

Excerpts from Hearings of the Subcommittee  
on Executive Reorganization  
of the Senate Committee on Government Operations  
concerning federal drug research and regulation of LSD  
May 24, 1966

## **Audioreel #1**

**[Senator Robert F. Kennedy:]** . . .of the adequacy of communication, coordination, and cooperation among these agencies was in order. Since that time, widespread public attention has focused on a problem which is a prototype of the problems that we will examine in our hearings on the handicapped, a problem which raises many of the same questions that we will be asking as the weeks pass.

I refer, of course, to the controversy over the use and abuse of the drug LSD. It's been the subject of cover stories in national magazines and news documentaries on network television, of widespread public debate, and new legislative action within the states.

In all of this, I do not believe there has been an adequate inquiry into the organization of the federal government to deal with LSD, and to whether the government has fulfilled its responsibilities in connection with research on LSD and regulation of its use and in particular, whether difficulties of interagency coordination and cooperation have hindered or are likely to hinder, an effective federal response to the program and to the problem.

Here is a drug which has been available for over 20 years. Research on its effect and its possible therapeutic uses has been going on for a long time. Yet suddenly, almost overnight, irresponsible and unsupervised use of LSD for nonscientific, non-medical purposes has risen markedly. Such use carries with it grave dangers.

Panic reactions or temporary personality changes that cause a person to harm himself or to harm others while under the influence of the drug. Without careful psychological screening, the drug will be used by some who will suffer permanent damage as a result. In a word, what was an experimental drug has become, now, a social problem. We must be prepared to deal with that problem to educate people, particularly young people, about the dangers of LSD.

And as LSD has become a problem, the possibility has arisen that public reaction will discourage and dry up legitimate research into the therapeutic use of LSD. Experiments indicate that LSD may be useful in treating alcoholics, one of the largest groups of the handicapped, and has been helpful in some cases in adjunct in psychotherapy for mentally ill people. If we in the federal government allow these legitimate uses to be interfered with, the loss to the nation and potentially for the handicapped would be serious indeed.

There are three federal agencies with an important medical interest in LSD: the Food and Drug Administration, the National Institute of Mental Health, and the Veteran's Administration. We have asked representatives of all three to appear here today. Tomorrow and Thursday, we will hear from those who have worked with the drug in research and treatment. Most of them with federal funds.

We want to know how these agencies have coordinated their efforts in connection with LSD. We want to know what kind of research the NIMH and the VA have stimulated and whether there are areas in which they should be encouraging further research.

We want to know if the NIMH and the VA have worked adequately with the FDA in translating the results of research into an effective educational program.

We want to know the plans of FDA and NIMH as regulator and sole distributor of legal LSD, respectively, to encourage and supervise legitimate research in the future. And above all, we want to know whether our government structure is adequately prepared to deal with all of the problems which LSD now presents to all of us.

The National Institutes of Health sponsored research in the use of the drug since 1953. The VA has been involved with it for 11 years, and the FDA has had a direct involvement with it since 1953 when the Sandoz Corporation first contacted FDA for permission to produce LSD as an investigational new drug. The subcommittee will be interested in determining whether we at the governmental level have created a situation where research and development may be inhibited at a time when we can least afford it.

And in asking these questions, we will not just be looking into the answers for the problem of how to handle LSD. For our handling of LSD is a prototype of the way in which we will have to handle our research for newer and better methods of treatment and rehabilitation of the handicapped, particularly the mentally ill.

We spend millions annually on research into new ways to treat the mentally ill. I'm concerned that the problems we face regarding LSD are typical of the problems of cooperation, coordination, and communication among different agencies that we really face on a much broader scale.

If LSD has slipped away from us, other new discoveries might be misused and other social dangers might be created because we pay too little attention to an interlocking design for our programs. One has only to think of how close we came to tragedy in connection with the Thalidomide to realize the seriousness of the problem. So the problem we discuss in these hearings is a classic example of the relationship of government and of science. The issue we examine is as broad as our fight against mental illness and our efforts to aid the handicapped in general.

We must have a decision-making process about research and new discoveries that works. We must as a government weigh the social implications for the research that we encourage, and heed the warnings of reputable people about the dangers of any particular course of action. And we must be properly organized to do the job and to make and carry out public policy in this important area.

In the end, we in government must bear the responsibility of weighing the importance of large-scale experiments for the advance of knowledge against the possibility of adverse and destructive effects. That is the responsibility which we undertake to fulfill during the course of these hearings. And if there should be any doubt in the role of the legislative branch in fulfilling that responsibility, I need only refer to President Wilson for an answer. He said, "What I fear is that government of experts."

God forbid that in a democratic society, we should resign the task and give the government over to experts. What are we for if we are to be scientifically taken care of by a small number of gentlemen who are the only men who understand the job? Because if we don't understand the job, then we are not a free people. That is why we have convened these hearings today.

Mr. Chairman, this is your subcommittee and you were kind enough to make the arrangements for us to hold the hearings in this important matter, and I'd like to ask, see if you have any comment before we begin.

**[Senator Abraham Ribicoff:]** Senator Kennedy, I look at these hearings as part of an overall pattern that this subcommittee has undertaken. Basically, we are concerned with man and his entire environment and also how the government is organized to take care of these problems.

With your experience in the cabinet and my own experience in the cabinet, it is very obvious that we have a very complex, complicated, overlapping, duplicated executive branch in our government. I think that senators have a duty to act on their own initiative to try to handle many of these problems in which sometimes the executive branch is slow in undertaking.

Now, the question is as I see it, from a senatorial standpoint, whether the environment that man has created will control man or man will control the environment with his exotic and sophisticated inventions. To this end, we entered into hearings on the whole field of pesticide, and I believe as a result of this committee's work, we have made great strides into better understanding the field of pesticide.

The same with the field of traffic safety. What is the federal role of traffic safety? And as a result of hearings that lasted some one year, we have changed the entire attitude and the prospective program of highway safety for this entire nation.

Now, you are interested in the problems of the handicapped. You always have been. The problems of the unfortunate, the children, the mentally ill, the mentally retarded, the blind, the lame and the halt. I know of no person who is better qualified to handle these problems both out of experience and out of compassion and what do we do about it? Now, LSD, of course as you say has been in the public eye in public discussion. There have been many abuses, yet the question comes are there any good factors of LSD?

And how is the government prepared to strike a balance and not to throw overboard those elements of a drug that may be good because there are certain elements that are bad? And I want to point out this, that as far as this is concerned, LSD is practically yesterday's problem.

There are newer and even more exotic products coming out of the laboratory. There is a form of LSD that works its effects in a half hour rather than a 10, 12-hour period of LSD. There are memory pills and smart pills, and all sorts of new chemical discoveries which stagger the imagination.

We aren't dealing with aspirin here or with a cure for the common cold. We are dealing with compounds having fantastic social implications that the old medicines did not have. Is FDA equipped to cope with them? Should there be some new technique of regulation for these mind-altering drugs?

After all, shouldn't the law itself recognize the social implications of these products and therefore treat them differently than a cure for the common cold? I don't have all the answers, and no one does. We look for the experts for guidance and for some of the answers. I'm very concerned about how we are handling the legal use of these drugs.

Do we have imagination enough and flexibility enough to weigh the proper course of new drug development and guard against abuse? From the LSD experience, are we losing on both counts? Mr. Chairman, I am pleased that you are undertaking the entire field of the problems of the handicapped and the organization of the government.

It is my hope that as a result of this series of hearings which you will conduct as acting chairman, we will chart new courses for the entire federal government and for the nation, in the field of the handicapped and not only will the government of the United States be better off for it, but it is my prediction that all people in the entire world will be better off as a result of the hearings that will be conducted over the next few years in this entirely important field.

**[Senator Kennedy:]** Thank you very much, Senator Ribicoff, and I'm delighted that you brought up about the fact that there are now going on development of new drugs and new ways to treat those who are mentally ill and those who suffer this, these handicaps, because the question of LSD, as you point out, perhaps is a problem of yesterday.

We're going to, we're really dealing with what's going to arise in the future and whether we are really, whether our governmental agencies and departments have the authority and are working closely enough together, to deal with some of these problems.

There's an article I'd like to put in place in the record, in view of your remarks, that appeared in the Wall Street Journal in connection with -- "Scientists test ways to improve memory-learning chemically," which I'm sure all of you are familiar with that.

Let me just take a moment. I'd like to just read one part about this because I thought it was interesting – may be applicable to the Senate: “The psychologist McConnell’s work, in the area, a species of common flatworm, an inch-and-a-half long, has been dramatic. Several years ago, he began subjecting such worms to a light followed by shock. The shock caused the worms to contact their bodies. Soon in the classic Pavlovian dog fashion, the worms were conditioned to contract when the light appeared, whether or not shock followed. These trained worms were then cut up and fed to other planaria, which are naturally cannibalistic at a certain stage in their lives. The untutored cannibals fed a diet of trained worms learned to respond to the light shock significantly faster than worms fed a normal diet. These experiments led to a possibility, or the possibility was raised of then feeding [inaudible] as a possibility.” I didn't know whether that was applicable here in the United States Senate. Senator [Javits].

**[Senator Jacob Javits:]** Mr. Chairman, I shall make only a very brief statement. I think I'm the member, the one member of this committee who's also a member of the Judiciary Committee and of the subcommittee under Senator Dodd, which has been hearing this testimony as recently as yesterday. However, Mr. Chairman, I consider the jurisdiction of this committee to extend to the operation of all government departments, which includes Food and Drug and HEW and their organization for dealing with their responsibilities.

I consider the jurisdiction of the Judiciary Committee to extend to the substantive questions of law involved here, one of which is the way in which the Drug Abuse Control Act should possibly be amended. The issue, the real issue before us is one of a governmental department handling this situation as they should organizationally, and I think the Government Operations Committee and this subcommittee have an absolute right to dig into that matter, and I approve thoroughly of these hearings accordingly. I hope they will be directed essentially toward that end.

The substantive question of whether or not we should amend the Drug Abuse Control Act in order to deal with the specific problem which is involved of inhibiting the use of LSD or similar drugs for personal use must go to Labor and Public Welfare, which I am also a member, as is Senator Kennedy or to Judiciary.

And there's no inhibition in that, we've done it before in many cases. So I, Mr. Chairman, I think you're quite right to proceed. I hope very much that the witnesses as well as we ourselves and our questioning will not duplicate what's already taken place, and I welcome the sharp search light of public attention, which is being focused upon this matter.

I think there is a grave issue involved as to whether we get more out of freedom of experimentation and perhaps even the experience which comes from a multitude of cases in this field, or whether we really should prohibit individual use except on the sharp experimental control.

Our natural sympathy is for the latter as this is a very, apparently can be a very harmful drug. That's my natural sympathy. I think the burden of proof is on the scientists and the government

departments which contend against individual prohibition, that is prohibition of individual use and possession and leaving the law as it is.

And I think the burden of proof definitely is on you, gentlemen, as that as I understand it is what you contend for. But I'm certainly willing to listen, and I'm open-minded, as I'm sure are others of my colleagues, and I see no inconsistency whatever in pursuing the matter along the government organizational line as well as along the substantive line in the, in Senator Dodd's committee.

Thank you, Mr. Chairman.

**[Senator Kennedy:]** We've had fine cooperation from the Department of HEW, the office of Food and Drug Administration, the National Institute of Mental Health, and the Veterans' Administration. And I would like to ask for the first witnesses, representatives of those departments, I would like to have each one of you identify yourselves. Could you identify yourself?

**[Dr. Philip Lee:]** Mr. Chairman, I'm Dr. Lee, Assistant Secretary of Health and Scientific Affairs, and we'll make an opening statement. I have with me Dr. Stanley Yolles, Director of the National Institute of Mental Health who will also make a statement. Dr. James Goddard, Commissioner of Food and Drug who will also make a statement in more detail. With us also, Mr. Goodrich, who is the General Counsel of the Food and Drug Administration and Dr. Robinson who's the Acting Director of the Bureau of Medicine of the Food and Drug Administration.

**[Senator Kennedy:]** And you have an opening statement?

**[Dr. Lee:]** I have an opening statement.

**[Senator Kennedy:]** Would you proceed then, please?

**[Dr. Lee:]** I might--Mr. Chairman, for the sake of time, submit my statement for the record and move to that part of the statement that deals directly with the organizational aspects.

**[Senator Kennedy:]** Fine. Thank you.

**[Dr. Lee:]** This is approximately page five on the statement. We believe that the department is in the early phases of my statement, I describe in general terms the problem as you have done, Senator Kennedy, the need for more research, as well as the problems related to the abuse of LSD.

We are now in a position, I think, to take the necessary action with respect to abuse. Within the past few months, Dr. Goddard has taken over his duties as the Commissioner of the Food and Drug Administration. Even in that brief period, he has given ample evidence that he is an energetic, courageous, and able administrator.

With the legislative authority recently provided by Congress, the Food and Drug Administration can take forceful and effective steps against the illicit traffic in LSD. The authority exists particularly in the Drug Abuse Control Amendments of 1965.

Under regulations which became effective only last week, LSD can now be seized and action can be taken against the illicit manufacture, the illicit distributor and the illicit salesman or pusher.

To implement the Drug Abuse Control Amendments of 1965, the Food and Drug Administration has already established a Bureau of Drug Abuse Control responsible for the development and execution of appropriate inspection, analytic, and enforcement programs relating to the control of depressant, stimulant, and counterfeit drugs.

In utilizing governmental authority to restrain the abuse of LSD, the greatest care must be taken to avoid steps which will simply glamorize the drug and make its illicit use even more appealing to adventure-seeking individuals. Our major goal should be prevention, by means of vigorous law enforcement, to dry up the illicit sources of LSD and by means of education to alert people to the hazards inherent in its abuse.

In addition to the new authorities and to the recent actions being instituted by the Food and Drug Administration, a number of steps have been taken during the past year or so, within the department, which have markedly increased our capacity to deal with these problems. Approximately a year and a half ago, a careful analysis of the organization of the National Institute of Mental Health was initiated.

After very careful study, a reorganization was proposed by the Director of NIMH and approved by the Director of the National Institutes of Health, the Surgeon General, and the Secretary. This reorganization now permits a more effective attack against a variety of mental health problems. It has resulted in the establishment of special centers to focus on major mental health problems including mental and social problems—mental health and social problems, narcotic and drug abuse, the mental health problems of children, crime and delinquency, and the mental health problems in metropolitan areas.

The activities of the National Clearinghouse on Mental Health Information are being utilized more effectively as a result of this reorganization. A special assistant to the Director for Communications has been appointed to coordinate and improve the pooling and dissemination of information and educational materials to federal and state health agencies, to members of the health professions, and to the general public.

In addition, the National Institute of Mental Health has established an office of interagency liaison to provide effective coordination of the efforts of that institute with those of about 40 other agencies with which it maintains important relationships. These coordinated interagency activities may from time to time involve about 30 percent of the institute staff.



Institute personnel are now on detail on a fulltime basis to the Peace Corp, to the Department of Housing and Urban Development, and to the Office of Economic Opportunity, in order to develop close liaison. Liaison between the National Institute of Mental Health and the Food and Drug Administration is now maintained through a variety of mechanisms. The Commissioner of the Food and Drug Administration holds a commission as an Assistant Surgeon General in the Public Health Service.

He has been working closely and effectively with the Surgeon General of the Public Health Service, with the Director of the Institute of Mental Health and with the other senior Public Health Service officials on a variety of matters including the area of drug abuse in general and LSD in particular.

Dr. Jonathan Cole, Chief of the Psychopharmacology Research Branch of the National Institute of Mental Health, which includes the new Center for Narcotic and Drug Abuse, participates in a number of Food and Drug Administration activities. He serves as a liaison observer with the FDA's Drug Abuse Advisory Committee.

He works closely with Dr. Francis Kelsey and others on her staff on matters of investigational new drug applications. At the same time, Dr. Dorothy Dobbs of FDA serves as a liaison observer with the NIMH Clinical Evaluation Committee.

Dr. James Fox, Deputy Director of the Center of Narcotic and Drug Abuse in the psychopharmacology research branch of the institute, holds a joint appointment as Chief of the Division of Drug Studies and Statistics in the Bureau of Drug Abuse Control in the Food and Drug Administration.

At present, the FDA and NIMH are in the process of developing overlapping membership on their respective advisory committees which are concerned with drug abuse and similar problems. These close working arrangements were not developed merely to allow us to cope specifically with the current problems related to LSD.

They were established to improve communications and cooperation within the department so that we may be more effective in dealing with a variety of problems which are facing us today. And with which we shall undoubtedly need to deal in the future.

The proposed reorganization of the Public Health Service, submitted by the President as Reorganization Plan Number Three, will further improve its efficiency and will give clear recognition to mental health as a public health problem of great significance in this country. If it becomes operative, the reorganization will bring together in one administrative unit the bulk of the mental health activities in the Public Health Service.

It will give bureau status to the National Institute of Mental Health and thus bring its director closer to the Surgeon General and to the Secretary of Health, Education, and Welfare in order to meet developing problems more efficiently, more effectively and more rapidly than ever before.

Finally, in the Office of the Secretary, the Assistant Secretary for Health and Scientific Affairs is charged with the responsibility for stimulating effective, cooperative efforts by the operating agencies, as well as advising the Secretary on the development of new policies and legislative programs.

There is already in the Office of the Assistant Secretary a Deputy for Science and Population who is working closely with the Public Health Service and the FDA. There will soon be a special assistant to work closely with these agencies, other departments of the federal government, state agencies and outside organizations on such specific problems as the control of alcoholism and drug abuse.

Mr. Chairman, this concludes my statement. With your permission, my statement will be followed by the statements of Dr. Yolles, Director of the National Institute of Mental Health and Dr. Goddard, the Commissioner of the Food and Drug Administration.

**[Senator Kennedy:]** That'd be fine. There might be a few questions that we would have before we hear from them. I just have a couple that I'd like to address to you. How would this, under the organizational structure that you described, how would this alter the way, for instance, LSD has been handled in the past or how you would handle memory pills, smart pills or these kinds of developments that are coming along in the future?

**[Dr. Lee:]** From the Office of the Secretary standpoint, we will have the special assistant who will be working directly in this area, bringing the matters directly to the attention of the Secretary. In addition. . .

**[Senator Kennedy:]** How has that varied with what has been going on?

**[Dr. Lee:]** There has been no one in my office, for example, to relate to these problems. In the past, there was a special assistant to the Secretary for Health and Medical Affairs. After Secretary Gardner took office, and the Congress approved the development of three new assistant secretaries, one of these he created for Health and Scientific Affairs.

We've been developing our staff within that office and because of the problems particularly of alcoholism and drug abuse emerging as major public health problems in the country, we felt that it was of sufficient importance that one of the few staff positions that I have should be devoted fulltime to this area. This is one step.

The Deputy for Science, also working closely with Food and Drug and Public Health Service on the development of a sound scientific base in both of these organizations and working closely with them and outside organizations. This staff position did not exist in the past.

Within the Public Health Service, the importance of mental health is highlighted in this reorganization. I think the two areas that receive special emphasis are the areas of health services, with the plan to create a Bureau of Health Services and a Bureau of Mental Health,

which will take from research to the delivery to the community mental health center, to the individuals in the community the advances in research, and this is a direct operation with all the functions in this one organization.

At the present time, the institute is within the National Institutes of Health which focuses, as you know, primarily on research and not on the application of that research, not on the education of the public.

The new Bureau of Mental Health which expands the functions of the present institute, raises its status, will give greater importance and I think a much more effective means of dealing with these problems. Dr. Yolles may wish to comment on that. I'm sure he will in his statement.

**[Senator Kennedy:]** Now, let me ask you. In addition to dealing with the problems, for instance, of alcoholism or mental illness, will there also be a greater, more intensified effort to deal with the various social problems that exist in communities, perhaps even before they reach that acute stage?

**[Dr. Lee:]** Very important in this area, for example, is the assignment of Dr. Doul to the Department of Housing and Urban Development. He was on the institute staff. He is a psychiatrist and widely recognized for his knowledge of the social problems in urban areas. There has been created also in the Institute. . .

**[Senator Kennedy:]** Would that be a new and --

**[Dr. Lee:]** Absolutely new position. It's a new relationship with another department.

**[Senator Kennedy:]** Now, does that indicate a good deal more will be done in that field than has been done in the past?

**[Dr. Lee:]** We feel it must be done and certainly the creation of a center to deal with these problems, to study the problem specifically in the institute, a staff will be created for this purpose. We'll be working directly with Dr. Doul and with the people in the Department of Housing and Urban Development.

**[Senator Kennedy:]** What—has there, any effort been made to determine what kind of a budget will be worked out for that kind of an effort for instance?

**[Dr. Lee:]** Well, Dr. Yolles may wish to comment more specifically on that. From the department standpoint, we have many of these interagency, interdepartmental problems. And of course, the development of budget, the traffic safety is another good example of this. Alcoholism is another example.

We hope to develop, for example, in all the departments of government, active programs for the treatment of federal employees suffering from alcoholism, and there has to be a focal point to push this effort or it doesn't take place. And we feel that the focus will be in the Institute of

Mental Health where they have again created a special center to study, we need more knowledge in order to apply it, but this gives us a means to rapidly apply that knowledge.

**[Senator Kennedy:]** I raise this question because uh, and I'll go into perhaps more detail with some of the other witnesses, particularly Dr. Goddard, but on the fact that some of those who are now taking LSD, I question whether we have enough information to determine why they're taking LSD, what the reason or purpose of their taking LSD.

And whether there has been, from a number of them at least, no indication of mental illness and whether we should be doing more, making more of an effort to prevent the kinds of situation arising where they turn to LSD or they turn to some of these other drugs, that our efforts should not therefore—you've described it very well—

but our effort therefore should not be just on the question of curing those who have already been found to have been victims of alcoholism or mental illness but really to be doing research and making an effort on behalf of those who are living in this environment in the 20th century and who will turn to these kinds of reliefs or outs in order to find some hope for some kind of future for themselves.

**[Dr. Lee:]** We completely agree with that, and Dr. Yolles will discuss in his testimony some of the studies that have been initiated by the Institute to determine more accurately in a more scientific way who is taking LSD and why are they taking it in this. . .

**[Senator Kennedy:]** The fact is, I would, or is it a fact that really even though we've known about this drug for some 20 years and even though some research has been done, we don't have the answer to that.

**[Dr. Lee:]** We certainly don't.

**[Senator Kennedy:]** But that is a reflection really on the fact that perhaps we haven't put the emphasis in the right place in connection with some of these matters.

**[Dr. Lee:]** I think that this is very definitely true. I think the focus which is now coming, I think one of the developments, the poverty program which has begun to focus on an area that the country hadn't focused on in the past, and we've looked at this problem of the preschool child, and we see the number of emotional, physical problems that are present in that very young group and the needs to reach down to that group and to the families in the urban communities particularly where the problems appear to be, uh,

well, they're certainly more concentrated and they're growing rapidly and I think that we're going to see a very significant shift in our research efforts in behavioral science. The Institute again in this area is developing a broadened program, in the behavioral science area.

**[Senator Kennedy:]** I'd be interested in having, perhaps at some future time, perhaps you could send it to me, what the figures are, have been in the past, of the financial efforts that have been made in this area in the past and what you intend to do as far as the future is concerned.

**[Dr. Lee:]** We would be glad to supply those.

**[Senator Kennedy:]** Perhaps a little bit more detail. . . maybe we're going to develop with Dr. Yolles and Dr. Goddard. But it seems to me that it's most significant and most vital if we're going to really make any progress in this field, and I think that from what you learned of LSD and the fact that we've had this knowledge about some of the problems of LSD for an extended period of time, and yet we reach this crisis period in 1966 as an indication that there may be a different kind of procedure is warranted. Senator Ribicoff?

**[Senator Ribicoff]** I'm delighted to see Dr. Kelsey here too, and I'm pleased that we have such a competent, dedicated lady in charge of the nation's medicine cabinet so to speak. And you're always a valuable and still very valuable adjunct to this nation in HEW.

I think, Mr. Chairman, that it might be good for the record to have Dr. Yolles at this standpoint give a brief history of the development and the use of drugs in treating mental illness, what successes we've had, and the relationship of LSD in the line of drugs used to treat mental illness, because this is just part and parcel of the overall problem, and since the chairman is going into the entire problem,

LSD is just one of the fractions of the entire problem. And I think it would be good for the record, Dr. Yolles, if you'd give us a little rundown on the history on drugs and mental illness.

**[Dr. Lee:]** Mr. Chairman, I think we'll switch seats so he can face the microphone.

**[Senator Kennedy:]** Do we have another microphone? That's all right. That'll be fine, why don't you change?

**[Senator ?]** Well, Mr. Chairman, may I inquire whether you want questions asked of these witnesses separately or should we wait until the whole panel has testified?

**[Senator Kennedy:]** I think that if you have some questions for the particular witness, it would be fine. I'd like to. . . having looked at these statements, I would like to have Dr. Goddard's statement as early as possible in the record because I think he goes into some of these matters. Go ahead.

**[Dr. Stanley Yolles:]** Senator, the use of drugs and treatment of mental illness, of course, has been a growing field. We started off many years ago with the very simplest of drugs in trying to deal with mental illnesses, essentially sedatives. And as we have studied more and more of the physiology of the brain, and understand some of the complex biochemical changes which go on in the brain, we have been led to development of newer and more sophisticated types of drugs.

I think Senator Ribicoff indicated before, when he talked about the drugs and the mind, that there's a wide array of drugs that have suddenly burst forth in the last five years, which affect the mind directly. Just a few examples off the top of my head at this point in time, for years in the treatment of drug addiction, heroin addiction, we were in the status of being rather disillusioned with the types of treatment.

The results were very poor in terms of treatment, and yet within the last two or three years, we have on the scene two potent drugs which offer great hope for the alleviation of drug addiction at the present time. In the treatment of alcoholism within the last two years, a drug has been on the market which offers great hope in the treatment of alcoholics.

For the first time, alcoholics on the drug do not finish their drink. They push it aside, and this has been termed by those researchers who are working on it very hopeful sign. Certainly in the development of the drug we're talking about this morning, LSD, which has been for many many years an experimental drug. In the last few years, experimenters have been developing its use as an adjunct both in psychotherapy and in the treatment of alcoholics.

In the treatment of the alcoholic, the drug is alleged to—and the results as yet are very preliminary, and we're not sure what the results will be, but they're hopeful at the present time, indicate that there is great hope that this will be a very useful adjunct in the treatment of alcoholism.

The drugs that alter consciousness, the drugs that affect memory, the beginning experiments to which you referred, Senator Kennedy, in terms of the planarians and the flatworms, the experiments with the nuclear drugs, the nuclear proteins, RNA and DNA, have opened a vast new world as far as the functioning of the brain is concerned, and the effect of drugs on the functioning of the brain.

If I were to be allowed a guess into the future in the next five to ten years, one will see a hundredfold increase in the number and types of drugs capable of affecting the mind directly. At this point in time, it's no exaggeration to say that we are very close to a breakthrough in the cure of depression, because of our knowledge of new effects of drugs.

I wish this were true in perhaps the major mental illness of schizophrenia, but we're not quite as close there. But the entire field of drugs has developed so rapidly that we are most hopeful that not only will we have new means of alleviating the distress of those who are mentally incapacitated, but also of curing some of the mental illnesses which presently exist.

**[Senator Ribicoff:]** So the point that Senator Kennedy made at the beginning becomes a very important one for the inquiry of this subcommittee. Is how do we assure that our governmental agencies utilize drugs when under proper control can alleviate illness and can bring much good to society, and yet control the use of the drugs in such a way that their harmful effects and impact

will not be felt by society and parts of society which should not be using them except under strict control and supervision of properly trained people.

So then the inquiry that Senator Kennedy has started is appropriate as to how we will organize the means, the control, the supply of drugs of this character. Isn't that correct, Doctor?

**[Dr. Yolles:]** Quite right.

**[Senator Ribicoff:]** Thank you.

**[Senator Kennedy:]** Can I ask in connection with that, when you talk about the fact that there will be a hundredfold increase in drugs that will deal with the mind, you include LSD as a drug that deals with the mind, no doubt?

**[Dr. Yolles:]** Yes, sir.

**[Senator Kennedy:]** Will the drugs that, these drugs that you've described in addition to the possibility that they can help, will they also, is there also great possibility that they can also do damage as LSD does?

**[Dr. Yolles:]** Yes, sir. All of these drugs are very potent.

**[Senator Kennedy:]** So what we're dealing with now basically is not just a question of LSD, but LSD is a symptom of what is being developed in the scientific world all across this country.

**[Dr. Yolles:]** Yes. It's a prototype of what's, of the drugs that are being developed. And the problems.

**[Senator Kennedy:]** And these other. . . when we talk about the fact it will be a hundredfold increase, these other drugs could be equally dangerous to the mind as LSD is?

**[Dr. Yolles:]** Quite so. Quite possible.

**[Senator Kennedy:]** Would you want to read your statement, Dr. Yolles.

**[Dr. Yolles:]** Yes, I would like to. That was very helpful. Mr. Chairman and members of the committee. LSD 25, more correctly lysergic acid diethylamide was, I'm sure you know, synthesized by Dr. Albert Hofmann, a chemist with Sandoz Research Laboratories in Switzerland in 1938.

It has been the subject of special scientific interest since 1943 when its special pharmacologic properties were accidentally discovered by Dr. Hofmann while synthesizing new ergot alkaloids, a series of compounds originally found in the fungus ergot, which exists in nature as a plant disease agent on rye plants.

The compounds isolated from ergot are medically most useful, for example, in treatment of migraine headaches and as uterine contracting agents. The drug that Dr. Hofmann had discovered

turned out to be pharmacologically quite similar to the active principle in peyote, to some naturally occurring hallucinogens such as mescaline, the active principle in peyote, but it was much more potent.

Hallucinogenic drugs of this type include psilocybin, an indole compound found in a mushroom, a Mexican-type mushroom; mescaline, the most active alkaloid present in the buttons of a small cactus called the mescal or peyote plant; and in the seeds of some varieties of morning glory plants, the active principle of which is closely related to LSD.

The mushrooms, cactus buttons, and the morning glory seeds have been part of religious ceremonies practiced by American Indian tribes, or are employed by medicine men in treating illness. Such religious and ritualistic use does not seem to lead frequently to drug dependence.

These drugs have been called hallucinogenics; that is, producing hallucinations, psychotomimetics or psychosis-mimicking, and more recently by some, psychedelics or mind-manifesting drugs. Somewhat arbitrarily, the hallucinogenic drugs commonly abused are divided into three groups according to their potency. And these can be summarized as follows:

The mild hallucinogens such as airplane glue, nutmeg, marijuana of the American type and morning glory seeds; the moderately potent hallucinogens such as dimethyltryptamine when smoked, psilocybin, [pheuphotanine?], peyote, mescaline, the more potent preparations of cannabis or marijuana including the Indian hashish and Charas; and finally the highly potent hallucinogens, and there's only one member of this group, LSD 25.

All of these drugs have been used for thrills or kicks, to modify and clarify perception to the environment, to alter mood, to induce reveries, and to seek psychological insight into the personality problems of the user. The drugs are usually taken orally and in the company of other users. Ingestion of a single dose or of several doses over a period of two or three days is the most frequently recorded pattern.

Prolonged or continuous use is more unusual. LSD is a most powerful drug and the usual dose is about 1 to 200 micrograms, micrograms, or 1/15th to 1/30th millionth of an ounce, and just for the sake of demonstration, I brought along with me an ampule this morning, which contains 1000 doses of LSD or enough, as they say, to put on a thousand trips for those who want to use this potent drug.

This drug has been studied by many investigators from a variety of standpoints. The National Institute of Mental Health has been supporting studies of LSD under its research grant program since 1953. From that time through fiscal year 1966, some 84 grants totaling about seven and a half million dollars have been supported. In 1966, some 38 research grants are being supported at an annual expenditure of a million and a half dollars.



These studies gave substantial national emphasis to the study of LSD and other related psychomimetic substances. This work has included the synthesis of similar chemical compounds to determine what aspect of LSD's chemical structure accounts for its unique properties.

One compound uncovered in the course of this work, dimethyltryptamine, or as it's known commonly DMT, is of some interest in that it produces a state similar to that of LSD but of much shorter duration, the so-called 45 minute psychosis versus a seven-to-ten hour or longer effect of LSD. Other studies have been concerned with the biochemical mode of action of LSD in the central nervous system. Its actions appear to be related to the levels of serotonin in the brain and perhaps to catecholamine levels as well.

Both of these latter substances are thought to play important roles in brain physiology. As our knowledge of the roles of these substances and brain functions steadily increases, a better understanding of the effect of LSD on these systems will emerge. Other studies have sought to clarify LSD's effects on the electrical activity of various parts of the brain.

Here, the drug has been shown both to have an alerting effect on the reticular activating system, stimulating the alertness center in the brain, and to interfere with visual sensory pathways. Newer and more sophisticated approaches to these phenomena in both animals and man are developing and are being used to study LSD.

A rather complete reference file on the LSD literature, especially relative to clinical studies, is maintained by the National Clearinghouse for Mental Health Information. This includes translations of articles previously not available in English and to the best of our knowledge, it is the largest such information file in the world and information from the clearinghouse is available upon request.

I've brought with me for the use of the committee, if it should so desire, the complete references in the 1966 and '65 literature on LSD, which are available upon request to any investigator as a means of disseminating scientific information.

**[Senator Kennedy:]** Thank you very much.

**[Dr. Yolles:]** During the 1950s, there was widespread interest in studying the possibility that these agents could reproduce naturally-occurring schizophrenic states. After a number of years of research, it became apparent that these drugs produce a state which has some characteristics of a true psychosis but is not identical with one.

The nature of the acute psychological and behavioral effects of these drugs in animals but more importantly in man, have been subjected to study from a variety of approaches. More recently, attention is being given to long-term effects of the drug which might persist after the acute effects have passed.

The effects of the drug in normals have been compared and contrasted with the manifestations of schizophrenia. In general, although we have learned some things about the pharmacology and behavioral effect of the drug LSD, much more needs to be discovered before its mechanisms of action in altering man's psychological state can be fully and adequately understood.

Drugs of the LSD type produce mock excitation of the central nervous system as well as changes in mood, usually euphoric and sometimes depressive, anxiety, distortion in sensory perception, which is chiefly visual, visual hallucinations, delusions, depersonalization, dilatation of the pupils and increases in body temperature and blood pressure.

Psychological dependence on drugs of the LSD type varies according to the drug used, but it is usually not intense. The thrill-seekers and nonconformists may enjoy the effects of these agents and may wish to repeat them, but if such agents are not readily available, these persons will either do without them or substitute another substance. No evidence of physical dependence can be detected when the drugs are withdrawn abruptly.

A high degree of tolerance or the need to increase subsequent dosage to obtain the same effect to LSD and to psilocybin, develops rapidly and disappears rapidly in about three days. Tolerance to mescaline develops more slowly. Persons who are tolerant to any one of these three drugs are cross-tolerant to the other two. The chief dangers to the individual arise from the psychological effects. Impairment of judgment can lead to dangerous decisions or accidents.

Occasionally persons may become depressed, so that suicide is a possibility in users of these drugs. In the early 1960s, interest in LSD shifted to two new and related areas. The powerful effects of the drug on emotions and perception began to be assessed as a treatment adjunct in association with psychotherapy in resistant psychiatric conditions, severe neuroses, personality disorders, and chronic alcoholism.

The National Institute of Mental Health has been actively encouraging and supporting a research program designed to study these new issues. Five grant-supported studies of the drug's clinical usefulness in the treatment of chronic alcoholism and severe psychoneurosis have been developed. Several different psychotherapeutic approaches are being utilized, along with LSD administration in these projects.

It is too early to clearly anticipate the final results of these controlled clinical trials, but preliminary results suggest that the short-term effects of these types of treatment are sufficiently interesting to warrant continued support for this work.

At about the same time, lay interest in experiencing the unusual effects of the drug were stimulated in part by the activities of Aldous Huxley and Timothy Leary and their strong endorsement of its mind-altering effects. More recently, the deleterious effects of the drug when taken outside of appropriate medical and scientific supervision has become increasingly obvious. Four varieties of adverse psychiatric effect have been identified.

These are one, severe panic states occurring during the acute effects of the drug. Two, prolonged schizophrenic-like psychotic states lasting for weeks or months after a single dose. Three, recurrent waves of symptoms resembling LSD-induced state, feelings of unreality, disordered visual bodily sensations, uncontrolled and very rapidly shifting emotional states, recurring again and again weeks or months after the last experience.

And four, a gradual deterioration of efficient and effective reality-oriented behavior, loss of interest in work or study in social relationships and obligations. Background data on individuals having these reactions, particularly the second, third and fourth suggest that the patients had unstable borderline adjustments prior to their experience with LSD.

There is clearly an LSD problem in a number of colleges. Its extent and nature, however, are far from clear. As to extent, several points need to be made and three groups of students need to be identified.

One, regular if sporadic continuing LSD users. Two, students who have taken LSD once or twice at some time in the past and no longer do so. Three, students who are actively involved in thinking about the drug and are ambivalently interested in taking it some time.

Survey approaches to the study of the extent, patterns and dynamics of the abuse of these drugs including LSD in college students and in the population at large, have been and are being developed. The first such survey was planned in August of 1965. Three grants in this area have already been activated and other studies are being planned. It is, however, too soon to expect data from this research.

The nature and magnitude of the LSD abuse problem is still a matter of speculation. Guesstimates have ranged widely depending on the point of view of the individual respondent. At present, we do not know exactly what percentage of individuals using the drug have severe adverse effects. One study based on over 25,000 administrations of LSD and mescaline to over 5,000 persons showed an extremely low percentage, less than 4/10 of one percent of individuals having adverse effects.

While this one study carried out in 1960 cannot be considered definitive until there have been replications, it is interesting to note that the number of adverse reactions from the drug administered under medical supervision is in the same range of magnitude of occurrence as in any other type of psychiatric treatment. During the past year, the NIMH has been increasingly close in active contact with the Food and Drug Administration's Drug Abuse Control Program and with the FDA's Bureau of Medicine.

**[Senator Kennedy:]** Can I just interrupt, just for clarification. On the study based on 25,000 administrations of LSD, I gather that that has, was under medical supervision?

**[Dr. Yolles:]** Yes, sir.

**[Senator Kennedy:]** Because it follows right after talking about what is going on in universities, "It is, however too soon to expect data from research . . . makes your magnitude of the LSD abuse problem still a matter of speculation. Guesstimates have ranged wildly depending on the point of view." Up to there you're talking about unsupervised medical attention, is that right?

**[Dr. Yolles:]** That's quite correct.

**[Senator Kennedy:]** Thereafter you're talking about the [unintelligible], but you don't have an answer if I gather from your statement, you don't have any answer on what has been the result of the adverse effects on those who have taken the drug without medical supervision.

**[Dr. Yolles:]** That's quite right. We don't know as yet. Studies are going on now.

**[Senator Kennedy:]** Well, I think it's important to distinguish that.

**[Speaker whispering:]** You might mention the dosage. . .

**[Dr. Yolles:]** One of the points I might mention just as further extension of reply is that with the crude means that are used to ingest LSD, the use of one drop on a sugar cube so to speak, and in some of the modes of manufacture which have been very crude, it's very difficult to estimate what the real dose is that some of these college students are getting.

And in some cases, they're getting very high doses and this would account for some of the pathology that we see. We're not sure as yet really what the extent is. During the past year, the NIMH has been increasingly close in active content with the Food and Drug Administration's Drug Abuse Control Program and with the FDA's Bureau of Medicine.

NIMH staff have been attending meetings of the FDA's Committee on Drug Abuse and have been working actively with Dr. Frances Kelsey and other FDA staff members on problems inherent in the use of LSD as an investigational drug in clinical studies.

The NIMH's decision to accept residual supplies of LSD and related hallucinogenic compounds from the Sandoz Company a month ago and to develop a system for making the drug available to appropriate and responsible investigators was developed in consultation with the FDA. At the same time, NIMH worked with the Sandoz Company and the Veterans' Administration Psychiatric Research Program to ensure that VA investigators received supplies of the drug adequate to continue their research work with it.

Recently, as an outgrowth of continuing collaboration, Dr. James Fox, the Deputy Chief of NIMH's Center for Narcotic and Drug Abuse has in addition been appointed as Chief of FDA's Division of Research and Statistics in the new Bureau of Drug Abuse. Dr. Fox's dual assignment is designed to maximize effective coordination and liaison between research programs in the areas of drug abuse carried out by both the NIMH and the FDA.

Senior staff members of the NIMH's Biological and Psychopharmacology Research Branch had already been devoting a considerable portion of their time to LSD and related problems and have been actively involved in work with the FDA and the VA. In summary, the NIMH clearly recognizes that LSD presents both unusual research opportunities and an abuse problem.

Both areas require continued and expanded research effort. Therein lies the present problem. As Dr. Jonathan Cole puts it, "Rather than remaining solely the subject of careful scientific inquiry, these agents have become invested with an aura of magic offering creativity to the uninspired, kicks to the jaded, emotional warmth to the cold and inhibited."

On the west coast, the effects are judged by some to be related to the insights of Zen Buddhism. On the east coast, they're judged by others to lead the way to a new and free social order. They are judged by others to lead the way. Like the broom in the Sorcerer's Apprentice, the drugs seemed to have walked out of the laboratory into the outside world on their own feet and to have turned on the unsuspecting apprentice.

The drug, however, is important both for the understanding of brain function and behavior and as a potentially powerful therapeutic tool. And as such, supplies should be available to responsible investigators, but it is also, it also presents dangers.

We agree with the recommendation of the New York County Medical Society that no hallucinogen—LSD, mescaline, psilocybin, or dimethyltryptamine—should be administered except by a physician trained in its use and this should apply even if the current studies show LSD to be of value in the treatment of psychoneuroses, sexual perversion, frigidity, alcoholism, or other illnesses.

Even use by trained physicians should continue to be limited to carefully controlled experiments until incontrovertible data are available documenting LSD's efficacy and safety. Appropriate educational materials should be made available to the public emphasizing the potential dangers of the more potent hallucinogens as well as the amphetamines and barbiturates.

LSD abuse needs to be better understood at several levels. The prevalence of abuse in various population groups and the frequency and nature of its adverse effects must be better understood. Perhaps more important is the need to study and understand the reasons underlying the drug's illicit use, the individual motivations and the social pressures contributing to the problem.

Such understanding is fundamental to the development of effective education and prevention programs. We feel strongly that vigorous enforcement of the Drug Abuse Control Amendments of 1965 is needed in conjunction with an imaginative educational program because as in all areas of public health, ultimately the most effective control of the problem is through prevention.

**[Senator Ribicoff:]** Dr. Yolles, you mentioned here that, you just mentioned the name Sandoz. Are they the only manufacturer of this LSD?

**[Dr. Yolles:]** The only manufacturer that was providing drugs, providing LSD in this country. There are sources of supply in Czechoslovakia as well I understand.

**[Senator Ribicoff:]** And where?

**[Dr. Yolles:]** And in Italy.

**[Senator Ribicoff:]** Well, where is the legal source of supply now? Does NIMH have all the legal supply?

**[Dr. Yolles:]** That's quite correct.

**[Senator Ribicoff:]** In other words, all the legal supply is in the hands of your department?

**[Dr. Yolles:]** Exactly.

**[Senator Ribicoff:]** All right now, that vial that you showed us, dimethyltryptamine...

**[Reel 1 ends]**

## **Audioreel #2**

**[Speaker:]** . . .when these laboratories are not under supervision. Of course the press has spoken occasionally of it being made in high school chemistry laboratories when the teacher, who has too many students, has to turn his back. Now that's a little bit of exaggeration.

**[Senator Ribicoff:]** In other words, can, is LSD so simple to make or is it, isn't this a sophisticated drug to manufacture?

**[Speaker:]** As I understand it, the actual manufacture of the drug is not terribly difficult. It's not the easiest thing in the world to make, but it is not terribly difficult. The difficulty is in purifying the drug. With relatively crude apparatus, you can get roughly a 15 percent yield.

**[Senator Ribicoff:]** Now you say some of this is made in open laboratories. That means you know where it's being made?

**[Speaker:]** No, I didn't mean to infer that, but in college laboratories as a possibility, or in commercial chemical laboratories. Dr. Goddard may wish to comment further on that.

[Background noise]

**[Senator Ribicoff:]** Now, Sandoz is withdrawn from this field?

**[Speaker:]** Sandoz has, distribution of the drug and is no longer manufacturing it. All of the supply that, the residual supply that Sandoz had was delivered to the National Institute of Mental

Health by armored car about a month ago, and its value was estimated to be 21 grams, that we have, was estimated about \$300,000 on the black market.

**[Senator Ribicoff:]** In other words, because of all the publicity, Sandoz wanted no part of this anymore, is that right?

**[Speaker:]** That's the way we understand it.

**[Senator Ribicoff:]** That was there and they figured they would send it to you or you could distribute it for experimental purposes or your own use to legitimate users and experimenters of this drug.

**[Speaker:]** Exactly.

**[Senator Ribicoff:]** So then you are faced with the problem, since you have the only legitimate supply, how do you stamp out the bootleg supply or the illegitimate supply?

[inaudible]

**[Speaker 2:]** [Murmuring voices] Senator Ribicoff, the stamping out of illicit manufacture and distribution is the task of the drug abuse control activities within the Food and Drug Administration. We have now approximately 240 people in the Bureau of Drug Abuse Control.

Only a small number of these have completed their training as investigators. Increasing numbers will be completing this training as this fiscal year winds up and in the early part of next fiscal year.

Our main efforts with respect to LSD will be directed towards identifying those who are engaged in illicit manufacture and distribution and making use of the penalties available to us under the Drug Abuse Control Amendments of 1965. We intend to move very vigorously in this area even though our resources are limited.

**[Senator Ribicoff:]** What is the difference, from a scientific standpoint, from a legitimate supply of LSD and from that manufactured in back rooms or in college chemistry laboratories in the quality and its impact on the individual from a legitimate source of supply that you control and the illegitimate source of supply that is being sold illicitly.

**[Speaker 2:]** The differences would relate, as Dr. Yolles has pointed out, to the purity of the drug. Secondly, the exact dosage involved in a given quantity is not known and therefore over dosage may occur rather readily as contrasted with the carefully controlled administration and scientific surroundings.

**[Senator Ribicoff:]** Now, Dr. Leary was getting this drug from England, was he not?

**[Speaker 2:]** We have some evidence that this may have been the case. The illicit importation of LSD through the mails and smuggling is also a source of concern at the present time.

**[Senator Ribicoff:]** Yeah, but did Dr. Leary get this illicitly or did he get this openly?

**[Speaker 2:]** Originally, he obtained it through Sandoz I believe. He was carrying out investigations, which we felt had to be terminated, and we did in fact terminate those investigations. But since then I am not aware. Mr. Finlator, do you know where the supply has come from?

**[Mr. Finlator:]** No. . .we know that we got some from England and uh. . .

**[Senator Ribicoff]** Or what, but when. . .

**[Speaker 2:]** Any supplies he has now, Senator, would be illicit in nature.

**[Senator Ribicoff:]** Do you work with the Bureau of the Customs, or was it smuggled in to...

**[Speaker 2:]** We do work with the Bureau of Customs. However, the problem is that we do notice by the very small quantity, which could provide a thousand doses, is extremely difficult for them to detect the presence of this either in an airmail letter or upon the person of an individual coming into the country.

**[Senator Ribicoff:]** But did you know the sources of where this came from?

**[Speaker 2:]** We don't know the exact sources of the supplies in that instance.

**[Senator Ribicoff:]** In other words. . .

**[Speaker 2:]** Other than his early work.

**[Senator Ribicoff:]** Are the sources in England legitimate sources as far as England is concerned? Are they also illicit in England?

**[Speaker 2:]** Mr. Finlator is going to visit England to discuss their control of this drug. I'm told that it is illicit now in England. There has been indicated other manufacturers on the continent, and I've recently met with some of my counterparts in European nations. They're very much concerned about the smuggling of LSD from one nation to another. It can apparently be readily obtained on some parts of the continent.

**[Senator Ribicoff:]** How do you handle this internationally? Let us say that you and your counterparts in other lands are deeply concerned with this problem whether you're an Englishman or American or a Frenchman or a German.

Now how do you work internationally to control what could be a legitimate drug if used properly, and yet would be very harmful if used illicitly without control. Now how do you work together with representatives of foreign lands?

**[Speaker 2:]** There are two mechanisms available, Senator. The first is through the World Health Assembly, the meeting of which was either just concluded or was about to end, and at the



meetings of the World Health Assembly, discussions are held, committee meetings, to attempt to have the member nations represented adopt legislation which will place under control drugs which are of serious concern.

If they fall, however, into the category of what we commonly call the hard narcotics, there is a commission of the United Nations, which handles this special problem. And that commission accepts recommendations from the World Health Assembly for additions to the list of controlled drugs.

And then through the United Nations, additional legislative programs are developed, attempting to get the member nations to carry out, individually, responsibilities which will cut the traffic and illegal narcotics.

**[Senator Ribicoff:]** Well, what would you do, let us assume you determine that LSD is legitimate for certain experimental work, and you use up your supply, then what do you do to get additional LSD. Do you go to Sandoz?

**[Speaker 2:]** We could in this instance approve the importation of additional LSD from a manufacturer abroad, or we could request a firm to manufacture on contract and provide them the necessary approvals to do so for the National Institutes of Mental Health.

**[Senator Ribicoff:]** Your total supply that you now have can be used for how many trips, let us say.

**[Speaker 2:]** This, Dr. Yolles says would suffice for the anticipated level of research for the next two to three years. There are 250,000 doses available, so . . .

**[Senator Ribicoff:]** Dr. Yolles, the central question to me is do you need to expose students to the use of this drug in order to have materials for research?

**[Dr. Yolles:]** No sir, we do not.

**[Senator Ribicoff:]** Then why should it not, in your judgment as a scientist, we'll find out from the others, why should not its possession be prohibited?

**[Dr. Yolles:]** Senator, I have a very strong feeling that if we make the possession of LSD illegal, that it will drive it further underground and make what perhaps is the beginning of a flaunting of authority and experimenting with something new perhaps a more pathologic process and a more strongly accented rebellion.

**[Senator Ribicoff:]** Well, is this unique to LSD and unlike handguns and lots of other things which we prohibit the possession of? I mean, on your theory you'd have anarchy in this world, no law, if people are going to make it the fetish to disobey the law because there is one. Why don't you let all kinds of poisons, potassium cyanide, and everything else reside in the hands of anybody that wants it?

Why do you stop somebody from committing suicide, on that theory? Well, seriously now. You pick out LSD, and you say the possession of LSD is prohibited, will encourage its use and drive it underground. Well, that's true of lots of other things we prohibit. Is there some special, unique reason which the possession of LSD should be favored against lots of other things, the possession of which we prohibit?

**[Dr. Yolles:]** It's our feeling that insofar as the individual is concerned and is experimenting with a drug that that should be handled on a medical basis. If he needs treatment, he'll receive treatment, but that the manufacture, control of the distribution, the supply, should be on a regulatory basis and not. . .

**[Senator Ribicoff:]** Well you propose, you gentleman propose, an educational program directed against the use of LSD so that the young people understand what it's all about. Well wouldn't that be much more effective if coupled with a prohibition against its possession?

**[Dr. Yolles:]** We don't believe so, Senator.

**[Senator Ribicoff:]** Well, why do you--now what about heroin and similar narcotics? You think that we should prohibit their possession, don't you? That's in the federal law now. As a matter of fact, Senator Kennedy and I think that the penalties for it are much too stringent, as they're strictly criminal.

**[Dr. Yolles:]** Senator, we are dealing with a different class of compounds and dealing with the hard narcotics. One or two exposures and a continued use of them leads to physical addiction to the drugs. This is a different story.

One or two uses of LSD may be all that the student will ever use, and if we made this a crime, we'd find that we'd fill up our jails with a bunch of college students who were rebelling at one time or another.

**[Senator Ribicoff:]** Well, I happen to agree with you about filling up our jail. Now is your reason, now we're getting down to the nubbin of the case, is your reason that if we made, if we inhibited possession, prohibited possession, that would make it a crime analogous to the possession of narcotics, which does carry a jail sentence because we are not yet mature enough to make it a medical problem. Is that right?

**[Dr. Yolles:]** Yes.

**[Senator Ribicoff:]** All right. Would you agree, therefore, as a scientist, that if we made the possession of LSD subject to medical correction, but compulsory medical correction, that that would be all right to write into the law.

**[Dr. Yolles:]** Senator, again, I don't know how to deal, I frankly don't know how to deal with a college student who uses it once or twice. I can deal with a college student who has a panic reaction. I can deal with that in any hospital, in any general hospital.

Any psychiatrist can deal with it. I can deal with the individual who continues to use it and has a borderline adjustment. I can deal with his borderline adjustments, but I cannot deal with what seems to be at this point in time, until we know better, a perfectly normal college student who is rebelling and using the drug once or twice. I don't know how to treat that.

**[Senator Javits:]** But you're going further than that. You want to prevent me, as a legislator, from voting to take it away from them. I may agree with you. I'm trying to get your best advice. I really am, as I say, my instinct would be to prohibit its possession, but I may not, I could be very wrong, and I'm trying very hard to get enlightenment from you. I think that's the central question here. Otherwise, you've got a pretty good law.

**[Speaker:]** One other aspect of this, I think, Senator Javits, relates to the maximum or optimal use of the personnel that can be devoted to this problem, and I think that we must focus these resources immediately as Dr. Goddard is organizing to do and has initiated actions already on the sources of supply, on the distributor, on the manufacture, and on the pusher,

and in this way, we will much more effectively deal with the broad problem than if we allocate the same resources that would take much more in terms of manpower to reach the individual who might take the drug once or twice. So I think this is another consideration that you should keep in mind in examining this question.

**[Senator Javits:]** Well, may I ask you a question, Dr. Goddard? Do you have power, in your judgment, under the law to seizure LSD in the possession of a student?

**[Dr. James Goddard:]** Yes, we do have that authority, Senator Javits. We can seize any quantity of LSD in the possession of any individual that is not approved as an investigator on one of the .

**[Senator Javits:]** But the exemption in the law for personal possession, which says for the personal use of himself or a member of his household does not protect him in the possession of it.

**[Dr. Goddard:]** It only protects him against prosecution. We can make executive seizure of the drug in his possession at that point in time.

**[Senator Javits:]** In other words, he's not guilty of any crime--

**[Dr. Goddard:]** That's correct.

**[Senator Javits:]** But you will seizure it, not only you can, you will.

**[Dr. Goddard:]** We will.

**[Senator Javits:]** I see, and that's going to be part of your educational process.

**[Dr. Goddard:]** We will inform them that they are subject to this type of seizure of the drug. It's also important to note as a practical measure that these individuals provide very valuable leads as

to where the drug is coming from, and to make this a crime we feel would make our task of identifying the manufacturers and the distributors or pushers much more difficult. So it has that practical implication as well.

**[Senator Javits:]** But you also opposed making the one found with it in his possession subject to let's say, civil commitment for medical treatment.

**[Dr. Goddard:]** At this time, yes.

**[Senator Javits:]** On the ground, on what grounds do you oppose that?

**[Dr. Goddard:]** On two grounds. One, we feel that it would tend to discourage them or dissuade them from seeking medical attention when they may need it. It would make our task more difficult of identifying the sources, and the third point, Dr. Yolles mentioned, would make large numbers possibly of our college students criminal, and fourth, with limited resources we feel that the major thrust should be at the manufacturers and the distributors.

**[Senator Javits:]** But I can't accept your statement that it would brand them as criminals because what I'm suggesting would not brand them as criminals. You, you understand that?

**[Dr. Goddard:]** Yes, I understand.

**[Senator Javits:]** All right. Now may we take it, gentleman, that this is administration position. The administration does not wish to have an amendment to the law prohibiting possession.

**[Dr. Goddard:]** That is correct, Senator Javits.

**[Senator Javits:]** On any basis, criminal, civil, commitment, medical care, anything else.

**[Dr. Goddard:]** At the present time--

**[Senator Javits:]** That's the administration's position?

**[Dr. Goddard:]** That is right.

**[Senator Javits:]** Thank you very much.

**[Senator Kennedy:]** This really was gone into, to some extent, gone into a good deal of detail when we dealt with the Drug Administration Act of 1965, because at that time the Congress made the determination about, hereby finds and declares that there is widespread illicit traffic into depressant and stimulant drugs moving and otherwise affecting interstate commerce. The fact is that LSD comes under that category, does it not?

And therefore is covered by the law at the present time, which is section C, 511, section C, which was passed by Congress. No person other than a person described in subsection A, subsection B, shall possess any depressant or stimulant drug otherwise, and one, for the personal use of himself or a member of his household, and two, for administration to an animal owned by or a member

of a household and any criminal prosecution for possession of a depressant or stimulant drug in violation of the subsection, the United States shall have the burden of proof that the possession involved does not come within the exceptions contained in clauses one and two of preceding sentence.

There was a determination, therefore, by Congress last year to differentiate between these drugs and, for instance, heroin, and that it is a fact that some of these other depressant drugs and stimulating drugs have been also found to be extremely dangerous in the hands of unauthorized people or used in an unauthorized way.

So what I've gathered from the administration's position, at least at the present time, that we should follow the same kinds of procedures that we have followed in the past when dealt with a rather serious situation in connection with goofballs and some of these other kinds of pills or narcotics, which have proved perhaps somewhat dangerous.

[**Senator ?:**] Mr. Chairman, do I have time for one question. . .

[**Senator Kennedy:**] Yes, can I just finish. Do I understand that in fact there hasn't been sufficient research, or the results of the research haven't been sufficient to have the administration arrive at any other conclusion in connection with this?

[**Dr. Goddard:**] I think that's quite a fair statement.

[**Senator Kennedy:**] Is it also a possibility that further research, or if the results of the research that you're presently doing might possibly make you reach a different conclusion than you have at the present time?

[**Dr. Goddard:**] This is entirely possible on the basis of research.

[**Senator Kennedy:**] I think what is of some concern is the fact that this drug has been known for a long period of time, and I read an article that Dr. Leary wrote for the Harvard Review in 1963 in which he pointed out that this was a very dangerous drug and could cause tremendous damage to an individual. Why it is that in 1966 we don't have enough information, which would lead us to reach some conclusions in connection with this matter?

[**Speaker:**] By and large, Senator, the early research, and the research that's been going on for the first 10 years or so, was aimed at finding out the pharmacologic effects of the drug and trying to determine how the drug acted in the biochemistry of the brain.

It's only in the last few years that we have started to study some of the more deleterious effects of the drug, as it became obvious that more experimentation was going on outside. You know, this is a relatively recent phenomenon, the widespread experimentation outside of the laboratories.

[**Senator Kennedy:**] What do you mean, widespread experimentation?

[**Speaker:**] The use by college students and others.

**[Senator Kennedy:]** Is it a fact then that the government just didn't anticipate that this would spread to [unintelligible].

**[Speaker:]** There was no way, really, of knowing that there would be a sudden availability of the drug through clandestine channels.

**[Senator Kennedy:]** Why wouldn't you anticipate that? It's not difficult to make, and it's a major stimulant, and we saw it from goofballs and all the other stimulants that have been very actively accepted on the market. There has been an illicit movement of those drugs. Why wouldn't there have been, why couldn't you have anticipated the same thing would have happened for LSD?

**[Dr. Goddard:]** I think it was the feeling of most people concerned, who were dealing with the drug on an experimental basis, that it was such an esoteric drug, that it would never come out in the open in terms of widespread use in colleges. What we are seeing now is that it has escaped from the laboratory, in effect, as I said before.

[Murmuring]

**[Senator Javits:]** Can I ask a question?

**[Senator Kennedy:]** Yes.

**[Senator Javits:]** Dr. Yolles, it is a fact that when we passed the Drug Abuse Control Act we didn't have anything near the order of magnitude of use in the colleges, etc., we have now, isn't that right?

**[Dr. Yolles:]** That's quite right.

**[Senator Javits:]** And you would agree, would you not, all three of you, that it would be fair now to consider whether any amendment to the law is needed? I'm not convinced it's needed myself, but I do think we ought to explore it under these circumstances.

**[Dr. Yolles:]** I think we would all agree that that consideration certainly is most appropriate.

**[Senator Javits:]** And that it's not the same as it was in 1965. Now, can you tell us, I notice that you use the word "experimentation in colleges." I hope you'll expunge that.

Don't give these kids any idea, you know, that they're contributing to your great scientific experiments when they endanger themselves for life in taking LSD. Now, I'm very serious about that. Will you put something on the record on that?

**[Dr. Yolles:]** Certainly, certainly. This is misuse by individuals of --

**[Senator Javits:]** And it's dangerous, how dangerous is it? Will you tell us that? How dangerous is it to the individual boy or girl who takes this?

**[Dr. Yolles:]** We have no idea of how threatening it is, or how dangerous it is to any one individual at any one point in time. We know that there are certain individuals who have panic reactions, who become psychotic. And for a dangerous drug, even if one individual has that reaction, it's a dangerous drug, but to state specifically what his chances are of having an adverse reaction is too difficult to [speculate?].

**[Senator Javits:]** Well, it's like Russian roulette, he can be psychotic and remain psychotic.

**[Dr. Yolles:]** He's playing chemical Russian roulette.

**[Senator Javits:]** And one shot is it.

**[Dr. Yolles:]** Quite correct.

**[Senator Javits:]** Now one last question. It took you apparently eight months before you applied this act to LSD. That is not you, but I'm talking to Dr. Goddard, on May 18, 1966, the law became effective July 1965. Now Dr. Goddard, I'm not accusing anybody of anything, but I do think there ought to be some statement of record as to why the lag.

**[Dr. Goddard:]** It's my understanding, Senator, that the law actually took effect in February of this year. Also, in order to implement the provisions of the act with respect to LSD, we first had to publish in the Federal Register, allow 30 days to comment, and then 60 days before Notice of Final Action.

So that moves it right about up to the May 18th date. We also on that same day took action to bring lysergic acid, one of the most common precursors of LSD, under the same types of controls that LSD is now under. So it's rather a truncated period of time when one considers the act actually became effective in February.

**[Senator Javits:]** Thank you very much.

**[Senator Ribicoff:]** Just going back to a first series of questions to Senator Javits, you say that what you don't want to do is make possession illegal, because you want to encourage youngsters who get sick to go to a doctor, otherwise, they would not. Now what figures do you have about young people going to a doctor on their own after taking LSD?

**[Dr. Goddard:]** We have no statistics on a national basis. Some of the poison control centers in different parts of the country have become involved in this problem by virtue of the fact that individuals present themselves, who apparently are suffering some form of a toxic reaction, and in some instances, they're unable to communicate properly.

And so the experts in poison control have been called in to assist the clinicians, and they began to gather this data in several centers. Now in New York City, it's my recollection that during the preceding 12, or during a 12-month period, Dr. Frosch at Bellevue had approximately 80

admissions. Many of these were young individuals who came in voluntarily or were brought into the hospital by friends who became concerned with their panic reaction.

This pattern, as we know it, has existed in other parts of the country as well, so it seems quite clear to us that individuals who have misused the drug, perhaps for the first time, gone into a panic reaction, have voluntarily sought out medical assistance or some of their friends or sitters as they call them have recognized the need for this kind of attention, and were this to be accompanied, possession were to require a civil commitment or a criminal penalty, we fear that this might reduce this.

**[Senator Ribicoff:]** Now, in other words there are very few doctors in this country who would know what to do with an LSD, with a person who had taken LSD and became ill. The average doctor wouldn't know how to handle it, isn't that correct?

**[Dr. Goddard:]** I hesitate to comment on what the average doctor does and doesn't know anymore, Senator.

**[Senator Ribicoff:]** Well, that may be so, but I mean after all, you're all medical, scientific men. It's no reflection on a medical profession that if they don't know how to handle a sophisticated reaction to a sophisticated drug they've had so little experience.

**[Dr. Goddard:]** Well, my problem is related to the general problem of communications in the medical field. There have been articles in the literature, which clearly point out the anecdote that can be used in LSD reactions. Now how widely read and known this form of treatment is, I really can't assess.

**[Dr. Ribicoff:]** You mentioned, you say about 80 cases went into Dr. Frosch at Bellevue.

**[Dr. Goddard:]** Yes.

**[Dr. Ribicoff:]** Now how did those 80 cases come to Dr. Frosch, did other doctors send these patients to Dr. Frosch?

**[Dr. Goddard:]** No, in general these people either came in to Bellevue, which of course is I think a general pattern in New York City for emergency care, they go to Bellevue quite often, and they were not referred in by other physicians to my knowledge.

**[Dr. Ribicoff:]** Is Dr. Frosch a psychiatrist?

**[Dr. Goddard:]** Yes.

**[Dr. Ribicoff:]** Dr. Frosch is a psychiatrist. Now you don't know what the situation is in other hospitals, where it may be a boy of the middle class or upper-income groups whose parents see them sick or taking drugs, you don't know where that boy or girl goes.

**[Dr. Goddard:]** No.



**[Speaker:]** He's going to Bellevue.

**[Dr. Goddard:]** They would be treated initially, they would initially be treated by the unsuspecting person, a physician if he did not know LSD was involved as if the person were suffering from an acute psychosis.

Now, in answer to another question, you say you just recently found out the problems of this, and yet here's the annotated bibliography put out by Sandoz itself. . . indicates that back in 1956 the research done by C. Savage, the experience of this patient as well as those of another patient who took LSD while alone, made clearly evident the person with an acute LSD psychosis needs somebody with them all the time.

That self-experimentation without supervision is dangerous and that LSD should only be taken under medical supervision. So here Sandoz itself back in 1956 ten years ago realized the danger of self-experimentation.

**[Dr. Lee:]** Senator, I'd like to make an additional comment on Dr. Goddard's remarks as the one who was recently in practice, and I'm acquainted with a good many physicians not only in practice but in student health services around the country with the increasing abuse of LSD by the students, the student health service physicians have become increasingly aware of the problem and capable of dealing with it.

And I think that there is an increasing awareness on the part of the profession, this has been in the professional journals, as Dr. Goddard has indicated. It's been in the general journals like Medical World News and the AMA News and these other means that reach the physician so that physicians are becoming increasingly aware of the problem.

I think that none of us can say precisely how many physicians are qualified to treat this acute situation, but certainly there are many, many physicians and many of them in student health services around the country who are in direct touch with these students.

**[Senator Ribicoff:]** Now Dr. Lee, you are at Palo Alto, and you are associated with Stanford University.

**[Dr. Lee:]** Right.

**[Dr. Ribicoff:]** And I assume that Stanford like other, no reflection on Stanford, you must have seen students with LSD. Dr. Osborn, who is the present director of the student health service has told me that he believes that perhaps as many as five percent of the students may at some time be taking LSD or may have taken a dosage.

**[Senator Ribicoff:]** For the purpose of the record, and I think for enlightenment, give us a typical case history. How does this work? John Jones comes into the student health clinic. What does he look like?

What is his problem. What does he tell you? How does he feel? What do you do with him? How do you talk. . . what do you do with his parents? What do you do with the school authorities? How do you handle Johnny Jones who comes into the student health clinic?

**[Dr. Lee:]** Dr. Yolles has indicated the variety of different clinical situations that can exist in a person with an acute LSD intoxication. There can be a psychotic reaction.

They can have hallucinations. They can come in with merely an acute panic reaction. Usually in these situations they're brought in by one of their associates who is aware of the fact that they have taken LSD.

Of course the dosage is not known. This can be terminated very quickly with an intravenous dose or with an intramuscular dose of thiorazine, and usually this is given at about 50 or 100 mg, and this will terminate this acute toxic reaction within approximately 30 minutes.

Now this is again, the reactions to different individuals vary. As Dr. Goddard has indicated, some of the experience at Bellevue, they've had people who have been uncommunicative.

They've had others who have had these various different reactions, so that you can't generalize because there are these different patterns, and this can occur with other types of toxic reactions to drugs.

**[Senator Ribicoff:]** Well what do you find from your own experience as a doctor that when a youngster comes into a clinic, who has had this reaction and is treated, does he go back to taking LSD, or has he had it?

**[Dr. Lee:]** Well I think this varies of course, Senator, with the individual and depending on their underlying problem. We know that many of them do not take the drug again, having this kind of violent reaction.

Some continue to have symptoms subsequent to this original acute reaction. Some undoubtedly go back to taking this or other drugs.

Now Dr. Goddard does have some case studies, which we would be glad to submit for the record, Senator, on this.

**[Senator Ribicoff:]** I think they would be good. I'm just curious, Dr. Yolles, as a psychiatrist, from your experience and what you've read in this field, have you any indication or could you come to any conclusions of what type of boy or girl generally goes in for LSD from your experience.

Have you seen enough cases? Is enough written to indicate what type of boy or girl goes in for it?

**[Dr. Yolles:]** It could be anyone. Senator, I think as Dr. Lee has indicated, it could be almost anyone. We have no way of knowing that there is any one particular type.

There's the type that have swallowed goldfish, you know, in college before. There are ones who use marijuana. There are those who use LSD. There are the ones who ride motorcycles if you will. And I don't think there's any one particular type that uses the drug.

I think what you see, at least this is my general impression. What you see is a cross-section of the general college population, who because of perhaps prestige problems, on the campus, at least these are indications we are getting now, in association with others in a group who are using it, use the drug, try it once or twice.

**[Senator Ribicoff:]** Well is this a college-oriented drug as against marijuana or cocaine or heroin or, is this a college-oriented drug? Do you find that this is something that you need a college education for to take?

**[Dr. Yolles:]** Generally speaking Senator, the drug is used by quotes, unquote, bohemian groups, fringe groups, and is also being used to a certain extent on college campuses, but it is not solely a college drug.

**[Senator Ribicoff:]** But in other words why all the emphasis on LSD in colleges, just curious.

**[Dr. Yolles:]** Because it has occurred on campuses and because it has happened, you have a group of youngsters using a very potent drug, and I think this captures the imagination. Its numbers have increased over the past year or so, and I think this has been alarming both to college authorities and to the federal government that this has happened.

**[Senator Ribicoff:]** Do you find that the girls or the boys use it more than the others?

**[Dr. Yolles:]** We have no way of knowing, but I would suspect that both use it. Generally speaking, I think from a few reports that we have had, the boys use it a little bit more than the girls. And the question of marijuana, I think from what we know, it's equally distributed on the boys and girls.

[background noise]

**[Senator Kennedy:]** In answer to an earlier question, you indicated that it was quite widespread on the campuses now.

**[Dr. Yolles:]** On some campuses, yeah.

**[Senator Kennedy:]** More widespread than some of the pep pills, the goofballs, several years ago.

**[Dr. Yolles:]** There's no way of knowing, Senator.

**[Senator Kennedy:]** Your answer to the question of Senator Javits, as to why this situation is distinguished from the youth goofballs and pep pills in 1965 at the time we passed this

legislation, you indicated that LSD is more widely used on the campus than these other drugs. If that's true, I would like to know. If it isn't true. . .

**[Dr. Yolles:]** No, sir. The LSD was less frequently used as a drug on college campuses at the time the drug abuse control amendments was passed than it is presently being used on campus [inaudible].

**[Senator Kennedy:]** What about the use of LSD as compared to the drugs that were the ones that were most intimately considered in the drug abuse bill?

**[Dr. Yolles:]** We have no way of knowing at this point.

[Senator Kennedy:] Well then when we talk about who is using the drug and how widespread it is used on campus, you really don't have that information?

**[Dr. Yolles:]** That's quite right.

**[Senator Kennedy:]** I have corresponded with uh, I wrote the medical directors at a hundred universities, and I received replies back from, so far from 50 of them, and their reports indicate, there was some variety but indicate I think less than one percent of those [on the?] university, but again, I don't know whether that's authentic information or if they have any way of telling.

**[Dr. Yolles:]** I think it varies according to the respondent.

**[Senator Kennedy:]** I thought that [in fairness to] students as well as [in fairness] in dealing with this problem, maybe the problem is going to become more acute, but I don't think that we should think that every college student or every university student is dying to get back to school so he can get some LSD [laughter]. I don't think that really is the situation at the present moment.

**[Dr. Yolles:]** No, sir.

**[Senator Kennedy:]** And if there are still students who are concerned about the world around them and making a contribution and not just having a kick on LSD.

**[Dr. Yolles:]** I'm quite sure . . .

**[Senator Kennedy:]** I think it would be well if put it in its perspective. It seems to me, based on your testimony and what I know about it, there are great dangers of LSD.

There are also tremendous possibilities for LSD. And if it's kept in perspective, it's not as widely used amongst our university students and amongst the rest of our population as has sometimes been reported.

**[Dr. Lee:]** We completely agree with that balanced view of the problem. I think that we have felt concern and felt that these hearings have been very important from the standpoint of making a balanced presentation rather than the--

**[Senator Kennedy:]** Yes, because I think if we all, and I think also what's so important is what we touched on earlier about the fact that this is just the beginning of these kinds of drugs, these drugs are going to be available, and there are going to be those who are going to be attracted to them and feel that this is going to be the answer for all their problems,

and as the world becomes more complicated and we can't make some of our own difficulties within our country or in our relationship with other countries immediately that people are going to try to find easy solutions.

So I think the problem becomes more acute. What does concern me, and I must be quite frank about it, is the fact that we've talking about this drug since 1938, and we're only beginning to, you were unable to answer some of these rather basic questions at the present time.

I'm not criticizing anybody who is here at the table, but I think that we can learn a lesson from it as to how we have to deal with this kind of problem in the future, because it can destroy individuals and it can destroy not only physically but it can destroy their minds, and maybe some of these other drugs that you touched on or discussed are going to be even more dangerous and perhaps even more available.

And I come back to this, the Harvard Review of 1956 where Dr. Leary wrote and Dr. Alpert. . . "Now in '63 the mind-opening substances are available for the first time in limitless, mass produced quantities, what a threat and what a challenge, and what a widespread menace."

Now if he was writing about it at that period of time, some of the difficulties that he has had, if he was writing about it, it would occur to me that somebody was in the governmental structure had also been aware of it, and started to take the steps to carry on research and be prepared to deal with the problems that arise in 1966, that would be the first question,

and Dr. Goddard, if you could also, and any of you answer the question of whether this, under the circumstances, from the lessons that we've learned from LSD, whether we will be prepared to deal with this kind of problem for the future LSD.

**[Dr. Goddard:]** The Food and Drug Administration, Senator Kennedy, was aware of LSD as a problem with respect to misuse as early as 1961 and diverted investigators from other activities to work on LSD as these reports were received.

Now every report, whether it came from a newspaper account or came from a health service at a university or a poison control center has been tracked down and investigated completely. Now, why this did not result in the kind of research that would enable us to define the parameters of the problem, I can't give you an intelligent answer on.

We have learned a good deal about the control of investigational drugs in the past few years, and as you know, the 1962 amendments provided the agency the specific authority for the regulations under which investigative new drugs are now handled.

These regulations, we feel, provide the measure of protection that you and your colleagues seek as we move ahead in the years of increased research with more potent therapeutic agents, and the manufacturers, the research community have worked increasing well with these new rules and regulations as they've learned to operate within their confines.

So I feel a degree of confidence that we have strong authority, that we're gaining the practical experience in the Bureau of Medicine and throughout the Food and Drug Administration, to handle these drugs in an appropriate way and at the same time not block the research that we badly need to overcome some of the major social problems of our times.

**[Senator Kennedy:]** Is the structure of government dealing with these kind of problems, the basic problems, is that being changed now so that you can deal with the future LSDs, because if I read the law correctly, it appears to me that even back as far as 1938, at the time that this drug was being developed, even going back to the basic food and drug law, the 1938 law, there was authority to control the experimental use of such drugs as LSD.

**[Dr. Goddard:]** There was a general authority--

**[Senator Kennedy:]** And that wasn't really necessary to wait until just lately.

**[Dr. Goddard:]** There was indeed a general authority. The agency did not, however, require submittal of a plan of investigation in advance of that investigation. The sponsoring firm was required to obtain from the investigator the details of how he intended to use it, but this was not, this same plan was not required to be reviewed by the agency.

**[Senator Kennedy:]** Couldn't that, those regulations have been issued by the agency?

**[Dr. Goddard:]** I believe they could have. However, I must point out in 1962 prior to the passage of the Kefauver-Harris amendment, the agency did promulgate regulations and. . .

**[Senator Kennedy:]** That's because they had such. . .under the outstanding leadership of Senator Ribicoff and committee.

**[Dr. Goddard:]** That's correct. And at that time a veritable storm developed, Senator Kennedy, about these regulations. Senator Ribicoff will remember full well the medical profession, the manufacturers and the scientists were opposed to the adoption of these regulations,

but following the thalidomide episode, the Congress passed the amendments in 1962, and there was then clear authority for the agency to adopt these regulations. And I must say, they have worked increasingly well since then.

**[Senator Kennedy:]** Could you focus attention really on the second part of my question--

**[Dr. Goddard:]** Yes.

**[Senator Kennedy:]** There has been authority. There were, it appears, from periodicals and by statements that were made by various individuals who knew about LSD, that there were warnings whether you believe they were sufficient,

I think there were indications that this was a dangerous drug and that there could be widespread use of it across the United States during the '50's and during the early part of the 1960's. Number two, that there was authority to deal with the problem, whether it was felt that it would be popularly accepted or whatever the inhibitions were, there was authority to deal with it during that period of time, the fact was that it was not until 1966.

Do you feel that now you've established a relationship with the other government agencies and departments and within your own agency and department with the right kind of personnel that will prevent this kind of problem arising in the future with the future LSD? Could you address yourself to that question?

**[Dr. Goddard:]** We feel that the relationships we've established with National Institute of Mental Health, the public health service, other components of the federal government, and within the Food and Drug Administration itself are of the nature that will facilitate our handling of new drugs, investigational new drug applications, in a fashion that will not inhibit research and yet impose the appropriate controls.

But we must recognize that inherent in this situation, there is always the opportunity for a drug, which is in the stage of study to be illicitly synthesized or manufactured as knowledge of the drug becomes more widespread.

So I can't a priori rule out the development of a comparable situation in the future. This is a matter for, as we have indicated, our responsibility is to carry out a vigorous educational activity, and through this, if we can educate the students not to misuse these compounds, we perhaps may have a residual effect that could dampen any repetition. Bill?

**[Dr. Lee:]** Senator, there are several additional comments that I'd like to make from the standpoint of the department.

First of all, we believe that this type of hearing and the Congressional oversight of our activities is very valuable in detecting flaws in our programs. Now if these arise, often Congress detects them earlier than we do and takes appropriate action. I think that the example of traffic safety is one of the best in recent years on this, certainly the drug abuse area is another.

A very major weakness in the federal programs, which Congress brought to the attention of the public and initiated the policy changes and the program changes so that effective action should be taken.

Senator Ribicoff is well aware of the weaknesses of our research efforts in traffic safety, of the lack of the adequate base of knowledge on which to develop safety programs at the present time. There are many other areas.

Then these problems that are emerging today are ones that cross over departmental and agency lines. They really defy the bureaucratic line operations of the past, and as Dr. Yolles has indicated, they have interagency liaison with 40 different other federal agencies from one institute of the public health service.

Dr. Goddard has many such interagency activities relating to Food and Drug, and I certainly think that we don't feel that we have a perfect solution at the present time at all, but I think that the mechanism exists within the department and with this type of Congressional oversight and inquiry to keep more on top of the problems than we have perhaps in the past.

**[Senator Ribicoff:]** May I say, first, I want to compliment the three of you for the balanced statements that you've made with very good judgment and probity, and of course, Dr. Lee, you do point out a problem that concerns us, the unwillingness within the executive branch themselves, to try to do something about the overlapping and the diffusion. This is what has been bothering me all the time, and what we intend to do with our committee.

We find not enough cooperation in the bureau of the budget, not enough cooperation from the departments themselves because the desire to keep on empire-building and the fear of having a piece of a program taken away from them or transferred to someone else, which causes great problems, and it is only when you sensationalize a subject matter do you get reform, and without sensationalizing it you don't.

I mean one of the great problems, you scientists know something. A senator may know something. But until the press and television come in and give it a real play because it hits home to something that affects all of the country, only then do you get action. And so therefore we got three parts of this triangle, the scientists, members of the Senate, and the press of the country to really call attention to some of the abuses that need correcting.

Now Senator Kennedy mentioned this Harvard article going back to 1963, and I want to take Senator Kennedy's proposal one step further. What is a dilemma that you scientists face? You start investigating and experimenting with a drug.

Then, of course, this may be a panacea of, or a cure-all, or it may be just a plain ordinary bust. You don't know. It takes years to find out after very careful study whether this is meaningful or meaningless.

Senator Kennedy points out that there were warnings written in the Harvard Review in 1963 by the two doctors that received the notoriety. I point out that experimentations by Sandoz themselves in 1956 indicated the potential danger.



At what stage does a scientist or a governmental agency with responsibility make a public statement or take a public position? Do you take a chance and jump in in 1963 or do you wait until it becomes popularized in the press in 1966? I mean, how do you make these judgments?

**[Dr. Yolles:]** I think, Senator, that we have been aware, certainly in the NIMH for many years of the dangers of this drug, and you point out correctly that Sandoz has it in its bibliography and that it has been mentioned before, but it's equally true that our scientists, who have been working on it, and our grantees have been publicizing it equally well, that there are dangers, and we have consistently had this, uh, taken this position.

**[Senator Ribicoff:]** This is the point. That's esoteric. It gets published in the scientific journals. Scientists talk about it. And this is also always one of the great dangers when those who know something well talk about it among themselves; they assume that everyone has the same knowledge, but they don't.

Now here we have Senator Kennedy pointing out this article in 1963 calling forth the potential danger, and yet here it is in 1966 before it's seen the general light of day, and Dr. Lee says you welcome it. Now I think the point, how do you jump between '63 and '65 as far as the public is concerned. How does a scientist, what's the scientific thinking of when you make this public or when you warn the public as against waiting until '66 for a Congressional investigation?

**[Dr. Yolles:]** I think scientists are normally cautious about alerting the public to a danger if they don't have adequate information on which to base their warning. In addition, while they may be concerned about the possibilities, they may initiate research activities or try to initiate research activities to find investigators who will work on certain problems.

And this has been the case over the years in the last three or four years or five years as a matter of fact. We have been encouraging investigators to work on exactly these problems. It is only now when we have some investigators working, that the methods of doing these surveys and this type of research and the facilities for doing them have been developed so that for the future, the pattern is already fairly well established.

And we hope that if we have dangerous drugs developing in light of what we said originally, that this will be happening, the methods of surveying the alerting procedures will be rather well established on the basis of this experience.

**[Senator Ribicoff:]** What you have here, as long as this drug or other drugs like this is within the control of the administration or supervision of a psychiatrist or the scientist, then there's no great danger involved because they're under controlled experimentation. Now at what stage does the leap take place from the controlled scientific usage to general public use illicit as it were. Where does that come in?

**[Dr. Goddard:]** Senator Ribicoff, I would say that traditionally that change has taken place when the drug becomes available in the marketplace. One need only look at the example of the

barbiturates and the amphetamines. These drugs, the Food and Drug Administration recommended as early as 1950 with respect to barbiturates and in 1952 that the act be amended in order to provide controls because we were concerned as early as that time about their misuse.

I should point out that in 1953 Sandoz itself recognized the potential for abuse of LSD because although it was not required to preclear the drug for investigational use with FDA, it did come to the Food and Drug administration and tell them of their plans for research to be carried out with this very powerful compound, which had largely been studied in Europe up to that time.

Now from 1953 on to 1963, as I mentioned our investigations of LSD abuse began in '61. As late as '63, our investigations did not disclose any widespread abuse of this drug. There were limited foci around certain institutes and individuals where it was being misused, but it wasn't until there began to be publication of newsletters and distribution of information on how this drug was synthesized illicitly that it began to be used in a more widespread fashion.

So the point I'm trying to make is it's a function of availability, and most drugs do not become available to the public for misuse until they have gone through phase three of the investigated-new-drug stage and been approved as a new drug for marketing.

**[Senator Ribicoff:]** Yeah, but you see now here the opposite takes place here. It's when the general distribution is drawn, in other words, Sandoz drives up a Brink truck and piles it all out and says, here, we want no part of this anymore.

I mean this is a Frankenstein, and we want no part of it here. Put it in your vault. So you've got the whole world, you've got the whole legitimate supply of the world in your vaults. All right, so then you. . .

**[Dr. Goddard:]** In this country.

**[Senator Ribicoff:]** Well, in this country, in this country. So the general distribution you've got now. Now you've got the illicit use. So it isn't general distribution.

**[Dr. Goddard:]** No, it's both these, as I mentioned earlier. It's when the information on how to manufacture it illicitly began to become available, this was we think from 1963 on, the usage of it illicitly increased. It got out from under the hands of the approved investigators beginning about that point in time.

**[Senator Ribicoff:]** But basically it was very easy, if you couldn't get it in the United States, you could write to England, to the supplier there, and he would send it to you through the mails, right?

**[Dr. Goddard:]** This is correct.

**[Senator Ribicoff:]** Now, so here we come, what Senator Kennedy has started, the function, how do you work with the Customs Bureau, with the Treasury Department. In other words, here you do not approve this drug for general distribution in the United States.

**[Dr. Goddard:]** That's correct.

**[Senator Ribicoff:]** And you can't go into a drug store or a supply house and get this drug, but somebody can write a letter to X supply house in England and it's sent through the mails to the United States.

Now if something, if you've got a drug that cannot be sold, and you do not approve, in the United States, how can somebody write a letter to England and get that drug across the ocean? Where's the failure there?

**[Dr. Goddard?] Perhaps Mr. Goodrich would answer that?**

**[Mr. Goodrich:]** I'm [within?] the law. He can order some heroin, if it comes in here, it gets here, but that still doesn't make it legal.

**[Senator Ribicoff:]** But was this hidden, wasn't this written to the pharmacy, was this sent out in an unmarked package, or did it have the return address from the supplier?

**[Mr. Goodrich:]** Sent out so far as we know in a first-class airmail envelope, but it was certainly illegal to bring it in here, and it was illegal for the person to cause it to be shipped in here.

We have had that basic control over this drug as an investigational new drug since the start, never been approved for commercial distribution, and all this underworld distribution is illegal, our problem . . .

**[Senator Ribicoff:]** But this is the point I'm making. You see, basically, this is the supplier of that English drug was not an illicit supplier who works in the basement, right? This was a legitimate pharmaceutical house in England that you would write to, isn't it?

**[Mr. Goodrich:]** It's just as illegal to ship it here if he hadn't made it in the basement.

**[Senator Ribicoff:]** No, no, no. But I'm driving at something else. That this was sent to a drug manufacturer or a pharmaceutical house who was a legitimate supplier in England just as Sandoz was, or any of the legitimate suppliers that would be very careful and would not violate any law. Isn't that correct?

**[Mr. Goodrich:]** But the man that we caught in New York who was getting it from England was causing it to be shipped illegally here, and he was convicted for bringing it here.

**[Senator Ribicoff:]** Yeah, but who did he get it from from England?

**[Mr. Goodrich:]** He ordered it from an English firm. English laws do not have the same control as we have here, and you remember when we were discussing the drug amendments of '62 they simply don't control drugs that we do.

But under our law, any drug that comes into this spectrum is subject to our laws when it comes here, forbidden to bring an unapproved new drug into the United States except under an approved investigational program.

**[Senator Ribicoff:]** All right, now, does that English concern that sold that drug to Americans, does that concern sell other drugs legitimately to the United States market?

**[Mr. Goodrich:]** We're told that they do. We do not have an inspection on that firm. Mr. Finlator's going over there to check on this very thing, among other things, but there are other sources abroad, which do business with us in drugs, and it's entirely possible for someone to buy in England a drug of this kind and put it in an envelope and send it to friend in the United States [unintelligible].

**[Senator Ribicoff:]** All right. Well, then if you, then shouldn't it be possible or shouldn't we be considering that if anyone is a supplier of drugs to the United States that they should have a general license to send drugs to the United States, and they should only be allowed to sell drugs to the United States, which you have approved, and if they sell a drug, which you have not approved, that. . .

**[Reel ends]**

**Identified Speakers:**

Senator Robert F. Kennedy (D-NY)

Senator Jacob Javits (R-NY)

Senator Abraham Ribicoff (D-CT)

John H. Finlator, Director, Bureau of Drug Abuse Control, Food and Drug Administration

Dr. James L. Goddard, Commissioner, FDA

William W. Goodrich, General Counsel, FDA

Dr. Philip R. Lee, Assistant Secretary for Health and Scientific Affairs, Department of Health, Education, and Welfare

Dr. Stanley F. Yolles, Director, National Institute of Mental Health