An Interview With Mr. George P. Larrick

George P. Larrick devoted his career to the Food and Drug Administration, becoming an inspector in 1922 and serving as Commissioner from 1954 until his retirement in 1965. He was Associate Commissioner and Deputy Commissioner during the years of effort to secure legislation which became the Durham-Humphrey Amendment of 1951, with which this interview is concerned. Richard J. Hopkins, the interviewer, wrote his master's thesis at Emory University on the background and enactment of this law.

This is an oral history interview with Mr. George P. Larrick, former commissioner of Food and Drugs. The interviewer is Richard Hopkins and the interview is being held in Marathon, Florida, January 12, 1968. The questions will be directed primarily to the Durham-Humphrey Amendment of 1951 to the Federal Food, Drug, and Cosmetic Act.

Mr. H.:

Mr. Larrick, could you briefly describe the background leading up to the 1948 definition of a prescription refill which changed the whole prescription policy?

Mr. L.:

During the commissionership of Dr. Paul B. Dunbar, it became increasingly apparent that very valuable drugs when properly used, were being misused for non-medical purposes. Among these were the stimulant amphetamines, and the sedative barbiturates. At the convention of the National Association of Retail Druggists in October, 1948, Paul Dunbar enunciated the principle that drugs of this category should be sold only on prescription. He declared that the Food and Drug Administration would regard their sale for non-medical purposes as illegal. This principle was incorporated in regulations of the Food and Drug Administration. Subsequently, it was subjected to review in the courts in an historic case known as the Sullivan Case. One of these drugs

had been sold by the pharmacy without a prescription and the validity of the Food and Drug Administration's regulation was challenged. The case was tried in Georgia and the history-making decision was rendered by Federal Judge T. Hoyt Davis. He had previously been a most capable United States attorney. He had been the prosecutor in a case where it was charged that the defendants had falsely represented "Warm Springs Crystals" as a treatment for disorders such as those experienced by President Franklin D. Roosevelt. Judge Davis was a student of the Pure Food and Drugs Law. The Sullivan Case was appealed to the Circuit Court and to the Supreme Court. There the principle of dividing drugs into those that could properly and safely be sold without a prescription and those that could not was upheld. The Department was not satisfied to deal with this growing problem exclusively on the basis of administrative rulings. It was thought that it would be wise to submit the whole question to the Congress so that their will could be expressed. Congressman Carl Durham of North Carolina and Senator Humphrey of Minnesota sponsored legislation to incorporate into the law the philosophy which was expressed in the Sullivan decision. Congressional hearings were held. All manner of views were expressed. Finally, the legislative proposals, after amendments and careful consideration, were enacted.

Mr. H.:

The Sullivan Case, which you spoke about, that had a peculiar aspect to it, too, didn't it--that the part of the question involved was intrastate versus interstate commerce--that a federal regulation could cover only interstate movements of drugs?

Mr. L.:

One of the questions for decision was, "Where does interstate commerce and therefore Federal jurisdiction end?" The decision was that interstate commerce carried through to the ultimate consumer.

Mr. H.:

Concerning food substances, I think another Georgia case brought about the norm in only something like six months after the Sullivan decision which incorporated that same idea that once it had moved in interstate commerce that then it was fair game for federal regulations.

Mr. L.:

I don't recall that case in detail, but broadly I think that's a fair statement of it. The Phelps-Dodge decision, of course, that involved food, had pretty well destroyed the federal government's control over food once it got to the retail level. These two historic decisions restored the authority of the federal government.

Mr. H.:

I think that you, during the Congressional hearing, the House hearing, in 1951, in your testimony said that there was a good deal of disagreement among legal authorities concerning whether or not the federal government, and the Food and Drug Administration in particular, did have the authority to separate drugs into prescription and over-the-counter categories merely by regulation, even taking into account the Sullivan decision. Could you explain that a little bit more?

Mr. L.:

The Sullivan decision concerned itself with the particular set of circumstances that surrounded the commercial transactions in that instance. The drugs involved were so clearly inimicable to the public interest when sold without medical supervision that I think the sympathies of the courts were to protect the public health. Many drugs are extremely useful when properly prescribed. The same drugs may be detrimental to the individual who uses them for non-medical purposes. This was responsible for the decision to separate drugs into the two categories mentioned. The Department decided that it would be good to have the Congress of the United States enunciate some broad, general principles upon which the industry could rely and the Food and Drug Administration could depend, in making the rules that would govern the determination of whether a drug should be sold only on prescription or

whether it was safe for self-medication.

Mr. H.:

Shortly after the speech that Dr. Dunbar gave to the National Association of Retail Druggists in October of 1948, when he pronounced this idea of a prescription being a cancelled check once it had been filled, Dr. Robert Fischelis, who at that time was the executive secretary of the APhA, charged in several articles in 1949 and 1950, even in 1951, that the Food and Drug Administration really wanted to control amphetamines and barbiturates; that the cases which the FDA had brought involved almost exclusively those two drugs or their derivatives; and that it was really sort of a power grab on the part of the FDA in defining dangerous drugs much more broadly than just "amphetamines" and "barbiturates". Do you think this was at all a valid assessment of the situation?

Mr. L.:

Well, since I was one of those who would have perhaps been accused of "power grab," I am not unprejudiced, but the times were changing rapidly. Drugs, previously, largely, had been palliative drugs, rather than curative drugs. We had a few curative drugs or drugs that suppressed symptoms to the point that they were practically curative. We had insulin, quinine and some others. Scientific research, speeded by the war, entered the field of drugs. It produced substances that are useful in controlling or curing

disease but may be harmful, if misused. While Bob Fischelis' comments that we were using amphetamines and barbiturates pretty largely as a basis for the cases that were brought, the people in the Food and Drug Administration and their advisors saw in the present at that time, and particularly in the future, the development of drugs which, if not restricted, would do great harm. That was why they tried to get ahead of the problem or at least to meet it by definitions that would give broad authority to deal with drugs that the ordinary layman couldn't possibly be expected to understand.

Mr. H.:

Dr. Fischelis also criticized the FDA officials very, very, strongly, especially in late 1950 and 1951 when the split with the NARD came out into the open--the APhA-NARD split-- for announcing the refill policy in a speech to the NARD but never putting it into the form of a proposal for regulation in the Federal Register. And he, I think, said point blank a few times that this was just an evasion on the part of the FDA to get around any sort of court challenge to this policy which even, according to Fischelis, FDA officials doubted was valid. Once again, do you think this has any validity?

Mr. L.:

Well, of course, Dr. Dunbar was commissioner at that time and he

made up his own mind as to what he would say to the National Association of Retail Druggists. And I don't know all of the motivating factors that led to his decision. Having worked under him and with him for so many years, my conclusion would be he was invited to give this speech to an important pharmaceutical association group. He did have in mind some fundamental changes in the procedures of the Food and Drug Administration which would enforce their activities mightily, and so he thought that the forthright thing to do was to tell them about it. He knew, of course, that the whole drug trade press and the daily press, for that matter, covered this association meeting with complete coverage, and I think that he deliberately determined to enunciate this principle there to give them a chance to consider it and make any comment that they cared to. The regulations, as I recall it, were forthcoming at a later date and there was a very substantial period of time given for favorable or unfavorable comment. They were not promulgated until after the time had elapsed.

Mr. H.:

Are you referring to the APhA attempt in August of 1950 to get Secretary Ewing to issue a regulation? That's the only one that I recall. This is the only regulation which was issued which referred to the retail problem.

Mr. L.:

Well, I can't recall dates. That goes back a long time, but I recall very vividly a conference that I had with Secretary Ewing. Mr. Goodrich was there and the General Counsel of the department and that had to do with the regulations which roughly paralleled the later Durham-Humphrey Amendment. It is hard to remember.

Mr. H.:

I'd like to come back to that. I think maybe that was the meeting in October of 1950 when Thurman Arnold and Walton Hamilton---

Mr. L.:

No.

Mr. H.:

No? It wasn't? Well, anyway, I'd like to come back to that meeting a little bit later. I think you were there at that time.

Mr. L.:

Oh, I was.

Mr. H.:

I also wanted to ask you about the complete about-face which the NARD accomplished when the refill policy of the FDA was announced in October of 1948. The immediate reaction of the NARD and of the APhA was complete hostility, and the first Durham bill, as I

recall, was written so that the FDA would have been deprived of all jurisdiction over prescription refills and prescriptions themselves. But sometime at the end of 1949 or at the beginning of 1950, NARD officials did a complete about-face and apparently got together with officials of the FDA and wrote the first Durham-Humphrey Bill which was introduced in June of 1950. Can you explain why NARD officials did do this--a complete about-face from complete opposition to cooperation with the FDA on the bill?

Mr. L.:

In the beginning, in answer to this question, I think there was a very sincere desire by the leadership of the American Pharmaceutical Association and by the National Association of Retail Druggists and by the Food and Drug Administration to bring about a meeting of the minds of these groups so that legislation could go through the Congress with as little controversy as possible. Historically, many groups oppose change and this certainly was the case when the Food and Drug Administration's proposals on Durham-Humphrey were introduced and made public. There were a number of meetings held between the American Pharmaceutical Association leadership, the National Association of Retail Druggists leadership or their representatives, and the Food and Drug Administration. It became apparent that it would be most unlikely that there would be a complete meeting of minds. There were many

factors involved: the question of states' rights; what the federal government's function should be in regulation of retail sales; what the federal government should do and what they should leave to the states. I am very sure that there were developments between the two great representatives of retail pharmacy that we did not know about. As an opinion, I think that one man in the National Association of Retail Druggists, who was basically a humanitarian, became convinced that the problem involved was one that did involve necessarily federal control. That man was Herman Waller, and I think that he was responsible for persuading his principals to go along with the essential principles of the Durham-Humphrey Bill as it was then pending before the Congress.

Mr. H.:

During the initial controversy over the retail opinion as Dr. Dunbar announced it, this was during 1949 that I am speaking about, Dr. Fischelis announced something called the Joint Conference Committee on Food, Drug, and Cosmetic Law Problem which was intended to include not only the American Pharmaceutical Association and its various constituent societies but also the NARD, and was intended to talk with FDA officials about various problems including the recently-announced refill policy. Fischelis wrote up a meeting in August and he also mentioned one in November, but apparently nothing very substantial happened at these meetings.

In other words, both parties agreed to disagree and it was sometime after this that, according to you, Mr. Waller had a change of opinion about the whole problem. Is this really the beginning of the open split between the APhA and the NARD?

Mr. L.:

No, I wouldn't think so. In the first place, perhaps oversimplification would permit us to say that the NARD had historically concerned itself primarily with the economic side of pharmacy and the American Pharmaceutical Association prided itself on dealing almost exclusively with the professional side of pharmacy. I find it very difficult to deal with these questions because, one, they're philosophical, rather than strictly factual, and also I'm an honorary member of both groups. But I would think that the personalities of the leadership of the two groups, with their rivalry for leadership of the whole profession was significant. The proposals of the Durham-Humphrey Bills really involve a number of fundamental questions in addition to the drug involvement. States' rights were included; the power of state boards of pharmacy; the individual professional rights of pharmacists. I do not think that it is unusual to expect, under these circumstances, where pioneering new principles are being proposed to deal with matters as important to the public health as drugs were and are, would involve some fundamental differences of opinion. Certainly, as things developed, there was a basic cleavage between the NARD and the American

Pharmaceutical Association. Just what led the NARD to change its view and join with the Food and Drug Administration is speculative. As I said before, I think it was led by Herman Waller's conclusion that it was in the public interest.

Mr. H.:

You started to speak, I think, before about the personalities of the two leaders of the Associations. Would you feel free to comment on the possibility of a personality clash, as well as the clash of doctrine, being a factor in the complete split during the Durham-Humphrey controversy?

Mr. L.:

Well, I think personality clashes in men that are tremendously able leaders is commonplace. Certainly, John Dargavel was a strong man. He built the National Association of Retail Druggists from a position of almost bankruptsy, I've been told, to a position of affluence and certainly of great influence. Dr. Fischelis, likewise, was a man of strong, vigorous personality, and I think that the two men had personalities that were not convivial.

Mr. H.:

The APhA and the National Drug Trade Conference--this was something which I think you touched on a minute ago when you mentioned the states' rights--the APhA and the National Drug Trade

Conference worked throughout the late 1940s to draw up a model pharmacy act, and a bill to pass on to the states to control amphetamines and barbiturates at the state-level rather than to create any sort of situation, as was in fact created, which would require federal control. Of course, during the Durham-Humphrey controversy, Dr. Fischelis and the APhA and most of the members of the National Drug Trade Conference continued to use this as an argument. In your opinion, was there any possibility that separate state regulation of these dangerous drugs could have been sufficiently close to have protected the public health?

Mr. L.:

Well, this goes back a great many years. I would think basically that any regulation that needs to be accomplished and can be accomplished at the level of control closest to the people is the most desirable. I was mildly unhappy to think of the retail pharmacist in some remote state who never would have access to the top administrators of the federal government agency that determined what his course of conduct should be and appraised what it was. If it could have been done uniformly throughout the country by the states whereby administrators are close to the problem, I think that would be better. But as it was and because of the urgency of the problem, it was just completely unfeasible. As of today, I think that as much

of the problem as can be assumed of control at the state level, at the city level, at the county level, should be had, and idealistically the federal government would just pick up where the states and cities leave off. Now as a practical matter, regardless of the fact that increasingly the local authorities are taking over a greater proportion of this responsibility, I think the federal government will have to be in on it and will have to grow in it.

Mr. H.:

Something which I think is related to the struggle between those who wanted state regulation and local regulation as opposed to those who wanted federal regulation may have involved what some journals in the late 1940s described as a drop in the status of pharmacy as a profession in the United States. There was talk that with the therapeutic or the pharmaceutical revolution, that is, with the major pharmaceutical houses producing pills rather than ingredients which the pharmacist would then compound into a medicine, that this was really pushing the pharmacist into the status of a pill-roller rather than a professional member of the medical team. First of all, do you think there was such a status revolution downward for the pharmacist? And do you think this played a significant part in the opposition of the APhA in particular to the Durham-Humphrey Amendment? Is that too complex a question?

Mr. L.:

No. I think that those who saw a problem in the transition of the compounding of drugs from the corner drug store to the pharmaceutical manufacturing plant were mistaken. I think that it was inevitable that as drugs became increasingly complex and as control procedures and legal techniques became so complicated, few if any retail drug stores could have the facilities to perform them. The transfer to the pharmaceutical house from the corner drug store of compounding drugs was inevitable and very much in the public interest. The same transition from the compounding of drugs to the dispensing of previously prepared drugs brought about a situation where the average doctor cannot or could not possibly keep abreast of all of the indications, contraindications, dangers, hazards, dosages of these new drugs. I think that the professional pharmacist saw that and began to bring about this transition from compounding to dispensing in such a way that he would keep informed in his mind and in his files of the latest information dealing with all of these new drugs. Time has shown that the really professional pharmacist today is a person that the doctor calls to get the latest information on pharmaceutical products. He can perform a more useful function with drugs that are life-saving and drugs that are curative than he possibly could by compounding a palliative for the ills that beset mankind.

Mr. H.:

This brings up another point, too. I think you mentioned that NARD was more concerned with the individual retail drug store, the small retail drug stores, as it were. Dr. Fischelis, on the other hand, throughout the controversy kept talking in terms of the cooperation and very close relationship between the physician and the pharmacist, which might seem to have some indication of a sort of a big city type of situation where you have a doctors' building with many doctors' offices and a medical pharmacy there. That is, one of the arguments Fischelis used was that the doctors usually had an understanding with their pharmacists as to how to handle prescription refills. Is this at all a valid point of view? In other words, could you say that the APhA and Dr. Fischelis really were representing the larger, more professional pharmacy practioner in the relationship to the large group of doctors rather than the corner druggist?

Mr. L.:

I would think that during the term of Dr. Fischelis' leadership of the American Pharmaceutical Association that their principal ties were with the academic side of pharmacy. They had and have close ties with the pharmacy colleges. They put great stress on their participation with the undergraduates.

Mr. H.:

Who actually wrote the first Durham-Humphrey Bill, once the NARD

and the FDA minds had met on common ground? I'm thinking especially of the administrative listing provision which would have empowered the administrator of the act, that is, Administrator Ewing in this particular case, to have listed those drugs which could be sold only on prescription, all the rest obviously being over-the-counter drugs. Was this the brain child of the FDA or was it something that Mr. Waller may have proposed, or how did it come about?

Mr. L.:

It was an evolutionary process. The originators of the idea were Crawford and his associates.

Mr. H.:

Are you implying here then that the FDA took the initiative in drawing up this bill and that the NARD merely sat in on the sessions and perhaps gave their approval?

Mr. L.:

I would say that Crawford was the most articulate draftsman and that he would be extremely patient and would take a suggestion from anybody that was in the conference and reduce it to writing and then make changes in it if and as the two groups agreed; but there was no fundamental difference. It was a matter of getting it down on paper and making sure that it didn't have an ambiguity that could make for trouble in the future. Each group, of course,

tried to be sure that the people they represented were not short-changed.

Mr. H.:

One of the prime arguments, if not the prime argument, that the NARD used in supporting the administrative listing provision of the bill was this situation of what I think they called misleading, certainly confusing, labeling on the part of drug manufacturers where one manufacturer would take a drug which could be sold legally over-the-counter and either label it with the prescription legend or label it with such directions as "Take as directed by your doctor"--by your physician--which contained neither the legend nor the adequate directions that the regulations required. Was this really that much of a problem for the retail pharmacists of the period?

Mr. L.:

Yes, I would say it was a very serious problem because one drug that would--well, two brands of the same drug, one of them could legally be sold over-the-counter and the other couldn't, and there were chaotic conditions because of that difficulty.

Mr. H.:

In effect, then, what these various drug manufacturers were doing by using such labeling was, as far as regulation is concerned, pretty much daring the FDA to take every one of these separate

drugs to court in a separate case which, under the procedure, had to be done, and knowing full-well that the FDA couldn't possibly do that. Is that a fair statement?

Mr. L.:

I don't think it was general motivation of so many different firms, but I am very sure that there was a strong belief in the legal departments of many of the pharmaceutical houses that the construction that we had placed on the law was invalid. Some of them subscribed basically to the philosophy that the doctors should be given complete freedom in the prescription of drugs. They wanted to challenge the government's view that the drug should have either complete directions for use that the ordinary layman could follow with reasonable safety and reasonable assurance that it would do the things that the label claimed.

Mr. H.:

Yes. In late August of 1950 Dr. Fischelis and the other officials of the American Pharmaceutical Association engaged the firm of Thurman Arnold and Walton Hamilton, a firm of lawyers in Washington, to try to achieve a settlement of the retail controversy other than by legislation; and the device which the lawyers came up with was an attempt to force the Federal Security Administrator to issue a regulation which would detail the refill

policy of the Administration which then could be tested in court. Do you think that this basically was a sincere attempt to find a solution to the refill problem, or was it again part of the rivalry between the APhA and the NARD--remembering that at this period the NARD seemed to have the upper hand because it was pushing the new bill?

Mr. L.:

I wouldn't attempt to diagnose the motivation behind that move. I think at that time that Dr. Fischelis was basically opposed to the extension of federal control and perhaps that was the motivation.

Mr. H.:

One possible outcome of this attempt of the APhA was a meeting of the NARD and the APhA and the various drug manufacturers with Congressman Durham in February, I think, of 1951, in which they attempted to reach some sort of compromise on the administrative listing provision. No compromise was reached. Was this largely because of the FDA's desire to have the drugs listed administratively?

Mr. L.:

Representative Carl Durham was himself a pharmacist and was very respected by both groups. And I think this was a genuine attempt on his part to bring about a meeting of minds, but the

differences were so fundamental that that did not result. The Food and Drug Administration was very anxious to have included a provision that would give them the power under appropriate circumstances and with public hearings and other procedures to list the drug. But looking back on it and the way it has worked, particularly with the new drug provisions becoming increasingly significant in this whole picture, contrary to my view at that time, I don't think that made much difference.

Mr. H.:

After the House hearings in the early part of May, 1951, on the new Durham-Humphrey Bill which was slightly rewritten, with a major change being the appeal procedure for anybody who objected to the listing of the drug, the trial de novo instead of the Administrative Procedures Act, which the federal court system had representatives at the hearings to virtually kill--After these hearings, there was a good deal of lobbying going on, especially after the House committee reported the bill favorably when it appeared the bill didn't have that much of a chance to come out of committee. The very puzzling part of this whole picture is the sort of enigma of the American Medical Association throughout the whole discussion. The AMA Journal, for example, said very little. I think there was only one article prior to the enactment of the Durham-Humphrey Amendment, and that was merely a statement of the various positions of the drug manufacturers and

the pharmacy associations. On the other hand, the Council on Pharmacy and Chemistry of the AMA did have a meeting in November, 1950, and there was a new chairman of this council, Dr. Robert Stormont, who had gone to the council from the FDA. The rumors in the early part of 1951 were that the council had approved of the bill as it was presented to them, that is, approved of the administrative listing and of the efficacy standard. First of all, so far as you know, did the council approve of this?

Mr. L.:

I don't know whether they formally approved the bill or not. I do know that a number of individual members approved the bill and advocated it quite strongly. I don't know that these people were acquainted in complete detail with all of the provisions of the bill, but I'm very sure that many of them approved of the general principles that were sought to be enacted.

Mr. H.:

Various members of the---excuse me.

Mr. L.:

I think, though, that Bob Stormont, even though he had been with us, pretty largely acted as a secretary rather than an advocate. He stayed in the background. At least he told me he did.

Mr. H.:

Several congressmen at the House committee hearings expressed surprise that there was no member of the AMA, no representative of the AMA, who had asked to give testimony at the House hearings in May. In fact, it was not until about mid-June that the AMA's Legislative Committee decided to oppose the bill. The reason that was given was that it was a long, involved process. As a matter of fact, I think that you gave this reason when someone, one of the congressmen, asked you in the House committee hearings. Was this, in fact, the case, or was the AMA really unsure of what it was trying to do?

Mr. L.:

No. I think that the mechanism of the AMA on a major piece of legislation is such that it has to go to a pretty important body--I've forgotten--House of Delegates, I believe, before anyone is empowered to speak for the AMA. I think that is what happened.

Mr. H.:

After the bill was reported out of committee favorably as it was written, with some re-writing, to be sure, but with the major provisions still intact--that is, administrative listing, efficacy standard, and so forth--the Proprietary Association of America seems to have taken the lead in trying to kill the bill in the House. Most observers, at that time, feeling that the committee

vote was so strong in favor of the bill, felt that there was little chance to head the bill off in the House of Representatives--to change the administrative listing provision and the efficacy standard. Did the Proprietary Association lead this lobbying attempt to head it off?

Mr. L.:

I think they were strongly opposed to the bill at that time. Whether they took the lead or whether they didn't is difficult to determine because people who are influential before Congress don't always identify themselves very clearly.

Mr. H.:

Once the American Medical Association had decided to oppose the bill, one of the trade journals in the drug industry reported that the AMA and the lobbyists from the American Pharmaceutical Association worked very closely together in button-holing congressmen and urging them to vote against the bill, to vote against the efficacy standard and the administrative listing provision, in the House floor debate. Can you give me any more details about what this lobbying was like?

Mr. L.:

In the first place, I think the American Pharmaceutical Association, as of that date, would insist that they had no lobbyist; they had no one registered. I don't know whether the American Medical

Association did or didn't. I know that both of them were opposed to that provision of the bill and I suspect that when they were asked, they expressed that viewpoint quite volubly.

Mr. H.:

So what you are saying then is that, so far as you know, they did not make an active effort to go up to the Hill and make known their opposition to the bill.

Mr. L.:

That I don't know.

Mr. H.:

A good deal has been written in the various histories of federal government about the lobbying done by federal agencies themselves on bills, such as in the 1930s, the Wheeler-Lee Act when the Federal Trade Commission tried to retain and, in fact, did retain, control over advertising in the drug field. In the 1951 instance, Durham-Humphrey, how much lobbying did the FDA do?

Mr. L.:

"Lobbying"is a rather difficult term to define. The FDA from bottom to top is made up of civil servants, and lobbying in the sense of the initiation of the contact by the agency is strictly prohibited. A great many congressmen would send for representatives of the FDA, myself included, and anytime that they sent for

us to answer questions, we would go. During the pendancy of this legislation that you are interested in, there were many, many occasions when congressmen, senators, who were in sympathy with the viewpoint of the department would call up and ask for various of us to go up on the Hill and meet with them or meet with some of their collegues. When we got such a request, we would honor it and we would meticulously make a record of the meeting and turn it in to the department.

Mr. H.:

It seems to me, from reading the Congressional Record, that the strongest argument that the opposition to these two clauses in the bill, the efficacy standard and the listing provision, the strongest argument that the opponents to these clauses had was the Truman Compulsary Health Insurance Plan and the fact that Oscar Ewing was Administrator of the Federal Security Agency and therefore, of the Food and Drug Act. And the hue and cry was "socialized medicine" and Mr. Ewing, during the House committee hearings had given ammunition to that by admitting that aspirin some day might be put on the list of prescription drugs by some administrator other than himself. Was there any substance to this charge of socialized medicine coming out of this bill, or was it merely demagoguery?

Mr. L.:

I think it was just a red herring.

Mr. H.:

But an effective one?

Mr. L.:

Yes, quite effective. But it just slowed it down. It didn't kill it.

Mr. H.:

You're referring to the 1965 bill?

Mr. L.:

Right.

Mr. H.:

In which the efficacy standard was re-written into the law.

Mr. L.:

That's right. There's one basic principle that runs through almost all advances in Food and Drug legislation and that's "catastrophe." You can take amendment after amendment from the early part of this century clear on through. The programs and the attempts to get them go on and on. Then there comes a major catastrophe in the area of the controversy and the Congress and the people are galvanized into action and they pass the amendment. For example, the thalidomide episode was an important factor in the enactment of the Kefauver-Harris Amendment to which you just referred.

Mr. H.:

Such as the Elixir Sulfanilamide disaster in 1938.

Mr. L.:

That's right--1937. That's a milepost in Food and Drug legislation and led to the inclusion at the last minute of the new drug provision.

Mr. H.:

A couple of final questions. First of all, in my researches on the bill, I used the F-D-C Reports, what's commonly known as the "Pink Sheet," which comes out weekly, I think, in Washington, as a major source of information. Generally speaking, how accurate is the "Pink Sheet?"

Mr. L.:

I'd say, generally speaking, it's very accurate.

Mr. H.:

Very accurate? So far as you can remember in this period it's very accurate?

Mr. L.:

Yes. There are, of course, bobbles, but I would say it's very accurate.

Mr. H.:

And, the second question is: what is the significance of the

Durham-Humphrey Amendment in the subsequent enforcement of the laws in the United States?

Mr. L.:

I think it was very significant. The start was made in controlling the sale of drugs without prescription. The first effect was a very general observance of its provision by the bulk of the ethical pharmacists of the country. Before that, you could walk in almost any drug store and buy practically any drug except those restricted by the Federal Narcotics Act. This amendment provided penalties for its violation. These were strictly enforced. I would say that in recent years, as the mis-use of LSD and other drugs has become more publicized, the problem is far from being solved. I think that for many reasons, the Durham-Humphrey Law is not an effective instrument to deal with these modern-day problems. But by and large, I think it was an advance. I'm personally unconvinced that by law alone you can solve the problems of the use of drugs for non-medical purposes, particularly if there is widespread publicity about the effects of some of them, as there will be.

Mr. H.:

And I think you were also mentioning, while we were talking informally, the new drug code of the Food and Drug Act which has taken over more and more. Is that correct?

Mr. L.:

Yes, the new drug section gives an opportunity to review the labeling of each drug and the requirement can be made or suggested to the manufacturer that if he wants to sell this drug, he will have to put it on prescription only. As far as I know, the manufacturers go along with that.

Mr. H.:

So that as the years have gone by and more and more new drugs, more effective drugs, have come onto the market and the older drugs have faded away, the Durham-Humphrey Amendment has been less and less significant; is that correct?

Mr. L.:

Well, it is less and less significant until you come to things like the barbiturates and the amphetamines, which are old drugs, and then it's a tool that can be used along with the new drug section in charging offenses when LSD and the wide variety of things with similar physiological effects are used.

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