HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Arthur A. Dickerman

Retired Principal Attorney, OGC.

and

Fred L. Lofsvold

U. S. Food & Drug Administration

Laguna Hills, California

January 28, 1981

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.

The tapes and transcriptions will become a part of the collection of the National Library of Medicine and copies of the transcriptions will be placed in the Library of Emory University.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Room 500 U.S. Customhouse
721 19th Street
Denver, Colorado 80202
303-837-4915

TAPE INDEX SHEET

CASSETTE NUMBER(S): 1 - 3

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

DATE: Jan. 28, '81 PLACE: Laguna Hills, Calif. LENGTH: 138 Min.

INTERVIEWEE	INTERVIEWER
NAME: Arthur A. Dickerman	NAME: Fred L. Lofsvold
ADDRESS: [redacted]	ADDRESS: U.S. Food & Drug Admin.
[redacted]	Denver, Colorado

FDA SERVICE DATES: FROM 1942 TO: 1970 RETIRED? Yes

TITLE: Principal Attorney, Office of General Counsel, FDA
(If retired, title of last FDA position)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
1	A	0	1	Summary of A. A. Dickerman's Career
		5	2	General Description of Work with U.S. Attorneys
		10	3	Negotiations with Defense Counsel
		18	5	Trial of Cases (General)
		20	7	Fresh Grown Preserve Case
		27	11	Bodine Produce Case
	B	0		Bodine Produce Case continued
		2	14	Penicillin Regulations
		7	15	Commissioner C. W. Crawford
		11	17	Ozone Generator Case
		20	20	Golden Grain Macaroni Trial
		27	23	Relaxicisor Case
2	A	0		Relaxicisor Case continued
	B	0		Relaxicisor Case continued
		7	38	Wilhelm Reich Case
		12	39	Experiences with Judges
		28	47	Drown Case
		29	48	Apple Juice Case
3	A	0	[illegible]	Apple Juice Case continued
		8	50	FDA Employees
		10	51	Allan Drug Case
		18	55	End of Recording

This is a recording in the FDA oral history project. We are interviewing today Mr. Arthur A. Dickerman, a retired attorney from the General Counsel's office, at his residence in [redacted], [redacted]. The date is January 28, 1981. My name is Fred Lofsvold.

FL: Mr. Dickerman would you briefly describe your career with FDA--where you were stationed and what you did?

AD: I came to the FDA in 1942. At that time, I was stationed in the Headquarters of the General Counsel's Office in Washington, D.C. Five years later, in 1947, I was sent out to the West Coast, to Los Angeles, to work as a field attorney, representing the Agency in Food and Drug matters, mostly in the 12 Western States, although my work also took me to the East Coast. I used Los Angeles as my headquarters, from 1947 until 1970. I was the only attorney during that period in the Food and Drug Division of the General Counsel's Office who was stationed outside of Washington, D.C.

While I was in Washington, D.C., I went to various parts of the country to assist U.S. Attorneys in litigation matters involving Food and Drug cases. I also worked on regulations, especially with respect to penicillin. We helped U.S. Attorneys by writing briefs, preparing matters for trial, interviewing witnesses.

When I was sent to the West Coast, I did the same work, but the area in which I operated was generally more restricted in that, for the most part, I worked, as I said before, in the 12 Western states. The advantage of being stationed in the field was that I worked closely with the same U.S. Attorneys offices, and I got to know the people well. A number of these people later became judges, and they were familiar with the work of our Agency.

FL: In your work with the United States Attorneys, my recollection is that you did a lot of educational work with new assistants who were unfamiliar with the statute.

AD: That is correct. The Food and Drug law, even then, was quite complicated. Of course, now it is more complex, but it was necessary for me to give a brief course in Food and Drug Law to the assistants who handled our cases. After a while, some of the assistants became quite proficient and, of course, that was about the time when they left the office to engage in private practice, using their proficiency against us. However, generally, I would say that we had created, in the minds of most of the U.S. Attorneys and their assistants, a friendly atmosphere toward the Food and Drug Administration, so that when they were engaged in practice against us, it was not with hostility, but in an attempt to minimize the

damage to their client, without inflicting damage on the consumer.

FL: Also, didn't your work include handling of appeals?

AD: Yes. I did a lot of writing of appeal briefs. Usually it was as a follow up to trials in which I had been involved where the government hadn't prevailed or lost the case and it went up for appellate review. Sometimes I wrote briefs in matters where I had not been present at the trial. Occasionally, I would argue the appellate matters myself or shared the argument with the Assistant U.S. Attorney.

I remember one unfortunate experience where the Assistant U.S. Attorney was well disposed and, while trying always to be helpful to us, really never understood the case at all. We agreed that he would take the first 15 minutes of the government's argument on appeal, and I would take the second 15 minutes. It was my duty, when I argued my portion of the appeal, as diplomatically as I could, to undo all the misconceptions that he had created without causing him any grief. This would be done through the guise of clarifying a point that had been made by my colleague.

FL: When defendant's counsel sought to negotiate settlement of a case with the United States Attorney, did you

participate in such negotiations?

AD: Yes, I frequently did and would often suggest to the U.S. Attorney that the government initiate a conference with opposing counsel to narrow the issues, in the course of which we would perhaps arrive at a negotiated disposition. Under the rules today, pretrial agreements are sanctioned by the courts formally. At that time, there was no formal procedure for pretrial agreements, but it worked essentially the same way, except that we did not commit ourselves to recommending a specific sentence in a criminal case.

One technique that I found helpful to dispose of pending litigation was to suggest that each of the defendants plead guilty to one or more counts and also consent to a permanent injunction. The case usually was initiated by the government only as a criminal case but, if my suggestion was accepted, we would also file a complaint for injunction, together with a consent decree of permanent injunction.

The appeal this had to the defense counsel was that it would let the court see that his client genuinely repented and had no intention of repeating the offense. The benefit to us was that the matter was more fully disposed of in that the defendant was deterred from

further wrongdoing by the probability of a contempt action for violation of the injunction. The defense counsel also often felt that, because of the attitude of his client in consenting to a permanent injuction, the court might be more lenient in imposing sentence.

Even if the case went on to trial instead of being disposed by a consent decree of injunction and a guilty plea, we were usually able to agree with opposing counsel on certain facts to which we stipulated that would minimize the government's expense in bringing witnesses to prove allegations not in dispute. It was helpful, in arriving at such stipulations, to point out to defense counsel that, even in criminal cases, the defendant could be required to pay the government's costs of proving its allegations. This fact was not generally known to defense counsel, and it was useful to point it out to them because, if they knew that we could easily prove a fact, it was pointless for them to require that we do so through live evidence in court. Of course, the Federal Statute which authorizes a District Court, in its discretion, to impose costs upon the defendant does not apply where the offense is a capital offense, which illustrates that the death penalty might be less expensive for the defendant, in some instances.

FL: In those years that I worked with you, I remember that your negotiating skills were widely recognized as being very beneficial to the government, especially in those cases where the defendant stipulated to so many facts that we were able to then move for a summary judgment on the grounds that no material facts remained at dispute.

AD: I'd like to interject at this point the idea that the Food and Drug people with whom I worked, all of them, had a great deal to offer that was beneficial in pretrial, as well as trial stages of litigation, and I would recommend to the General Counsel's Office of the future to pay attention to their suggestions because they usually know more about the facts of the case than the lawyers ever will know. While some of the suggestions made by these non-lawyers might seem bizarre at first, it often proved to be the case that I was able to utilize the suggestions, perhaps with some modification, to our best advantage.

FL: Were there any times when you actually tried the case, rather than having the United States Attorney do so?

AD: Yes, there were a few such cases. The litigation enforcing the Food and Drug Law is under the control of the Department of Justice and, of course, it can determine who will try the case. The U.S. Attorney was usually the

one who tried the case, that is either he or one of his assistants. From time to time, I would be asked to try the case, and I would do so if I thought it best. My usual approach was that, if the U.S. Attorney had a sufficient grasp of the case to present it in a satisfactory manner, it would be better for him to do so, rather that to have an agency attorney try the case. On appeal, it didn't seem to matter as much which attorney argued the matter, but at the trial there were sometimes local prejudices against the Agency attorney who the judge might feel was not impartial, had an axe to grind, was overzealous, or didn't know the local rules as well as the Assistant U.S. Attorney. On the other hand, sometimes the Assistant U.S. Attorney was so much under the control of the judge that he was afraid to say anything he thought might displease the judge. It is necessary to speak candidly, though always with respect, even though the result might not be pleasing to the judge. The fact is that, many times when a judge is displeased and rules against us, his ruling is reversed on appeal.

FL: Could you describe some of the circumstances under which the United States Attorney preferred that you present the case?

AD: Yes, I'd be happy to do this. I remember I came to the Agency in 1942, fresh out of law school. Except for

being admitted to the bar, I had never even been in a court. A short while thereafter, I was sent to one of the Southeastern states to present the government's case in a precedent-making bond forfeiture matter. When I got to the city in which the case was to be tried, I was greeted warmly by the U.S. Attorney himself. I presented him with a copy of the brief which I had prepared, and he glanced at it. I always used tabs and indices and a table of contents, so he was happy with its appearance. He never read it. He then told me that the case was going to trial the next day, and that he would introduce me to the judge and have me admitted specially in that state. I was not a member of the bar in that state, and he wanted me to try the case because he had to go duck hunting. He was very affable, yet I was thrust into this case, my first trial, without any prior experience, but before a very kindly judge. It was a trying experience for me. At one point I was uncertain of what my next move should be, and the judge leaned over on the bench and said graciously, "I would now be happy to entertain a motion for (something or other)." I forget what it was. So I said, "Your Honor, I move that we do that." He said, "Granted." That judge has always remained in my mind as the ideal judge, who was just not eager to trample upon inexperience, but ready to help to see that justice prevailed. The case was won, and affirmed on appeal.

FL: Was that, by any chance, the Stinson Canning Company case?

AD: No, this one was an earlier case, the Fresh Grown Preserve Case, in which we established the principle that a bond (which is given in a seizure action to assure that salvaging of a condemned product will conform to the law,) may be forfeited in toto when there is any deviation from the salvaging provisions of the court order, even though not all of the product had been mishandled by the owner of the goods.

The Stinson case came later. In the Fresh Grown Preserve case, the bond was valued at $1,000 and was forfeited in toto. In the Stinson case, I believe it was a $20,000 bond.

FL: Well, I was interested because I recently recorded a similar interview to this one with an old retired inspector who was involved in that case.

AD: In the Stinson case?

FL: Yes. He pointed out that the whole thing came to light when the claimant returned a seized shipment of canned sardines from New York to his cannery in Maine and then

distributed them. In order to cover up this shortage of the seized material, he packed another lot of similar size using the same code marks on the can.

AD: The same code marks that were on the product that had been seized?

FL: Right. The only mistake he made was that he put the wrong lithographed label on the cans so that his substitution was very apparent when the inspector went to the cannery to examine the goods which were supposedly being held under bond. After that, the whole story came out, and the bond action followed.

AD: This may have been the claimant's first attempt at misfeasance, and that brings to mind a couplet of Alexander Pope, a well-known couplet, in which Pope wrote, "Oh what a tangled web we weave, when first we practice to deceive." Many years later, a jokester added another couplet to that one in which he said, "But when we've practiced quite a while, how vastly we improve our style." So, in the Stinson case, no doubt a little more practice would have been helpful to the claimant.

FL: After that initial baptism of fire in court presentations, did you have any other experiences furthering

your education along that line?

AD: Yes I did. Throughout the years of my work with the U.S. Attorneys Offices, I found that there were many able and experienced U.S. Attorneys and Assistant U.S. Attorneys. Of course, there were young Assistants who came in without experience, and who were put in charge of some of our cases. They later turned out to be very good, in many cases. However, if I knew that an important and difficult case was to be sent to the U.S. Attorney with whom I had, in the meantime, established a good relationship, I would seek out a conference with the U.S. Attorney giving him a little insight into the type of litigation I expected would reach his office. I would ask him to designate his chief trial attorney to handle this matter, pointing out the mutual advantages to his office and ours in having the most experienced attorney on this particular case. For example, this was done in the Relaxacisor case, and in a number of others, though I would not wear out my welcome by seeking that special dispensation in every case.

I had one experience with a young, but experienced, trial assistant in the Bodine Produce Case. He did something that startled me and opened my eyes to the importance in evaluating the credibility of a witness. In that case,

the defense produced a chemist who had made an analysis of the lettuce and had determined that it contained far less than the 7 parts per million of DDT, which was then the tolerance the FDA had established. The witness spoke at some length about the method of analysis he had used and detailed the results he had obtained. When he concluded his testimony on direct, the Assistant U.S. Attorney, who was about to cross examine him, leaned over to me and said, "Watch this one." He then rose and looked at the witness and was silent for an unusual period of time. He really stared at the witness. Finally he said, "Now Mr. so and so, the fact is that you made no analysis of this product at all. Isn't that the case?" To my surprise, the witness, in Perry Mason style, acknowledged that the assertion of the Assistant U.S. Attorney was true. That, of course, demolished, not only his testimony, but the entire defense. That was the only question that the Assistant asked of this witness. So, I don't know how you teach somebody to be able to do this. I don't know that I could do it, because I was not a trial attorney in that class. But it was an experience that I'll never forget.

FL: Ordinarily you would think that would be a very risky question to ask a defense witness because the witness could simply insist he had made the analysis exactly as he had testified.

AD: It would wind it up.

FL: It would have reinforced his testimony in the minds of the jury.

AD: That's right. But this man, the Assistant U.S. Attorney, whose last name was Green, as I recall, put on an outstanding performance. And this was typical of the way he handled the entire case, which was a difficult case--well tried by both sides. The defense attorney subsequently became judge in the U.S. Court of Appeals

FL: When you requested a United States Attorney to assign his most experienced trial lawyer, were the U.S. Attorneys generally sympathetic to that request?

AD: The answer is yes, but I should say this, that I limited my requests only to the most important and difficult cases. I made the request only where I was about 99% certain that it would be granted, because I knew I was dealing at that time with an able and sympathetic U.S. Attorney who had the interests of the FDA at heart, even though he himself was not going to try the case. So I can't remember any instance where I made the request and it was refused.

FL: Earlier you mentioned that, in your first years with the Agency, you were involved in preparation of regulations. What regulations were those?

AD: In the mid-forties, Congress had enacted the first of the amendments that dealt with antibiotics. At that time, it was penicillin. It was my good fortune to work with Charles Crawford, who was then Associate Comissioner, as I recall. Was it Dunbar who was Commissioner before Crawford, I don't remember?

FL: Right.

AD: Anyway, it was Crawford who had the task of drafting the penicillin regulations, and I would trot down to his office every morning, first thing, and we'd work all day long. There was a member of the staff in the General Counsel's office who was inspired to write poetry about my running down there every morning. I remember the first two lines he wrote, "There goes Arthur in a hurry, with his penicillin worry." At any rate, it was a singular privilege to have spent a few months in close contact with Charles Crawford, who had a fine command of the English language and a dedication to the consumer, which rubbed off on all who came in contact with him. Early in our association, he called my attention to the

Supreme Court decision in the Antikamnia Chemical Company case in which the Court had this sentence, "The purpose of the law is the ever-insistent consideration in its interpretation." And he felt that those of us who were entrusted with the execution of the law should bear that sentence in mind at every turn.

One idiosyncracy of Mr. Crawford's was that he liked to write his regulations using only pencils. This required his secretary, I believe it was Miss Koegler, to sharpen many pencils every morning and put them in some kind of a holder. He would take a pencil and begin writing the regulations that we worked out between us and then, when the pencil no longer had the sharpness that he desired, he would simply throw it on the floor, thereby perhaps venting some of his frustrations. We had many laughs about that. I never could acquire that habit myself, not having reached his stature.

FL: What kind of a man was Mr. Crawford?

AD: He was a mixture of an idealist and a pragmatist. There were some provisions in the Act of 1938 which he had helped to author, of which I was critical. When I voiced my concern about the language in those provisions, he who had gone through the Congressional gauntlet told me he

wanted more, but he couldn't get it. His attitude was, if he couldn't get the whole loaf, he would take half a loaf. He was a man who had great personal tragedy in his life, but he did not let that interfere with his consuming passion for achieving the goals of the Food and Drug Law.

Several years later, when Mr. Crawford announced, after he had been Commissioner for a while, that he was going to retire, I was devastated by that announcement because he looked sturdy and seemed to be in good health. He tried to console me by saying that the place would not fall apart on his leaving, that he felt that there were many good people ready to carry on, and he said, if there were not good people of that kind, then he had been a failure. He was, of course, right, and there were many good people to carry on.

After his retirement, he moved to one of the suburbs of San Francisco where he built a home for himself and his wife. Unfortunately, after a few years, he developed leukemia. Dr. Ralph Weilerstein and I went out to see him. Ralph often was his attending physician. I would see him whenever I was in the area. We saw him deteriorate. I wrote his will. It was a great tragedy to me to see this man, who had been like the Rock of Gibralter

so many years, just fade away in front of our eyes.

FL: During those many years that you were involved in the trial of Food and Drug cases there must have been some interesting things happen, could you tell us about some of them?

AD: Yes. The first case that comes to mind is one that transpired, I would say, in the early '50's. We had a seizure action of ozone generators in New Mexico. The U.S. Attorney, who did not fully understand the facets of that particular case, was nevertheless very cooperative and anxious to help us. The case was set for trial, let us say, on a Monday. Dr. Weilerstein and I came to Albuquerque the preceding Wednesday or Thursday. In my judgment, the case was ripe for summary judgment. It involved a 502(f)(1) violation in which we charged that the labeling of the device failed to bear adequate directions for use since it did not state all of the conditions for which the device had been promoted to the public through means other than the labeling.

At my urging, the U.S. Attorney filed a Motion for Summary Judgment, since the admissions and the other facts elicited during the discovery stage of the litigation were enough to support our Motion for Summary Judgment. It was the practice of the judge who was to try the case

to set aside every Friday for the hearing of motions. The agreement that I had with the U.S. Attorney was that I would argue the Motion for Summary Judgment.

We got into court that Friday morning, and there were about 10 or 12 cases ahead of ours. It looked as though it would be some time before the judge would reach our case. The U.S. Attorney then whispered in my ear that he had had a call of nature, and that he would leave the room, but would be back as soon as he could. I became apprehensive because, by that time I had learned that a great many cases can be resolved in a very short time during Motion Day, since the parties, prior to coming to court that day, had been trying to resolve their cases. Unfortunately, that was the situation that day. One, two, three quickly all the cases vanished before ours. This one required additional time. That one had agreed to withdraw the case. The other one had stipulated to a disposition. There was no case left before ours, and in no time at all our case was called.

The judge ran a tight ship, and I had not been admitted to practice in New Mexico, which meant that I could not present argument. The U.S. Attorney was going to move my special admission that morning, but he wasn't there. So, when our case was called, and the judge looked around for the U.S. Attorney, with some trepidation I arose to tell

him that the U.S. Attorney had been called out of the courtroom, but would be back very shortly. The judge, who had many other cases after ours, decided that he would simply pass over the Motion and take it up Monday morning just before trial. My heart was heavy then because I knew what was entailed. When the U.S. Attorney returned, it was too late, and he did not want to ask the Court to take it up again that morning.

We had previously arranged that our witnesses be alerted and ready to come to Albuquerque if the case was going to go to trial. We then set in motion the forces that would bring all these witnesses--there were many--to Albuquerque that weekend, where we could meet with them, go over their testimony and be prepared to go to trial on Monday. We estimated somewhere between $5,000 and $10,000 was spent that weekend for transportation, per diem, and other expenses.

The following Monday, when the case came up for trial, the judge announced that there was a motion pending that he would hear. By that time I had been specially admitted and I argued the motion. Lo and behold, the judge agreed that the case was ripe for Summary Judgment and granted a Summary Judgment. So bringing all these witnesses was a complete waste of time. My only comment is that the untimely peristaltic action experienced by the U.S. Attorney was a very expensive one.

One other event transpired. The defense had its witnesses, mostly satisfied users, ready to stand up and extoll the virtues of this device. They were prepared and eager to give testimony to that effect, and they were shattered by the fact that the case was over before they could say a word. They didn't understand the Summary Judgment procedure. One woman approached me, and she had a pretty good sized handbag, which she proceeded to swing at me, because I was the satan of the day. I tried to calm her down and explained that it was a court procedure, but I don't think she understood. I never brought any action against her for assault and battery.

Another case that I remember well involved the Golden Grain Macaroni Company. It went to trial in Seattle. Harry Sager, who was one of our best Assistant U.S. Attorneys, tried the case for the government. During a period before trial--a week or two before trial--the defense attorney asked for a portion of each of the official samples. There were 5 counts, based upon 5 separate samples. Each sample contained macaroni which had been insect infested, mostly by moths. In response to the request for a portion of the official samples, we proceeded to open up the reserve samples in the possession of the laboratory in the Seattle District. Four of the

samples were in good condition, and a portion was set aside from each of those four samples. The fifth, however, had not been fumigated sufficiently to preserve the sample. The result was just a mess of material that was not identifiable. We therefore were unable to furnish a portion of the fifth sample.

The defense attorney thereupon filed a Motion to Dismiss Count 5 because, under the statute and the court decisions which had interpreted the statute, the count was subject to being dismissed for our failure to furnish a portion of the official sample, unless it fell within some exception. In my judgment, it was highly questionable that our failure to furnish this sample fell within any exception, although it was arguable. The Assistant U.S. Attorney, Harry Sager, felt very strongly that we should proceed to trial on all 5 counts and that we should argue that it was not incumbent upon the government to do any more than it had done to preserve that sample, and that failure to preserve it should not require dismissal of the count. I felt that we had 4 good counts, and why muddy it up with a fifth questionable one. But Harry was all for arguing against the Motion to Dismiss that count, and so I thought, if he wants to argue it, fine. But he turned to me and said, "I want you to argue that," which I proceeded to do because it was arguable, but I was greatly relieved when

the judge ruled against us on that point. The case thereafter was tried on the remaining counts. The defendants were convicted and the conviction was affirmed on appeal.

There was another episode in the course of that trial that shed some light on the way judges may view evidence. The judge in the case was an able judge. I remember he always ruled quickly. Whenever a matter came up, a motion of any kind, he would rule very quickly. His observation was, "The Court may be in error, but it is never in doubt." After we had presented some devastating evidence to show the insanitary conditions under which the macaroni in question had been produced, those conditions consisting of moths and cocoons all over the place--on the walls, on the ceiling, they were all over--the defense attorney filed a motion asking the Court to view the premises as they now existed. We objected to granting that motion because our position was that first we knew that the premises, no doubt, had been cleaned up. Secondly, it was clear that the current condition would not reflect the conditions which the inspectors had observed when the macaroni in question had been produced a year or two before that. Nevertheless, the Judge ordered that there be a view of the premises. The Judge, accompanied by the court entourage and the attorneys for both sides then proceeded to the plant of the Golden

Grain Company where, of course, as anticipated, the place looked spotless. I was concerned that the Judge might dismiss the case because it looked so good, even though that fact was not relevant to the issues in a criminal action. If the case were dismissed at that point, the government could not appeal. The Court looked over the premises and said nothing at the time. We all came back to the Judge's chambers, and there the Court expressed great indignation over what he had seen. I remember a statement that he made, "Did you see that fly on the premises?" After he made that statement, we proceeded with the trial, and won the case. A rather stiff sentence was imposed which was affirmed on appeal. So the Judge apparently denied the Motion to Dismiss properly, but for the wrong reason. It didn't seem to me that one fly on the premises, and it was a large plant, would indicate that there were grossly unsanitary conditions at this time which would warrant criminal action. On the other hand, it was irrelevant, in view of the evidence, that showed gross insanitation at the pertinent time.

FL: You've mentioned some food cases. Were there some drug or device cases that were of particular interest?

AD: Yes, I'd like to say a few words about the Relaxacisor case. I could say many thousands of words about this

case, but I'll just select a few episodes at this time. The findings and conclusions of the District Judge in the Relaxacisor case are reported in the Federal Supplement, so I won't attempt to restate them now. It involved a device which, in effect, put electricity into the body. It was a pulsed muscle stimulator--electrical muscle stimulator. The government's principal theory was that a product of this kind could cause great harm to a person by aggravating pre-existing conditions. A secondary theory was that the labeling was false and misleading in that it represented that the use of the product would cause girth reduction, and that the product was also a good exerciser. The impression was created by extensive promotional material that the product would help to realize the American dream: You could sit on an easy chair, look at television, eat chocolates, yet lose girth and do your exercises, because the machine would do it for you.

The case was tried by Judge Gray over a five month period. Since it was an injunction suit without a jury, the Judge tried to work it out so that he would not devote full time to this case, but assign a few days at a time to us. He would give us notice in advance that he would be trying the case next Tuesday, Wednesday, or all of the following week, something of that kind, because he did not want to permit the rest of his calendar to pile up

on him. At one point he told us--it was, let us say, a Wednesday afternoon, we were in the middle of presenting our evidence--he told us we were not going to have any more trial that week, Thursday or Friday, but that he would give us all of the following week. The government had many witnesses to call, among them a number of users who had been injured.

Consequently, when the Judge told us that we were going to have a full week of trial the following week, we promptly notified about 35 or 40 users of the device to come to Los Angeles prepared to testify about their experience with the machine. The user testimony subsequently was to be corroborated by the physicians who had attended the users subsequent to their injuries sustained by reason of their use of the Relaxacisor. We had worked out these arrangements in advance, subject to being triggered whenever the Court was willing to give us a whole week. Everything went well though there were many problems connected with getting all these witnesses at the same time, or even at all. In one instance there was a young bride who had just been married, and her husband was afraid of the wolves in the big city, so he didn't want her to go alone, or at all. In other instances the employers didn't want to spare their employees. In some instances, there was a husband who had to be accompanied by his wife, or vice versa. There were

little children to be taken care of while the mother came to California. There were many problems, but we had resolved them all within a very short time because we had done a great deal of work on it before that time. All the witnesses were on their way or about to be on their way by Friday afternoon, when a call came to me from the Clerk of Judge Gray. The Clerk said he had tried to reach Don Fareed, the Assistant U.S. Attorney who was trying our case, but Mr. Fareed was not available. The Judge wanted to let me know that he was sorry he could not give us the following week which he had planned to give us, because he had to accomodate a lawyer who had come from New York to try some other litigation before him. The lawyer had been in court that Friday and the Judge wanted to finish up that case before resuming ours. After I recovered my speech, I told the Clerk that this was a devastating bit of news he had brought me, and I asked to speak to the Judge. The Judge got on the phone. I explained to him that we had all these witnesses coming in. It cost a lot of money. That there were about 30 or 40 witnesses. We were going to meet with them that weekend. It would be a blow to our case and a great expense to the taxpayer if we could not have the following week and were compelled to reschedule those witnesses. The Judge was very gracious, saying that he did want to accommodate the New York attorney, but that was only one person, and since we had so many and it

would be so expensive, he decided to let us have that week as originally planned. I breathed a sigh of relief, but I think my hair turned quite gray in that hour.

One source of leads in the Relaxacisor case was the Good Housekeeping Magazine file. Good Housekeeping Magazine had given its Seal of Approval to the Relaxacisor device. As a result, over a period of a year or 15 months, it had received thousands of complaints. It was the practice of Good Housekeeping to destroy their files after a certain period of time. By the time we got to Good Housekeeping, they had destroyed about half their files on this device. But, nevertheless, there were about 800 complaints that they had not yet destroyed. We obtained Xerox copies of all the letters of complaint and had investigators all over the country check them out. We didn't just tell them to check out all the complaints; we read the complaints; we sifted them; we had a color system on our folders--red, yellow and green. Red meant we were not ready, at that point, to consider using this person as a witness or even to investigate. Yellow meant we'd better investigate to see wheher there was something worthwhile. Green signified that, after investigation, this person would be a probable witness. Throughout our investigations, we kept switching colors as the investigations indicated it was desirable.

There was one letter that was written by a man who was not very eloquent, who did not write in a particularly articulate manner. It was a simple letter in which he complained that he used the machine, and he got an abdominal hernia from its use. Some of us felt that there was something more to be ascertained, if we could only find that user. The letter had been written a few years before, the time when we were doing our investigation. Some of our best Los Angeles investigators were put on this matter. I remember Frank McKinlay worked on it. We searched and searched for this dissatisfied user. Ultimately a death certificate was found for this man. However, the death certificate indicated that the man had died for some reason, in our judgment, which could not possibly have been related to the use of the Relaxacisor device. In the letter, there had been reference to the fact that this man had filed a suit against Relaxacisor. When, in the course of our discovery work, we asked the Relaxacisor people to furnish us with information about any person who filed suit, sure enough this man's name was given to us by Relaxacisor as an individual who had filed a suit against them which had been disposed of by a $2,000 agreement, sort of a nuisance suit, they claimed that they had just settled that for $2,000. Since we knew there had been a suit, and by this time we also knew the court number, the docket number, and the place where the suit had been filed, we went to the clerk's office of

the Superior Court in Los Angeles and asked for the file. Unfortunately, there had been a fire in the court file room, and this particular file was gone. It had burned. All that remained was a docket sheet which indicated when the suit had been filed, by whom, against whom, and what the name of the user's attorney was. We scrounged around, and we found that the user's attorney was in San Marino, about 20 miles or so outside of Los Angeles. I called the attorney, and he remembered the case quite well. I asked him if there was anything in his file that would be useful to us. He said, "Well I have the file right here. Let me check it out." He came back and said, "I can't see anything that would be useful to you." At that point, I thought that we had spent too much time on this matter simply to drop it. I'd better go out and see the file myself. So, with the permission of the attorney for the user, Frank McKinlay and I went out to San Marino and were given the file. It was quite a thick file, and we looked through every sheet in that file. Lo and behold we found a statement from a physician who worked for the insurance company. Relaxacisor was insured against personal injury suits by the insurance company. When the user had filed a claim and then a court suit, the insurance company had referred the user to a doctor who did this type of examination for the insurance company. The doctor had written a two page letter in which he described the symptoms experienced by this man

who had come to him. The doctor concluded that the man had had an asymptomatic hernia which had become seriously symptomatic as a result of using this machine, because the pulling action created by the use of the machine tore the hernia beyond what it was and caused him a lot of distress.

The user's Attorney permitted us to keep that letter which had been signed by the doctor. We then found the doctor and were a little concerned because the doctor said that was his signature, but he couldn't remember anything about the case, and his own files were gone. He had handled thousands of cases for the insurance company involving many products. However, he said, "That is my signature, and I'll testify to it," which he did. It was very useful to have this doctor at the trial. All I can say is that sometimes persistence will produce something worthwhile in preparing for trial. Many kudos are due to Frank McKinlay who was probably one of the most persistent investigators that I have ever worked with.

The defense in the Relaxacisor case spent a lot of money, both in legal talent and in investigational work done by medical and clinical experts. In getting ready for trial, they produced charts that they wanted to bring into the courtroom. But these charts were so big that they could not fit into the doors of the courtroom. The

charts were then cut down by the defense and brought into the courtroom where they were reassembled and were stood up against the wall. They were about 12 feet high and 30 feet wide. It was a very impressive set of charts; however, upon close analysis, we were able to utilize them to our benefit. One of the studies done by the defendants, or their experts, involved a number of dogs. These dogs were anesthetized during the studies, and their abdominal areas were shaved. The electrodes were placed against the shaved areas and near the heart, and the current was turned on. The purpose of these studies was to show that no harm was suffered by the dogs. During the course of our pretrial work, we took the deposition of the doctor who had conducted one of these studies. He produced the notebooks which described the dog, the particular model of the Relaxacisor device that was used, the anesthetic that had been given to the dog, the amount of current that had been applied to the dog, and the conclusion. And in every instance, the conclusion was that there was nothing untoward observed.

The clinical data was recorded by the defendant's experts in a bound notebook--one sheet for every dog, and one notebook for each set of studies. Consequently, the notebooks were rarely full; they were about half full. In this particular case, the dogs were identified by date, the date on which the experiment was conducted.

The dog in question had the date 8/6/68, meaning August 6, 1968 was the date when the experiment was conducted. When you looked at the bound notebook, the study on this dog seemed seemed just as uneventful as it appeared to be with respect to all the other dogs. Dr. Weilerstein, always the skeptic, looked through the pages that had no no writing on them to see if there was anything in there and, sure enough, he found a few loose sheets which also related to dog 8/6/68. They told a different story from what was told in the bound notebook.

When we went to trial, of course, we had a Xerox copy of what the bound notebook said, as well as a Xerox copy of the loose pages that had been inserted in the back of the notebook. When the doctor who conducted this particular study had finished his testimony on behalf of the defendant and was being subjected to cross examination, we asked him what was the significance of the loose sheets. His reply was that the day when they went to do the study on dog 8/6/68, they could not locate the notebook. Consequently, the notes were jotted down on loose sheets and thereafter transcribed by the secretary into the bound notebook. That, of course, was an abnormal procedure, but we made no comment on that particular point, since it spoke for itself. According to the testimony of the witness, therefore, the loose sheets should be identical with the bound notebook, as far as the data was

concerned. We then pointed out to the witness in cross examination that the loose sheet shows that Model A had been used, whereas the bound notebook said that Model B had been used. We asked him to explain that. He said, "Well, they thought they were going to use Model B and therefore, the day before they went to conduct this study on dog 8/6/68, in other words, on August 5, 1968, they had written the initial data about this dog indicating that Model B was to be used. However, when they got down to the laboratory the next day, it developed that Model B was not available, so they used Model A. This, of course, was another significant discrepancy, and we asked the witness whether it was a practice in his laboratory to write up part of the experiment the day before it took place. There was a howl of objection on that point, but the Judge let it stand. There were other discrepancies. The bound notebook had a set of numbers regarding the values of elecrical current, the milliamps and millivolts--I'm not a scientist--I can't remember the details, but the numbers that were in the bound notebook were entirely different from the numbers that were on the loose sheets. Also, the bound notebook showed that nothing untoward had transpired. The sheets, the loose sheets indicated that an autopsy had been performed suggesting that the dog had died during the course of the experiment. When we asked for clarification of these descrepancies, the defense witness became a little flus-

tered. He said this was a sick dog, and he should never have been used in the experiment anyway. We asked him whether the machine was sold only to persons who were in good health. Obviously, they were sold to anyone.

The loose sheets spoke of this dog having myocarditis that was ascertained during the autopsy, and that there was arrythmia and other heart abnormalities. It may be that the dog didn't actually die during the course of the experiment, but that he was sacrificed because they wanted to check into the causes of the abnormalities. We're not certain about that. But, at any rate, the loose sheets told a story that was far different and impaired the credibility of the entire defense. So this, I felt, was an extremely significant development in the case and resulted ultimately in the victory of the government.

There was another episode in the Relaxacisor case that perhaps is worth mentioning here. During the course of our trial preparation, we tried to interview every doctor who had treated a patient where the patient had been injured by the use of the Relaxacisor. There was a doctor in New Jersey, who was a surgeon, located maybe 40 or 50 miles from New York City. His patient, in this case, was a woman whose stomach he had removed because of a malignancy. She had been sold one of the Relaxacisors, after

her surgery, because she thought it would help to reduce her flabbiness in the abdominal area. She used it a few times and it caused her great pain and distress. Her doctor, when he found out about it, ordered her emphatically not to use such a device. She was to be one of our witnesses. Dr. Weilerstein and I were in New York interviewing other prospective witnesses, and we called this particular doctor in New Jersey and asked him if he would agree to see us. He asked us what it was about. We mentioned that it was about his patient and described what had happened. He then said, "I'm not going to see you, and I'll tell you why." And he proceeded to give us a scenario as to what would happen. He said, "You're going to come to my office and you're going to tell me how important it is for me to testify in your case. I'll grant you it is important," he said. "Then you're going to persuade me to go to Los Angeles, give up my busy practice here, spend a week in Los Angeles, give me some pittance of compensation. I'll be in court and have to deal with lawyers who are cross examining me . . . " I think he suggested something about being subjected to the usual barrage that lawyers can subject a witness to. He said, "I'm not going to do all that, therefore I won't see you." Well, Dr. Weilerstein used his most persuasive manner, appealing to his public-spirit interest. Ultimately the doctor did agree to see and, I might say, that the scenario he had described worked out to the letter.

What the doctor did not say in the scenario that he forecast was that he would turn out to be one of our very best witnesses, because he was aghast at the thought that a patient of his who had had a malignancy that he had removed would be subjected to the trauma of this device. He stated that he hoped he had removed all the malignancy but he could not be sure and that, if any malignant cells remained, the traumatizing of those cells could well activate them and cause them to metastasize. The surgeon, at the trial, spoke with great vehemence and indignation because he was outraged by anybody selling such a device to his patient and subjecting the patient to what he felt could be a fatal result.

Another aspect of the Relaxacisor case related to the promoter's use of misleading testimonials from movie stars such as Kim Novak, Doris Day, Corinne Calvet and many others. With respect to Doris Day, when we took her deposition, she stated that she was the athletic type. She played tennis and she would never use a machine like this for her exercise. Apparently her manager had agreed to a testimonial describing benefits she had received from the machine. In fact, someone had tried it on her once but she didn't care for it. Yet there was a testimonial from her.

There was also a testimonial from Corinne Calvet. She said that she had never used it at all. There was a group of the movie star testimonials which contained a very beautiful portrait of each of the movie stars with a few words underneath it. Now, with respect to Corinne Calvet, the words underneath her picture said, "This is my way." That was all it said. Now "this is my way" implied that Relaxacisor was her way. She said she never used the machine at all. She simply went to some outlet in Hollywood which was run by some gentleman who gave away refrigerators and other products to celebrities. He was referred to as "The Giveaway King" by the stars, and if you wanted any of these appliances, you would go there and sign some statement and he would give you one. Now she got this device; she never used it; she gave it to her mother-in-law. That was her testimony.

I can't remember what Kim Novak did. The only thing I remember about Kim Novak is that she came to the Food and Drug office to have her deposition taken, that was in Los Angeles. When knowledge that she was to come spread amongst the employees, everything was spiffed up. They all wore their best. She was very gracious. At the end of her deposition, we told her that the staff would be greatly disappointed if she didn't make a tour of the office and she graciously accompanied our leaders, who took her to the laboratory and the inspection room. She was very nice about it.

None of the testimonial writers supported the Relaxacisor promoters when all the facts were known. In any event, these testimonials were written with respect to efficacy. Since we never went to trial on efficacy, we didn't have to present that evidence in court, but we had it ready.

FL: Do you recall any other therapeutic device cases that would be equally interesting?

AD: Yes, there's one case involving the Reich device, Wilhelm Reich. We had much litigation with Dr. Reich, with his firm, with his devices, all over the country. Dr. Reich was a German psychiatrist, apparently a man of stature who came here during the Hitler period. I gather from others who knew more about the case than I that something went wrong and that he developed a device which was of no value and tried to promote it really as a panacea. In the course of preparing for trial in that case, the FDA had its investigators all over the country contacting purchasers of the device.

One purchaser was a professor at the University of Oregon and Irv Berch, who later became a Regional Director, was at that time an inspector in Oregon. Mr. Berch went to see the professor, who was not only a personable man, but a man who seemed knowledgeable enough not to be taken in by the claims that were made for the device.

The device, as I recall it, looked like a little telephone booth, and it was lined with steel wool. The directions called for the user to sit in the device for an extended period of time. The device was designated as an Orgone Accumulator and, the theory was that when a person sat in this device orgone energy from outer space would be concentrated in the device to the great benefit of the person seated therein.

When Mr. Berch spoke to the professor, he asked him how a man of his stature came to buy such a device. The professor responded by saying that he knew that the device was a phoney, but he found that it had great value in this way. He said, "My wife sits in it four hours a day and keeps her mouth shut." I am not, I hope, indicating that I share this male chauvinist pig response, but this is simply the story as I heard it.

FL: In the course of your work, I'm sure you met a great variety of judges on the bench. Are there any experiences there that stand out in your mind?

AD: There is a series of experiences with Judge Ritter in Utah. Before I come to the main thrust of what I'm about to relate, I have to preface it by discussing a court case that was tried before Judge Ritter. It was a criminal case, and the Defendant was the manufacturer and

distributor of canned vegetables. A purchaser of these canned vegetables who lived in California opened the vegetables, put them into a sauce pan and cooked them and tasted them to see if they were ready, as she was cooking them. She had three small children who were tugging at her skirt, and she didn't pay too much attention to what was in the saucepan while she was tasting the vegetables, but when she poured the vegetables into dishes, she noticed that, in one of the dishes, there was a dead mouse that had come out of the can. This caused her great emotional and physical distress so that she had to be hospitalized. She came to Utah, to Salt Lake City, to testify in the case. She had brought along her three children, because she had no one with whom to leave them, and during the course of her testimony, one of our inspectors was designated as a babysitter outside of court to take care of the children.

The defense, as often happens in such cases, produced inspectors from the Department of Agriculture who had been on the premises on or about the same time as we had been, and there was some apparent conflict of testimony. As a result, it appeared that their inspectors and ours weren't looking at the same thing that day. However, the judge convicted the defendant. He called the government attorneys into his chambers after the conviction to congratulate us on putting on a good case and to express

his opinion that the FDA inspection was far superior to that of the Department of Agriculture. While we didn't belabor the point, the fact is that the Department of Agriculture investigator had not been there for the same reason as we had been there and could well have not been looking where we looked. But, at any rate, the judge was pleased with the FDA work.

Within a few weeks after this case was over, the General Counsel's office decided that something had to be done about another practice of Judge Ritter's. Many seizure cases came before Judge Ritter, and most of these cases resulted in a default by the owner. In every default case, he required that the government produce all of the witnesses to prove every element of a case. This meant that in Judge Ritter's court is could cost the government more money to win a default case, than a contested case. When a case was contested, through discovery or through stipulation many of the issues were eliminated--issues such as interstate commerce or identity of sample or labeling--but when there was no one in the case with whom to negotiate a stipulation, there was no one to stipulate, and we had to prove the entire case, which was expensive and time-consuming, both to the government and to the judge. So we decided that since the judge had expressed so much satisfaction with the work done by the FDA, this might be a good time to seek a modification of

his practice. So we filed a motion to have the Court review and modify the procedure that he followed in in default cases. I wrote a brief on the subject, and the case most relevant to our position was a Supreme Court decision which had been handed down in the 1880's. While it was old, it had never been overruled and it was quite in point. When you argued a motion before Judge Ritter, and you wanted to rely upon a particular court case, you had to bring the volume which contained that particular decision into court with you so that, if the judge wished, he could look at it right then and there, since you would hand it to him, if he asked. I brought in the volume of that 1886 decision of the Supreme Court and then, when our motion was called, I got up to argue the motion and on the table in front of me was the volume. The binding on old Supreme Court opinions is quite revealing in that you can tell by looking at the outside that it is an old Supreme Court case. The Judge asked me if I intended to rely upon a case in that volume. I answered that I did. He said, "What's the date of the case?" I said, "1886." He said, "How can I rely upon a Supreme Court decision of 1886, when I can't rely upon what they said last week, since next week they're going to change their minds. So therefore, the motion is denied." He had never read the brief, and he had not listened to my argument, but he was ready to throw us out on that point. I felt quite desparate then because it

was a significant procedure that was causing us expense and undue expenditure of effort. I then appealed to the Judge. I said, "Lunchtime is approaching. We had just recently demonstrated to the Court that the FDA does a good job," reminding him of the canned vegetable case and the mouse. He had expressed satisfaction with our work. I felt that we had a reasonable case before us. The Judge did have discretionary power to require the procedure which he did require, but that he also had discretionary power not to require it. I felt that his objective, namely to make sure that no food or product was condemned unless there was evidence to support it-- that that objective could be achieved by sworn affidavits which would be a substitute for live testimony, be much cheaper, and yet enough to carry out his wishes. I begged him to read the brief over the lunch hour and then give me another chance to argue the case. He agreed and, when he came back in the afternoon, after a short argument, he granted our motion and agreed to accept affidavits. That is one memorable experience with a judge.

FL: Considering Judge Ritter's well-deserved reputation as an irascible and unpredictable man, you were very fortunate in the kind of outcome that you obtained.

AD: That is correct. Another instance where I had an unusual

experience with a judge took place in Los Angeles. I don't remember the name of the defendants or the name of the product. It was an eye remedy of some kind. We had two cases pending against the firm. One was a criminal case which charged them with shipping a volative drug in interstate commerce. The other was an injunction suit which asked the court to prevent them from shipping such eye remedy in the future. In accordance with the practice in Los Angeles at the time, the civil suit was assigned to one judge, the criminal suit to another. Let's say Judge A had the injunction suit, Judge B had the criminal suit. Through extensive negotiation with the defense counsel, the defendents consented to a permanent injunction and they also pled guilty to several counts in the criminal case. Judge A, who handled the injunction tion suit, upon being presented with a Consent Decree of Permanent Injunction, signed the injunction and that was the order that restrained the defendants from shipping in interstate commerce. Judge B, who handled the criminal aspects of the case, took the guilty pleas in the counts agreed upon by the defendant and referred that matter for a pre-sentence investigation by the probation officer. A few weeks before the defendants were to come up for sentencing before Judge B in the criminal case, Judge B died. Thereafter, the chief judge reassigned the criminal case to Judge A. On the day previously set for

sentencing, we all--the U.S. Attorney and I and other representatives of the Los Angeles District as well as the defendants and their attorney--appeared in Court before Judge A for a sentencing of the defendants in the criminal case. Judge A looked at the case and said, "Didn't I have a similar case before me recently?" The U.S. Attorney pointed out to him that he had signed a Consent Decree of Permanent Injunction in this case some weeks before. Judge A then said, "I think maybe the defendants have suffered enough. I would be willing to entertain a motion to withdraw the guilty pleas." The defense attorney, with alacrity, moved orally to withdraw the guilty pleas, and that motion was granted. Thereafter, the judge turned to the U.S. Attorney with a suggestion that the case should be dismissed. The U.S. Attorney said that there was no reason to dismiss the case, and he had no authority to dismiss the case. So the judge said, "You then want to go to trial on the case?" And the U.S. Attorney said yes. So the judge said, "Put on your first witness now." The U.S. Attorney was flabbergasted because we had come into court to be present at the sentencing of the defendants and had no witnesses to put on at the time and he so told the Judge. The Judge responded by saying, "If you have no witnesses to put on, then the case is dismissed for want of prosecution."

That was a bizarre situation. It is possible that it could have been appealed, but the U.S. Attorney's office decided not to appeal it.

FL: Probably because they had to live with the judge on other cases on other days.

AD: Yes. They were mad.

Another unusual experience with a judge came up in a case involving the use of a color additive. It was a criminal case, and the defendant had pled guilty to using the color additive. The matter had been referred to the probation officer for pre-sentence investigation, and then the parties and the defendant gathered in court for the sentencing by Judge Hall in Los Angeles. Judge Hall was a very large dignified judge with large dark eyebrows, very impressive to look at. He asked the defense attorney whether he or his client wished to say anything before sentence was imposed. The defense attorney said no, his client didn't have anything to say, but he himself would merely offer the comment that he had read the color regulation in question and had to confess that he couldn't understand it. The judge glowered at him and he said, "Young man, if you know anybody who can understand any federal regulation, I want you to bring him into my

court. I want to meet him."

My only comment on this is that the color regulation was very complicated then, and probably is more so now. I would urge, upon those who write regulations, to bear in mind that they are to be understood, not only by those who are technically versed in the subject matter, but by judges, jurors, U.S. Attorneys, and other attorneys who are not well versed in those subjects. It would be very helpful if they could be written so that they could be easily understood. I know it's not easy to do this, but we should try.

After delivering himself of these remarks, the judge proceeded to impose a very nominal fine upon the defendants.

Another one of our bizarre cases, maybe one of the most bizarre that I've ever worked on, was a case of the U.S. against Drown. The defendant was convicted, the conviction was sustained in the court of appeals, and the Supreme Court refused to review it. The Assistant U.S. Attorney who tried this case thereafter wrote a law journal article in which he summarized all of the bizarre aspects of the case and, for historical interest, I would urge you to read his article. The name of the article is "Conflict with Quackery". The writer of the article, of

course, Tobias Klinger. The article appears in the FDC Law Journal, volume 8, page 777, and it was written in 1953.

FL: It seems to me, Arthur, that the things you've been talking about are an excellent illustration of how this law can be applied to a variety of circumstances. Have you got any case that really illustrates what a flexible instrument the Food, Drug and Cosmetic Act is?

AD: Yes, I do have. It was a seizure action in Seattle, maybe 25 years ago. Under seizure was an article of food, namely apple juice. The apple juice was packed in glass jars, and the jars were transparent. There was a label on each jar. When you looked at the apple juice, it looked very nice, very clear, as any well filtered apple juice would look. The background of the case was that our investigator had been present in the manufacturer's plant when this juice was produced. He had beautiful color pictures taken at various stages of the processing of the apples, from the time that they were lumped together in a pile, while they were being transported on a conveyor belt and were being sorted, and then as they went into the hopper after having been sorted. These pictures, from the very beginning until the end, deomonstrated the revolting nature of the raw materials that were used in making this apple juice. They were rotten,

wormy, moldy, black--whatever shouldn't happen to an apple had happened to these apples--and they were excellent pictures. The charge in the seizure action was that these apples were prepared, packed and held under insanitary conditions whereby they may have become contaminated with filth. The case was set for pre-trial hearing in Seattle and, when we met with defense counsel, we showed him the pictures that we had, expecting that he would roll over and give up, at that point. However, he called our attention to the fact that the judge before whom this case was to be tried was very conservative in enforcing any law and would be susceptible to a defense argument that the raw materials used in the making of the juice could not be considered an insanitary condition. In other words, he felt, and he said he would argue very vigorously, that insanitary conditions referred to such things as mice running around or insects, but not to the raw materials themselves. And that therefore, since this judge was technical, he would likely refuse to permit any of that evidence in, which would of course be devastating to our case. We thought about it overnight, and met again the next morning with the defense attorney. We said if that was the way he felt about it, we would ask the judge for permission to amend our pleadings to include an additional allegation. The allegation, as it then stood, was an adulteration allegation under 402(a)(4). We would ask the Court to add the charge that

the product was mis-branded under 403(a) because its labeling was misleading since the vignette on the labeling depicted two beautiful apples which created the impression that the juice in the bottle was made from Grade A Fancy wholesome apples, and it failed to reveal the material fact under 201(n) that the product in fact was derived from wormy, moldy and rotten apples, such as would be demonstrated by these photographs. At that point, the defense collapsed because the photographs would unquestionably be relevant to prove that charge. My comment here is that the statute is a broad one and provides an opportunity to make charges to fit whatever evidence we have. Why should we take a chance on whether the judge would accept a more sophisticated theory on the Section 402(a)(4) change, which he might, and which has been actually done later on, when we also had a good basis for charging a misbranding where the evidence would unquestionably be relevant. So, those of us who frame the charges should look not only to the obvious possibility, but to the possibilities that do not, at first glance, seem to be there.

To terminate this discussion, let me just add a few words about my personal experiences with the Food and Drug Administration employees. I worked with them for 28 years, both at headquarters and in the field. I felt that they

were an outstanding group of dedicated people, whether they were directors, chemists, inspectors, dishwashers, whatever their capacity. It was gratifying to work with people who cared as much about the goals of the FDA and who acted without regard to their personal convenience or time, always to achieve those goals.

Having just delivered myself of a "final statement", I want to add something. No self-respecting lawyer is ever really through, there is always something to be added. In this case, I want to speak about the Allan Drug Promotion and the litigation which we had in Denver some years ago. The product was an acne and pimple remedy. We were unable to charge that this product was a new drug because it met the conditions of exemption. In other words, it had been on the market before 1962, and the promoters had not changed their claims, and they had met all the other conditions which, at the moment, I can't remember. We went to trial then, charging that the product was misbranded under 502(a) in that it was offered as an acne and pimple remedy and was not effective as an acne and pimple remedy. After a trial with some unusual developments, the judge ruled in our favor, but wrote his own findings and conclusions in which he said that, while the existing labeling claims were false and misleading, he believed that the product might, in some instances, be

effective in the treatment of acne and pimples. He then ordered that the claimant be given an opportunity to relabel the goods. The principal ingredient in the drug was Vitamin A.

We pointed out in court that, if the product was to be relabeled, within the discretion of the court, the statute required that the relabeling be done under supervision of the FDA. The defense attorney somewhat angrily told the Court that he knew the FDA would never approve any revised labeling (in which, of course, he was correct), and he requested that the Court permit his client to relabel it without going through the procedure of seeking FDA approval. However, the judge, who was a stickler for the statute, upon reading Section 304, declared that it did require the FDA to review it. So the defense attorney said, "They'll just drag their feet." And the judge said, "They'll not drag their feet. I'm going to give them 30 days to do it." So the judge directed that the defense attorney submit proposed revised labeling to us, and that we meet within a certain period of time. We suggested that the meeting take place at headquarters and that the matter come back to court within a month, if there was any problem. So Dr. Weilerstein and I went to headquarters in advance of the meeting with the defense attorney to discuss the position the FDA was to take. Dr. Weilerstein and I felt that, if

a drug was exempt from the new drug provisions, and especially the 1962 Amendments, by reason of meeting the conditions of exemption, it would lose the grandfather status which it had if there were any changes in the labeling of the product, because one of the conditions of exemption required that the labeling remained constant. Now, in this case, it was essential that the labeling be changed, under the court order, since the Court had said only that it might be of value in some cases of acne and pimples instead of overruling the current labeling that it was of value in acne and pimples. When we met in Washington with our own people, the reception was a mixed one. Some agreed with us; some felt that the FDA had an obligation to consider the overall picture, and that if the position espoused by Dr. Weilerstein and me were accepted and upheld by the court, it would mean that any person who was manufacturing or distributing a grandfathered drug would be loathe to make any changes dictated by current scientific knowledge for fear of losing the grandfathered status, and therefore the public might suffer because it would not have the benefit of current scientific information. However, ultimately the agreement was reached amongst ourselves that the Agency would require a new drug application whenever a grandfathered drug no longer bore the same labeling which had given it the grandfather status.

When we met with opposing counsel, he submitted his proposed revised labeling which was totally unsatisfactory. We pointed out that it did not conform to the conditions specified by the judge. It didn't have enough "maybes" nor did it refer to possible usefulness in "some cases" of acne and pimples. However, we pointed out there was a more fundamental problem confronting all of us, and that was that the legislative history of the 1962 New Drug Amendments and the enforcement policies of the FDA would render this product a new drug divested of its grandfathered status if he made any changes at all in the labeling. His agument was that the labeling changes would not add to the conditions of use, but would diminish them, to some extent. We pointed that the statute did not distinguish between adding and diminishing. He was stunned there for a moment, slammed shut some volume which he had before him, packed up his briefcases and said, "We'll see you in court," which we did. We lost before the District Judge on that point, but it was reversed on appeal.

It is true that the FDA did have to reach a policy decision here as to where to go and how sharply to draw the line between a grandfathered drug and a new drug. I feel that we made the right decision. When I say we, I mean the Agency made the right decision.

FL: Thank you, Mr. Dickerman, for taking the time to record your experiences and opinions for us.