JUDICIAL REVIEW OF ORDERS CONCERNING BIOLOGICAL PRODUCTS

HEARING

BEFORE THE

SUBCOMMITTEE ON PUBLIC HEALTH AND SAFETY

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH CONGRESS

FIRST SESSION

ON

H.R. 3408

A BILL TO AMEND THE PUBLIC HEALTH SERVICE ACT TO PROVIDE JUDICIAL REVIEW OF AGENCY ORDERS CONCERNING BIOLOGICAL PRODUCTS

JULY 9, 1963

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JUDICIAL REVIEW OF ORDERS CONCERNING BIOLOGICAL PRODUCTS

TUESDAY, JULY 9, 1963

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND SAFETY
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to call, in room 1334, Longworth Building, Hon. Kenneth A. Roberts (chairman of the subcommittee) presiding.

Mr. ROBERTS. The subcommittee will please be in order.

The hearing today is on H.R. 3408 introduced by the distinguished gentleman from Illinois, Mr. Libonati.

The bill seeks to amend the Public Health Service Act.

It would provide judicial review of orders concerning biological products.

We are very happy to have you, Mr. Libonati, to appear before our subcommittee. You may proceed with your statement.

(H.R. 3408 and departmental reports follow:)

[H.R. 3408, 88th Cong., 1st sess.]

A BILL To amend the Public Health Service Act to provide judicial review of agency orders concerning biological products

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 351 of the Public Health Service Act, as amended (42 U.S.C. 262), is further amended by adding the following new subsection:

"(h) If the Secretary refuses to issue, suspends, or revokes any license for the maintenance of an establishment or for the propagation or manufacture and preparation of products described in subsection (a) of this section, he shall do so only after due notice to the applicant or the party in interest, as the case may be, and after having given him an opportunity for a hearing.

"An appeal may be taken by the applicant or party in interest from an order of the Secretary refusing to issue, suspending, or revoking any license covered by subsection (a) of this section. Such appeal shall be taken by filing in the United States Court of Appeals pursuant to section 2112 of title 28, United States Code, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall, upon filing, be forthwith transmitted to the Secretary by the clerk of the court and the Secretary shall thereupon file in the court the record, if any, upon which the order complained of was entered, in accordance with section 2112 of title 28, United States Code. Upon the filing of the petition, the court shall have jurisdiction, which upon filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record, the Secretary may modify or set aside his order. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

"If application is made to the court for leave to adduce additional evidence and the court is satisfied that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceed-

ings below, the court may order such additional evidence to be taken by the Secretary or his delegate in such manner and upon such conditions as the court may direct. The Secretary may modify his findings by reason of the additional evidence taken and he shall file with the court such modified findings as well as any changes he may make with regard to the original order. The court may order such additional evidence to be made a part of the record and if supported by substantial evidence, the findings of the Secretary shall be conclusive.

"The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code."

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
July 3, 1963.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of February 22, 1963, for a report on H.R. 3408, a bill to amend the Public Health Service Act to provide judicial review of agency orders concerning biological products.

This bill would amend section 351 of the Public Health Service Act (58 Stat. 702) as amended (42 U.S.C. 262), to provide that an applicant or party in interest may be given due notice and an opportunity for hearing if the Secretary refuses to issue, suspends, or revokes any license for the maintenance of an establishment for the propagation or manufacture and preparation of biological products as described in section 351. The proposed amendment would also provide review in the U.S. court of appeals of an order of the Secretary refusing to issue, suspending, or revoking a license.

This Department recognizes the appropriateness of adequate legal safeguards to protect the rights of applicants and licensees affected by the provisions of section 351 of the Public Health Service Act, which requires the Surgeon General to prescribe standards designed to insure the continued safety, purity, and potency of the products subject to license. Accordingly, Public Health Service regulations (pt. 73) provide, in addition to other safeguards, an opportunity for hearing by a special review board to any manufacturer whose application has been denied. It is also provided that (except where there is a danger to health) a licensee shall be advised in writing of the facts or conduct which may warrant the suspension or revocation of his license, and shall be accorded an opportunity to demonstrate or achieve compliance. In the event that noncompliance is continued, the licensee will be afforded notice and an opportunity for hearing prior to the decision of the Surgeon General as to whether he will recommend that the Secretary suspend or revoke the license. Moreover, the validity of a denial, revocation, or suspension is undoubtedly reviewable by the courts in an appropriate proceeding.

Since the enactment of the biologics control programs in 1902, the provisions of which later became section 351 of the Public Health Service Act, there has, so far as we are aware, been no instance in which an administrative hearing has been requested, or judicial review of a determination sought, of any action taken under this program.

Nevertheless, we would have no objection to the inclusion of appropriate specific provisions, in the statute, for opportunity for hearing and for judicial review, if the committee should feel the insertion of such provisions to be desirable, notwithstanding the remoteness of any occasion for their actual use in the light of past history. However, while the basic pattern of the bill is in the main soundly conceived, we believe that the following amendments are required:

First, provision should be made for the summary suspension by the Secretary of a license pending hearing, when the distribution or sale of a licensed product pending hearing constitutes a danger to health. This would be in line with the summary-suspension provision enacted as an amendment to the new-drug section (i.e., sec. 505) of the Federal Food, Drug, and Cosmetic Act by last year's Harris-Kefauver amendments (Drug Amendments of 1962). Such provision, moreover, is now made administratively for biological drugs in section 73.11 of the above-mentioned Public Health Service regulations. Obviously, the

provisions of H.R. 3408 requiring due notice and opportunity for hearing would be too time-consuming to provide adequate protection for the public health in certain health emergencies.

Second, we believe that the notice required to be given under the bill, the opportunity for hearing, and the right to appeal should be limited to applicants and licensees under section 351 of the Public Health Service Act. Inasmuch as such applicants and licensees constitute the only interested parties for the purposes of notice, opportunity for hearings, and judicial review, the bill's extension of these provisions to "the party in interest" is unnecessary and, because of its vagueness, likely to encourage claims for redress by those without legal interest in the subject matter of such claims.

Third, we concur in the suggestions, made in the Justice Department's report, that the bill be amended to (*a*) delete the word "or" at the beginning of line 8 on page 1; (*b*) specify the venue and the time limit for appeal, e.g., 60 days; and (*c*) make clear that an appeal shall not, unless specifically ordered by the court to the contrary, operate as a stay of the order of the Secretary. (Cf. sec. 409(g)(5) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 348.)

We are, therefore, constrained to object to the bill in its present form but would have no objection to enactment of the bill if it is amended in the respects above stated.

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely,

ANTHONY J. CELEBREZZE, *Secretary.*

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., July 2, 1963.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Bureau of the Budget on H.R. 3408, a bill to amend the Public Health Service Act to provide judicial review of agency orders concerning biological products.

The bill would amend section 351 of the Public Health Service Act (42 U.S.C. 262), which prohibits interstate traffic in certain biological products unless they were propagated or manufactured and prepared at an establishment licensed by the Secretary of Health, Education, and Welfare. A new subsection (h) would be added to provide that the Secretary shall suspend, revoke, or refuse to issue a license only after due notice and an opportunity for hearing to the applicant or party in interest. The Secretary's order in such a case would be appealable to the U.S. court of appeals which would have jurisdiction to affirm or set aside the order in whole or in part. Findings of the Secretary concerning questions of fact would have to be sustained if supported by substantial evidence when considered on the record as a whole.

Subject to revisions in the bill indicated in the reports of the Departments of Justice and Health, Education, and Welfare, there would be no objection from the standpoint of the administration's program to enactment of H.R. 3408.

Sincerely yours,

PHILLIP S. HUGHES,
Assistant Director for Legislative Reference.

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D.C., July 5, 1963.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning H.R. 3408, a bill to amend the Public Health Service Act to provide judicial review of agency orders concerning biological products.

The bill would amend section 351 of the Public Health Service Act (42 U.S.C. 262), which prohibits interstate traffic in certain biological products unless they were propagated or manufactured and prepared at an establishment licensed by the Secretary of Health, Education, and Welfare. A new subsection (h) would be added to provide that the Secretary shall suspend, revoke, or refuse to issue a license only after giving due notice and an opportunity for hearing to the applicant or party in interest. The Secretary's order in such a case would be appealable to the U.S. court of appeals which would have jurisdiction to affirm or set aside the order in whole or in part. Findings of the Secretary concerning questions of fact would have to be sustained if supported by substantial evidence when considered on the record as a whole.

The Department of Justice makes no recommendation as to whether judicial review of the Secretary's orders in such cases should be provided. However, the committee's attention is directed to several aspects of this measure.

We assume that the term "party in interest," used in the bill, is intended to refer to a person whose license is suspended or revoked by the Secretary. However, in order to eliminate any possible ambiguity as to who is meant to be included within this term, thereby precluding demand for judicial review by persons not directly affected by the Secretary's order, it is suggested that the word "licensee" be substituted.

The bill fails to specify the particular court of appeals to which an appeal from the Secretary's order shall be taken. Accordingly, the committee may wish to include a provision establishing venue in the court of appeals for the circuit in which the applicant or licensee resides or has his principal place of business or in the U.S. Court of Appeals for the District of Columbia. This would be in keeping with statutes similarly providing for direct review of administrative action in the courts of appeals.

In addition, the measure fails to specify a time limit within which an appeal from the Secretary's order may be taken. Other statutes providing for direct appeal from administrative orders require that any appeal be filed within a designated number of days, usually 60, from the date of the order.

Since the national health and welfare are so vitally involved in matters arising under this section of the Public Health Service Act, it is desirable to make it clear that the initiation of an appeal does not operate as a stay of the Secretary's order.

Further, there is no provision in the bill for summary suspension of a license by the Secretary although such immediate action could be required for the protection of the national health and welfare. We suggest that provision for such a contingency be made in this measure.

Finally, in the event of an appeal, the Secretary would be required to file in the court of appeals the "record, if any." If jurisdiction over these appeals is to be vested in the courts of appeals, the bill should require that a record be filed.

By way of a technical suggestion, the word "or" at the beginning of line 8, page 1, would appear to be incorrect and should be deleted.

The Bureau of the Budget has advised that there is no objection to the submission of this report from the standpoint of the administration's program.

Sincerely yours,

JOSEPH F. DOLAN,
Assistant Deputy Attorney General.

STATEMENT OF HON. ROLAND V. LIBONATI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. LIBONATI. Mr. Chairman, I am proud to come before this subcommittee.

I realize that time is of the essence and you have been solicitous and cooperative to give me this time to speak on this bill.

It is a short bill and it has for its purpose the addition of subsection H which provides for a judicial review upon the refusal of the Department of Health, Education, and Welfare, Food and Drug Administration, to issue, suspend, or revoke any license for the maintenance of the establishment or for the propagation or manufacture and preparation of a drug.

This is purely in accordance with the legalistic verbiage of the act, but all it actually does is this: If a petitioner or applicant for a license to manufacture, et cetera, is refused, and then through HEW all of the processes there are activated on this question. Then he has the right, if he so sees fit, to present to a court a petition. That does not mean that the court in procedure will grant the petition but at least it gives him an opportunity to place before the court such documentary evidence and testimony as necessary to sustain his position, that they acted arbitrarily, or they did not act at all or some confusion resulted in their refusal to act.

I think all other drugs, except those, are biologically active, this actually takes place. Biological drugs, in accordance with our present programing of scientific presentation of issues before courts, there certainly cannot be any retention on the part of the authorities to say that a court could not pass upon at least equities involved and the question of whether or not a toxic effect is actually prevalent or other matters which may affect the drug on the market which might affect some other organ or membrane of the body.

Anyway, it gives an opportunity to an individual or a group of individuals who feel that they have a remedial method through a drug to curtail or, in a measure, to benefit the man on the street that they ought to have a judicial form to make that determination.

With respect to the determination, of course, it is within descretion of the court to send it back to HEW to determine whether they took such preliminary steps in accordance with the procedures of the Health, Education, and Welfare.

As you know, Mr. Chairman, the question of judicial review has been accepted in many fields of the law, and I recommend this bill to you for the purposes intended. It will not in any way affect or destroy the competence in the Government operation of HEW.

Sometimes themselves they, with the medical men who are expert in fields disagree but at least it would add to the question of a precaution to not destroy in part or in whole the advancement of medicine and drugs.

Further, Mr. Chairman, if I may add this, it will give an opportunity for a public evaluation of the progress of research and a determination on having the public represented by a neutral court that will weigh the evidence and make a determination in accordance with the scientific facts of experts who will testify before the court.

I think it is a needed step.

It would also relieve the Department of Health, Education, and Welfare from certain responsibilities where there is such a disagreement or where they feel that the procedures have not been met in accordance with the rules of the scientific development or research as to drugs, and relieve them as to confusion in the public issues.

I am sure that this would only be used in a controversial sense in matters where the determinations must be made carefully and with an intent to protect the public if the drug is not the type of drug that should be placed upon the market.

I think this is an absolutely necessary remedial legislation in view of the fact that we passed a strict drug law this last session and this will be a type of remedial legislation which will give rise to a prevention of a shutoff with the Food and Drug Administration as the final judge.

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I ask your favorable consideration of this bill.

Mr. ROBERTS. The gentleman, as usual, is very persuasive and the Chair concedes that there may be a great deal of logic in his position.

Does the gentleman know or think of a concrete example where he feels there may be some abuse of discretion, some arbitrary situation or some improper judgment that has been used where this bill would correct it?

Mr. LIBONATI. I understand there are some situations in the past and present of which I could apprise the chairman—and of course they are very rare—of these situations where this would apply.

Mr. ROBERTS. Can the gentleman think of any concrete example? Say, for instance, in the thalomide situation, what would have happened under this bill if this type of legislation could have taken the doctor to the courts?

Mr. LIBONATI. I think if the facts were known after the Department approved the drugs, I don't think the Department would have ever released the drug. I think in that field there was no measurable apprehension that they had notice of until the drug was actually used which affected other organs of the body.

In other words, it had its effect in accordance with the control of what they were endeavoring to perfect with the drug in a curative sense, but it is only after the use of a drug that if there are aftereffects that can be curtailed immediately by order of the HEW. After all, no one, even the good Lord, can determine which ill effects which benefits one part of the body will do in the long run to some other organ in the body. That can only come unfortunately, through studying the effects of this drug and determining whether those effects of this drug have also created this problem in another area of the body.

Mr. ROBERTS. Did not the gentleman state in his formal statement that in the case of other types of drugs, we have this type of review; is that correct?

Mr. LIBONATI. Biological drugs have never been given this opportunity of review.

Mr. ROBERTS. I said the gentleman said in cases of other types of drugs there is this review.

Mr. LIBONATI. Yes, I would say ordinarily no one can measure the total effect of a drug except for the purpose intended unless in their study and in its application on humans which comes after they have tested the drug on animals or plants as the case may be, then they can make a determination when these effects show up.

There are today some drugs that are used where it is understood that a certain organ of the body will be affected but the fact that the devastation of the disease will destroy the human if he does not get help, they try to alleviate the effects of this drug on the organs, and in those cases it is a diagnostic fact which the medical profession has tried to control.

Mr. ROBERTS. I thank the gentleman.

Mr. Brotzman.

Mr. BROTZMAN. I would like to welcome our distinguished colleague to the subcommittee and I would like to ask two or three questions.

If I understand correctly, the refusal by the Secretary to issue a license or if he suspends or revokes a license to prepare products is what gives rise to this bill's operation; is that not correct?

Mr. LIBONATI. I would say yes; in terms.

Mr. BROTZMAN. My first question is this: A quick reading indicates that this appeal shall first go to the court of appeals. An appeal is taken from a suspension and then that appeal goes to the U.S. court of appeals rather than to the Federal district court.

Mr. LIBONATI. U.S. court of appeals, but they can refer it for fact-finding.

Mr. BROTZMAN. What is it that the U.S. court of appeals has before it to consider? What kind of record do they have to review?

Mr. LIBONATI. They take the record from HEW that is prepared and then whatever other supplemental evidence there is from the petitioner or the licenses.

Mr. BROTZMAN. I am not acquainted with all of the administrative procedure.

Is there a record that is prepared before the Secretary that he would certify to the U.S. court of appeals so that they could in fact review that record?

Mr. LIBONATI. Yes, they prepare a record and they incorporate in the record the entire proceedings relative to what they ask in the way of affirmances and interrogatories and forms and they make a determination then and they will also put in their conclusion why they refused the issuance of a license.

It may be even on a question involving the procedures in the research of the drug that were not in conformity with the norms or laws that have been set up by the AMA on questions of the proper preparation for research in drugs, first on animals or plants and so forth in order that the toxic quality of the drug can be measured very minutely and what effect it will have on humans.

Mr. BROTZMAN. Correct me if I am wrong, but if a court is reviewing a decision made by an administrative agency, is it not correct that short of arbitrary or capricious action, they will uphold the finding of the administrative agency.

Mr. LIBONATI. I do not think that is correct if the ruling is based on where they are limited to making a ruling by their rules and the court, on the other hand, will look at the rules derived to the individual.

I do not think you are correct, if the drug has a curative effect and the end result would delay the progress of the disease or diminish the effect of the disease.

Mr. ROBERTS. I think the question of the gentleman from Colorado is answered in the bill on page 2, line 19, where you say, "The finding of the bill states the findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence and considered on the record as a whole."

Mr. BROTZMAN. This is what I was getting at. I had read this specific sentence.

The determination, therefore, to be made by the court of appeals is whether or not there was substantial evidence presented to the Secretary to substantiate his particular finding?

Mr. LIBONATI. To issue a license or to withhold a revocation.

Mr. BROTZMAN. Issue, revoke, or suspend. In other words, Mr. Libonati, if there is substantial evidence on the record certified to the court of appeals, to support the position of the Secretary, then the case is all over; is that right?

Mr. LIBONATI. No he may call them in to sustain their position. I am sure you realize in instances like this where so much is dependent upon the welfare of human beings that they would be very thorough in their investigation and determination.

Mr. BROTZMAN. I want to know your concept on this. If the court determines there is substantial evidence, then the case is all over; isn't that correct?

In other words, the Secretary would be right.

Mr. LIBONATI. They could serve notice on the Secretary to issue the license by order of the court. Primarily, in most instances where the Secretary has some reason to deny the license, they may ask the applicant for the license to correct those procedures and continue on and then make a reapplication. It is purely a question of procedure as to what in the court's determination would be proper relative to this drug which must have some remedy in its application.

Mr. ROBERTS. Let the Chair state there can be some disagreement as to what the procedure will be but I am sure counsel can straighten us out on this in executive session.

Mr. BROTZMAN. I know our colleague is a distinguished attorney himself and I am not trying to be argumentative about the provisions. I just want to understand what the bill is supposed to do so I can understand the rest of the testimony.

Mr. LIBONATI. A judicial appeal is to do equity where equity is found. If there are no equities and in the practical acceptance of the report of the HEW, you will find they will be sustained in most cases.

It is the one case where they, by their own limitations and rules and procedures must frown against or deny that the court can alleviate this situation if the drug is worth saving. I think we will all agree to that, that no man advancing a drug that he formulated through research and so forth would persist if there were no value to the drug at all to follow this procedure.

It certainly would expose him to the fraudulent position that he had taken to the drug and the misrepresentations made.

I think that in itself is a guard against this law being used promiscuously by persons who have no honesty of purpose in pursuing their rights.

Mr. ROBERTS. Even under this procedure, if the gentleman from Colorado will yield, the proponent or applicant would be at a tremendous disadvantage.

The burden of proof is going to be upon him to reverse the agency under this bill. So he would be in a very bad position to start even with this legislative authority.

Mr. LIBONATI. He would have to show that he followed and served every requirement of the law in order to get into the court. His petition can be dismissed without giving him any judicial appeal at all if they feel there is no basis upon which to issue.

Mr. BROTZMAN. Thank you.

Mr. ROBERTS. Mr. Rogers.

Mr. ROGERS of Florida. The purpose, I understand, of your legislation, is simply to allow an aggrieved party to have some remedy beyond the departmental level, to go to the courts, if necessary, to set aside an order which would not be sustained by substantial evidence.

Mr. LIBONATI. And also the public interest involved, of course, if the drug has remedial application.

Mr. ROGERS of Florida. Thank you very much.

Mr. ROBERTS. I thank the gentleman.

The next witness will be Dr. Roderick Murray, Director, Division of Biological Standards, National Institute of Health; accompanied by Mr. Theodore Ellenbogen, Office of General Counsel.

We are glad to have you before our committee and you, Mr. Ellenbogen. We have not seen you since the Drug Act.

STATEMENT OF DR. RODERICK MURRAY, DIRECTOR, DIVISION OF BIOLOGICAL STANDARDS, NATIONAL INSTITUTES OF HEALTH, PUBLIC HEALTH SERVICE, BETHESDA, MD.; ACCOMPANIED BY THEODORE ELLENBOGEN, DEPUTY CHIEF, DIVISION OF LEGISLATION, OFFICE OF THE GENERAL COUNSEL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Dr. MURRAY. I am Dr. Roderick Murray, Director of the Division of Biological Standards of the National Institutes of Health, U.S. Public Health Service.

This Division has the responsibility for carrying out those provisions of the Public Health Service Act which deal with biological products.

We have no prepared statement. The Department has presented formal comments on this bill and included in this document are some recommendations for perfecting amendments and if there are any questions on that, Mr. Ellenbogen would be happy to speak to it.

Mr. ROBERTS. Do you favor the bill with the amendments?

Dr. MURRAY. We have no objection to the bill.

Mr. ROBERTS. The Department has not taken a formal position as yet.

Mr. ELLENBOGEN. We have taken the formal position that we have no objection.

Dr. MURRAY. I would like to say in the history of this type of activity; that is, the licensing of biological products, which does go back to 1902, we have had no occasion where such a grievance has come up, and there does exist within the regulations relating to biological products a procedure under which the Surgeon General can appoint a board in order to look into a grievance and give whatever redress is necessary.

I would like to point out, parenthetically, that the substance of all of these actions is actually scientific and technical in nature. Action on licensing of biological products will depend upon such matters as the safety, the purity, and the potency of these products, and that in licensing a product or in denying the license for a product, all of the available information will be taken into consideration, and that the expertise in this regard does not completely reside within our Division or within the Public Health Service, inasmuch as when particularly difficult problems of a scientific nature come up, it is possible to confer with the very best scientific talent in the country on this matter.

Mr. ROBERTS. Dr. Murray, give us a good example of what you would consider a product covered by this bill.

Dr. MURRAY. I would think that the recently licensed live measles vaccine is a good example. If I might take a few moments and de-

scribe what is involved in this licensing, it might give some clarification.

Mr. ROBERTS. You may do so.

Dr. MURRAY. As soon as measles virus was isolated some 8 or 9 years ago by Dr. Enders, it was immediately evident to those active in this field that a vaccine was a definite probability, once the necessary scientific processes had been worked out.

This proved to be a long-drawn-out business and it was only this year that the vaccine was eventually licensed.

In order to meet this eventuality the Public Health Service started very early in order to meet the problems involved, to develop scientific research programs so that information would be available at about the time the product might be available for licensing.

In addition, it conferred with experts in this country and from abroad and in the process of this it developed a series of recommendations which industry could use for the testing and production of such a vaccine. This was looking forward to the development of a set of regulations which would cover the essential aspects of safety, purity, and potency. This also included the clinical efficacy of the vaccine in the field, so that these would be in effect at the time that manufacturers were ready to apply for a license.

This was a very laborious task, as you might imagine, but it was accomplished, and in the spring of this year measles vaccine was licensed on the basis that the manufacturer had met the requirements which had been set forth in these regulations which had been previously published.

Mr. ROBERTS. That is very interesting, Doctor. When will we make this measles vaccine available and, if so, will we do it under the provisions of the mass vaccine program?

Dr. MURRAY. That is completely outside of my field of responsibility and I am unable to answer that. Our Division is concerned with the problems entirely related to the safety, purity, and potency of the product and not in its supply in the field.

Mr. ROBERTS. Do you know when the vaccine will be available in volume?

Dr. MURRAY. It is available in rather substantial amounts at the present time.

Mr. ROBERTS. So far, have you had any reaction from the use of it? Have you had any response, or is it successful, in your opinion?

Dr. MURRAY. The reports from the field have been rather gratifying. It is expected from the clinical evidence that was available even before licensing that there will be a certain number of children who would have mild reactions, such as a fever for a couple of days, and some might even have rash, but this would be a mild illness and would in no way incapacitate them.

Upward now of 2 million doses have been used.

Mr. ROBERTS. Upward of 2 million doses?

Dr. MURRAY. Yes, sir.

Mr. ROBERTS. How many injections would they have to have?

Dr. MURRAY. One.

Mr. ROBERTS. Would they be given with other vaccines?

Dr. MURRAY. Not mixed, but separately. It is possible to give them simultaneously.

Mr. ROBERTS. How serious is measles as a problem in this country?

Dr. MURRAY. I cannot give you any exact figures but it is considered to be a rather serious problem in the sense that it does cause a considerable amount of encephalitis and a number of children who have had measles do suffer from mental dullness as a result of that.

Mr. ROBERTS. Thank you, Doctor. The committee would certainly like to compliment you and all the members of your staff and the people at the NIH and everyone who has a part in bringing this wonderful blessing to our people and the people of the world.

Mr. Brotzman?

Mr. BROTZMAN. When you say "biological products," what does that mean?

Dr. MURRAY. Largely this concerns materials which are in the nature of vaccines, serums as commonly understood, and human blood for transfusion and products made from human blood such as albumin and gammaglobulin. Some of the vaccines I could mention are smallpox vaccine, typhoid vaccine, cholera vaccine. Serums would be tetanus antitoxin, diptheria antitoxins and products which are analogous to these.

Mr. BROTZMAN. I think you stated that you make a determination as to "safety, purity, and potency." Is that correct?

Dr. MURRAY. That is correct.

Mr. BROTZMAN. You have looked at this particular bill we are considering here this morning?

Dr. MURRAY. Yes.

Mr. BROTZMAN. What I am interested in knowing is what kind of record is made in your agency that would be available for review by the Court.

Can you explain to me what sort of hearings are prepared? I am talking about just fundamental things such as, does a reporter take testimony or are documents filed to make a record.

Dr. MURRAY. What usually happens is that a manufacturer interested in a particular product will submit documents which constitute an application for a license for this particular product.

The documentation will vary according to the kind of product. Obviously in a thing like measles or polio vaccine, the documentation will be very extensive.

Mr. BROTZMAN. Pardon me at this juncture. To whom does he submit this documentation at the initiation of his application?

Dr. MURRAY. To the Surgeon General but it is handled within the Division of Biological Standards.

Mr. ELLENBOGEN. You asked before what kind of hearing record was made. The fact is that there has never been an application for a hearing under section 351 of the Public Health Service Act so that there is no actual case of a hearing.

Never in the history of this program has there ever been a request for an opportunity for a hearing although the regulations do afford that opportunity, so the documentation that Dr. Murray referred to was not at the hearing stage although if it went to the hearing stage these documents would presumably be submitted for inclusion in the record.

Mr. BROTZMAN. Now I think we are making some progress as far as I am concerned.

If the hearing is requested under the applicable regulations, then a record would be made at that particular juncture? Is that right?

Mr. ELLENBOGEN. That is correct.

Dr. MURRAY. As I understand Mr. Brotzman's question, it was, how did we develop the record for a new product so that in the event that a hearing might come up at a later date this documentation might be available?

Mr. BROTZMAN. This is correct.

Dr. MURRAY. I mentioned, first of all, the documentation in connection with the initial application by the manufacturer. Subsequent to that there would be correspondence, clarification, there would be conferences held with the manufacturer's scientific personnel in order to clarify points that were not clear, there might be requests for additional information, and in addition to that there would be a record of laboratory and other tests which are carried out by our own division and other scientific bodies, references to the scientific literature, and so on.

Usually this would all culminate in the issuance of a license, because if the license is not going to be issued it becomes evident at an early stage that the information required is not going to be available.

Mr. BROTZMAN. In the event the license application was refused and let us say the aggrieved party desired to pursue his or her remedy under section 351, at the hearing is the right of cross-examination and all of the other rights of a fair hearing afforded to the particular individual at that juncture?

Dr. MURRAY. I would have to defer to Mr. Ellenbogen.

Mr. ELLENBOGEN. The regulations do not spell out the procedures for the hearing but the right of cross-examination is inherent in the concept of a fair hearing, so that my answer would be "Yes," but it is not spelled out in so many words in the regulations.

It just says "an opportunity for hearing."

Mr. BROTZMAN. That is section 351.

Mr. ELLENBOGEN. Yes, of the Public Health Service Act.

May I say that section 351 does not refer to a hearing. Section 351 says, "All such licenses shall be issued, suspended, and revoked as prescribed by regulations," and the regulations, in turn, provide for an opportunity for hearing.

Mr. BROTZMAN. The reason I am asking these questions is I was trying to find out what kind of record there would be at the time the Court might be called upon to review them.

Mr. ELLENBOGEN. If we had a hearing there would be a presiding officer or board; the regulations provide for a board, in certain cases, of officers. While this is not spelled out in the regulations, there would be documentary evidence, there could be oral testimony on both sides and cross-examination, and all of this would be taken down and included in a full record, just as it is in hearings under the Food and Drug Act.

Mr. BROTZMAN. Is testimony taken under oath?

Mr. ELLENBOGEN. I don't recall offhand whether under the Food and Drug Act testimony is taken under oath. Presumably an oath would be administered when there is oral testimony.

Mr. BROTZMAN. The answer really is you do not know?

Mr. ELLENBOGEN. I would have to inquire how we proceed in that respect under the Food and Drug Act. The Administrative Proce-

dure Act, in enumerating the powers of presiding officers, says that the hearing officer, subject to the agency's rules "and within its powers," may administer oaths. I can supply the information for the record as to how we proceed under the Administrative Procedure Act on that point, under the Food and Drug Act.

(The following letter was later received from Mr. Ellenbogen:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
July 12, 1963.

Hon. KENNETH A. ROBERTS,
Chairman, Subcommittee on Public Health and Safety, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: At the hearing on H.R. 3408 held before your subcommittee on July 9, I was asked by Congressman Brotzman whether, if the bill were enacted, witnesses appearing at hearings under the bill would be put under oath. I responded that we would follow the same practice as is employed at hearings under the new-drug section (sec. 505) of the Federal Food, Drug, and Cosmetic Act, and I undertook to supply the information as to that practice for the record (pp. 21 and 22 of typed transcript).

I have now examined the applicable regulations under that act and find that section 130.17 of the regulations provides that the hearing examiner "will have the power to administer oaths and affirmations * * *," and section 130.21 provides: "Each witness shall, before proceeding to testify, be sworn or make affirmation."

I should appreciate it if you would be good enough to have this information inserted at the appropriate place in the record of the hearing.

Sincerely yours,

THEODORE ELLENBOGEN,
Deputy Chief, Legislation Division, Office of the General Counsel.

Mr. BROTZMAN. I think it makes a difference, and I believe the sponsor would agree, what kind of record there was available for the court to review.

Mr. ELLENBOGEN. The provision in this bill is a fairly standard provision subject to certain corrections.

Mr. BROTZMAN. Did I understand there were certain amendments your agency is recommending that might improve the bill?

Mr. ELLENBOGEN. Yes, indeed. When I said before that we had no objection to the bill, I should have said," if certain perfecting amendments are made." I can summarize those if you wish.

Mr. BROTZMAN. Maybe the chairman intends to proceed to find out what they are but I would be interested, of course, in knowing what they are at the appropriate time.

Mr. LIBONATI. They are purely amendments within the procedures of the HEW itself to arrive at the situation where they have in fulfillment carried out their questions of appeal, giving the right of appeal to the applicant.

Mr. ROBERTS. I have just one brief question. I am sure, Dr. Murray, you and your associates are familiar with the various efforts that have been made to license Krebiozen.

Would this bill or its provisions cover that particular product?

Dr. MURRAY. I think it is fair to say the Department made a determination some years ago that Krebiozen was a biological product subject to the Public Health Service Act and therefore would be covered.

However, it was in an investigative state and a license application for the product has not been filed so we have taken no action on it.

Mr. ROBERTS. No application for a license has actually been made?

Dr. MURRAY. That is correct. The proponents have stated that they believe it is subject to the Food and Drug Act and I understand they did submit a new-drug application.

Mr. ROBERTS. No application has been made so far as you know to the Division of Biological Standards for the issuance of a license?

Dr. MURRAY. That is right. No license application has been filed.

Mr. ROGERS of Florida. There are no substantive amendments; is that right?

Mr. ELLENBOGEN. We consider them all procedural. The only amendment that may have substantive implications is one which your committee included in the Harris-Kefauver amendments last year authorizing a summary suspension pending hearing where there is an imminent hazard to the public health.

I might say that that is also provided for in the regulations at present.

Mr. ROGERS of Florida. In your mind, who has the burden of proof on an appeal of this nature?

Mr. ELLENBOGEN. The appellant has the burden of showing that either the findings of fact of the Secretary are not supported by substantial evidence when considered on the record as a whole, or that there was some error of law.

Mr. ROGERS of Florida. Must the Secretary make a positive showing that the questions of fact are sustained by substantial evidence?

Mr. ELLENBOGEN. I think the burden is on the other side. Whoever appeals to an appellate court always has the burden of showing that the order from which he appeals is wrong, whether on the facts or on the law.

Mr. ROGERS of Florida. What, in your definition, is substantial evidence?

Mr. ELLENBOGEN. The bill refers to substantial evidence on the record as a whole. This phrase, or a similar one, is used in the Administrative Procedure Act and has been interpreted by the Supreme Court in the *Universal Camera* case. That case arose under the National Labor Relations Act but that decision, I think, is pertinent in answering your question, and there Justice Frankfurter explained that the term "substantial evidence on the record as a whole" does not permit the court to search the record for some isolated piece of evidence that might, in itself, be substantial and say that that supports the decision below. It must look at the record as a whole, and only if on that basis the evidence in support of the findings is substantial will the findings be sustained.

Mr. ROGERS of Florida. It is your understanding, then, that this law would allow the Court to determine facts, as such.

Mr. ELLENBOGEN. Not to substitute its own judgment for that of the factfinder below. This is a standard provision, requiring the court to determine whether on the record—looking at the whole record, both pro and con—it can be said that the evidence that supports the findings is substantial.

That much the Court would do on the facts, and I would say that under the National Labor Relations Act the Court has sometimes gone pretty far in upsetting decisions as not being supported by substantial evidence on the whole record.

I imagine that where the facts are so highly scientific as they are likely to be in cases that might arise under this bill, a court would be rather conservative in upsetting the findings of fact.

Mr. ROGERS of Florida. Pretty much, then, you feel they would adhere to the facts as found by the Secretary?

Mr. ELLENBOGEN. Unless it were a case where, fairly clearly, looking at the record as a whole, there was not substantial evidence to support those findings.

There might be an error of law, too, and on questions of law the Court would, while giving due weight to the administrative interpretation, use its own judgment as to whether there was error.

Mr. ROGERS of Florida. Will the person who applies for licensing of a biological product also, at the same time, have to comply with the new provisions set out in section 505 of the Federal Food, Drug, and Cosmetic Act?

Mr. ELLENBOGEN. The situation is this: If it is a new biological product, it is undoubtedly also a new drug within the meaning of the Food and Drug Act. In that case, you look to the regulations under the new drug section, section 505, of that act. These regulations provide that if the product has actually been licensed under the Public Health Service Act, if it is a biological product that has actually been licensed, it is exempt from the new drug section. If it has not yet been licensed, then there are two aspects. If it is at the investigative stage, then it is subject to the regulations under section 505(i) of the Food and Drug Act which exempt a drug from the provisions of section 505 only if it meets the conditions set forth in the regulations. The regulations on new drugs intended for investigational use are very extensive now, and your committee last year, in reporting out the drug amendments, amended that very subsection of the law.

If the drug has passed the investigative stage and at that point there is an application under section 505 for marketing of the drug—for clearance for the market—then the regulations under the new drug section provide that if it is a biological drug subject to the Public Health Service Act, the application would be refused.

The theory of that, I think, is that it would be a futile gesture and a duplication to pass on this under section 505 if the drug is subject to licensing under the Public Health Service Act. This provision of the regulation makes that duplication impossible; in other words, the proponent of the biological drug will at that stage have to go to the Public Health Service and try to get a license.

Mr. ROGERS of Florida. Suppose a man is coming to you for the first time and nothing has been done on his proposal. Does he have to travel both avenues?

Mr. ELLENBOGEN. If there is any doubt in his mind he would undoubtedly consult with the Public Health Service and the Food and Drug Administration as to whether this is a drug subject to the provisions of this section of the Food and Drug Act or section 351 of the Public Health Service Act. I would ask Dr. Murray to speak to this.

Dr. MURRAY. We have to work closely with the Food and Drug Administration on such things. I might say biological products by their nature carry certain unpredictable hazards because they are prepared in many instances from dangerous bacteria or viruses and this is the reason we have these special precautions.

Congress recognized this in 1902 when it enacted this special law.

Usually, as the result of the first correspondence or telephone call to either agency the matter can be decided and then the individual deals either with the Food and Drug Administration, if it is clearly a drug coming under their jurisdiction, or if it is potentially a biological product then with the Public Health Service.

This, then, actually develops along a program of consultation from that point onward then between the proponent and the agency involved.

Mr. ROGERS of Florida. I realize consultation would help but what happens now if you consult? Does one take jurisdiction or does the other or does he still have to proceed?

Dr. MURRAY. No, where it is clearly a licensable product, which means a product which eventually will be licensed, the matter is turned over to the Public Health Service and the Public Health Service then will keep the Food and Drug Administration informed.

Mr. ROGERS of Florida. You said up to a point of investigation, it would go both routes, as I understood your statement.

Mr. ELLENBOGEN. Were you speaking about my reference?

Mr. ROGERS of Florida. Yes, sir.

Mr. ELLENBOGEN. What I meant to say was that when the drug was still at the investigative stage, was not being offered for sale, and had not yet reached the stage of application for a license, there are no applicable provisions under the Public Health Service Act, and the drug, if it is shipped in interstate commerce for investigative purposes, has to comply and the manufacturers have to comply, with the investigative—drug regulations under subsection (i) of the new drug—section of the Food and Drug Act.

I believe in that connection there is also close liaison between the Food and Drug Administration and the Public Health Service.

Dr. MURRAY. That is correct.

Mr. ROGERS of Florida. Do you feel, then, there is no duplication?

Dr. MURRAY. No, there is no duplication.

Mr. ROGERS of Florida. You feel the coordination brought about by consultation does not require, then, a manufacturer to have to go through both routes. This is not necessary?

Dr. MURRAY. No. That would be highly undesirable.

Mr. ROGERS of Florida. How many amendments do you have?

Mr. ELLENBOGEN. To the bill?

Mr. ROGERS of Florida. Yes.

Mr. ELLENBOGEN. I did not count them but I can quickly summarize them.

The first amendment we think essential, that I mentioned before, is authority for summary suspension of a license.

Under the 1962 amendments to the new drug section of the Food and Drug Act, when there is a finding that there is an imminent hazard to the public health, the prior approval of a new drug could be suspended summarily, in which event notice would be given immediately of the opportunity to an expedited hearing.

There is a provision along those lines under the Public Health Service Act at the present time.

Mr. ROGERS of Florida. Would this be a new section?

Mr. ELLENBOGEN. This would be inserted in the bill. We did not supply language, but if the committee so desires, we will do so.

Mr. ROGERS of Florida. All right. Go ahead, sir.

Mr. ELLENBOGEN. The second provision is purely a technical one. The bill provides that the applicant or the party in interest, as the case may be, is entitled to a hearing and then may take the matter to court. Both the Justice Department and we were afraid that the words "party in interest" might be construed to include someone other than the licensee or the applicant for the license, and we suggest it be limited to the applicant for a license or licensee.

Third, there are a number of other suggestions on which, we say in our report, we concur with the Department of Justice: First, to delete a typographical error which is pointed out in the report, and, secondly, to specify which court of appeals these cases should go to. The bill says the U.S. Court of Appeals, but it does not say which one.

The bill might provide that the appellant can take the appeal either to the U.S. Court of Appeals for the circuit in which the appellant has his principal place of business or to the Court of Appeals for the District of Columbia, or it could just provide for the former or the latter, whichever the committee desires.

Mr. ROGERS of Florida. What is the recommendation of the Department?

Mr. ELLENBOGEN. We leave it to the committee. To give a choice of both possibilities, which I mentioned as one approach, is most favorable to the appellant.

Mr. LIBONATI. You must understand that there is a cost involved here so it should be in the local district.

Mr. ELLENBOGEN. Third, the bill does not specify any time limit for filing the appeal in the court of appeals, I think 60 days is the usual time limit specified in such provisions.

Mr. ROGERS of Florida. Is this recommended by the Department?

Mr. ELLENBOGEN. We would recommend the normal time limit.

Mr. ROGERS of Florida. How about the Department of Justice?

Mr. ELLENBOGEN. They mention the normal time period. I assume a report has been filed by them.

Fourth, we and the Department of Justice recommend a provision that, unless ordered by the court to the contrary, the appeal itself does not operate as a stay of the order of the Secretary. That has no special significance for the denial of a license but it has it for the revocation of a license or suspension. Only when the court believes there should be a stay, and the court so orders should there be a stay.

This morning one other question occurred to me, and I merely mention it. The present regulations provide that in certain cases the hearing shall be before a board of three officers appointed by the Surgeon General. These cases involve highly technical and scientific matters. If this bill is enacted and if this automatically makes the Administrative Procedure Act applicable, I doubt that the Surgeon General would be able to do that. It might be desirable—although as I say, this just occurred to me this morning and we have not consulted on it—to amend the bill to specifically authorize the Department—not to require it but to authorize it—to use that kind of procedure.

Mr. ROGERS of Florida. Under the Administrative Procedure Act.

Mr. ELLENBOGEN. The Administrative Procedure Act says:

> There shall preside at the taking of evidence (1) the agency, or (2) one or more members of the body comprising the agency, or (3) one or more examiners

appointed as provided in this Act; but nothing in this Act shall be deemed to supersede the conduct of specified classes of proceedings in whole or part by or before boards or other officers specially provided for by or designated pursuant to statute.

Unless the bill is amended to specifically authorize the designation of a hearing board of some sort, I doubt that the Administrative Procedure Act, if it applies, would permit this. I doubt that we could continue in effect now the regulation which says that in certain cases we would have a hearing board.

I am merely raising the question whether it would authorize——

Mr. ROGERS of Florida. Giving you permission to use the Administrative Procedure Act?

Mr. ELLENBOGEN. Yes, sir.

Mr. BROTZMAN. Will the gentleman yield?

Mr. ROGERS of Florida. Yes.

Mr. BROTZMAN. Do you share my concern that if the hearing is not conducted properly then the court of appeals may have a lot of reversals, so to speak, because of the failure of due process in the hearing?

Mr. ELLENBOGEN. Let me say first that we have never——

Mr. BROTZMAN. This is why I was asking you the questions a few moments ago. It is not a novelty, I realize, but it would seem to me it might be a problem.

Mr. ELLENBOGEN. When you say "not conducted properly," are you referring to who shall preside or what?

Mr. BROTZMAN. If a hearing is requested and held, I am concerned about whether or not procedural due process is accorded at that particular hearing, because this, I understand, will be the record that goes up to the U.S. Court of Appeals.

Mr. ELLENBOGEN. There is no doubt in my mind that procedural due process should and would be accorded and that the hearing would and should be properly conducted.

If there is a hearing, we would undoubtedly be represented by counsel before the presiding body. If there is a hearing board, I would hope that at least the chairman would be a person skilled in the conduct of hearings.

Mr. BROTZMAN. You say you have no fear of that but if I understood your response to my question before, the present regulations do not set certain requirements.

For example, I asked you about the right of cross-examination, did I not?

Mr. ELLENBOGEN. I said that is inherent in a hearing.

Mr. BROTZMAN. It is not provided for.

Mr. ELLENBOGEN. It does not have to be. If the right of cross-examination is denied, I think that would be ground for reversal.

The Administrative Procedure Act does provide for the right of cross-examination.

Mr. BROTZMAN. That is right. I am quite positive of that.

Mr. ROGERS of Florida. If the gentleman will yield, is it not normally so that the Administrative Act is normally triggered in these hearings?

Mr. ELLENBOGEN. Unless this falls within one of the exceptions to the application of the hearing requirements of the Administrative Procedure Act in cases of adjudication—and licensing is defined as

included in the term "adjudication"—then the Administrative Procedure Act automatically applies.

Mr. ROGERS of Florida. Would they not then automatically apply under this bill?

Mr. ELLENBOGEN. In my opinion, it would, unless this is a proceeding in which the decision is rested solely on inspections or tests. We are exploring this but we have not resolved this. If it is, then I think it would not automatically—I mean, the hearing provisions. If it is not, then it would apply.

Mr. ROGERS of Florida. If it is just tests—and what else did you say?

Mr. ELLENBOGEN. Section 5 of the Administrative Procedure Act excepts cases in which the decision rests solely on inspections or tests or elections, and elections do not come into play here.

Mr. ROGERS of Florida. Inspections are set down in the act.

Mr. ELLENBOGEN. It would not apply.

Mr. ROGERS of Florida. There is not need for it to apply, if it is an inspection of records, if it is before the court or hearing record there is no necessity for all of this business because the facts are before it, so where there is any necessity for actual cross-examination, your Administrative Procedure Act would apply; would it not?

Mr. ELLENBOGEN. That is correct.

Mr. ROGERS of Florida. Does that conclude all the amendments that the Department has?

Mr. ELLENBOGEN. Yes, sir.

On that last one, as I say, it occurred to me this morning——

Mr. ROGERS of Florida. It might be wise for the committee to consider some mention of the Administrative Act.

Mr. ELLENBOGEN. It disturbed me because under the present regulations there is provision for such a board.

Mr. ROGERS of Florida. I think it would be automatically triggered but we can go into that.

Thank you very much. Thank you, Mr. Chairman.

Mr. ROBERTS. At this point would the gentleman from Illinois have any objection to the amendments proposed by the Department?

Mr. LIBONATI. I spoke to the gentleman and on the question of administrative procedure, I think that is important. He is going to submit the amendments to me and submit them to the committee and then I can look them over and reconcile them with the purpose intended.

I do not see anything wrong with the amendments in conformity with what we are trying to do here at this time.

Mr. HARRIS. Have you had occasion to read the report of the Department on the bill, Mr. Libonati?

Mr. LIBONATI. I did previously when I introduced a bill some years ago. I had no opportunity to read any report since that time, however.

Mr. HARRIS. I think you should have a copy of this and read it over and then submit a supplemental statement for the record with respect to whether or not you agree with it.

Mr. LIBONATI. I expect to do that as soon as they draw their amendments. I am reserved about delegating powers to any appointed officer in Government, prosecutory in nature, when we are seeking an

equity determination in a bill apart from the various departments of Government and rest it with the courts.

There may be some reason for this procedure and if there is I would be glad to look it over and make a determination of whether or not it would in fact defeat the very purpose of the bill by taking this question out of one arm of Government with respect to the Department and then having the Attorney General move in, whether that would be detrimental to the interests of the applicant for a license, et cetera, or whether it would be—I mean there comes a time when we seek judicial interpretation in accordance with the purposes of this act, free and independent of anyone, because there will—this will only lead to a reconciling of facts that might have been judged in accordance with the Department but differently from the court.

So I do not know whether this delegation of power to the Attorney General would conflict with the interests and the purposes of the bill.

Do you understand my position, Mr. Chairman?

Mr. HARRIS. No; I do not. The gentleman can make up his mind after he has had a chance to read the letter.

Mr. LIBONATI. I know the Attorney General approved the bill in a previous bill.

Mr. HARRIS. I am talking about the letter which HEW submitted here under July 3.

Mr. LIBONATI. I never saw the letter.

Mr. HARRIS. They offer certain suggestions and I merely suggest, Mr. Chairman, that the gentleman from Illinois have the benefit of this letter and then advise you, by supplementary statement if he desires, whether or not he agrees with the suggestions of Health, Education, and Welfare.

Mr. LIBONATI. That is very fair. I appreciate that.

Mr. HARRIS. We are not interested in the amendments and I don't care about them offering amendment to you for approval. We have staff members to take care of that. We just want to know what your feelings are on this.

Mr. ROBERTS. The chairman will make this letter available to the gentleman for his comments.

Did you want to say something additional, Mr. Ellenbogen?

Mr. ELLENBOGEN. No. Although I am not sure what Mr. Libonati's suggestion was with respect to the Attorney General.

Mr. LIBONATI. It was my understanding that you were going to appoint the Attorney General to a board.

Mr. ELLENBOGEN. No; the Surgeon General would be authorized to appoint a board. I think there was a misunderstanding. If I said "Attorney General" I misspoke myself.

Mr. LIBONATI. Then you might as well not appeal at all. You lead me to the gallows and then hang me on a pillow, because the Surgeon General is part and parcel of the Department.

Mr. ROBERTS. Is there anything further?

Mr. ROGERS of Florida. I think the point was in the initial hearing the appeal would go to this board to see if any errors were made there and then from there to appeal it to the court which would be independent to review what this board had done under the Administrative Procedure Act.

Mr. LIBONATI. I understand the Surgeon General on any medical question controls the entire situation. I certainly don't want him to be appointing a board of appeal.

Mr. ROGERS of Florida. I think the point would be that he would simply appoint as a first step, for review what his group had done to make sure they had been fair within the Department itself. Then after three people from the Department had gone over the record to see if they had been fair, then the appellant has the right to go to the court to say it has not been fair.

Mr. LIBONATI. I am thinking of the delay and passing through these various watersheds of screening of factual data.

By the time it gets to the court of appeals a fellow would not have anything in the record. It is something like the "kangaroo courts" they have on the deportation of immigrants. They prepare their own record and you can't get anywhere in there except through their approval and they even put in evidence after the hearing.

We cannot stand for that on a scientific question basically involving probably the best testimony you can ever receive before any hearing body or court, as far as technicalities and determinations in research.

Mr. ROGERS of Florida. I agree with the gentleman on that.

Mr. BROTZMAN. May I ask you one more question, Mr. Libonati?

You might have answered this one but I don't think I heard it. Did you have a recommendation as to which court of appeals should have jurisdiction over such a case?

Mr. LIBONATI. Do we have that?

Mr. BROTZMAN. As I understand the bill now, it does not designate whether it will be in Washington, D.C., or elsewhere.

Mr. LIBONATI. Yes; I have the opinion that where a resident with all of his witnesses resides, that district should have jurisdiction over the question involved.

Look at all the expense it would take to come to Washington with all of the testimony, lawyers, all these records and so forth that they have, covering their proof for the purposes of procuring a license.

I think the least the Government could do is have the individual present that evidence in the local area where all of the activities of the applicant are being handled, and his witnesses can come into court there.

I do not think there is any preference as the circuit court of appeals is concerned to bring them all to Washington and with those costs it might be prohibitive, particularly where most of the funds are expended for developing the formula and gathering evidence and data and research in accordance with the rules HEW lays down before a drug can even be considered. These procedural steps must be made and this type of research must be adhered to and records kept.

I think it is self-evident that the loci should be in the circuit in which the operation is involved.

Mr. ROBERTS. Let the Chair suggest, I think, the best procedure would be for the gentleman to review the procedures and make his comments in writing so we will have them when we get to executive session on the bill.

Is there anything further from the committee?

Thank you gentlemen.

The next witness is Mr. Clinton Miller of the National Health Federation.

STATEMENT OF CLINTON R. MILLER, NATIONAL HEALTH FEDERATION

Mr. MILLER. We have prepared a short statement for a short bill.

The National Health Federation is a national organization with thousands of members who believe in freedom of choice in matters of health where the exercise of that freedom does not interfere with the safety or health of another and thereby deny him an equal freedom.

We favor any legislation that is designed to prevent or correct any accidental or deliberate maladministration of any laws governing the health of Americans. The present bill is primarily written to correct rather than prevent unjust acts but will serve to deter improper agency rulings.

The National Health Federation endorses H.R. 3408 by Representative Libonati of Illinois. We compliment him for its introduction. We respectfully urge this subcommittee to give the bill a favorable report. We are pleased that this busy subcommittee has scheduled hearings on Mr. Libonati's bill at this time.

Mr. ROBERTS. Thank you very much for your appearance and we appreciate your statement.

Mr. BROTZMAN. With respect to your organization the National Health Federation, you said you represent thousands of people?

Mr. MILLER. Yes, sir.

Mr. BROTZMAN. What is the basic objective of your organization?

Mr. MILLER. It is stated in my first paragraph. We fight for freedom of choice in matters of health. We feel that people should have the same freedom to make a determination in health that they have in religion. We feel if an error is made the person himself suffers for it and we feel in this country if we had the same rights in the matters of health as we have in matters of religion it would be a far healthier country.

Mr. BROTZMAN. Do you have organizations in all of the States of the Union?

Mr. MILLER. I believe we have members in just about every State. Without having the records available—I never had that question presented—but I know we have them in most every State.

Mr. BROTZMAN. I have one more question.

You probably stated this but I did not hear it. What is your relationship to the organization.

Mr. MILLER. I am assistant to the president of the National Health Federation in charge of the Washington office.

Mr. ROBERTS. Thank you.

This will conclude hearings on H.R. 3406, H.R. 3407, and H.R. 3408, gentlemen.

Mr. LIBONATI. These are from all over the country as to the programing of the bill. I have hundreds of letters also in addition to these cards.

Mr. ROBERTS. Without objection, they will be included in the files of the committee.

Mr. MILLER. I believe these postcards are from members of the National Health Federation which Mr. Libonati is holding up.

Mr. HARRIS. I think, Mr. Chairman, the cards, might be referred to in the record and if Mr. Miller desires, I would suggest that he be permitted to take them on back with him.

Should we have any need for them we could ask him for them.

Mr. ROBERTS. With that recommendation, the hearings on this bill are concluded and the record will remain open for 5 additional legislative days for filing of any additional statements or information.

The hearing is adjourned.

(The following statement was received for the record:)

SUPPLEMENTAL STATEMENT OF THE NATIONAL HEALTH FEDERATION ON H.R. 3408

At the conclusion of the July 9 hearing on Mr. Libonati's bill, H.R. 3408, Representative Harris kindly volunteered to turn over the letters and post cards to the National Health Federation's Washington office, which had been written by our members favoring the bill. Rather than request that each individual's statement be included in the record we have compiled these names by States and request that they be made a part of the record as favoring the bill, H.R. 3408. This will aid interested Congressmen to quickly find constituents who are on record as favoring the bill.

MEMBERS OF THE NHF WHO SENT LETTERS OR POST CARDS FAVORING H.R. 3408

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Tauchen, Ernest, Brandon, Wis.
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(Whereupon, at 11:35 a.m., the subcommittee was recessed to reconvene subject to the call of the Chair.)

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