where this could be done to the greatest benefit: first, by serving as a regulatory official, and second, by getting into a manufacturing house to exert the influence that he could there on the improvement of, not only products,

but also the marketing of products that (tape 0154)

were really valuable—not only products that were up for sale. Then, of course, with the development of manufacturers' literature and advertising, he had the feeling that the general practitioner was not getting the facts that he should from the producer of some of these products. In the Federal Trade Commission he would have some control over that kind of advertising, but he would have more control over advertising to the public and the statements that were made on remedies that were supplied for self-medication.

Dr. Y.:

I don't think the Federal Trade Commission ever did bring a case against drug advertising aimed at physicians until the power was taken away from them in 1962 in the bill.

Dr. F:

That's right. So, Durrett, to my mind . . . of course, he then became Dean of the Medical College at the University of Alabama, I believe, and I corresponded with him from time to time. We exchanged comments on various things, and that's where

(tape 0172)

I learned of his sense of humor more than I did with his enforcement work.

Dr. Y.:

Surely.

Dr. F.:

He is a very serious and devoted individual, in my judgment.

Dr. Y.:

Well, let's turn to Robert L. Swain who preceded you the year before as President of the American Pharmaceutical Association. When would it have been, 1933 or '34?

Dr. F.:

He went out of office in May 1934 and I went in at that time.

Dr. Y.:

And who played an important role, I think, from the drug side with respect to the 1938 law, being in some ways, I take it, a kind of an ally of Dr. Beale. So, would you tell me a little about him, his background and his structure of ideas and his motivations for the position that he took, as you saw it?

(tape 0188)

Dr. F.:

Well, Swain was a graduate of the Maryland University School of Pharmacy of which Dr. Kelly was, at that time, the dean. Kelly later became secretary of the American Pharmaceutical Association, on a part-time basis and then finally on a full-time basis, and Swain and Kelly worked very closely together in Maryland. They both lived . . . one lived in Baltimore and the other one just outside of Baltimore. Swain operated a retail drug store after he finished, in a small town in Maryland. When the State Board of Pharmacy and the State Board of Health were combined in some way so that the State Board of Health had jurisdiction over the quality of drugs in the state and the Board of Pharmacy confined itself mainly to regulation of the practice of pharmacy, examining candidates for registration and inspecting drug stores, there was a combination of jobs of the secretaryship of the Board of Pharmacy and the deputy commissionership of Food and Drugs in the State Department of Health.

This became a full-time job which Dr. Swain was asked to fill or which he applied for,

(tape 0211)

I'm not sure, and he then became, in a sense, a contemporary of mine, because I was Secretary of the New Jersey State Board of Pharmacy, and we met in the district meetings of boards of pharmacy and colleges of pharmacy and also in the district meetings of Food and Drug officials and, of course, in the meetings of the National Association of Boards of Pharmacy. And I found him to be a very able person. He was a good writer and a good thinker and had the interest of the public as well as the profession at heart. He also knew the retail drug business as one who had practiced in it as a pharmacy owner. I felt that he was quite cognizant of the trend of things and was enough of a student of the medical and pharmaceutical professions to really give good guidance to his constituents. He was never Secretary of the Maryland Pharmaceutical Association, but he had a great influence in that association, and when these matters of food and drug legislation or state pharmacy legislation came up, he was a leading factor in appearing before legislative committees to

(tape 0237)

stress this or that point about the character of legislation that ought to be enacted. He had the additional advantage of being on the staff of the State Department of Health and, therefore, the confidant and adviser of the Commissioner of Health on drug matters. He earned the recognition that he got by the kind of advice that he gave. He also was close to the federal Food and Drug Administration and was a collaborating, cooperating official, just as I was, and so we had many contacts about what to do

about this or that problem that arose in the development of the practice of pharmacy in those days. He studied law while he held this position at the University of Maryland School of Law, not so much with the idea of practicing law, but rather of acquiring this additional tool to enable him to work more efficiently in his own enforcement area. When he finished his law course, he still carried on in the same capacity that he had before. He didn't get into court work at all, but the fact that he had become a lawyer and had

(tape 0262)

passed the bar examination put him in the same position with respect to the attitudes of practicing pharmacists, not only in Maryland but over the United States, as Dr. Beale had because of his legal and pharmaceutical training. But I do not believe that Swain ever had any consulting work with the drug industry or was connected with the drug industry in any way except as he was called upon in the state enforcement procedures.

#### Dr. Y.:

During the thirties, when he expressed himself and you expressed yourself, there's a kind of difference, it seems to me. His point of view was much closer to that of the major pharmaceutical manufacturing concerns and associations than yours was, and this bent to his thoughts you attribute to his legal training?

## Dr. F.:

In part and also to the influence of the drug manufacturing industry in Maryland on his outlook. There were the Sharpe and Dohme Laboratories there,

(tape 0282)

and there were some of the proprietary manufacturing people such as Bunting, who headed up the company that manufactures Noxema. He was an old practicing pharmacist who had originated this formula in his pharmacy and was a member of the State Board of Pharmacy. Of course, he was very close to Swain.

Dr. Y.:

Bromo-Seltzer was made there, too.

Dr. F.:

Yes. The Emerson Drug Company was another.

Dr. Y.:

Emerson must have been a person of some political power, is that right?

Dr. F.:

Right. And Swain didn't exactly defend him, but he was never very strong on any enforcement in connection with this kind of people.

Dr. Y.:

But there were companies in New Jersey, too, but that didn't seem to influence

(tape 0297)

your point of view.

Dr. F.:

Well, that's true. I think he had a much more lenient attitude toward the manufacturing industry than I had. I felt that they were getting enough money for their products to make the necessary adjustments for high quality and that sort of thing. I don't think that Swain quite felt that way. He thought that it was a matter of free enterprise and as long as they weren't hurting anybody, they shouldn't be interfered with too much. In fact, this, of course, has been the attitude of health

departments. I'm not saying now that he wasn't strong for enforcement of the law if there were any infringements of the law, but he didn't go out looking for things that the industry might do which were harmful or things that they could do to improve the situation with respect to self-medication products and that sort of thing.

(tape 0313)

Dr. Y.:

And he wasn't for as radical revision of the law toward protection as some people were?

Dr. F.:

Yes. And he wasn't strong for the matter of having professional supervision right from the start to finish. Although he wrote articles along that line, he never did very much enforcement, as I saw it, with respect to sale of products in places that were not supervised by pharmacists. It didn't seem to be the politic thing to do in Maryland, but it wasn't in New Jersey either, as far as the legislature was concerned, because they liked to have these small merchants on their side; however, we had made the point, and it was understood pretty much there that you'd better not do this or the State Board of Pharmacy will prosecute you.

Dr. Y.:

Now, let me come forward a while to another person . . .

(tape 0330)

Dr. F.:

May I say one more thing about Swain?

Dr. Y.:

Yes, sir. Of course.

Dr. F.:

Swain was a really excellent writer and he wrote many articles for the . . . in fact, he became the editor of the Maryland Pharmacist. I was the editor of the New Jersey Journal of Pharmacy, and he wrote editorials, as I did, and this caught the eye of the editor Drug Topics, and they instituted a column there called "Your Pharmacy and Mine" which Swain edited. In this way, he got across to the practicing pharmacists in the United States, because Drug Topics was a throw-away publication which went into every pharmacy in the United States, without charge. He would take the things that were bothering the retail druggist and write his column about that, and this got him a lot of friends and applause. When Jerry McQuade, the editor of Drug Topics,

died,

(tape 0349)

Swain was asked to take the editorship of this publication. He then moved to New York and, of course, this gave him an opportunity to develop his journalistic efforts. I don't think he got into the business end of it very much, but he certainly didn't rub the drug industry the wrong way in any of his writings, editorials or otherwise.

Dr. Y.:

Of course, the magazine, if it was a throw-away, was entirely supported by the advertising. And he probably was chosen to do the column with full awareness of what opinions he expressed. But this would magnify his voice . . .

Dr. F.:

And the editorship later . . .

Dr. Y.:

Yes, and the editorship.

Dr. F.:

I had the feeling that I know he had some kind of a struggle with himself as to whether to go into this editorship rather than stay in the public work,

(tape 0365)

the law enforcement work, and this may not be relevant at all, but he had a son who was a deaf mute, as the result, I think, of scarlet fever in his very young days of childhood. I know that he felt very strongly about providing for this youngster. I think this was the thing led to his decision, because the salary obviously and the income in that editorship was many times, I think, what it would have been in his law enforcement job. So, I think there were other things besides just the financial attraction per se that made him decide on taking that job. But he became an influence, and he tried not to antagonize anybody in his views and always came along with an editorial proposing a compromise of some kind which the drug industry could live under or felt it could live under. So, he was a friend of the industry, there's no question about that, and he was called in to conferences many times, and, of course, by having this medium for publishing views of people who would like to get their views

(tape 0389)

before the public, he could pretty much guide things along lines that were helpful to numerous people, including his own paper, of course.

Dr. Y.:

Sure. Well, the jump toward the present that I wanted to make was one to ask you questions about the motivation of Senator Kefauver. This is

based on what you said to me when we weren't on tape that you, so far as you knew, were the only person who had been in the audience for every single session of Senator Kefauver's Senatorial committee hearings. Now with this opportunity to observe as closely as you did all that went on there, and with your knowledge of all the background, it seems to me that you are in as good a position to make some kind of estimate as to the Senator's motivation, his political motivation as against his social service motivation perhaps, one might say, as anybody is. I'd like you, if you will, to say whatever you'd like to say, addressing yourself somewhat to this point.

(tape 0415)

## Dr. F.:

Well, I didn't go along with the industry view that Kefauver went into this for political purposes to help him in being re-elected as senator or to make headlines favorable to himself. He might have had that in view incidentally, but I think fundamentally, he went into this investigation for the benefit of the people. That's my general impression after having sat through the hearings. I think that he wanted to get to the bottom of a great many things. I think as the hearings progressed and the material that he had subpoenaed was made a part of the record and subject to questioning of individuals in the firms that were under investigation, it became rather clear that there was a basis for an investigation of that type. I presume that after having reviewed the material, which had been subpoenaed before the hearings began, and having been briefed by his staff people, that he felt that it was something that ought to be done and went ahead with it. Now, he had other investigations, of course. There was the steel industry, I think, that he investigated; the bread

or

(tape 0450)

baking industry; and I don't know that anybody ever accused him of making those investigations just to serve his own purposes and not for the public's benefit. I don't think that . . . I didn't see any reason by anything that he revealed for him wanting to select the drug business particularly as a goat to get himself into public eye anymore than he would normally be.

## Dr. Y.:

Dr. F.:

So that you are coming strongly for his genuineness and integrity, giving him a pretty strong vote of confidence based on your own observations.

Yes. I thought he handled the witnesses rather decently. As someone said about the hearings, the headlines that got into the papers which were unfavorable to the drug industry were not created by Kefauver. He only asked the questions. It was the answers that brought the headlines and got the unfavorable publicity that was generated as far as the drug business was concerned. I don't think that he ever accused anybody of doing anything unlawful or unethical. He

(tape 0481)

just let that develop, if there was anything unlawful or unethical in their procedures, by the questions which were asked. Of course, the Republican people on the committee, notably Dirksen and Hruska, and particularly Hruska, seemed to be defending the drug industry and asking the kind of questions and making the kind of speeches which perhaps should have come from the industry, and from the representatives of the industry in their defense, rather than from members of the investigating

committee.

Dr. Y.:

You are suggesting that they made more speeches than Kefauver made. That he mostly asked questions and didn't elaborate . . .

Dr. F.:

The answers speak for themselves.

Dr. Y.:

And you thought he was, with the advice that he had from his staff, able and clever as an attorney?

(tape 0500)

Dr. F.:

As an interrogator, and prosecutor, if you will, although he didn't act like a prosecutor. He was simply digging for information and he kept on digging. He was a persistent person. If the answer was evasive, he found other ways of putting the question, so as to get a definitive answer. I thought he was very able along that line.

Dr. Y.:

Now, one other question that I wanted to ask you, or a topic that I wanted to suggest, really, on which I hope that you might make some comments was the matter of the United States Pharmacopoeia, particularly, in its role as an official standard under both the 1906 law and the 1938 law.

Dr. F.:

Well, the United States Pharmacopoeia and the National Formulary are known as official compendia under the Food, Drug and Cosmetic Act, and they occupy that position on the basis that the definition for drugs (tape 0523)

begins by saying "any article listed in the United States Pharmacopoeia, the National Formulary or supplements plus other articles which are defined are drugs and ought to be considered as drugs and subject to the provisions of the act." Now the United States Pharmacopoeia was first published in 1820, and the objective of such a publication was to list for the benefit of physicians those drugs which because of their effectiveness and use, demonstrated usefulness, could be and should be prescribed for certain types of ailments for which they were supposed to be effective. And this, of course, made it necessary for the Revision Committee—which met, which was appointed every ten years and which acted in the interim between these decenniums—to investigate and locate those drugs which met that criterion. The method of selection left something to be desired. Dr. A. G. Du Mez, who was Dean of the College of Pharmacy, University of

(tape 0556)

Maryland, and I were members of the Revision Committee in the 1940-1950 decennium, and we were both made pharmacist members of the Committee on Scope. Now, the Committee on Scope of the United States Pharmacopoeia consists of all of the physicians on the Pharmacopoeia Revision Committee. The total Revision Committee was 50 at that time, and I believe there were 17 physicians. It was felt that the selection of the drug should be referred to a Committee on Scope, which should consist of the physicians on the committee, because they were the ones who were presumed to be familiar with drugs and were the first, or at least among the early people, to become cognizant of the existence of the drug and would have experience with the drug as far as administration was concerned. Then, there were five pharmacists added to this Committee on

Scope, so that there would be pharmaceutical advice with respect to the quality and the adaptability of the drugs for manufacture into preparations. The pharmacists also would give advice as to what kind of preparations of the

(tape 0585)

drugs selected by the committee should be recognized by being listed and have standards set and formulas for preparations worked out. Well, we noted that the chairman of the Revision Committee, who was at that time Dr. Bastedo, a New York City practitioner, would take the list of the drugs in the previous Pharmacopoeia, plus lists of drugs which had been approved by the Council on Pharmacy and Chemistry of the American Medical Association, and other drugs which got into the literature as having served a therapeutic purpose, and the chairman would say, "Well, now we'll consider digitalis. Is there any comment?" And if there was something new about digitalis, for example, the fact that a tincture of digitalis sometimes was not tolerated well by a patient because digitalis contained certain fats which were brought into the tincture, and that it should be fat-free so as not to cause a nausea which the normal tincture did. Well, this would be brought out in the discussion and then the chairman would say, "Now, vote on the admission or non-admission of this drug." And the

(tape 0618)

committee would have a voting sheet before it and would vote.

Dr. Y.:

This wasn't the Scope Committee?

Dr. F.:

This was the Scope Committee. The Scope Committee would then recommend

(tape 0670)

to the committee as a whole that these drugs would be approved, and it would be a very unusual thing for a drug that was recommended by the Scope Committee not to be approved unless something was found that was brought back to the Scope Committee as a reason for non-admission. Well, this procedure went on with numbers of drugs, and one physician would say, "I don't use this in my practice." Incidentally, some of the M. D.s were not practicing physicians, but were pharmacologists. And we would have a colloquy like this, that came down to strychnine. And a pharmacologist would say, "Now, gentlemen, strychine is not a drug of any real value. There has been no demonstrated pharmacological action that would make it a good therapeutic agent for any purpose." And (tape 0641)

they might make a stronger statement, as I recall in one instance, saying, "I don't think a practitioner of medicine ought to use this drug." And then there'd be a response from a practitioner, probably a professor of medicine who was using strychnine routinely for various types of complaints, usually in tonics and that sort of thing. He would say, "Why, I use strychnine and I'm a reputable practitioner, and I wouldn't do without that drug. I insist that it be recognized." And then there'd be more argument and the chairman would say, "Well, vote." And everybody voted. Well, Du Mez and I, in a recess of the committee meeting, said to each other, "Look, these fellows are voting on these drugs purely on the basis of their prescribing habits. Nothing is being introduced here that supports their view, pharmacologically or clinically, that these drugs are really valuable and necessary. There are other substances that do

the same thing that strychnine is supposed to do, and they're not poisonous in the sense that strychnine was." We were having all kinds of strychnine-poisoning from, not necessarily prescriptions, but from mistakes in prescriptions. If a fellow didn't triturate his powder very carefully, and got the strychnine distributed, there might be one capsule that had much of an overdose, and another capsule would have an underdose, and the overdose might be enough to do a good deal of harm. So, we picked up enough nerve to say this to the committee, the Scope Committee, and immediately there was a reaction from the general practitioners, and another reaction from the pharmacologists, and they got into a real argument about this. This was the first time that there really was any argument about the admissability of items to the Pharmacopoeia on the basis of clinical and pharmacological evidence of value.

#### Dr. Y.:

That is to say, in terms of the law, efficacy. The problem of scientific (tape 0702)

efficacy wasn't being approached scientifically. And yet every time that the committee voted, granted that its decision was backed up by the entire Revision Committee, you were making law.

## Dr. F:

Exactly, because the drug had been defined as an article in the United States Pharmacopoeia. Well, there was so much logic to the argument that we put out that one of the physicians, who was the physician—in—chief at one of the Boston hospitals affiliated with Harvard University and who was a professor of medicine at Harvard University, came out and said, "Well, now, these men are right. We have not been supplying evidence of

(tape 0792)

efficacy, and we've been relying completely on the experience and prescribing habits of those of us who are in the practice of medicine. We ought to have as a sub-committee of this committee, a Committee on Therapeutic Efficiency. And such a committee was appointed then, and from then on evidence was brought, especially in connection with some of the older drugs, and, of course, naturally, with the newer drugs. (tape 0740)

I cite this simply to indicate that the selection was rather arbitrary, and since the Pharmacopoeia became the legal standard for drugs, there was a tendency to do away with formulation in the Pharmacopoeia, to more or less confine the Pharmacopoeia recognition of the drug to the nomenclature, the standard, and the tests for absence or presence of impurities, and the method of assay, and then some reference to dose. E. Fullerton Cook, who was the chairman of the Revision Committee at the time, and who was never one to go into detail about the efficacy of drugs beyond the decisions of the Scope Committee, was very much annoyed about this type of thing and kept saying, "Well now, we, the Pharmacopoeia, being the recognized standard under the Food and Drug Act, must confine itself largely to supplying standards of identity, purity and strength—nothing about pharmacological or therapeutic action or efficiency." This was something with which the committee couldn't concern itself too much because it might lose the opportunity of having

the Pharmacopoeia remain as the official compendia. Well, of course, at that time, Food and Drug legislation did not require any efficacy standard, and the selection, therefore, by this Scope Committee was practically final, and identified the drug as either one that should or

should not be used. This, of course, had a bearing on the standard, and it got away from making the list that was included a list of actually the most effective drugs, and this, we felt, was really harmful. There's another phase of this that now comes up because when World War II came along, I was then heading up the Division of Chemicals, Drugs and Health Supplies, in the Civilian Supply Division of the War Production Board, and we were compelled to supply a list of drugs which were indispensable, because of the necessity for diverting raw materials from which a good many drugs were made or which entered into the synthesis of drugs, these raw materials also being used in the preparation of weapons and other war supplies: sulfuric acid, for example, steel, iron,

and many other basic chemicals. And it got to the point when we were asked to make a selection of what we considered the most important and needed drugs, and we even got to the point of having to plan an austerity program with respect to drugs. So, the question arose as to: "Where do we turn for this kind of decision?" The Pharmacopoeia listed many drugs; the National Formulary listed many others. We knew that they were not all necessary, that physicians could get along without some. So Fishbein and two or three AMA representatives, and some people from the Food and Drug Administration and from other government agencies, the Public Health Service, were brought together as a committee

(Side 10, tape 0000)

(tape 0857)

on essential drugs. This committee met at monthly intervals, and the agenda always had on it consideration of a number of drugs which required raw materials that were essential and which some had felt were unnecessary or had substitutes of equivalent therapeutic action. Now,

this committee was very loath to express itself on any products, whether brand-name products or otherwise, because of the customary AMA attitude not to interfere with the prerogative of the individual physician who is supposed to know all about all drugs when he prescribes for a patient and picks the one that he knows is best. And, so, unless it could be proven that it was absolutely necessary to have a decision, the thing was held in abeyance for additional information, and it was usually referred to the National Research Council for pharmacological or other types of tests to establish the essentially of the item in question.

(tape 0020)

They did not want to get into anything that would, after the War, categorize any drugs as unnecessary or unessential and interfere with the drug industry's activities. But, we're getting right to that point again, now that the Food and Drug Administration has authority to determine the efficacy of a product. Where are we going to determine that? Well, the recent Food and Drug Commissioner . . .

# Dr. Y.:

James Goddard.

#### Dr. F.:

James Goddard had to make decisions on all of the new drug applications that had been made effective since the law went into effect.

#### Dr. Y:

On the grounds only of safety.

# Dr. F.:

Yes. On the grounds only of safety, and now establish their efficacy.

And, of course, he turned to the same agency, the National Research

Council, and

(tape 0033)

they are pussyfooting about a lot of these items, too, because they can't find evidence of efficacy on all of them, and they are not finding very good evidence on some that are considered partially efficacious. The list has not been issued yet, but individual drugs have been . . . names have been given out form time to time as being apparently not efficacious, and giving the producers thirty days in which to file any information to the contrary.

## Dr. Y.:

That's written into the law—I guess they have to do that. I'm interested in what you say here. Your view is that insofar as the National Research Council has submitted names of drugs with the categories in which it has put them, that it has been squeamish and perhaps not as rigorous in calling things "not efficacious" as you might, in your judgment, have done. Is that right?

# Dr. F.:

Or as, let's say, Dr. Goddard would have done if he had the whole authority, because it's very difficult to say that any substance that has been used

# (tape 0048)

therapeutically is not effective when somebody, a qualified medical practitioner, has used it and said that he got results. This has been proven by the placebos that are used in connection with new drugs to establish to what extent they really are effective and to what extent the patient reacts as though they were effective.

# Dr. Y.:

Your ascribing motivation to the National Research Council on these

reports is based on the utter complexity of the situation and the lack of evidence or presence of conflicting evidence or at least conflicting voices. It isn't that they are interested in protecting the drug industry particularly, you think?

# Dr. F.:

No, they're not interested primarily in protecting the drug industry, but they are interested in not harming private enterprise, such as is inherent in the drug industry, and this has been the deterrent in the past. It has been the salvation of many proprietary products, or so-called patent medicines, because

(tape 0065)

you never could find anybody who could prove that the product didn't do something that had a therapeutic effect on the person taking it if that person claimed to have improved.

## Dr. Y.:

At least, it was a very difficult case in which, if you went to court, you would have to prove that it <u>never</u> did good. That burden of proof has been assumed by the government in a few cases, but it's a very difficult one. Going back to the problem of the forties that you were speaking of in connection with the Scope Committee and the voting in or out for inclusion in the next revision, many of the drugs that would be voted upon presumably, that had been brought from the AMA lists, for example, were drugs that had been marketed by industry. Isn't that true? That is to say, they were new drugs that had been discovered by industry, formulated by industry, and therefore had a certain amount of experience and would eventually come up, as some

(tape 0080)

of them would this time, for admission to the USP or non-admission, depending on how the vote went. You said that there were on the Scope Committee practicing physicians, medical men in clinical work in hospitals and medical schools, some pharmacists. Was industry represented? Is there any problem at all of pressure, either internal or external or subtle or overt, with respect to industry trying to get developments that they have engaged in in the past over the hurdle and into the Pharmacopoeia and, therefore, into the this privileged, official status?

#### Dr. F.:

Well, as a matter of fact, the Pharmacopoeia has lost its standing as the book of the most efficacious remedies on this basis: progress in the development of new drugs has been so rapid that any book that is only issued every five years is behind the times when it's issued, even though they are permitted to provide supplements, and issue supplements and intermediary recognition of

(tape 0099)

these drugs. The whole situation has changed, especially in connection with the new drug application, so that a manufacturer has to provide the Food and Drug Administration with complete information, complete methods of analysis and standards, and now additional information on efficacy. So, once the drug becomes an approved drug in this sense—they always call it a drug that has a new drug application approved, or become effective; they don't use the word "approved," or didn't until more recently—everything that is needed for the protection of the public has already been provided, and the book then becomes merely a repository for information that has already been supplied. A Revision Committee is not

necessary to formulate the standards, because the Food and Drug
Administration has either rejected or approved the standards that are
being used, and in addition, they have long dossiers of evidence of
efficacy.

(tape 0116)

Dr. Y.:

So that especially since the 1962 law, there is this tendency for the Pharmacopoeia to become somewhat irrelevant?

Dr. F.:

That's right.

Dr. Y.:

Now that wasn't so in the forties, though, when you were . . .

Dr. F:

No, because at that time, there was no such thing as a new drug application.

Dr. Y.:

It was just getting started.

Dr. F.:

Yes.

Dr. Y.:

It applied only to safety and not to efficacy.

Dr. F.:

That's right. And the question now is, there's agitation for formularies to be

(tape 0122)

issued by the government, and this has been brought into play in connection with the controversy over drugs that are marketed under

generic names and drugs that are marketed under trade-mark names. There is an economic factor involved in asking for the lists. This comes from the Welfare Administration which wants to make available effective drugs at lower prices and wants to do away with the branding and that kind of thing. But this is incidental, really, to the matter of defining a drug. The drug is not only defined in the Food and Drug Act, but, by means of the New Drug Application, everything passes through the Food and Drug Administration before it even can be marketed. Under the old regulations, anybody could put out a new product, and it became an official product when it gained entrance into the Pharmacopoeia by way of the Revision Committee and the Sub-Committee on Scope. So, the Pharmacopoeia was referred to very frequently as the "Druggist's Bible." But it's no longer the "Druggist's Bible" and (tape 0140)

hasn't been for a long time. "New and Nonofficial Remedies" really superseded the Pharmacopoeia long ago and gave more information about the drug than the Pharmacopoeia gives. The Pharmacopoeia has confined itself to standards, and it says nothing about usefulness. Again it was only by a strong representation on our part to include information about the use of the drug, the therapeutic use, that adoption of a category for each item in the Pharmacopoeia finally was made a part of the book, and all it says about the drug is that it's an antiseptic or an analgesic or a depressant or a stimulant. It doesn't say to what extent it is active, and whether it's a mild narcotic or sedative, a mild sedative, or a long-acting sedative, or a short-acting . . . it simply says "sedative." Dr. Y.:

No detailed indications.

Dr. F.:

No detail of any kind. Now, this is of no value to the practicing physician,

(tape 0156)

and it's of no value to the pharmacist who has other sources of information and, as far as the physician is concerned, the PDR—the Physician's Desk Reference—is a much more valuable book to him than the Pharmacopoeia, because it has all of the information that the manufacturer of the drug has, and that information now has to conform to the regulations under the Food and Drug Act with respect to warnings and all of the other things. So, this Pharmacopoeia is in a rather sad state. Dr. Y.:

And the same is true of the National Formulary. It's the same kind of problem. And even with regard to the standards, which really was one of the most important factors after 1906. The Food and Drug Administration, then the Bureau of Chemistry, it's apparent to me, had problems with respect to standards that, in the case of given drugs, really weren't answered by the Pharmacopoeia as it then stood, and there's a lot of by-play on up at least into the thirties

(tape 0172)

regard to the standards. In fact, sometimes the Food and Drug

Administration will work out a standard. I think this was perhaps

particularly true with bio-assays in the twenties, which, as far as

science was concerned, rapidly superseded the kind of standard that the

previous Pharmacopoeia had had, and then were quickly worked into the

next Pharmacopoeia as to standards. So this business of the standards

getting out-dated, too, when the Food and Drug Administration needed to have ever more sophisticated standards in order to be able to differentiate mixtures and things of that kind, must have been a problem during these years. Did this come up in your experience?

## Dr. F.:

It wasn't a very difficult situation, because the Food and Drug

Administration had its own laboratories and when it discovered that a

test in the Pharmacopoeia did not really determine the effectiveness or

the activities of the drug

(tape 0199)

pharmacologically, or if the test didn't reveal certain impurities, they, in their own laboratories would work on this problem and then communicate it to the Revision Committee, or they would call it to the attention of the proper subcommittee of the Pharmacopoeia Revision Committee, Organic Chemicals or Crude Drugs or Inorganics or Animal Drugs—whatever they were. Some action would be taken and an interim revision sheet could be issued. And that's what most of the interim revision sheets have been, corrections or additions to tests. The machinery for that was good enough to take care of contingencies like that. Where the big difficulty has been, there's nothing in the Pharmacopoeia to guide a physician as to the effectiveness of a drug in particular conditions, or anything in the way of warnings about side-effects.

#### Dr. Y.:

So that the Pharmacopoeia is still an official standard, but that isn't so important

(tape 0209)

now as it was in 1906, mainly because the new drug provisions of the '38

law and then the '62 law mean that all new drugs are automatically under the control of the government in any case, and, being under control, they don't have to go through the Pharmacopoeia to be controlled, or the National Formulary. So they are already under control, and the major segment of drugs being employed in therapy, I take it, percentage-wise, consists of new drugs, rather than the old drugs which were included in the Pharmacopoeia, as the new drugs have come along. So that means that even legally these books of standards have shrunk in importance compared with what they were when the 1906 law was passed.

# Dr. F.:

Yes, they still cover standards with respect to identity, purity and strength, and therefore serve as the basis for labels as to these three factors. But as to effectiveness of therapeutic use or dosage, while there is a dosage given, there is no explanatory matter to the physician as to the

# (tape 0228)

effects of continued use or the side-effects in certain areas or incompatibilities with other types of drugs which might be given to a patient simultaneously. This is all to be found in other books or in publications, journals, and that sort of thing.

## Dr. Y.:

If one went over to your shelf and took down the Pharmacopoeia that was prevailing when the 1906 Pure Food and Drug Act was passed, and then took down the latest one, and ran an analytical comparison as to what kinds of drugs were contained, in other words, revealing the difference between the drug situation at its most official level, then and now, what are the broad, sweeping generalizations that such an analysis would reveal?

Dr. F.:

Well, I don't think that there would be a great deal of difference as far as the categories of material printed in these standards is concerned.

There would be a great difference in the types of tests for identity, purity and strength,

(tape 0253)

because of the instrumentation that has replaced a good deal of quantitative analysis, volumetric and gravimetric and so on, but there wouldn't be a great deal of difference really.

Dr. Y.:

What kinds of drugs have gone out and wouldn't be official? That's what I mean.

Dr. F.:

The vegetable drugs, let's say, would have been replaced very largely by their active principles if they had any.

Dr. Y.:

Then a lot of them . . .

Dr. F.:

Didn't have . . .

Dr. Y.:

Didn't have, and therefore, just dropped out completely.

Dr. F.:

Dropped out completely. The synthetic drugs would show replacement where drugs with greater efficiency and smaller dosage have replaced the earlier synthetics used

(tape 0280)

for the same therapeutic purpose. But, as far as the information being

right up-to-date with respect to the hundreds and even thousands of drugs and dosage forms of the drugs that are on the market today, there would be a very small number of those that would be in the Pharmacopoeia today. Dr. Y.:

How about calling it a night and resuming for a little while in the morning to do something that we began at the very beginning of our conversation and then branched off into particular subjects without quite getting as complete as I would like to have it on the tape, your own view of the positions that you held. You talked about your education and some of the positions and then have mentioned others as various problems have come up, but I'd like to go through that in the morning just a little more systematically, beginning around 1920. And so I'll see you in the morning?

Dr. F.:

Yes.

(tape 0292)

Dr. Y.:

Dr. Fischelis, this morning we're going to return, as we said last night, to some of the professional experience which you had in a somewhat more chronological way. We have talked about your editorial experience with <a href="mailto:Druggists">Druggists</a>' Circular and, after that was completed in 1916, you served with industry for a while, with the H. K. Mulford Company in Philadelphia. What was there about this experience, that lasted about three years, that helped form your thinking?

# Dr. F.:

In the capacity of assistant editor of the <u>Druggists' Circular</u>, I had, of course, met not only people in the profession, but also people in

industry. In the contacts with the editorial staff of the <u>Druggists'</u>

<u>Circular</u> and the <u>Oil, Paint and Drug Reporter</u>, which was published by the same organization, I frequently was called on to write on professional aspects of subjects that were in the industry's mind from time to time.

So I was a contributing

(tape 0315)

editor to the oil, Paint and Drug Reporter and through that, I had industry contacts, and of course, in the advertising department of the publications, the advertising managers and solicitors frequently contacted me about problems that had been put to them by their industrial contacts. So I got a pretty clear picture of what was going on in various phases of pharmacy, and I had always been interested in the broader aspects and also the public aspects of this pharmaceutical service. One of my teachers at the Medico-Chirurgical College, in fact, two of my teachers there, were part-time professors. Charles E. Van der Cleed, who was professor of pharmaceutical chemistry and talked on the industrial areas of pharmacy, was the chief chemist for the H. K. Mulford Company, and Dr. F. E. Stewart, who was professor of materia medica and was an M. D. as well as a pharmacist, was director of the scientific department of the H. K. Mulford Company. Both had influenced me to come with the Mulford Company, and

(tape 0337)

I was ready to go back to Philadelphia after the New York experience. I became assistant to the director of the scientific department and also assistant to Dr. Van der Cleed who, as chief chemist, had charge of the writing of labels, and between Dr. Van der Cleed and Stewart, most of the literature accompanying drugs and advertising was either written by them

or was passed upon by them. And I became the person, because of my editorial experience, who had to revise and originate a good deal of the literature about new products and those products that were specialities of the company. This firm was a pioneer in the preparation of biological products as well, and they made diphtheria antitoxin and tetanus antitoxin and bacterial vaccines. I became associated with their plant at Glenolden, a suburb of Philadelphia where the biological products were manufactured. Dr. A. Parker Hitchens who was head of that indoctrinated me in the biological products field. I had difficulty in (tape 0367)

dividing my time between these groups, but it was a fine experience in that it showed how conscientious the people were about the quality of their products, and it also showed some of the short-cuts which were taken in the preparation of the products that were of lesser importance. One couldn't escape being drawn into policy decisions with regard to the Food and Drug legislation, and so on, and I gradually was brought into the relations with the Council on Pharmacy and Chemistry of the American Medical Association, because in those days, that council was the agency which, to an extent, at least, was the equivalent of the New Drug Application Department of the Food and Drug Administration. I was brought into all of the new developments, and it was one of my duties to have the products approved by the Council on Pharmacy and Chemistry. This brought me in contact with the American Medical Association and Dr. Puckner, who was then secretary of the council, and with whom I had worked while I was on the <u>Druggists' Circular</u>, as I have (tape 0387)

already mentioned. So, my experience was broadened considerably and the

regulatory phases of the production and distribution of drugs were brought to my attention from the manufacturer's or producer's angle. Dr. F. E. Stewart was an unusual man and I think the reason—he had worked for Parke, Davis and Company, Frederick Stearns and Company and now the Mulford Company—they really had a man like him on the staff to get the physician's point of view. He had no hesitancy in expressing it and guarding the policy—makers against overstatement of effects of products, and he insisted in the early days there, as I recall it, on giving contra—indications, which was a rare thing in the literature of drug manufacturers expounding the virtues of a product that they wanted to sell, especially that they wanted to sell.

## Dr. Y.:

Besides the biologicals, what kind of medicines and drugs did the Mulford Company

(tape 0412)

mainly make?

#### Dr. F.:

They made what was in those days called a "full line" of USP and NF preparations, which pharmacists were no longer manufacturing, and bought, and then, of course, they had their own line of specialities. I can illustrate that best by fluid extract of <u>cascara segrada</u>, which was a laxative, but every one of the drug manufacturers had a special cascara preparation. Lilly made one with chocolate and somebody else made one with vanilla and somebody else made one with other flavors; in those days, palatability was an important factor. That's why these elixirs came into being. They made what was called a full-line of products, such as the old-time pharmacist manufactured himself, but always where there

was a considerable call for a drug they developed a specialty, which, of course, was branded.

Dr. Y.:

So you had experience in the problem of developing the labeling for these drugs,

(tape 0431)

not only with the drugs that had to be made in conformity with the USP, but also with some of the specialities which would be different and somewhat more complex non-USP compositions.

Dr. F.:

And sold under brand names so as to identify it with the company. In those days, a little more attention was paid to the name of the firm; for instance, physicians would prescribe tincture digitalis—Mulford, because Mulford was the first to remove the fat from digitalis in the manufacture. Then, of course, when Mulford developed a business on this, they gave their particular digitalis tincture the name "Digital" and so the "Mulford" was no longer necessary. I've never been able to quite understand why a manufacturer wouldn't prefer to have his name as a part of the title of the drug, rather than be given a fanciful name.

Dr. Y.:

But this was the period in which those special trade names were beginning to develop;

(tape 0451)

that was to become the wave of the future in pharmaceutical manufacturing.

Dr. F.:

Right.

Dr. Y.

Were there a few touchy or borderline problems that came up that made you see the difficulties that a manufacturer had with getting his labeling in accordance with the Food and Drug Law, and let you see also some of the problems from the perspective of the Food and Drug enforcers who were trying to get labeling in accordance with the law as they understood it? Dr. F.:

Yes. This occurred more particularly with the Council on Pharmacy and Chemistry than it did with the Food and Drug Administration, because the Council insisted that a product should not have a therapeutic title. In other words, you couldn't use the disease name for which the drug was supposed to be helpful in the title of the drug. It had to be adjusted to the content rather

(tape 0469)

than to the action, and, in your advertising, you could not make invidious comparisons between one type of product and another. This was supposed to be left to the physician. You were to tell the physician what the product contained, how it was produced, but not how to prescribe it, and you were supposed to give as full information as possible. This was really the best guide that the physician had at that time. He couldn't rely very much on the Food and Drug Act, except for identity, purity and strength of the product. He couldn't rely on the regulatory people to guarantee usefulness or efficacy or anything of that sort.

Dr. Y.:

Can you remember an example of negotiation that went on about labeling in this area?

(tape 0487)

# Dr. F.:

Well, they had a silver salt, colloidal silver salt preparation, which they called Cargentas, and there was a product known as Argerol, which this simulated, and Argerol had been the original product. The Pharmacopoeia then developed a name; they called it "Strong Silver Protein" and "Mild Silver Protein"—there were two types of products. Questions arose constantly as to which was the better to use, and there were quite a number of restrictions that had to be devised in the labeling and in the expounding of the virtues of the product to prevent overlapping and to prevent the making of statements that couldn't be proven. There was a good deal of the patent medicine idea about some of these products. The physicians were influenced by the same type of psychology that influenced the laymen. In the testimonial—writing this was another thing you had . . . In quoting literature of a subject, you had to stay within the context of the scientific paper that had been published and not take

# (tape 0518)

a sentence or two out of context which happened to bear particularly laudatory. These were some of the technical difficulties involved, and I'm quite sure that Dr. Puckner and the members of the Council became pretty cognizant of which firms were on the side of exaggerated claims and which firms played them down to keep within the truth.

#### Dr. Y.:

And because of the caliber of the people at the Mulford Company, you were placed in an atmosphere that was at the high level of ethics from the point of view of promotion and got to see it from that perspective?

Dr. F.:

That's right. Well, then came the War and in 1918, even though I had been exempt from the draft, I joined the Chemical Warfare Service, Gas Defense Division. My service was not very long, because the Armistice came in December 1918, and I think I joined in August of 1918. I did not go overseas. I worked in the Gas Defense Division in Long Island City, principally on

(tape 0543)

gas masks, material for absorbing the new gases that were being developed and so on. And then I went back to the Mulford Company after the War, and I had an offer from an advertising agency in Philadelphia called the Matos Advertising Company. They were developing a technical and chemical department, and I was asked to give them help on this thing; I wanted to learn something about the insides of an advertising agency. I'd been on the manufacturing side and the editorial side, and I got an experience there. While I was with this agency, I was, of course, continuing my teaching at the Philadelphia College of Pharmacy with which the Medico-Chirurgical College had merged. The college as a whole, the medical department, had merged with the University of Pennsylvania and became a graduate school of medicine of the University of Pennsylvania. This all happened because Philadelphia built a parkway from City Hall to Fairmount Park, and the Medico-Chi buildings were right in the road of that. They got something like a million dollars for (tape 0570)

their buildings and equipment, but rather than build a new place they joined with the University of Pennsylvania, and the Pharmacy College joined with the Philadelphia College of Pharmacy, and the Dental College joined with the Dental School of Temple University. So these faculties

were taken over and, in that way, I became a lecturer at the Philadelphia College of Pharmacy. Dr. Stewart had also been a lecturer there, and jointly, we lectured on the Food and Drug Law and the effects on pharmaceutical management. Of course, I was then able to talk from a good many angles on the subject.

Dr. Y.:

Was your work with Matos part-time?

Dr. F.:

No, that was a full-time job for about a year.

Dr. Y.:

Is that M E T O S?

Dr. F.:

MATOS

(tape 0586)

Dr. F.:

And I then decided to start a consulting office of my own, because I had been asked by other manufacturers to come with them, and I thought that maybe I could do better if I had an independent office and just did consulting work with different manufacturers as they wanted that kind of work. I moved to New York, that is, I moved to Newark, New Jersey, as far as my residence was concerned, but had an office in the Metropolitan Tower in New York, and that came about because the editor of Industrial and Engineering Chemistry (this was a publication of the American Chemical Society), Dr. Herty, when I was in New York during the War, had asked me to help him out on an occasion when the Priestley Medal was awarded in the old Chemists Club there. I wrote the thing up for him and he liked it

(tape 0616)

so well that he gave me a job of writing odds and ends which fitted in with the consultant thing, and also an office in the Metropolitan Tower right above their office. This worked out very well, because the William S. Merrill Company in Cincinnati had me come out there for a week a month, each month, to consult with their people on literature, production and advertising, and that sort of thing, which was another connection. The Heyden Chemical Company, which was a chemical manufacturer of salicylic acid and salicylates and so on, also asked me to work for them part-time, and between the editorial work on <u>Industrial and Engineering</u> and Chemistry and the Merrill Company and the Heyden Company, I was kept quite busy. Then, came the New Jersey College of Pharmacy episode. It was at that time that the proposal from the New Jersey College of Pharmacy came for the deanship, and I took that on, and we've already discussed some of the things in connection with that. I maintained my office in New York for a while until this college work became a full-time (tape 0650)

job, and then I only did the <u>Industrial Engineering News Edition</u> which had been started by that time, and I was asked to be managing editor of that. So those were the two that then occupied my time. I'd been going pretty fast and I became ill on one of my trips to Cincinnati toward the end of my work there; I was laid up pretty much for the summer. This was in about 1925, and my physician suggested that I give up the deanship and just rest for awhile. I did give up the deanship, and there was a company, the Maltby Chemical Company in Newark, New Jersey, where I was living, that needed some help on labeling and that sort of thing and advice on some manufacturing problems, so I became consultant to them.

This was work that I could do and still rest, and then the New Jersey

State Board of Pharmacy wanted a full-time secretary and chemist and

offered me the opportunity to go with them. I had been recovering pretty

much and I took that on as a full-time position.

(tape 0791)

Dr. Y.:

When was that?

Dr. F.:

That was in 1926. And while I was with the New Jersey Board of Pharmacy, I did have some freedom to do writing. As I got the work of the Board routinized, we moved to Trenton which was the capital city. It was no state office. The Board of Pharmacy was one of the independent agencies. It was not on state appropriation. It handled its own funds, licensing, examination fees, and even the fines for violations were credited to the Board, and it could spend as much as it took in. The balance, if any, had to be turned into the state treasury. So, with that kind of an arrangement, I was able to do some outside work, and the Committee on the Costs of Medical Care was then organized

(tape 0815)

and . . .

Dr. Y.:

Who organized it?

Dr. F.:

Ray Lyman Wilbur, who was Secretary of the Interior in President Hoover's cabinet and president of Stanford University, who was on leave there, and who, incidentally, was a physician. He was the chairman of the committee. It was not a governmental agency. It was financed by

numerous foundations, the Twentieth Century Fund, I think, the Rosenwald Foundation, and some other prominent foundations, to the extent of about a million dollars in a five-year program.

Dr. Y.:

I take it that your work on this gave you a broader overview nationally of problems of this sort than even the wide variety of experience you had had up to this time had permitted you to acquire.

(tape 0834)

Dr. F:

Yes, the Committee on Costs of Medical Care selected me to be the pharmacy member of the staff because of my rather broad experience and, then, of course, I made contact through this committee with over fifty members representing medicine and sociology, economics, and the public. I, of course, came in contact with people who were socially minded and who had a deep interest in future medical care. In fact, I hadn't recognized the problems as many of them had. It gave me an insight into the methods of the American Medical Association. Its representative, Olin West, who was Secretary of the American Medical Association, was a member of the committee, and, of course, he was a target for a good many things. This Committee on the Costs of Medical Care, of course, had a broad outlook on the professions which were supplying medical care, and they were going into the economic phases, both from a standpoint of those who were delivering medical care and those who were on the receiving end. But,

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of course, they were principally interested in the receiver, and it gave me a point of view which coincided with my own ideas. I felt that I had, in these people, an ally for making a real effort inside the industry and professional pharmacy for improvement in the methods of providing our phase of medical care. I also became aware of the reaction of the public, especially the knowledgeable people in various walks of life, to their evaluation of the services that were supplied. In other words, I got it not from our own selfish point of view but the viewpoint of those who were interested in the overall. This has been tremendously helpful in all of the future relations that I maintained. I gained considerable confidence in my own views of our place in the scheme of things by recognizing that these people who represented the hundred million, rather than those who represented the hundred thousand pharmacists or people in the drug industry . . . and, of course, it led to what I felt was the public interest in legislation dealing with drugs

and with medical care in general. After the <u>Cost of Medicines</u> by Rorem and Fischelis, which was one of the publications of the Committee on the Costs of Medical Care, was published, I found myself being asked at various times by the voluntary health organizations . . . and even the <u>Encyclopedia of The Social Sciences</u>, for example, asked me to write a column on the drug industry. I received many requests for information about pharmacy and was asked to serve on various committees, not within the industry, but outside the industry, where I could be speaking for pharmacy and, at the same time, giving them the essential information for their evaluation of pharmacy.

#### Dr. Y.:

(tape 0821)

Dr. Fishelis, I can't say how much I appreciate your patience and time and your recollections as you have told them to me and to Mr. Hopkins while he was here in connection with your experience in pharmacy, and, most especially, as this experience was related to the problem of food and drug regulation and the general social dimension of drugs. I want to thank you and say that I've enjoyed (tape 0870)

this, and I know those who will use the record of our conversation will profit very greatly from your willingness to make it available to scholars.

Dr. F.:

Well, Dr. Young, it's been a real pleasure for me to join you in this effort, and if I've contributed anything that's worthwhile, I'm very happy about it.

Dr. Y.:

Thank you, sir.