WILBUR J. COHEN

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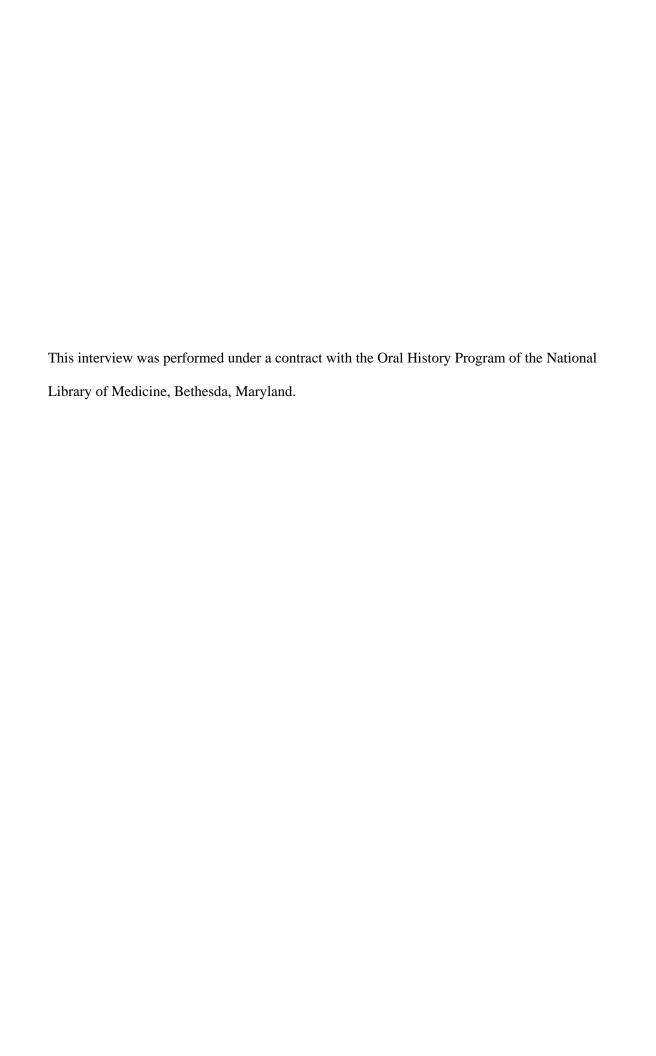


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Introduction

This interview with Wilbur J. Cohen 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.

Wilbur Cohen, the subject of this interview, was in a key position to observe the struggle over the passage of the Kefauver bill. With the election of John Kennedy to the presidency, Cohen was appointed to the position of Assistant Secretary for Legislation of Health, Education and Welfare. As Assistant Secretary for Legislation, Cohen was in charge of

the overall evaluation and management of all legislation affecting the HEW.

Cohen had long training for the job. After receiving his degree in economics in 1934 from the University of Wisconsin, he traveled to Washington to join Franklin Roosevelt's New Deal effort. He spent some twenty years in the Social Security Administration from 1934 to 1955. He returned to the HEW with the Kennedy administration and ultimately became Secretary of HEW in the last years of Lyndon Johnson's administration. At the time of this interview, Cohen was Dean of the School of Education at the University of Michigan at Ann Arbor.

This oral history transcript is derived from approximately a two hour tape-recorded interview held with Dean Cohen at his home in Ann Arbor, Michigan on September 29, 1973. Dean Cohen was a most pleasant and cooperative interviewee. In editing the transcript, Dean Cohen made only minor changes.

Richard E. McFadyen, Ph.D. History Department University of North Carolina at Greensboro This is an interview with Dean Wilbur J. Cohen. My name is Richard E. McFadyen of the History Department at the University of North Carolina at Greensboro. Today is September 29, 1973. We are conducting this interview in Dean Cohen's home in

M: I guess the first thing I want to ask you...had you been following the Kefauver hearings before you came into the Kennedy administration?

C: Yes. I had read several of the Kefauver hearings beginning I think in either late 1959 or 1960. I had written away to the Committee and they had been sending me the hearings and as they came I glanced through them and read things of interest primarily because I was interested in drugs and drug prices in connection with my interest in health insurance. I had not developed my interest so much in connection with patents or licensing or any of the other matters of the Food and Drug Administration which were up to that time not been my particular concern or interest, but I was interested in the general problem of what do you do about covering drugs and how did you price them in relation to having a national health insurance program.

M: Right. Were you impressed by Kefauver's argument? Were you convinced by the kind of argument that was made?

C: Yes, yes. I was not only favorably, then, disposed to his argument, but over the years I had felt that the problem of bringing coverage of prescription drugs into a health insurance system was a very complicated and difficult problem--which I still think it is--and the question of how you price the drugs in relation to brand names and generic is something that was exceedingly difficult and that's what I was interested in finding out. I hadn't

reached any conclusion about what he was doing; I was just interested in following it as a matter of professorial interest.

M: Right. I gather from that then that you do favor the use of generic drugs?

C: Oh, yes. Very much so. And I think...I don't know whether you know...
one of the things that I did in my last year as Secretary was to submit a
report on how we would cover prescription drugs under a health insurance
system with regard to the use of generics.

M: So, in short, you were somewhat sympathetic to Kefauver's...

C: Well, I was sympathetic, let me say, to the problem yet I didn't know where it was going to lead or how to do it and I was mainly interested in following it from the standpoint of amassing technical information about drugs, and about brand names and about generics and about research in the pharmaceutical companies and pricing and so on so I'd be more informed about the problem from the standpoint of my own interest. I didn't actually read the hearings with a view of coming out with a solution to my particular interest or his at that time. It was simply a matter of pulling in a great deal of information which of course they were doing.

M: Right. In fact wouldn't you say that was one of the important things that he did was to amass this information?

C: No question about it. He not only amassed a great deal of information but the comparative data and the analytical material he used was very helpful.

M: You are an economist, aren't you?

C: I was originally trained as an economist. I would say by now I don't know what I am, but my original training was as an economist at the University of Wisconsin.

M: Okay. Can you tell me a little bit about when you came into the Kennedy administration and what your responsibilities were when you came into the administration.

C: Just to go back a little bit... I had not only campaigned for Kennedy, but after he was elected president he made me the chairman of his task force on-called -- health and social security and while that report recommended a number of things, its main recommendation was medicare for senior citizens. And, as you can see from that, medicare for senior citizens had a big relationship in the long run to drug coverage for older people and that's the point of my connection with all this. After I had submitted my report to President-elect Kennedy in January of 1961, he, through Ted Sorensen and Ribicoff, offered me the position of Assistant Secretary of HEW in charge of legislation. And, I accepted that position with a great deal of enthusiasm and I went to Washington, I think, about two days before the inauguration, to meet with Mr. Ribicoff, who was the Secretary-designate of HEW, to deal with the budget. Now, I was one of the few people who had been in HEW before. I had spent some twenty years in the Social Security Administration from 1934 to 1955 and consequently I knew a lot of the people, the procedures, the organization, and so on, and so as one of the first people to come down with Mr. Ribicoff I had a lot to do with setting up a lot of things in the Department and in developing relationships with the career people in the Department. The position of Assistant Secretary for Legislation in the Department is somewhat unique as compared with other government departments. That person has charge of the entire process of managing and the logistics, preparation, clearance, relationships on

all legislation affecting HEW. And the position has been held by several people who have been, like myself, strong on the substance of legislation as well as the process. For instance, Mr. Richardson was an Assistant Secretary for Legislation -- Elliott Richardson, in the late fifties and a large part of Mr. Richardson's expertise which he has now been demonstrating (M & C: chuckle) comes from that experience. I have held that position, and I would say that both Richardson and myself were deeply involved and concerned about both the legislative process as well as substantive legislation. So, it naturally came to be my responsibility for handling the relationships in the Executive Department on the Kefauver bill. That's how I got into it. Now, I had employed, early in my career when I needed some help, a young lawyer named Jerry Sonosky as one of my assistants, and that's how Jerry Sonosky got in it. He was my assistant and he was the man I had assigned to handle that area of legislation. I had two or three different assistants -- one handling education legislation - Phillip Demaree; one handling some other kind of legislation; somebody else responsible for reporting to me. Sonosky was the man who reported to me on handling the Kefauver legislation.

M: So then he reported directly to you.

C: Directly to me. Of course there was so much to do that of course I gave my assistants a great deal of freedom just like Ribicoff and Kennedy and Sorensen gave me a lot of freedom and I didn't manage things in a hierarchical manner so that Sonosky had a lot of contact directly with a lot of people--always reporting to me and letting me know what was happening but I gave him a lot of leeway.

M: All right. Did you report directly to Ribicoff?

C: Yes, I reported directly to Ribicoff and I reported directly to Sorensen and Feldman. We had a very good relationship. That is, Sorensen, Feldman, Ribicoff and myself worked very closely together and many times we cut across lines because we had a good working relationship and we just told the other person what we were doing. My statutory relationship was directly with Ribicoff, but you know the peculiar thing about the governmental process is an Assistant Secretary is appointed by the President not by the Secretary, and although you report to the Secretary, the President nominates you and you're confirmed by the Senate and then while you report to him you are still a presidential appointee -- you're not a secretarial appointee. That is a point that many people overlook in our constitutional and political system-that the undersecretary and the assistant secretary have a dual relationship and this complicates matters many times. If you don't have the right people working together this dual relationship can really get you down because if the person thinks his relationship is with the President who appointed him rather than the man he reports to, sooner or later there's going to be a difficulty.

M: Okay. What was your relationship or your office's relationship to Ellenbogen?

C: In HEW is an office of the General Counsel which is the legal services unit. These legal services handle such matters as actually drafting the legislation and contacting other people to be sure that all legal matters in drafting and in different points of view are represented and that there is a method of reconciling differences and clearing legislation with the budget bureau and handling the matters with other lawyers up on the Hill. On this particular piece of legislation Ted Ellenbogen was the lawyer in the General

Counsel's office who handled the drafting and re-drafting of it and, therefore, Ellenbogen and Sonosky were the two people that had to work together. Sonosky on the policy, the process, the overall clearance with me; Ellenbogen on the legal drafting and interpretation. And this is important because so much of food and drug legislation goes to the courts. As you know, because you are dealing with drug companies, every word in the food and drug law is subject to very careful court review and every word—if you use the term in the law "good manufacturing procedure," inevitably there are 20 court decisions on that—and so you really have to work carefully with somebody who knows the background. And of course we also worked very carefully with Billy Goodrich. Do you have Billy Goodrich in this?

M: Right.

C: Billy Goodrich, now, was the lawyer who handled the interpretation of the food and drug laws and was the legal adviser to FDA in handling the day-to-day operations. That wasn't Ellenbogen's job; Ellenbogen's job was the drafting. So Goodrich, Ellenbogen, Sonosky and I had to work closely together in the Department. We were the four in the Department who worked together.

M: Is Goodrich in a separate department or is he the liaison?

C: He was in the General Counsel's office but in a different unit. Ellenbogen was in the legislative drafting unit and Goodrich was in the operationals unit. They did not report to each other. Both of them reported to Mr. Wilcox. Mr. Wilcox was the General Counsel. And Mr. Wilcox, in effect, was a person who was on my level--in other words, I would deal directly with Wilcox as the superior of Goodrich and Ellenbogen.

 $^{
m M:}$ Yes, that's very clear. All right. I wanted again to find out at what

r int did you become aware or did your office become aware of Kefauver's bill?

den't have any documents here--I really can't tell you that. I've thought about it many times--when did I first become aware of it--and I can't pin-point it in my mind. I'd have to go back and look at the documents and see. I was aware of the Kefauver hearings before--in '59 and '60. As soon as my appointment was announced in Washington, I got a call from the "Pink Sheet" saying "what is your view with regard to the Food and Drug Administration in the Kefauver investigation?" and I made some very general statement--"well, I'm aware of it and I certainly will give it very careful consideration."-- a very innocuous statement. So it's obvious that I knew about it, but when....

M: Well, it's not really important to get the exact date.

C: No.

M: Let me refresh your memory and tell you that the major bill that Kefauver introduced was introduced in April--April 15, 1961--the spring of 1961.

C: '61--that's it.

M: But you certainly wouldn't have--on the 16th you wouldn't have....

C: No. As a matter of fact, that first few months in there I was so deeply involved in the elementary and secondary education bill and the medicare bill that I wouldn't have been paying much attention to it at that time, I can tell you that. That the two major things that occupied my attention—let's say the first six months of 1961, were—because they occupied the President's attention—were the elementary and secondary education bill and in our relations to Adam Clayton Powell and the Rules Committee and then the introduction of the

Fine-Anderson bill and the Medicare bill--so that took me 15, 16, 17 hours a day.

That's really what I'm trying to get at--is that you were interested in other major bills and weren't particularly--

C: Right. I wasn't paying any attention to it then.

M: Right. All right--when Kefauver introduces this bill in April of 1961, the HEW has to begin formulating the official report (C: Right) to go to Congress. Do you have any recollection of who was formulating the report on that--at that point?

C: No. Let me tell you what happens of course. The request for that report, along with hundreds of others, similarly, comes in and is handled by the General Counsel's office and it would then be sent out--by regular procedure--to the interested agencies--and you can get that from the file if you want (M: Right). Certainly one went to the Food and Drug and one might have gone to Biologic Standards and maybe to the Public Health Service and so on (M: Right). Then that would have become Ted Ellenbogen's responsibility. (M: Right--yes sir, it was) and he would have been in on it (M: Right, in fact, he wrote the report). He wrote the report. And he--then--that is, circulated it to a person like myself--I would then have seen any such report--whether at that initial moment Sonosky saw it, you can check from the records--I don't know. But it would have cleared through me before it was sent up.

M: Right. What I'm trying to get at is--somewhere between April and September of 1961--in September, Ribicoff had to appear before Kefauver's committee to present HEW's position on this report. Before he appears before Congress, already a controversy has to begin in HEW on "what stand are we going to take." Did you play any part in this?

well, I probably sat in a meeting. I doubt that I played any significant part at that point. A draft report was probably prepared. We probably had a meeting with Ribicoff in which we discussed it. There probably was some views of the budget bureau that came in.

M: But you can't recall any--

C: I don't recall anything at that time. No.

M: No great controversy--

C: I remember the testimony and so on. At that particular moment--I would any this that might be helpful to you. I don't think that at that early stage, between April and September, we yet realized what was going to happen with this legislation. In other words, it was still too early--while Blair and Kefauver were working on the thing, I don't think that there had been as extensive relationships within the administration--there may have been others--there may have been a lot that I am not aware of--but it certainly was not high on the administration's list. The administration's list was elementary and accondary education and Medicare and federal aid to medical schools and higher education and those things. And we were so preoccupied with that that really the Kefauver bill was just one of a number of interesting things which we were neither greatly for or against. But certainly our energy--our psychic energy and our physical energy--was not directed toward spending a lot of time on those

M: It was elsewhere. Uh--

C: Now, the reason I want to say that is I doubt that Kefauver himself, at that point, had made much about it. You would have to document that by finding out whether Kefauver had talked to Ribicoff at some length to try to impress upon him its importance--whether he had talked to either Sorensen or Feldman before then--there may have been some, but, for instance, Blair might have talked to some of the people, but I doubt that there was that degree of contact to make the people in the administration familiar with the importance of it at that early stage.

M: I know from the written documents that people at the lower levels like Ellenbogen and Quigley (we haven't mentioned him--is it James Quigley?)--

C: James Quigley. Yes.

M: He was concerned, I think.

C: Well, Quigley had been a congressman, see. Quigley had been a congressman and it's entirely possible that somebody had talked to Quigley and tried to impress him with it. But actually, at that given point, Quigley was not the important one to talk to--he wasn't unimportant but he was not the man who was primarily going to make policy in that area.

M: Who would be?

C: It would be myself, Ribicoff in the Department, or John Newman, his assistant, plus Sorensen and Feldman.

M: See--the problem is that at this level, already, Ellenbogen was having to decide whether the Department was going to support Kefauver's bill or not--particularly on the patent provisions (C: yeh) which were very controversial, but--er--were going to be controversial.

C: Yeh and that--well--let me revise my statement. On that point is where

Quigley had some authority because patent policy as a separate area in the Department was under Quigley's jurisdiction.

- M: All right, uh --
- C: That's the reason--not the food and drug part--not that. But simply patent policy throughout the Department including NIH was deemed to be Quigley's responsibility.
- M: From reading the documents I get the feeling that Ellenbogen was in a quandary. His position was, 'this is controversial, we need to study this provision more before we can support it,'--uh--so therefore he wanted to duck it. In other words we wouldn't take a position on it (C: yeh, well). Quigley said, 'shouldn't we perhaps take a position on it' (C: right), but then Ellenbogen came back and said, 'Well, we don't have enough information--'
- C: And here at that particular point--I'd like to reiterate again--the rest of us were so busy with these other things we couldn't spend that much time on it. I know at that particular time--and I say this because I think I became a decisive element in the patent thing at the end--we just didn't have time to deal with that and since the hearings were just starting, it didn't seem to me that we should stop everything and put that up--n--that was problem number 37 at that given moment, you see.
- M: That -- that helps us put it into perspective. That's good.
- C: Yeh. It's not that we thought it was unimportant or that we didn't think of it--we had so much to do when we came in in '61 that things had to be lined up--you had to get a <u>number</u> on your particular proposal--(laugh)--(M: right)--in order to get it in line for what to do because, simply, it was impossible

for the President, for Feldman, for Sorensen, for Ribicoff and myself--who were the main people to handle these things when we had all these issues on race and religion, federal aid to education and Medicare and the AMA right on our backs.

M: Is it safe to say that when Ribicoff testified before Kefauver's Committee in September 1961 that the Department really, for all the reasons you have explained, was not--uh--I don't want to put this in a bad way--you really just weren't that interested in the bill?

C: Well, it wasn't that we were not that interested. We hadn't had that much time and energy to be able to devote ourselves to handling it as a major matter.

M: So you really aren't even aware of too much of the discussion going on about what position the--uh--HEW should take.

C: Well, I remember hearing the talk at lunchtime, you know. We all used to have lunch together, see, and people would say, 'Well, X bill is coming up and Y bill is coming up' and we'd say, 'Yeah, that's coming up and there're looker things coming up, too.'--and, 'Get somebody studying that, will ya.'--you know, sort of that same Ellenbogen thing--'that's a big problem and we'd better get somebody working on that', see.

M: Because when Ribicoff appears before the Kefauver committee he says, 'we support what you're doing, but we don't support your bill.'

C: Yes.

- M: It's kind of a strange presentation because--
- C: Well we do that -- we did that quite frequently. What we would testify on

once we had--we'd say 'we support the <u>objectives</u> of your legislation, but we haven't had enough time to decide whether section 202 is the right way to do it and we'd like to study that (M: right). That was a very typical response in complicated things that were <u>not</u> that high on the President's list.

M: Right. Very understandable.

C: What I'm trying to say, too, to you is I don't think that Kefauver and Blair had at that moment, themselves, really worked within the administration to get it at a high level. My feeling is that while they knew they had a bear by the tail that might prove to be important, they did not know themselves yet how far or how fast to go and so they really had not brought the administration into it other than saying 'here's a piece of legislation that might--'. So I think it was reciprocal in the sense that Kefauver and Blair had worked at lower levels but I don't think they had worked as extensively at higher levels to bring it to their attention for the simple reason that they knew that Kennedy and these people had other things higher on their list. (M: OK--that, that--) It was only until the end of '61 or the beginning of 1962 that they saw that they had a horse named Secretariat that was running down that pike real fast, see. (C & M: chuckle) That's my--that's my explanation of the problem.

- M: Well, this brings me to the next point. Did you know Kefauver at all?
- C: Yes. I had known Kefauver in connection with the '56 campaign and so on.
- M: Well, can you tell me what was the attitude of people in the Kennedy administration towards Kefauver--as best you know? Or do you have a feel for that?
- C: Well--I can tell you my feeling and--but I don't know whether that was shared by other people--but I think so. We tended to--downgrade Kefauver. He seemed to have such a queer combination of attributes that made it difficult to

appraise him in a way. On the one hand he was an extremely intellectual guy and the next minute he had a coonskin cap on, you know, and it was really hard for me, many times, to judge him. His wife, for instance, in a way we got to know his wife almost better than the Senator, she was very much interested in art--and they seemed to be a strange collection of very sophisticated people--very knowledgeable--and very, you know, sort of arty and intelligent and at the same time extremely populistic and down-to-earth and--it was difficult to really appraise what Kefauver was doing--you always had the feeling that you didn't know what he was really up to.

M: Do you have any feel for the personal relationship between Kennedy and Kefauver--are you aware of any animosities or--

C: Well. I am not aware of anything that I heard or saw. I don't think that the Kennedy people thought much of Kefauver. And I don't know where I got that—although, as I will tell you later, Kennedy instructed me to do everything I could to help get the Kefauver bill passed. So I never heard anything on the point that was anti-Kefauver although I thought in my own mind when he told me that, that he was recognizing that Kefauver had a good political bear by the tail and that he wanted to support it.

M: Uhhh--

C: I don't think that they were--I don't think the Kennedy people would have gone out of their way to help Kefauver--

M: That's interesting--why not?

C: Well, I don't know--I think that--I think just the point I was making-he seemed to be difficult to categorize--I don't think they wanted to do anything
to hurt him, but I don't think they thought of him as just a great big fellow-

crony. They figured, 'Kefauver's up to something himself and we'd better watch him pretty carefully or--'

M: Just kind of wary of him then.

C: Yeh, yes.

M: This is the sort of picture I've gotten. They sort of were sitting on the fence almost.

C: Well, I think that's due to the--Kefauver's approach, see. Kefauver's approach was kind of unsettling to people. You didn't know what Estes was really up to. Everybody thought he was still running for president (M: chuckle). Well, if he was running for president, was he going to run 8 years later or 4 years later or what's he up to--and so on.

M: Were you aware at all of what kind of legislation was being developed within the FDA at this time? In other words, once Kefauver introduced his bill, the FDA began to work up its omnibus bill which was introduced.

C: Well, I was aware of it certainly at some time because I utilized the materials. But that's a very typical situation throughout the agency--what we usually tell a group when a piece of legislation comes up--'not only formulate your views on theirs, but what is it that you are in favor of--be affirmative, be constructive.' and quite frequently that's what happens. These two lines go this way--(gestures)--and somewhere along the line they meet. So that would not have been not only unusual but--I might say this--this was always my instruction. During the five years I was Assistant Secretary for Legislation, in meeting the people I would say, 'Look, if a bill comes in, whether you are for it or against it, give your best views but

then develop what you think is what you would like to see. And when we've got that in front of us, we can look at the whole picture.' A very typical way of going about it.

- M: But you weren't personally involved--
- C: No, no.
- M: I'll have to talk to other people about that.
- C: That is correct.
- M: OK. Uh--Kennedy began working on a consumer message which he gave in March of 1962. Now, as I understand it from reading Harris, it was at this time that Kefauver began to approach the higher-ups--say Feldman. I think he approached Feldman and said, 'Since Kennedy is going to be making this consumer address, how about putting in a plug for--'
- C: I think from '61 up until that time Kefauver hadn't paid much attention to the White House or Kennedy. Probably he was just leaving him alone not knowing what he was going to do. I doubt that he knew what he was going to do yet. But at that point it was my understanding that he got in touch with Feldman--I think--first. Maybe, maybe Sorensen originally, but referred to Feldman and said, you know, 'put something in' and that in effect says 'They're for our bill.' Then that began the discussions with our department.
- M: You said it was your understanding--did somebody tell you this--or--that Kefauver had gotten in touch with either Sorensen or Feldman?
- C: I was constantly in discussion with Sorensen and Feldman on the consumer message, see.

M: Right.

C: The consumer message--the general idea was--we were involved in the writing of that (M: right) with them--on some points (M: sending suggestions). Yes--on a point Feldman or somebody says, 'Well, Kefauver says this' or something like that.

M: At that point were people beginning to consider whether to support Kefauver's bill or not or was it still a pretty low priority?

C: Well, I think that we all felt we had to say something in the consumer message about it. The question was what -- how far to go and why. (M: Right.) And in general there was no question about doing something with regard to trying to lower the prices of brand names and getting the use of generics. Those two were not, you know, those were not the controversial things. The real controversial thing in the beginning was the patents (M: right). And how far to go with patents and licensing and profit regulation -- those things together would have been--all the rest of the other stuff took a lot of time and so on but it didn't have the big political implications. And I'll now tell you the story--'cause I don't remember the date, I'll have to look that up--but in one of those sequences President Kennedy said to me when we were talking with him about it, 'Wilbur' he said, 'Why don't you work out something with Kefauver in connection with the patent-licensing-profit regulation.' I said, 'Mr. President, there's nothing I can work out with Kefauver that will get the other votes of the subcommittee -- I can work out anything with Kefauver, probably, but that won't add a single additional vote at the present time to getting the bill out.' He said, 'Oh, you certainly can,' he said, 'Go ahead, change the profit ratio (from whatever it was--8 or 10%) and the patent from 17 years to 8 years and the licensing from 4 years--any of those things--

work out something.' And I said, 'Mr. President, we can work it out with Kefauver but that will not bring a vote from Dirksen or Hruska, it will not bring us support from Eastland. We will still be in the same place where we are.' He said, 'No, you go ahead and do it.' I said, 'Mr. President'-- it was the first time I ever said that and I use this in my classes--I said, 'Mr. President, unless you order me to do it, I am not going to do it.' I said, 'I cannot see at this time that we will advance the vote on the thing unless something else happens by doing it.' So he didn't order me to do it. And that was the crucial point, see, 'cause I think if at that point I'd said, 'Yes, Mr. President, I'll do that' maybe something else would have happened. I don't know, but until we got the matter opened up through Eastland in connection with doing something else, I was convinced we weren't going to get anywhere--that Kefauver was going to pound away and pound away and make an issue of it, but you couldn't get a favorable vote out of the subcommittee.

- M: Why did you make this judgment?
- C: Why? Because that was my responsibility.
- M: Uh--no, I mean on the basis of what information? Was this just purely your assessment of the situation?
- C: That was whatever my assessment was of the situation from whatever lines of contact I had at that particular point. I had talked with Feldman. I'd talked with people on the Hill. I'd gotten whatever advice Sonosky and Ellenbogen had told me about. I'd talked with Larrick, I'd talked with Goodrich—and by that time I had talked with a <u>lot</u> of <u>people</u>, and I'd—had come to my own assessment. I did my work with the President by always telling him what I thought and as I said, 'If you order me to do it, I'll do it, but

- if you don't order me to do it, my judgment is not to do it.'
- M: Right. But you can't remember exactly at what point this took place?
- C: It must have taken place--it must have taken place somewhere between March of the consumer issue because the consumer--consumer (M: message) message was out. And--what date was the Kefauver bill passed?
- M: About August of '62.
- C: Well, I'd say it was halfway between (chuckle) those two dates.
- M: But it was after the consumer -- uh -- message?
- C: Oh yes -- this had nothing to do with the consumer message.
- M: Right. Well--could we go back to the consumer message just a minute. Uh--Kefauver wanted S.1552 mentioned in the end of the message (C: right) by number (C: right). Uh--but it was not.
- C: Well, that was largely Feldman's responsibility because we normally didn't do that for any (M: uh-huh) anything. Even if you look at Medicare--now we did not refer to a bill by number--why?--because we knew damn well that while you could be for an idea, who the hell was in favor of a particular number? Only Kefauver! We didn't care if it passed under 1552 or 1987 or something else, but Kefauver wanted--you see, Kefauver wanted to get Kennedy locked in to the smallest detail--the big issue and the small detail. But our attitude always is--'Look, we want the end result--we don't give a damn'--just take like Medicare--when Medicare finally passed, it wasn't the King-Anderson bill, it was the Mills bill! (M: right) We didn't care at the end whether it was the King-Anderson bill. Nobody out in the country knew which number or what it was.

We wanted the end result--Medicare. Well, that was the same view that we took on that matter. And not only on Kefauver, but on everything.

M: Right.

Eastland bill or it wasn't going to be an Eastland-Kefauver bill? Nor did

Kefauver know that. If you go back in legislative history, and you'll find

--like--Landrum-Griffin bill; the Wagner-Peyser bills--there's all sorts

of combinations. So, we just didn't--we just didn't like that kind of trying

to tie us down to the specifics and not to the general idea.

M: And it was not due to any animosity towards Kefauver that the bill wasn't included--

C: That was too simplistic a notion--as to how things worked. And that again is one of the things about Kefauver and Blair--they always--they were looking through small glasses, always, at their responsibility. Whereas we were looking at that in relation to if we had put 1552 in, every congressman and senator who had a bill would want us to put the number of their bill in and we knew we'd be inundated.

M: All right. I have--I have a memo from you to Feldman, I believe, in which you comment to Feldman that on the--in the consumer address Feldman <u>had</u> mentioned some other bills, and you say--uh--you say 'We haven't mentioned 1552 for understandable reasons. We should either mention it or leave out all the numbers.' (C: Yeh.) And so all the numbers were left out--left out, weren't they?

C: Well that would have been my view whether it was the Kefauver bill or anything

else. I wouldn't have suggested that we use a number for the education bill or the Medicare bill for the generalized reasons that I have mentioned. At the end, if somebody came up and gave you everything you want with a different number, who cares! (M: Who cares.) (chuckle) But Kefauver cared--Kefauver cared because Kefauver wanted it to be called the Kefauver bill and it had to be his bill and his way of doing it, see. I don't want to say [he] wasn't concerned about the end result--but he and John Blair got very proprietary (M: right).

M: Uh--all right. The consumer message is in March of '62. In the subcommittee most of the patent provisions were lopped off and then the bill, minus the patent provisions, was sent back to the larger committee. On April the 11th, '62, Kennedy sent a letter to the committee saying, 'Let's pass the thing.' Were you--did you take part in writing that letter?

C: Yes, yes. I think that was one of those joint-big joint efforts--Ellen-bogen, Sonosky and myself and Feldman.

M: Right. And obviously, already at that point, the decision had been made to--to--well--that the patent provisions could not be passed so we just--

C: Well, it may well be that my meeting with Kennedy was--you know--right before that. Or right after that (M: uh-huh). It's more likely to be--it's likely to have been after that, because he may have sent that letter--and I don't know what the next thing--but then when he talked with me--I think it was after that because he was getting pressured to do something and people were saying to him probably, 'Well, you could get it through if you could work out something on the patents.' And that's when he called me in and said to me 'Why don't you go ahead and work something out.' And that's when I said, 'I

don't think it'll make a damn bit of difference.' I wasn't talking about what I believed -- as far as I was concerned, I would have been glad to have a patent provision in terms of my personal position. But the point where the President's asking you what to do you have to say, 'Look, you won't have the votes.' The President was also saying to me too about the federal aid to education bill, 'Why don't you go and get one more Republican vote in the Rules Committee.' and I said, 'Mr. President, why don't you get one more Catholic vote for the bill and we'd win!', see. And you'd have to say to the President at a certain point, 'We don't have the votes!' Be deadly realistic. You know, when you get at that level, it's not any longer a seminar. You either got the votes or you don't have the votes -- or you think you've got the votes or you think you don't have them. You gotta be deadly realistic or people will say, 'Well, that guy has just leaped way up in the clouds somewhere. (M: Right.) So when I talked to the President I always told him exactly what I thought -- how many votes we had--how many soldiers we had to carry it through. If I didn't think we had it, I didn't tell him to go ahead and do it.

- M: How interested do you think Kennedy really was in all this?
- C: Well, I think he was quite interested. Being a former Senator, he felt that--he kinda acted a little bit like he was still a Senator--you know--'Well, can't you see if you can do this and do that--then maybe this guy'd vote for that--if you do it.' --'n sometimes that happens.
- M: But--how interested was he in the Kefauver bill?
- C: Well, I think he was interested. He wanted it to pass. And it was in his consumer message. He wanted it to pass, but he didn't necessarily think every word that Kefauver had written was inscribed in stone. (M: yeh) Get the general

idea passed. (M: Right.) I think that was his idea.

M: Okay. Kennedy sends his letter to the committee urging that the bill be sent out. Then in May, FDA introduced <u>its</u> own bill into the House. So now we have Kefauver's bill in the Senate and we have the FDA's bill in the House--and there's really--

C: Who introduced it in the House?

M: Uhh--Oren Harris. It went through the proper channels in the Commerce Committee. Uhh--so now we've got the Kefauver bill in the Senate and the FDA's bill in the House. And they really are fairly different kinds of bills, and the problem is to get them together--from Kefauver's point of view it was to get his bill (C: right) passed. Now in June of 1962, the so-called "secret meeting" takes place. Are you aware of the (C: oh, yes) "secret meeting"? (chuckle) What can you tell me about the "secret meeting" or do you even like that terminology?

C: Well--

M: It's Kefauver's terminology.

C: You know--it was both a secret meeting and it wasn't a secret meeting so it depends on how you look at it. You and I are having a secret meeting right now. (M: right.) We haven't gone outside and said 'Anybody who wants to come in is now free to come in.' And we haven't called up John Blair and said 'John, do you want to come over (chuckle) and meet with us now?' or the head of the Food and Drug Administration or all sorts of people. Well, you have to go back to the point where, as I said, Feldman and I went to see Eastland and Katzenbach was in on that meeting and I was directed by this arrangement through the White

House, to go into the meeting with all these people and my instructions were, from Eastland as well as the White House, that <u>any</u>thing that I could obtain agreement upon with these people in there would be acceptable.

M: Could we place this in time? Was this the "secret meeting?"

C: No.

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M: This was before?

C: No, this was another secret meeting, though (M & C: laughter). Coming-this meeting--during this period of the impasse, in which nothing was happening, these letters and everything were going back--Feldman and I were trying to figure out some way to move to second base, and so Feldman and the President and Eastland and Katzenbach must have had some discussions which I was not in I was advised, though, by Feldman, to come with him to the meeting with Eastland that was going to unlock the situation -- which I felt was the situation --Eastland was the chairman of the committee and a powerful member of the conservative bloc and we knew that very little could be gotten out of the full committee -- even if the subcommittee recorded everything that we wanted, it still had to pass the full committee. We didn't have the votes in the full committee. And especially if you have the animosity of the chairman -- all the chairman had to do is just not call it up even (M: right). So, how to unlock the thing! And out of this came the idea -- we gotta work something out with Eastland that would be acceptable to Dirksen and Hruska to do it. What was that? I didn't know what it was. But, I'm called and told to come with Feldman to the meeting -- which I did. And I'm told, 'Go into that room next door and anything you agree on, Wilbur Cohen, with those men in there, will be acceptable to me.'

M: All right. Now. Where--where was this meeting held?

C: This meeting was held next to the office of the Chairman of the Judiciary Committee.

M: So it was in Eastland's office?

C: Eastland's office -- next door.

M: But you don't recall exactly when this meeting was held?

C: Well, I don't recall right now. It obviously--what is the date of the so-called "secret meeting?"

M: It was June 8th, '62.

C: I would say this is probably the end of May--around the end of May--a week or two ahead of time.

M: Uh-huh.

C: I start meeting with these people in this secret meeting--

M: Okay, who--who was there that you recall?

C: Well, there were people who represented Dirksen and Hruska and if I recall, that was Chumbris who--wasn't he the minority (M: Minority Counsel)--yeh. And there was Lloyd Cutler who represented the pharmaceutical interests and a number of other people, none of whom made any difference. The two--what I'm saying is--the two key guys were Cutler and Chumbris and in the end, it was what Cutler, Chumbris and I agreed upon that was the key point.

M: Did this <u>bother</u> you--that, in effect, the pharmaceutical interests were taking half of this conversation?

C: Well, let me say--bother--no, it didn't bother me for this reason. You know darn well--in the legislation in the Congress--if you're going to deal with railroad retirement legislation in comes the railroad brotherhoods and the railroad companies (M: right) and if you're going to deal with Medicare, you're gonna deal with the AMA and when you deal with elementary and secondary education, you deal with the NEA and those groups and--life on Capitol Hill is made up of trying to reconcile the differences between vested interests.

M: Right.

And while I must say I didn't enjoy it very much, I knew it was inevitable. I was a realist enough to know, as I had said to the President, we don't have the votes. What's the way you get the votes? You gotta get Hruska and Dirksen who are beholden to the pharmaceutical interests to come out--much better to have the pharmaceutical interests right in there with you--if you just were dealing with Hruska and Dirksen, all they would do is negotiate with you and then say, 'Come back tomorrow.' while they talked with them. So it was much better to talk directly with Cutler than it is to talk with somebody else. Many times this happens on Capitol Hill where you deal with somebody on the Capitol, but they're not really the ones who are making the decision -- somebody back in their office is talking with them. So it's much better, because Cutler is a brilliant man and I think Cutler is a socially responsible man. That is, he tries to represent or balance the interests of his clients with a socially responsible position which other people may disagree with, or I do, but you can talk it out with him. He's very frank and very aboveboard. He'll absolutely tell you what he can do and what he (chuckle) can't do. There's no chicanery in Cutler.

M: Right.

C: And therefore, I thought that was good. It cut through a lot of red tape.

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M: I think I know the answer to this, but I have to ask it anyway. Why were no Kefauver people involved in this discussion?

Because most people felt that John Blair was such a unreconciled advocate of his position that he wouldn't agree to anything. That what you had to do is come to an agreement with these other people -- you knew John Blair's position, you knew Kefauver's position, you knew what they want, and why should they compromise? (M: right) What you had to do was get some other compromise and then say to them, 'This is the best we can get through.' And that's my point about the secret -- the, the, these "secret meetings" -- that 's -- that 's used in the pejorative sense. You have to find a resolution to these differences and at a certain point you gotta get one side--everybody knew what Kefauver was for--everybody knew what Blair was for. And their position was-- This is what we're for.' Now, until you had a position of the other people which would say 'We will support this bill if you will do (C: smacks fist!) so and There wasn't a good bona fide offer to make to Kefauver and Blair and ourselves. And the key point was, what position were we gonna take? As the intermediate -- what position was the Kennedy administration -- because, you see, what people are failing to understand -- the resolution of the issue wasn't completely with Kefauver; you still had the Senate -- the full Senate subcommittee and the Senate committee -- and then you had Oren Harris over in the House. Right.) My job for Kennedy was not only to remember -- like a guy running a twomile race, that I can run the first 100 yards, but how am I gonna get to a point in agreeing to a position that I can also sustain when I get over to Oren Harris in the House Interstate and Foreign Commerce Committee? Kefauver didn't care about that, (M: Right.) He and Blair weren't worried about what we had to do

when we were negotiating with Oren Harris. All he wanted was the (C: smacks fist) Kefauver bill reported out of the Senate committee. That's as far as he -- he was willing from then on to see what happened. I'm thinking about the Kennedy position in the large--so, we have these series of meetings, which-anybody's entitled to negotiate (M: right) -- and then, there had to be some of these changes that were made--to be made--and I said to Sonosky, instead of my going -- I'd attended these other secret meetings, and, the matter began to get more time consuming and there were some other amendments, and I said to Sonosky, 'You go up there and meet with so and so to arrange these things.' And that is what Kefauver heard. Now, Kefauver picks up the phone -- I don't know who -- in what sequence he called people -- whether he called me first, Sonosky first, or Feldman, or so on--you ought to ascertain that--but in any case, when he called me, he says something about a secret meeting. My answer is, "secret meeting?" --What're you talking about?' It didn't dawn on me that he was talking about Sonosky going up--there are hundreds of secret meetings every day--when somebody goes and sees somebody else or three or other people--is that a secret meeting?

M: But surely you must have known--you must have known that Kefauver was gonna be angry at what was going on.

C: It didn't cross my mind at the time because Kefauver didn't have the votes.

M: Right.

C: We're trying to help Kefauver get the votes to pass the bill. Kefauver and Blair had the idea that whatever Kefauver and Blair had agreed upon, everybody else was gonna vote for. Well, that was living in a dream world.

M: Right.

C: So, we're trying to get the other people to come along to a position that they can support something in the Kefauver [bill] and their attitude was 'We weren't in on the meeting.' Well, hell, they weren't in on the meetings in the White House! They weren't in on the meetings in HEW! They weren't in on the meetings over on the House side! They weren't in on the meetings of the--of all the meetings of the subcommittee staff! They weren't in on the meetings of the--if they were in all the meetings we'd never have a Kefauver bill.

M: Right.

C: So. If you want to call it a secret meeting, that's fine with me, but all I say is there're thousands of secret meetings on the Hill like that every day, every hour (M: chuckle) which is the only way legislation could pass. I was in hundreds of secret meetings on Medicare. And not once did a man like King or Anderson--or any of the people complain that we were in secret meetings. They're idea probably was: 'Fine! Have all the secret meetings you want if it helps us get the bill through!'

M: So you think--you think--

C: Kefauver was the only one--

M: You think Kefauver was unjustified in being angry at what was going on.

C: Well I think he was unjustified in calling them secret. Meaning, in a sense, that—that something was happening which was detrimental to his interests because—detrimental in the sense that maybe some subsection of his or some idea of his wouldn't go through, but the whole idea of the meeting was to help him get his bill through!

M: OK. Uh--uh--a subcommittee meeting was held and then at this subcommittee

meeting, Sonosky was there and there were some 12 amendments that Eastland began to--that Eastland, perhaps Dirksen, began to propose. And it's at this point that Kefauver learned that these changes were going on. This is when he called you, I believe, and perhaps others, and said, 'What's going on?' And he was trying to find out did HEW support these 12 amendments.

- C: Yeh. Well, if he'd said that to me, I would have said 'Yes.'
- M: That HEW did support these 12 amendments.
- C: Yeh. Those were the ones that we worked out.
- M: So HEW did support--
- C: Oh, I don't remember the 12 right now but we were supporting amendments to get these people to approve the bill. Here I think that there was a--here I think is where--what happened--where somebody made a mistake--and it was probably Eastland. Wasn't it Eastland who was offering the amendments?
- M: I believe it was Dirksen (C: Dirksen was in--) was offering them in the subcommittee. [Dirksen did offer the amendments ed.]
- C: You see, something there must have happened in the subcommittee where

 Dirksen said--I don't know what he <u>did</u> say--he said, 'Well, hell, Estes,'-
 I could conceive of him saying that--'what are you getting so excited about?

 I've got HEW backing these amendments,' and, you know, and that's when--'Where'd you get 'em?' 'Well, we had a meeting with HEW.' 'Well, where?' and, you know, 'Well, we had this meeting with Sonosky and this is where we got 'em from.' and he hadn't heard about 'em. Now what Dirksen should have <u>done</u>--I don't remember it, but most of the time--what normally a guy does in a case like this is goes up to Estes before the meeting and says, 'Estes, I got the thing stacked

against ya.' (M & C: chuckle) 'I got the votes and I checked it out with HEW and they'll go along, see.' Something like that. But that obviously didn't happen, see, and so Kefauver--

M: From reading Harris, what happened was that—or at least the view he gives is that Kefauver asked Sonosky if HEW supported these amendments. Sonosky said 'I'm here just as a technical adviser,' leading Kefauver to believe that HEW did participate. And then he called you to find out.

C: Uhh, what'd I say?

(At this point the interviewer stopped the recorder and read Cohen's answer to Kefauver's inquiry as found in Richard Harris' The Real Voice, p. 168.

Kefauver said later. "Then I phoned Cohen, and he said that he'd been asked to send someone to the meeting but that he knew nothing about the amendments.

Back in the conference room, Kefauver asked Sonosky if he spoke for Cohen. Sonosky answered that he had shown the amendments to Cohen but not in their final form. "How can that be true?" Kefauver demanded. "I just talked to Cohen, and he said he knew nothing about the amendments."

The recorder was then turned back on. Ed.)

M: Okay--go ahead.

C: Whatever those amendments were, I presumed they had been worked out, in that--with the agreement of that larger group that we have talked about and I have assumed that somebody--like Eastland or somebody--was gonna offer 'em. I think the big mistake was to allow Dirksen to offer them, see. Some other more neutral person should have offered them.

M: Uh-huh. So--

C: Somebody should have offered them who said, 'I'm willing to go along with this bill. But in order to go along and get enough votes, here are my amendments.' Then I could have said, 'Yeh, I did consult with the HEW people on them and I don't have any view as to whether they're for or against it but this would carry out what I wanted to do.' And then Sonosky would say, 'Yes, I helped him do what he wanted to do.' You see, in Congress many times--quite frequently--this business--here's part of the difficulty, too--this technical advice--many times on a committee, I've been on a committee where I helped them draft both amendments that I was for and against. In other words, you gotta get the bill off the dime. I don't remember all the details, but the difficulty grew out of the fact that Kefauver and Blair were not in a mood to compromise at that point.

M: All right.

C: See? So that the difficulty was that you couldn't go to them to compromise it and in working with the other people who instructed you there was a lack of communication.

M: All right. Now we--so--as I understand it, you're telling me that these 12 amendments were supported by HEW.

C: I don't know. Well, I don't remember the 12 amendments right now, but whatever they were--

M: There were--were 12.

C: I don't know whether we supported 8 of them or 12 of them or -- I can't remember what they are--but whatever the amendments are that we'd been working with the group, grew out of the meetings that I had (M: right) with

these people in which, in a sense, <u>Eastland</u> had said to me, 'If you, Wilbur, agree with them and they do, I will support it and <u>that</u> will get the bill out of the <u>committee</u>.' That's all!

M: So Eastland didn't particularly care, just so you and the drug people worked something out.

That's right. In other words, Eastland's attitude was--he didn't give one damn about that bill at all. It didn't interest him. But in the interests of helping the administration get something that would carry out the consumer act, he was willing to help the administration get the bill out provided that the amendments were not violently in opposition to what the drug industry wanted. And his attitude was, 'I don't care what the drug industry is for or against 'cause they don't mean a thing to me, but if you're gonna get a bill out on the floor, I want it to be something that they won't organize opposition to because then you'll have Dirksen and Hruska against it and you can't get the bill through. Therefore, find some area of agreement -- don't find what you disagree on; you can't get a bill through that you disagree on--get a bill through that you agree on. Find some area of agreement.' So I went to work and met with Larrick and the other people and I worked out these whatever X amendments -- I don't remember if there were 12. And Eastland in effect said that with those he'd support the bill. Well, I assumed as chairman of the committee he would do something and probably say 'I will support the bill if you will adopt these amendments.'

M: Right.

C: He obviously didn't do it that way. He gave it to Dirksen and--but Dirksen, by offering them that way, incurred Kefauver's enmity because he thought that we had conspired against him with Dirksen--whom he viewed as a

mortal enemy on this. Whether he knew that we had worked these out with Eastland or not, or whether if we told him these were <u>Eastland</u> amendments, it would have made any difference--I don't know. I don't think it ever got to that point.

M: All right. Now we run into some difficulties because in June--sometime between June 19th and 22nd, Ribicoff appeared--uh--well perhaps I'd better back up just a second. Kefauver makes these calls to you--

C: One call. One call.

M: One call. One call to you. He reads the amendments, then he appears on the floor of the Senate and denounces the "secret meeting." During that speech on the floor, Eastland—now Eastland gets into the picture—Eastland says 'High officials in the department of HEW support the amendments.' and then Kefauver goes through the bit that he has called you and you said you knew nothing about it, but then Eastland said, 'Well, I've just spoke to high officials in HEW.' and he wouldn't name the individual, but he said HEW does support it. Was he referring to you? That is, Eastland?

C: Eastland? No.

M: I don't know that that's really important.

C: Yeah. I don't know whether he called me or he called Ribicoff. But the point is, the point is, that telephone call--first--here's what you gotta remember psychologically--as shocking as the "secret meeting" was to him--

M: To Kefauver.

C: To Kefauver. It was a big surprise to me when he calls me and says 'What

about this secret meeting?' Well, in the first place, my mind doesn't work that (M: uh-huh) quickly to think of whatever all these things were--"secret meetings"--(M: right) they were--were--just a series of (M: but surely--)--in effect, I say 'No.' Then when he says 'Do you favor these amendments?', I don't remember what I said but I don't even know what the amendments are that he's talking about--much less over the telephone. (M: all right) And, I'm assuming all along that whatever the amendments are that Eastland is supporting them. (M: All right.) So, all I can say to you about the telephone call-there's no meeting of minds (M: right) see. In other words, it's the old story like that when you're on the witness stand--if you ask a certain question, you're going to get a certain answer, but if you ask a different question, you get a different answer. Kefauver says two things -- 'Did you authorize or do you know about the secret meeting?' and I say, 'No.' Therefore, he concludes from that that it's secret without our participation and therefore we have nothing to do with it. Then the amendments, which I don't know whether you-either I didn't react guickly enough or he didn't know what he was talking about -- he was very excited, by the way -- so whatever I said in answer to his two questions gave him a different kind of reaction than what was really the true state of facts. If he'd asked a different kind of question--

M: But surely you could have anticipated he would be quite angry at these amendments.

C: But I thought that that's what Eastland would handle with him--after all,
I wasn't chairman of the Judiciary Committee. You go to another committee-I've dealt with Oren Harris and Wilbur Mills--when we worked out something
with them, they went before the full committee and they said, 'Gentlemen, you
don't have the votes. I got the votes. Here, you adopt these--I'll report the

bill out.' Very typical. The department doesn't show up; nobody shows up. That's a very typical kind of response. And I don't know what the situation was, but I just thought anybody up there was a little more adept and adroit in the matter and I'm sure that was in the back of my mind. (M: Right.) And at the end, then we would have said, 'Well, we go along with it.'

M: OK. Now the problem comes--uh--that things are up in the air. Uh--uh-Kefauver's not sure if--what--what the administration's position is. In other
words, does HEW support this or not. Now, in June--19th through 22nd--I've
forgotten the exact date--Ribicoff appears before Congress and says (C: Senate
committee? I think he testified before the Senate--or did we go to the House?)
I think it was the House [Ribicoff appeared before Harris' committee in the
House - ed.] (C: Yeah.) I can check that but it's not really (C: yeah) that
important (C: all right). Ribicoff said, 'We do not support the so-called
Dirksen-Eastland amendments,' which were these amendments presented. (C: Did
he? - chuckle) Yes! (chuckle) Ribicoff declared, 'We do not support these 12
amendments.'

C: Well. But I believe what happened was in the intervening time, Kefauver put a lot of pressure on somebody--I don't know who--for us to change our position. But I imagine that's what happened.

M: You're not aware of what went on to--

C: Gee, I would--I'd have to scrounge up in my mind to recall it, but that--I mean, we'd done that before and subsequently. Where some guy puts the pressure on you--says, 'Don't--even if that's what you think--don't say it now; give me more chance to bargain.' That's just like in the collective bargaining situation where all of a sudden you come practically to agreement

and somebody says, 'Don't say you're for it because--make 'em push you to do it.'--or something. So it's entirely--

M: Is it possible that these amendments were (C: changed, or something?) changed --could it be that the drug company had gotten more--

C: I don't remember now. I'd have to go back and resuscitate the whole thing (chuckle) in my mind.

M: Right.

C: There is no question in my mind that at that given point--I think he was testifying over in the House--

M: I think he was, too. I can check that.

C: And the House being more conservative and so on, probably the idea was to say 'Well, we were not supporting them at that moment.' to see what was going to happen--I don't know.

M: That you were not supporting--what--now Ribicoff says 'We're not supporting the Dirksen amendment (C: the Eastland--) the 12 amendments (C: yeh) that Kefauver opposed--

C: Probably we wanted to see what was gonna happen, I don't know. By that time, too, by that time, too, Kennedy was real mad at Blair because Blair was doing everything he could all during that period of time to leak out information. He leaked to Drew Pearson and a lot of this stuff. It was making the whole situation more complicated.

M: OK. Maybe you can tell something about the Kennedy relationship with Blair

and the story you were telling me earlier about it.

Well. In connection with the writing of the consumer message, that came out in March, 1962 (M: right) Kefauver had talked with, I think, Feldman and then Blair had followed up with some material that he was giving Feldman and he came over to see Feldman. And negotiations were still in progress, when the next day or so some of that information found its way into Drew Pearson. Kennedy concluded that the only way that information could have gotten into Drew Pearson was for John Blair to give it out. And he called me to his office --I think because probably he couldn't get Feldman--I don't think Feldman was with me--and directed me to tell Feldman and myself to see that Blair never got back into the White House because of, you know, trying to put pressure on the President through leaking information. So that I think the President and Feldman are both aware of the fact that in dealing with Blair, they were dealing with a man who was very skillful in using a lot of other sources to put pressure on the administration. And I don't think they liked that particularly, and so their animosity toward Blair was very extensive. I think they had a lot of respect for his ability -- for his technical, economic ability, but they just didn't like the way he was handling their relationship with him. But why, or how, Ribicoff made that statement, I can't now recall how that all originated -- except it was a very complicated set of -- situation.

M: Do you know who--who would have been involved in making that decision?

C: Well, probably Feldman, myself--

M: You just can't recall the circumstances?

C: No.

M: All right. Now, this is the summer of 1962. Things are still kind of up

in the air. Now, Ribicoff has said, 'We don't support the so-called Eastland-Dirksen amendments. Things are up in the air. Everybody is saying the bill is going to die; Congress is running out. Then, boom! The thalidomide business hits! (C: umh) I'm sure you remember (C: like that!). Did you have any personal dealings with any of the thalidomide business? (C: No-o-o-not--) Probably you wouldn't.

C: No. Not other than Larrick coming and telling me about it, you know.

M: The FDA was certainly scurrying around--but that's not your area.

C: No.

M: All right. But it is thalidomide that finally pushes things off dead center and it seems to get the Kennedy administration finally going again because in August, Kennedy now says, 'We've got to get a bill through.' and he sends an additional seven amendments to the Senate on August the first.

Do you remember anything about--

C: Well, I remember we worked on those, but we had the--Ellenbogen, Sonosky, myself and Feldman worked on those.

M: All right.

C: I forget what the seven were, but--they were part--we had worked on them previously. You know, they were in this--all this packaging previously and we worked on them and they were the remainder of them--I remember very personally, I didn't think they were very important, if you asked me--but it was a method-ology to say 'If you'll accept these, why--. (M: Right.) You had to have something. You had to have some olive branch to hold out to make everybody be able--all sides to say, 'Well, it's OK!' The pharmaceutical people recognized

you had to say something to change it, we did, and FDA and Kefauver. Seven, or I don't know how many. But the one that was on good manufacturing procedure-that was the one that I worked on very hard--and I thought that was a very constructive amendment.

M: Right. I think generally what the seven did was to sort of tighten up--the 12 had really sort of gutted the bill and then the seven helped to tighten it up in some areas (C: right). You were telling me earlier why you think the bill finally passed--the package deal with Eastland.

C: Well. I think that while you can say the thalidomide disaster was the culminating point in getting it passed, the question still was, what kind of a bill was going to get passed. I mean, you could have gotten a bill passed saying 'We're against thalidomide.' or something like that. So the question was what was the particular bill, and I think all those previous negotiations still proved to be important, valuable and essential in arriving at a point so that the -- for instance, I had spent days on this point of good manufacturing. technique -- which incidentally, did you happen to see, was just upheld by the courts this year? Ten years later (M: no, I didn't). Ten years later. It was an interesting court decision--I haven't read it, but I saw it in the paper. Which is an indication of how long it takes. Well, as I got into the legislation--particularly as a result of Mr. Larrick coming to see me--what happened during this period of time--an interesting thing--is FDA was largely out of this whole thing--this was an interesting point. FDA had a lot of contacts and I don't say they wanted to but the whole thing about this was really handled at this political level by a lot of us who knew not a damn thing about food and drug. I mean, I'm no expert on food and drug--Sonosky wasn't--now Ellenbogen was, but Ellenbogen we didn't allow to get into more than one or two key meetings so that he could just --

M: Why--why was that?

C: Well, Ellenbogen is very verbose. When you ask Ted if 2 times 2 is 4, you get a lecture on the beginnings of geometry, algebra, calculus, and so on. So that if you only want a simple answer, Ted'll go on for 3/4 of an hour. He's a very exact--have you met him? (M: Yes.) He's a very exact--a very close friend of mine. He's a wonderful fellow. But he is a lawyer's lawyer. When you put him on the witness stand or anything, he will discuss everything he knows from the year one, and you're exhausted, bored (M: laughter) and worn out by that time--but you got a lot of information! But most of the decisions on all this were made by a group of people like Feldman, Ribicoff, myself, Sonosky, and whoever else were in--who were not food and drug experts. But in the course of it--the education I got--the one thing I came out with that -- a long-run constructive result would be this good manufacturing procedure. I gotta tell you something else I did. What I did, after I got into this, I went back and I read the whole history of the 1938 Act. Now, I came to the conclusion when in 1938, Tugwell, who had been responsible for the '38 Act lost most of the show--and he says so himself in his memoirs--and so on--that he'd just not been able to get what he wanted because the right combination of circumstances -- the way Senator Copeland got into the thing and so on -- the exact period of time and so on--didn't work out. And I said 'Look, what would have been important in 1938 to enact, which by now would have made a real contribution, in this area?' and the one thing I came out with after long discussions with Larrick and so on, is this idea of good manufacturing procedure-or process it was called -- that that would be a real fundamental -- sure, you want to keep "Slim"--I don't want to make you--don't want to get Geritol off the market (chuckle) -- you -- there's a lot of -- you want quacks off -- you want -- don't want chiropractors practicing -- treating you for cancer -- but what is something

that if you enacted it would have a tremendous effect in changing the relationship between the government and the manufacturers that might have broader effect—next time it isn't gonna be thalidomide, it's going to be something else. And I came to the conclusion that this was good manufacturing process—so I worked on that. I figured—what would make a difference over 10, 20 or 30 years? I may have been wrong 'cause I didn't know enough about it, but that's where I came to the conclusion of it.

M: So you felt the most important thing was the good manufacturing --

In addition to whatever else we got, but I began to look at this as a C: method, then, of how do you get some basic legislation affecting food and drugs because -- Larrick had also said to me -- when I got talking with Larrick -he was a very interesting man--people under-appreciated him because they thought he was a bureaucrat and so on, which he was. But I sat for many hours over lunch with Larrick and I said, you know, 'Give me a little history -- ' and we took what happened in 1906--the basic act--Wiley and then the next big thing didn't come 'til 1938--then we went through all the little things--I shouldn't say "little" but the amendments and so we could see that 1962 was the next thing and maybe nothing was going to happen--as is pretty much the case--for another 10 or 20 years--until you have something like this. So what could you get that was of some permanent value? If you weren't going to get patenting and licensing and that, what could you really get at? It happened to be the one thing that the pharmaceutical industry was not against, see. Good manufacturing process is a method of assuring that there was fair competition and all people were doing the same thing. It was perfectly respectable, desirable, and so on and so I worked on that.

M: What other things--or what kind of attitude did Larrick seem to have toward

the Kefauver bill? Or did that--

Larrick's attitude was, 'This is a big political issue. You fellows gotta decide how that's to be handled. I'll help you with anything I can and I'll do anything you want.' But he was a man who had been brought up in the Food and Drug Administration and he didn't want to politicize the FDA. And he said, 'If you fellows decide anything, for or against any Kefauver amendment, that's fine--I'll go along with it, to the extent that it's workable and do my best to implement it. I'll cooperate with anything you want. But, I do not decide the political views.' We thought that was a fair point and I respected him for it. And so that -- he didn't primarily come into--as you can see from all this--he played a very subsidiary role--deliberately so from his standpoint and I think properly so from our standpoint. But I consulted with him on every stage of the way. Now, the main thing I did--and here again is another matter -- that wouldn't have been dealt with apparently. I was a civil servant for 20 years before I got in this political role. My idea always was -- well, when the fight is all over, who is gonna administer it? And that's exactly what happened. After everybody--after Harris walks away, after Kefauver dies, after Blair is through with this, who is gonna do it? It's gonna be Larrick and the FDA.

M: That's right.

C: Ellenbogen's gonna be there for another 10 years. Goodrich is gonna be there for another 10--Larrick died, but then later on, of course, I got more of the responsibility for doing it. So my job was to keep Larrick--not that it was my job, but I conceived of my role as not merely satisfying Kefauver--which was a big political one, but being sure that whatever was finally enacted would be a workable instrument and wouldn't be ruled either illegal by the court or

would not be administered. Now that's the <u>same</u> role I played in Medicare.

And, incidentally, for your information, that's why so much that is <u>good</u> in

HEW --that's been retained--is different than let's say the O.E.O. program

where Sarge Shriver and those people didn't worry about how anybody (chuckle)

could administer anything. They were attracted to something like community

action or this or that. And then later they couldn't put it into realistic

effect. And <u>my</u> attitude all along is I never went along with something that

I didn't feel could be administered efficiently, economically, satisfactorily,

later on. Pharmaceutical companies were going to still be in business later

on. You had to live with them. I'm not saying that you have to agree a

hundred per cent with them, but if it's an unworkable thing, all they're

going to do is take it to court or they're going to the congressional committees

and see that there's no money to appropriate, so <u>my</u> objective was to find a

workable instrument. I worked with Larrick. That doesn't show up, you see,

on that kind of--this, 'cause this is a legislator!

- M: Right. (Dean Cohen was pointing to Harris's book!)
- C: (chuckle)
- M: We need a video tape to get this whole thing.
- C: Yeh--that's right (chuckle)
- M: You say that the good manufacturing regulations you felt were very important.

 What about Kefauver's emphasis on advertising control? Efficacy?
- C: That we were already in agreement on. That was just a matter of--I'm not saying that those were not--I'm saying the good manufacturing control was an additive factor in it. That was not really in Kefauver's original conception of the whole thing.

M: Well, he had a licensing provision.

C: Right.

M: Which was replaced by the good manufacturing--which I guess really does the same kind of thing--

C: Which was the objective, yes.

M: Right. And Kefauver's objective was so that he could claim that <u>all</u> generic drugs are produced safely--all drugs are produced safely.

C: There was <u>never</u> any disagreement on the efficacy. We were for that <u>right</u> from the beginning. So that was not an arguable area. The advertising was not an arguable area except with some minor details--exactly, you know, what size print are you going to use and things like that which are not matters of big principle--they are just matters of some agreement on where the package inserts would be and what size they would be and how many and all that sort of thing. Which was only a matter of detail--but important. So then when you get down to dealing with those things which we were in agreement with and were never big issues even between the pharmaceutical companies, you know. So, the big issue was over the patent and licensing and the substitution of the manufacturing procedures for the licensing law.

M: Now. The bill passes in the Senate. (C: When?) In August, I think. In the <u>House</u>, now, the bill runs into some trouble because Representative Younger from California tries to cut out the advertising provisions. Do you remember?

C: I don't remember that. I remember Younger playing a significant role, but I don't remember what he did.

M: Right.

C: Because Younger was also one of those who was--for some reason--connected with the pharmaceutical interests and so on.

M: So you don't remember the controversy?

C: No.

M: Well, his attempt was defeated and the bill passed. Do you remember--Harris makes a point that at the signing ceremony Kefauver was almost not invited. Are you--do you--were you aware of that situation at all?

C: No. I had nothing to do with that, so I don't know about that. I'm sure that we sent over--it was normally our practice to send over some kind of list.

M: I believe I've seen that.

C: Did you see the list?

M: Yeh.

C: Well was his name on the list or not?

M: I believe his name was on the list.

C: Well--but I don't remember--I always paid a lot of attention to those lists because they were very important and--but what happened at the White House level on that, I don't know. But I am sure that the--the attitude of the White House at that time was to invite people. I'm sure they--I don't know what happened, but--they would have invited--at the last moment he would have been invited even if he had been forgotten or somebody was against him because the attitude of the signing ceremony was a peace-making operation. They always invited people to the signing ceremonies on other bills--even people who had proposed and advocated terrible amendments and so on. After all, at that point, the

bill was passed so no use continuing old animosities. Now is the time--you see, and also because--again, here, I've got to say another thing that's in the back of my mind--I used always the signing ceremony as a healing thing because the next step was to get the appropriations for it. My mind was always on the next step down there. If you got the bill through and the appropriations committee wasn't going to give you any money to administer it, there was no use getting the bill through!

M: That was only a quarter of the battle, huh?

C: Yeh. You see, the next big battle always is to get the money and the stuff to do it! And, again, my twenty years in the federal government had attuned me to that and I always said, 'Well, now let's--I'd say to the President or to Feldman or someone, 'Let's invite these guys to come down. We're going to want to, you know, get it.' And secondly, we want to get some credit for what we did. Kennedy was always saying, 'Let's get a little credit for doing something.' Let's not tell everybody 'We're going into the next election soon-let's take some credit for it!'--not tell people all the trouble we had and the internal fights we had (M: chuckle) and how we lost this. Let's tell about what we want.

M: Let's stop there a moment.

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