

HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Maurice D. Kinslow, Director, Region IV
U. S. Food and Drug Administration

and

Dr. James Harvey Young
Emory University

Fred L. Lofsvold
U. S. Food and Drug Administration

Atlanta, Georgia
September 16 and 18, 1982

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter and Fred L. Lofsvold, retired employees of the U. S. Food and Drug Administration. The interviews were held with retired F.D.A. employees whose recollections may serve to enrich the written record. It is hoped that these narratives of things past will serve as source material for present and future researchers; that the stories of important accomplishments, interesting events, and distinguished leaders will find a place in training and orientation of new employees, and may be useful to enhance the morale of the organization; and finally, that they will be of value to Dr. James Harvey Young in the writing of the history of the Food and Drug Administration.

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TAPE INDEX SHEET

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DATE: Sept. 16 & 18, 1982 PLACE: Atlanta, Georgia LENGTH: 220 minutes

INTERVIEWEE

INTERVIEWERS

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FDA SERVICE DATES: FROM 1961 TO: Present RETIRED? No

TITLE: Regional Food and Drug Director, Region IV
(If retired, title of last FDA position)

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This is a recording in the series of FDA oral history interviews. We are interviewing today Mr. Maurice D. Kinslow, Regional Food and Drug Director at Atlanta, Georgia. The interview is taking place in his office in Atlanta. The date is September 16, 1982. Interviewers are Dr. James Harvey Young, Professor of History, Emory University and Fred L. Lofsvold.

Lofsvold: Mr. Kinslow would you begin this recording by giving us a sketch of your career, when and where you were born, where you were educated, when you came to Food and Drug Administration and what positions you have held over the years with that agency.

Kinslow: I was born June 16, 1932 in New Albany, Indiana. I attended public school there and then entered the University of Louisville, Louisville, Kentucky and completed my schooling at a small school right outside of Lexington, Kentucky called Georgetown College where I graduated in 1953 with a Bachelors Degree.

Lofsvold: What was your major?

Kinslow: My major was psychology. I suspect you might find that a bit surprising since most Food and Druggers have a very heavy scientific background. However, unlike most of my colleagues I did not come into the Food and Drug Administration as my first federal employment. I originally was employed by the Social Security Administration. I started

working for Social Security in January 1955 and was employed by that agency for several years prior to coming to the Food and Drug Administration. As a matter of fact I had been with Social Security just under five years when I was selected for the Department of Health, Education and Welfare Management Development Program. I left Indiana in August of 1960 to go to my first assignment in Social Security Headquarters in Baltimore, Maryland. After completing about a year there, I went to the Food and Drug Administration as my second assignment in the Management Development Program and that is how I began my FDA career. It was really simply designed to be a six to twelve month assignment, from which I could have gone on to some other agency. However, I became so intrigued with the activities of FDA and so highly impressed by the people that I met there, I hadn't been there very many weeks until I decided that this was the agency where I wanted to stay.

Lofsvold: That was in 1960?

Kinslow: It was in July 1961. My initial assignment was as a Staff Assistant in the Office of the Commissioner working specifically for Assistant Commissioner Winton B. Rankin. I considered myself very lucky for two reasons in connection with this first assignment with the agency. One, I was very lucky to have the opportunity to work for Mr. Rankin because he was "the best teacher" to which I have ever been exposed

and also a very fine gentlemen. The second reason I considered myself so lucky was that I came into the agency at a very interesting time and have had the opportunity over the past twenty-one years of observing a fascinating collage of situations, developments, activities, that really have been just a marvelous experience. Not everything that has happened has been to my liking, but all in all I think the opportunity to work for the Food and Drug Administration, which has a very basic, fundamental role in our society in protecting consumers has been a marvelous opportunity and I've enjoyed it thoroughly.

I had an interesting experience during the first two weeks that I was with the agency. My office was on a corridor in the north HEW building leading down to the Commissioner's office. Approximately across the hall from me was the office of Mr. Frank Clark who at that time was an Assistant to Deputy Commissioner John Harvey. As I say, within the first two weeks that I came on this assignment Frank took me aside one day and explained to me that I had two strikes on me and he felt that I needed to be aware of that. So I told him that I appreciated the information but I would like for him to explain it a little more. He said, "Well, number one, you did not start your government career in the Food and Drug Administration as almost all of the rest of Food and Drug Administration employees did. Number

two, your first assignment is in the Commissioner's office. Therefore, for those two reasons you are going to be immediately suspect with everybody in the agency." He said, "I just thought you should be aware of that." I thanked him for that information, which I took to be advice and I found that Frank was 100% accurate as weeks and months and years passed. Interestingly, Frank and I became very dear friends and indeed were peers as Regional Food and Drug Directors at the time of his death some years ago. I always appreciated that advice from Frank.

The first thing that happened when I started my assignment with Mr. Rankin was to begin a training program, or orientation program that he had developed for me, which gave me an overview of all of the activities of the agency both in the headquarters offices and the field activities. I went around from place to place and met with various people to learn something about FDA. As I said earlier, Mr. Rankin was an excellent teacher. I learned about the agency, not because I had a good technical or scientific background from my schooling, but through on-the-job training. At that point in time, Mr. Rankin had significant responsibilities regarding legislative activities with the Congress and congressional liaison. My first assignments in the agency related to a congressional hearing that was coming up in September 1961, where Secretary Ribicoff was going to appear

before the Kefauver Committee, which was holding drug hearings. This, according to my recollection, was a hearing on legislation that had been introduced by Senator Kefauver, subsequent to about two years of investigative hearings regarding the drug industry.

Perhaps at this point I should step back from that assignment for a moment and give a brief resume of the things that I've done in the Food and Drug Administration subsequent to my initial assignment as a Staff Assistant in the commissioner's office.

In the fall of 1964, while still working in that office, I was selected by the Department of Health, Education, and Welfare as the Department's representative for the American Political Science Association Congressional Fellowship Program. So I spent about the first eight months of 1965 on Capitol Hill participating in that program. Then I returned to the agency and in early 1966 was designated as the Director of FDA's first Office of Legislative Services.

Lofsvold: This was after Dr. Goddard came as Commissioner?

Kinslow: Yes it was. Just a few months after he came on as the Commissioner. I continued to operate in that office until June 1967, when I went to the Baltimore District as the District Director. I stayed there until December 1969 when I returned to Washington as a Special Assistant to the Commissioner who was then Dr. Charles Edwards. I stayed in

Washington as the Assistant Commissioner for Program Coordination until September 1971 when I came to Atlanta as the Regional Director where I have been since that time.

Young: Maurice now that you have encapsulated your career, lets go back to its beginning, and to that September 1961 hearing in which the Kefauver Committee was beginning to move from investigation to legislation.

Kinslow: All right, Dr. Young. That began a fascinating year during which there was an enormous struggle going on in the Congress relative to the passage of revised drug legislation in this country. My only regret, in retrospect, is that I was such a neophyte in the Food and Drug Administration, even though working in the Commissioner's office, I really didn't have the background to understand or appreciate many of the things that were going on around me.

However, as the legislative battle heated up in the late spring and early summer, as I recall, of 1962, the Kefauver Committee drafted a bill which the administration requested the Food and Drug Administration to review.

Young: Do you mean '62 or do you mean '61?

Kinslow: No, I mean in '62.

Young: Right.

Kinslow: This bill was written essentially by industry lawyers. Senator Dirksen was the ranking minority member

on the Kefauver Committee and he had brought some lawyers in who had developed a bill. This was submitted to the Food and Drug Administration and the agency made some very negative comments about the bill to the Department of HEW. I recall a very interesting development concerning that particular document which went up to the Department. I had been around, by that time, long enough to do a few productive things, so I had taken the comments from various offices of the Food and Drug Administration on various provisions of the bill as drafted and put them together in a report to the department, which I am sure was signed by Commissioner Larrick. However, somehow a copy of that document which had my name down in the bottom left corner of the last page, as the drafter, got in the hands of some of the staff people in the Department. While I did not attend the meeting at which this occurred, it was reported to me that there was a rather heated discussion in which some of the hierarchy of the department were chiding Mr. Larrick about the nature of the agency's negative comments on this bill and held up this copy of the draft and said, "But those are Kinslow's views." And it was reliably reported to me that Mr. Larrick said very gently, but very firmly, "Those are the Food and Drug Administration's views." That was the first time that I really felt that I was indeed a part of the organization and I was walking on air that evening

when I went home after I heard about that little scenario. Notwithstanding the Food and Drug Administration's negative views on the bill, it appeared clear that legislation coming out of the Kefauver Committee was not going to be the kind of legislation that the Food and Drug Administration felt was needed. The circumstance that derailed that freight train, and that is precisely how we viewed it--was the thalidomide episode. I had the unique opportunity of sitting in Assistant Commissioner Rankin's office the afternoon that Morton Mintz, of the Washington Post, interviewed him about thalidomide. So I heard that interview conducted and, of course, the subsequent newspaper article written by Mr. Mintz about thalidomide created such an outcry that there were some very significant changes made in the legislation. Many of the provisions that we felt were previously lost were included in the 1962 Kefauver-Harris Drug Amendments. I had the privilege of being in the Senate anteroom the afternoon that Senator Kefauver, as the floor manager of the bill, brought the bill to a successful conclusion in the Senate. As he came off the Senate floor, I had an opportunity to shake hands with him. He didn't know who I was, but this had been arranged by Mr. Rankin so that I could meet him.

Young: May I ask you if you could characterize the nature of FDA's objection to the original bill. Was this because

the original bill represented more Kefauver's ideas in connection with the pricing of drugs and less things that had to do with the scientific dimensions of testing new drugs?

Kinslow: No, that was not the problem. In the first place, even the legislation as originally introduced didn't go nearly as far as Senator Kefauver would have liked in dealing with the pricing of drugs. The Food and Drug Administration's problem with the bill that came out of the committee prior to the thalidomide publicity was that it did not go nearly far enough in dealing with some of the problems that FDA perceived should be addressed. For example, it did not deal with efficacy, or at least it did not deal with it in the way in which the ultimate legislation did. So our principal concern related to the fact that the bill was weak. It gave the appearance of strengthening drug legislation in this country, but it was more appearance than substance. It was an industry drafted bill.

Young: Right. Now as time went along, under the thalidomide pressure toward the final successful enactment of the bill, there were tensions about what that final bill should contain between FDA and HEW and as I understand it even between HEW and the White House. Did you have any insight at the time into these problems?

Kinslow: Not really. I was there and I was aware of enormous conflicting pressures about what the ultimate bill

would include, but I was not personally involved in most of these things. As a matter of fact, the key people from the perspective of the Food and Drug Administration were Commissioner Larrick, Assistant Commissioner Rankin and General Counsel Goodrich.

Young: Right. Kefauver was disappointed that the final bill didn't contain more provisions that related to pricing.

Kinslow: Very much so.

Young: Would you say that the Food and Drug Administration, when the bill finally was passed, was satisfied and pleased with what had been secured from the point of view of securing safe and effective drugs?

Kinslow: Enormously pleased. As a matter of fact, I think that the provisions that were included in the final legislation were more than we ever expected to get.

Young: While we are talking about this stage, might I ask what associations you had with Commissioner Larrick and how you would characterize him as head of the agency in this period, in his last several years of being commissioner, the last of the dynasty system?

Kinslow: Well, for a period of two or three years, immediately before his retirement, I had an office immediately adjacent to his. And indeed had the opportunity to work with him on a number of issues. The one that, I guess, where we had the most contact was in connection with the

legislative proposals to deal with dangerous drugs, the legitimate drugs which were being distributed in illegitimate channels and were being severely abused.

Young: Had there not been a law? Was it in 1965?

Kinslow: It was passed in 1965 and I worked on that legislation from essentially the time I started with the agency until its passage. My evaluation of Mr. Larrick was that he was a very fine gentleman and a very dedicated Food and Drugger. He had the best interests of the agency at heart and I admired him enormously. As I say, this dangerous drug legislation gave me the opportunity to work with him quite closely. In connection with that, I, having not had field experience, was having a little difficulty dealing with some of the problems that our field people were experiencing in trying to control the illegal distribution of dangerous drugs. So, in the summer of 1963, a field trip was arranged for me to Cincinnati District, so that I could get some first hand experience as to what the problems were with pill pushers. I spent a very interesting three days in Cincinnati, northern Kentucky which was in Cincinnati District then, and Lexington, Kentucky where the US attorney had his offices, getting papers filed which requested the institution of criminal proceedings against a whole raft of folks up in Newport and Covington, Kentucky. And in the

process, I learned about many of the short-comings of trying to deal with illegal drug distributors under the terms of the existing Food, Drug and Cosmetic Act. One of the things that impressed me was that we did not have authority to arrest people. We didn't have authority for investigators to carry firearms and they were dealing with some very dangerous people. After I got back to Washington I had a much better perspective of the problems. Notwithstanding this, when the administration's legislation was developed, I was responsible for preparing FDA's comments on this legislation and I was very satisfied with what I had done, until Commissioner Larrick called me into his office and said that there was a terrible deficiency in this bill. I was dumbfounded at that point and said, "What is it Commissioner?" He said, "There is no provision in this bill for our inspectors to exercise police powers and carry firearms." I said, "Well, sir, I didn't realize that you wanted to have that kind of authority in the bill." He said, "Absolutely, it is no good without it." So, I drafted a provision which would provide that which ultimately became a part of the law. I guess it is probably one of the very few actual pieces of federal legislation where I was responsible for the language, notwithstanding the fact that I worked on literally scores and scores of bills. But I actually drafted that provision that

was in the Drug Abuse Control Amendments as it was passed in 1965.

To give you some insight into Mr. Larrick's thinking. I had some reservations about the creation of the Bureau of Drug Abuse Control, I believe that is what BDAC stood for. This was the group created to enforce the dangerous drug legislation. I was concerned because there was this separate group set up into which many of our people were assigned. It seemed to splinter the organization. I was told that this was done by Commissioner Larrick very deliberately because he recognized the fact that that area of responsibility was going to be taken away from the Food and Drug Administration. So, rather than assimilating that responsibility into our on-going activities, he made it a separate organization so that it would be nice and clean and neat and simple when it was snipped off of FDA's organization chart. I was not perceptive enough to recognize that but I am absolutely convinced that was an accurate conclusion that was conveyed to me by someone who was in a position to know what was in the Commissioner's mind. So, I think, he had the best interests of the Food and Drug Administration at heart. I, unfortunately, did not get to know him as well as I would have liked to.

Lofsvold: Don't you think, possibly too, that he did not like this kind of an activity and was not at all averse to

having someone take it and really sort of invited the loss of this activity to the Food and Drug Administration?

Kinslow: That's true, Fred. I agree that was probably also part of his reasoning in creating the separate activity. He didn't like it. Indeed I came to view it in that same light even though I had worked very hard to try to get the Food and Drug Administration better tools to deal with this problem. I ultimately came to see that this was a very unpleasant kind of activity and we were dealing with criminals, hoodlums, the dregs of society, and we were putting our inspectors in circumstances that they should not have been put into. I was delighted when that activity was taken away from the Food and Drug Administration.

Young: Commission Larrick retired, I think, in December, 1965.

Kinslow: That's right.

Young: This is one of the major watersheds, the choice of the next Commissioner, whether the system that had prevailed essentially from the beginning of a new Commissioner being chosen from within the agency should be followed or whether a new method of choosing a Commissioner who came from outside without previous Food and Drug Administration experience should be put in the spot. Can you comment at all upon your observations, through this transition and indicate why, from your observation, you thought it did happen that a

Commissioner was chosen from outside, instead of a Commissioner being chosen from inside the agency.

Kinslow: I really can't shed any light on that, Dr. Young, I had spent most of the year of 1965 on Capitol Hill, that was the period during which I was involved in the American Policial Science Association Congressional Fellowship Program. I really can't speculate on the reasoning behind going outside of the agency for the first time for a Commissioner.

Lofsvold: When you were talking about Mr. Larrick and how he operated, at about that time he was being subjected to criticism by the Senator Humphrey's investigating committee. Did you observe any of his reaction to those criticisms.

Kinslow: Yes I did. I accompanied the Commissioner along with other staff members at those hearings and I can tell you that they were, in some instances, almost vicious attacks on Mr. Larrick and his management of the Food and Drug Administration. I think Commissioner Larrick was very disappointed and disenchanted to have had to go through this experience, which in my view was dedicated to one thing and that was publicity for Senator Humphrey.

Lofsvold: As part of those hearings there were accusations made regarding FDA being too cozy with industry and specifically that Jack Harvey, the Deputy Commissioner had done some things favorable to Abbott Laboratories of Chicago

where his brother was a vice president. Did you observe any of that part of the hearings?

Kinslow: Yes, I observed it. I really wasn't that involved and I can't really comment on what Mr. Harvey might or might not have done because I have no personal knowledge about that. The whole tenor of that particular set of hearings was a negative one as far as the agency was concerned and I was personally sorry to see both Mr. Larrick and Mr. Harvey subjected to some of the things that occurred during that period.

Lofsvold: In the last four or five years that George Larrick was Commissioner it seemed to me from the field where I was, there were some serious tensions among their top staff and some of the bureau directors. Did that have any effect on the work you were doing? For example, the personality clash between Allan Rayfield and Malcolm Stephens?

Kinslow: I am not sure that it had any impact on the work that I did because I had to have a fairly decent working relationship with all of the top staff members because I could be calling on any of them at anytime for assistance in connection with an upcoming hearing, or developing a response to a congressional inquiry. So, I dealt with all of them and generally I would say that I got excellent support and cooperation from them. The tensions that existed were clearly evident to me. I think they may have affected other

operations in the agency more than they would have mine. I think it was unfortunate situation internally and I really don't know the dimensions of how it might have impacted the agency as a whole.

Young: You were on the Hill a lot involved with laying the ground work for appearances at hearings and if bills were up, talking to staff people. Was there such a thing as a typical day when you went from the Food and Drug Administration to the Congress? What was the routine, what kinds of associations did you establish on the Hill?

Kinslow: Well, there certainly wasn't a typical day. In the period we are talking about now, which is late in 1965, I had just returned to the agency from the Congressional Fellowship Program and it was the last days of the Larrick administration. Prior to that time, I had not worked that much as the principal contact on the Hill. Actually, Winton Rankin carried out that responsibility and dealt with staff people and most of what I did, I did back at the agency or in preparing background material for hearings, that sort of thing, dealing with the various offices of the agency to get materials prepared. It was only after Dr. Goddard came on board in January of 1966 that I really took on the principal contact role with Capitol Hill. So, I have a different perspective starting at that period. Of course that was after Mr. Larrick left.

Perhaps, unless you have some other questions, this would be a good place to start with the Goddard era, if you will. I was immediately impressed by Dr. Goddard because he was a very good subject to brief in advance of hearings. As soon as he came into the agency, he started spending a great deal of time on Capitol Hill, so I had to spend a lot of time briefing him and working on testimony and preparing for hearings. It was an interesting period but it was a very hectic one, because I recall very vividly that it seemed to me that I was constantly engaged in high pressure situations in getting ready for hearings. As I would walk out of the hearing room, after one was over, I would start thinking about the next one that was coming up that immediately demanded my attention. Dr. Goddard was a very interesting witness and as a consequence in great demand on Capitol Hill which put an enormous burden on me. I guess because of this close association, during that first couple of months, apparently he was satisfied with what I was doing because he created the first Office of Legislative Services in the agency and named me as its Director. An interesting anecdote occurred during that period. As a matter of fact, I was a bit surprised after this happened that he even kept me around.

During the first weeks that Dr. Goddard was in the agency as the Commissioner, he had to go to Capitol Hill to

see Senator Paul Douglas. As his top legislative person I accompanied him. I was very anxious to make a good impression on the new Commissioner so I was trying to handle everything perfectly and when we went in to Senator Douglas's office I walked over to the receptionist and I said, "Mr. Kinslow and Dr. Larrick to see Senator Douglas". Dr. Goddard leaned over from behind me and said very gently to the receptionist, "That's Dr. Goddard". At that point I wanted the floor of that portion of the Senate Office Building to open underneath me to permit me to escape. However, I think, Dr. Goddard was more amused than chagrined by this and obviously didn't consider it a fatal error.

Young: You say that there were a great many hearings right after Dr. Goddard came in and the fact that he was a good witness, an interesting witness, may have had some underlying factor in this. There must have been more substantive reasons as well for the hearings. Here he was a new Commissioner and a new Commissioner of a different type having come from outside; and everybody, including the Congress who were concerned with Food and Drug matters, were aware of this. Did you get the impression that the choice of Dr. Goddard was intended to be a sharp break with the past, as far as policy at FDA was concerned, by those who chose him? Did you get the impression that he was deliberately making, in his testimony and in his administering at FDA, a new

start? That he felt it was his obligation to do this?

Kinslow: Yes, I do think so. I think that he was deliberately picked for some of the characteristics that we've discussed. I should note that one of the reasons he was a popular witness was because he generated a lot of publicity. When you generate publicity, that makes you a valuable commodity on Capitol Hill. I've worked in connection with Capitol Hill for a good many years, had the opportunity to see it from the perspective of working in the offices of members of Congress during the Congressional Fellowship Program. Publicity is a very important commodity up there and Dr. Goddard generated a great deal of publicity. I observed after he had been there for a while that I suspected a very small percentage of the American public in 1965 could have named the Commissioner of Food and Drugs, George Larrick, but I will assure you that a significant percentage of the American public by June of 1966 knew that Dr. James L. Goddard was the Commissioner of Food and Drugs. I think that he felt it was important for him to demonstrate that here was a "new broom" at the head of the agency and it was going to sweep pretty clean.

Young: Right. Well, all of the immediate predecessors had deliberately underplayed publicity. That is really apparent as their desire. They often spoke of it. One of them said that he didn't want his name to be known, he wanted the

agency to be respected, but he didn't want his name to be known. There was very little publicity. This, just from the point of view of publicity, is a watershed. This is but one element of the watershed.

Kinslow: That is true.

Young: What are other elements of the watershed?

Kinslow: Let's talk about publicity for just a moment, if we may, please. I would say that one of the first times that the agency achieved national publicity was in connection with the aminotriazole contamination of cranberries at Thanksgiving time, in the late 1950's. The next time that a similar nation wide splash hit was during the Kefauver investigative hearings when the Henry Welch episode was laid out for the American public. Then in June 1962 when the thalidomide story hit the press the agency moved into an era of press coverage that has been essentially constant since that point. We went onto the front pages in July 1962 and have never, in the succeeding twenty years, gotten off of the front pages. Now, the interesting thing about this, relative to the comment that you just made Dr. Young, about Jim Goddard was that he brought a consummate publicist into the agency in the press office, in the form of Mr. Ted Cron. Ted was a very talented person who knew how to get publicity. He knew what would capture the attention of the media and indeed Ted Cron made Jim Goddard a household word.

Lofsvold: How much influence did Cron have, in addition to the publicizing of Dr. Goddard and what he was doing, in helping him with decisions?

Kinslow: I can't really speak to that, Fred, because he may have had a great deal of impact in other areas. He did not have that much impact in my area. Frankly, I was so busy trying to keep track of what I was supposed to be doing that I just can't be responsive to your question, although I know that they had a very close relationship and feel reasonably certain that Ted had quite a bit of influence on Jim Goddard.

Lofsvold: I ask the question because I remember that about that time a meeting of Consumer Affairs Officers in San Francisco where, as reported to me by my Consumer Affairs Officer, Cron made a statement intimating that he was the one who identified these issues and brought them up before the Commissioner and got the decisions that he was then able to publicize.

Kinslow: Well, I think that sometimes he had an over inflated view of his role, but he was very good at what he did. I can't say whether or not the circumstance you cite was accurate.

Young: It was always my view that Goddard was definitely his own man. Had his own ideas, he didn't lack for a store of ideas.

Kinslow: He certainly did not. I found him to be absolutely brilliant. I enjoyed a very close working relationship with him and I admired him enormously.

Lofsvold: And he had the opportunities. There were a number of problems that had developed over the years and had been staffed out and were ready for decisions and he was willing to make those decisions, some of which had been pending for quite awhile.

Kinslow: He had no trouble making decisions. He was very decisive about it.

Young: Let me just ask one other question in connection with the publicity. It did seem that there was, within the agency, a deliberate desire and a belief that it made for good policy to increase the image of the agency, the recognition of its mission. That could be done in some ways with the press from within the agency. You indicated that there were more hearings and that was part of the publicity, too, but the initiative on hearings couldn't come so much from within the agency.

Kinslow: Oh, no.

Young: It had to come from within Congress.

Kinslow: Absolutely.

Young: So, why, what was the reason, what were the underlying factors that caused the Congress to latch upon this new Commissioner in order to increase their publicity upon their initiative?

Kinslow: It just became evident to observers, after his first appearances up there, that he was a crowd pleaser. He was a very articulate witness and, of course, he had the advantage of being the new boy on the block, as the new Commissioner. Whatever situations existed in the agency, whether it was why did you clear this drug or what is the potential for this investigational drug, or why was this done, he did not have to take the responsibility for the decisions leading up to that point. So, he could testify and take the position that we will look into this and we'll see what needs to be done there. So, he had, as most Commissioners do, a honeymoon with Capitol Hill in which there were a number of very important, legitimate issues of great interest to the American public that were discussed during congressional hearings in the first six months of Dr. Goddard's tenure.

Young: Can you mention some of the issues, perhaps?

Kinslow: Well, one that sticks in my mind most was the first hearings on DMSO which occurred during the spring of 1966. Interestingly, DMSO is still a controversial drug now, 16-1/2 years later.

I had one other comment that I wanted to make about Ted Cron, just to put in perspective some of the earlier discussion we were having. About a year after Dr. Goddard came on board, I became aware of a situation. I am not going to

describe the precise circumstances because they are not important, but I became aware that Ted Cron had become involved in what I considered to be "my business" which was dealing with a staff member on Capitol Hill regarding some proposed legislation. I further learned that this was done without any involvement of the staff people at the department level. I always worked with and through those staff people. So I went to Dr. Goddard about this and observed that I personally would not touch with a ten foot pole any of the developments that came out of this particular contact and suggested that I needed to touch base with people in the department and get our lines straightened up. And he supported me totally on this. Nothing ever came of it and to the best of my knowledge Mr. Cron did not get involved in the business of dealing with the congressional staffers after that.

Young: He did one thing that I remember. He sought to develop from within the agency a slicker type of public relations outside. Part of this came with the creation of the new magazine, which still continues, but in order to get the funds for it, as I understood at the time, he eliminated the traditional publication as a separate entity of Notices of Judgment which from the start had been the way in which the Food and Drug Administration under the law had indicated the result of actions taken. There was a lot of criticism

both within and outside the agency, and the Notices of Judgment sort of appeared in considerably abbreviated form in the magazine. Well, here was a sort of change.

I would like to use that as a springboard to ask a question, if a certain amount of change for change's sake represented the Goddard Commissionership and if there was also change for other more substantial reasons from the way that things had been done before? That is a kind of big questions, but what are your thoughts on that?

Kinslow: I did not perceive the changes as being for change's sake. I recognize that Ted Cron did develop some very professional materials that surpassed the quality of many of the things that we had produced in the past. And I think those were positive accomplishments on which the agency has built in succeeding years.

Lofsvold: Actually a publication like the magazine was not being done anywhere in government.

Kinslow: That's very true, Fred, and the importance of creating a very professional staff to deal with the media and with publications, I believe, was a positive step for the agency. I have had the opportunity to know all of the people who have worked in the press relations job for over twenty years. It is a very critical job in the Food and Drug Administration since we have been in the media, as I have described earlier, for essentially all of that period.

I have seen some highly competent professionals in that job and I have seen some utter disasters in it. We are much better served during those periods when we have highly competent professionals.

Young: What about the broader question of the change in policy and organization and in methods of operation, that came with Commissioner Goddard?

Kinslow: I think he sincerely believed that these were things that should be done. A small example, but it really isn't small, is one when he found that the agency didn't have a rapid communications mechanism tying all of the districts offices together with headquarters. He was appalled and he directed that one be installed forthwith. I felt like I knew Jim Goddard pretty well. I think that the bulk of the changes, modifications, revisions, or what have you, he thought were in the best interest of the agency.

Lofsvold: Using your example, a proposal for a teletype network had been made several years before that and had not been approved by the previous management. When Goddard came and made the decision that we needed something like that it was an item that was widely supported by a great many people in the agency who had advocated this previously. Some of his other changes ran so counter to the regulatory philosophy of people in the agency, that they were regarded, I think, as rather revolutionary at the time.

Young: The relative relationships and the nature of relationships between headquarters and the field in the reorganization might be considered one of those. Is that not right?

Lofsvold: That changed radically.

Kinslow: Indeed it did. The kind of organizational structure that developed under Dr. Goddard with the principal Field Managers, District Directors in effect reporting directly to him, was a dramatic change, as Mr. Lofsvold knows better than I.

Lofsvold: In making those changes, did you ever get any clue as to how he arrived at some of these policies that were rather different from what had happened before? Did he spend any time studying the agency before he became Commissioner, to your knowledge?

Kinslow: I haven't the foggiest notion.

Lofsvold: There was no contact, for example, with Rankin or you for early briefings before he took office?

Kinslow: No sir. I did not meet him before he walked in the door as a Commissioner. But he certainly studied the agency after he came to the agency. As I mentioned earlier, he was a very quick study. As a result, I think he gained a good insight into the agency rapidly because he had an enormous capacity to absorb and evaluate information. I observed him using this information after being briefed, either

on Capitol Hill or in other settings. He understood what he was talking about. So, I think he gained a good appreciation for what was going on in the Food and Drug Administration, fairly rapidly.

Young: Another element of change might be indicated by the fact that Commissioner Larrick had sometimes been criticized for his frequent, friendly lunches with members of industry at the Press Club. Whereas Goddard came to be criticized for the way he dressed industry leaders down when they came by for conferences at his office. This maybe symbolic of a significant change or it may not. Do you have any comment on that?

Kinslow: I, of course, was aware of the Commissioner's public statements to a variety of audiences. I know that in some of his first appearances, before some associations, he made some very strong statements but I was really not involved in any of that. How that method of operating occurred, I couldn't say.

Young: So, you had no way of knowing, I take it, if Dr. Goddard had come with any sort of instructions as to changes in policy.

Kinslow: No, I have no way of knowing if that is the case.

Young: Do you think that the kinds of qualities that made him an exciting witness before congressional committees, for example, or in making speeches, were the same kind of

qualities that led him into difficulties and maybe shortened the term of his office?

Kinslow: I most assuredly do. He was very outspoken. He said what was on his mind. I definitely think that he was his own worst enemy because there were a couple of things that he said shortly before his departure from the Food and Drug Administration which, I believe, were instrumental if not specifically involved in his departure.

You will recall that in the spring of 1968, President Johnson indicated that he would not be running for re-election. Vice President Humphrey was very interested in achieving the nomination of the Democratic party. At this crucial point in time, the Commissioner made a comment about the potential demise of the corner drug store. Now, as a former pharmacist, Vice President Humphrey didn't look very kindly on that remark. But more importantly, the professional druggist's association, I believe, counseled with the Vice President as to how outrageous this statement of the then FDA Commissioner was.

In approximately this same time frame, Dr. Goddard honestly answered another question regarding the relative hazards of either smoking a marijuana cigarette or drinking a martini and I believe he genuinely said what he felt and that was he would rather have his daughter smoke a marijuana cigarette than drink a martini. I don't think he said that

to get headlines, I think he said it because that was how he felt.

Unfortunately, the circumstances at that time made that a very unwise political statement. I believe that those two things made him a liability to Vice President Humphrey. Vice President Humphrey, at that point, did not need any liabilities in his fight for the presidential nomination. I am convinced in my own mind that he simply felt we have to get rid of this man. He can't afford carrying that extra baggage any longer.

Lofsvold: Especially, perhaps, because the comment on marijuana was made on the campus of the University of Minnesota in Mr. Humphrey's home state.

Kinslow: Yes, a very unfortunate geographical juxta position with the comment.

Lofsvold: Along that line. Some other people have speculated that persons higher in the government echelons in the Department and in the White House were somewhat jealous or perhaps envious of the kind of publicity that Dr. Goddard was able to engender. Did you ever hear anything along that line?

Kinslow: No, I did not. That may well have been the case but I was not aware of that.

I would like to say one other thing about Jim Goddard. He was directly and specifically responsible for me going to

my first field assignment. I can't recall exactly when the conversation occurred, but it was about a year after he became Commissioner. He called me in one day and he asked me what I wanted to be doing in the Food and Drug Administration, five or ten years from that point. I said, "Well, Dr. Goddard, I can't really tell you what I would like to be doing then, but I sure as hell know what I don't want to be doing and that is doing what I am doing now." It had been a very interesting, fascinating experience to work in the legislative arena, the congressional arena, for most of six years, but I had had about as much of it as I could enjoy. So he said, "Well, what would you think about going to the field as a District Director?" And I looked at him as if he had taken leave of his senses because nothing like that had ever entered my mind. So, after I realized he was serious I said, "Well, maybe if I went out to the field as a Deputy Director first and sort of learned what they did out there, then I might be in a better position to go out as a District Director." He said, "Well, I want you to think about it." That was the end of that conversation. Maybe a month to six weeks later he raised the issued again. So, I thought, well I demurred the first time Commissioner, I am not going to the second time. So when he said, "What would you think about it?" I said, "I think that is a good idea, I would like to try that." Shortly thereafter I was selected with a

group of other folks, who were put on special training assignments. We didn't know it at the time, but we were the first group in FDA's Executive Development Program.

I started into some developmental assignments in February of 1967, including spending some time in a couple of District Offices. In June of 1967, I reported to the Baltimore District as the District Director. I am sure that there were a number of people, at that time, who thought that this was one of Jim Goddard's worst decisions. To send somebody out to run a District who had never actually worked a day in his life in a District. It may not have been a great decision, but I don't think it was the worst, because here it is fifteen years later and I am still an FDA Field Manager.

Young: Pre-Baltimore. Were there elements of continuity that should be stressed, that linked Goddard and earlier periods? We have been focusing on change.

Kinslow: Yes, there definitely were. For example, Winton Rankin became Deputy Commissioner under Dr. Goddard and Ken Kirk became the Associate Commissioner for Compliance. While there were new people in the press office and the planning office and some other jobs throughout the agency, the key roles of Deputy Commissioner and Associate Commissioner for Compliance were filled by men who had been with the agency for a number of years and had had very

responsible positions as Assistant Commissioners working for George Larrick. So, there was certainly a very strong continuity in the Goddard era, if you wish to call it that, in the form of Ken Kirk and Winton Rankin.

Lofsvold: What kinds of subjects did they deal with Dr. Goddard on? Principally regulatory matters or...

Kinslow: They dealt with him across the board, to the best of my knowledge. Certainly Mr. Rankin did in his role as Deputy Commissioner. I know he was involved in issues that covered the spectrum of FDA activities.

Lofsvold: They were able to advise him then on personnel, also, as to the strengths and weaknesses of the various managers.

Kinslow: I am quite certain that they did that. I think it is fair to say that Winton Rankin had a very significant impact on some of the decisions that were reached during that period.

After I went to Baltimore District as the Director I, of course, lost immediate touch with the activities in the office of the Commissioner at headquarters. However, I was fully occupied in learning what goes on in the Food and Drug Administration's field operations. I already felt that I was a dyed-in-the-wool food and druggist when I went to Baltimore. I learned after being there for a short while that even though I had worked for the agency for six years,

I really didn't know where the Food and Drug Administration's most important operations were carried out. I previously had thought that all of the important things happened in Washington, whereas after I went to Baltimore I learned that the heart and soul of the agency was really in its field activities. I enjoyed my tenure at Baltimore enormously. I learned a great many things that I knew about only in a very peripheral fashion while working in Washington. I got to operate in these areas on a first hand basis and it was a very enjoyable experience.

After being there something less than a year, in the Spring of 1968 I began to hear that the Food and Drug Administration might be reorganized and put into a larger organization with some of the Environmental Health Programs of the Public Health Service. Indeed, I have some personal recollections that this was something that was, if not being promoted by Dr. Goddard, was something that he looked forward to with considerable relish. However, the opportunity to head this newly created organization never was available to Dr. Goddard because he resigned, I believe, in July of 1968. At approximately the same time the new organization, which was known as the Consumer Protection and Environmental Health Service (CPEHS), was created.

Young: Why had he looked forward to this kind of fusion with relish?

Kinslow: Well, I think he saw an opportunity to do some things in the air pollution and water pollution activities that were not being done up to that point. I think he intended to utilize some of the regulatory attitude that he had learned in the Food and Drug Administration against violators in those areas, people who were significantly polluting the air and water. So, I think, he saw a larger role there to provide consumer protection and had this master plan worked out. With him as the head of the reorganized operation the Food and Drug Administration might have fared very well. However, it didn't work out that way. That was the beginning of a very bleak period for Food and Druggers because the hierarchy of CPEHS who came from the Public Health Service environmental health programs knew little and cared less about traditional food and drug programs. As a consequence, the prospects for traditional food and drug programs were very dark.

Young: Why specifically were prospects for the Food and Drug Administration dark under these potential circumstances?

Kinslow: Well, there was a proposed reorganization package that kicked around for a number of months. This reorganization package related to the amalgamation of the Food and Drug Administration and these other Public Health Service programs. One of key issues in that for the Food and Drug

Administration related to whether or not line authority over Food and Drug District Directors would be exercised by the CPEHS administrators office. We were very concerned about that because the orientation of the Public Health Service had been significantly different than the Food and Drug Administration. Historically the Public Health Service programs, in great measure, had been carried out through money provided by PHS to the states to carry out programs. The traditional Food and Drug Administration programs consisted of FDA employees scattered across the country making inspections, collecting samples of products, analyzing products in our laboratories and then taking action when we found that firms were not producing products in accordance with the standards, or when we found products that were outside of standards. Taking legal action in the courts was simply a foreign situation to the people in the Public Health Service and we were very concerned as to what the direction of this new organization would be. Since, as I mentioned earlier, the hierarchy came from the environmental programs, we suspected we knew what direction we would be going.

Young: Did that fear in fact begin to become reality?

Kinslow: Yes it did. To be more responsive to your question, I would like to discuss an incident which occurred in December 1968. I would like to begin by mentioning a speech

that Deputy Commissioner Rankin made at the Food and Drug Law Institute Food and Drug Administration Conference, on December 3, 1968. That speech was a very pivotal situation or circumstance in the history of the Food and Drug Administration. The agency had been in the new organization, which was called the Consumer Protection and Environmental Health Service, for slightly over five months at that time. There had been an organizational document under consideration for many weeks and there was speculation in the trade press that Secretary Cohen of DHEW was rushing the transfer of FDA management functions to CPEHS. There was speculation that these moves could destroy the relative independence of the agency. At the December 3rd meeting, that I mentioned earlier, Mr. Rankin made a speech which was characterized to me by a member of my staff who heard it, as a "bomb shell". He reported that in his view it was designed to acquaint the conferees with the fact that FDA had taken about as much reorganization, over the past year or so, as it could stand without detracting from its role as an effective consumer protection organization. This speech threw down the gauntlet to anyone who was interested in the ultimate fate of the Food and Drug Administration. In effect it said, if you would like to see the Food and Drug Administration go out of business, why then just sit back and leave things alone because that is what is going to happen to us. If you don't

like that, then you had better do something about it. Because of illness I did not attend that meeting and I did not hear that speech. As I said, I had it reported to me by a staff member who was there and then I, of course, subsequently read about it in the trade papers. Two days after the speech I got a call from Mr. Rankin, who asked me if I had heard it. I told him the circumstances, that I had not, but that I was aware of it. He said at that time that he intended to do what he could to save the Food and Drug Administration. He speculated that it might not be possible to do much before the new administration came in the 20th of January, but he proposed to do whatever he could.

I think it's important for any students of history to understand the significance of what Winton Rankin did in December 1968. He was a career employee with perhaps thirty years service, at that time, but he was not eligible for retirement because he had not reached the age at which he could retire. Yet, he very deliberately set about, in the best way he could, to save an organization for which he had worked for most of his adult life. This, in effect, since his action was done publicly, put his head on the chopping block. I am convinced that what he did set in motion a pattern of events which culminated approximately one year later with the dissolution of the Consumer Protection and Environmental Health Service.

However, at the same time it also cost Mr. Rankin his job but I am certain that he realized that that might be the outcome, and he was willing to pay that price in the interest of having an independent Food and Drug Administration.

Young: Eventually the document did come down making the Food and Drug Administration, in what proved to be temporary fashion, subservient to CPEHS. How did the new organization affect life in the field, as you viewed it in Baltimore?

Kinslow: Well, it was really more of an annoyance than anything else because the people in the field organization had a very strong feeling that CPEHS was not going to last. It was essentially a "lame duck" creation of the prior administration, or at least the organizational statement certainly was done in a "lame duck" fashion after the election. With the change of administration, we anticipated that it was just a question of time until CPEHS would no longer exist. So, I don't know a great deal about what was happening in headquarters but I know that in the field we just resisted, at every opportunity, and tried to carry out our activities in the best way possible. At the same time we had to pay lip service to the regional administrators for CPEHS and the one with which I dealt was located down at Charlottesville, Virginia. So, I periodically had to get in my automobile and drive from Baltimore down to Charlottesville and listen to this chap down there talk about all

sorts of things. Then I would tip my hat, get in my automobile, go back to Baltimore and run the Baltimore District pretty much as I had before. I think the hierarchy of CPEHS was nervous enough about their future so that they didn't try to exercise the line management control which they could have under other circumstances. For example, they sent out some directive about having the name "Consumer Protection and Environmental Health Service" put on our buildings, either on the windows or as some other kind of sign on the exterior. For some reason we just never got around to doing that in Baltimore. I know that some of my other colleagues for some reason or other were never able to make the appropriate arrangements to have that name put on their windows or otherwise identify their buildings in that fashion. We had some meetings where Mr. Johnson, Charles C. Johnson, the CPEHS Administrator, spoke to us, and they were pretty deadly I might add.

I became involved in a project in May of 1969, which totally preoccupied me for many months thereafter, and frankly I didn't have time to even think about CPEHS during that period. Perhaps I should start describing that assignment, unless you have some other questions about CPEHS?

Lofsvold: Just a comment. One thing that I think made it difficult for the Regional Administrators to get any

kind of hold on FDA was the fact that they never did get around to moving the budgeting and accounting function from the FDA offices to their offices. We kept control of our money in the field, rather than having it thrown into some common pot that could be administered by the Regional Administrator.

Young: Then, finally, the end did come of this CPEHS fusion. That was an administrative decision by the new administration, after it had time to consider what ought to be done from its perspective with respect to all the agencies of government.

Kinslow: That is entirely accurate. Indeed the final dissolution of CPEHS occurred February 1, 1970. However, the decision was made January 5, 1970. That is when Secretary Finch signed the order and that, of course, was after Dr. Charles C. Edwards came on board as the new Commissioner in late December 1969.

Young: Well, we put a period at the end of that sentence. I think it is proper, in sequence, now to have you turn to this engrossing assignment that you have alluded to, just a minute ago.

Kinslow: Well, I was called in to talk to the Commissioner in the late spring of 1969 and he asked me to head a group to take a look at the Food and Drug Administration. The group consisted of several folks in the agency who could be

considered youngsters in terms of their total tenure with the agency.

Young: This was Commissioner Ley.

Kinslow: Yes, Dr. Herb Ley.

Young: Just a word. What relationships did you have with him prior to this?

Kinslow: Well, he had taken over as Commissioner when Jim Goddard left in July of '68. So, at that point I had been serving under him for approximately one year as a District Director reporting to him as the Commissioner. I had previously had some dealings with him while he was the Director of the Bureau of Drugs, prior to July of '68. So, I had not known him as well as I knew Jim Goddard. But since Winton Rankin was still the Deputy Commissioner I could see his fine hand in the fact that Herb Ley called me in to talk to me about this assignment.

The Commissioner wanted a group to take a look at the agency and be completely candid as to changes that we thought should be made. We were not supposed to be restricted by limitations of whether or not we had legislative authority, whether or not we had enough people, or whether we had enough money. We were just supposed to take a very broad look at the agency and make recommendations to the Commissioner about things we thought should be considered for change. I started to say previously that this

group was made up of fairly young people who did not have long tenure with the agency and the idea here was supposed to be that we would be able to have a fresh perspective. I had been around, at that point, for less than eight years. Some of the other folks who served on the group had been around slightly longer but not a great deal longer. We worked for many weeks in May and June of 1969 in Washington on this project. We met with people from all over the agency. We got their ideas and their recommendations. For example, I think that we met with all of the Bureau Directors. We tried to get a broad cross section of opinion. Then we had to come up with a report for the Commissioner. As Chairman of the committee, it fell on my lot to do the final drafting of the report. Of course the other members of the committee worked on various sections and recommendations, but somebody had to take all of this and try to pull it into one reasonably cohesive document and that job fell to me. I must admit it was a very onerous job. I ultimately took all of my files and materials back to my office in Baltimore to work on the final draft.

I must tell you that I was so frustrated by this project, that I came close to leaving the Food and Drug Administration. The reason for my frustration was that in trying to carry out the charge from Commissioner Ley, we in effect were saying there were many things wrong with FDA that

needed to be changed. While some members of my committee felt very strongly about some of these things, I frankly did not feel that strongly about most of them. I did not think that FDA was that badly managed, or that badly organized. As a consequence, I had a terrible conflict in trying to carry out the charge from the Commissioner and still do something that I could live with in good conscience.

In any event, I ultimately pulled together what was a draft report to the Commissioner. I delivered it to him and promptly went on annual leave, to take vacation. I took my family back to Indiana to visit with our families there. We first spent some time in my home town of New Albany, Indiana and then we went north to Indianapolis, which was my wife's home town. I'll never forget sitting in the living room of my mother-in-law's home one evening when the 6 o'clock news came on T.V. I was carrying on a conversation with somebody else in the room, but suddenly I heard some of my own words in my ears and my attention was drawn to the national news report. That was how I learned that somehow the draft report that I had delivered to the Commissioner had gotten in to the hands of the press and was becoming, or apparently already was a cause celebre, since it was on the national news. It was a very unsettling experience, to say the least.

Within a day or two, I received a call advising me that I needed to get back to Washington because there were going to be Congressional hearings on this report.

Regrettably, as the Chairman of the committee and the author of the final draft, the report became known as the Kinslow Report. I can assure you that the last thing I wanted was to have my name associated with that report. But regrettably that's what occurred. I find it almost beyond belief that, over thirteen years later, there are people who still dredge up that report. I was in Washington, only last week, for a Regional Directors meeting and heard two high level officials of the agency refer to it on separate occasions.

Young: Let's go back to the beginning of the report. The appointment of the committee and you as chairman to do it. What, rather specifically were the directions that were given to you by Commissioner Ley? What was the motivation for undertaking this kind of study of FDA's mission at this particular time.

Kinslow: Well, it was pretty well set out in the memo that the Commissioner sent to me and other members of the group, which was called a study group. We were supposed to define the consumer protection objectives of FDA, analyze and compare the agency's programs in light of these objectives. We were to identify existing or anticipated problem areas

resulting from gaps between the objectives and current programs and suggest changes in programs to meet these objectives. This was a very large order and we recognized it. The Commissioner said that he thought it was something that we needed to undertake immediately to be assured that we had explored every possibility of meeting our consumer protection responsibilities to the fullest. And he wanted us to undertake this on a full-time basis from the first week in May and wanted a finished draft proposal from the group by June 13. So that gave us about 6 weeks. I didn't meet his deadline, we didn't have a draft until July 14th.

Young: What about the environment within which the agency was functioning. Do you believe it called for a study at that particular time?

Kinslow: Well, I didn't make the connection at that time but one very important thing that was going on then was that we had had Nader's Raiders in the agency for a considerable period prior to May 1969. In retrospect I imagine that they provided significant impetus for Dr. Ley to conclude that there should be this kind of a review of what FDA should be doing and how well we were doing it.

Young: The short time-frame makes it apparent he wanted to beat the deadline of the researchers for Nader.

Kinslow: In retrospect I think that one can draw that conclusion but I certainly did not perceive that at the time.

As a matter of fact, I originally made no connection between the two.

Young: You were absent from Washington when these young people working with Ralph Nader were given permission to have free access to the records.

Kinslow: That's correct. I was in Baltimore at that time.

Young: And so the decision to permit free access to the records of FDA, a decision which was not made by all federal agencies was the one that you weren't privy to.

Kinslow: I was not. I had no idea who made the decision or the basis upon which it was made.

Young: Well, then what about the process of the reaching of a conclusion. You indicated that there were some who, like yourself, felt relatively satisfied with the way the agency was organized and functioning. And there were others within the agency . . ., I take it all members of this committee came from within the agency?

Kinslow: That's correct, perhaps I ought to identify the other members. There was Dr. Robert Angelotti from the Bureau of Science, Mr. Tom Brown the Detroit District Director, Dr. Marion Finkel from the Bureau of Medicine, Mr. Nathaniel Geary from the Bureau of Compliance, Mr. Leroy Gomez from the office of the Assistant Commissioner for Planning and Evaluation, and Dr. Richard Lehman from the Bureau of Veterinary Medicine. Dr. Angelotti was the most

recent . . ., let me say that another way. He had come to the Food and Drug Administration most recently from another part of the Department, from the Public Health Service. When the Commissioner charged us, he said that while the members of the group would be expected to bear the major burden of preparing the study, that it might be necessary for us to call on other bureaus, offices or districts for assistance. And we did indeed conduct interviews, as I mentioned earlier, with a broad cross section of representatives of the agency. After we did that, we started developing recommendations. The dynamics of this particular group turned into quite an interesting exercise. I can say interesting now because I look back at it from the perspective of over 13 years. At the time, it was in some respects, very unpleasant because we had some very strong opinions, divergent opinions on a number of things. I must say that the most bitter conflicts occurred between Dr. Angelotti and me and some of my other colleagues on the committee. Dr. Angelotti had a perspective from working in the Public Health Service that was significantly different than ours and he was a very forceful personality. There were times when I very cheerfully would of been happy to have thrown him out the window of the 5th floor office in which we were working, except that that building had fixed windows and you couldn't open them.

Young: Could you give a precise example from memory of the thrust of one of these sharp debates?

Kinslow: No, I really can't recall any specifics at this time, but I do recall that we had some fundamental differences of opinion regarding the philosophy of enforcement. How we should be going about our business. Dr. Angelotti, although he had been with the agency but a few weeks, had some very strong views as to how we should operate and we simply had strong differences of opinion.

Young: Well, the report was a stone thrown into the water. What kinds of ripples resulted?

Kinslow: Well, there were some very large ripples. For one thing, Congressman Paul Rogers had some hearings regarding the report, and the whole committee or study group was invited up. We were asked about various recommendations, what led us to various conclusions that we had made and the hearings received a great deal of publicity. As I mentioned earlier, it was sent to the Commissioner in draft form and then in some fashion, and I do not know how, was leaked to the media. As a result the report was never produced in anything except that draft form because it got into the public domain before anything further could be done with it. I sincerely did not recognize this at the time but I feel rather strongly now that there was a major game plan involved in the creation of this group to look at FDA and come

up with recommendations about what's being done right and what should be revised. Because the media attention to our report in effect stole the thunder from the Nader's Raiders, who were getting ready to come out with a report on the Food and Drug Administration that was going to be very negative. And when somebody does an internal review and says these are the things I have wrong in my operation and this is what I should do about modifying them, he is a less likely target to be beat over the head with deficiencies than somebody who hasn't made their own personal evaluation or audit. As a consequence, the Nader report was delayed for quite a long time, I guess to let some water go under the bridge before they took their shot at the Food and Drug Administration. And in the process, they developed a chapter on the "infamous Kinslow Report" and said some very nasty things about the report and about me personally. In the interest of having a complete record for history, I would like to note that I was the only living person mentioned to any degree in the book that they published on the Food and Drug Administration, the author of which was listed to be James Turner, who was not interviewed by Nader's Raiders. They at least had the courtesy of interviewing everybody else mentioned prominently in the book. They gave them an opportunity to respond to various things that they proposed to say. But they never interviewed me and I consider that a very unprofessional aspect to that document.

Young: In a general way how would you compare and contrast the Kinslow Report and the Nader Report on the agency.

Kinslow: By the Nader report you are talking about the book entitled The Chemical Feast?

Young: Yes.

Kinslow: Well, the report that my study group made had a lot of recommendations regarding structure, management, and processes. The Nader blast was, in many respects, directed towards specific actions that we had taken or not taken on various food products and had a lot of verbiage charging political influence by various people. It was a totally different kind of look at the Food and Drug Administration than ours was. As I mentioned before, my report was taken to task, very extensively, in a chapter that I believe was entitled "The Kinslow Report Fraud."

Young: You characterized for us on the basis of your observation, Commissioner Larrick and Commissioner Goddard, would you do the same for Commissioner Ley?

Kinslow: Yes, I would like to very much because since I reported to him as a District Director and subsequently took on the special assignment, I had a lot of personal contact with him. I found him to be a very honest, decent person to work for. I respect Herb Ley; he was very different than either George Larrick or Jim Goddard, but I'm convinced he was dedicated to the best interests of the American public.

And indeed, I believe that he got into significant trouble during his last days in the agency during the fall of 1969, in connection with the banning of cyclamates because he did what the Secretary told him to do. He was a good soldier. He would get called over to the Department to participate in meetings associated with the proposed banning of cyclamates. He would be told, "Do not discuss this with any of your staff members when you return to the Food and Drug Administration." And being a good soldier he came back to the Food and Drug Administration and did not discuss it. I suspect that that partially was responsible for his demise because it's impossible for the Commissioner of Food and Drugs to be as technically well advised as he should be on something that complex without getting counsel from his subordinates. I don't know for a fact that it occurred. I was back in Baltimore, happily back in Baltimore after spring, summer and early fall spent in Washington. And so I only know that from being told that was the case. But the source of my information is such that I believe it to be true.

Young: I'm puzzled as to why he was so instructed.

Kinslow: Because the issues that were being discussed at the Departmental level were so sensitive that Secretary Finch and his subordinates didn't want them to leak out before they were made public.

Young: Sensitive for...you mean for financial sensitivity or political?

Kinslow: Probably both. Because the decision under consideration was to ban a very popular non-nutritive sweetener used in literally hundreds of different products. So it was a very touchy situation as it was developing. I believe they were trying to keep it very close to their vest, until the final decision was made and then it would be announced and everybody would be in the same boat at the same time.

Young: It was a FDA decision that the HEW people were coming to agree to, is that...

Kinslow: That's an interesting question Harvey. It was an FDA issue that I believe was decided at the Department level. I'm simply giving you my personal perspective. One other thing that I would like to say about Dr. Ley is that he happened to be the Commissioner of the agency through essentially the entire period that FDA was in CPEHS and while he was not a long time FDA'er, I know that he worked vigorously to get the agency out of CPEHS because he spoke to us very openly about this during the meetings he had with the District Directors from across the country.

Lofsvold: And then soon after the cyclamate affair we had a change in Commissioners in a rather sweeping reorganization. Can you tell us something about your role in that?

Kinslow: For the second year in a row some rather interesting developments occurred at the Food and Drug Law Institute meeting in December 1969. I've previously described the speech that Winton Rankin made at that meeting in December 1968. In December 1969 I did attend the meeting because we had heard that Deputy Undersecretary Malek was going to be on the program and talk about his review of the Food and Drug Administration. We anticipated that there might be an early change in Commissioners. There was a lot of electricity in the air and I decided that I would go to this meeting and see what I could find out. The interesting personal development was that during the lunch hour I was advised that the Commissioner had called asking for me to get in touch with him. So I called Dr. Ley and he asked if it would be convenient for me to come to his office that afternoon. I told him "certainly I would". The FDLI meeting was being held at the Marriott Twin Bridges hotel so I was only a few blocks from Crystal Plaza. I went down to the Commissioner's office at the appointed time, which was approximately mid-afternoon. He told me that a new Commissioner was going to be taking over the Food and Drug Administration almost immediately and that this new Commissioner, Dr. Charles Edwards, had asked that I come in to meet him. I said that I would be very pleased to do that. I can't remember whether I met Dr. Edwards that afternoon or the

following day but at one of those two times I did meet him and he asked me if I would be willing to serve on a special assignment in connection with his taking over the agency as Commissioner. I was very surprised by this, and frankly at that point didn't understand why I was being given this opportunity, but I agreed that I would do so. Fortunately, I lived at that time at Laurel, Maryland, which is approximately half way between Washington and Baltimore. So instead of getting up in the morning and heading my automobile north towards Baltimore I could get up and head it south toward Crystal Plaza and it was very convenient.

Young: Maybe he knew where you lived.

Kinslow: No, no I don't think so. He knew where I worked, he knew I was the Director of Baltimore District. But at that point I'm sure he knew absolutely nothing about where I lived. As a matter of fact, I found he really knew very little about me at all except that I was associated with the infamous Kinslow Report. He had been serving as some sort of consultant or advisor in the office of the Assistant Secretary for Health for some weeks prior to that and I assume that he saw or heard about the report during that period. With that introduction and opportunity offered to me by the new Commissioner, there began one of the most fascinating, exhilarating and debilitating periods in my life because the new Commissioner was still living in the

Chicago area. I started serving as his Special Assistant during the last week or so of December 1969. He was spending a lot of time back in Chicago trying to wind up his affairs there and so we talked a lot on the telephone, nights, on week-ends and during work days when he was out there. During this period, Dr. Edwards was learning about the many responsibilities of the Food and Drug Administration and he was constantly receiving briefings on the multiplicity of programs in the agency. It can be almost overwhelming for an outsider who has never had day to day contact with the agency to come in and learn about the breadth of our responsibilities. Dr. Edwards was somewhat overwhelmed by the enormous amount of responsibility he was learning was vested in his office and in his person as Commissioner of Food and Drugs. And I well recall a weekend conversation I had with him when he was in Chicago. He was relating to me a newspaper story he had seen that day in which he said there was some other poor bureaucrat in a lot of trouble because of human waste on the railroad tracks. It was my unpleasant duty to advise Dr. Edwards that he was the unfortunate bureaucrat because that program also fell under the jurisdiction of the Food and Drug Administration. However, notwithstanding the significant amount of information to be absorbed rapidly, Dr. Edwards moved very quickly to implement a very significant reorganization of the

Food and Drug Administration. Some of the basic elements of that reorganization were recommended in the so-called Kinslow Report.

Young: Is that the basic reason that he had called you in for this special assignment?

Kinslow: If your asking me did he call me in so I could be involved in this reorganization, I don't think so.

Young: I see.

Kinslow: I don't really think so. It was just a circumstance where coming in as a person who had no real involvement with the Food and Drug Administration, I think he wanted to have somebody there that he could consult outside his immediate office staff. The Kinslow Report was seen by many people as the product of mavericks within the agency and therefore I think he wanted to have some opportunity to tap this maverick attitude as opposed to the old line Food and Druggers, if you will. What he didn't recognize was he was tapping somebody who was as old line in much of his thinking as anybody else he could have brought in, although that didn't seem to impact negatively on our relationship. One of the things that did impact most negatively on me was that being a surgeon he was a very early riser and he wanted to start the business day at the ungodly hour of 7:00 a.m. I was not accustomed to being up and about and doing business at 7:00 a.m. This represented something of a wrench on

my personal life, but in the process I did my best to accommodate that and at the same time explained to him he could not expect assemble rooms full of government bureaucrats at 7:00 o'clock in the morning, it just wasn't done. Young: While you were there at that high level, there were a lot of new people who came into the agency under the reorganization. Could you define the reorganization first of all?

Kinslow: Yes, it essentially changed the Food and Drug Administration from an organization built along functional lines of science, medicine, enforcement, and voluntary compliance to one that was organized along product lines. And each of the product-oriented bureaus was in a sense free standing. Each had its own compliance activity, its own voluntary compliance activity, its own science activity, etc. So it was a very fundamental change in the organizational structure of the headquarters of Food and Drug Administration. It changed hardly at all the way the field offices were organized.

Young: What was the rationale for this change and whose basic idea was it?

Kinslow: Well, I must admit that some of the basic ideas came out of the task group that I headed and it was because of the changes in the industry, the increased sophistication of the industry, the divergence of technical processes associated with food production versus drug production, for

example, versus medical devices, versus veterinary drugs. It seemed that there could be greater focus brought to developing our own scientific expertise, our own technical competence if we were organized around product lines. With this modified organizational structure, Dr. Edwards had to bring in new bureau chiefs. Because there was an elimination of other high-level officials at the time Dr. Ley left, Dr. Edwards had other high-level positions in his office to fill; the Deputy Commissioner slot, and the Associate Commissioner for Compliance. And so over a period of months, there were many new faces principally at the Deputy Commissioner's level and the Bureau Director's level are coming into the organization.

Young: Why is that? Was a high proportion from within the agency brought in from the field or was there a high proportion of completely new faces?

Kinslow: A high proportion of completely new faces.

Young: Who didn't have knowledge from experience as a tradition to...

Kinslow: That is correct.

Young: So when policy issues were discussed by this group, a good deal of reliance was placed upon the old hands necessarily, at least to make certain suggestions?

Kinslow: Well, that was the case initially. However, as time passed, the Commissioner became more comfortable with

his new team and there was less and less reliance placed on, as you characterized them, "the old hands."

Young: Besides yourself, who were the chief old hands?

Kinslow: The chief old hands were essentially all in the Commissioner's office. In addition to myself, there was Mickey Moure as the Assistant Commissioner for Administration, there was Paul Hile who was the Assistant Commissioner for Field Coordination, and there was Sam Fine who was the Associate Commissioner for Compliance, and of course there was Billy Goodrich who was the General Counsel. On the other side we had the new Deputy Commissioner who was Jim Grant, and the Director of the Bureau of Foods who was Virgil Wodicka, we had Henry Simmons who was the Director of the Bureau of Drugs, we had Malcolm Jensen as Director of the Bureau of Product Safety, and a new Assistant Commissioner for Planning and Evaluation, who was Sherwin Gardner.

Young: With the great many new people, and just the relatively small number of old timers, if we may call them that, was there any sort of policy split that might be detected?

Kinslow: Yes, there was one that was very evident to me. I increasingly found myself in meetings where I would be along side Mr. Goodrich on one side of an issue and essentially everybody else at the table would be on the other side. Now I'm talking about dealings with, principally with bureaus, because quite often when we were discussing issues that

related to compliance or field activities, why I would have allies in Sam Fine or Paul Hile or with Mickey Moure on Administrative matters. But when we were talking bureau programs or issues, very often they were not involved. As I said, more and more, I saw Bill Goodrich and me on one side and the other folks on the other side. This suggested to me that maybe the relevance of the position I was holding was diminishing. I decided that perhaps my usefulness to Dr. Edwards in Washington was becoming less important and perhaps it would be better if I got back to the field from which I had come into that job and which I enjoyed very much. So about February of 1971 I suggested to him that I would like to go back to the field. At that point he assured me that he wanted the role of my office to continue and told me he did not want me to go back to the field so I dropped the subject for the time being. However, a few months later in May 1971 when I learned that Bill Goodrich was retiring, I went back to Dr. Edwards and again told him that I thought it was in my best interest and the agency's best interest for me to go back as a field manager and at that point he agreed to send me back to the field.

Lofsvold: Is that when you came to Atlanta?

Kinslow: Four months later I came to Atlanta, yes.

Young: I'd like to have you characterize Dr. Edwards as Commissioner, his management style, anything in the way of significant innovations besides the reorganization, with

respect say to policy. How he compares with the other Commissioners, with whom you worked.

Kinslow: I was so closely associated with him that it's somewhat more difficult for me to characterize him. He had a much different management style, in that he believed in pulling together his management team, I'm specifically talking about the bureau directors, and letting them run their own operations. I very often wanted him to interject himself more in the activities of some of the bureaus where I perceived there were problems. He really did not like to do that but was willing to do so with adequate cause. But he believed in letting these high level managers do what they were getting paid for. I can't quarrel with that approach to management, but from time to time, there were some of them that I thought needed to be knuckled! He was very capable of knuckling somebody but he didn't relish the idea of doing it. So I sometimes felt like I had to make a nuisance out of myself with regard to some issue to achieve this kind of high level intervention in some of the bureau activities. I might add that because of the nature of my responsibility as Assistant Commissioner for Program Coordination, I was widely disliked by the bureau directors because I constantly was getting into their bureau's affairs and they didn't care for that. Of course it was my responsibility to look into things that needed more attention, but I wasn't the most popular guy in the organization.

Young: Policy, nature of relationship with the regulated interests?

Kinslow: I had a very broad mandate. It could deal with policy, it could deal with programs, it could deal with personnel. I was in effect the Commissioner's troubleshooter, and so my area of responsibility crossed all of those boundaries and you can imagine that with that kind of mandate and a staff to look into various issues, from time to time I ended up at cross purposes with bureau directors.

Young: How about Dr. Edwards, how about his general point of view in the particular administration in which he was serving. How did he define the agency's relationship with regulated industries? Some different from Goddard's, say?

Kinslow: There's one thing that we have to recognize and that is while Jim Goddard was the first outsider to be brought in as a Commissioner of the Food and Drug Administration, he was not a total outsider because he was in the Public Health Service Commissioned Corps and had previously been working within the Department. Herb Ley, who succeeded him, also came from a position as a Bureau Director to the Office of the Commissioner. And so Charlie Edwards was really the first totally political appointment to the office of Commissioner of Food and Drugs. As a consequence, you might expect that he would have a somewhat different perspective than his predecessors. More importantly, he

brought people into the agency from business and industry into top level positions. They obviously had different perceptions, different approaches to dealing with issues than people who had historically been in the agency and moved up to top positions. So its only natural that we had some differing views from these folks coming in from the outside. However, I want to add that this was not a unique situation in the Food and Drug Administration. This was happening throughout the federal bureaucracy and indeed was a very calculated effort by the Nixon Administration to try to gain greater control of the bureauracy. Mr. Malek, who started in the Department of HEW and ultimately went to the White House, I believe, was a principal architect of Mr. Nixon's efforts to gain greater control of the bureaucracy.

Lofsvold: Maurice, at that time did you see any examples in FDA of the Nixon Administration attempt to apply the political test to any people who were being promoted or appointed?

Kinslow: As a matter of fact I did, Fred. I saw it very personally because my promotion to Assistant Commissioner for Program Coordination was held up for many, many months. I'm quite certain that was because I had been a life-long registered Democrat; and, in addition, when I was working on Capitol Hill in connection with the Congressional Fellowship Program in 1965, I had worked for a freshman Democratic Congressman from my home state, in fact my home district.

And then, on the Senate side, I had worked for Senator Jennings Randolph. All of these things I just mentioned were a matter of record and while nobody ever told me this, I felt certain that this was the thing that was holding up my official promotion, although I continued to operate in this job for over a year before the promotion came through. What I would like to stress regarding this matter is that Charlie Edwards persistently fought with the Department about this on my behalf and ultimately succeeded in getting their okay on it. I have to give him a great deal of credit for that because he was swimming against the tide in connection with this and I feel a very deep sense of appreciation to him for being a stand up guy in connection with this matter. He also felt that Jack Walden was the kind of person he wanted running his press operations. And he was engaging in the same kind of battle with the hierarchy of the Nixon Administration; or, at least the hierarchy in the Department, regarding Jack Walden. Jack Walden had Democratic credentials that went back to his first job in Washington working for Senator Lister Hill of Alabama.

Lofsvold: As far as I know, the only FDA field job where the political question arose was Frank Clark's appointment as District Director in Seattle which occurred during the early years of the Nixon Administration. Frank was required to get some sort of clearance from the local Republican authorities, but it really didn't amount to much.

Certainly we didn't get the kind of flak that some other parts of HEW field organization did when they were applying the political test to appointments down to as low as GS-13. Kinslow: Just after I left headquarters and came here to Atlanta as Regional Director, I also heard similar stories, as you say, regarding people as low as GS-13 in other agencies but we never had anything of that sort in the Food and Drug Administration to my knowledge.

Lofsvold: At this point we concluded the interview on September 17. We are now resuming the interview on September 19, again in Mr. Kinslow's office. The interviewers still are Dr. James Harvey Young and Fred Lofsvold.

Young: Well, as the political nature of at least the central appointment, then lower level appointments becomes more evident than in the past, does this affect policy and how do political appointments and more rapid change as a consequence, effect the determination of regulatory philosophy?

Kinslow: Well, such appointments can't help but change things because there are philosophical differences between people who have been steeped in the Food and Drug Administration operations. People who have spent their lives enforcing the Food and Drug Cosmetic Act and folks who come in from the regulated industry might see issues in different ways and they can have very honest differences of opinion. But certainly, you have the potential for some rather strong disagreements, in differences in opinion. And these have

occurred since the period when the central position, as you described it, the Commissioner's job, was clearly a political appointment.

Young: One of the big generalizations that certainly can be made about the history of the agency is that initially it went to court trying seizures and criminal actions and that eventually, under the 1938 law, it acquired the power of injunctions. And then, at some point, a shift began that has, I think it's fair to say, accelerated since to move somewhat away from that mode of regulation and into more administrative methods. This is a big question. I'd like to ask you to comment on it. Is it related to what we've just been talking about, in some measure, the shorter terms of people and the greater turn-over of the higher echelon of people when new commissioners come in? Is it, on the other hand, related to other factors and what might they be?

Kinslow: Well, I think it's partially related to those factors that you described. However, there is an additional, very significant aspect of this which you did not mention, and that is the administrative approach that was the keystone of Peter Hutt's tenure.

As Chief Counsel of the Food and Drug Administration, Mr. Hutt had an abiding conviction that we needed to publish everything that we did in the Federal Register. In addition, he thought we needed to have a very complex set of

administrative procedures governing every aspect of our activities. I think those regulations and the approach of which we are now forced to follow, even though Mr. Hutt has been gone for several years, is a legacy that will be with us for decades if not forever. They have an enormous impact on the way we do business.

Young: How would you contrast the way things were when you were District Director, was it District Director in Baltimore?

Kinslow: Yes, I was District Director in Baltimore.

Young: And Regional Director in Atlanta. On the way business is done, doing business then and now.

Kinslow: Doing business now is a much more cumbersome, convoluted procedure than it was back then. I believe that the rights of the regulated industry were fully protected by the approaches that we took back at that point 15 years ago. I think they were, in every instance, accorded due process, but it was much easier to do business then than it is now. And of course Mr. Hutt left the agency and went back to working within the framework of those regulations on the other side of the fence.

Young: This isn't to say that mode of handling things through the Federal Register that he framed was the beginning of a movement away from handling everything by cases in court to more administrative procedures. Of course it had

never been handling everything by cases in court, but as I recall, there was certainly elements of this in Dr. Goddard's approach. It might have begun, Fred, at sometimes you suggested, with the Citizen's Advisory Committee reports.

Lofsvold: Well, the second Citizen's Advisory report did emphasize the need for FDA to begin using, to a greater extent, educational means of gaining compliance with the law, rather than bringing as many formal court actions as it had in the past. And I think there was a conscious trend in Mr. Larrick's administration to do that and when Goddard came in he espoused the educational approach to an even greater extent than Mr. Larrick had.

Young: In some measure this, I suppose, is based on the presupposition that the law has been going a long time, and industry's gotten used to it, and more sophisticated, and there isn't a need for such rugged and harsh means as going to court.

Kinslow: No that isn't entirely it Harvey. There's another aspect to it and that is the theory that if you will simply layout in a detailed fashion what it is you want the industry to do, then the vast majority of people who are in that industry will comply with the guidelines that you set down for them, and there will be no need for the rigid and rugged enforcement except with a minor percentage of the industry.

Young: But in fact things do come along that are violations of the law even under this system but then what happens, much more often than going to court is recall or some other administrative handling of the problem, so that the assumption here is that either this is more efficient or that it's a more proper way to treat industry because the violation had been an accident without there being culpability. Why the constant decrease, statistically speaking, through these years in the original techniques of going to court, with the simultaneous growth of other modes of correcting errors as they appear in an industry which you do presume to be behaving better than was so initially?

Kinslow: Well, we've already talked about a number of reasons. The industry is more sophisticated, we have done a better job of explaining what we expect, in some instances in exquisite detail. We have used mechanisms, such as recall, because to get a large amount of product off of the market in a short period of time it is clearly the most efficient and effective mechanism for doing that. There have been changes in the kind of industry that we regulate, there have conglomerations of smaller operations which as individual firms probably could not afford the kind of a quality control that a larger operation can afford because at that point then they can have their extensive quality control, laboratory, technicians, and what have you. There

also have been changes in the programs that we carry out. When you're out making undercover buys of illegally distributed pep pills, versus making inspections of clinical investigators of new drugs or investigators who are doing basic work on food additive petitions, you have a different rate of regulatory activity associated with the programs that you're carrying out. So that there are a whole range of things that have occurred which legitimately have resulted in a reduction in the number of actions that we bring. Whether the number that is now being brought is appropriate in light of our programs and priorities, I won't speculate, but there are a number of reasons why you very legitimately would expect this number to shift.

Young: How about the manner of problems in going to court. In the old days, this was regarded as a chancey thing. Juries were uncertain. Food and Drug cases, at least for a long time, were not thought of too highly by local district attorneys and they tended to shun them and often the Department of Justice, as I recall, was unwilling to bring cases that the Food and Drug Administration was quite eager to have brought. Do you think that the factors of this sort had any significant place in the shift over?

Kinslow: No, I really don't think that that has had much impact, because we still have situations today where there are jurisdictions that will take our cases more willingly

than others, but that generally is not a controlling factor. A more important issue, in my view, was the change that occurred after Peter Hutt came in as Chief Counsel, regarding the office of the General Counsel. Prior to that time, there had been rather rigid supervision of the attorneys who handled the FDA's cases, our trial attorneys. Many of them had been there for a period of time and were quite skilled in bringing our cases. Mr. Hutt was able to get increases in the numbers of attorneys in the office of General Counsel, Food and Drug Division. He brought a lot of new folks in and he used a different approach to running the office. It was run more like private law practice where individual attorneys had cases and did their own thing with them. Regrettably, some of the newer folks didn't really know what to do with the cases they had and this contributed to some significant problems. Unfortunately, in my view, that approach to managing the office of the General Counsel has continued until today with the individual attorneys having pretty much full responsibility for handling cases assigned to them, and they really are not supervised and controlled in a fashion that expedites the flow of case work through that office.

Another issue that has created difficulty over the past ten years has been the fact that some of these attorneys will substitute their judgment for their client's position.

Of course, in this instance, the client is the Food and Drug Administration. Prior to Mr. Hutt, we didn't have that. We generally didn't have that sort of problem but under this law office approach we have had situations in which attorneys from General Counsel have made commitments with U.S. attorneys, and the Food and Drug field office involved didn't find out about these commitments until later.

There are some additional things I'd like to add here regarding why cases have been reduced in numbers. First, you have to remember that when lawyers are working on regulations, as they did for a number of years after Mr. Hutt came in, they don't have as much time to engage in case work and we were turning out enormous numbers of regulations for a period of several years. Also, I mentioned earlier that the kinds of programs that you carry out, very often impact on the number of cases you find. One of the things that we've done very little of in the last 8 to 10 years is economic work. In earlier times a lot of our activities were directed against economic cheats, which resulted in a number of cases: seizures, injunctions and prosecutions. In addition to that, the review process for legal cases in the Food and Drug Administration has become so elaborate and cumbersome that it can tend to stifle the initiative of individuals who would be disposed to developing cases and sending them forward. And last but not least, we have a planning

and management control system in the agency that is extraordinarily complex. It requires us to collect enormous amounts of data which is then put into a form to go into a computer and we spend a lot of time feeding a computer, and to the extent that people are doing those kinds of things, they're not out collecting evidence and developing cases.

Lofsvold: During this period of change in emphasis on court actions, Sam Fine was the Associate Commissioner for Compliance. What was Sam's role in all of this?

Kinslow: Well, as you know Fred, Sam was a long time FDAer. He represented a very positive influence in the Office of the Commissioner regarding compliance policy. As long as Sam was there, I know as personal fact that he continued to attempt to influence the development of regulatory policy in the fashion that he thought was in the consumer interest. I believe the fact that he had that role in the Office of the Commissioner was a very good thing for the American public.

Lofsvold: Did Sam have considerable influence both on Dr. Edwards and his successor, Dr. Schmidt?

Kinslow: I can't speak to the influence that he had on Dr. Schmidt because I was gone from headquarters back to the field at the time Dr. Schmidt came to the agency. But I can assure you he had a very strong influence on Charlie Edwards.

Young: I have been thinking about our conversation the other day and wanted to ask a further question that relates to the period in which you were the principal liaison from FDA with the Congress. While you were there representing FDA's interests, did you observe activity on the part of groups lobbying efforts on the part of groups that might be considered to be regulated by FDA?

Kinslow: That's an interesting question because I had an impression that I gained during that period that I think is a bit unusual. I don't know whether others would share this view or not but as you know, I did have the opportunity to deal in that area for a number of years. You would expect that the large drug industry in this country would have a very important influence in the Congress or you could expect that the large food industry in this country would have a big influence with the Congress. However, there was a group that had an influence, as I perceived it, totally out of proportion to their importance in our society. And that group was made up of people who were involved in either producing, selling or using so called health foods, irrational vitamin combinations and associated products. Many of the people who were involved in any one of those three activities, either producing, selling or using these products, in my personal view, were very close to being on the lunatic fringe. They had a fanaticism about the use of such products that bordered on something that you would associate

with fundamentalist religion. I was very surprised, and indeed somewhat perplexed, by the enormous influence that these folks seemed to have on members of Congress.

Young: Did you ever find any satisfactory explanation as to why it was such persuasive influence?

Kinslow: No, frankly I can't put my finger on that except to tell you that there are very great profits in many of these quack products. With high profits, comes the capacity for organization and mobilization of people when it comes time to mount a letter writing campaign or a project to contact your local Congressman, and all I can tell you is they seem to be very, very well organized.

Young: This is a decade before pressure of this kind did lead to the 1976 vitamin amendments which did seriously curtail the authority of the Food and Drug Administration to police this field. Did you see these people personally or are you drawing these conclusions from...

Kinslow: I'm drawing these conclusions, Harvey, from very personal experience that pre-dated the '76 amendment by 10 years. I had very personal involvement with some of those folks 10 years earlier and indeed at one time, was specifically named in an item in the Congressional Record of the United States for my part in dealing with one of these issues.

Young: I see you have the pages from the Congressional Record. This is from the House side of February 16, 1966,

Page 3072. Do you want to comment on any personal confrontation you had with people representing the camp you've just mentioned?

Kinslow: Well, I don't think that the incident is terribly noteworthy, except that there were aspects of it that are not reflected in the documents put into the Congressional Record by Congressman King of Utah. What the record doesn't show was that during the period he was attempting to get information from the Food and Drug Administration, Clinton Miller of the National Health Federation was camping outside of my door almost on a daily basis, harassing me in connection with this issue. That, of course, is not reflected in the Record.

Young: Would you describe Mr. Miller as a person, his appearance and his demeanor?

Kinslow: I find it difficult at this point to even recall what he looked like but I can remember his name and his attitude very clearly. He was a very tenacious individual who could not be insulted, who kept boring in, in his attempts to get what he wanted.

Young: Thank you.

Young: Soon after you came to Atlanta as Regional Director, and Dr. Schmidt had become Commissioner, there was an episode that made big headlines, and certainly in the aftermath occupied a great deal of the Commissioner's time, and that

was the complaints made by certain members of the Food and Drug Administration before a Congressional committee. Complaints that evidently it wasn't known to the Commissioner were going to be made when he went to testify...

Kinslow: These were the so called conscientious objectors...

Young: That was the phrase that was used. Is there any background to this which, from your experience in Washington before you came to Atlanta, that you might supply?

Kinslow: Just a bit. I knew some of the people who were involved in that particular episode. While I would not want to characterize all of the people in this way, there were some of them that I had known for some years, specifically gaining information about them during my tenure as the Assistant Commissioner for Program Coordination. In my view, they were simply malcontents, who should not have been working for the Food and Drug Administration and probably would not have been had there been stronger management exercised in the Bureau of Drugs. As Assistant Commissioner for Program Coordination, I was aware of a number of personnel, employee problems in the Bureau of Drugs during the period of 1970 and 1971. For example, we had a doctor who worked there who would take off without signing out to go play golf. We had another who worked there who was supposed to be in his office working but was off conducting a private

practice. Now neither of those individuals I mentioned were involved in the situation that you have described on Capitol Hill, but I simply raise those to point out that there were some serious personnel problems in that bureau and that some of the individuals who were afforded very gentle treatment on Capitol Hill were known to me to be problem children and had been for a number of years.

Young: How was this viewed, as to the legitimacy of the kinds of charges that were made? This was to be carefully studied but what was the first reaction within the agency when this was known?

Kinslow: I can't speak for the agency in general, I can only speak for my own reaction, and that was that I questioned whether many of these charges were valid. This particular episode had a very profound impact on the Food and Drug Administration over a significant period of time because Commissioner Schmidt took the situation very personally and became personally involved in developing responses to it and the approach that would be taken to deal with the issue. And as a consequence, that preoccupation meant that other things requiring decision did not receive timely attention.

Lofsvold: Those charges and the subsequent hearings were before Senator Kennedy's Health Sub-committee. And a few years later we were before that committee again with the

proposed revision of the drug sections of the Food and Drug and Cosmetic Act. You were somewhat involved, at least in one of those hearings, would you tell us about that?

Kinslow: During the consideration of the proposed drug bill that you've described, Senator Kennedy scheduled an unprecedented hearing out at Rockville, Maryland at the Parklawn Building to give Food and Drug employees an opportunity to testify regarding various provisions of that bill. In preparation for this, the field organization of the Food and Drug Administration had concluded that there was one provision of that bill to which we objected quite violently, which was the elimination of the strict criminal liability provision. So there was a piece of testimony developed regarding the field organization's concern with this modification of the law and I was selected to serve as spokesman for the field organization. I had a lot of help in developing that testimony. We thought it was a very good statement in opposition to revising strict criminal liability. I recall that hearing very vividly because I was accompanied by two associates, Regional Director Dick Davis from Philadelphia and the Deputy Executive Director of Regional Operations, Ron Ottes. At the conclusion of my prepared statement, the audience behind me, which probably numbered 200 or 300 Food and Drug employees, broke into spontaneous

applause, which is not appropriate for Congressional hearings, but they did it anyhow. After that had died down, Senator Kennedy asked me if either of my associates had anything to say and I told him no unless they had some questions. We were immediately excused. He seemed to be very happy to have us away from the witness stand.

Young: Can you put a rough date to this occasion?

Kinslow: I think it was in May of 1978.

Lofsvold: While we were recording the other day, you talked about the situation when Winton Rankin made his speech, which ultimately went a long way toward preserving FDA as an entity by getting us out of the Consumer Protection and Environmental Health Service. It has been my impression over the years that similar, if not such dramatic battles, have occurred and other Commissioners have made efforts to retain the independence of the agency. Have you observed anything of that sort?

Kinslow: Yes, I definitely have. As a matter of fact, some of the Commissioners in the past have described meetings that they've had at the Department. Many of our activities are very technically complex and very often we're engaged in controversies about issues which don't give us good press. I've seen some of the Commissioners almost gleeful about the fact that they've been able to convince the hierarchy of the Department that FDA activities are so different and so

specialized than the rest of the Department that they are often happy just to leave us alone and let us take care of our own business. I think that Commissioners have almost uniformly sought to achieve this kind of relationship for the Food and Drug Administration because it's almost impossible to operate the agency in any other fashion. There are now some charges that the current Secretary and his staff are dipping deeper and deeper into the Food and Drug Administration. I am not in a position at this time to conclude whether or not that is accurate but if it is, and if it continues and if the activities of FDA are subordinated to the Department, I predict that it will be a tragic mistake and it will not be in the interest of the American consumer.

Young: This calls to my mind a period in which a sort of threat to the integrity of the Food and Drug Administration was posed in a proposal to split off the food part of FDA and fuse it with something in the Department of Agriculture on the premise that FDA was more and more concerned with drugs and that the food thing should be a separate agency. I can't remember exactly when this occurred, but did this occur when you were privy to what was going on and are there any comments at all that you can make about it?

Kinslow: I believe that that proposal has come up more than once. I was privy to it to the extent that I knew that this was under consideration. I also am having trouble with

identifying precisely when it was, but the Commissioner at that time said don't worry about it, it's not going to happen. But that proposition seems to be cycled through periodically.

Lofsvold: The first I remember hearing it was when the Hoover Commission reported around 1950. And it has surfaced several times since then, most recently, I think, about 2 or 3 years ago. Generally, the fact that it would require duplication of offices, staff and support groups and so on, has been enough to discourage anybody trying to make a full-fledged split of that sort. Of course, if a drug law had passed, the one we were talking about, it would have made it simpler to have divided the Administration because that statute was based on some concepts quite different from those in the current Food, Drug and Cosmetic Act.

Are there any other subjects that you think of that we should include in this interview?

Kinslow: No, I don't think so at this time.

Young: I feel the same, I feel that we have had a very rich and reflective experience and I'm very grateful for your taking time from your busy schedule to give us a day and a half for this purpose.

Kinslow: Delighted to do it.

Lofsvold: I don't have any other questions and that note seems to be a good one to close on. Thank you very much, Maurice, for your assistance in our history project.

History

of the

U. S. Food and Drug Administration

Interviewee: Maurice D. Kinslow

Interviewer: Fred L. Lofsvold

Date: January 30, 1993

Place: Austin, Texas

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administrations History Office. The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.



TAPE INDEX SHEET

CASSETTE NUMBER(S) 1,2

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

DATE: Jan. 30, 1993 PLACE: Austin, TX LENGTH: 80 minutes

INTERVIEWEE

INTERVIEWER

NAME: Maurice D. Kinslow NAME: Fred Lofsvold

ADDRESS: 40 Wingreen Loop ADDRESS: FDA

Austin, TX 78738 Eugene, OR

FDA SERVICE DATES: FROM 1961 TO 1989 RETIRED? Yes

TITLE: Regional Food and Drug Director, Region IV
(If retired, title of last FDA position)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT	
1	A	0	1	Creation of CPEHS	
		3	2	Its effect on FDA	
		5	2	Rankin speech to FDLI	
		10	4	Delays in implementing CPEHS field structure	
		17	6	Kinslow decides to help Rankin resist	
		24	8	Delivers FDA draft of organization to Dr. Solomon	
		B	0	10	CPEHS organization published
			3	11	Political assessment of future for FDA and Rankin
	6		12	Wilbur Cohen evaluation of FDA motives	
	9		13	Rankin reaction to political assessment	
	12		14	District Directors meet with CPEHS and Dr. Ley	
	15		15	Kinslow discusses CPEHS-FDA relationship with industry	
	25		18	C.C. Johnson orders J.K. Kirk to threaten industry	

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
2	A	0	19	Johnson and Kirk continued
		5	20	Kinslow gauges Congressional reaction
		15	21	Secretary Finch leaves FDA in CPEHS for 10 months
		20	22	CPEHS abolished but Rankin career ends

Appendix: Copies of trade press and newspaper articles cited by
Mr. Kinslow during the interview

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

MAURICE D. KINSLOW

As a conditional gift under Section 2301 of the Public Health Service Act (42 U.S.C.3300cc), and subject to the terms, conditions, and restrictions set forth in this agreement, I MAURICE D. KINSLOW of 40 WINGREEN LOOP, AUSTIN, TX, 78738 do hereby give, donate and convey to the National Library of Medicine, acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at AUSTIN, TEXAS on JAN 30, 1993 and prepared for deposit with the National Library of Medicine in the form of recording tape and transcript. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

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Date: September 27, 1993 Signed: Maurice D. Kinslow

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National Library of Medicine

FL: This FDA oral history interview with Maurice D. Kinslow supplements an earlier interview with him conducted on September 16 and 18, 1982, by Dr. James Harvey Young, professor of History, Emory University, and Fred L. Lofsvold of FDA. The present interview is being conducted on January 30, 1993, at Mr. Kinslow's home in Austin, Texas. The interviewer is Fred Lofsvold.

Maurice, in the previous interview we talked at some length about a time in FDA history when the agency was submerged in the Consumer Protection and Environmental Health Service (CPEHS) and was in serious danger of disappearing as a separate agency of the government. Would you care to enlarge a little on that period of the time in our history?

MK: During my original interview, I was not completely positive in my statement regarding Dr. Goddard's involvement with the creation of the CPEHS. However, upon further reflection and review of documents, I can state unequivocally that he was actively promoting this idea.

Indeed, an article in the *Drug Trade News* of January 13, 1969, by Stephens Rippey, entitled "Dr. Goddard's Dream Fades Away," describes Dr. Goddard's efforts in promoting a new Department of Health which would incorporate the health activities and facilities of DHEW (Department of Health, Education, and Welfare) plus the environmental health activities. This article indicates that this proposal was initially recommended in December of 1966 in a formal memo to then-Secretary Gardner. It says that the hierarchy of the department were not enthusiastic about this idea, but subsequently a significantly less dramatic organization was created by incorporating the Food and Drug Administration and certain of the Public Health Service environmental programs.

However, by the time that organization was created as the Consumer Protection and Environmental Health Service on July 1, 1968, Dr. Goddard was no longer around to head it, and the organization was headed by Charles C. Johnson.

FL: I remember that in the spring of 1968 there was a district director's meeting that you and I attended at New Orleans where Dr. Goddard and Winton Rankin, the deputy commissioner, told us very openly that there was going to be this particular organization and that it was expected that Dr. Goddard would head it and that Winton would be his deputy. It's my recollection that when Mr. Johnson was named the head of that agency there was considerable concern among FDA people that this was going to have a very negative impact on the Food and Drug Administration, because the hierarchy of the new organization was almost entirely career Public Health Service officers with their particular philosophy which differed radically from that of FDA.

Then later I remember seeing in the trade press accounts of a speech that Mr. Rankin made at FDLI (Food and Drug Law Institute) early in December of 1968 where he openly requested the assistance of the regulated industry in preserving FDA. He said something, I guess, to the effect that if they had an interest in seeing that FDA continued as a separate entity, now was the time to come to our assistance.

MK: Yes, my first knowledge of that speech you described came on December 5, 1968, when I received a call in my office from Mr. Rankin. After discussing another matter, he asked if I had heard his speech at the Food and Drug Law Institute FDA Conference on December 3 in Washington. I had not because of an injury which kept me in bed for a couple of days, but I told him I had an employee who had attended who could brief me on it. He then asked if I had seen the December 2 issue of a trade paper, *Food Chemical News*. I told him I hadn't because I was just returning to my office from sick leave. He said that his speech and an article in the *Food Chemical News* would give me the picture. He went on to say that he intended to do what he could to save the FDA.

He speculated that it might not be possible to do much before the new administration took over on January 20, 1969, but he proposed to do whatever he

could in the interim. I indicated my interest and my commitment to his stated goal and agreed that with Congress out and the holiday season coming it might be difficult to do much, but it would be worth trying. He told me he did not want me to make any reports to him on this matter. I then thanked him for alerting me to his speech.

I immediately called in my food and drug officer, Mr. Pat Ryan, for a report on the FDLI meeting that he had attended. And after his summary of what the speakers said, it was clear to me that Mr. Rankin's speech was the only one of any substance. Pat's report suggested that Rankin had dropped a bombshell designed to acquaint the conferees with the fact that FDA had taken about as much reorganization over the past year or so as it could stand without detracting from its role as an effective consumer protection agency.

Pat recalled an analogy Mr. Rankin used regarding the fact that a fine watch needed to be adjusted periodically to keep it in precision working order. He had suggested that there were many ways in which it could be adjusted, and one of these perhaps would be to set it a fence post and blaze away at it with a shotgun; but in his view this would not be a very effective way to achieve the adjustment.

I was interested to learn that this speech had been delivered with Mr. C. C. Johnson sitting on the platform, and according to Pat's report, exhibiting no visible reaction to Rankin's speech. In response to a subsequent question from the floor asking if the incorporation of the FDA into CPEHS could be construed as a downgrading of the FDA's role in consumer protection, Mr. Johnson said, to the contrary, he believed the FDA's role had been strengthened by its inclusion in the new organization and referred to changes which had been made in relation to this. He presumably was referring to transfer of the shellfish certification program and the product safety activity to the Food and Drug Administration.

I located the *Food Chemical News* of December 2 and found an article in which Secretary of DHEW Cohen was said to be rushing the transfer of FDA management functions to CPEHS and characterized these as moves which could

destroy the relative independence of the agency. This was the first time I had any hint that these shifts were being contemplated. After reading the article, the full impact of my conversation with Mr. Rankin hit me. The hierarchy of the department was supporting CPEHS in dismantling the FDA, at least to the degree that it would no longer be an identifiable entity with any voice in its own future or the approaches which would be taken to solving consumer problems. And Mr. Rankin had put his career on the line in an attempt to prevent this.

FL: Did this statement by Mr. Rankin come as a surprise to you, Maurice?

MK: Well, I wasn't inordinately surprised by what he had told me. Any reorganization being carried out by an unknown quantity contains the potential for disrupting effective operations that are not clearly understood by the reorganizer. There had been a number of signs in the preceding months which didn't augur well for the FDA. The first of these came a few days after we received our first message from Administrator Johnson dated July 1, 1968. Among other things, he had assured us that no movement of people into new locations was planned for the immediate future. When I asked a Washington-based colleague about her reaction to Mr. Johnson's memo, she expressed concern, because she said it contained a flat lie. People in Federal Office Building 8 were already on notice they were going to be moved.

Signs of more substance continued to emerge during the months following that remark. There was a fight within the task force on organization of the field activities, which resulted in a compromise report to Mr. Johnson that was then rewritten by his staff before it was sent to Secretary Cohen. I didn't know the details about this, but I knew enough to be sure that the rewrite in CPEHS had not been to the FDA's advantage.

Then there had been the continuing delay in the issuance of the details of the Consumer Protection and Environmental Health Service organizational statements.

I think for ease of discussion, I'm going to call that organization CPE now, because that was the three-letter designation that we used to use. On September 9, 1968, Mr. Johnson issued his second employee's memo in which he reported on progress in establishing CPE to that date and predicted hopefully that the task force reports and recommendations would be approved by Assistant Secretary for Health, Dr. Philip R. Lee, before October 1 and he could report the results to us.

At our district director's conference in Denver on September 13, 1968, Commissioner Ley gave us a status report and alerted us to the prospect of being called into Washington early in October to discuss the details of this new field organization with us. The call came, but the meeting wasn't held until October 25.

At that meeting we received copies of the field organization task force recommendations, which we were told that the secretary had approved, but we were further told we shouldn't make any of this public until after the *Federal Register* document covering it was issued. That issuance was expected to come any day, but it didn't. Election day came and went, but still there was no *Federal Register* document. On November 7, 1968, at a meeting of FDA employees in the departmental auditorium, Dr. Lee took full responsibility for the delay and stated it would be published within a week to ten days, but it wasn't.

FL: Your being located at Baltimore, so close to Washington, gave you a lot better indication of what was going on. I was out in Denver at the time, and a lot of this I didn't even hear of until long afterwards.

MK: Well, that's very understandable, but it was a mixed blessing being that close to Washington. We had the commissioner visit Baltimore District on November 22, and when he met with the general staff he gave a few of the highlights of what we expected to be in the organizational document. He also told the staff he planned to name me as the principal Food and Drug representative in Region Three. This was

said to the staff without advance warning to me, but the fact that I had no advance warning did not diminish my gratitude for this expression of confidence. I concluded the publication date must be close at hand in view of his comments. This impression was reinforced when Mr. Sam Fine visited the district on November 27.

FL: Sam was then the . . . What job did he have? He was in Washington then?

MK: Yes. He was I think then the assistant commissioner for field coordination, I believe was the title of that job. However, by the time Mr. Rankin's telephone call to me on December 5, there was still no document published and no firm information about when it would be.

Another troubling factor was the continuing lack of resolution about what was going to happen to our consumer specialists. This appeared to be a power struggle between CPE and the department over the transfer of FDA employees, but about which the commissioner was being kept in the dark. And finally there was the fact that on October 1, 1968, the Divisions of Data Processing, Management Systems and Financial Management, and the Office of Policy Management, which was the inspector general activity, had been transferred to CPE. Thus there had been ample storm warnings to condition me for Mr. Rankin's assertion that he intended to try to save the FDA. But I wasn't prepared for the jolt I got when I realized things had deteriorated to the point that he felt compelled to throw down the gauntlet in public.

FL: What was your reaction when you realized what a grave step that Winton was taking?

MK: Well there was really no doubt in my mind about the general course I planned to follow. I was determined that I would do everything and anything I could to assure the restoration of an effective FDA. My enormous admiration for and devotion to Mr. Rankin both as a highly competent and dedicated public servant and

as one of the finest and most genuine human beings I've ever had the privilege to meet would probably have caused me to follow the course I chose even if I hadn't been in complete agreement with the goal he sought. But I was totally committed to the concept that an effective FDA is in the best interest of the American public, so I had no reservations whatsoever. My only concern was whether I would be able to contribute anything meaningful.

On December 9, 1968, my conclusion about the importance of Mr. Rankin's speech was confirmed when I saw the trade paper reports about it. In an extensive "F-D-C Reports" article headlined, "Deputy Commissioner Rankin Questions the Merger of FDA Into CPEHS: In Carefully Worded Speech He Warns Against Weakening Essential Food and Drug Services," I found that Mr. Rankin had been very blunt. "If you're satisfied with things as they are now going," he told them, "relax. But if not satisfied, the agency needed the help of concerned consumers and the business community."

In a shorter and less speculative article, *Food Chemical News* said that while not opposing the reorganization, Mr. Rankin had warned against the loss of FDA in the CPEHS shuffle. That paper also had a squib which said Secretary Cohen was siding with Assistant Secretary Lee's recommendation to retain administration, planning, and information functions in FDA rather than centralizing them in CPE as recommended by Assistant Secretary Simpson. It said, "Ironically, CPEHS Administrator Johnson has opposed the Simpson plan to centralize the service operations in his domain."

I participated on a panel discussing national food protection programs at a course in Current Concepts in Food Protection put on by the Environmental Health training people at Cincinnati at the Baltimore City Health Department on December 9. A co-panelist was a milk and food program man from Charlottesville, Virginia, who told me the acting CPE representative in Region Three, John Faulkner, was an

old friend of C. C. Johnson's. At that moment I felt sure I knew who the regional assistant administrator for CPE would be, and I was accurate.

FL: Then when did you next hear from Rankin as to what he planned to do on this subject?

MK: I received a call from him on December 16, 1968, asking me if it would be possible for me to come to Washington, as there was something he wished to discuss with me. I asked no questions but responded that I could be there shortly after noon. I didn't know what he wanted, but I was excited by the prospect of doing something--anything. When I arrived at his office, Mr. Rankin asked me if I could do a job for him, and I said I certainly could.

He showed me two different documents. One discussed the proper placement of the FDA in the Department of HEW outside of CPE and recommended such a change. The other discussed the things which had occurred to FDA since its inclusion in CPE and how these were increasingly diminishing the viability of FDA. It was then I learned that the shift of additional management functions to CPE probably would not occur, blocked I suspected my Mr. Rankin's speech, but that CPE was planning to take control of FDA's field organization.

The latter explained to me the cryptic comment in the report at the commissioner's staff meeting of December 10 to the effect that the *Federal Register* document would be published soon with two compromises that CPE had to make to get it signed in HEW, and the field would be told about these when the document was published. One of the compromises was a complete negation of the very clear assurance Mr. Johnson gave the directors on October 25 that the CPE representative in the field would not be a line officer but rather would be a coordinator.

Mr. Rankin said those papers had to be delivered to Dr. Neil Solomon in Baltimore that evening. I said I didn't know Dr. Solomon but that I would be

pleased to assure that they were delivered. Mr. Rankin suggested that he would like to talk to me away from his office, intimating he wasn't sure about the security of any conversation we might have there. However, we couldn't leave because he was waiting for Dr. Ley's return so he could review one of the papers. While I was there Mr. Rankin said things were looking up but joked that CPE now required speech clearance. He also said that he wasn't welcome at CPE meetings. He attended one while Dr. Ley was ill, and they acted like they'd like to castrate him. I said I hoped this didn't bother him, and he said he laughed all the way home.

While waiting for Dr. Ley to return, Mr. Rankin had to make an emergency visit to a dentist. So I waited until Dr. Ley arrived and had a chance to see the second document. He gave it to me with the advice that while Dr. Solomon's contacts had been with Mr. Rankin, I should tell Solomon that Dr. Ley concurred completely with the information and recommendations in the papers I was to deliver.

When I arrived at Dr. Solomon's home in Baltimore, his wife was not there to receive my envelope as planned. Since his son assured me that the doctor was expected home for dinner, I left the envelope with him and attached a note conveying Dr. Ley's message and signed it. I wondered later what Dr. Solomon, whoever he was, would think of a note saying what it did signed my M. D. Kinslow, whoever he was. (Laughter)

FL: Well did you ever find out who Dr. Solomon was?

MK: Yes. I didn't have to wait long. The next day, which was December 17, 1968, an article in the Baltimore newspaper carried an account of the appointment of a seventeen-man transitional committee by Secretary-designate Finch to advise him prior to his taking on a position of HEW secretary, and it revealed Dr. Solomon's significance to me. He was a member of this seventeen-person committee. Then the next day, December 18, the *Baltimore Evening Sun* had an article on Dr. Neil

Solomon which said a top post in HEW was under consideration for him. I learned in that article that he was chairman of Governor (Spiro) Agnew's Advisory Council on Health Planning.

FL: And Governor Agnew had just been elected vice president of the United States.

MK: That is correct. The following day, December 19, 1968, we received a message from Commissioner Ley which said the *Federal Register* document would be published the following day on December 20, and that it would indicate the CPE field representative, who was technically called the regional assistant administrator, was to have responsibility for providing "leadership and supervision" for the total CPE effort in the region, but to continue business as usual until we received further notice. The next day, December 20, the long-awaited--which is a questionable use of the term (Laughter)--"CPE Statement on Organization, Functions, and Delegations of Authority" appeared in the *Federal Register*. It confirmed the message from Dr. Ley and appeared to set up a field organizational structure clearly under line control of CPE personnel. We took a wait-and-see attitude in the Baltimore District.

Three days later, December 23, 1968, trade sheets had stories about the *Federal Register* document, but of particular interest to me was the fact that the HEW press release about the *Federal Register* document didn't mention the major item of importance which was the realignment of authority in the field.

The next day, which was Christmas Eve, December 24, 1968, I received a message from Mr. Rankin advising the district directors to reserve January 8 and 9, 1969, for a CPE meeting to discuss the recently published CPE field organization document to be held in Washington at Federal Office Building #8. The location indicated that this was obviously going to be their meeting.

After I sent my employees home early at that conclusion of our Christmas party, a friend of mine dropped by my office unannounced. It didn't take long to hear through his light-hearted banter the message that he had been in Washington the night before and picked up information he found very interesting. He was unraveling it for me to get my reaction, but generally I just let him talk. He apparently hadn't heard about the Rankin speech previously. I did express surprise at that and chided him for letting his lines of communications go down. He was intrigued by the prospects this presented. At least some of his information had obviously come from Eugene Hegarty, Congressman Dan Flood's administrative assistant, whom my friend had let me know in private conversations he was cultivating.

He said that Mr. Rankin was in a marvelous position. All he had to do was reach out and grasp the commissionership and it was his. He said he had some powerful people interested in him, and my friend said that Rankin had had this opportunity before but was unwilling to take advantage of it. He said Dr. Ley was out because he had no stomach for the infighting that was required to acquire or maintain power. Several times during his conversation he mentioned what a nice man he thought Ken Kirk was. He also described Mr. Rankin as a good man, very tough but fair. I just let him run on generally without commenting on his statements.

We concluded our somewhat one-sided conversation when he said he had to leave to go to a Christmas party. He invited me to join him, and I told him I'd be glad to consider it but I had decided I wouldn't leave until our regular close of business at 4:30. And he said it would probably be over by then. Prior to leaving he mentioned he thought he'd arrange for Mr. Hegarty to visit an FDA district office, but I didn't take the bait. I didn't want to encourage this but thought it was an interesting possibility.

FL: Did it surprise you when your friend indicated that Rankin had a great opportunity to become commissioner?

MK: Well, I was very intrigued by this, and I thought a great deal about it, and I wanted to see him personally and discuss it; but I wondered how he would react to the speculation. I knew that he had no personal motivation in what he was doing. At the time I was considering contacting him over the weekend. But on Saturday, December 28, my wife was in bed with a bad cold and three of our children were also ill when the lead in Lefton Chinaware incident hit the fan. And I spent the day fending off telephone calls from reporters in between fixing meals for my children and looking after my sick wife. She continued her illness the following day, so all of that pretty well drove the conversation with my friend out of my mind until the beginning of the next work week.

That Monday, December 30, 1968, there was an article in that day's issue of the *Drug Trade News* about Wilbur Cohen issuing the *Federal Register* document of December 20, altering FDA's status in one of his last actions as HEW secretary. In this article he was quoted as saying, "If FDA were autonomous or semi-autonomous, it would be in a position where it would be subjected to greater political pressures. But when you say semi, then I know what they are talking about. They mean higher salaries for themselves. They believe the closer they are to the secretary's office, the higher their pay will be. And putting them down one layer in the organizational chart will prevent this."

I didn't see this article until three days later, but when I did I lost any remaining respect I had for Cohen, with whom I had worked very closely when I was in Legislative Services and he was assistant secretary for Legislation. If he had said that some people in FDA were power hungry, misguided, parochial, or narrow-minded, I could have more readily understood it. But to attribute it solely to a desire for higher salaries was in my view beneath contempt.

I spent most of December 30 on Lefton Chinaware, but I had a nagging desire to relate my Christmas Eve conversation to Mr. Rankin, and I was looking for an excuse to go to Washington.

FL: Well that shouldn't have been very hard, because you were only forty miles away.

MK: As a matter of fact, it wasn't. The next day, on December 31, I found my excuse. The Division of Case Guidance needed the Leftonware information as soon as it was ready, so I decided I'd take it to Washington and I'd see Mr. Rankin. I told him he owed me a talk, referring to our December 16th conversation, prior to his having to go to the dentist. We went to the Hot Shoppe for lunch, and he told me about discussing his speech with his wife prior to making it, and she told him to go ahead. He said he thought the drug industry was behind Dr. Ley, but he didn't know about the food industry. He asked me if I knew of anybody that was doing anything. I told him about my Christmas Eve conversation with my friend but omitted the part about how my friend thought he was in a position to become the commissioner. We discussed the reliability of my friend's information and my belief that I had been given an honest account of what he had heard in Washington.

On the way back to his office, he said there apparently was some feeling his speech was intended to undercut Dr. Ley, but it certainly wasn't. He said Dr. Ley couldn't make the speech, and I realized that was because of his short tenure and his lack of background on the full range of agency activities, among other reasons. Mr. Rankin said the speech had the completely unanticipated result of being viewed as a sign of weakness on Dr. Ley's part. My response was that it was better to be said and have this result than not to be said. I further told him that my friend said Dr. Ley wasn't viewed as being a very strong administrator. Mr. Rankin then said the worst possible thing that could happen would be to have another change of commissioners right now. He said there had been too much change and that the agency needed stability. He said we needed, if at all possible, to retain Dr. Ley as commissioner.

This came as something of a disillusionment to me, although I knew Mr. Rankin wasn't trying to unseat Dr. Ley. I felt certain he wasn't doing things due to

personal ambition. I knew him too well to believe that. But now I found myself in a position where I couldn't disagree with his view and I must work for Dr. Ley. This would have the effect of blocking the man I had thought for over three years should be commissioner. I honestly agreed to do my best for Dr. Ley.

He then said he wanted to show me a memo about acting Regional Food and Drug Directors. It was being recommended that I be named for Region Three. I told him I'd be pleased to serve for as short or long a period as they wished.

FL: Did they indicate that you would have to relocate to Charlottesville where the regional office of the department was located?

MK: No, I was able to be the acting Regional Food and Drug Director from Baltimore, but the CPE regional assistant administrator was located in Charlottesville, and I had to go down there a couple of times to meet with him.

On January 8, I participated in the CPE meeting with the other district directors, so that means you were there also, Fred, in Washington, D. C. And that meeting had a very dulling effect on me. In refreshing my memory about that time I reviewed a *Food Chemical News* article of January 13, 1969, and it's entitled, "CPEHS Johnson Asserts Authority Over FDAers." And it says, "Administrator Charles C. Johnson, Jr., laid it on the line to Food and Drug Administration staffers to play ball with the CPEHS team or get new jobs or face dismissal." I didn't recall that precisely, but I'm sure you will also recall it wasn't a very pleasant session.

However, the next day we had our own meeting with Dr. Ley and Mr. Rankin. And on the basis of confidential information they shared with us about the status of FDA, I recall the district directors broke into spontaneous applause. CPEHS was dead and didn't know it, but FDA was going forward. I was buoyed by the atmosphere created at this meeting by Mr. Rankin. I left immediately after it was

over to make a trip to Richmond, Virginia, where I had business scheduled for the next day, January 10.

On January 10, I met at 10:30 a.m. with people at the A. H. Robins Pharmaceutical Company, and at noon I had lunch with Mr. E. Claiborne Robins, president of the company, and the recently elected chairman of the board of directors of the Pharmaceutical Manufacturers Association. This luncheon gave me an opportunity to sound Mr. Robins out on the industry's attitudes about Dr. Ley, and I learned that they were strongly supporting him. And I shared with him some of the reasons why that support should continue due to the agency's placement in CPEHS.

I was very excited about the developments of the two prior days. While I was in Richmond I decided that I was going to do everything I could to get FDA out of CPE. Now I had plenty of ammunition to talk to people about. I was taking on the challenge of Charles C. Johnson, who despite Mr. Rankin's optimism obviously wasn't going to roll over and play dead. I decided to put my career on the block with Mr. Rankin's, and if we lost I would devote myself to remedying the situation. I didn't know what I'd be able to do if I lost my job, but I was sure I could find something either inside or outside of government, because I was still young enough to find something.

My trip to Dover, Delaware, the following Tuesday to the General Foods plant in connection with the self-certification pilot program would provide me with my first opportunity. I decided to take up the issue with Hal Golle, my counterpart at General Foods in connection with the program, even if I had to take him on cold.

FL: Maurice, perhaps at this point there ought to be something in the interview to explain a little bit about what the self-certification program was.

MK: It was a pilot project that was designed to permit a company to certify that because of its own internal quality control programs, it could certify that its products were in compliance with the Food and Drug Law. And General Foods had a large,

new, state-of-the-art food manufacturing facility in Dover, Delaware, which was in the Baltimore District territory. So I, as the Baltimore District director, dealt with the company and its officials in establishing and coordinating this pilot program.

FL: The program broadly speaking was one that was part of the FDA's industry education efforts trying to get industry and government involved in the common goal of zero defects or improving the quality of the food supply?

MK: Yes, it was. It came under the aegis of the newly created Bureau of Voluntary Compliance, which as you'll recall was headed by General Fred Delmore.

FL: Yes, who originally had been an employee of FDA, then had gone into World War II and reached the status of brigadier general, and when he retired came back to FDA.

MK: On January 14, 1969, I made my trip to Dover, Delaware. The meeting with General Foods set the stage beautifully for what I wanted to do, because their questions about CPEHS left openings I could drive a semitrailer through. On the way to lunch I made plans with Hal Golle for a private conversation at the conclusion of our regular meeting. When that took place I very candidly told Hal what I thought of CPEHS and that I thought it was on a calculated course to destroy FDA.

Hal was very receptive and said that Mr. Cooke, who was "Tex" Cooke, chairman of the board of General Foods, already was interested and had expressed amazement that Wilbur Cohen had put through a reorganization just thirty days before the inauguration of a new president. At first, Hal said Mr. Cooke didn't believe the staff was reading the *Federal Register* accurately. Then they drew up their own organizational chart, which I had seen and confirmed during our open meeting

as being accurate. Hal said one look at the chart told him that if someone wanted to design an organizational pattern that wouldn't work, this one would be a classic. He said that Mr. Cooke had been working with others in the industry who were also concerned.

I then unintentionally made a statement I hadn't planned to make. In an effort to impress him with my sincerity, I assured him my reading of C. C. Johnson was that he meant what he said, that my head was on the block if I opposed him, but this matter was of such importance I gladly took that risk even though I didn't know what I'd do if this resulted in the loss of my job. I was astonished when Hal said I shouldn't worry about that at all. He then asked me if I had any time schedule. At first I didn't understand his question. Then I realized he was saying, Had I set any limit on leaving government if things didn't get resolved to my satisfaction? I told him I wasn't even thinking in those terms. He said if I did conclude things were intolerable I should get in touch with him since they "had lots of contacts."

This came completely out of the blue, and while I was not excited by the prospect of being forced to leave FDA or voluntarily leaving because I was gagging on CPEHS, it was flattering and, more importantly, comforting to have this kind of contact in case I became desperate for some way to support my family. I very honestly told him I thought it was kind of him to say that, and then I let it drop.

But later he asked me again, saying, "Now do I understand you correctly that you are satisfied to continue what you are doing now?" I said, "Yes," and he said if I changed my mind to let him know. He explained he was saying this because they had been favorably impressed during our association on the self-certification program. I told him I appreciated his remarks very much.

He said Mr. Cooke was in Europe at that time but that he was meeting with Dr. Ley on January 24, and he, Hal, would be getting information together to brief the chairman before that meeting. He felt Mr. Cooke would be most interested in the information I had furnished and said to be sure to call him if there was anything else I wanted to discuss.

When I got back to my hotel room I felt about ten feet tall. By a fortunate combination of circumstances and my own willingness to follow my own best judgment of the situations, I had been able to put in a good word for Herb Ley with the chairman of the PMA, and get his message that they were in his corner, and pass on ammunition to a confidante of the chairman of the board of General Foods Corporation all within less than a week. I felt I had scored a fabulous coup.

FL: Wasn't it shortly after that then that you went up to West Virginia and learned some things from the state people there?

MK: Well, it was while I was in West Virginia on January 16 meeting with the cooperating state officials that I learned this, but I did not learn it from them.

FL: Oh.

MK: I learned it during the time I was in West Virginia, and it was a report of what I considered to be a bizarre incident involving Charles C. Johnson, the administrator of CPEHS, and J. Kenneth Kirk, who was FDA's associate commissioner for compliance. And this incredible incident demonstrated the attitude that Administrator Johnson had for the Food and Drug Administration. On January 15, 1969, Mr. Johnson called Mr. Kirk to his office to have Kirk brief him on procedures the agency has for administering the law, the legal procedures under which FDA operated. Mr. Kirk started his explanation by covering the seizure provisions but never got beyond that because it soon developed that what Johnson wanted to do was haze and browbeat Mr. Kirk.

Johnson said he didn't like court actions and pointed out that he, Kirk, was in the PHS and he could do things the way PHS does. Johnson said he wanted Kirk to send out FDA's guidelines for legal actions to every member of the industry. Kirk explained that these weren't tolerances which the agency believed ought to be met;

rather they represent the point at which the agency feels prepared to go to court. He suggested that, in his view, publicity of them would encourage industry to regress.

Mr. Johnson then said, "All right. Set up any guidelines you want and put them out." Kirk said, "If we start publicizing administrative tolerances on filth, for example, it will cause an uproar." Johnson said he wanted them publicized. He said, "We want to get the public so aroused it will go to Congress and raise such a stink that we'll get more appropriations." Kirk said, "We'd have to put the guidelines in the *Federal Register* as proposals." Johnson said, "We're not going to put them in the *Federal Register*. That causes too many delays." He said, "Just consult the experts, decide what you want to do, tell every manufacturer in the United States, and that's the way it is going to be. If the manufacturers don't meet . . ."

(Interruption)

MK: "If the manufacturers don't meet your tolerances, padlock their doors." Kirk told him we can't padlock doors under the FD&C Act. Then Johnson asked if the agency didn't have injunctive authority under the act. Kirk told him, "It won't work," and referred to a precedent case where a lower court had tried this approach but had been overruled on appeal. Johnson then said, "If a firm doesn't do what you want, we'll go for publicity. That will take care of it. 'The fear of publicity is the way to get compliance.'" Johnson went on to describe his experiences as assistant public health director in New York City explaining how he would discuss with firms that if they didn't straighten up, he was going to give their names to reporters.

This interchange took place during a two-hour conference which was very acrimonious and during which Johnson browbeat Kirk. Johnson was directing FDA--not suggesting--to adopt an arbitrary procedure which in my view would deny industry due process of law.

The following day on January 17, 1969, I called Hal Golle at General Foods and told him I had an incredible story to relate, but that it had come to me from a source which I considered unimpeachable. I suggested that since he might want to be sure he had it accurately, I'd have no objection to him putting a good stenographer on the line with us to take it down in shorthand. He did, and I dictated the details of the Charles C. Johnson/J. Kenneth Kirk incident of January 15. After the steno was off the line I said I felt sure he would see the implications of the action Johnson was directing us to take. He asked why this had happened with Kirk, and I explained because he is the associate commissioner for compliance and as such he's the commissioner's principal advisor on compliance matters.

Golle then asked me if he could read some material to me which was prepared for Mr. Cooke to see if it had the right flavor and if it was accurate. He then read me a very professional analysis of what I had told him on Tuesday. It was very thorough and accurate, and I told him it was excellent and then added, "And you didn't even take notes." We agreed we might be talking again soon.

As early as the trade papers of January 13, 1969, there were stories of Chicago attorney George M. Burditt being under consideration to be named the commissioner of the Food and Drugs. During a January 22, 1969, trip to Washington I heard that Burditt was claiming that he had the support of Senators Dirksen and Percy to get the Food and Drug Administration commissioner's job. Since I had spent the year on Capitol Hill in connection with the American Political Science Association's Congressional Fellowship Program in 1965, I decided that I would make some appointments with people I knew there to see what I could find out about the FDA commissioner's job from the Capitol Hill perspective.

My first appointment was at 5:00 p.m. on January 23, 1969. I told my contact there that I needed a political assessment. After briefly outlining the pertinent details, I asked him if there was any way to neutralize Senator Dirksen. He said it would be tough, witness the fact that there were two cabinet members from Illinois. He said things hadn't developed on the Hill to the point where he knew who the

kingmakers in the new administration were. He suggested that Dirksen's son-in-law, Howard Baker from Tennessee, did a lot of legwork in fronting for Senator Dirksen, and he might be a place to start if one wished to try to change Dirksen's view. I thanked him for his help, and he said he didn't think he had helped much.

He then asked where this fellow Johnson fit into all this. He said he had heard some unfavorable reports on him. I told him that Charles C. Johnson was the Consumer Protection and Environmental Health Service's administrator. My friend said he had heard Johnson was "an arrogant ass." I responded that I hadn't heard him called that, but we definitely were talking about the same person. I was interested to learn that his reputation was preceding him.

There continued in late January 1969 and into February to be articles in the trade press about the possibility of FDA being restored to a semi-autonomous position in HEW under the new Nixon-Finch administration. However, after reviewing the situation, it was reported in the early March 1969 lay press that Secretary Finch had disregarded massive pressures and had decided to keep FDA under CPEHS on a permanent basis. A copy of the secretary's February 24 memorandum was reprinted in one of these trade articles. In this the secretary indicated that FDA would continue to be a part of CPEHS. And he concluded by saying, "I believe that CPEHS is properly constituted to provide a central focus for our efforts to protect the public from environmental and consumer hazards. In the months ahead I think we will find that the present organizational structure will impart a new vigor in effectiveness to all of these activities." However, in less than ten months after that he signed an order which eliminated that organization from the government's rolls.

Despite this decision by Secretary Finch, during the balance of that year, 1969, as I mentioned in my earlier interview, at least we in the field to the extent possible ignored the Consumer Protection and Environmental Health Service and did as little as possible to deal with them in attempting to carry out our responsibilities and ignoring them whenever we could.

FL: It has always been a matter of regret to me that although Mr. Rankin's efforts preserved FDA as an agency of the government, he was not able to save his own career. When the reorganization of January 1969 was affected, there was no position left for him in FDA. He was transferred to the department's headquarters and given meaningless tasks until he reached the age of fifty-five so he could get his full retirement. It was a terrible waste of a very brilliant man. I saw him once during that period. Frank Clark, who was RFDD at Seattle, and I were in Washington and stopped in to see him. He was his usual cheerful self, but it was obvious that he was isolated without any meaningful work.

Well thanks, Maurice, for all your time and trouble and being so very well prepared for this interview. I think it will amplify some of the things that we've discussed previously when Harvey Young was with us and will complete this important bit of FDA history that so far as I know is not recorded anywhere in the files.

January 13, 1969

Dr. Goddard's Dream Fades Away

BY STEPHENS RIPPY
Washington Editor

WASHINGTON—The Consumer Protection and Environmental Health Service of the Department of Health, Education and Welfare is all that remains of a dream of former Commissioner of Food and Drugs James L. Goddard of a Cabinet-level Department of Health with—who but?—James L. Goddard, M.D., as Secretary.

The idea of a separate Department of Health did not, of course, originate with Dr. Goddard. It has been around Washington for many years. But, signs of germination appeared in his mind and in the hyper-active brain of Theodore O. Cron, his

alter ego and assistant commissioner for education and information, within a few months after Dr. Goddard became commissioner in January 1966.

It seemed logical to gather under a single department the vast health activities and facilities of HEW, plus the bound-to-grow environmental health activities. This still may happen at some time in the hazy future, but Dr. Goddard's idea really never got off the ground despite some rather strenuous efforts to launch it.

The dream was presented to Secretary John W. Gardner by Dr. Goddard and he was given the signal to go ahead with a plan. This was done, beginning in December 1966 with a formal

memo to Mr. Gardner, followed by briefings, replete with charts and other more or less sophisticated "presentations" to other HEW officials whose approval was needed.

They were not impressed, despite the charm and eloquence of Dr. Goddard. Nor was Donald F. Hornig, President Johnson's science advisor, who had a dream of his own which is still afloat—a Department of Science, which would encompass not only the health activities of the government, but its scientific activities as well.

Mr. Gardner didn't push the movement himself and there was definite coolness on the part of then Under Secretary Wilbur J. Cohen; the assistant secretary for health and scientific affairs, Dr. Philip R. Lee; the assistant secretary comptroller, James F. Kelly, and other key officials whose support would be needed for such a major upheaval. The matter never was presented to the chairmen of key Congressional

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Dr. Goddard's Dream Disappears

(Continued from page 1, Col. 4)
al committees without whose support, nothing could have been done.

By the time Mr. Gardner left HEW in July 1968, the Goddard dream had shrunk to an intra-departmental reshuffling which would put all HEW activities relating to the "ecology of man," including the Food and Drug Administration, under a single administrator. Mr. Gardner and Dr. Goddard understood that the latter would be appointed.

However, with Mr. Gardner's decision to leave HEW, Dr. Goddard lost his strong friend and supporter who wasn't perturbed by Dr. Goddard's other-world sorties, such as his misquoted marijuana remarks, and his not misquoted remarks about closing down drugstores. Mr. Cohen and Dr. Lee were not wave-makers, and let it be known they considered Dr. Goddard a liability, who might be permitted to continue as FDA commissioner but wouldn't be considered for a higher job.

Some of those who know Dr. Goddard well believe he might have swallowed his ego and remained as commissioner of FDA

if the new job for which he was bypassed had gone to an outstanding, nationally known scientist-administrator under whose shadow Dr. Goddard's pride would permit him to work.

But, this was not to be and Dr. Goddard had few illusions that it could be. For one thing, he had searched the country, even calling on the National Academy of Sciences for help, for an outstanding scientist-administrator to become FDA's associate commissioner for science. No such man was found who was willing to take that job, and there was little chance that any would be interested in becoming administrator of CPEDS. Secondly, Mr. Cohen and Dr. Lee weren't looking for a wave-maker. They wanted a solid man who wouldn't rock the boat.

They looked inward and found Charles C. Johnson Jr., a sanitary engineer with 20 years of engineering and administrative responsibilities in the U. S. Public Health Service, but for the preceding year New York City's assistant commissioner for health and environmental health. A personable man, and apparently a capable administrator, Mr. Johnson has let it be known that he wants to stay on in his job and demonstrate his ability to provide stronger and more cohesive all-around protection for American consumers.

at least in public!

several sections. The new version will be presented at an open meeting during APhA's 1969 conclave in Montreal, after which it is expected to be submitted to a mail ballot by the membership.

12-2-68
F-D-C Reports

No change was made in the proposed new section on advertising, which reads: "A pharmacist should not solicit professional practice by means of advertising; or by means inconsistent with his opportunity to advance his professional reputation through service to patients and to society."

The Judicial Board report at Chicago was made by Chairman Kenneth Griswold, secty. of the NY pharmacy board. It was followed by an address by the asst. staff director of the H-E-W Task Force on Rx Drugs, Dr. Mark Novitch, and a panel of community pharmacists discussing the task force's report.

When comments from the floor were invited, Delegate William Arland of Shelbyville, Ind., representing the American College of Apothecaries, unleashed gales of laughter with an observation about the extent of training needed for a pharmacist's aide. "All you need is a good-looking broad who can type," he said.

The preceding day, after discussion of changes in the House of Delegates reference cmte. procedure (see story page 25), nine APhA standing cmtes. made reports to the special meeting. Most of the reports drew little reaction from the delegates, but a sweeping criticism of APhA's PR activities -- made by Frederick Mayer of Sausalito, Calif., representing the Academy of General Practice -- drew rousing applause.

Mayer said the assn.'s PR program "stinks," and applied the same description to Poison Prevention Week materials. He termed Natl. Pharmacy Week "a dead horse," and urged APhA to turn its PR efforts to such health areas as stroke, heart disease and cancer, and to such other subjects as minority employment and Biafran refugees. Mayer criticized the PR cmte.'s \$15,000 budget, saying it should spend \$35,000 and hire a professional PR man.

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"LAME DUCK" H-E-W SECTY. COHEN RUSHING TRANSFER OF FDA MANAGEMENT FUNCTIONS TO CPEHS; MOVES COULD DESTROY RELATIVE INDEPENDENCE OF REGULATORY AGENCY

Destruction of the Food & Drug Administration (FDA) as a relatively independent regulatory agency of the govt. is imminent as "lame duck" H-E-W Secty. Cohen is reported to be speeding up reorganization steps apparently designed to transfer effective management and control of FDA operations -- as well as policy -- into the topside of the new Consumer Protection & Environmental Health Service (CPEHS).

The program of change, which Cohen is pressing feverishly before vacating his office to make way for Nixon's appointee, is creating the impression that he wants to leave FDA in a "Humpty-Dumpty" situation from which it can never be restored.

Management and operational functions which Cohen is reported to have ordered transferred from FDA to CPEHS immediately are understood to include budget and finance, planning and evaluation, legislation and information. Other operational functions have either already been transferred or are understood to be enroute.

Over the years, FDA has learned to live within the policy-making framework of the politically responsible topside cabinet level. The creation of CPEHA, and the merging of the reasonably effective FDA with the H-E-W Dept.'s moribund environmental health services, has only served to add an extra layer of bureaucracy between the regulatory agency and the politically responsible policy makers who can be held accountable. The extra layer

can't add anything to the policy recommendations of the committee on environmental health, its control conceivably could lead to the diversion of money, manpower and energy away from FDA's regulatory and scientific missions.

In fact, there is already some outside evidence to indicate that CPEHS has been leeching off FDA in the personnel area. Created at a time when limitations on the hiring and replacing of govt. personnel were imposed for budget reasons, CPEHS is understood to have lumped FDA's limited quotas into its own and to have used budget availabilities for the state of its own operations.

When first broached, there appeared to be some philosophical basis for combining the work of FDA with H-E-W's environmental health activities. But there was no real evidence at the Nov. 25-26 Airlie House, Va., conference on Human Ecology that there is any advantage in having FDA and environmental health together (see next story).

FDA Com. Ley is so new in his job that there hasn't been time enough to evaluate whether he has the leadership, skill and will to conduct an "inside fight" to preserve FDA's relative independence, at least until the Nixon Administration comes in and can take a fresh look at the CPEHS reorganization as well as the status of the regulatory agency.

Also, there is no current reading on how the regulated industries feel about the new position of FDA and the potential threat to its status as a relatively independent agency. In the past, there was some opinion among the leadership in the regulated industries that an effective FDA serves as a buffer on Capitol Hill and in the public arena.

No major protests were raised in industry when FDA was merged with environmental health, but this might have been on the assumption that CPEHS control would be a formality. This kind of assumption seldom is valid in govt.

Calif. Lt. Gov. Finch Still Best Guess For H-E-W Secretaryship

There was confirmation during the week, both on the West Coast and in Washington, that Calif. Lt. Gov. Finch, a close friend of President-elect Nixon, is the top candidate for the H-E-W secretaryship ("The Pink Sheet" Nov. 25). He is widely regarded as a GOP moderate and his acceptance of the cabinet post apparently hinges on whether GOP Sen. Murphy plans to step aside in 1970 so Finch could run for the Calif. Senate seat.

The Nixon Administration also has one undersecretaryship and five asst. secretaryships to fill in the H-E-W topside. The 162-page book -- titled "Policy and Supporting Positions" -- which was published by the House Post Office & Civil Service Cmte. as a guide to the jobs automatically open for appointment by a new president does not list any positions either FDA or CPEHS.

It can be assumed, however, that a new President or H-E-W Secretary could find a way to replace an FDA commissioner, if either felt there was need to do so. There have been no hints or indications of any kind that Com. Ley's job is in danger.

Recruitment and selection of people for topside policy jobs in the Nixon Administration is being coordinated by Harry S. Flemming, 28-year old VP in a small Alexandria, Va., electronics firm, and son of former H-E-W Secty. Flemming in the Eisenhower Administration. Working with Flemming are 13 experts in various areas of govt. activity and they hope to fill 2,000 policy posts, paying between \$20,000 and \$28,000, by Jan. 20. Nixon is concentrating on 300 higher echelon jobs paying up to \$35,000. Important to industries regulated by FDA is the post now held by Asst. H-E-W Secty. Lee.

DEPUTY COM. RANKIN QUESTIONS THE MERGER OF FDA INTO CPEHS; IN CAREFULLY WORDED SPEECH, HE WARNS AGAINST WEAKENING "ESSENTIAL FOOD & DRUG SERVICES"

Deputy Com. Winton Rankin Dec. 3 questioned the wisdom of merging FDA into the the Consumer Protection & Environmental Health Service (CPEHS). In a carefully worded speech that has to be interpreted against the background of recent reorganization moves by the "lame duck" H-E-W Dept. topside, Rankin warned against actions which weaken or destroy "essential food and drug services."

An SRO crowd at the FDA-Food & Drug Law Institute (FDLI) meeting heard Rankin warn that "it is important for all of us -- you consumers, you businessmen, and we in govt. -- to guard against a situation in which effective and essential food and drug activities are lost or harmfully diluted." The joint FDA-FDLI educational conference Dec. 3-4 drew a 753 registration.

- "If you consumers and you in industry are satisfied with things as they are now going, then you can relax and cheer at whatever success or failure we achieve," Rankin concluded. "If you are not satisfied, we need help."

In the lead-up to this sharp, but wry, comment, Rankin declared that the Food & Drug Administration (FDA) does "not exercise the full control over our program or the fate of the regulated industries that some might imagine. Our activities must be responsive to many controlling factors."

Listing the factors controlling FDA, he included: "The directives of our supervisors in the Executive Branch and the support they give; the organizational structure within which we operate; and other factors."

Rankin Could Become A Hero Or Martyr Depending On What Nixon's H-E-W Does

Rankin also listed two other factors as controlling FDA: "The wishes of the public as expressed through substantive legislation and appropriations that do or do not allow for effective administration" and "the willingness of the regulated industries themselves to participate in worthwhile control measures rather than fighting us at every turn."

CPEHS Administrator C. C. Johnson and FDA Com. Ley sat nearby on the podium, apparently unperturbed, as Rankin spoke. Earlier in the same morning session, Johnson and Ley had delivered prepared talks. Johnson's defended the H-E-W/PHS/CPEHS/FDA alignment, while Ley's, billed as his "first public address since he became commissioner" (July 1 merely mentioned CPEHS in passing. Ley talked about drug regulatory matters (see separate story).

- Rankin never criticized the CPEHS-FDA linkup directly, but he left no doubt that he disapproved strongly of high-level plans to transfer key FDA management functions into CPEHS ("The Pink Sheet" Dec. 2, page 28).

Only a handful of topside FDA-ers attended the FDLI conference, but the news spread rapidly and the halls of Crystal Plaza buzzed. Delivered with more fervor than he normally displays, Rankin's remarks carefully skirted the line of loyalty to the "lame duck" H-E-W administration.

As news of the speech spread, Rankin, who is probably one of the least likely men to win a popularity contest within FDA, was hailed by the workers in the ranks as either a hero or a martyr, depending on whether the Nixon Administration decides to revoke the FDA/CPEHS merger, or at least reverse the transfer of FDA management functions into the CPEHS.

(More

Rankin did not divulge what got his dander up, but it was known that he revised his prepared text substantially at the last minute. His talk was titled "The FDA Program for 1969" and it started with a review of the evolution of the agency's fiscal 1968-69 budget. But then he turned to the administrative structure:

○ "Last July," Rankin said, "the FDA, already a part of the Public Health Service, following a reorganization a few months earlier, became part of CPEHS of PHS. This permits a single agency to give its attention to the various pollutants and hazards that confront man because of his changing environment and the products he uses.

○ "The Service can now look at the air pollutants, the food pollutants, the drugs, which some people regard as pollutants, the various industrial and household poisons, the hazardous products man uses, and so forth, and be in a position to determine the significance of any one of them or any combination of them. At least we hope to be able to do this.

○ "There are a couple of potential problems in this arrangement that should be kept in mind" Rankin continued, explaining: "the control of traffic in food and drugs is a highly specialized activity in the U.S.; the system has evolved over more than two generations. Some of the other consumer protection systems now under the same supervision are relatively young.

○ "There is no doubt," Rankin said, "that some of the expertise which FDA has developed should prove useful to our companion agencies. We are anxious to help out in any proper way. But it is important for all of us -- you consumers, you businessmen, and we in govt. -- to guard against a situation in which effective and essential food and drug activities are lost or harmfully diluted.

○ "Don't misunderstand me; I am not opposed to general consumer protection -- I support it. But I would view with the greatest concern, general consumer protection measures that subsist at the expense of an established effective mechanism for insuring pure food and drugs."

Congress Blamed In Part For Slowdown On Voluntary Compliance Programs

Rankin went on to say that a second "potential problem" was "how to foster continuing evolution of food and drug control to meet the needs of changing times without destroying portions of that control, already developed and already serving a useful purpose." He said FDA "must continue to change" if it is to respond to society's needs, "but the change needs to be orderly, carefully thought out and constructive."

Some changes "that have been considered recently," Rankin said, "do not appear to meet these criteria." He mentioned only one, the proposal -- which "fortunately has received little support" -- to adopt a system of new drug approval similar to England's.

"It would be a serious mistake," he said "to throw our plan of control overboard in favor of a less well-developed and less effective one from another country that is only now beginning to catch up with the progress we have made over the past 30 years."

With reference to future changes in FDA, Rankin said, "we have to tinker with (it) to keep it up to date, just as you have to tinker with a fine watch occasionally to be sure it keeps the correct time." He said placing the watch on a fencepost and blazing away with a shotgun "would have a very small chance of success" and "perhaps it would be wise to avoid the buckshot approach as we tinker with food and drug control."

In his prepared remarks on the budget process, Rankin stressed that FDA had to follow "goals and financial guidelines of the natl. administration and the Congress." Breaking

of Voluntary Compliance received only 0.75%, compared with 38% for field forces, 24% for BuMed and 21% for the Bureau of Science.

Among his observations derived from the percentage breakdown, Rankin said, was that "FDA has not been very successful in getting funds to support the voluntary compliance effort." This, he said, is "the result of a number of influences" and "one of the most important (of these) is a belief" in some quarters that industry is "not ready to assume a significantly changed role; that the time for much more reliance on industry self-control is not here."

"This view is not restricted to the Executive Branch," he said, adding that a congressional cmte. (House Appropriations) "in approving our funds. . . singled out voluntary compliance as an area that is not to receive an increased push."

He was referring to a restriction included in the May 22, 1967, report of the House Appropriations Cmte. on the Labor-H-E-W appropriations bill for fiscal 1967-68. In the section dealing with FDA, the report said the cmte., in cutting \$524,000 from the \$66,749,000 Budget request for FDA, did not intend that any part of the reduction be applied to NDA approval work, or to drug efficacy studies.

Instead, the report said, "the activities on which the cmte. establishes a lower priority include education and voluntary compliance; food standards activities, including research; fair packaging and labeling; and the old-line activity of regulatory compliance" (emphasis supplied).

Later Rankin discussed self-certification in the food industry, saying that initially it would "take more FDA manpower than the conventional approach" and "I had hoped we could spend that manpower on several trials" to answer vital questions. One of these questions, he said, was: "When, if ever, should we consider extension of this control mechanism to drug mfrs.?"

C. C. Johnson, CPEHS' Head, Defends Placement Of FDA In His Bureau

"Whether we will ever learn the answers remains to be seen," Rankin declared. "We don't have the funds or manpower to run a test today on the scale needed to get good answers" as to the practicability of self-certification, "and if the current de-emphasis on FDA's voluntary compliance activities continues, then the self-certification (program) is headed down the drain."

During an hour-long Q&A session that followed the speeches by Johnson, Ley and Rankin, the deputy FDA head noted that FDA's attention to economic violations in the food industry, as well as to voluntary compliance, was curtailed by the House cmte.'s report.

"Congress did this to us," he said. "There's not a thing we can do. . . We cannot increase attention (to these programs) without receiving the wrath of the cmte., and that wrath would be reflected in a drastic way."

The question which prompted Rankin's remarks concerned the ways in which consumers could increase FDA's attention to their interests. "What can you do?" Rankin asked. "You can let Congress know if you're not satisfied."

Johnson's prepared talk dealt with the broad goals of CPEHS which, he said, was created "in a time when our Nation had reached -- or at the very least was rapidly approaching -- an environmental crisis. He enumerated eight environmental problems. The seventh he listed was that "the world clamors for new miracle drugs produced by pharmaceutical research to treat specific disease problems. Yet, in spite of our best efforts. . . they often produce unforeseen side effects, and may even offer sinister genetic threats." (More:)

Furthermore, he added, "what these new chemical formulations mean in terms of the total chemical assault on modern man is an area we have not even begun to explore."

In creating CPEHS and placing FDA, air pollution control and environmental control under it, Johnson said, H-E-W recognized that the U.S. is "courting inevitable disaster" unless it learns, "and learns quickly, to apply the scientific knowledge we have... to the problems of environment..."

"In our organizational structure," Johnson said, we have at last taken account of the interdependence and interrelatedness of all environmental factors as they affect man... As a direct result of the creation of CPEHS, FDA has assumed still more responsibilities -- in shellfish certification, training, and product safety."

He mentioned BuMed's new Office of Product Safety, with its divs. of poison control, hazardous substances, community studies, pesticide registration and safety services, and said it "will be perfectly at home because of course FDA has long experience with product hazards and their control."

The fact that FDA is now a part of CPEHS "will in no way diminish the effectiveness of the FDA in carrying out its several complex responsibilities," Johnson said. "Indeed," he added, "as time goes on and as we succeed in defining more precisely the adverse effects on man of contaminants, whatever their source, FDA should be able to perform its mission even better than it can today."

Johnson went on to say FDA "needs the support of consumer protection programs at state and local levels of govt. There is a lack of such programs now... We need, and I hope we can obtain, authority for H-E-W to fill the void, by providing financial and technical assistance for that purpose."

CPEHS' Johnson Promises To Speak For FDA To H-E-W Secty. In Loud Voice

Then he mentioned examples of FDA's "strengthening its ties" with non-federal govt. units and he advocated publication of a natl. drug compendium, premarketing clearance of medical devices and imprinting "each tablet and capsule" with the drug's identity code to assist in poison control activities.

During the Q&A period, Johnson said Secty. Cohen decided to set up CPEHS after "an administrative study of the various activities within H-E-W found that certain operations... were being carried on in four or five places..."

Responding to a question, "Has CPEHS pushed FDA down one more layer in the structure?" Johnson said "We have not in any way reduced the stature of FDA" and "if I do my job (properly), I will have a loud voice in meeting the responsibility of FDA to the secretary."

In further defense of the new hierarchy, Johnson said: "If all federal agencies reported directly to the President, it might seem better, but the govt. is just too big..." This, he said, was why CPEHS was created in a "conformation that does not just respect one part of the total environmental problem."

To another question, Johnson replied that by bringing FDA into the overall environmental scheme CPEHS "will not diminish the emphasis FDA brings, but will re-relate it (and consider the total impact of toxic insults on man. We believe this strengthens rather than weakens CPEHS; that it strengthens rather than weakens FDA. Also, it reflects (the thinking of) the President's advisory body, the Bureau of the Budget. We're not doing enough, anywhere but we don't want to drag one (agency) down to push another up."

After reading a three-part written question -- "Is there any understanding with the new administration regarding CPEHS? How will Nixon influence it? What effect will the change in administration have?" -- Johnson said:

"I can assure you that President-elect has not invited me down to Florida or to NYC. On the other hand, Congressman Laird is interested ("The Pink Sheet" Dec. 2, page 30). If there in any way evidences the concerns of the President-elect, then I would say we are going to get continued strong support. There are certain positions they consider career-type positions. Dr. Ley and I like to labor under the apprehension that we're in career-type positions."

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REPRESENTATIONS HAVE BEEN MADE TO PRESIDENT-ELECT NIXON ON FUTURE STATUS OF FDA; TIE TO H-E-W SUBCABINET LEVEL INSURES POLITICAL RESPONSIBILITY

Strong representations against downgrading the status of the Food & Drug Administration (FDA) within the H-E-W Dept. have been made to President-elect Nixon, and to key officials on his new staff, by people who have been personally and politically close to the new President for years.

An effort is being made to secure for FDA the status and relative independence it had before it was merged into the Consumer Protection & Environmental Health Service (CPEHS) via an inside H-E-W reorganization last July. Supporters of FDA pushed the "panic button" on the basis of reports that "lame duck" H-E-W Secty. Cohen was planning to transfer important management functions from the agency to CPEHS.

At this late hour, a rush by Cohen to implement a six-month old reorganization with directives transferring key FDA management functions would take on the appearance of being a political play designed to deprive Nixon's H-E-W topside of its choices and options.

- In any event -- whether Cohen decides to sign or withhold the reported FDA management directives -- there will be a "new ball game" starting Jan. 21 when Calif. Lt. Gov. Robert H. Finch, expected to be named H-E-W secty. over the weekend, takes office. Any last-minute Cohen directive in effect on Jan. 20 could be revoked with one word.

A key appointment for the future of FDA -- as well as the nation's entire medical care and biomedical research-education programs -- is the selection of an H-E-W asst. secty. to succeed Dr. Phil Lee. Among candidates for this post are Mo. GOP Rep. Thomas Curtis, defeated for re-election. Though he is not an MD, he reportedly has some support within AMA for the post. Best guess is that the Nixon Administration will look for an MD or for someone prominent in science or its administration.

All of the positions in the H-E-W topside are in the "political" category, including the undersecty. and the asst. sectys. -- with the possible exception of Asst. Secty.-Comptroller James Kelly, whose name is not listed in "the book" being used by the Nixon Administration for key appointments. A career man, Kelly, of course, could be transferred from this job, but might be kept on to provide budget continuity.

Partisans of FDA concede that the agency cannot be completely independent and must be subject to budget, management and policy or program controls imposed from the H-E-W topside. But they are unhappy about the submerging of the regulatory agency into CPEHS, heavily oriented to environmental health, and the interposing of an administrator, CPEHS' C.C. Johnson, between FDA's topside and at least the subcabinet level in the H-E-W Dept. In defending the merger of FDA into CPEHS before the Food & Drug Law Institute meeting (see preceding story), Johnson used an analogy with the President -- "If all federal

agencies reported directly to the President, it might seem better, but govt. is just too big...." At issue is not FDA reporting to the H-E-W Secty., but only direct to a subcabinet level.

Johnson confirmed the worst fears of FDA supporters when he told the law meeting that, "If I do my job (properly), I will have a loud voice in meeting the responsibility of FDA to the secty." This apparently means that FDA has been submerged another level in the dept. and that its contact with the H-E-W topline -- even with an asst. secty. -- will primarily be through an "outsider" whose major interest is in another area.

The objection is not to Johnson personally, who appears to be one of the ablest govt. men in the long-ignored area of environmental health. The pro-FDA-ers apparently feel the backlog of work to be done in environmental health is so great that men like Johnson should devote their entire time and attention to it.

- Restoration of FDA to a level in the dept. where it would have access at least to the staff of an asst. secty. would inject the element of political responsibility into the activities of the regulatory agency. Transfer of FDA into CPEHS has been defended on the ground that this puts an extra layer between the regulatory agency and the political area, but it is debatable whether this is a desirable objective.

Another Nixon appointment that could be of potential importance to agencies in the H-E-W conglomerate is the anticipated naming of Roy Lawrence Ash, head of Litton Industries and a close friend of the President-elect, to head a campaign-promised Commission on Govt. Reorganization. Ash is a pioneer in systems planning for "big science," and his conglomerate includes elements with knowledge of the health field -- Medical Economics and other related publishing enterprises; systems approaches to medical education and research.

Finch's private discussions on a possible reorganization of H-E-W move in the opposite direction from the usual approach. Generally, the thought has been that H-E-W would have to be split up someday, but Finch reportedly has broached the merging of other cabinet functions into H-E-W to make a Dept. of Human Resources.

○ TEXT OF ABBOTT LABS' "DEAR DR." LETTER ON ANALGIZER DEVICE FOR PENTHRANE ○

The FDA has called to our attention that the Analgizer Booklet "An Alphabet of Analgesia" recently mailed to you may be a source of misunderstanding for the practitioner who is not familiar with the use of an agent such as Penthrane (methoxyflurane). Although the Analgizer is designed to produce analgesia rather than anesthesia, it is essential that the practitioner be thoroughly familiar with Penthrane's characteristics, actions, and hazards, and take suitable precaution to see that the patient is appropriately supervised by trained personnel during the administration of Penthrane. The Analgizer should be restricted to the indications for Penthrane as listed in the approved Penthrane package insert. It is not available to the patient on prescription.

We therefore are currently revising our literature to clarify any misunderstanding which may have arisen from the above mailing. Until further notice, the Analgizer is offered only for hospital use. It will be available for use solely as approved through the Departments of Anesthesia in hospitals and only to other departments or physicians for use in hospitals, as approved by the individual hospital's Department of Anesthesia, or the physician in charge of anesthesia service in hospitals not having a Department of Anesthesia.

Appropriate resuscitative equipment should be available and the practitioner must be prepared to manage an anesthetized patient in the event anesthesia supervenes.

For your convenience we are enclosing a copy of our most recent Penthrane package insert. Thank you for your cooperation.

RANKIN WARNS AGAINST LOSS OF FDA IN THE CPEHS SHUFFLE

Food and Drug Administration Deputy Commissioner Rankin last week warned of "potential problems" inherent in the merging of FDA into the newly-created Consumer Protection and Environmental Health Service.

While not opposing the reorganization, he warned against FDA's program getting lost in the broad environmental program of CPEHS and also expressed concern lest broad changes which are not carefully thought out be made in FDA's operation.

Rankin's comments in a speech before last week's meeting sponsored by FDA and the Food and Drug Law Institute in Washington were regarded by insiders as courageous. His were the only reservations expressed from the rostrum during the day-and-a-half meeting about the new CPEHS setup within the Health Education and Welfare Department.

Despite strong assurances during the meeting from CPEHS Administrator Johnson that "we have not reduced the stature" of FDA, many of those who attended the meeting expressed concern in the corridors about the new status of FDA.

There was no public acknowledgement that FDA is no longer the separate entity it was at the time of last year's FDLI meeting.

Rankin said in his speech that, "I would view with the greatest concern general consumer protection measures that subsist at the expense of an established effective mechanism for insuring pure food and drugs." Asking the audience not to "misunderstand me," the Deputy Commissioner said, "I am not opposed to general consumer protection - - I support it." However, he explained his concern, as follows:

" . . . the control of traffic in food and drugs is a highly specialized activity in the United States; the system has evolved over more than two generations. Some of the other consumer protection systems now (under the same supervision are relatively young. There is no doubt that some of the expertise which FDA has developed should prove useful to our companion agencies. We are anxious to help out in any proper way. But it is important for all of us - - you consumers, you businessmen, and we in government - - to guard against a situation in which effective and essential food and drug activities are lost or harmfully diluted."

The long-time FDA-er said a "second potential problem is how to foster continuing evolution of food and drug control to meet the needs of changing times without destroying worthwhile portions of that control, already developed and already serving a useful purpose."

Again Rankin made the disclaimer "lest I be misunderstood" that "I do not oppose change - - I favor it, and the record of the past several years shows that FDA has undergone dramatic change." The Deputy Commissioner said FDA must "continue to change if it is to be responsive to the needs of our society," but he added that "the change needs to be orderly, carefully thought out and constructive."

Some changes "that have been considered recently do not appear to meet these criteria," Rankin said, giving as an example a proposal that the New Drug Application be abandoned. He continued:

"We have to tinker with food and drug control to keep it up-to-date just as you have to tinker with a fine watch occasionally to be sure it keeps the correct time.
... there are many ways you can tinker with a watch. Some are good. One that would have a very small chance of success would be to place the watch on a fence post and blaze away at it with a shotgun loaded with buckshot. Perhaps it would be wise to avoid the buckshot approach as we tinker with food and drug control."

Johnson told FDLI that, "The fact that FDA is now a part of the CPEHS will in no way diminish the effectiveness of the FDA in carrying out its several complex responsibilities." He said that "as time goes on and as we succeed in defining more precisely the adverse effects on man of contaminants, whatever their source, the FDA should be able to perform its mission even better than it can today."

As a result of the creation of CPEHS, Johnson said, "the FDA assumed still more responsibilities - - in shellfish certification, training, and product safety." As an example, the CPEHS Administrator noted establishment of the Office of Product Safety in FDA's Bureau of Medicine (See FOOD CHEMICAL NEWS, Dec. 2, Page 13). He said the Office "over the next few years will inspect the labeling of some 4,200 marketed products containing components which could cause injury or death; it will also determine the toxicity of the approximately 200 products associated with the most serious injuries."

Johnson promised to represent a strong voice for FDA at the HEW Secretary level.

Asked about his position under the Nixon Administration, Johnson said he has "no inside information." However, he said the interest in CPEHS displayed by Rep. Laird (R-Wis.) (See FOOD CHEMICAL NEWS, Dec. 2, Page 8) may reflect Nixon's position. Noting that career officials are usually not replaced by a new Administration, while political appointees are usually replaced, Johnson said he and FDA Commissioner Ley "like to labor under the apprehension that we're in career-type positions."

CYCLAMATES are expected to be shifted to a quasi-generally recognized as safe status as a result of the National Academy of Sciences' interim report, which calls for more work on the potential hazards of cyclohexylamine without any new evidence of dangers of the artificial sweeteners themselves (See FOOD CHEMICAL NEWS, Dec. 9, Page 2). FDA will probably call for some labeling limitations, along with a ban on drug use of cyclamates, when releasing the NAS report summary and conclusions this week or next in a low key manner designed to prevent any undue public concern. A final NAS report is expected by the end of 1969.

FDA HEARING procedures are being considered by Commissioner Ley in consultation with "outside legal advisers," he disclosed at last week's FDA-FDLI conference. He said he has asked advice on whether procedures now used by the agency must be used under the Administrative Procedures Act. Ley said the current dietary foods hearing has opened up the "whole question" of the hearing procedure.

HEW SECRETARY Cohen is expected to side with Assistant Secretary for Health Lee's recommendation to retain administration, planning, and information functions within FDA, Environmental Control, and Air Pollution, rather than centralize the services in CPEHS as recommended by Assistant Secretary for Administration Simpson. Ironically, CPEHS Administrator Johnson has opposed the Simpson plan to centralize the service operations in his domain.

CONSUMER BULLETIN - - Federal Register for Consumers - - has been fully endorsed by the Council of the Administrative Conference and will be proposed for approval at the Conference meeting tomorrow (See FOOD CHEMICAL NEWS, Oct. 28, Page 3).

BETTY FURNESS, President Johnson's Special Assistant for Consumer Affairs, told the annual NAM congress in New York City Dec. 5 that she will speak out on consumer issues after she has left office, and warned the NAM that the new Congress "will count among its members some of the most energetic and concerned consumer advocates that have ever served in government."

DR. LEE A. DUBRIDGE, 67, who was about to retire as President of California Institute of Technology, has been named by President-elect Nixon as his Science Advisor. The appointment of DuBridge, a renowned physicist, was hailed by the scientific community. Nixon also named Harvard's John Dunlop, professor of economics, to head a health task force, which will make recommendations to the next HEW Secretary.

CANADIAN Food and Drug Directorate has proposed lifting the exemption for ingredient statements on soups. The proposal would provide that all soups labeled after Jan. 1, 1970, "would carry a list of ingredients in descending order of proportion or in terms of percentage or proportionate composition."

TOILET GOODS ASSOCIATION named chemist Dr. Norman F. Estrin as Director of Science. He succeeds Harold D. Goulden, who retired Nov. 1 after 27 years with TGA. Estrin lives in a Washington suburb.

Top HEW Position Mentioned For Agnew's Health Adviser

By Michael Weiss

Dr. Neil Solomon, chairman of Governor Agnew's Advisory Council on Health Planning, is under consideration for a top position in the Department of Health, Education and Welfare under the Nixon administration.

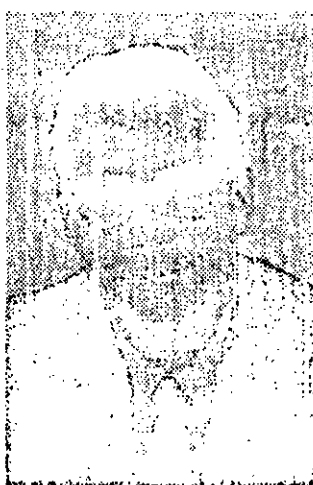
Dr. Solomon, 36, a physiologist on the staffs of the University of Maryland School of Medicine and the Johns Hopkins School of Medicine, has been mentioned as a possibility for either Under Secretary of Health, the second ranking position in the department, or one of several assistant secretarships.

"No Firm Offer"

He is in Washington today as a member of a 17-man transitional committee appointed by Robert H. Finch, President-elect Richard M. Nixon's designee as the next Secretary of HEW.

Reached there, Dr. Solomon acknowledged that, "I would think that people in this group will be offered something. But to the best of my knowledge, no one has been given a firm offer."

Other members of the transitional group include James Farmer, former national director of the Congress of Racial



DR. NEIL SOLOMON

Equality; Dr. James Hester, president of New York University, and Dr. Frank Rouse, president of the University of Alabama.

It is understood that Mr. Agnew, the Vice President-elect, has encouraged Dr. Solomon's entry into the subcabinet. Dr. Solomon would not comment about this.

Dr. Solomon has also been

mentioned as a leading candidate for state secretary of health, a position the General Assembly is expected to create at its 1969 session.

Advisory Council

The 74-member state council which Dr. Solomon was appointed to head in July was established under federal law to advise state officials on planning to meet health needs.

Dr. Solomon received his medical degree from Western Reserve University Medical School in 1961, served his residency and internship at the Johns Hopkins, and received a Ph.D. from the University of Maryland in 1965.

He was employed from 1963 to 1965 by the National Institute of Health in Washington doing research in child health and human development.

More recently, he has done research in weight reduction, helping 100 obese patients to lose a total of 6,000 pounds in a year of clinic treatment.

FOOD CHEMICALS
NEWS
12/23/68
FDA used the permissive word "should" in the requirement that equipment and utensils "should be suitable for their intended use and so designed and of such material and workmanship as to be adequately cleanable and should be maintained in good repair." The mandatory "shall" was used in requiring that equipment and utensils be designed, constructed and used to "preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants." This sentence OK's permitted residues of lubricants, whereas the original proposal had been worded so as to ban lubricant residues, whether or not they constituted "adulteration."

Requirement for Corrosion-Resistant Equipment Deleted

As a result of industry criticisms, FDA deleted requirements that food-processing equipment be corrosion-resistant and non-absorbent.

The section on water supply was revised to permit use of a qualified private water supply.

The section limiting use and storage of "toxic materials" in plants was expanded to permit those required "to maintain sanitary conditions, for use in laboratory testing procedures, for equipment maintenance and operation, or in manufacturing or processing operations."

In response to criticism of a provision that would have banned re-use of water, FDA broadened the provision to say that "water shall not be re-used for washing, rinsing, or conveying products in a manner that may result in contamination of food products."

A requirement for chemical, microbiological, or extraneous-material tests was limited to situations where they are "necessary to identify sanitation failures or food contamination . . ." The provision adds that foods and ingredients that have become contaminated may be rejected "or treated or processed to eliminate the contamination where this may be properly accomplished."

Coding of products was made permissive with a "should be utilized" provision. The retention of records provision also used the word "should," urging that they be retained for a period of time exceeding the shelf-life of the product, but not more than two years.

CPEHS TAKES LINE AUTHORITY OVER FDA DISTRICT OFFICES

The Food and Drugs Commissioner's traditional chain of command to the 17 District Directors has been overturned by the Consumer Protection and Environmental Health Service which holds line authority over FDA's field organization through the Health, Education, and Welfare regional office setup.

The long-awaited CPEHS statement of organization, functions, and delegations of authority were published in the Dec. 19 Federal Register with only one major surprise, the realignment of authority to FDA's field Districts through a new regional setup, which includes both a Regional Assistant CPEHS Administrator and a Regional Food and Drug Director, who hold line authority over the District Directors (See FOOD CHEMICAL NEWS, Nov. 4, Page 12).

CPEHS is expected to name its regional representatives soon. Until it does, there will be no change in the operation of FDA's Districts.

It had been expected that CPEHS and FDA regional officers would work in staff position, and would not interfere with the line from the Commissioner's Office.

The Regional Food and Drug Director will be assisted by an Associate Regional Food and Drug Director in each of the nine HEW regional offices.

The change in chain of command was reportedly ordered by the planners in the HEW Secretary's Office who were concerned that regional office operations would be hamstrung by communications through the CPEHS Administrator to the FDA Commissioner and back to CPEHS before actions could be taken in the field.

Administration, Planning, Information Left in FDA

One temporary victory won by FDA in its battle to retain some semblance to the previous autonomy of the agency was the HEW decision not to place the administrative, planning, and information services in CPEHS as recommended by HEW Assistant Secretary for Administration Simpson and Comptroller Kelly (See FOOD CHEMICAL NEWS, Dec. 9, Page 2).

One veteran observer noted that the battle isn't over, and Kelly is expected to press for the centralization of these functions in CPEHS if HEW Secretary designate Finch goes along with the newly restructured health activities of the Department, which include along with CPEHS, a Health Service and Mental Health Administration and the National Institutes of Health as part of a new Public Health Service.

There are behind-the-scenes efforts to undo this reorganization, and Secretary Finch's advisory committee, announced at his Dec. 16 press conference, reportedly will study this question.

Herbert Cornell, president of the United Fruit Co., is the only member of the advisory body who is associated with the food industry.

As expected, FDA's former Bureaus of Regulatory Compliance and Voluntary Compliance are being combined into a new Bureau of Compliance (See FOOD CHEMICAL NEWS, Aug. 19, Page 13). No decision has been made on the Director of the new Compliance Bureau. The merging of the old Bureaus into the single new Bureau is expected to be accomplished gradually.

The organization of the new Bureau was detailed in the reorganization document in the Federal Register. It will have two major parts. One of these is an Office of Operations and Industry Services. This Office will have a Division of Operational Services, which will develop and coordinate compliance and surveillance programs, develop "good manufacturing practices," and help develop regulation model codes, and other standards. It is understood that this Division will have Food Branch, a Drug Branch, a Data Branch, and a GMP and Model Code Branch.

The other Division in the Office of Operations and Industry Services will handle industry services, including industry education, voluntary compliance, and such activities as industry self-inspection. Branches are expected to be a Food Industry Branch, a Drug, Device and Cosmetics Industry Branch, and an Industry Self-Certification and Compliance Branch.

The other major portion of the new Bureau will be the Office of Control and Guidance. A Division of Sanitation Control will be concerned mainly with the shellfish sanitation program, which was inherited from PHS under the new organization. The other portion of the Office will be a Division of Case Guidance which, among other things, will issue "advisory opinions resulting from specific requests from industry, trade associations, government agencies, and Congress." This Division is also directed to maintain "a codified system for compiling and issuing regulatory policy and procedures for the guidance of FDA headquarters and field personnel." The Division will have a Food Case Branch, a Drug Case Branch, and a Guidelines Section.

Another major change in FDA's internal organization will be the establishment within the Bureau of Science of a new Division of Pesticides, as expected (See FOOD CHEMICAL NEWS, Dec. 2, Page 13). The new Division will handle some of the pesticide chemistry and toxicology work which was transferred from PHS and will also help review pesticide petitions.

Other pesticide functions are now in FDA's Bureau of Medicine's Office of Product Safety. This includes a Division of Community Studies to conduct epidemiology work and a Division of Pesticide Registration to review registration applications.

Petitions Control Branch Status Unchanged

There had been fears that the Petitions Control Branch, which handles both pesticide and Food Additives Petitions, might be split up in the reorganization. However, this was not done, and the Branch remains a single entity in the Bureau of Science, under the direction of Assistant Bureau Director L. L. Ramsey. The Branch, of course, will continue to work closely on petitions evaluation with other units, such as the Division of Food Chemistry and Technology and the Division of Pharmacology and Toxicology.

A new unit created in FDA under the reorganization is an FDA Training Institute. All three of the CPEHS constituent agencies - - FDA, Environmental Control Administration, and National Air Pollution Control Administration - - have Training Institutes. The FDA group is to conduct or arrange for training and

educational programs involving Federal, State and local personnel, and develop cooperative programs with States, local governments, universities, and others.

The lengthy Federal Register document outlined duties of all major units in FDA. Among other things, the Office of the Associate Commissioner for Compliance is to seek "a balance between voluntary and regulatory compliance." Associate Commissioner J. Kenneth Kirk is to be the "principal advisor to the Commissioner on regulations and compliance-oriented matters . . ."

In addition to operating FDA, Commissioner Ley and Deputy Commissioner Rankin will "participate in the development of CPEHS goals and objectives."

The Office of the Assistant Commissioner for Field Coordination, Sam Fine, has recently been built up to a staff of about three dozen persons. The Field Scientific Coordination Staff was recently switched from the Office of the Associate Commissioner for Science, Dr. Daniel Banes, to Fine's operation. The Inspection Staff was recently moved from Kirk's office to Fine's office.

An "order of succession" included in the document to provide for the absence or disability of the CPEHS Administrator or for a vacancy places the FDA Commissioner third in line. Immediate successor would be the Deputy CPEHS Administrator, followed by the Associate CPEHS Administrator, with the FDA Commissioner coming next. Below the FDA chief in the order of succession would be the heads of ECA and Air Pollution, and then the Assistant CPEHS Administrators.

~~COMMERCE PLANS TO ISSUE "HALLMARKS" FOR STANDARDIZED PRODUCTS~~

~~The Commerce Department on Dec. 20 proposed a revision of its voluntary product standardization procedures, indicating that it will establish "a hallmark which may be used as a certification mark on or for products that meet the requirements set forth in the standard."~~

~~This may be intended as an enticement for industry to use the Department's standardization procedures under the Fair Packaging and Labeling Act. So far, most of the non-proliferation voluntary standards reducing the numbers of package sizes have been worked out by industry associations, with advice from Commerce.~~

~~The Justice Department Antitrust Division recently indicated a preference for standards developed through the Commerce procedures, saying that standards developed outside of these procedures should represent the views of "producers, distributors, public bodies, (and) consumer groups" (See FOOD CHEMICAL NEWS, Dec. 9, Page 3).~~

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Lame-duck H-E-W Secty. Cohen's long-awaited Consumer Protection & Environmental Health Service (CP&EHS) reorganization statement was considerably less drastic in its dilution of FDA autonomy than the draft which environment-oriented forces had hoped would emerge.

The original reorganization plan, watered down after some intense in-fighting in the upper levels of H-E-W, would have shifted four vital functions -- budget, personnel, legislation and information & education -- in their entirety from FDA into CP&EHS ("The Pink Sheet" Dec. 2, page 28).

FDAers speculated that Cohen may have been pressured into modifying the reorganization plan after Deputy Com. Winton Rankin sounded an alarm against "dilution" of the agency's authority in a speech to the Food & Drug Law Institute ("The Pink Sheet" Dec. 9, page 9).

The reorganization, detailed in 10 pages of the Dec. 20 Federal Register:

○ Sets up CP&EHS regional assistant administrators in each of H-E-W's nine regional offices to provide "leadership and supervision for the total (CP&EHS) effort at the regional level," each to serve as "primary advisor and informant to the (H-E-W) regional director on all matters pertaining to activities of (CP&EHS) in the region" (emphasis supplied).

A few of these "regional asst. administrator" slots are expected to be filled by FDAers now holding positions as regional asst. FDA commissioners. Their jobs, established by Com. Goddard, now are consigned to oblivion by the new reorganization. The majority will be environment-attuned, however, and these may create problems of inconsistent FD&C Act enforcement as their authority is interposed between FDA regional directors and FDA top-side in Washington.

Cohen Signed Reorganization Statement, But Release Attributes It To CP&EHS Administrator

○ Consolidates FDA's Bureaus of Regulatory Compliance (BRC) and Voluntary Compliance (BVC) into a single Bureau of Compliance. This submerges the voluntary aspect -- for the time being, at least -- despite the fact that President Nixon's new administration promises to give heavy emphasis to closer coordination between govt. and the private sector.

BRC Director Alfred Barnard is expected to head the consolidated bureau, which will administer FDA's newly added shellfish sanitation control program, formerly handled by PHS's Natl. Center for Urban & Industrial Health, which was abolished.

○ Establishes in BuMed a new Office of Product Safety (OPS), with five divs. on a par with BuMed's existing Offices of New Drugs, Marketed Drugs, Medical Support and Medical Review. Heading OPS will be Gifford Hampshire, 44, former editor of FDA Papers.

○ Establishes an FDA training institute, to conduct "training and educational programs involving federal, state and local personnel in such scientific and technical areas as analytical chemistry, pesticides chemistry, advanced drug training, shellfish sanitation and certification, and science information..."

Although Cohen signed the reorganization statement, it was published under the heading "Public Health Service," and the two-page departmental press release summarizing its effects attributed its announcement to CP&EHS Administrator Charles C. Johnson, Jr.

The release quoted Johnson: "These changes were made to consolidate some scattered functions and arrange other activities so that we can assure more effective

protection for every American against controllable health hazards in his environment and the products and services which he uses."

Civil Service procedures establishing the new positions, and the screening of personnel designated to fill them, are expected to take more than a month, so for the present BRC and BVC will continue to function as separate bureaus.

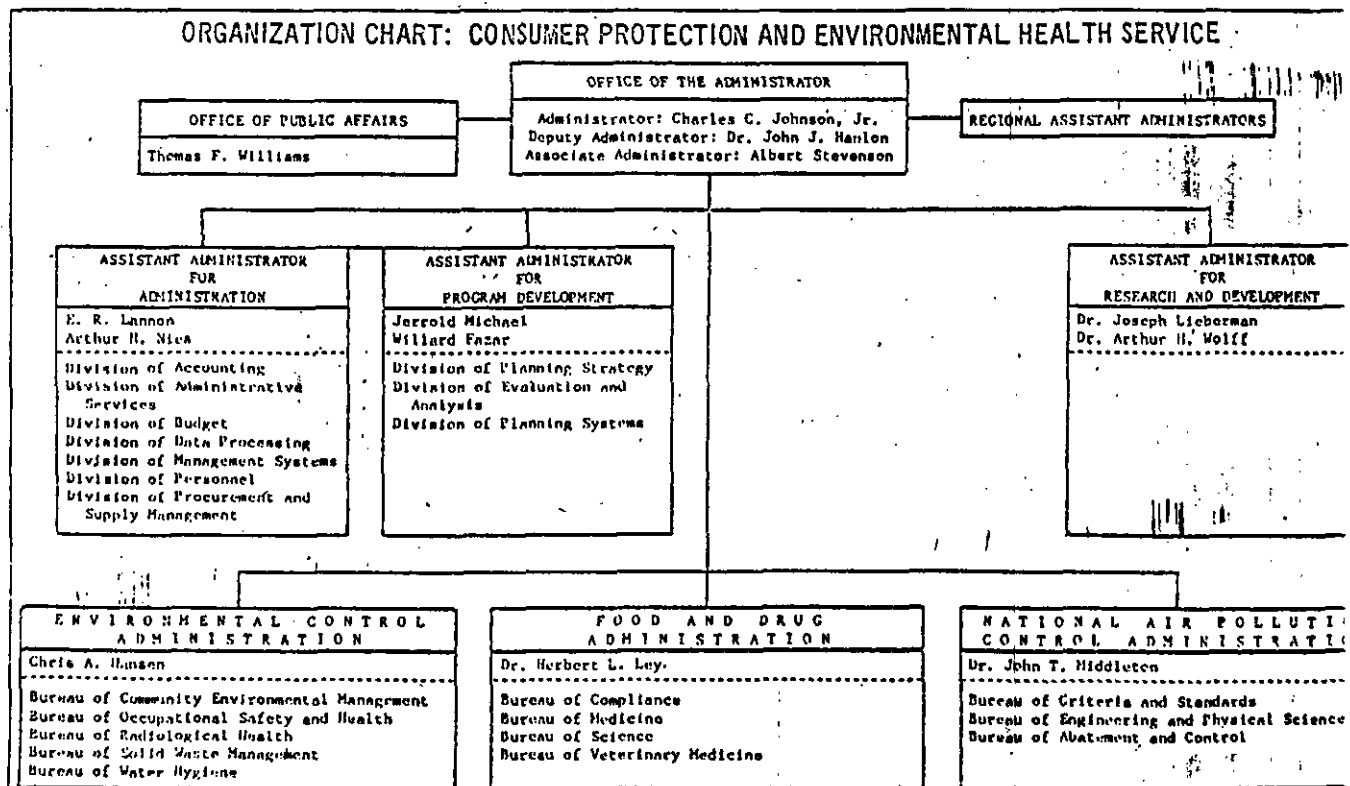
The reorganization order spells out the functions of officials and subdivisions of CP&EHS and each of its three agencies -- FDA, the Environmental Control Administration (ECA) and the Natl. Air Pollution Control Administration (NAPCA).

It establishes an "order of succession" specifying that, in the absence or disability of CP&EHS Administrator Johnson, the acting administrator shall be (1) the deputy administrator, (2) the associate administrator, (3) the FDA commissioner, (4) the ECA commissioner and (5) the NAPCA commissioner. Thus, Com. Ley is placed third in line, ahead of his counterparts in the other two CP&EHS agencies.

In describing the duties of the FDA commissioner, the reorganization order says he works "under the direction of" the CP&EHS administrator. It says the associate commissioner for compliance (Kenneth Kirk) is to assure "a balance between voluntary and regulatory compliance."

Duties of the new bureau of compliance are described as follows: "Develops compliance and surveillance programs covering regulated industries and areas of related economic activity. Foster's development of (GMPs)... Develops or coordinates the development of model codes, and other standards covering industry practices. Develops and carries out programs designed to encourage compliance by industry on a voluntary basis... Provides support and guidance upon request to the district offices in the handling of legal actions and provides headquarters case development, coordination, and contested case assistance."

Restored to FDA's Office of Legislative & Governmental Services, headed by P. Pumpian, was the handling of congressional inquiries, which had been switched last August to the Office of Education & Information ("The Pink Sheet" Aug. 12, "In Brief").



FDA recently seized mixed fruit shipped by Tri-Valley Growers, Modesto, Calif. to Consolidated Foods Corp., Columbus, Ohio, on the grounds that a label vignette was false and misleading, since the product did not contain approximate equal amounts of peaches and pears and peaches were not diced.

Seizures Involve Mixed Fruit, Puddings

The agency seized Gelatin Dessert, Custard Mix, Chocolate Creme Pudding, Vanilla Creme Pudding, and French Dressing, shipped by Kitchen Craft Foods Corp., Brooklyn, N.Y., to a branch in Miami, Fla. The agency said the products did not bear ingredient statements, were not labeled as "Imitation" in some cases where the products actually were imitations, and did not comply with the dietary food labeling requirements.

~~Sentence was deferred in a recent FDA criminal prosecution which involved a number of dietary supplement tablet products. Milan Pharmaceuticals, Inc., Morgantown, W. Va., pleaded guilty to three counts, and the other charges were nolle prossed. Charges against the president of the firm were dropped. The FDA charges had included alleged use of unauthorized food additives, vitamin A deficiencies, and violation of New Drug Application provisions.~~

CPEHS' JOHNSON ASSERTS AUTHORITY OVER FDA-ERS

Consumer Protection and Environmental Health Service Administrator Charles C. Johnson, Jr., laid it on the line to Food and Drug Administration staffers to play ball with the CPEHS team or get new jobs or face dismissal.

Johnson's pronouncement came at a meeting with FDA topsiders and the 17 District Directors who were called to Washington to learn how the new field operations of FDA and CPEHS would be handled (See FOOD CHEMICAL NEWS, Dec. 23, Page 23).

After the lecture aimed directly at FDA-ers, who ran outside to get industry support for a restoration of the independent status of FDA, Johnson attempted to reassure the agency that day-to-day program and policy decisions would still be handled by Food and Drugs Commissioner Herbert L. Loh, Jr., and his sta-

However, he made it clear that he and the CPEHS organization were the bosses a fact FDA only recently has come to recognize even though it was clear from the moment the CPEHS organization structure was being charted.

Ironically, the chief draftsmen of the organization that has become known as CPEHS were FDA-ers, who under former Commissioner Goddard sold the concept to then Health, Education and Welfare Secretary Gardner and Under Secretary Cohen.

At that time, FDA's hierarchy did not oppose the concept since Goddard, accompanied by his key aides, was slated to move up to run CPEHS as well as FDA, and the FDA appeared to be the tail that was going to wag the CPEHS dog. The plans called for CPEHS to be manned basically by the staff of the Public Health Service, but it would have been run by the staff of the FDA.

Goddard, however, fell out of favor with HEW leadership after several faux pas and the mantle of CPEHS leadership fell to Johnson, who has given most of the direction and supervision of the new organization to former PHS-ers.

The attempt by FDA-ers to have industry derail the CPEHS power play had little effect on the current Administration, but there is increasing evidence that the food and drug industry representatives have been attempting to get the ear of HEW Secretary-designate Robert Finch to restore FDA's autonomy.

CPEHS Will Represent FDA at HEW Secretary's Meetings

The final blow was delivered by Johnson last week when he announced that he would represent FDA at Secretary Cohen's staff conferences, ending the long tradition of FDA representation at the Secretary's meetings.

Johnson also announced that CPEHS-ers and only Ley (and no FDA-ers in his stead) would represent FDA at budget hearings on Capitol Hill. FDA-ers were also reportedly rankled about a chunk of FDA funds allegedly earmarked for a promotion effort to make CPEHS better known.

The 17 District Directors (or their representatives) apparently came away with mixed feelings from the meeting on how the FDA field operations would be run in the future under the new chain of command outlined by Johnson and other CPEHS-ers.

Johnson last week announced the names of the nine CPEHS Regional Assistant Administrators - - only two of whom came from the FDA ranks - - who will be his chief representatives in the HEW regions throughout the country. FDA Douglas C. Hansen, former FDA Regional Assistant Commissioner in Chicago, and Bill V. McFarland, Dallas RAC, were promoted to CPEHS post along with the others from the CPEHS staff or Environmental Control Administration. Hansen stays in the Chicago Region V office. McFarland stays in the Dallas Region VII office.

Other Regional Assistant CPEHS Administrators are: Frank Tetzlaff in Region I in Boston; Gerald M. Hansler in Region II in New York; John D. Faulkner in Region III in Charlottesville, Va.; Howard W. Chapman in Region IV in Atlanta; Robert P. Hayward in Region VI in Kansas City; Donald P. Dubois in Region VIII in Denver; and Russell W. Hart in Region IX in San Francisco.

Johnson and his staff emphasized their roles as coordinators of overall policy in the regions, but left little doubt that the CPEHS representatives were, in fact, in charge. However, it was emphasized that directions to FDA's nine new

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Assistant Regional Food and Drug Directors, not all of whom will be located in the same nine HEW regional offices, will come from Ley and his staff.

The new positions take the place of the former RAC's, which have been abolished, and will be for the time being filled by District Directors, who will be wearing two hats - - Assistant Regional Directors for FDA and District Chiefs.

(This terminology is inaccurate -- we are Acting Reg. Directors for FDA)
FDA District Directors within these regions will report to FDA's Regional Assistant Directors. The new FDA field organization lines up this way:

Region I Assistant Director Donald C. Heaton doubles as Boston District Director.

Region II Assistant Director Weems Clevenger is also the New York District Director. Region II also includes the Buffalo District, directed by Curtis R. Joiner, and the Philadelphia District, headed by Irwin B. Berch.

Region III Assistant Director Maurice Kinslow will be headquartered in Baltimore instead of Charlottesville, and he will continue as Baltimore District Director.

Region IV Assistant Director Leslie O. McMillan will double as Atlanta District Director.

Region V Regional Assistant Director Samuel Hart continues as Chicago District Director. Hart's Region also includes the Detroit District, headed by Thomas Brown, and the Cincinnati District, under Theodore Maraviglia.

Region VI Assistant Director Charles A. Armstrong is also Kansas City District Director, and his Region also includes the Minneapolis District headed by Joe P. Durham.

Region VII Assistant Director Will N. Swain, former Atlanta RAC, will take over the Dallas District directorship. Swain's Region also includes the New Orleans District, which had been headed by John Bologna, who is reportedly leaving for an industry job. New Orleans was represented at the meetings last week by Helen Barry, chief chemist. Chester A. Hubble, veteran FDA official, is the New Orleans Deputy Director.

Region VIII Assistant Director Fred L. Lofsvole is also the Denver District Director.

Region IX Assistant Director Frank Clark will be located in Seattle, where he is District Director, instead of San Francisco. Clark's Region also includes the FDA District Office in San Francisco, which is headed by McKay McKinnon, Jr., and the District Office in Los Angeles, under Gordon R. Wood.

Former RACs Nevis E. Cook in Denver, John H. Guill, Jr., in San Francisco, and Ralph Bernstein in New York are expected to get new positions.

Other CPEHS appointments made known at the meeting included the selection of Adrian (Duke) Sybor, former Department of Labor and PHS information specialist, as Assistant Public Affairs Program Review and Liaison Officer, with responsibilities largely for field information, and Mrs. Jean Elizabeth Drew Lightfoot,

former Department of State Conference Officer, who will take over the management of FDA's field Consumer Consultants as part of CPEHS Public Affairs operations.

Summerson Retiring Jan. 24

Meanwhile, Johnson, Ley, CPEHS Associate Administrator Albert Stevenson and Keith Lewis, who will take over as acting director of FDA's Bureau of Science when Dr. William W. Summerson retires Jan. 24 (See FOOD CHEMICAL NEWS, Sept. 16, Page 3), met with Wisconsin officials last week to get final clearance for the transfer of PHS' milk and interstate carrier programs from PHS to FDA. The transfer has been held up by objections from former Rep. Laird (R-Wis.), now Department of Defense Secretary-designate, because of objections from Wisconsin milk producers and other industry officials (See FOOD CHEMICAL NEWS, Nov. 4, Page 2).

Lewis, who headed the milk and food programs in PHS, had been named deputy to Summerson, and now appears to be in line to succeed him.

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Additional appointments were made last week by President-elect Nixon, with the naming of Georgia Agriculture Commissioner J. Phil Campbell as the Department of Agriculture Under Secretary and Clarence C. Palmby, executive director of the U.S. Feed Grains Council, as Assistant USDA Secretary for International Affairs and Commodity Programs.

Campbell has been a frequent critic of USDA policies, and appeared at hearings on meat legislation to condemn Consumer and Marketing Service inspection policies (See FOOD CHEMICAL NEWS, Nov. 20, 1967, Page 18).

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Congress convened with the usual rush of legislation covering dairy and meat imports, pesticides regulation, establishment of a Department of Consumers, food supplement labeling restrictions, fish and egg mandatory inspection control among others.

FDA, through CPEHS, submitted its annual report on activities under the Fair Packaging and Labeling Act in 1968, emphasizing coordination with State and other Federal agencies, and listing the numbers of extensions for revising labels it has granted plus exemptions provided to industries from FPLA requirements (See FOOD CHEMICAL NEWS, Dec. 16, Page 6).

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In other Washington activity as the Johnson Administration prepared to depart, Betty Furness, who resigned as Special Assistant to the President for Consumer Affairs, took some pot shots at Nixon's reported plans to abolish her office, and leave consumer responsibilities within the Departments holding traditional jurisdiction. In her final press conference Jan. 8, Miss Furness urged that her office be set up permanently by statute, and continued independent in the executive and not buried in some Department.

- She was not sure that a Department of Consumers was necessary, continuing to reserve judgment on this point in line with Johnson policy (See FOOD CHEMICAL NEWS, June 24, Page 2). She considered getting news of her activities off the women's page and onto the business page as one of her major victories.

Miss Furness said she has not made any plans, and joked that she had made it impossible for Nixon to reappoint her when asked if she would continue in the job, if asked.

There was speculation last week that Miss Furness' functions may be transferred to HEW, with the appointment by Secretary-designate Finch of Patricia Reilly Hitt as Assistant Secretary in charge of community and field services. The job will focus on consumer protection, and will include the Office of Consumer Services and a Center for Community Planning, as well as liaison with the HEW field activities. The Department recently upgraded consumer services by establishing the Office of Consumer Services (See FOOD CHEMICAL NEWS, Nov. 25, Page 7). Mrs. Hitt was co-chairman of the Nixon-Agnew Campaign Committee. She is a former Republican National Committeewoman from California.

Meanwhile, one of HEW Secretary Cohen's final acts was the establishment of a National Institute of Environmental Health Sciences as one of the National Institutes of Health. Established as an NIH Division in 1966, the facility is directed by Dr. Paul Kotin, and had appropriations of \$17.8 million for the current fiscal year.

RUMOR OF BURDITT FOR FDA JOB MAKES THE ROUNDS

In a period of rumors concerning Nixon Administration appointments, a rumor that Chicago Attorney George M. Burditt may be named Food and Drugs Commissioner last week stirred interest and emotion.

FDA-ers, almost unanimously depressed by the sudden realization last week that their agency is only a part of the larger Consumer Protection and Environmental Health Service (See preceding story), got at least a brief morale boost from the rumor.

Burditt, who has been a member of the firm of Chadwell, Keck, Kayser, Ruggles & McLaren and who has represented National Dairy Products' Kraft Foods for many years, is highly regarded in both industry and FDA.

The high feeling running for Burditt does not mean there is a lack of regard for current Commissioner Ley, who well may retain the top FDA position. However, CPEHS Administrator Johnson's comments to FDA-ers last week resulted in a feeling that Ley is not able to maintain the independence of FDA.

The Burditt rumors started with a column in the Chicago Sun-Times, which was followed by an article in the Chicago Tribune. The stories said that Burditt may be in line for the FDA Commissionership. There have been no confirmations of the rumors. Any denials have certainly not shut the door to such an appointment.

A strong recommendation that the Food & Drug Administration be restored to its pre-July status -- separated from the environmental health complex in which it now operates -- is reliably reported to have been transmitted to the incoming Nixon Administration through the "quickie" task force apparatus established by the President-elect under the leadership of Henry Loomis, former official of the Voice of America.

Included in the recommendations made by an informal task force on FDA, which worked quietly under pressure for 15 days at the request of Loomis, is a suggestion that the regulatory agency be given direct access to at least an asst. secty. or someone in the "political responsibility" area of the H-E-W topside ("The Pink Sheet" Dec. 2, page 28, and Dec. 9, page 13). Other recommendations spanned a wide area of FDA responsibilities.

Thus, the status of FDA, an agency whose \$60-mil.-plus annual budget represents only a small fraction of the money and programs managed by the vast dept., may become one of the first problems presented to new H-E-W Secty., 43-year old Robert H. Finch, Lt. Gov. of Calif. and one of the two men in the cabinet who are personally closest to President-elect Nixon.

The FDA task force, reportedly was more strongly oriented to the food field than to the drug industry. Those who participated in the study included a high percentage of people now working in industry who had previously been with FDA. Thus, the viewpoints presented were well rounded. Broadly speaking, the group is believed to be on the side of an effective FDA as the best way of protecting industry as well as the public.

Food & Cosmetic Industries Stress Administrative Ability Over MD Or Scientific Background

Aside from the task force report that is understood to have gone forward to Loomis over the week-end, individual representations on behalf of a relatively independent FDA have been presented in direct communications to President-elect Nixon from people who have been both personally and politically close to him over the years.

Also, Bryce Nathaniel Harlow, formerly director of govt. relations for P&G who was one of the first men named by Nixon to the White House staff ("The Pink Sheet", Nov. 18, page T&G 5), has an extensive background in FDA operations, particularly from the food and cosmetic viewpoints.

Running through most of the Nixon-oriented commentary on the future of FDA is the feeling that the most important ingredient -- from the standpoint of the public as well as the industry -- is a strong and able administrator for the regulatory agency. On this point, there is somewhat of a gap between the thinking of the pharmaceutical industry and others regulated by the agency, chiefly the food and cosmetic industries.



ROBERT FINCH
Nixon's H-E-W Secty.

Going all the way back to the Second Citizens Advisory Cmte. Report on FDA, whose deliberations were strongly influenced by John Conner, former head of M-S&D and at the time a leader on the Pharmaceutical Mfrs. Assn. (PMA) board, the pharmaceutical industry view has generally been regarded as favoring an MD or a scientist to head FDA.

The food and cosmetic industries, however, have not had the same dedication to the view that the regulatory agency should be headed by an MD or scientist. The pharmaceutical industry, of course, had reason to be unhappy with Dr. James Goddard, the first MD to head FDA. In urging strong

boycance of a Goddard and strong or effective leadership for the regulatory agency.

Leadership in the pharmaceutical industry has given indications it feels it can live with an FDA headed by Dr. Herbert Ley Jr., named to succeed Goddard when he left last summer. But important people in the food and cosmetic industries have raised the question whether he has the administrative qualities needed to direct the activities of FDA.

Wisely, Ley did not seek to follow the Goddard style, particularly in the matter of delivering speeches. But this has served to prevent Ley from developing the kind of leadership image that might weigh heavily in the mind of the new Nixon Administration. In fact, Ley has been caught between "loyalty" to the "lame duck" H-E-W which insists on submerging FDA into the environmental health complex, and "loyalty" to his agency which needs an articulate voice to insure its future.

**NIXON'S COMMENTS ON NATL. TV ANNOUNCING
FINCH'S APPOINTMENT AS SECTY. OF H-E-W**

For H-E-W Secty. I turn to my home state of Calif. and to the youngest man in this Cabinet team. Robert Finch has, however, lived a long time in his 44 years. I could mention the fact that he served as my administrative asst. as VP and that he has served two years as lt. gov., with great distinction, of the state of Calif.

But here again I saw in him some extra dimensions -- high intelligence, and then a passionate concern for excellence in education. He demonstrated that as one of the regents of the U. of Calif.

Beyond that, a passionate concern for better health for all our people, and particularly for our older citizens.

And also a concern for a better welfare system. So that a welfare system is something to escape from, rather than to. All of these factors were of interest to me.

One other thing motivated me. He is a lawyer. I am a lawyer. And we are proud of our profession. But we would both have to admit -- as would all the lawyers in this room -- that lawyers sometimes have one failing. They many times are how-not-to-do-it men.

Robert Finch is an unusual lawyer. He's a how-to-do-it man. He has an imaginative creativity. He will not simply come up with the automatic solutions of adding billions to programs that have failed. But he will not stop there and say that nothing can be done.

He will provide a way. How we can meet these immense problems in our cities, in our nation, in the fields of health, education and welfare.

Key to the long-term future of FDA -- and to the personal position of Ley under the Nixon Administration -- is the appointment of an as H-E-W secty. to succeed Dr. Phil Lee.

Curiously, there has been no significant Washington talk on who might get this job which is of importance to the drug industry, not only because of its relationship to the future of FI but also because of its impact on Medicare, Medicaid, NIH research and education, and a other programs in the medical field.

New H-E-W Secty. Finch has both political ambitions and ability to administer. As one of the closest friends and allies of President-elect Nixon, he could have had his choice of cabinet or key White House positions, but apparently chose H-E-W as the dept. that has a direct effect on the lives of more people than any other govt. agency.

H-E-W also distributes more money to more people than any other civilian agency, its total expenditures are exceeded only by Defense Dept. Also, Finch probably realize that cabinet posts, generally, are not the best springboards for advancement in the political arena, but the H-E-W Dept. was used by Sen. Ribicoff (D-Conn.) as the basis for his election to the Senate.

Finch, 43, was born in Tempe, Ariz., but moved to Calif. when he was eight. He has AB in political science from Occidental College and LLB and JD from the U. of Southern California law school. A marine in World War II, he was recalled to service during the Korean war. Tall and ruggedly handsome, Finch demonstrated an appeal to Calif. voters by being elected lt. gov. in 1966 with a total vote of 3,831,000, more than those received by Gov. Reagan or any other republican running in a partisan race.

The push for hiring of Negroes by drug mfrs. began Oct. 1967, at a White House meeting with 32 firms. Only 22 were chosen for the study, EEOC said, because they had complete employment records. Those threatened with suits included some in the 22 and some of the other 10. EEOC said that as of July 1968 the 73,000 persons employed by the 22 firms included about 4,000 Negroes. There were 46,222 white-collar employes, including 1,224 Negroes. During the first six months of 1968, the 22 firms added 530 white-collar workers, 225 of them from minorities -- 202 Negro and 23 with Spanish surnames. During the 12 months ending Jan. 1967, 7.4% of those hired were Negro. This jumped to 29.4% during the next 12 months, and jumped again to 48.7% during the first six months of 1968.

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NEW H-E-W SECTY. FINCH'S COMMENTS ON FDA & PHS in recent press interview indicates how much he has to learn about the inner workings of his sprawling dept. The new secty. said there are two H-E-W areas -- the Food & Drug Administration (FDA) and the PHS Surgeon General's Office -- in which he is likely to rely almost entirely on strictly professional advice. In a special profile published in the Washington Evening Star, Finch was quoted as saying: "Because they have to make judgments on very specific things, I doubt that I will go behind the political scenes... Once given the information, I will tend to bite the bullet... They (FDA and PHS Surgeon General) should be able to count on me to stand behind them and support them."

This statement indicates Finch's innocence of the fact that, in the H-E-W he is inheriting, recent reorganizations have separated FDA from the secty.'s office and buried it under two levels of bureaucracy -- also that the Public Health Service (PHS) Surgeon General has been reduced to a more functionary serving as a shadow to an H-E-W asst. secty.

There's little solid information in Washington on who might be picked by Finch to succeed Dr. Phil Lee in the key spot of asst. secty. for health and scientific affairs. Two highly capable MD-administrators included on Finch's H-E-W advisory cmte. ("The Pink Sheet" Dec. 23) reportedly are not available for the job. This leaves the only other MD on the advisory cmte., Dr. Neil Solomon of Baltimore, as a prospect. Solomon reportedly has close professional relations with the family of VP-elect Agnew. He is in private practice in Baltimore, has part-time medical school teaching assignments and has a major interest in geriatrics, with emphasis on obesity. His relative youth and inexperience in administering health or medical research-education programs could weigh against his appointment.

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.... IN BRIEF

~~Markel, Hill & Byerley: Walter Byerley, former FDA hearing and trial lawyer, now a partner in law firm of Michael Markel, long-time practitioner in food & drug law and presiding officer at FDA's first vitamin-mineral hearings in the early 1940s, and Wayne Hill. Byerley left FDA a year ago for the Markel & Hill firm. . . . Pharmacy merger: Exec Director of Ala. Pharmaceutical Assn., Mrs. Launia Lindsey Barranco, Southern belle of the conference of state execs, married Dec. 27 to Lester Thagard Jr., member of the pharmacy staff of the U. of Ala. Hospitals & Clinics and former president of Ala. Pharmaceutical Assn. a Ala. Pharmacy Board. . . .~~

~~Poverty program health centers: Naming of Dr. Joseph T. English, former health affairs asst. director of poverty program, to head new Health Services & Mental Health Administration in H-E-W Dept. means no change in attitude toward pharmacy vendor system if NARD succeeds in its drive to move poverty program health centers into H-E-W. . . .~~

Finch vs. HEW, the Politician Slayer

By JONATHAN SPIVAK

WASHINGTON — Robert Finch, a smart and so far successful politician, seems honestly enthusiastic about the prospect of becoming Health, Education and Welfare Secretary.

He has already mastered much of the lingo — "enormous and exciting challenge," "maximize human potential," "constructive and viable partnership." And he insists that helping people, the department's destiny, is very much what attracts him to the national scene.

Yet Abe Ribicoff, another smart and successful politician, talked much the same way before he took over HEW's helm in the last partisan shift of Administrations in 1961. The Connecticut governor soon learned that the gargantuan department (its activities have more than doubled since then) was ill-suited for advancing a politician's ambitions. Within 18 months he was back home, running for the U.S. Senate. "There are no political plusses at HEW," Sen. Ribicoff now ruefully recalls.

The bureaucrats believe Bob Finch will undergo much the same harsh awakening, once he begins juggling HEW's hot potatoes. "The problems will start the minute he moves in on January 20," warns a member of the department's old guard.

Dispensing Dollars

In theory, the department should be a happy place for an ambitious politician; the secretary's major duty is dispensing dollars to make Americans healthier, wiser and more content.

In actuality, HEW is an confusing and frequently frustrating collection of more than 200 separate do-good programs, so diverse and deeply enmeshed in conflict that no secretary escapes entirely unscathed.

The Ribicoff undoing, for example, was his inability to coax quick Congressional approval of John Kennedy's New Frontier; debate over Medicare and major new aid to education dragged on for five years. For successor Anthony Celebrezze, the cross to bear was the department's open advocacy of birth control during his 1962-65 tenure; the Roman Catholic Cabinet member found it difficult to reconcile the dictates of his conscience with the desires of President Johnson to provide public support for contraception.

Mr. Finch's burdens may be even greater. He confronts not only mounting—some say in-

soluble—health and welfare problems on the national level, but also troublesome controversies in his home state of California that could impede his avowed ambition to be a U.S. Senator someday. The lieutenant governor of the Golden State may have welcomed the move to Washington in part as a way of dissociating himself from Gov. Ronald Reagan's conservative clutches without a conflict. But HEW will not afford its new secretary the luxury of avoiding cross-country wrangles with his ex-boss.

What, for instance, will the Finch decision be on the department's proposal that, pending successful tests, needy families next year be allowed to obtain public welfare payments by signing a simple "declaration" of need? The change is intended to avoid demeaning investigations, and as such it is ardently advocated by welfare rights groups and liberal politicians of both parties. But "declarations" are just as strongly opposed by Gov. Reagan and other conservatives; indeed, the governor recently sent the state's own health and welfare secretary to Washington to voice bitter objections, calling the change an inducement to fraud.

Whatever he does, Mr. Finch is bound to anger one side or the other. "Trying to arbitrate the differences between Nelson Rockefeller and Ronald Reagan could be difficult, to put it mildly," comments an assistant to departing HEW Secretary Wilbur Cohen.

Another California controversy could be created by the Finch decision on Gov. Reagan's request for tougher authority to control air pollution. To help smog-laden Los Angeles, California wants permission to impose stricter-than-Federal standards on automobile exhaust emissions. But some HEW experts question whether existing technology will sustain the proposed California standards. And the automobile makers will object, of course.

California's costly (\$700 million a year) "Medicaid" program, second largest in the nation, could be another annoyance. Mr. Finch must attempt to hold down HEW's soaring Medicaid spending nationally; any effective restriction is sure to curtail California's share of Federal funds.

Budget Hard to Cut

But Mr. Finch faces more than California-type troubles. He'll be expected to solve costly national problems of poverty, ill health and the like against which even a liberal Democrat like Wilbur Cohen had trouble making progress. The HEW budget Mr. Finch inherits, while as usual larger than last year's, is hardly a spendthrift document; Congressional authorizations for education outlays, for ex-

ample, are more than twice the actual spending requests.

Thus the new secretary is likely to displease HEW's own money-hungry constituency. The school superintendents, university presidents, welfare lobbyists, medical researchers and public health professionals all tend to judge the new man, against a simple standard—his success in wheedling more legislation and more cash from Congress. Ever the Republican secretaries, such as Marlor Folsom and Arthur Flemming, were moved by these political pressures and public needs to advocate ever-bigger budgets.

But Mr. Finch also will inevitably disappoint the conservatives who expect the new Administration to succeed in curtailing the steady rise in Federal spending. Much of HEW's \$50 billion budget (by far the biggest of any domestic agency) is not subject to the secretary's control. It rises in response to increases in Social Security benefits and more spending by the states for public assistance vocational rehabilitation and medical care.

Federal public assistance payments, for example, now almost \$4 billion a year, are rising at a rate of \$300 million to \$400 million. Medicaid expenses are seen jumping \$600 million in the next fiscal year, to a \$3.1 billion total, and could reach \$7 billion annually by 1972.

Sweeping solutions to the financial problems of the poor, such as a negative income tax or universal health insurance, are popular in academic circles, but there is no consensus in the country or the Congress about what course to follow. Meanwhile, Mr. Finch has the unpalatable task of persuading the politicians to accept the inexorable increase in HEW expenses.

Mr. Finch's current concept seems to be that HEW's essential need is not more money but greater efficiency and more orderly administration. There's no doubt that the department's endeavors could be improved by more hard-nosed auditing, quicker communication and less legalism and regulation-writing. But the new secretary's opportunities for achieving effective reorganization and reform will be limited, at least for some time.

Already HEW has been shaken to its bureaucratic roots by Secretaries John Gardner and Wilbur Cohen, who sought to submerge the narrow-visioned traditional agencies, particularly the Public Health Service and the Welfare Administration, in broader-gauged, more adaptable organizations. But so far the civil servants have found this mostly a discouraging game of musical chairs. Mr. Finch risks total immobilization of his department if he embarks too soon on a new round of reorganization.



The biggest hazard of all for Mr. Finch will be his inevitable involvement in emotional national issues, jeopardizing his appealing public image of a moderate Republican as he is driven right or left. Among the unpleasant conflicts he confronts are:

The public pressure to regulate physicians' fees (rising twice as fast as total living costs) versus the politically powerful doctors' demands for freedom from Federal interference.

The conservationists' quest for tougher air pollution policies versus the established economic interests and entrenched political influence of the coal industry.

The consumers' demands for lower-cost drugs versus the pharmaceutical industry's insistence that liberal profits are essential for research and innovation.

The mayors' clamor for more Federal money and freedom of action to meet the needs of their urban poor versus the governors' demands for greater control over Federal funds and activities affecting their states.

The Big Battle

But all these conflicts may be bush league, in intensity and importance, alongside the coming civil rights fray. Secretary Finch must decide the extent to which he will employ HEW's powers to compel integration of public schools and other facilities, particularly in the South. The 1964 Civil Rights Act authorizes HEW to withhold its funds from discriminatory activities, but its use of this authority rouses the ire of Dixie politicians, such as Sen. Strom Thurmond of South Carolina, who helped elect Richard Nixon President. The states' rights Southerners hold key legislative positions and exert major influence on HEW's budget. Northern politicians, too, are becoming disenchanted; many of their constituents are angered by Negro militancy and oppose more government-fostered integration.

Thus it would probably be smart strategy for Mr. Finch to soft-pedal civil rights. He might attempt to have HEW's enforcement role transferred to the Justice Department, as the more logical legal agent. Or he could quietly allow the civil rights effort to atrophy.

Either way, the liberal forces—the NAACP, the national labor unions, anti-poverty organizations, socially minded private foundations—would raise a ruckus. Too, the Federal courts, through forceful pro-integration decisions, could make such backsliding difficult.

The result: Mr. Finch may find himself pushed into an aggressive civil rights role—fine in principle, but poor in practice for his California career.

As Abe Ribicoff says, "There are no political plusses at HEW."

F-D-R E P O R T S

1/20/69

RESTORATION OF FDA'S SEMI-AUTONOMOUS POSITION IN H-E-W DEPT. IS EXPECTED BY MID-FEB. UNDER NEW NIXON-FINCH ADMINISTRATION; MAXIMUM EFFORT MADE

A maximum effort has been made to restore the Food & Drug Administration (FDA) to the semi-autonomous position it enjoyed before it was merged into H-E-W's environmental health operation and optimists in the pro-FDA fight believe they have reason to hope that the Nixon Administration will take action by the middle of February to cancel the reorganization that put FDA in a subordinate position.

Key to the future of not only FDA but also the Natl. Institutes of Health (NIH) and the Health Services & Mental Health Administration (HS&MHA) rests in large measure on who is selected by new H-E-W Secty. Finch to succeed Dr. Phil Lee in the post of asst. secty. in charge of medical and scientific affairs.

Reliable reports indicate that Lee was willing to stay at H-E-W -- at least for three to six months -- but apparently Finch has decided he would prefer to start with his own team. Observers noted that Lee was packing his personal effects on Friday Jan. 17, apparently in preparation for leaving shortly after Finch takes the dept. over.

No questions relating to FDA or drug regulation were asked of Finch during his 70-minute appearance Jan. 14 before the Senate Finance Cmte. on his confirmation as H-E-W secty. There was no doubt that the Senate would approve.

At the same time, Dr. Neil Solomon, of Baltimore, a member of Finch's initial advisory cmte., disclosed to his local press that he had been offered a chance to succeed Lee in the asst. secty.'s post, but had decided not to take the federal job.

Two Anti-FDA H-E-W Asst. Sectys., Civil Servants, Transferring Elsewhere

Chances for George M. Burditt, food industry lawyer whose name has been mentioned as H-E-W general counsel or FDA commissioner, dimmed somewhat with the disclosure that a member of the Chicago law firm, with whom Burditt had been associated until Jan. 1, was slated to be named asst. attorney general in the Justice Dept. in charge of anti-trust enforcement. This raised the question of whether the Nixon Administration could name two men from the same law firm for top govt. posts.

Favorable to the chances for FDA regaining semi-autonomous status was the news that two civil service asst. H-E-W sectys., who had long advocated a subordinate position for the regulatory agency, were being transferred to other jobs. Initially, it has been expected they would continue their key H-E-W positions in the Nixon Administration.

Asst. H-E-W Secty.-Controller Kelly, who has long been an advocate of submerging FDA, is being transferred to the Defense Dept. where he will work under Secty. Laird who developed a great respect for his capabilities during his appearances in past years before the House appropriations subcmte. in charge of H-E-W appropriations. Laird was the key minority member of the appropriations subcmte.

Asst. H-E-W Secty. Simpson, in charge of administration, has already left for the regional directorship of the San Francisco office in charge of H-E-W's social and rehabilitative work.

In the event that FDA is restored to its semi-autonomous status, the position of C. C. Johnson, head of the Cohen-created Consumer Protection & Environmental Health Services (CPEHS), remains in doubt. Johnson in recent weeks has been taking a strong position that anyone in FDA who supports the regulatory agency's previous position is endangering his career with the govt.

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HEW's new topside appointments will be announced as a group this week, including John Veneman, California Legislator, as Under Secretary; Creed C. Black, Chicago Daily News executive editor, as an Assistant Secretary; L. Patrick Gray III, Connecticut lawyer who has held several Defense Department posts, as Secretary Finch's Executive Assistant; and George Brand, former California newsman, as HEW's Director of Public Information. A New York Times story of Finch's briefing by former HEW Secretary Gardner includes the advice that FDA "had to be directed with special effectiveness and strength," and aside from civil rights, Gardner told Finch, "It was the one regulatory agency in the Department that was 'absolutely laden with trouble and conflict.'"

CPEHS order to FDA requiring it to approve actual subsistence payments in lieu of the \$16 per diem, has been regarded as another attempt to subvert the agency, and keep FI officials away from important meetings. Requests for actual subsistence payments must be made to CPEHS at least 10 working days in advance of a trip, and "will be limited to unusual circumstances where the individual employee has no control over costs of carrying out official business," CPEHS advised FDA.

FPLA review to check on agency implementation of the law will be undertaken by the Senate Commerce Committee, Committee Counsel Michael Pertschuk indicated at a meeting held last week in New York City by the Soap and Detergent Association. Other speakers indicated apprehension that such an investigation would prove embarrassing to both industry and the Commerce Department by showing that the voluntary package size standards widely publicized by the Department (See FOOD CHEMICAL NEWS, Oct. 7, Page 6) have made little change in the marketplace.

FOOD FACTORY inspection powers for FDA were included in an omnibus FDA bill sent to the Hill by former Secretary Cohen before he left office (See FOOD CHEMICAL NEWS, Dec. 2, Page 13).

SEN. NELSON (D-Wis.) recently introduced legislation (S 365) to establish a Public Health Hazards Commission to investigate the potentially harmful effects of drugs, cosmetics, food additives, and other chemicals.

ANIMAL DRUG regulations, implementing last year's law, are expected to be issued as proposals by March 1, according to a target date established by FDA's Bureau of Veterinary Medicine, which must make the new procedures effective by Aug. 1, 1969 (See FOOD CHEMICAL NEWS, Jan. 20, Page 23).

CORRECTION: A pending Food Additive Petition to clear xanthan gum in nonstandardized foods was not found inadequate by FDA, as was indicated erroneously on Page of the listing of pending Petitions in the Jan. 20 issue of FOOD CHEMICAL NEWS. The Petition is pending in the same form in which it was filed by Kelco (See FOOD CHEMICAL NEWS, Oct. 7, Page 17).

FPC delivery by Alpine Marine, Inc., under a contract to the Agency for International Development, will be delayed four months from the contract date of Jan. 1, 1969, requiring one-third of the \$900,000 delivery and the remainder by July 1, Bureau of Commercial Fisheries Director Harold E. Crowther told the National Canners Association convention in San Francisco last week (See FOOD CHEMICAL NEWS, May 6, Page 2).

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Johnson's statement of Finch's assurances can be interpreted as indicating the H-E-W secty.'s intention to keep FDA submerged in CP&EHS, but it also can mean that the incoming head of the dept. was only promising Johnson that he would be called into any discussions on the separation of FDA from the newly formed CP&EHS. Finch has not yet felt the full force of all the pressures that are being exerted on the Nixon Administration to reverse the submerging of FDA into CP&EHS.

For the post of asst. secty. in charge of health and scientific affairs, the top name at press time was Dr. Francis Land, head of H-E-W's Medicaid operations. Land, 48, was GP at Fort Wayne, Ind., for 15 years before joining H-E-W as a consultant for the Medicaid program in Sept. 1966. He was named to his present job, commissioner of the Medical Services Administration, in Aug. 1967. A delegate to the AMA House for 10 years, Land continues to serve on the AMA's Council on Medical Education. He is a past president of the Indiana Society of General Practice, and was on the board of the American Academy of General Practitioners for four years, serving as VP in 1965-66. He received his MD from Indiana U. in 1950.

In addition to Land and Edwards, those mentioned for asst. H-E-W secty. include Dr. Carruth Wagner, retired director of the old Public Health Service's Bureau of Health Services; Natl. Cancer Institute Director Dr. Kenneth Endicott; and Dr. Richard Wilbur of Stanford, Calif., nephew of AMA President Dwight Wilbur.

Appointment of Wagner would have a dramatic aspect in that he would become boss over Public Health Service Surgeon General William Stewart under whom he served as asst. surgeon general until several years ago. Wilbur would seem to have a lot going for him if he wants the job, except that he comes from Calif. and there is a limit to the number of people Finch can appoint to high posts from his home state.

Creed Black, A Newsman, Asst. H-E-W Secty. For Legislation; Veneman May Be Undersecty.

Edwards, 44, has been Booz Allen & Hamilton VP for health & medical affairs since early 1967, when he left the AMA staff after five years as director of its div. of socio-economic activities. He is a Republican, and his wife is a member of the Cowles family, which owns "Look" magazine and a number of newspapers.

After receiving his MD from the U. of Colo. in 1948, Edwards won masters degrees in physiology and surgery. He was a general surgeon at the Mayo Clinic until 1957, when he returned for five years to his native Des Moines to set up a surgical group. Edwards also spent one year in Washington on the Georgetown U. faculty and as a consultant to Surgeon General Stewart, whose boss Edwards would be if he becomes H-E-W asst. secty.

In line to be H-E-W asst. secty. for legislation is Creed Black, 43, exec editor of the Chicago Daily News. A native of Kentucky and a career newsman, Black entered the profession at the Chicago Sun-Times. He later held various positions on newspapers in Nashville, Tenn., Savannah, Ga., and Wilmington, Del. Black became managing editor of the Daily News in 1964, and exec editor in Jan. 1968.

Finch is expected to name the H-E-W topside as a group in the next few days. A strong possibility for the major position of H-E-W undersecty. is John Veneman, a California legislator who headed his state's joint cmte. on Medi-Cal administration and who is regarded as having a basic knowledge of how H-E-W's major medical programs are administered at the state level. Veneman has been working closely with Finch in taking over the H-E-W D. He was a member of his advisory cmte. ("The Pink Sheet" Dec. 23, page 24).

The only topside appointment Finch had announced as of late Fri., Jan. 23, was Patricia Hitt, a G-O-P leader, as asst. secty. for community & field services. He also announced George Brand, 45, editor of the San Luis Obispo (Calif.) Telegram-Tribune, as director of the California Health Information. Brand served with Finch in the Marine Corps during the Vietnam War.

ODDS FAVOR CONTINUATION OF DR. LEY AS FDA COMMISSIONER, BUT DISCUSSIONS ON GOP TAKEOVER OF H-E-W INDICATE THAT HIS STATUS IS BEING CONSIDERED

The possibility that a new FDA commissioner might be named to succeed Dr. Herbert Ley Jr. cannot be ruled out entirely as part of new Secty. Finch's reorganization of the H-E-W. There is no indication that a definite decision has been made to replace Ley but there are reliable reports that his job has been under consideration.

Ley's job has been mentioned as a possible alternative in discussions with prospective candidates for the position of asst. secty. for health and scientific affairs, now held by Dr. Phil Lee. Reports that the post of H-E-W general counsel has already been filled leave the FDA commissionership as the only job that would interest George M. Burditt, GOP member of the H.E. by structure and food industry lawyer who headed the special task force on FDA for the incoming Nixon Administration.

Among the candidates for the asst. H-E-W secretaryship who also have been discussed as possible successors to Ley is Dr. Charles Edwards, VP of the management consulting firm of Booz Allen & Hamilton and former member of the AMA headquarters staff in charge of the socio-economic div.

At the present writing, the odds are that Ley will be continued in the FDA commissionership, but indications that the position and the man are being seriously weighed were contained in a pregnant comment made by Finch during an interview with the NY Times.

Telling of the process by which he decided to accept the job of H-E-W secty., Finch related in the NY Times interview that he had consulted former Secty. John Gardner, who counseled that FDA had to be directed with special effectiveness and strength. Aside from H-E-W's civil rights branch, Finch was told, FDA was the one agency in the dept. that was "absolutely laden with trouble and conflict."

CP&EHS Head Johnson Believes His Control Over FDA Is Safe, But

Tied into the selection of a new H-E-W secty. for health and scientific affairs is the status of FDA as a semi-autonomous agency, separated from the environmental health grouping into which it was merged as part of the H-E-W Dept. reorganization put into effect by former Secty. Cohen.

The task force report submitted by Burditt before the Nixon Administration took office called for a strong, effective and relatively independent FDA that would report to an H-E-W asst. secty. instead of the head of the new environmental health grouping. The strength and vigor of this recommendation serves to offset the fact that Burditt has been a lawyer for Kraft Foods and other industry clients. Also cited in Burditt's favor is the fact that the FDA commissionership had not been held by an MD until 1966 when former Com. James Goddard was named.

C. C. Johnson, head of the Consumer Protection & Environmental Health Service (CP&EHS) into which FDA was submerged as part of the H-E-W reorganization under Secty. Cohen, apparently is confident that he will continue in his post and that FDA will be continued under his jurisdiction.

At a Jan. 23 goodbye party held for FDA Bureau of Science Director Dr. W. H. Summerton, Com. Ley invited Johnson to speak. The CP&EHS head, in the course of his remarks disclosed that he had been called into a conference with Finch and the new H-E-W secty. had told him: "I have no present plans to reorganize CP&EHS, and if such plans come up in the future, you will be in on the discussions."

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~~He also exhorted the Government to get moving on preparing for its first written direct testimony, explaining that he would allow 15 days between the filing of the testimony and the "live" cross.~~

~~The Government expects to have its first witness available for cross under the new procedure in early March. Several witnesses are scheduled to return later this month to complete cross examination that has already begun.~~

LEY PLEDGES STRONG, UNIFORM LAW ENFORCEMENT

Food and Drugs Commissioner Ley last week pledged that his agency will conduct a uniform law enforcement program in the interest of "consumers and industries alike."

The pledge to the National Association of Pharmaceutical Manufacturers last week was similar to the promise he made recently to the National Canners Association to conduct a fair, but firm enforcement policy (See FOOD CHEMICAL NEWS, Jan. 27, Page 1).

The emphasis on uniform legal actions by Ley is in contrast to informal advice Consumer Protection and Environmental Health Service Administrator Johnson reportedly gave FDA-ers recently, when he questioned the need for large numbers of enforcement actions by FDA.

According to one widely-circulated report of Johnson's views of enforcement, the Public Health Service has been able to gain compliance with threats of unfavorable publicity and intimidation rather than go through the trouble of legal sanctions.

Ley told the drug group in Washington that "I can't think of anything that would be more disruptive to this great industry of yours than to have an oversight agency that is indecisive, or indulges in non-uniform law enforcement." He continued:

"If we in the FDA go soft on regulation, we not only will do tremendous damage to the consumer, but also we will thoroughly disrupt the drug manufacturing industry. I am committed to the concept that enforcement is in the best interest of business as well as the consumer. Good enforcement is what you are going to have.

"I believe in honesty, fair play, in law and order, and I pledge to you, as I pledged a few days ago to a national food group, that this nation will have full, fair, enforcement of the food and drug laws, in the interest of all, consumers and industries alike."

He credited former Commissioners Dunbar, Crawford, Larrick, and Goddard, in their own way, of stimulating great strides in FDA's science programs, and he promised to carry "this excellence forward," saying he would "resist any efforts to destroy its acknowledged competence."

"I will do everything in my power to insure the continued evolution of the FDA as a science-based agency," he said, declaring that "FDA has a great tradition to live up to."

Ley has told reporters he will not resign, unless requested to by Secretary Finch (See FOOD CHEMICAL NEWS, Jan. 13, Pages 30 and 38).

Meanwhile, additional Health, Education, and Welfare and Agriculture Department appointments became known during the week (See FOOD CHEMICAL NEWS, Jan. 27, Page 2).

Massachusetts' Knowles Selected for Asst. Health Secretary

Dr. John H. Knowles, director of the Massachusetts General Hospital, is expected to be named Assistant HEW Secretary for Health and Scientific Affairs, despite a battle between the American Hospital Association, which supports him and the American Medical Association, which is reportedly attempting to block the appointment.

Other HEW staffers selected include: Leon Panetta, former legislative assistant to ex-Sen. Kuchel (R-Calif.), as a legislative aide; B. Michael Kahl, California Senate aide, to Secretary Finch's policy staff, and Agnes Waldron, Nixon campaign worker, as a special welfare assistant.

Roy M. Lennartson, a career USDA-er who has been serving as Associate Administrator of the Foreign Agricultural Service, has been named Consumer and Marketing Service Administrator.

George V. Hansen, former Idaho Republican Congressman who was defeated in a bid to unseat Sen. Church (D-Idaho), was named USDA's Congressional Liaison Officer.

William E. Galbraith, a Beemer, Neb., farmer, has been selected Administrator of the Agricultural Stabilization and Conservation Service.

Agriculture Secretary Hardin and Under Secretary J. Phil Campbell met recently with members of the National Food Inspection Advisory Committee to discuss implementation of new meat and poultry laws. Hardin emphasized the need for effective Federal-State cooperation to carry out the programs.

Finch Will Review Cohen's Order On Status Of FDA

WASHINGTON—Review of the December 1968 order of Health, Education and Welfare Secretary Wilbur J. Cohen which has the effect of destroying the Food and Drug Administration's semi-independent status "will be one of the first things I'll do," incoming Secretary Robert H. Finch told DRUG TRADE NEWS.

"I'll give it high priority," Mr. Finch said. Answering a question, he said he had been asked to look over the order and to reverse it to the extent of returning FDA to its former status.

Mr. Finch smilingly declined to say who had asked him to do this or to give his own feelings about what should be done.

The order places FDA and the two other units of the Consumer Protection and Environmental Health Service under the control of Administrator Charles C. Johnson, Jr.

Meanwhile, Mr. Johnson told DRUG TRADE NEWS that one section of the order which seems to place all of the CPEHS field activities, including those of FDA, under CPEHS regional assistant administrators doesn't mean what it seems to. This portion of the order provides that the regional assistants shall exercise "leadership and supervision" over the "total efforts" of CPEHS in their respective regions.

"But, I'm not interpreting it that way," Mr. Johnson said. He acknowledged that the normal meaning of the words "leadership and supervision" would indicate that the regional assistants would be in charge of the field activities of FDA, the National Air Pollution Control Administration and the Environmental Control Administration.

The commissioners' representatives (in FDA's case the food and drug directors) should represent their respective commissioners, the task force stated, and "exercise such managerial functions as planning, organizing and directing area resources in the region." Direction of national resources—as distinguished from area resources—should be from headquarters, the task force said.

Its report listed three FDA

Secretary Finch Will Review Order On Status Of FDA

(Continued from page 1, col. 5) activities as national resources—the National Center for Drug Analysis in St. Louis; the proposed National Center for Microbiological Analysis, in Minneapolis; the Pesticides Research Laboratories, in Wenatchee, Wash., and the proposed National Food and Drug Training Institute.

FDA area resources would consist of "a wide variety of inspectional, laboratory, educational and administrative activities designed to assure and encourage compliance with the Food, Drug, and Cosmetic and related acts," the report said.

"This report will form the basis of CPE regional operations until such time as it proves unsatisfactory with respect to accomplishing the mission for which the administrator of CPE has been made responsible," said the paper handed his subordinates by Mr. Johnson.

"Should such circumstances develop, the administrator is prepared to avail himself of the authority provided him in the approved statement or organization functions and delegations of authority as it appeared in the Federal Register." (Dec. 20, 1968—Ed.)

Two of the nine regional assistants whose appointments were announced by Mr. Johnson Jan. 10 were drawn from FDA ranks. They are Douglas C. Hansen, who has been regional assistant commissioner of FDA in Chicago, and Bill V. McFarland, who held a similar post in Dallas, Tex.

The other new regional assistant administrators, their former connections, and their headquarters cities are Frank Tetzlaff, Environmental Control Administration, Boston; Gerland M. Hansler, ECA, New York; John D. Faulkner, ECA, Charlottesville, Va.; Howard W. Chapman, ECA, Atlanta; Robert P. Hayward, Environmental Health Services Branch, Indian Health Service, Kansas City, Mo.; Donald F. Dubois, assistant to the associate administrator, CPEHS, Denver, and Russell W. Hart, ECA, San Francisco.

"Those words mean what I say they mean and they don't mean

that the regional assistant administrators will control the field activities of the three administrations," Mr. Johnson said. "They will not have any direct line responsibilities, but will act as coordinators of the total CPEHS efforts at the regional level. The regional food and drug directors will report direct to the commissioners, as will the regional directors of the other administrations."

Mr. Johnson said he had made this clear at a staff meeting attended by representatives of the three administrations. Elsewhere it was learned that at this meeting Mr. Johnson had distributed to the participants an undressed, undated and unsigned paper setting forth his intentions vis a vis the authority of his newly appointed regional assistant commissioners.



Industry Group Calls for Stronger FDA, With Voluntary Compliance Program

By JACK KIESNER

Feedstuffs Washington Correspondent

WASHINGTON—A group of food and drug industry executives and lawyers has called for a stronger Food and Drug Administration, with more emphasis on inspection and enforcement and an effective voluntary compliance program.

FDA should be "free from bureaucratic or political control and meriting the confidence and respect of consumers, industry and government" and should have regulatory programs geared towards encouraging voluntary compliance, according to a memorandum submitted to the Nixon Administration by a "Committee of 16" persons from the food, drug and legal fields. The memo was offered as a "preliminary guideline" for use by the new administration. It said FDA should act cooperatively, but still carry a big stick.

Among key recommendations of the panel, headed by Chicago lawyer George M. Burditt, was a suggestion that FDA be re-established as an independent agency within the Health, Education & Welfare Department. Since last July 1, FDA has operated, along with the Environmental Control and the National Air Pollution Control administrations as part of the new Consumer Protection & Environment Health Service of HEW.

Old Status Sought

Burditt and his committee felt FDA would be stronger and more effective if the Nixon administration would restore it to its old status.

The FDA commissioner should report directly to the HEW assistant secretary for health and scientific affairs, it said. Presently, the FDA commissioner reports to the administrator of CPEHS, who is an assistant surgeon general presumably reporting in turn through the surgeon general to the assistant secretary. The complicated new structure has been under strong criticism from many quarters, including FDA staff members, who believe CPEHS represents another level of bureaucracy and a downgrading of their agency and its programs.

Burditt, a member of the Illinois state legislature and chairman of the state's food and drug commission, was Illinois chairman of the Lawyers for Nixon-Agnew in the presidential campaign, and has been mentioned as a possible HEW general counsel or even FDA commissioner, if the new administration decides to replace Commissioner Herbert L. Ley.

'Committee of 16'

Of the "Committee of 16," five are food firm officials, four are from drug firms, four are lawyers who specialize in FDA matters and three are consultants or trade association officials. Several of them were said to be former high FDA staff members. Names are not being disclosed.

Burditt told Feedstuffs no one from the Nixon camp has talked to him about a job at HEW or FDA, and that, if asked, he doesn't know what his response would be, "it would depend on the conditions." Burditt said he'd like to see a very strong FDA and gave the impression he thinks there's plenty of room for improvement. He said he'd prefer not to comment on what is in the memorandum, since he had simply been asked to prepare it and submit it to Henry Loomis, a former director of the Voice of America, who served as executive director for the various task forces created since Nov. 21 by President Richard M. Nixon. Burditt said he was the only person to sign the memo sent to Loomis.

The memo indicated that FDA should be dedicated to protecting the health and best economic interests of consumers by assuring compliance with laws and by encouraging technological advances. If this is done,

then the regulated industries will benefit, it was mentioned.

Nixon and the new HEW officialdom were called upon to enunciate their programs and policies for the best interest of consumers and to promote scientific and technological progress in the regulated industries.

More emphasis, it was noted, should be put on execution of the congressional mandate to protect consumers through enforcement actions in order to promote voluntary compliance with food and drug laws.

FDA Organization

The "Committee of 16" called for an efficient and simplified internal FDA organization with clear delegation of authority to staff and line officers. It also said the new administration should reassess the scientific function of determining the safe and efficacy of drugs, particularly new drugs. It recommended a finer line between the scientific and enforcement functions.

Procedures and practices in handling new drug applications were criticized as being unsatisfactory "either from the public's or from the industry's viewpoint." More expeditious review and scientifically sound decisions were suggested in determining the safety and efficacy of products submitted. "Scientists should be relieved of any responsibility for enforcement action, and, conversely, enforcement officials should not make scientific decisions."

The memo asked for consideration of an administrative review procedure for scientific decisions, not only because of the difficulty of such decisions but also "because of loss of confidence in FDA."

Administrative changes suggested for FDA included:

- Acceptance of the mandates of Congress without attempting to expand the agency's power and activities beyond that authorized.

- Acceptance of court decisions without attempting to avoid or evade judicial interpretations.

- Termination of "enforcement by news release or threat of news release."

- Reconsideration of the policy of publicizing voluntary recalls not involving a public health hazard.

- Elimination of the office of Federal regional assistant commissioner.

- Reevaluation of the policies requiring non-significant indirect food additive regulations.

- Elimination of submissions not

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(Continued from page 7)

pertinent to safety or effectiveness in new drug applications (NDAs), supplemental NDAs, investigational NDAs and food additive petitions.

—Consultation with consumer and industry groups in preparation of proposed regulations.

—Establishment of an efficiency review unit responsible to the commissioner.

—Emphasis on improved inspector training.

Voluntary Program

The committee said the de-emphasis of regulatory actions during the last few years has undermined the voluntary enforcement program at FDA. It produced figures showing that while the FDA budget was increased from \$18.8 million in 1961 to \$71 million in 1968, seizures, criminal prosecutions and injunctions are 20% smaller. "Firms which undertake voluntary compliance at considerable expense and competitive disadvantage are entitled to expect vigorous action against non-compliers," it was mentioned.

The official FDA magazine should be continued, it was said, but the emphasis should be shifted from being a propaganda piece to a voluntary compliance tool with industry and consumer comments and with the author of all articles identified.

The panel called for more emphasis on inspection and enforcement, and reevaluation of the expensive "and probably unsuccessful" experiment in self-certification.

In the long run, legislative steps may be needed to eliminate duplication of effort between FDA and other federal agencies, it was pointed out, but in the meantime, some administrative steps can be taken. For example, coordinated regulations regarding meat and poultry and food between FDA and USDA were suggested.

As a final recommendation, the "Committee of 16" suggested President Nixon set up a long range advisory group for FDA with government officials, consumers, industry and academicians participating, and it called for consultation with the Drug Research Board of the National Academy of Sciences/National Research Council.

It was argued that the problems of FDA are so great "that immediate attention to this important agency should be given by the Nixon Administration."