WINTON RANKIN

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Introduction

This interview with Winton Rankin is one of a series of interviews carried out with key persons involved with the passage of the Kefauver-Harris Amendments of 1962 to the Food and Drug Act.

This act comprised the most significant alteration of the Food and Drug Act since the 1930's. In part the amendments tightened pre-market clearance of prescription drugs by adding the requirement that drugs had to be proven effective, as well as safe, for their intended purposes. Among other things the act also attempted to correct advertising abuses, tighten labeling requirements and broaden inspection powers of the Food and Drug Administration.

The passage of the act was preceded by an extensive investigation into the economics of the ethical drug industry under the guidance of Senator Estes Kefauver's Antitrust and Monopoly Subcommittee. Senator Kefauver's main legislative goal had been to reduce prescription drug prices by infusing greater competition into what he felt was a market dominated by a relatively small group of large manufacturers. He intended to do this through a series of regulations the most controversial of which involved alteration of the patent laws as they pertained to prescription drugs. Most of his pricing amendments were deleted from the law before passage. Indeed there probably would have been no legislation enacted at all except for the thalidomide tragedy which spurred Congress to action.

Winton Rankin, the subject of this interview, is one of the few top ranking career Food and Drug administrators active in the FDA in the 50's and 60's who is still alive. Both George Larrick and John Harvey, the commissioner and deputy commissioner of the FDA in the era of the Kefauver legislation are now dead.

Mr. Rankin's long experience in the FDA makes him a marvelous source for agency attitudes concerning Kefauver's legislative efforts. He began his career with the FDA in 1939 as a seafood inspector. Over the years he worked his way up the ranks of the agency. From 1954 to 1961 he was assistant to the commissioner. By 1961 he had become assistant commissioner and in 1966 he became deputy commissioner, a post that he held until late 1969 when he was moved into a position in HEW out of the FDA. As assistant to the commissioner in the fifties and early sixties, Mr. Rankin was involved in the passage of food and drug legislation and congressional relations.

This oral history transcript is derived from a tape-recorded interview of approximately an hour and a half held with Mr. Rankin at his home in the suburbs of Washington, D.C. Mr. Rankin, now retired from government service was a gracious host and cooperative subject. In editing the transcript, Mr. Rankin made only a few minor changes.

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M: This is an interview with Mr. Winton Rankin of Arlington, Virginia. I am Richard McFadyen of the History Department at the University of North Carolina at Greensboro. Today is February the 1st, 1974. I'm going to start off by asking Mr. Rankin to tell me a little bit about his background in the FDA--the various positions that he held to help us place him in the FDA hierarchy. So, if you will start with that question.

R: All right. I began work with the FDA in 1939 as a seafood inspector. In 1940 I became a food and drug inspector covering all phases of the agency's work. I operated at several locations along the Atlantic coast as inspector and chief inspector. In 1946 I was transferred to the administrative offices in Washington, D.C. and served there as administrative assistant and in several other capacities until I became Assistant Commissioner in early 1961. In 1966 I became Deputy Commissioner and held that post until late '69 when I was transferred to the departmental offices out of the Food and Drug Administration.

M: What position did you hold in the late '50's--about the time of the Kefauver hearings?

R: Starting in 1954 I was assistant to the Commissioner. First for pesticide activities until 1956 and for general activities--covering legislation, planning, public relations--until I was made Assistant Commissioner in the early '60's.

M: So from about 1954 to about 1961 you were assistant to the Commissioner?

R: That is correct.

M: And could you describe a little bit more fully what kind of responsibilities this entailed?

R: During much of that time I was involved in legislation and congressional relations. I was active in work on the food additives amendment before it became law and in helping to implement it after it became law. I was active in the work leading to the passage of the hazardous substances labeling act and the color additives amendment--both in 1960. And also in work leading to the enactment of the drug amendments of 1962. In addition to the legislative activities, I was invloved in general administration under the supervision of the Commissioner.

M: Now, in relation to legislation--was it your responsibility to be creating new legislation--in other words, to be looking to the future in terms of what kinds of legislation was needed--or--does this question make any sense?

R: At a later time that was my responsibility, but in the late 1950's and very early 1960's--the time of the Kefauver hearings--I would say that my responsibilities were more of a technical nature and the Commissioner and Deputy Commissioner assumed primary responsibility for the "looking to the future."

M: Yeah, yeah--as a kind of planning. So yours was a technical responsibility. That is...

R: At the time of the Kefauver hearings, yes.

M: Right. In other words, you would be the man who would help in the actual wording of the legislation or...?

R: I would work with the Department's attorneys on wording. I would serve as

a go-between between the Commissioner and the scientists whose views needed to be taken account of; the Commissioner and the lawyers upon occasion although the Commissioner himself was intimately involved in much of this work. He didn't delegate all of the responsibility.

M: Maybe this would be a good point to--I guess I'm trying to find out who were the people who were responsible really for what's going on. I know Larrick at this point was Commissioner. Who were the men directly under him?

R: The people that were primarily responsible for the legislative effort--that's what you're referring to?

M: Well, that too. I'm sort of looking at an overall kind of picture.

R: Overall: Larrick as Commissioner and John Harvey as Deputy Commissioner were responsible for the total operations of the FDA. Under them there were, for a period of time, two Associate Commissioners: Malcolm Stephens who was engaged primarily in the enforcement activity and Robert Roe who was engaged for a period of time in the planning activity and later as director of the scientific activities of the Agency. Then our operation was heavily dependent upon our general counsel, Mr. William Goodrich, who was also quite active in the legislative picture. That gives you a picture of the key people who were running the Agency at that time.

M: Would it be accurate to say that Mr. John Harvey was the man during this time who was the most responsible for future planning or--in terms of legislation?

R: Probably so. Although Larrick kept his hand in on that as well. The two of them were responsible; yes, I expect Mr. Harvey had a greater percentage of the responsibility for day-to-day planning.

M: I'm interested in trying to learn a little bit about the kind of environment that existed in FDA in the late '50's. What do you see as some of the solid achievements of the FDA--or can you make some kind of general comment about morale--or the general feeling of the FDA in the late '50's? Do you get the gist of what I'm...

R: Yes. You're referring to the time between roughly 1955 and 1960?

M: Yes.

R: Well, to respond to your question in the light of some discussions that we had just a moment ago, I believe I need to go back beyond the mid-'50's and state very briefly some background from--oh, even 1938, when the Federal Food, Drug and Cosmetic Act was enacted--the real modernization on the old nineteen-hundred and six law. The Agency started in after the 1938 law was passed, with a tremendous amount of energy, enforcing the new provisions of the law. And, as the years went on, there were areas in which the law proved itself to be deficient. Efforts were made to correct those--some successful and some not successful. Of perhaps even more importance as the years went on, the tremendous technological developments of World War II became available to the civilian sector of the economy as well as to the military, after the war ended. And, really, the technological explosion in the food and drug industries from about 1946 up until 1960 was something that few people could keep abreast of. FDA tried manfully to do so. Former Commissioner Paul Dunbar, I know, in 1948 was largely responsible for stimulating interest in Congress that led to the Delaney Hearings on chemical additives in foods and later to the passage of the pesticide law in 1954 and the food additives law in 1958. But FDA did not get adequate staff to keep abreast of all the new developments. I think one of the major contributions that FDA <u>did</u> make during the period of

the '50's was to recognize how far it was falling behind the progress of the industry and to seek assistance from an outside group, the Citizen's Advisory Committee, which was formed about 1954 and rendered its report more than a year later. Now what was your question--I've established my background.

M: I was just asking you generally what was the atmosphere in the early '50's and '60's.

R: Yes. All right. The atmosphere in which we operated in the period of time from about 1955 to 1960 was one of trying to catch up. The Citizen's Advisory Committee that I mentioned found that there should be a tremendous expansion of money and competent personnel in FDA. The Department and the Congress were responsive to the needs and began furnishing funds to permit such expansion. A great many new people were brought into the Agency. We didn't have time to give them the long, slow training that had been given to some of us who came in earlier. A number of the newcomers were unhappy about what they regarded as the backward ways of the Agency. There was, I would say, some considerable discontent both within and outside the Agency about the way things were going. But, despite that, there was a feeling that the Food & Drug Administration was making very worthwhile accomplishments--was doing a job that it could be proud of.

M: Would you agree then that FDA was trying to catch up in the area particularly of prescription drugs--was this an area that some catching up needed to be done in?

R: I'm not sure that FDA realized in--well, before the Kefauver Hearings--how far behind it was in the area of prescription drugs. Yes, it was trying to catch up--there was no question that the answer is 'yes' to that question, but I would have to qualify it by saying that it probably didn't know how much

catching-up needed to be done.

M: Well, good--that's just the point I was trying to get to. Then you do sort of agree that the Kefauver Hearings perhaps--sort of--maybe "woke up" the FDA is too strong, but at least alerted the FDA to problems in the drug area that they just really weren't aware of--of course, that may be a little too strong.

R: It--I wouldn't say it quite that way--it might come out to much the same conclusion as your statement--we were not aware--I wasn't, and I believe most of the others in FDA were not--we were not aware of the extent of the abuses that were revealed by Mr. Kefauver in his hearings. Certainly the hearings "woke up" FDA as you expressed it. I think that's a fair way to put it. They brought to our attention and to the attention of the general public just how much more was needed in the way of attention to drugs. Now, I think it is also fair to point out that even though we had been as aware of what was going on as Mr. Kefauver, I believe we couldn't have done anything about it until the public also became aware. A regulatory agency, contrary to the belief of many people, doesn't run out in front of public support and create the climate in which it operates. A regulatory agency must follow the wishes of people generally and operate in the climate that they set for it and the public awareness of what was going on just prior to the Kefauver Hearings was such that the Agency couldn't have done much more than it was doing anyway.

M: Well then, that brings us to an interesting question then. How did the FDA receive Kefauver's hearings? In other words, on the one hand, if what you say is true, and I agree with you, it would seem that FDA would have said 'good, here's someone who will stir up controversy and will get us this climate of opinion so that perhaps we can get new legislation through.' But on the other hand, the FDA might have said, especially in light of the Henry

Welch affair and other things, 'This guy is being critical of us.' How did--in other words, I'm asking you how did the FDA react to Kefauver's probe?

R: Well in the first place, for my part and I expect for the part of a number of the others, I had considerable doubt before it started that Mr. Kefauver's probe would have much to do with FDA anyway.

M: Unh-huh.

R: Because his investigative hearings that started in late '59 were concerned principally with prices and monopoly questions and we had maintained for many years that FDA had nothing to do with prices. And while the question hadn't been asked in those words, if it had been, we certainly would have maintained that we had nothing to do with monopolistic practices, or controlling them. So, our first reaction was 'Fine, Mr. Kefauver, you've got an interesting investigation, but what's it go to do with FDA?'

M: Uh-huh.

R: Now, as the investigation progressed, it became quite apparent that Mr. Kefauver was getting into areas that are of concern and were of concern to FDA--the purity of drugs, the confidence that the American public can place in claims made for drugs. But even then for a period of time, I for one and I expect others, felt that this Kefauver investigation really wasn't the one that was going to do much for us because Mr. Kefauver was not a part of the committee structure up on Capitol Hill that ordinarily dealt with substantive food and drug matters.

M: Uh-huh.

R: By the time Mr. Kefauver got around to making his revelations about Dr.

Welch and Dr. Welch's outside activities, there wasn't any question in anyone's mind but that his investigation did bear on us quite heavily.

M: And I suspect in a way that you would rather it hadn't. In other words, it wasn't setting the kind of climate for legislative changes.

R: Well, it was acutely embarrassing (M: yes, yes)--no question about that. Oh, we would have been much happier had we realized what was going on and been able to take care of the matter ourselves, without having it spread out on the public record of an investigative hearing, but since we didn't, I must agree that it's fortunate that Mr. Kefauver did delve deeply into what was going on and lay the facts on the record.

M: We can go in two directions here. We should talk, I think, some about the Henry Welch affair, but before we get into that, what would you say was the attitude towards Kefauver? Was it a kind of--a--maybe belligerent is too strong a word--a--how was the relationship between Kefauver and his staff when the FDA began to realize that maybe some kind of legislation was going to come out of this?

R: Well, the reaction toward Mr. Kefauver when he first indicated that he wanted to introduce legislation that would help the Agency do a better job was that Mr. Kefauver probably was just trying to grab some handle that would help him get his price and anti-monopoly provisions before the Congress and hopefully through the Congress. And, as I mentioned, we didn't believe we were going to get any legislation through Mr. Kefauver. So the attitude at that time was certainly not belligerent--ah--perhaps tolerant would be the word? 'Let's humor the gentleman and he'll go away eventually when he finds out he can't get any law!' (M: Heh-heh) Later, as it became apparent that Mr. Kefauver was having some considerable impact on the Hill--I believe you

pointed out in your thesis--there wasn't a great deal of assistance given Mr. Kefauver. In fact there was a considerable rush to come up with an administration bill that could be introduced in lieu of the Kefauver bill.

M: Is my judgment accurate on that?

R: Some of the other people that you're going to interview will have more first-hand knowledge of the actual decision-making process. But--yes--my observation is that there was a considerable rush to get an administration bill up there before Mr. Kefauver got his bill passed.

M: Because, I haven't gotten this down on tape yet but I've got the impression that certain people think that the FDA had long been working on its own omnibus bill and that Kefauver actually took much of his--his provisions from the FDA bill.

R: Well--let's look at what happened. Mr. Kefauver and his staff came down to Commissioner Larrick's office before he introduced any bill and said 'Commissioner, what would you like to have in the way of drug legislation concerning prescription drugs? You tell me and I'll--if I can agree with it--I'll put it in my bill.'

M: Do you have any idea when this was?

R: Ohh. Do you want to save some more tape while I think?

M: All right--when did you recall that Kefauver met with Larrick?

R: This was before Mr. Kefauver introduced his first bill. He came to the Commissioner's office with his staff. I was present at the meeting. John Harvey was present. Larrick, of course. And perhaps others--I'm not sure.

M: Was John Blair there?

R: Yes, John Blair was there. The Senator explained that in his view, legislation was necessary to deal with areas not adequately covered as regards prescription drugs. And he would like to have his staff, in drafting it, consider any recommendations that FDA wished to make for new legislation. Commissioner Larrick did outline a number of provisions--the exact ones I wouldn't try to state at this time, but there must be a record in FDA files of that conference. And, while Mr. Kefauver did not pick up all of them in the bill that he introduced, there obviously had been some attention given to Commissioner Larrick's recommendations in the drafting of portions of his legislation. So it isn't surprising to me that Mr. Kefauver's bill reflected some of FDA's views--it should have.

M: Yes--and of course that's what he intended it to do.

R: That's what he intended it to do. Yes.

M: Right--but again, FDA's attitude was to--ah--I think maybe you used the word--"to humor him"...

R: We didn't think he was going to get any law passed.

M: Right.

R: We didn't have the foggiest idea that man was going to get his law through Congress!

M: Right. This wasn't the right committee, as you said.

R: While I worked on it--give the man his due--he's a Senator, he deserves respect and help, but don't get your hopes up! That was the reaction.

M: That's interesting. Well, could we talk about Dr. Welch--that situation--a little bit. Did you know Dr. Welch? Do you...

R: Oh, yes. I knew him.

M: Do you care to make some comment on the kind of person he was?

R: Dr. Welch was a very personable man, well-educated, likeable. He was a friend of mine--a friend of most of the people in FDA, I believe. I was never more surprised than when I heard what Mr. Kefauver had developed through his subpoena power as regards Dr. Welch's financial dealings.

M: Did you know Dr. Barbara Moulton?

R: Yes.

M: What would you have to say about her?--The kind of person she was?

R: Dr. Moulton was an extremely intelligent--I should say "is," I guess, I believe she is still alive. She is an extremely intelligent person and she expresses her views very forcefully, and upon occasion in such a way as to irritate those who do not agree with her. She was not the smooth operator that Henry Welch was.

M: Actually, this gets away from Dr. Welch, but what do you make of Dr. Moulton's charges that too much pressure was brought to bear on doctors who are assigned to work on the new drug applications? This was one of the charges that she made before the Kefauver Committee.

R: I think to some extent Dr. Moulton's charges were justified. I'm inclined to believe that either she over-reacted to the pressures that a public servant must expect, or else there were pressures brought upon her that never did come

out in the open record. For my own part, I expected industry representatives to come in and to argue their case just as forcefully as they could, and I accepted the fact that they have a right to do that--that didn't mean I had to agree with them. Now, there is such a thing as having too much repetition of the argument and I think the facts do bear out that--do support Dr. Moulton's statement that there's just too much of this business of industry representatives running up and down the halls of the Bureau of Medicine--day in and day out. So while I would not agree with all that Dr. Moulton stated, I certainly would not dismiss it as all poppycock.

M: Of course this theme will again come up when we talk about thalidomide...

R: Yes.

M: The pressure.... One would wonder if perhaps the person working on the new drug applications should not remain anonymous.

R: Oh, no, I don't think so.

M: Don't you think that should be...?

R: I think it would be a serious mistake for a regulatory agency to begin hiding its activities just to get away from having people come in to talk about it. In fact, the more openness you can have about your operation, the better off you are. I--I'd really rather see the review of the new drug application conducted in public with the newspaper reporters looking over the doctor's shoulders than to try to keep the doctor anonymous. You'd be surprised how much publicity of that sort would cut down on the industry pressure too. If responsible scientists outside were able to see what was going on and to see what the drug firm was trying to pull.

M: Right. I guess Dr. Moulton's complaint would be that too often it was

just the drug representative that was getting in...

R: And it was a valid complaint. Yes. (M: Right.) I think it's interesting to compare the two doctors whose names you brought up--Dr. Moulton and Dr. Kelsey. Now, Dr. Kelsey was under terrific pressure from Merrell to approve the new drug application for thalidomide. She didn't conclude that it was necessary to resign. She stood her ground and I, for one, am very thankful that she did! I'm sure a lot of others are...

M: We all are!

R: So, a lot depends upon the personality of the individual that's being approached by industry. Some may regard as pressure--undue pressure--the kind of approach that others will take in stride and not worry too much about.

Break in recording

M: Okay. We're talking about the Henry Welch affair and you were saying that the question was put to Welch about his outside affairs and what the remuneration was for this.

R: Yes. Dr. Welch had been given authorization to engage in some editorial activities for one or two medical magazines. The articles in Saturday Review by John Lear charged conflict of interest and made some allegations about the remuneration that Dr. Welch was receiving. These stimulated inquiries from the Department to Food and Drug Administration and Mr. John Harvey, the Deputy Commissioner of FDA at one time--and I would guess this was in Fall of '59--asked Dr. Welch how much money he was getting from his outside activities. Dr. Welch declined to state how much remuneration he was getting. Mr. Harvey reported the results of the inquiry to our Secretary who had asked that the question be made--be put to Dr. Welch. And the matter rested there until Mr. Kefauver revealed the extent of the remuneration.

M: Why did FDA not pursue this further?

R: You'd better turn that off again.

Break in recording

M: All right. I had asked you why did not the FDA pursue this question further.

M: Well I suppose then, in view of that, you were really doubly disturbed when the Kefauver revelations came out.

R: Well--I wouldn't say we were doubly disturbed--we were greatly disturbed, but looking back on it I would say that there was much more to the Welch affair than any of us had imagined.

M: Yes. I can see that. The point I was making was that you had--internally--you had almost straightened the thing out, but, for the reasons you have stated, it wasn't.

R: There was some considerable regret that we hadn't pursued the matter further...

M: Earlier...

R: Yes.

M: Yes. Well I guess we can leave that topic and move on to others. Are you aware of whether the Department--the FDA--was aware of the abuses that the Kefauver Committee was turning up in regard to false and misleading advertising

R: Well, the answer that I give, I'd like to have withheld from public view until June 1, 1984. When Dr. Welch declined to answer Mr. Harvey's question, Mr. Harvey and Mr. Robert Roe, who was then in charge of the scientific divisions and Henry Welch's immediate superior, and I met with Commissioner Larrick to discuss the matter and Harvey, Roe and Rankin expressed the view that Dr. Welch should not be permitted to refuse an answer if he were to remain with the FDA. It was our feeling that the man was pursuing two loyalties and that this was inappropriate in a government official. So we recommended to Commissioner Larrick that Dr. Welch be informed that if he could not see fit to answer Mr. Harvey's questions fully about his outside employment, that he should take steps to remove himself from FDA's employment. Commissioner Larrick did not wish to take that step. I know that Mr. Larrick regarded Henry Welch very highly as a scientist and as an administrator--as did many other people. And the Commissioner expressed the view that you don't get the best scientific effort if you have administrators looking over the scientists' shoulders at all times and trying to direct their activities. The Commissioner believed that you should pick good men and you should give them a great deal of latitude within which to operate. And that belief, I'm sure, influenced his decision not to authorize a further inquiry by FDA into Mr. Welch's activities. Now that's the end of the part that I would ask be blocked out.

in prescription drugs? In other words, was the Department aware of this kind of problem--had it been mulling it over?

R: Yes. Yes. There was an awareness that drug companies were doing a considerable amount of lying to the doctors. (M: Oh....) The view within the Agency was that the doctors were smart enough so that they wouldn't be misled and it remained for Mr. Kefauver to lay on the record the extent of the lying that was taking place and establish unequivocably the fact that doctors couldn't help but be misled by it.

M: Rather quickly, after Kefauver's discoveries in this regard, new sets of regulations were written. Do you remember the occasion of those regulations--or did you have anything to do with them--or--?

R: I was not at that time in the regulation-making end of the operation but, yes, I do recall that--well, I was in it, too--let me correct that...

M: All right.

R: I was assigned, after the drug amendments of '62 were enacted, to be sure that everything was done that needed to be done to get the new law into effect.

M: Now this is a different--this is the writing of regulations after the law was passed...

R: Yes--now what time are you speaking of?

M: I'm speaking of the time before the law was passed. In other words...

R: Which regulations--do you know?

M: These are regulations referring to package brochures...

R: I was not intimately associated with that and wouldn't be able to help you much on that. My first answer was right. I was not then...

M: At that point--involved...

R: Involved with regulations.

M: I guess the only point I wanted to try to establish here was that this is again evidence that Kefauver stimulated activity on the FDA's part--that they came out with these regulations.

R: He stimulated activity. There's no question about that.

M: Yeah, yeah, we determined that.... Who--when--when Kefauver introduced his second bill, which was, which became the bill in April of 1961, who, in the FDA, helped to formulate policy? In regard--towards that bill. Or was this really an FDA responsibility? In other words, I know in HEW, Theodore Ellenbogen is the man who has to write, I guess, the departmental report...

R: I was the man responsible for dealing with Ellenbogen and while I would not say that I formulated policy, I was responsible for keeping the Commissioner and Deputy Commissioner thoroughly briefed on what was going on and for determining what their wishes were with respect to policy. The people who made policy on that matter were the Commissioner and the Deputy Commissioner.

M: The Commissioner and the Deputy Commissioner...

R: Yes, and it was a joint operation. I kept both of them fully informed and they conferred frequently before making decisions on the matter. I didn't state that quite right--they conferred always with each other before deciding what the policy was going to be on that matter.

M: All right. What I'm trying to get at--and maybe we've already sort of touched on this--was, was FDA's reaction to Kefauver's bill, which was S1552--(R: what was...?) What was--what was FDA's reaction to the bill--I guess--we've already sort of touched on that--

R: Yes. Now what date are we talking about?

M: Well, it was introduced in April of 1961.

R: We still didn't think Mr. Kefauver was going to get his bill passed. It had too much thrown together. It had the patent provisions, the other anti-monopoly provisions, plus a number of things that we would have liked to see enacted into law. We were beginning to believe that there might be drug legislation passed, but we didn't think it would be Mr. Kefauver's bill.

M: All right. Help me to identify--and I think I know who most of these people are--the team that would be working on FDA's own bill. I know that in HEW this would be, I guess, Cohen at the top, Sonosky, Ellenbogen (is it Ellenbogen [soft "g"] or is it Ellenbogen [hard "g"] ?)

R: Ellenbogen [hard "g"].

M: And then <u>who</u> in the FDA would be--Larrick and Harvey and yourself?

R: Yes. Now there was a--sort of a--jealousy that existed in the General Counsel's office of the Department. Mr. William Goodrich was the Assistant General Counsel for Food and Drug matters and Mr. Ellenbogen was at one time, I believe then, Assistant General Counsel for legislation--or, if not, he reported to that Assistant General Counsel. Mr. Ellenbogen was extremely jealous of his prerogatives on legislation and he didn't want Bill Goodrich horning in on his legislative activities. Bill Goodrich was consulted by us

essentially as a part of the FDA team though technically he was part of the General Counsel's office in the Department.

M: Why did you feel it was necessary to do that?

R: 'Cause Bill Goodrich was a very smart lawyer and he kept us out of a lot of trouble with his advice.

M: So you felt that perhaps he knew more about food and drug legislation than Ellenbogen did--or...?

R: I wouldn't state it that way. Bill Goodrich knew more about what was possible to administer successfully after legislation was passed than Ellenbogen did--because Bill was the guy that had to go into court and fight these cases out. And we wanted this practical experience combined with Ellenbogen's theoretical expertise and we got both.

M: Right. Was anybody interested or sensitive to the economic questions?--that's not very well put--what about the secondary clauses, like generic labeling, the size of the labeling, attempts to straighten out generic naming--this kind of thing?

R: We thought it all a bunch of hog-wash--put in by Kefauver just to salvage something from his original position.

M: The whole generic labeling business you didn't feel was--

R: We didn't feel that that was a key part of the bill.

M: Huh! Why not?

R: Well, before I answer why not, let me say that I now realize that it <u>was</u> a key part. I can only answer for myself--I didn't see how the name applied

to a drug could have so much importance to a doctor's prescribing habits--at that time. I believe now that the names that are adopted for drugs have a--play a key role in prescribing habits.

M: Did most of the group agree with you on this--or was the group kind of divided, perhaps?

R: There was general agreement in FDA.

M: Okay. You were saying that--well go ahead and make your comment about generic prescribing again.

R: For my part I did not see the importance in the 1960's--early 1960's--of generic prescribing and some of the other provisions that Mr. Kefauver wanted to put into the legislation for economic purposes. And I believe that the FDA people concerned with the legislation as a whole didn't attach too much importance to that. My explanation, in part, would be that the Agency, for more than 50 years, had gone on the strong belief that it didn't have anything to do with prices--it was just concerned with the quality, the purity, and truthful labeling of foods and drugs. And it takes some time to change 50 years of tradition and thought pattern. I expect we were going through that transition period right then.

M: And of course, in regard to the patent provisions, this was certainly the case...

R: We considered it foreign to anything that was of interest to us.

M: Right. Did you have any contact with Mr. James Quigley in HEW?

R: Not very much.

M: Because it...

R: I knew him and worked with him upon occasion but not regularly.

M: Evidently, in going over the written record, he seems to be one of the people in the Department who seemed to be at least leaning towards accepting Kefauver's patent provision.

R: That's my understanding. Yes.

M: Your understanding from--where do you get that understanding?

R: Probably from reading the same record that you've been reading. I have no recollection that I heard Mr. Quigley make such a statement or that I saw any of his memorandums that made it.

M: Evidently, in the early September period, before Ribicoff was to appear before Kefauver's committee and make the Department's report, a series of meetings were held. Do you remember these meetings? Around September, 1962, I believe.

R: Meetings with whom?

M: Evidently those meetings with yourself, Goodrich, Cohen, Ellenbogen--I gather once you were discussing--you were probably discussing among yourselves 'what is our attitude and how are we going to brief Secretary Ribicoff.'

R: I do not have any personal recollection at this time of those meetings but it was standard operating procedure when the Secretary was getting ready to go up on the Hill to testify on legislation--or any other matter--the knowledgeable people in the Department got together the facts and laid them out for him and sought his advice as to how he wanted his testimony drafted.

We prepared extensive informational material in the form of back-up books so that the Secretary could study it at leisure. So it was--would have been according to procedure to have such meetings at this time.

M: Some other provisions of the Kefauver bill: (1) would have provided that HEW--and I guess through FDA--would take a lead in the selection of generic names. What was the attitude of the FDA towards--

R: We opposed that.

M: Why? Why was this the case?

R: Again, we did not feel that the generic name of a drug would have much to do with the use of the drug in actual medical practice and we saw no reason why the Agency should be saddled with this extra duty and it obviously would have been a very time-consuming duty.

M: Right. I think it finally ended up in the bill that it was a kind of stand-by authority.

R: That's right. (M: Yeah.) I believe that's the compromise that we suggested (M: right) to get out of the business of establishing the generic names.

M: But as far as you were concerned, you wanted as little to do with it as...

R: We wanted to compromise our way out of that one just as thoroughly as we could.

M: I think that Kefauver also wanted more information to go directly to the doctor about drugs.

R: Yes. I believe he would have had FDA preparing a volume to be mailed to every physician. We opposed that. It was our view that the package insert

could serve quite adequately on that score without--well, we felt that this volume would simply be a compilation of package inserts and didn't see why we should have to go through the business of compiling and mailing all that material once a year.

M: Also Kefauver wanted to require licensing of all producers of prescription drugs. Do you remember any discussion on that?

R: Yes. Opinion was a little bit divided on that within FDA. It was a very appealing provision to some of us, in the abstract, but Mr. Goodrich pointed out that it was unenforceable, that in those occasions where the government--particularly the states--have licensing authority that either grants a man an opportunity to do business or puts him out of business that they just don't exercise that authority to put him out of business. It's too drastic a remedy. And so if it's something you can't use, why put it in the law? He also pointed out that the biologics law--which is a licensing law--had never been used to put a firm out of business-though it could be used, under the law, that way. So in deference to those views, we decided not to support that. Nor to press for it.

M: Yes, and the Department suggested as an alternative that drugs would be deemed adulterated if they had not been prepared under adequate manufacturing conditions.

R: And that was in the law as that was finally passed and that was Mr. Goodrich's suggestion again. He said, 'We can enforce that. That doesn't put him out of business but it puts us in a position to take a bad product off the market and to prosecute him for putting it on.' I think it was a very fortunate compromise that we got on that.

M: Another provision was the efficacy provision. (R: M-unh-huh) What was the FDA's attitude towards the efficacy--

R: We recommended that it be included.

M: Was there any debate over this?

R: Oh, there sure was.

M: Who--uh--

R: The doctors weren't sure a government agency could establish efficacy of drugs. They didn't want to see that provision go in.

M: I mean--within FDA.

R: I'm talking about the FDA doctors--

M: Ohh--

R: We put that one in against the advice of some of our physicians. We did have strong support from a number of physicians outside the agency.

M: That's interesting. Why--the FDA seems to be a little slow in inserting that provision.

R: Nobody had any idea it would pass.

M: You felt it was too extreme--?

R: Too early and not enough support for it and who could have foreseen thalidomide--that's why we got the efficacy provision passed. Although the thalidomide episode didn't have to do with efficacy at all. That, clearly in my mind, is what got the efficacy provision in the law.

M: Got the whole law--

R: Got the whole law passed. Yes.

M: No question about that. What things did the FDA feel that Kefauver was leaving out? In other words, I've just been asking what FDA...why FDA was reacting to Kefauver, but--

R: You're talking about his re-written bill?

M: Yes.

R: I don't recall all the details of Mr. Kefauver's bill at this time. But my recollection is that when his staff re-wrote it, and introduced the--and he introduced the improved bill, that he had picked up, almost as we wished it, the various things that we had recommended for inclusion in the legislation. There may have been one or two left out, but if so, I don't recall what.

M: I know that the earlier FDA bill was really much broader--that is, involved patent drugs; it involved cosmetics--and devices--

R: You reminded me--there is one thing that Mr. Kefauver left out that we asked him to put in and that was non-prescription drugs.

M: Right--

R: He said 'No.' That in his view, if we make this bill too broad, it would harm his chances of success. He said 'I'll introduce another bill that covers non-prescription drugs, if you wish, but I do not want to complicate this one with that added question! (M: Right.) Now that's the only thing I remember that he left out.

M: And as I remember, the FDA--the <u>original</u> FDA bill <u>did</u> include much broader

scope.

R: Yes. It got into non-drug matters as you mentioned and Mr. Kefauver didn't want to go into those either. (M: Right.) Understandably. He had established the basis for action on prescription drugs and I can't fault him for saying 'let's stick to this area where I have a good foundation.'

M: Right. Could we stop on that--

M: As the tape ran out, I was asking Mr. Rankin about the controversy that the new investigational drug regulations stirred up. Do you remember much about that?

R: Oh, yes. The regulations certainly were controversial. The medical profession generally--certainly organized medicine as represented by the AMA--had resisted for years any approach that even remotely suggested a supervision or auditing of the practice of medicine--any phase of it--by people outside the medical profession. And these investigational drug regulations <u>did</u> amount to a statement to doctors as to what they could and could not do. (Although legally they were simply instructions to drug manufacturers as to the conditions under which investigational drugs could be shipped across state lines, still, to a considerable extent they constituted a statement to the medical profession of principles that should be followed by the members of the profession.) (M: Oh. That's interesting.) So there was a great deal of opposition by the drug manufacturers, by the doctors, perhaps by others.

M: To go back to the thalidomide business. FDA asked or recommended that the Justice Department bring charges against Merrell.

R: Yes.

M: This was turned down. Do you have any idea why or--?

R: As I recall, the explanation that we got from the Department of Justice was that a review of the material we had submitted in support of the recommendation did not justify, in the Department's opinion, the bringing of criminal action. I don't know what went on behind the scenes, if anything, to lead to that decision.

M: I also remember in looking at some of the Justice Department's--well, the Justice Department's letter turning you down on this--turning the Agency down on this--that they held that the old regulations regarding investigational drugs was too vague--or too--in other words, a case couldn't be made against it.

R: Yes, I recall that now.

M: And...and...well, I guess we can--

R: The old regulations did not seem too vague to us in view of the commercialization that had taken place. (M: Right.) We were bound, of course, by the decision of the attorneys in the Department of Justice who made the review.

M: Right. On one document I saw someone said 'We're going to appeal this decision.' Do you have any idea what that would mean?

R: Well, an appeal of a decision of that nature would be a renewed request to the Department of Justice addressed to the supervisor of the man who made the original decision. 'Won't you look at this file and see if you can't agree with us instead of your man.'

M: Right. Dr. Young and I had quoted that document--Dr. Young asked me what that meant.

R: It would have been an administrative appeal--

M: Right--rather than some kind of judicial--well it's all sort of--

R: We had no authority--we had no authority to go to the courts.

M: Right, right--so it was just asking for them to reconsider it--this--. Any other comments you'd like to make on the thalidomide episode--anything you can think of? That I haven't asked?

R: Oh, a comment that I have made on a number of occasions before--I'd like to make again. I think that the nation is indebted to Dr. Kelsey for the outstanding job she did in reviewing the thalidomide application, detecting deficiencies and declining to approve it. I think this, contrary to the statements that the drug industry--the views the drug industry has tried to promote ever since--that Dr. Kelsey was just not able to make up her mind and therefore never did get around to approval--I think Dr. Kelsey made up her mind very firmly and did an outstanding job for the American people. She still deserves credit for it.

M: I'm glad I asked that question and that you gave this statement. Let's move on to try to wind this thing up with making some comments on things that happened in the House with the passage of the bill. I think you indicated earlier that again HEW--I guess--Sonosky and other people in HEW were really the main spark plugs here, again.

R: In dealing with the Representatives, yes.

M: Right, right--on the House side--but did you personally have any dealing with what was going on on the House side?

R: Yes. Yes, I did.

M: What--in what regard--what--

R: I recall having been involved in a number of conferences with the staff of the Interstate and Foreign Commerce Committee of the House. I recall having been questioned by some Representatives--not a great number--perhaps three or four--as to the FDA view on the legislation and whether it was in complete agreement with the departmental view that had already been expressed to the Representatives. I was present at some of the discussions between Representatives and the Departmental agents about the bill.

M: Do you remember controversy that centered around transferring complete control of drug advertising from the FTC to the FDA? --Maybe Sonosky's...I'll turn off the tape and let you think...

Break in recording

M: Yes, you were going to comment on the effect of Kefauver in getting this bill passed.

R: Well, when you try to get a piece of complicated legislation--as complicated as the drug amendments of 1962--through the Congress, you anticipate five to ten years of effort. Without Mr. Kefauver's investigative hearings, and his legislative hearings, and his flare for bringing issues of this nature home to the public, in language the public can understand, we would not have got the drug amendments through in 1962. We might have got a less comprehensive, less effective, bill through sometime toward the late 1960's--but I think Mr. Kefauver deserves a lot of credit for the pressure that he put behind the bill. Certainly the technical competence of the bill as submitted--credit for it goes largely to the HEW legislative draftsmen. Mr. Ellenbogen in particular had made a career of drafting complex laws in language that would express the views of the lawmakers and hold up in court and he did his usual professional job this

time and large parts of what we had drafted were picked up without significant change in the law that was finally passed.

M: So you would agree that the FDA/HEW version was a much better-written version than the Kefauver version?

R: Oh yes. Much better, because we had a professional drafting service and the people that were drafting Mr. Kefauver's version, in my view, were not professionals at that particular operation.

M: Right, right. You make some--you already commented that the enactment of the--the performance of the bill after 1962 is a story in itself. Could you comment on some of the areas you feel have been particularly successful or areas that have been particularly troublesome, perhaps.

R: Well, I think the provision requiring a drug to be proved effective for the disease for which it's offered before it may be marketed is a landmark provision. Experience since the law was passed proves that it <u>is</u> possible for government to call upon medical science for the kind of proof that is required. This may be the most outstanding development of this particular law. There was a view among large parts of the medical community before the law was passed that it would not be possible for the government to establish the efficacy of a drug--that that had to be left to the individual physician as he prescribed at the bedside of the patient. The good manufacturing practice provisions have proved to be most worthwhile--

M: Do you think those provisions have helped to end the controversy over whether generic drugs are of a <u>one</u> quality? In other words, I'm sure that was the intention of it--or at least in Kefauver's mind.

R: Well--it has not ended the controversy. The controversy is just coming to

a climax now. The Department of HEW is taking the position this year that generic prescribing of drugs is something to be desired--something to be supported by the Department and hearings are coming up shortly I--within a matter of months--before Senator Edward Kennedy--at which this will be fully aired. I would expect the industry representatives will argue just as strongly as they did in 1962 that prescribing by generic names is not the way to practice good medicine. However, the good manufacturing practice provisions have strengthened the hand of the government in its present position that generic prescribing is proper and is good practice of medicine.

M: I'm sure the drug companies will argue it as they did before Kefauver--that the FDA doesn't have the manpower to see to it that these good manufacturing processes are put into effect. That would be my guess.

R: Possibly. They probably would go on--go further--and say 'and even if they did have the manpower, we don't have the science today to detect all of the niceties in manufacture that contribute to good drugs by our companies and to ineffective drugs put out by others.'

M: What other provisions do you think were good?

R: In addition to the efficacy provisions which have had a very profound impact on drug manufacture and, I believe, on medicine, the new procedures for withdrawing new drug applications have contributed to the ability of the government to get a new drug off the market once the need has become apparent. The stronger requirements for experimental drugs were desirable--as shown by the thalidomide episode. There was a strengthened factory inspection provision with respect to prescription drugs that was much needed and has helped the Food and Drug Administration do a better job of determining what goes on in the manufacturing industry. The advertising provisions, no doubt, have curbed many of the most

flagrant abuses that were occurring in prescription drug advertising. There's a very broad gap, however, that hasn't been covered and I don't know when it will be covered--that's the use of so-called "detail men," really high-powered drug salesmen who go around and lie orally to the doctors about what their drugs will do and what their competitors' drugs will not do. We don't have an answer to that problem yet.

M: This gets into wire-tapping--

R: Yes, it does.

M: Well. Thank you, Mr. Rankin. We'll end this interview after some three or four hours of conversation.

R: I've enjoyed it. It's been a pleasure talking with you.

M: Thank you.

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