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OF THE

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COMMITTEE ON COMMERCE

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ON

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*Effect of 2,4,5-T on man and
the Environment
Dr. Jesse Steinfield*

EFFECTS OF 2,4,5-T ON MAN AND THE ENVIRONMENT

WEDNESDAY, APRIL 15, 1970

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON ENERGY, NATURAL RESOURCES AND THE
ENVIRONMENT,
Washington, D.C.

The Subcommittee met, pursuant to adjournment, at 10 a.m., in room 1318, New Senate Office Building, Hon. Philip A. Hart, presiding.

Present: Senators Hart and Baker.

Senator HART. The Committee will be in order.

Our first and distinguished witness is the Surgeon General, Dr. Jesse Steinfeld.

STATEMENT OF DR. JESSE STEINFELD, SURGEON GENERAL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE: ACCOMPANIED BY DR. DAVID GAYLOR, DR. DIANE COURTNEY, AND DR. DALE LINDSAY

Dr. STEINFELD. Thank you, Senator Hart.

Accompanying me are Dr. Diane Courtney, on my right, of the Pharmacology and Toxicology Branch of the National Institute of Environmental Health Sciences, Dr. Dale Lindsay, associate commissioner for science (FDA) and Dr. David Gaylor, chief of the Biometry Branch of the National Institute of Environmental Health Sciences.

I have a prepared statement.

Senator HART. Yes. I suggest you read it and if there is any footnoting or extension that you want to make as you go along, feel free to do it.

Dr. STEINFELD. Thank you, sir.

I am pleased to appear before you today to discuss the herbicide known as 2,4,5-T, our efforts to determine its hazard to health, and subsequent action to protect human health.

The production of 2,4,5-T (2,4,5-trichlorophenoxyacetic acid) in the United States increased from 8 to 40 million pounds per year in the last decade. In the United States, 2,4,5-T is principally used as a weedkiller in clearing range and pasturelands, roadsides and rights-of-way, in suppressing aquatic weeds, and in eliminating weeds in croplands. It is also used to reduce weeds in turf. The use of 2,4,5-T and its salts and esters on food crops has been registered by the

U.S. Department of Agriculture on the basis of no residues in the marketed food.

To insure that the foods reaching markets are free of residues, the FDA has monitored the food supply in selected cities. About 5,300 food samples were analyzed for 2,4,5-T and other pesticides in the last 4 years. Residues of 2,4,5-T, at trace levels (less than 0.1 part per million), were found in 25 of these samples. In 1965, one sample contained 0.19 parts per million; in 1966, another sample contained 0.29 parts per million. It is my opinion that the results of the monitoring program justified the registered use of 2,4,5-T on selected food crops, in the absence of any known toxicity of 2,4,5-T.

The development of a balanced public policy which considers benefits and risks associated with the use of a compound such as 2,4,5-T is an exceptionally difficult matter. Great public fear of the possible implications for man has followed reports of harm in laboratory animal tests. And yet frequently it is not known with certainty what laboratory animal tests may mean for man. We are obligated to make decisions of great health and economic importance on the basis of very limited evidence of potential hazard; prudence allows no other course. We are aware that both good and bad consequences may result from our actions.

The enormous strides taken in achieving the prosperous and healthy life we now enjoy in an industrial age has created problems and uncertainties which are not easily overcome. The resolution of these uncertainties and solution of these problems will require national commitment and broad public education and understanding.

At this point, I would now like to read the joint announcement of Secretaries Hardin, Finch, and Hickel, prepared in accord with the Interagency Agreement for Protection of the Public Health and the Quality of the Environment in Relation to Pesticides. This is the first public release of this announcement.

Agriculture Secretary Clifford M. Hardin, Interior Secretary Walter J. Hickel, and HEW Secretary Robert H. Finch today announced the immediate suspension by Agriculture of the registrations of liquid formulations of the weed killer, 2,4,5-T for use around the home and for registered uses on lakes, ponds, and ditch banks.

These actions are being taken pursuant to the Interagency Agreement for Protection of the Public Health and the Quality of the Environment in Relation to Pesticides among the three Departments.

The three Cabinet Officers also announced that the Department of Agriculture intends to cancel registered uses of non-liquid formulations of 2,4,5-T around the home and on all food crops for human consumption (apples, blueberries, barley, corn, oats, rye, rice and sugar cane) for which it is presently registered.

The suspension actions were based on the opinion of the Department of Health, Education and Welfare that contamination resulting from uses of 2,4,5-T around the home and in water areas could constitute a hazard to human health.

New information reported to HEW on Monday, April 13, 1970, indicates that 2,4,5-T as well as its contaminant dioxins, may produce abnormal development in unborn animals. Nearly pure 2,4,5-T was reported to cause birth defects when injected at high doses into experimental pregnant mice, but not in rats. No data on humans are available.

These actions do not eliminate registered use of 2,4,5-T for control of weeds and brush on range, pasture, forest, rights of way and other non-agricultural land.

Users are cautioned that 2,4,5-T should not be used near homes or recreation areas. Registered uses are being reviewed by the three Departments to make

certain that they include adequate precautions against grazing treated areas until long enough after treatment by 2,4,5-T so that no contaminated meat or milk results from animals grazing the treated area.

While residues of 2,4,5-T in meat and milk are very rare, such residues are illegal and render contaminated products subject to seizure. There is no tolerance for 2,4,5-T on meat, milk or any other feed or food.

USDA will issue guidelines for disposal of household products containing 2,4,5-T. The chemical is biologically decomposed in a moist environment.

BACKGROUND INFORMATION

Secretary Finch's Commission on Pesticides, which reported its findings in November and December 1960, expressed concern that research conducted at Bionetics Research Laboratories, under the direction of the National Cancer Institute, indicated that 2,4,5-T had produced a number of birth defects when fed or injected into certain strains of mice and rats. Because the test material contained substantial concentrations of chemical impurities (dioxins), the birth abnormalities could not be attributed with certainty either to 2,4,5-T, or to the impurities known to be present.

Representatives of the chemical industry pointed to evidence of extreme potency of the impurities as toxic agents. They demonstrated that 2,4,5-T now being marketed is of a greater purity than that which had been tested in the Bionetics experiments and urged that further testing be undertaken to clarify the questions raised.

Responding to this suggestion and utilizing materials supplied by one of the major producers of 2,4,5-T, scientists at the National Institute of Environmental Health Sciences promptly initiated studies to determine whether 2,4,5-T itself, its impurities or a combination of both had caused the earlier findings, and whether the 2,4,5-T now being marketed produces birth abnormalities in mice and rats.

The experiments were completed last week and the statistical analyses performed over the weekend. On Monday and Tuesday of this week the analyses of the data were presented to the regulatory agencies of the Federal Government and to the members of the Cabinet.

The dioxin impurities and the 2,4,5-T as it is now manufactured, separately produced birth abnormalities in the experimental mice.

Because absolutely pure 2,4,5-T was not available for testing, it is possible only to infer from certain of the observations that the pure 2,4,5-T probably would be found to be teratogenic if it were tested. But, since pure 2,4,5-T is not marketed and could not be produced in commercial quantities, this is not a practical issue for consideration.

In exercising its responsibility to safeguard public health and safety, the regulatory agencies of the Federal Government will move immediately to minimize human exposure to 2,4,5-T and its impurities. The measures being taken are designed to provide maximum protection to women in the childbearing years by eliminating liquid formulation of 2,4,5-T use in household, aquatic and recreational areas. Its use on food crops will be cancelled, and its use on range and pastureland will be controlled. Maximum surveillance of water supplies and marketed foods will be maintained as a measure of the effectiveness of these controls. These measures will be announced more specifically in the Federal Register shortly.

While the restriction to be imposed upon the use of this herbicide may cause some economic hardship, we must all cooperate to protect human health from potential hazards of 2,4,5-T, other pesticides and the dioxins.

The three Secretaries commended the chemical industry for its prompt and willing cooperation with the National Institute of Environmental Health Sciences in the studies to clarify questions raised by the initial studies of this herbicide and for working closely with the FDA in the other studies still underway. They urged the full support of industry, agriculture and the home gardener in insuring the safe use of 2,4,5-T and other pesticides which contribute in important ways to the welfare of the Nation.

That is the end of the press release and I would add that it is my understanding that Secretary Packard of the Department of Defense sent a memorandum to the Joint Chiefs of Staff saying the Department will suspend the use of 2,4,5-T in all operations pending evaluation of the data.

I will return to the prepared testimony.

At this point, we would like to provide for the record a summary description of the results of these latest studies of the National Institute of Environmental Health Sciences,¹ completed this past week. I shall be pleased to respond to questions about these data but suggest that the Committee not be burdened by a detailed oral presentation of the findings which have been stated briefly in the foregoing announcement.

This leads me to brief mention of the studies which will be presented next by Dr. Verrett. Commencing in the fall of 1969, Dr. Verrett reinstated tests of the embryotoxicity and teratogenicity of 2,4,5-T, its contaminating dioxins, and related chemicals.

Dr. Verrett is to be commended for promptly attacking these problems and for going to the very considerable trouble of purifying the 2,4,5-T by repeated recrystallization. However, I must express concern about the degree of reliance which has been placed upon chick embryo studies. While the studies in chick embryos are in general agreement with those in studies of rodents at the NIEHS, it is to be emphasized that they do not clarify the uncertainties as to significance for man.

I believe that it is imperative that everyone involved in the development of a national policy for dealing with the many questions posed by 2,4,5-T and other pesticides be aware of the complexity as well as the importance of the issues, together with the limitations of our ability to estimate potential hazards to human health posed by these substances.

It is essential that we strive to respond wisely to the discoveries which have been made in this field, and resist the temptation to resort to measures which may be more extreme than the evidence warrants. For example, 2,4,5-T is probably the most effective means of controlling poison ivy, poison oak, and other noxious weeds to which a substantial portion of the population react badly. It has been estimated that 60 percent of the American population is sensitive to either poison ivy or poison oak, and that from 5 to 10 percent of Americans suffer a reaction to the poisons from these weeds each year. Some of these individuals become quite ill and incapacitated by their reaction to these poisons.

By contrast, we are not aware of any reliable evidence that 2,4,5-T, indeed any of the pesticidal chemicals, has resulted in human birth abnormalities. These remarks should not be interpreted as evidence of indifference to what may be a potential hazard to health. The record clearly reveals a series of responsible actions by the Administration to the results of recent laboratory tests. Prudence has characterized these decisions and actions and will continue to guide the Department in these matters.

¹ See p. 98.

In keeping with the pattern established with the naming of the Secretary's Commission on Pesticides, the thorough study of pesticide problems by the Commission, and the Administration's prompt action to implement the recommendations of the Commission, we now commit ourselves to the following actions:

We shall strive to develop better means for predicting in laboratory animal systems the potential hazard posed for man by chemical pesticides.

We are aware of a great need for a centralized clearinghouse for information of all types on pesticides. We plan to have such a clearinghouse established jointly by the National Library of Medicine and the FDA in the very near future. Other agencies having similar interests and needs will be invited to participate in this undertaking.

The need to continue certain closely restricted uses of 2,4,5-T will require a high level of surveillance activity to insure protection of the human population from exposure through water sources. This will be done.

The Food and Drug Administration will continue to examine a variety of foods for the possible presence of residues of pesticides, and will take appropriate action through the interdepartmental agreement to protect the public health.

This completes my prepared statement, Senator Hart.

My colleagues and I will be pleased to answer any questions.

Senator HART. Thank you Doctor.

Just as you began, we were joined by the able Senator from Tennessee, Senator Baker.

I understand that the announcement you just read us relates to both powdered and liquid forms of 2,4,5-T shipped in interstate commerce.

But what about the 2,4,5-T which is now on the shelf? What do we do about that?

Dr. STEINFELD. You mean on the shelves in the homes and the shelves in the stores?

Senator HART. Yes, the places for retail sale.

Dr. STEINFELD. I think there is a distinction between the suspension of the registration and the cancelling for registration and I would like to call on Dr. Lindsay to describe in more detail, the procedures involved.

Dr. LINDSAY. The suspension is a little more drastic than the cancellation, because it is a final action until some other action is taken, whereas the cancellation permits hearings and has the statutory procedure for appeal during which time the pesticide may be used while it is being reviewed.

Senator HART. Well, the suspension, the more drastic remedy, was directed at the liquid form.

Do I read that correctly?

Dr. STEINFELD. Yes.

The suspension by Agriculture of the registrations of liquid formulations of the weed killer for use around the home and for registered use on lakes, ponds, and ditch banks.

We reviewed the concentration of 2,4,5-T in a number of formulations and found the concentrated form is present in liquids and could present a hazard.

The amount of 2,4,5-T in some of the solid fertilizer-type materials was much less and therefore, the more drastic action was not taken regarding those compounds.

Senator HART. As you read that suspension sentence I did not hear a suspension extended to the use of 2,4,5-T on food crops.

Dr. STEINFELD. The three Cabinet officers announced they intended to cancel the registered use of nonliquid formulation around the home and on all food crops for human consumption, so that all of these registered uses will be cancelled.

Senator HART. But the use of liquid formulations on food crops, as I understand the announcement, was not.

Dr. LINDSAY. As far as I know all of the use on food crops is from the liquid application.

Senator HART. So there would be no application to food crops under this order, as you understand it?

Dr. LINDSAY. As I understand it.

I am not aware of any dry material used on food crops.

Senator HART. Well, let me get back to my point of departure. You have suspended for certain applications 2,4,5-T in liquid form. As Dr. Lindsay said, that is the more drastic sanction.

Now, with respect to that 2,4,5-T in liquid form, the order today has what effect on the marketing and use on shelves or in homes?

Dr. STEINFELD. Well, I don't know exactly what the Department of Agriculture will do. This is not an FDA activity. I am certain they will move quickly and appropriately. I think a significant statement is on page 2 of the release, which says the "U.S. Department of Agriculture will issue guidelines for disposal of household products containing 2,4,5-T. The chemical is biologically decomposed in a moist environment".

The intent is to get rid of all 2,4,5-T around the household. I assume it would not be available for use in households where pregnant women would have access to it. I don't have the details of those actions.

Senator HART. I see we don't have anybody on the witness list this morning for the Department of Agriculture, but would you agree it would be very inappropriate for the Department of Agriculture to permit continued vending of liquid 2,4,5-T for any of the purposes for which you have suspended it, even though it is now in retail distribution?

Dr. STEINFELD. I think this announcement will have dramatic impact. Our meetings with the Department of Agriculture on Monday and Tuesday would lead me to believe they are going to take appropriate and vigorous action.

Senator HART. Would you describe as appropriate, walking into a store and seeing the thing on the shelf and saying, take it off? That seems appropriate to me.

Dr. STEINFELD. I don't know the mechanisms which they have to insure compliance.

Senator HART. If they have it and don't do it, don't you think it would be inappropriate and if they don't have it, don't you think Congress should give it to them?

Dr. STEINFELD. Certainly they should have the authority to do what is required to protect the public health, and I think they do have this.

Senator HART. Well, we will find out.

Dr. STEINFELD. I am sorry, I don't know.

Senator HART. You are talking to another nonexpert, so don't feel bad.

Mr. Bickwit has greater expertise than I, so we will let him deal further with the problem.

But there is one passage in your announcement that particularly interests me. In the press statement which you read, there is a paragraph which states: "The regulatory agencies of the Federal Government will move immediately to minimize human exposure to 2,4,5-T and its impurities. The measures being taken are designed to provide maximum protection to women in childbearing years by eliminating formulation of 2,4,5-T use in household, aquatic and recreational areas. Its use on food crops will be canceled and its use on range and pasture land will be controlled."

You say on food crops its use will be "canceled."

But is it not a very technical definition only of that term that permits you to say it will be canceled on food crops, because in liquid form I take it, it may still be used, or am I wrong about that?

Dr. STEINFELD. When the use is canceled, such a notice is published in the Federal Register, I believe.

And then there is a 30-day period for comments, is that not correct, Dr. Lindsay?

Dr. LINDSAY. Yes.

Dr. STEINFELD. After which appropriate action is taken.

Senator HART. I think what I am more concerned about is my desire to understand precisely what may or may not be done with this formulation in application to food crops.

In liquid form may it continue to be used?

Dr. STEINFELD. You mean during the 30-day period while the—I am afraid I don't understand.

Senator HART. It has been suggested to me that there would continue to be no restrictions with respect to the use in liquid form on food products.

Now, is my information correct on that?

Dr. STEINFELD. No, sir, the use on all food crops will be eliminated as promptly as the law permits through cancellation of the registration, whether in dry or liquid form or any form. There will be no use on food crops, Senator Hart.

Senator HART. All right. I think this is a desirable clarification, since there were some who had felt otherwise.

You say it will be eliminated as promptly as is possible under the law. It could be eliminated more promptly by a suspension than a cancellation?

Dr. STEINFELD. Yes.

Dr. LINDSAY. Yes, I am not aware of what the Department of Agriculture's intent is with regard to carrying this on.

The main idea was to get it into effect at the earliest possible time where it would be likely to come in contact with women of child-bearing age.

Senator HART. I am trying to ask why the different treatment? Why with respect to certain forms and use is it merely canceled?

Although that sounds very dramatic, it means if you want to use it, go ahead and use it until somebody resolves differences which may arise over the action. Why handle some uses on a cancellation basis and some by suspension?

Is it because those uses and forms that you suspended more intimately or directly come in contact with women of childbearing age?

Dr. STEINFELD. Yes, I believe that is the reason.

Right now there is a zero tolerance on foods, and any foods that had any measurable toxicity would be subject to seizure. I believe the intent was to move as quickly as possible, but we wanted to alert women who may have liquid formulations around the home, who may be spraying it, that it may present a hazard. We will take appropriate steps to try to warn the female population, particularly of childbearing age.

That is the reason for the more dramatic action in the one instance, and the less dramatic but, I believe nonetheless complete, action, however, nonetheless in others.

I guess I have here a legal phrase: I think for suspension one must show an imminent hazard to health, and this, perhaps, is the reason.

Senator HART. I don't envy you that business of interbalancing.

You describe the judgement that you seek to arrive at as a product of weighing the imminence of danger against the values that are identified as following from the use of the pesticide. As a layman, probably we would tend to oversimplify it.

Now, having admitted this may be an oversimplified impression, why isn't it a more prudent balancing act to say, well, there is danger here because we can't establish that there is no danger and we are not going to get hung up on the degree of imminence of the danger. We are just going to say, to be sure there isn't any danger, we are going to suspend this.

Why aren't you tempted to resolve this balancing operation in that manner?

Dr. STEINFELD. I am not sure I am the one who makes all these decisions of balancing, Senator Hart. My role of course, is concerned with public health and safety. But we are always balancing things.

Certainly in medicine, in picking drugs to use for diseases, sometimes the treatment is worse than the disease. If it should turn out that these materials can be safely used on range and pastureland, that there is a period in which there is biodegradability during which the materials will effectively disappear, and yet permit the person who raises his cattle or dairy cows to have a better—I don't really know the name, I am a city boy, a small-town boy, not a farmer—but better able to have better cows, more milk, better meat, then there are appropriate reasons for using this chemical.

I think the real problem, Senator Hart, is that we do not have an effective, adequate substitute for certain uses. I think this is the key issue.

The other good chemical which kills poison ivy and poison oak is a carcinogen in some animals and not proven for many, but it is a

very potent chemical that will destroy poison ivy and poison oak. So there is another balance that one must weigh.

Senator HART. But into that formula you have to throw the sort of economic possibility that if this were suspended, if it just wasn't permitted to be marketed for this purpose, and if there is a need for a cure for the ill that this thing treats, maybe there would be a renewed effort to find a third alternative.

Dr. STEINFELD. I believe the action which has been taken today will lead to more intensive research to find an alternative to 2,4,5-T to destroy the particular kind of herbs it is capable of destroying.

Senator HART. Mr. Bickwit.

Mr. BICKWIT. I am sorry to go over the matter of use on food crops again, but I do want to clear this up so that we know precisely what the situation is. It says in the first paragraph of your press release that liquid formulations of the weed killer 2,4,5-T for use around the home, for registered use on lakes, ponds and ditch banks will be suspended. Do you intend to include within that list of uses, the use on food crops?

Dr. STEINFELD. I think that the wording for food crops is otherwise. It would be canceled rather than suspended.

Mr. BICKWIT. I am talking about liquid formulation.

Dr. STEINFELD. As I read the actions taken, there will be a cancellation of registered use of nonliquid formulations around the home and on all food crops.

Mr. BICKWIT. That is clear. but what I want to know is what action is proposed with respect to the use of liquid formulations on food crops.

Dr. STEINFELD. My interpretation of this would be—I am not a lawyer but I now see what you are driving at. I think this should have been worded, and we will have to check into it, "liquid and nonliquid formulations around food crops." The intent is not to use the formulation on food crops.

Mr. BICKWIT. So the use of liquid and nonliquid formulations on food crops will be canceled?

Dr. STEINFELD. I cannot speak for the three Cabinet officers. It is my understanding that the intent is not to permit use on any food crop for human consumption.

Mr. BICKWIT. Well, you will permit use on it pending appeals?

Dr. STEINFELD. Pending the legal activities.

Dr. LANDSAY. But there is no permitted residue of 2,4,5-T on any food. It would be subject to seizure.

Mr. BICKWIT. Now, I would like to deal with your statement that an imminent hazard needs to be present before suspension can take place. Is that to say that there is no imminent hazard from the use of 2,4,5-T on food crops?

Dr. STEINFELD. In the studies which have been done, the market basket sampling and the measurement of foods for 2,4,5-T, as I mentioned, it is a very rare instance where these things are found, and in sugar cane the herbicide is probably destroyed in the processing by heat. We do not really know. The action we are taking is based on teratogenicity in mice and the fact that dioxins also cause teratogenicity in rats and perhaps in hamsters. It is a possible hazard.

Mr. BICKWIT. Is that what you need to cancel as opposed to suspend—a possible hazard?

Dr. STEINFELD. I do not know the law that well. I really do not know the exact wording of the law, do you, Dr. Lindsay?

Dr. LINDSAY. No. I am sorry. This is Agriculture's bag, and I do not know it.

Senator HART. Let us order printed in the record at the conclusion of your testimony the appropriate sections of the Federal Insecticide Fungicide and Rodenticide Act.

Dr. STEINFELD. Fine.

Mr. BICKWIT. Have you any information derived from your tests on the degradability of dioxin?

Dr. STEINFELD. Dr. Courtney is a pharmacologist.

Dr. COURTNEY. We have no information on that.

Mr. BICKWIT. In other words, then, it is possible that dioxin is both persistent and accumulative in human beings?

Dr. COURTNEY. That is possible. It is also possible that it can be metabolized.

Dr. STEINFELD. I would like to volunteer something, that is, that the dioxin which produced the results that we will submit for the record is a very potent teratogen for mice in 10,000 to 30,000 times smaller a dosage than 2,4,5-T as we could obtain to pinpoint which chemicals were the villains. And I think it raises another issue, that is, where else in man's environment could these chemicals be found?

We have not shown that these chemicals are teratogenic for man, but we may want to take action. The Food and Drug Administration and Agriculture are presently studying a number of other pesticides in the manufacture of which poly-chlorinated phenols are subjected to heavy temperatures and may produce dioxin. So I think we are having an important study carried out there.

Mr. BICKWIT. Are you looking outside the herbicide area as well?

Dr. STEINFELD. We must look wherever polychlorinated phenols are subjected to high temperatures. We must look for the presence of dioxin and if we find them we shall have to take appropriate action.

Mr. BICKWIT. But the appropriate action is not to find that an imminent hazard exists?

Dr. STEINFELD. I do not know what the appropriate action is. I know we are going ahead with this activity.

Mr. BICKWIT. I take it you do know what the data are with respect to 2,4,5-T and you do know dioxin is present and you do know it is very potent and yet you have concluded it is not an imminent hazard. If it were you would have suspended rather than canceled use.

Dr. STEINFELD. You mean suspended all use everywhere? Is this what you mean?

Mr. BICKWIT. Yes.

Dr. STEINFELD. I think the question of imminent hazard would relate to pregnant women, but we do not know it is teratogenic for man. Use out in rangelands and forests and so forth, I do not see as a hazard to pregnant women.

Mr. BICKWIT. Clearly you have no evidence that it is not.

Dr. STEINFELD. No, I have no evidence that it is not, nor that it is, actually. It is a potential.

Mr. BICKWIT. And when you have no evidence either way you conclude that it is not an imminent hazard?

Dr. STEINFELD. I am tempted to make an analogy, but I probably should not. It is difficult to state that there is no evidence that a number of things are not a hazard to health. I think we are in a never-never land, and where we can, we should try to get as much good hard data as we can and act accordingly.

Mr. BICKWIT. Is there any evidence either way on the accumulativeness of dioxin?

Dr. STEINFELD. I do not think there is any evidence on dioxin. This is a new area which has opened up which we will have to study intensively.

Mr. BICKWIT. Thank you.

Senator HART. I am not sure this will come out as an effective analogy, but think for the moment of the general attitude on pot—marijuana the prevailing view appears to be that since we cannot be sure it is not harmful, it ought not to be used. Is it not correct now that there is at least disagreement as to whether it is harmful or not?

Dr. STEINFELD. I think most physicians, and I am the father of teenagers, feel that pot is harmful.

Senator HART. You cannot be sure it is not harmful. Is not that your parental attitude?

Dr. STEINFELD. I feel it is harmful because it represents an attempt to escape from reality at a time when children must adjust to the outside world and become independent. So I find it harmful as a crutch which particularly the teenagers and those growing up must not use.

Senator HART. Well, you have destroyed my analogy. I was going to pursue it on the assumption that you would agree you cannot be sure it is not harmful. You say you are darn sure it is harmful?

Dr. STEINFELD. Yes, as far as teenage use, I think psychologically it is harmful. I do not think we can be sure of enzyme changes or long-term liver effects, this sort of thing. I do not think it is possible to be sure, but I would say it is harmful.

Senator HART. What if you were unsure, then would you say let us go ahead, although I am not sure? Or would you say do not use it? You say with respect to the pesticides, you balance it and say since we are not sure it is harmful, go ahead?

Dr. STEINFELD. I think we have some evidence in animals that 2,4,5-T is a teratogen and dioxins are present, and while we cannot be certain that women, mankind, behave similiary to the mouse, yet pregnant women should not be exposed to this. This is a prudent action.

Mr. BICKWIT. Do you know the date on which the National Cancer Institute received the first progress report raising the possible teratogenic nature of 2,4,5-T in mice?

Dr. STEINFELD. I have with me a chronology regarding 2,4,5-T. It is a few pages, but it is triple spaced. If you would like I could read it to you.

Senator HART. Was that a part of the insert that you presented?

Dr. STEINFELD. We can provide it to you, and if you would like I can read it into the record.

Mr. BICKWIT. We would like it for the record.

Dr. STEINFELD. Maybe it would be useful to go through the chronology. With your permission, I will.

Senator HART. Please.

Dr. STEINFELD. In presenting the following chronology I should take a moment of the Committee's time to commend Dr. Kotin and Dr. Falk for their foresight and initiative in undertaking the studies which were conducted under their guidance by Bionetics Research Laboratories. This commendation extends also to the scientists in the National Cancer Institute who assumed responsibility for successful completion of the study after Drs. Kotin and Falk transferred to the National Institute of Environmental Health Sciences. It consumed large amounts of their time and energy without assurance that the investment would be rewarded. The total cost of this study approximated \$3.5 million, and approximately 20,000 animals were studied.

Summer 1963: The National Cancer Institute (National Institutes of Health) awarded a contract to the Bionetics Research Laboratories (Falls Church, Va.) to perform studies of the toxicology, carcinogenicity, teratogenicity, and mutagenicity of pesticides and industrial chemicals which were to be selected by scientists of the National Cancer Institute, according to protocols to be devised by the scientists of the Institute.

During the fall, 1963, the chemistry and toxicology of the chemical compounds to be studied were examined and planning of the large-scale carcinogenicity screening operations was initiated.

Fall and winter 1964: Large-scale screening activities in carcinogenicity were initiated and plans for teratology studies were drawn up.

June 1966: First indication of possible teratogenicity of 2,4,5-T. At a dose of 113 mg/kg of body weight, 2,4,5-T, now recognized as containing substantial concentrations of dioxin impurities, produced an elevated incidence of cystic kidneys in one strain of mice. The 2,4,5-T had been administered by injection.

At that point we did not know whether the results produced by injection were significant. The 2,4,5-T had not been fed.

November of 1966: 2,4,5-T of a similar grade of purity administered by injection at a dose of 133v./kg. body weight was found to be teratogenic in another strain of mice.

The results obtained in June and November 1966, in the absence of information about rates of clearance of injected 2,4,5-T from the blood stream, were regarded as of uncertain significance. This route differs from human exposure and possible differences in metabolism could be very important.

January 1968: Oral administration of 2,4,5-T of similar purity was initiated in mice. The data produced in this study indicated teratogenicity (cystic kidneys and cleft palate).

May 1968: Oral administration of 2,4,5-T of similar purity at a dose of 113 mg./kg. of body weight produced cleft palate in another strain of mice.

September 1968: First draft of the final report of the data on carcinogenicity and teratogenicity was delivered to the National Cancer Institute by the Bionetics Research Laboratories. It should be emphasized that these carcinogenicity data were in an incompletely analyzed state and required scrutiny for possible errors, plus numerous statistical analyses. The first evidence of teratogenicity obtained in rats fed 2,4,5-T was reported.

October 24, 1968: The draft report of the "raw" data mentioned immediately above was provided to Dr. Fitzhugh in the Food and Drug Administration.

October-November-December 1968: Scrutiny of the carcinogenicity data was undertaken by the National Cancer Institute scientists and report writing begun.

January 30, 1969: At a meeting of scientists from the National Institutes of Health with representatives of the regulatory agencies, Consumer Protection and Environmental Health Services, the National Academy of Sciences, and the chemical industry, attended also by Drs. Philippe Shubik and Samuel Epstein, the first two volumes of the final report of data on carcinogenicity, submitted by Bionetics Research Laboratories were made available. In addition a special preliminary report on the teratogenicity of 2,4,5-T, exclusive of data pertaining to the other teratogenicity studies, was provided to all participants in the meeting.

The analyses of the carcinogenicity data had been given priority because of its volume and the apparent potential significance, based upon the indications of the raw data. It had been intended to completely analyze the teratogenicity data immediately following completion of the analysis of the carcinogenicity data.

At the meeting of January 30 a number of uncertainties in the analyses of the carcinogenesis data were pointed up by Drs. Epstein and Shubik and one of the senior scientists in the National Cancer Institute. On this basis, it was decided to withhold publication of the data and findings until additional animal specimens had been examined and certain features of the study design had been reanalyzed. For the same reason, it was decided that a presentation planned for the March 1969 meeting of the Society of Toxicology would be withdrawn from the program.

January-September 1969: Extensive statistical analyses of the teratology data were performed by the National Institute of Environmental Health Sciences.

March 1969: In the course of the appropriations hearings, Dr. Endicott promised to provide the results of the carcinogenicity studies to the Congressional Record just as soon as the analyses could be completed. This was accomplished in the last week of April or the first week of May 1969.

June 1969: The preliminary report of the carcinogenicity findings was made in the Journal of the National Cancer Institute.

June 1969: The Technical Panel on Carcinogenicity for the Secretary's Commission on Pesticides was appointed and included scientists from the National Cancer Institute and the National Institute of Environmental Health Sciences.

June 1969: The intent to name a teratology panel to the Secretary's Commission on Pesticides was made known to the National

Cancer Institute liaison member of the Commission. The spontaneous offer by the Institute's liaison member of the commission to supply the Bionetics data on teratology was declined by a member of the staff of the Commission.

July-September, 1969: Members of the staff of the National Cancer Institute and the National Institute of Environmental Health Sciences actively engaged in the work of the technical panels on carcinogenicity and teratology. Further analyses of the teratogenicity data were performed.

August 15, 1969: Request made by the Teratology Panel for the Bionetics data on teratogenicity.

September 11, 1969: Data on teratogenicity provided to the Teratology Panel. Delay in part related to procedure involved in clearing permission for the data and in part related to putting the data into a condition suitable for examination by those who had not participated in their development.

Fall 1969: FDA studies on embryotoxicity, and teratogenicity of 2,4,5-T and dioxins reinstated, as described in Dr. Verrett's testimony.

November 25, 1969: Meeting of National Institutes of Health scientists with those from FDA and Dow Chemical Co. to plan further studies to clarify roles of 2,4,5-T and dioxin impurities in the production of teratological abnormalities.

November and December 1969: Secretary's Commission reports published.

January 1970: New teratological studies initiated at National Institute of Environmental Health Sciences using materials provided especially for the purpose by Dow Chemical Co.

April 10, 1970: Above teratological studies completed.

April 12, 1970: Analysis of the above data completed.

April 13 and 14, 1970: Interpretations of the above-mentioned findings by representatives of the regulatory agencies and parties to the interagency agreement for protection of the public health and the quality of the environment in relation to pesticides, and presentation of conclusions and proposed actions to members of the Cabinet.

That is a long chronology. I am sorry. I thought it would be shorter.

Senator HARR. You have taken the words from me, it is a long time after that first bell was sounded before we got this morning's action. I am sure it is always easier to play it from the 20-20 vision of the grandstand up here than from the vantage point of the summer of 1966 when the first bell rang. But that is still a long time.

Dr. STEINFELD. The studies were initiated at a time when this sort of thing was not ordinarily done. As we have more and more chemicals and materials put into our environment we must be more and more careful about the effects they produce.

Senator HARR. How can we compress the period between June of 1966 and April 15, 1970, in the future? What mechanism do you now visualize which will avoid this sort of lag from recurring?

Dr. STEINFELD. If the procedures for registration of materials for use on food crops required teratogenicity studies as well as other

long term chronic toxicity studies, as it is my understanding that they now do, we may be able to avoid this in the future.

The idea would be to prevent the introduction rather than react some years later, after the material was used, not only ubiquitously but in large quantities. I think this is the direction we must go, to prevent the introduction of materials rather than to react after they are used.

Senator HART. Wouldn't this require the burden of proof to be on those who want a market?

Dr. STEINFELD. Yes.

Senator HART. To make the affirmative case that it is not dangerous. That is correct, isn't it?

Dr. STEINFELD. Yes, I think the thing we really need are good predicting systems for man. I think it would be ideal if we had some in vitro systems which would tell whether a compound is going to be toxic. This is what we need, a lot more research and correlation of animal data with human epidemiologic data. I hope we never do experiments on man but we can collect data in retrospect epidemiologically in individuals who may have been exposed to chemicals or certain diseases and so forth.

Senator HART. Mr. Bickwit?

Mr. BICKWIT. You obviously have done some thinking about how to patch up the system and I don't want to cry unduly over spilt milk, but do you have any idea why, when NCI received this first progress report, that it did not immediately pressure Bionetics to go into an all out effort to acquire further data quickly instead of allowing them approximately 2½ years to complete their tests?

Dr. COURTNEY. The first statement NCI made was "Repeat the study and make sure it is right," and that is just what we did. We went to a different strain of mouse, then we went to a rat. By the time we did all of these studies, it took a bit of time.

Dr. STEINFELD. We were also studying similar chemical pesticide structures, so we could see if it was a larger problem than just this one. This was all going on at the same time.

Mr. BICKWIT. Did the other pesticides that you were studying exhibit the same kind of alarming data?

Dr. COURTNEY. I don't know how you describe it as alarming.

Mr. BICKWIT. Would you not describe it as alarming?

Dr. COURTNEY. Yes. We had some other pesticides that we were concerned with at the time and, of course, without repeated studies we could not make a judgment. So some pesticides were not as alarming and some were more and as we repeated the tests we got our results. This pesticide seemed to give us a positive response every time we studied it.

Dr. STEINFELD. I would say we are not particularly pleased with the fact that it took so long to get all the data out. The first time around in one of these situations always takes longer and hopefully in the future we will be able to move much more rapidly.

Senator HART. I was just thinking of all the things that have happened since that first alarm bell. We have elected two-thirds of the Senate, a new President, gotten further into Vietnam.

Mr. BICKWIT. According to your chronology, if I read it correctly, the data from Bionetics were first made available to FDA on October 14, 1968?

Dr. STEINFELD. Yes, the draft of the raw data was provided to Dr. Fitzhugh on October 24, 1968.

Mr. BICKWIT. Do you believe FDA, one of the government agencies responsible for the regulation of pesticides, should have known about these preliminary indications prior to a time more than 2 years after the data first became available?

Dr. STEINFELD. I think in retrospect we could look at this and speed everything up and inform everyone very quickly. I can't give you the reasons why, (a), the information was not rapidly disseminated as soon as it was confirmed and, (b) why things didn't move much more rapidly and on a larger scale. But I would point out that the material used was heavily contaminated with dioxins. In this interval we have identified the dioxins, and we are moving, I think, on a broad scale to try to find out where else dioxins may be found. I am not trying to look for a silver lining in a dark cloud but I do think we have a lot better data and a lot more information as to just what did the job; it probably was the concentration of the dioxins used in the Bionetics experiments which was responsible for the teratogenicity.

Mr. BICKWIT. Then you do regard this as a dark cloud?

Dr. STEINFELD. I would say the darkest part is that, whatever the rules were, we permitted the utilization of the material without testing for what may be a significant hazard to man, teratogenicity.

Senator HARR. Doctor, I commented earlier on the fact that no witnesses are scheduled today from the Department of Agriculture. My interest at that time bore on the action, if any, that would be taken to remove from retail channels and from shelves at home, perhaps, this product as a result of the announcement that you gave us today.

The Secretary of Agriculture participated with Secretary Finch and Secretary Hickel in this announcement suspending or canceling 2,4,5-T. I am reminded and I must confess my own memory of this testimony is not clear, but it has been suggested to me that when witnesses speaking for the Department of Agriculture testified before this subcommittee last week, they took the position that the evidence did not warrant an action such as is taken today.

I won't say that they promoted or advocated its use, but—Mr. Bickwit, have you found any passage that bears on this?

Mr. BICKWIT. Yes.

Senator HARR. From the transcript this sentence is cited. This is from a Department of Agriculture witness who addressed us on the seventh of this month.

In view of all the information now available, we have not found that registered use of 2,4,5-T without a finite tolerance on food crops warrants a suspension or cancellation of such registered use.

Now, that testimony is April 7. You say that on April 13 the analysis which had been completed 2 days before were presented for proposed action. Whatever else you can say about it, it points up again the fact that on April 7, notwithstanding the patterns beginning in June of 1966, indicating possible serious danger, this one Department was still telling us, on the record, what I just read you.

Dr. STEINFELD. I would have agreed with that position last week. I was surprised to see the data that developed over the weekend. It

appeared to me it was the dioxin that was the likely villain in this piece, not the 2,4,5-T; the particular batch of the 2,4,5-T used in the experiments was heavily contaminated with dioxin. Our goal was to pin down the fact that it was dioxin and probably not 2,4,5-T which was the teratogen and get rid of dioxins wherever they are found.

So I think last week I would have said the same thing, Senator Hart. The data over the weekend have changed the picture completely

Senator HART. Yes; that will be made part of the record.

Well, then we all wind up saying it is a darn shame this past weekend had to be the first time when you got the solid information, which information was a result of an alarm bell that rang in June of 1966.

We all agree on that.

Do you anticipate that the centralized clearinghouse which you made reference to in your prepared testimony can assure that this kind of timelag no longer will occur?

Dr. STEINFELD. I hope that that will help. Our other attempts at coordinating activities with regard to pesticides will also help. The Secretary has a special commission; we have an interagency group of Agriculture, Interior, and HEW; we have Dr. Russell Train, Environmental Quality Council; I hope all of these will help us avoid problems such as we are facing today.

Senator HART. I would ask our staff to obtain for the record the announcement which you anticipate the Department of Defense is about to make. You did indicate that they were—

Dr. STEINFELD. I don't know if they will make an announcement. It is my understanding that this is an action that Deputy Defense Secretary Packard has initiated this morning.

Senator HART. If there is any announcement in connection with this, let it be a part of the record. I understand there is a big departmental request outstanding for a major purchase order for 2,4,5-T. I would like to find out whether that contract request now will be withdrawn in light of Deputy Defense Secretary Packard's position. I would assume it would. But let us make it a matter of record.

Is there anything any of you would care to add, given the exchange we have had this morning?

Dr. STEINFELD. I would add one final statement. We used inbred strains of animals and large doses of compounds in order to try to find a particular phenomenon. The problem is that man is not inbred; we don't breed brothers and sisters and so we can't predict. We have a tremendous variation among people in this country; some people may have missing enzymes of a particular type that may make a chemical extremely hazardous at a very low dose.

We have taken actions because we must act prudently. We don't want to alarm the public, but we do want to react prudently and protect the public health.

Senator HART. Amen.

Thank you very much, gentlemen.

Dr. STEINFELD. Thank you.

(The information referred to earlier follows:)

REGISTRATION

Sec. 4.a. Every economic poison which is distributed, sold, or offered for sale in any Territory or the District of Columbia, or which is shipped or delivered for shipment from any State, Territory, or the District of Columbia to any other State, Territory or the District of Columbia, or which is received from any foreign country shall be registered with the Secretary: Provided, That products which have the same formula, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same economic poison may be registered as a single economic poison; and additional names and labels shall be added by supplement statements; the applicant for registration shall file with the Secretary a statement including--

(1) the name and address of the registrant and the name and address of the person whose name will appear on the label, if other than the registrant;

(2) the name of the economic poison;

(3) a complete copy of the labeling accompanying the economic poison and a statement of all claims to be made for it, including the directions for use; and

(4) if requested by the Secretary, a full description of the tests made and the results thereof upon which the claims are based

b. The Secretary, whenever he deems it necessary for the effective administration of this Act, may require the submission of the complete formula of the economic poison. If it appears to the Secretary that the composition of the article is such as to warrant the proposed claims for it and if the article and its labeling and other material required to be submitted comply with the requirements of section 3 of this Act, he shall register it.

c. If it does not appear to the Secretary that the article is such as to warrant the proposed claims for it or if the article and its labeling and other material required to be submitted do not comply with the provisions of this Act, he shall notify the applicant for registration of the manner in which the article, labeling or other material required to be submitted fail to comply with the Act so as to afford the applicant for registration an opportunity to make the corrections necessary. If, upon receipt of such notice, the applicant for registration does not make the corrections, the Secretary shall refuse to register the article. The Secretary, in accordance with the procedures specified herein, may suspend or cancel the registration of an economic poison whenever it does not appear that the article or its labeling or other material required to be submitted complies with the provisions of this Act. Whenever, the Secretary refuses registration of an economic poison or determines that registration of an economic poison should be cancelled, he shall notify the applicant for registration or the registrant of his action and the reasons therefor. Whenever an application for registration is refused, the applicant, within thirty days after service of notice of such refusal, may file a petition requesting that the matter be referred to an advisory committee or file objections and request a public hearing in accordance with this section. A cancellation of registration shall be effective thirty days after service of the foregoing notice unless within such time the registrant (1) makes the necessary corrections; (2) files a petition requesting that the matter be referred to an advisory committee; or (3)

files objections and requests a public hearing. Each advisory committee shall be composed of experts, qualified in the subject matter and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence, all of which costs may be assessed against the petitioner, unless the committee shall recommend in favor of the petitioner or unless the matter was referred to the advisory committee by the Secretary. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee. The Secretary shall forthwith submit to such committee the application for registration of the article and all relevant data before him. The petitioner, as well as representatives of the United States Department of Agriculture, shall have the right to consult with the advisory committee. As soon as practicable after any such submission, but not later than sixty days thereafter, unless extended by the Secretary for an additional sixty days, the committee shall, after independent study of the data submitted by the Secretary and all other pertinent information available to it, submit a report and recommendation to the Secretary as to the registration of the article, together with all underlying data and a statement of the reasons or basis for the recommendations. After due consideration of the views of the committee and all other data before him, the Secretary shall, within ninety days after receipt of the report and recommendations of the advisory committee, make his determination and issue an order, with findings of fact, with respect

to registration of the article and notify the applicant for registration or registrant. The applicant for registration, or registrant, may, within sixty days from the date of the order of the Secretary, file objections thereto and request a public hearing thereon. In the event a hearing is requested, the Secretary shall, after due notice; hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: Provided, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, but not later than ninety days, the Secretary shall evaluate the data and reports before him, act upon such objections and issue an order granting, denying, or cancelling the registration or requiring modification of the claims or the labeling. Such order shall be based only on substantial evidence of record of such hearing, including any report, recommendations, underlying data, and reason certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the order is based. In connection with consideration of any registration or application for registration under this section, the Secretary may consult with any other Federal agency or with an advisory committee appointed as herein provided. Notwithstanding the provisions of section 3.c. (4), information relative to formulas of products acquired by authority of this section may be revealed, when necessary under this section, to an advisory committee, or to any Federal agency consulted, or at a public hearing, or in findings of fact issued by the Secretary. All data submitted to an advisory committee

in support of a petition under this section shall be considered confidential by such advisory committee: Provided, That this provision shall not be construed as prohibiting the use of such data by the committee in connection with its consultation with the petitioner or representatives of the United States Department of Agriculture, as provided for herein, and in connection with its report and recommendations to the Secretary. Notwithstanding any other provision of this section, the Secretary may, when he finds that such action is necessary to prevent an imminent hazard to the public, by order, suspend the registration of an economic poison immediately. In such case, he shall give the registrant prompt notice of such action and afford the registrant the opportunity to have the matter submitted to an advisory committee and for an expedited hearing under this section. Final orders of the Secretary under this section shall be subject to judicial review, in accordance with the provisions of subsection d. In no event shall registration of an article be construed as a defense for the commission of any offense prohibited under section 3 of this Act.

d. In a case of actual controversy as to the validity of any order under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. 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, including any report and recommendation of an advisory committee. If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order. 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 18 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

e. Notwithstanding any other provision of this Act, registration is not required in the case of an economic poison shipped from one plant to another plant operated by the same person and used solely at such plant as a constituent part to make an economic poison which is registered under this Act.

f. The Secretary is authorized to cancel the registration of any economic poison at the end of a period of five years following the registration of such economic poison or at the end of any five-year period thereafter, unless the registrant, prior to the expiration of each such five-year period, requests in accordance with regulations issued by the Secretary that such registration be continued in effect.