The remainder of the increases in employment in fiscal year 1962 have been divided among the Food and Drug Administration, the Office of Education, St. Elizabeths Hospital, and the Office of the Secretary, and are related to the expanding programs of those agencies.

Mr. NELSEN. That is all.

The CHAIRMAN. Mr. Secretary, what is the difference between project grant and a formula grant?

Dr. SMITH. The project grant is a grant to the State made on the basis of an application that describes the activity. The amount of a formula grant is commonly determined on the basis of extent of the problem, the State population, and the per capita income in the State.

This means that in formula grants, every State, whether ready or not for this program, would receive its share of the total appropriation each year.

In project grants, the moneys can be distributed over the 3-year period according to the need and readiness of the particular State involved.

The CHAIRMAN. In other words, you prefer the project grants?

Dr. SMITH. Yes, sir.

The CHAIRMAN. And a formula grant under this program, you do not think would be suitable?

Suppose the costs of the program submitted by the States were to exceed the amounts that would be obtained from the bill. What would happen then?

Secretary RIBICOFF. In this case we don't believe so. We have very carefully figured out by the costs of the vaccine and previous experience that there is enough money to take care of all the children under 5.

The CHAIRMAN. In other words—I know, but if you didn't get what you asked for, would it be then administered pro rata?

Secretary RIBICOFF. Then you would have to cut back the program. In other words, if Congress did not give you what you had requested, then, of course, you could only take care of a smaller number of projects. Then, of course, if you had a formula, instead of a project grant, you might have a problem. Money might be allocated for State X who had no program and you might have State Y who would not have enough; and there might be some children who could have been inoculated and weren't because money was set aside for a State that didn't seek it.

The CHAIRMAN. This money would be for the purchase of the vaccine?

Secretary RIBICOFF. For the State personnel to ——

The CHAIRMAN. To be administered?

Secretary RIBICOFF. To administer and to do the job, yes, sir.

The CHAIRMAN. You would have in mind making vaccine available without charge to doctors?

Secretary RIBICOFF. The State would have its own policy. In other words, we would give the State money. It could purchase its own vaccine or we could purchase vaccine for the States, depending on the State preference. The State then would come up with its plan for the locality—to supply it to doctors or to public health centers or to school systems—whatever system or program the State itself or the locality developed, Mr. Chairman. But it is contemplated that

if a State wanted vaccine to go to private physicians to be administered, the vaccine would be supplied to the States for distribution to the private doctors.

The CHAIRMAN. Mr. Secretary, let me on behalf of the committee thank you very much. We appreciate your appearance this morning and the testimony on this part.

Secretary RIBICOFF. Thank you very much.

(The following letter was later received from the Department of Health, Education, and Welfare:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, May 28, 1962.

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

DEAR MR. CHAIRMAN: In response to the committee's request, I am enclosing a draft of two amendments to the proposed Vaccination Assistance Act of 1962 (H.R. 10541) which would reconcile the bill more closely with two suggestions for revision proposed by the Association of State and Territorial Health Officers.

The first amendment relates to the question of direct grants to local political subdivisions. We feel it important that such local communities not be denied the opportunity to participate in the vaccination programs proposed in the bill when a State for any reason is not prepared to take leadership in a statewide program. On the other hand, we agree that it would be desirable to obtain the approval of the State health authority in such cases. The amendment suggested would retain this authorization for direct grants to local areas, but would require the approval in such cases of the State health authority.

The second amendment would modify the limitation contained in the bill with respect to the age group of children eligible to receive free vaccine under the program. It would recognize that there may be some other selected groups of children in addition to those under 5 years of age who are not normally served by school vaccination programs. The amendment would authorize the Surgeon General by regulation to extend the eligibility for free vaccine to such groups.

We have also given further consideration to the suggestion discussed during the hearings that the legislation be amended to provide special Federal financial assistance for continuing vaccination programs against polio, diphtheria, whooping cough, and tetanus after the 3-year intensive programs now covered by the bill. It is our recommendation that such an amendment should not be adopted at this time because there are already two authorizations for grants to States which can be and are being used for this purpose. These are the maternal and child health grants appropriated under authority of title V of the Social Security Act, and the grant funds appropriated under authority of section 314(c) of the Public Health Service Act. We believe that with these two existing authorizations no additional continuing authority would be needed.

I am also enclosing for inclusion in the record, a statement on the national defense implications of the proposed vaccination program which more fully answers the question asked on this subject during the hearings.

Sincerely yours,

WILBUR J. COHEN, *Assistant Secretary.*

Enclosures.

AMENDMENTS TO H.R. 10541

(Requested of Secretary Ribicoff by Congressman Moss at May 16, 1962, hearing on bill)

(1) Approval of State health authorities

Page 2, line 7, insert the following before "political": ", with the approval of the State health authority, to".

(2) Purchase of vaccines for additional groups

Page 2, line 13, insert the following after "years": "and such additional groups of children as may be described in regulations of the Surgeon General upon his finding that they are not normally served by school vaccination programs".

NATIONAL DEFENSE IMPLICATIONS OF THE VACCINATION ASSISTANCE ACT OF 1962

H.R. 10541 has many implications important to the Nation's defense.

At the present time the adult population of this country has a low level of immunization against tetanus and diphtheria. In time of disaster these two diseases could be of major importance.

It is estimated that 70 percent of the casualties of a nuclear disaster would have traumatic injuries. Many of these injuries will be penetrating wounds, contaminated with dirt. The spores of tetanus are universally present in the soil, and therefore many of the wounded will be potential cases of tetanus Even with intensive hospital treatment, which will not be available in time of disaster, less than 50 percent would survive.

The crowded living conditions in shelters, would be conclusive to diphtheria, Diphtheria was a major health problem during the saturation bombings of Germany.

Therefore, establishing immunity to these two diseases now would be of immeasurable importance in time of disaster. The health mobilization activities of the Public Health Service and the disaster committees of medical societies strongly endorse the concept of immunization for the Nation's defense.

The provisions of H.R. 10541 would provide the basis for widespread vaccination of children under 5 years of age and, through the promotion and organization of intensive community vaccination programs, greatly stimulate the diphtheria and tetanus vaccination of the adult population. In addition, the experience gained from conducting such intensive community programs would be of considerable value in terms of emergency.

Thus the bill, while not designed as a general defense measure, would be of substantial benefit in this regard.

The CHAIRMAN. We have a statement here from Dr. Alfred Frechette and if there is no objection, it will appear at this point in the record.

(The statement of Alfred L. Frechette, M.D., commissioner of public health, Commonwealth of Massachusetts, follows:)

STATEMENT OF ALFRED L. FRECHETTE, M.D., COMMISSIONER OF PUBLIC HEALTH, COMMONWEALTH OF MASSACHUSETTS

The President's proposal to provide Federal assistance to State and local programs for immunization of preschool children is praiseworthy and timely. The value of such a program lies in the impetus that it can give to local programs which in many cases do not provide sufficiently thorough coverage of young children with regard to the immunizations that they should have. The Massachusetts Department of Public Health wishes to record itself in strong support of this program.

When the percentage of immunized schoolchildren is only moderately good there is a continuing danger that outbreaks of diphtheria, whooping cough, smallpox or poliomyelitis may occur. Such outbreaks are dangerous to all persons, young or old, who are not immune, and also their control is far more expensive and time-consuming than their prevention by means of thorough preschool immunization. In such a program, tetanus toxoid immunization should also be included, not only to protect individual children against this dreadful disease, but eventually to eliminate the need for tetanus antitoxin with its risk of severe reactions.

This comment is not intended to be critical of local programs; indeed the essence of effective public health activity—as with all similar activities—is local interest, initiative, and participation. Ths has been abundantly proved—if proof was needed—by the various community drives for mass oral poliomyelitis immunization which have taken place in many other areas, and recently in Massachusetts. In all such programs the degree of success is very much dependent on the extent to which the community takes active responsibility for the program.

However, dedication and enthusiasm are not in themselves enough. Futhermore, the lack of sufficient funds frequently kills of such enthusiasm before it can take root; and the lack of adequate technical guidance and careful surveillance of local programs often spells failure for such programs. As pointed out above, the emphasis must be on the importance of excellent rather than merely "good" immunization programs. And it is in maintaining excellence that Federal support can be most valuable. Past experience has shown repeatedly that Federal participation in the support of State health programs has often made a critical difference in the chances of achieving success in such programs. This principle will certainly apply to State and local immunization programs, since the provisions of H.R. 10541 and S. 2910 for assisting vaccine purchase, epidemiologic and laboratory surveillance, etc., are exactly what is generally needed to convert an inadequate program into a really effective one.

The proposed bill would presumably operate in basically the same way as the already well-tested Federal programs to support State and local control of venereal diseases, tuberculosis, etc. The principle of State and local planning and action, with Federal fiscal assistance and technical guidance, is a sound and accepted one. If applied to immunization, as proposed in these bills, it should make it possible to eliminate poliomyelitis, diphtheria, whooping cough, and eventually tetanus as public health problems.

The CHAIRMAN. It is now 12 o'clock. The House is in session.

May we have order just a minute.

I would like to see what we can do about hearing the other witnesses. We have four witnesses yet to be heard. I wondered if those witnesses who are to be heard could be back at 3 o'clock this afternoon?

We will undertake that, then, and see if we can't——

Dr. DAILY. I'm sorry, I cannot.

The CHAIRMAN. What is your name?

STATEMENT OF EDWIN F. DAILY, M.D., VICE PRESIDENT, HEALTH INSURANCE PLAN OF GREATER NEW YORK

Dr. DAILY. Dr. Daily from New York.

The CHAIRMAN. Dr. Daily, we are going to have a rollcall right away. We can't go on now. We will just have to arrange some other convenient time for you. I had hoped to get through with this this week if we could. I assume that it will not be satisfactory just to submit your statement?

Dr. DAILY. I would be very happy to. It is ready for submission. I can submit it to you now.

The CHAIRMAN. Very well. We will be glad to have you submit it for the record, and you are Edwin F. Daily, vice president of the Health Insurance Plan of Greater New York, and also representing Group Health Association of America, 625 Madison Avenue, New York 22, N.Y.

You may submit your statement for the record.

(The prepared statement of Dr. Edwin F. Daily with attached resolution follows:)

STATEMENT BY EDWIN F. DAILY, M.D., VICE PRESIDENT, HEALTH INSURANCE PLAN OF GREATER NEW YORK

I am Dr. Edwin F. Daily, vice president of the Health Insurance Plan of Greater New York, a nonprofit health insurance plan providing comprehensive medical care for 630,000 men, women, and children. I speak today both for HIP and for the Group Health Association of America, of which HIP is a member organization.

I wish to endorse the bill and commend the Members of Congress who are interested in furthering such legislation. The purpose of the bill—to protect all the American people against diseases such as poliomyelitis, diphtheria, whooping cough, and tetanus—is admirable.

In my own organization, HIP, we have made a major effort to immunize our large insured population. Studies have shown that our infants are 95 percent immunized for smallpox, diphtheria, whooping cough, and tetanus before they are 1 year of age.

In organized medical care plans, such as HIP and the other prepaid group practice plans affiliated with the Group Health Association of America, standards of care can and are established and carried out, families can be regularly informed about immunizations, and all participating physicians gladly carry out our immunization efforts. Since our physicians are paid on a salary basis rather than fee for service, there is a very real incentive to prevent illness and thereby lessen the need for medical care during illness.

Last year HIP decided to provide, without charge to its subscribers, all materials used for immunization. The cost of some vaccines can be a deterrent to a family with several children. For example, the Salk vaccine had cost us approximately $1 per injection and, with three injections per person, the cost to a family with two parents and five children would be $21.

When the Surgeon General of the U.S. Public Health Service recently approved type III oral vaccine for polio, HIP, with the advice of eminent epidemiologists, decided to immunize promptly as many of its insured persons as possible. In less than 5 weeks we had (*a*) sent special letters to all of our subscribers telling why they should have the new vaccine and where and when it would be provided by the 31 HIP medical groups; (*b*) solicited bids and purchased the vaccine needed; (*c*) rehearsed with the staff of each of the 31 medical groups every detail for carrying out a large-scale mass immunization program; and (*d*) requested and received the cooperation of the police department in handling anticipated traffic problems.

On a Saturday and Sunday early in May, over 150,000 men, women, and children took the new oral vaccine for polio from small paper cups and, for infants, by a dropper directly into the mouth. It was a joy to see these families happily participating in a well-planned immunization program. No one had to wait more than a few minutes since 1 nurse can easily feed the vaccine to over 1,000 persons per hour.

I have told you about this one effort at mass immunization because it is a clear cut, timely example of what you are desirous of accomplishing under the provisions of H.R. 10541.

I heartily endorse this legislation.

I also wish to present the following resolution adopted unanimously at a meeting of the Group Health Association of America now in annual session in Washington, D.C.

(At its annual meeting today in the Hotel Shoreham, Group Health Association of America voted unanimously to adopt the following resolutions in support of the Vaccination Assistance Act of 1962 (H.R. 10541 and S. 2910):)

"Whereas it is a basic tenet of the Group Health Association of America, Inc., that preventive medicine is one of the keystones of high quality medical care; plans affiliated with GHAA, with a total membership exceeding 4 million persons, have long implemented this conviction by utilizing all available techniques for the prevention of unnecessary illness and premature death; activities toward this end have frequently included leadership and cooperation in broad community immunization programs; and

"Whereas there are still large numbers of people who are not yet adequately protected against certain preventable communicable diseases, and who apparently cannot be reached by conventional immunization programs that have been tried in the past; and

"Whereas the proposed Vaccination Assistance Act of 1962 would 'assist States and communities to carry out intensive vaccination programs designed to protect their populations, especially all preschool children, against poliomyelitis, diphtheria, whooping cough, and tetanus, and against other diseases which may in the future become susceptible of practical elimination as a public health problem through such programs'; and

'Whereas it can be expected that programs carried on with aid provided for by the Vaccination Assistance Act of 1962 could effectively eliminate preventable communicable diseases: Therefore, be it

"*Resolved*, That the Group Health Association of America, Inc., urges the prompt enactment of the Vaccination Assistance Act of 1962, (H.R. 10541 and S. 2910); and be it further

"*Resolved*, That GHAA urge its member plans to cooperate fully in the implementation of local community programs that can be expected to be undertaken under the provisions of the Vaccination Assistance Act of 1962."

The CHAIRMAN. Off the record.

(Discussion off the record.)

Mr. DINGELL. Mr. Chairman, I wonder if the Doctor could just tell us whether he favors the legislation or not?

Dr. DAILY. I am completely in favor of the legislation.

Mr. DINGELL. Do you have any suggestions or amendments or changes?

Dr. DAILY. I do not suggest any amendments or changes in the language.

Mr. DINGELL. You have been very helpful. Thank you.

The CHAIRMAN. The committee will adjourn and will be back here at 3 o'clock.

(Whereupon, at 12 o'clock noon the committee recessed, to reconvene at 3 p.m., on the same day.)

AFTERNOON SESSION

The CHAIRMAN. The committee will come to order.

Off the record.

(Discussion off the record.)

The CHAIRMAN. We are very glad to have as our next witness Mr. Andrew J. Biemiller.

Mr. Biemiller, we are glad to welcome you back to the committee. It is always a pleasure to have a former member of this committee return and give us the benefit of his wisdom, counsel, and good judgment.

STATEMENT OF ANDREW J. BIEMILLER, DIRECTOR, DEPARTMENT OF LEGISLATION, AFL–CIO; ACCOMPANIED BY LISBETH BAMBERGER, ASSISTANT DIRECTOR, DEPARTMENT OF SOCIAL SECURITY, AFL–CIO

Mr. BIEMILLER. Thank you, Mr. Chairman.

For the record my name is Andrew J. Biemiller. I am the director of the AFL–CIO Department of Legislation, and my office is at 815 16th Street NW., in Washington.

I am accompanied by Miss Lee Bamberger, assistant director of the AFL–CIO Department of Social Insurance.

The support of the AFL–CIO for the Vaccination Assistance Act of 1962, H.R. 10541 is based on a very simple premise. We have at hand the scientific tools to eliminate entirely the suffering and death caused by polio, diphtheria, whooping cough, and tetanus. We have had these tools available for a number of years. But until now these tools have not been employed effectively enough to accomplish the job—the total eradication of these diseases.

It is clear that the methods used up to now to provide protection against these inflectious diseases have simply not reached large numbers of the Nation's citizens—and what is particularly deplorable, vast numbers of children have been left unprotected.

The children who are adequately immunized today are the fortunate ones. A breakdown of vaccination statistics shows that the protected ones are fortunate not only in that respect, but that they tend to be the children blessed with other advantages as well.

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Take protection against polio, for example. Among children under 5 in Harrisburg, Pa., 65 percent of the upper socioeconomic group had received three or more Salk vaccine shots, compared to 35 percent in the lower socioeconomic group. In Atlanta, Ga., 78 percent of the children under 5 in the upper group were protected. For the lower group the figure was 30 percent.

Maps that plot the geographic location of cases of paralytic polio in recent years graphically tell the story of our failures. Before the advent of vaccine, cases of polio were spread out quite evenly, throughout a city. Today, cases of paralytic polio are concentrated in a city's central core. This is where the poorer, the less privileged, the minority groups are to be found, and this is where the unvaccinated remain.

At the 1960 midwinter clinical sessions of the American Medical Association, Dr. E. Russel Alexander, Chief of the Surveillance Section of the U.S. Public Health Service Communicable Disease Center, gave a report on the distribution of cases of paralytic polio since the discovery of Salk vaccine. We find this report profoundly disturbing. I am now quoting from it:

> Fundamentally, there is a concentration among preschool, lower socioeconomic children in crowded urban areas and selected rural localizations. This pattern was first seen in 1956, after widespread use of vaccine * * * a rather general distribution in Chicago in 1952, (contrasts) with a well demarcated concentration among lower socioeconomic groups in crowded slums in 1956, predominately Negro in this instance.
>
> This year in Providence, R.I., poliomyelitis was concentrated in children in lower socioeconomic housing developments, where failure to utilize the available vaccine, completely, has resulted in islands of susceptibles in an otherwise well-protected community. In Baltimore, the localization in crowded slums was even more evident; the attack rate in Negroes was approximately twice that in the white population, and large suburban areas remained free of disease.
>
> When the occurrence is in other than urban areas the pattern persists. Besides the concentrations among Negroes and Puerto Ricans in cities, we find concentrations in poor farming areas, among Indians, and isolated religious sects. In all instances the pattern of polio is the pattern of the unvaccinated.

The bill now before you represents the first proposal of sufficient scope and vision to deal effectively with this situation. With its enactment we can expect finally to reach those who have remained beyond the reach of the programs that have been attempted in the past, and thus to eliminate at last class differences in the protection of children against preventable infectious diseases. Attempts at the application of scientific diseases. Attempts at the application of scientific developments to prevent these diseases have depended until now on a combination of hopes, uncoordinated and loosely organized local campaigns, and on often chaotic distribution of vaccine supplies. This bill seeks to supplement the efforts which have not wholly succeeded with a program where the resources of the Federal Government can be utilized by local communities to make vaccines available and to provide needed organizing skills.

From the experience of the AFL–CIO in many community vaccination drives of the past, we are led to agree with the observation of the Secretary of Health, Education, and Welfare that "convenience and inexpensiveness will be the deciding factors to many groups of

individuals who have not been previously immunized." We support heartily Secretary Ribicoff's conclusion that it will be—

> necessary for each program to provide enough public or nonprofit community vaccination facilities to vaccinate at no or low cost all who wish to avail themselves of this method of vaccination and, in the case of children under 5, without charge for the vaccine or its administration.

The executive council of the AFL–CIO has reviewed the proposed legislation, and acted on April 27 to give its unanimous endorsement in the following statement:

> The executive council is most gratified to note that the President has proposed a program to eradicate polio, diphtheria, whooping cough, and tetanus from the Nation, and that legislation to put this program into effect has been introduced in the Congress by Senator Lister Hill and Representative Oren Harris.
>
> This country has the resources to eliminate these diseases, but these diseases are still causing disability and premature death. We are not applying our technical know-how, and we must.
>
> Improved techniques to control infectious diseases have not, up to now, benefited all Americans. For example, while the advent of Salk vaccine has greatly reduced the incidence of paralytic polio, among children under 5—a group particularly susceptible to polio—less than half have been adequately protected through vaccination. Children who live in slums and other blighted areas remain unprotected in even larger numbers, and these are the areas where the remaining cases of polio are predominantly to be found.
>
> The President's program, incorporated in the Hill-Harris vaccination assistance bills (H.R. 10541 and S. 29010), would authorize Federal funds to cover the full cost of vaccine for all children under 5 years of age, and to assist in meeting the cost of organizing vaccination drives.
>
> The AFL–CIO has long urged that more be done to make the benefits of medical discoveries widely available to all the American people. We are gratified that the Federal Government is exerting its leadership in this direction. We heartily support H.R. 10541 and S. 2910, and expect to cooperate with other voluntary groups and public agencies in implementing in all communities the immunization program contemplated by this legislation.

In conclusion, Mr. Chairman, on behalf of our members and their families, we strongly urge this committee to act promptly and favorably on this program, so that we may hasten the day when suffering and death from polio, diphtheria, whooping cough, tetanus, and other infectious diseases will no longer coexist with the scientific techniques which could prevent them.

The CHAIRMAN. Thank you, Mr. Biemiller.

Mr. Hemphill, have you got any questions?

Mr. HEMPHILL. No, thank you, Mr. Chairman.

The CHAIRMAN. Mr. Younger, do you have any questions?

Mr. YOUNGER. No.

The CHAIRMAN. We appreciate having your support for this program. There have been a good many questions that have cleared up some of the things in the program and you heard the testimony of the Secretary this morning. Would it be appropriate to say that you share approximately the same views that he expressed with reference to some adjustments that could be made to this bill?

Mr. BIEMILLER. Yes, Mr. Chairman, that is correct. I sat through practically all of the Secretary's testimony and I would concur in the views that he expressed this morning on certain adjustments that you think are needed in the bill.

We in the labor movement have known for years that almost any piece of legislation can be improved and sometimes modifications are needed here and there. Certainly I saw nothing in the testimony of

the Secretary this morning that I think would do harm to the bill, and any improvements that will hasten its passage are devoutly to be desired.

The CHAIRMAN. Thank you very much. We do appreciate your appearance here.

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

The CHAIRMAN. And the lady with you, Mr. Biemiller.

Miss BAMBERGER. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Clinton R. Miller, assistant to the president, National Health Federation, here in Washington.

Mr. Miller, you may proceed.

STATEMENT OF CLINTON R. MILLER, ASSISTANT TO THE PRESIDENT, NATIONAL HEALTH FEDERATION, WASHINGTON, D.C.

Mr. MILLER. Mr. Chairman, for the record I am Clinton Miller, assistant to the president of the National Health Federation. Our main office is 709 Mission Street, San Francisco 3, Calif. Our Washington office is at 1012 14th Street, Washington, D.C.

Mr. Chairman, in order to save the time of yourself and the committee, may I request that my statement be included in the record and I should like to confine my oral statement to a few brief remarks.

The CHAIRMAN. Mr. Miller, under the rules, that is the procedure that we have here which, of course, is part of the Reorganization Act of 1946, and therefore I was going to suggest that you might pursue this course and your statement will be put in the record at this point.

(The document referred to follows:)

STATEMENT BY CLINTON R. MILLER, REPRESENTING THE NATIONAL HEALTH FEDERATION

The National Health Federation is a nonprofit, health rights corporation with its main offices at 709 Mission Street, San Francisco, Calif. Our Washington office is in the Continental Building, 1012 14th Street, NW., Washington 5, D.C.

The National Health Federation is a national organization, composed of thousands of members who believe in freedom of choice in matters of health where the exercise of that freedom does not violate the equal freedom of another.

We wish to appear as a witness and to file a statement for the record. The presentation of testimony by the National Health Federation in opposition to H.R. 10541 does not mean that the National Health Federation is opposed to vaccination as a means of protection of individuals against poliomyelitis, diphtheria whooping cough, tetanus, and other diseases which may in the future become susceptible of practical elimination through vaccination.

The National Health Federation has members who believe in the efficacy of vaccination, who have had themselves and their children vaccinated, and who urge others to do likewise.

Their urging, however, would stop short of supportiing legislation to make their own views the official views of America. They would stop short of supporting legislation to require other members of the National Health Federation and of America, who do not believe in vaccination to pay the cost of intensive community vaccination programs through taxation to support Federal grants.

They believe in freedom of choice in matters of health with the same intensity that they believe in freedom of choice in matters of religion. The only time they would feel justified in violating an American's exercise of his freedom of choice in matters of health would be when such exercise of freedom violated the equal right of another. Clearly at the present time no one is denied vaccination for themselves or their children if they desire it. Therefore, citizens who exercise their freedom of choice by choosing not to be vaccinated are not denying an equal right to another by the exercise of this freedom.

This principle of freedom is a superior and more fundamental consideration than that of vaccination. There are those people who so stoutly believe in the principle of vaccination that their enthusiasm leads them to an intolerance of anyone who just as stoutly does not believe in it.

So long as the Government maintains a neutral role, and allows the exchange of ideas on vaccination or other health beliefs to be between individuals and groups of individuals, there will be a healthy exchange of ideas and approaches which will lead to practical elimination of the specific diseases mentioned in H.R. 10541, and others.

It is granted that this insistence on freedom will allow some to make mistakes. It is acknowledged that some will make bad choices. But isn't that what freedom is?—the right to be wrong? If we are not free to make wrong choices, then we are not free. The tyranny that forces a man to be healthy is as much to be feared as the tyranny that forces a man to be good.

To those who would argue that freedom in economic matters is one thing, but that a mistake in the matter of vaccination can be fatal, we would agree that this is true. Those who defend freedom must be prepared to share the responsibility for those who suffer from poor choices. But we would point out that if a person makes a poor choice in religion, some claim that they might be consigned to an eternity of torment. Yet we allow people in this country freedom in such an important matter.

This does not mean that we are indifferent to God as a nation, or are unaware that individuals will make bad religious choices. It does mean that we believe as a nation, and the founders of our Constitution believed that the protection of the freedom of choice in these matters is the best way for the most people to make the right choice. It has the refreshing defense that those who make the wrong choice have only themselves to blame, and are the only ones to suffer.

Those who believe in freedom of choice in matters of politics, religion, and health, emphasize that minority views of one generation become majority views of another. History has a wonderful lesson to teach us here if we will learn it. History will record a man of one age as a wise man, even though subsequent research might prove his theories to be in error, if he refrained from force of any kind in sharing of his beliefs with his disciples and contemporaries. But it will record the same man with the same theories as a fool or a tyrant, who uses, or allows to be used, force of any kind—not the least of which is governmental force—to gain acceptance for his beliefs.

Humility about the extent of one's knowledge, or of the collective knowledge of any age is always the mark of greatness, progress, and understanding. It breeds tolerance, love, unity, and all the other human virtues that make for a happy existance while we individually and collectively live our earthly existence.

Freedom in matters of religion were not lightly come by, for history records many martyrs who died to explain this yearning for freedom to later generations. The problem is still unresolved as to which martyr died for the truest religion, but it is clear that there was a unity among all martyrs in their belief that "Congress (the state) shall make no law respecting an establishment of religion or prohibiting the free exercise thereof * * *". It remained for American patriots to embody this belief in a Constitution.

Dr. Benjamin Rush a signer of the Declaration of Independence, and Congressman is quoted as saying "The Constitution of the Republic should make provision for medical freedom as well as for religious freedom. To restrict the art of healing to one class of men and deny equal privileges to others will constitute the bastile of medical science. All such laws are un-American and despotic. They are fragments of monarchy and have no palce in a Republic."

We maintain that this right was implied, if not written. If his suggestion had been embodied in the Constitution as one of the Bill of Rights, we would be considering this legislation in a different light today. Substitute the phrase "intensive religious programs" for "intensive vaccination programs" in the bill H.R. 10541, and you will see how clearly it would have violated such an amendment, had it been written, and included in the Bill of Rights.

But the fact is that it was not written, and we are left to argue that it was certainly implied. At the time Benjamin Rush made this plea, it was argued that this "right" was assumed by the guaranteed freedom of religion and didn't need to be codified. This was true for his time. Dr. Rush's concern was for the future, not the then present possibility of abuse in this matter. Incidentally, Dr. Rush was a strong believer in vaccination theories of Jenner, but emphasized the greater need for freedom in all health matters. It has fallen the lot of this

generation to solve this problem. The bill H.R. 10541 is one testing ground for the limitation or extension of governmental control in matters of health.

Dr. Herbert Ratner, M.D., director of public health, in Oak Park, Ill., and associate clinical professor of preventive medicine and public health, Stritch School of Medicine, Chicago, has raised some penetrating questions on the Salk vaccine and mass vaccination. In my written statement, I have included his letter to the editor published January 21, 1956, in the Journal of the American Medical Association (vol. 160, No. 3, pp. 231–232). At this time (1956) Dr. Ratner was a rather lonely voice, critical of the Salk vaccine promotors inadequate information to the medical profession. He charged "We should recognize that only one side of the ledger is being presented by the promoters of this vaccine."

Other prominent medical doctors, biostatisticians, and scientists were found to share Dr. Ratner's concern to have both sides of the ledger fairly presented. The Illinois Medical Journal of August 1960 (vol. 118, No. 2), printed a panel discussion entitled "The Present Status of Polio Vaccines." This was presented before the section on preventive medicine and public health at the 120th annual meeting of the ISMS in Chicago, May 26, 1960. I have included this article with bibliography and notes in my written statement. The distinguished panelists were Herald R. Cox, Sc. D., Pearl River, N.Y.; Bernard G. Greenberg, Ph. D., Chapel Hill, N.C.; Herman Kleinman, M.D., Minneapolis; Paul Meir, Ph. D., Chicago.

In this article, Dr. Herbert Ratner points out that—"In the fall of 1955 Dr. Langmuir had predicted that by 1957 there would be less than 100 cases of paralytic polio in the United States. As you know, 4 years and 300 million doses of Salk vaccine later, we had in 1959 approximately 6,000 cases of paralytic polio, 1,000 of which were in persons who had received three, four, and more shots of the Salk vaccine. So you see, expectancy of the Salk vaccine has not lived up to actuality, and Dr. Langmuir was right when he said the figures of 1959 were sobering."

A quote by Dr. Langmuir pointed out the reason for the panel. He was in charge of polio surveillance for the U.S. Public Health Service, and had been an ardent proponent of the Salk vaccine even prior to the Francis report of 1955. In a symposium on polio in New Jersey the previous month, he had stated that a current resurgence of the disease, particularly the paralytic form, provides "cause for immediate concern" and that the upward polio trend in the United States during the past 2 years (1958 and 1959) "has been a sobering experience for overenthusiastic health officers and epidemiologists alike."

Dr. Ratner pointed out that "Prior to the introduction of the Salk vaccine, the National Foundation defined an epidemic as 20 or more cases of polio per year per 100,000 population. On this basis there were many epidemics throughout the United States yearly." After its introduction, a community was considered to have an epidemic when it had 35 cases of polio per year per 100,000 population. No reason is given for changing the rules. But in a community that before Salk vaccine release and by the old rules (of 20 per 100,000) would attract headline attention because of an "epidemic" could have the same number and more cases after 1955, and not a word woulld be printed. Indeed, there were less "epidemics" after the introduction of the Salk vaccine in 1955. But it was because they had changed the definition of an epidemic. It was not a real, but a semantic elimination of epidemics. It is no wonder that some physicians who remained skeptical about the original theories behind the vaccine, became increasingly bold in exposing the fallacies used in its evaluation.

Dr. Bernard Greenberg, the panel's statistician states: "as such (a statistician), my primary concern, my only concern, is the very misleading way that most of this data (on the Salk vaccine) has been handled from a statistical point of view."

He deals a devastating blow to the arguments of the Public Health Service that the increase in paralytic polio for 1958 and 1959 could be blamed on those who refused to be vaccinated (about 49 percent of the American population). Professor Greenberg is head of the Department of Biostatistics of the University of North Carolina School of Public Health and former chairman of the Committee on Evaluation and Standards of the American Public Health Association. Follow carefully his excellent argument, for it is a sound rebuttal against the need for the mass vaccination bill, H.R. 10541.

Dr. Bernard Greenberg: "There has been a rise during the past 2 years in the incidence rates of paralytic poliomyelitis in the United States. The rate in 1958 was about 50 percent higher than that for 1957, and in 1959 about 80 percent higher than in 1958. If 1959 is compared with the low year of 1957, the increase is about 170 percent. At the same time, the rates for nonparalytic polio have been declining in relation to the 1957 base.

"As a result of this trend in paralytic poliomyelitis, various officials in the Public Health Service, official health agencies, and one large voluntary health organization have been utilizing the press, radio, television, and other media to sound an alarm bell in a heroic effort to persuade more Americans to take advantage of the vaccination procedures available to them. * * *

"One of the most obvious pieces of misinformation being delivered to the American public is that the 50-percent rise in paralytic poliomyelitis in 1958 and the real accelerated increase in 1959 have been caused by persons failing to be vaccinated. This represents a certain amount of doubletalk and an unwillingness to face facts and to evaluate the true effectiveness of the Salk vaccine. It is doubletalk from the standpoint of logical reasoning: If the Salk vaccine is to take credit for the decline from 1955 to 1957, how can those individuals who were vaccinated several years ago contribute to the increase in 1958 and 1959? Are not these persons still vaccinated?

"The number of persons over 2 years of age in 1960 who have not been vaccinated cannot be more, and must be considerably less, than the number who had no vaccination in 1957. Yet a recent Associated Press release to warn about the impending threat referred to the idea that the 'main reason is that millions of children and adults have never ever been vaccinated.' If they were never vaccinated, undoubtedly many more than were reported were unvaccinated during 1955, 1956, and 1957 when the same officials were claiming that the reduction in rates was due to the vaccine. * * *

"A scientific examination of the data, and the manner in which the data were manipulated, will reveal that the true effectiveness of the present Salk vaccine is unknown and greatly overrated."

Dr. Greenberg further reveals two instances where the PHS revealed bias in faulty statistical manipulations in the poliomyelitis surveillance unit study. The PSU had reported about 80 percent effectiveness in North Carolina for a single shot when in fact one dose was practically ineffective.

But the most incredible discovery is a change in the rules by changing the definition of "paralytic poliomyelitis" before and after the 1955 introduction of the Salk vaccine. It is like comparing a sneeze and pneumonia. "Prior to 1954," Joan Beck, in reporting this same panel in the Chicago Sunday Tribune (Mar. 5, 1961), observes, "any physician who reported a case of paralytic poliomyelitis was doing his patient a favor because funds were available to help pay his medical expenses (from a large voluntary health organization). At that time most health departments used a definition of paralytic poliomyelitis which specified "partial or complete paralysis of one or more muscle groups, detected on two examinations at least 24 hours apart." Laboratory confirmation and the presence of residual paralysis were not required.

"In 1955, these criteria were changed. Now, unless there is paralysis lasting at least 60 days after the onset of the disease, it is not diagnosed as paralytic polio.

"During this period, too, Coxsackie virus infections and aseptic meningitis have been distinguished from paralytic poliomyeltis," explained Dr. Greenberg. "Prior to 1954, large numbers of these cases undoubtedly were mislabeled as paralytic polio."

One cannot expect these startling facts to be kept under cover in America, no matter how strong the national desire to believe in the Salk vaccine. As I have indicated, the Chicago Sunday Tribune featured a three-page article by Joan Beck entitled "The Truth About the Polio Vaccines" (Mar. 5, 1961) which I have included in full in my written statement.

This was followed by "A Note on Polio" in the Saturday Review on April 1, 1961. I have included the note in full with its chart in my written statement, but a significant political tie-in is worthy of note here—I quote the Saturday Review:

"During the month of March 1961, the President of the United States, John F. Kennedy, announced that in the name of the American people he had authorized a gift of Salk 'killed virus' polio vaccine to the people of Cuba to fight a polio epidemic on that unhappy island.

"At least one physician who heard of the President's action wired the White House an immediate warning that the Salk vaccine is known to be ineffective in stopping the spread of a going epidemic.

"The warning wire pointed out that the Russian wooers of Cuba's Fidel Castro are well acquainted with the superior effectiveness of oral live vaccines (the Sabin vaccine is only one of three) developed in this country and used widely in the U.S.S.R. but not yet available here.

"It was after that wire was delivered that President Kennedy asked the Congress to appropriate special funds for a standby supply of oral live virus polio vaccine.

"Who gave the President the poor advice that led to the meaningless gift to Cuba?

"SR's science editor does not pretend to know. But normal routes of responsibility in such matters lead to the U.S. Public Health Service, which, along with the National Foundation for Infantile Paralysis, has been pushing the Salk vaccine.

"Around the same time that the President was being taken off balance, the Journal of the American Medical Association published, in answer to a doctor-reader's question, a statement by Dr. Herbert Ratner, public health officer of Oak Park, Ill. (largest village in the world), that "it is now recognized that much of the Salk vaccine used in the United States has been worthless. * * * because it is an unstandardized product of an unstandarized process."

It should be observed here that H.R. 10541 is an amendment to sec. 2, part B, of title III of the Public Health Service Act, and we assume would be administered by the PHS. A subsequent issue of the AMA Journal carried a series of articles by three U.S. Public Health officials admitting that the Salk vaccine's value had been greatly overestimated, but still insisting that it was highly effective. Now we are faced with the possibility that it causes cancer. In the Chicago Sun-Times, Monday, April 16, 1962, there is an article by Earl Ubell on SV–40, a newly discovered "something" in Salk vaccine. The article contains this conjecture:

"Conjecture No. 1: SV–40 may cause cancer in human beings. This, of course, is the most frightening idea. Millions of persons have received Salk injections (killing the polio virus does not mean killing SV–40).

"Now the latest work shows that SV–40 can grow in the tissue of human beings and can make cells grow faster. But many viruses can do this without causing cancer. However, the report on the chromosomes makes the cancer possibility somewhat stronger."

Now the purpose of the NHF in reading this testimony into the record is not, we again emphasize, that we are opposed to vaccination, and certainly not to the Salk vaccine as singled out from the others. As strong a case can be made against the oral vaccines (there are now three), and the vaccines used for diphtheria, whooping cough, and tetanus, the other three specific concerns of the bill. We simply want to be sure there is a clear understanding that there is far from unanimity of thought in America on the subject even among those who believe in the principle of vaccination. To rush through H.R. 10541 without fully amending it to allow no whisper of force or coercion to be exercised against those who might oppose the particlar vaccination approach chosen would be less than wise.

Here we wish to point out that in local and State laws, it has been customary to allow those who have contrary religious convictions to be allowed to refrain from participation in otherwise compulsory vaccination programs. We believe that this protection (of religious conscience) should be included in any legislation on vaccination, but further, that it should clearly specify that a person can refuse vaccination if it is contrary to his beliefs. They do not have to be religious.

We are aware that there is no provision for complusion in H.R. 10541, but the phrases "intensive community vaccination programs (p. 2, lines 3, 10, 19, etc.), and "the immunization over the period of the program of all, or practically all" (p. 3, lines 7, 8, and 9), and especially, "and which includes plans and measures looking toward the strengthening of ongoing community programs for the immunization of infants and for the maintenance of immunity in the remainder of the population" (p. 3, lines 10 and 14), raises questions of compulsion. Many "ongoing community programs have compulsory requirements, often tied into registration for public schools. This would be a possible place for the insertion of the amendment "provided that any person may refuse vaccination for themselves, their children, or wards if it is contrary to their belief, which includes, but is not restricted or limited to, religious belief."

If, in the light of all the testimony given to this committee, it is decided by the majority that the bill is desirable, we most strongly urge that this guarantee of freedom be included as an amendment.

We further urge that no money be granted to support an "ongoing community program" unless that local program carries the protection of this freedom-of-conscience amendment.

People feel very deeply about their religion, health, and politics, and should have freedom under the law from compulsion in these fields, so long as by the exercise of this freedom they don't endanger the health of others and thereby deny them an equal freedom. Clearly, a demand for protection against force or compulsion to participate in mass vaccination programs does not deny any citizen an equal right to participate in them nor the protection that such participation provides.

THE QUESTION OF SIDE EFFECTS OF SERA AND VACCINES

At this point in my written statement, I have included seven pages from the book "Side Effects of Drugs" compiled by L. Meyler, M.D. This reports on the unwanted effects of drugs, sera, and vaccines, as reported in the medical literature of the world during the period 1958–60. It was published in 1960 by the Excerpta Medica Foundation, Amsterdam, London, and New York. We have reprinted pages 194–200.

The bill does not concern itself with the matter of side effects of vaccines. It assumes that there is either a broad general knowledge among the public of this ugly, dangerous (and sometimes fatal) side effect of vaccination, or else that such information is not needed or wanted by the mass of U.S. citizens to be vaccinated. We disagree with either assumption. We insist that the American public have the right and the intelligence to evaluate the good with the bad of any vaccination program. They should be fully informed of the expectations, limitations, and most certainly the side effects of vaccination. The critic of the program should have the same right to file a "minority report" which should accompany press releases lauding the efficiency and stressing the urgency of any particular vaccination program. This should be a built-in safeguard of check and balance in medical experiments with mass populations. There is no more validity here for the argument that "this is a matter for the experts" than there is in the field of politics. After all, in politics we are concerned with a possible loss of freedom, and in vaccination programs with loss of life or health. There are some cures that are worse than the disease.

Consider the following from page 197 of Dr. Meyler's book:

"Pertussis vaccine (whooping cough). Up to now some 100 cases of encephalitis have been reported. In half of the cases, the phenomena set in within 6 hours after the injection, and never later than 72 hours. About half of the patients made a complete recovery, about one-third had serious permanent neurological lesions, and about one-sixth died. The increased susceptibility to poliomyelitis is stressed. The value of pertussis immunization is stressed, but so is the grave danger of further inoculations when a previous one has produced any suggestion of a neurological reaction.

"On account of the risk of encephalitis, it is advised not to vaccinate children if epilepsy, seizures, encephalitis, or mental disorders have occurred in their family history. If the child has had an infectious disease, the vaccination should be postponed until 4 months afterward. Children who have recently been vaccinated against variola or polio should not be vaccinated. During an epidemic of poliomyelitis, no vaccinations should be given."

Here it should be noted that maybe there is room for a congressional investigation into the problem of reporting epidemics. Is a polio epidemic 20 cases per 100,000 or is it 35 cases per 100,000? Who decides upon what evidence what constitutes an epidemic? Was importance of polio epidemic knowledge to parents about to consider whooping cough vaccinations taken into consideration when the rule was changed in 1955? Does the change in the rule of reporting polio epidemics present a hazard to children planning whooping cough vaccination because epidemics that were epidemics in 1954 are not now reported as epidemics in 1962? To what degree are other vaccinations contraindicated during polio epidemics?

On page 198, Dr. L. Meyler reports:

"Diphtheria vaccine: A 1½-year-old child became severely ill after the second injection and died in coma 4 days afterward. The first injection had not produced any signs."

In mass vaccination programs it is common practice to omit or ignore such information in presenting the case for vaccination to the public. There is a tendency to let the "experts" make the decisions, after which they summarize the evidence with such press release statements as "absolutely safe," and other statements designed not to educate, but to inspire absolute confidence.

We point out that the tendency of a mass vaccination program is to herd people. People are not cattle or sheep. They should not be herded. A mass vaccination program carries a built-in temptation to oversimplify the problem; to exaggerate the benefits; to minimize or completely ignore the hazards; to discourage or silence scholarly, thoughtful, and cautious opposition; to create an urgency where none exists; to whip up an enthusiasm among citizens that can carry with it the seeds of impatience, if not intolerance; to extend the concept of the police power of the state in quarantine far beyond its proper limitation; to assume simplicity when there is actually great complexity; to continue support of a vaccine long after it has been discredited; to make a choice between two or more equally good vaccines and promote one at the expense of the other; and to ridicule honest and informed dissent.

President Kennedy, in the state of the Union message January 30, 1961, said: "Let it be clear that this administration recognizes the value of daring and dissent—that we greet healthy controversy as the hallmark of healthy change."

A bill such as H.R. 10541 without amendment safeguards could well discourage what little "healthy controversy" still exists in the field of vaccination.

John Stuart Mill has said: "It often happens that the universal belief of one age—a belief from which no one was free, nor without an extraordinary effort of genius could, at that time, be free—becomes to a subsequent age so palpable an absurdity that the only difficulty is to imagine how such a thing can ever have appeared credible."

It is conceivable that a future age may disdainfully look at our preoccupation with vaccination. Indeed, the entire concept may be replaced with another approach. In such an eventuality, it would record as statesmen or tyrants the lawmakers who protected or trampled the rights of those who opposed the concept for one reason or another in this age.

I submitted or will submit with this summary, to the clerk of the committee, the following articles or abstracts of articles or books which I respectfully request be inserted into the record of this committee hearing:

1. A letter to the editor by Dr. Herbert Ratner, M.D., to the Journal of the American Medical Association, January 21, 1956, volume 160, No. 3, pages 231 and 232.
2. Part I and part II of an article, "The Present Status of Polio Vaccines," a panel discussion reprinted from the Illinois Medical Journal, volume 118, No. 2, August 2, 1960, and volume 118, No. 3, September 1960.
3. Bibliography and notes on the article "The Present Status of Polio Vaccines," Illinois Medical Journal, prepared by Dr. Herbert Ratner, M.D.[1]
4. An answer to a doctor-reader question by Dr. Herbert Ratner in the Journal of the American Medical Association.
5. A three-page article in the Chicago Tribune magazine, March 5, 1961, by Joan Beck, entitled "The Truth About the Polio Vaccines."
6. "A Note on Polio," with chart, from April 1, 1961, issue of Saturday Review.
7. An article, "Polio Vaccine Virus Puzzles Scientists," from the Chicago Sun Times, April 16, 1962.
8. Pages 194 to 200 (ch. XXVI), "Sera and Vaccines," from "Side Effects of Drugs," compiled by Dr. L. Meyler, M.D., 1960.[1]
9. Pages 138 to 150 and pages 163 to 172 from "Who Is Your Doctor and Why?" by Dr. Alonzo J. Shadman, M.D., House of Edinboro, Boston, 1958, Library of Congress catalog card No. 58–10390. This briefly explains the homeopathic medical doctor's approach to vaccination and polio.[1]
10. A booklet, "Diet Prevents Polio," by Dr. Benjamin P. Sandler, M.D.[1]
11. An article, "The Changing Incidence and Mortality of Infectious Disease in Relation to Changed Trends in Nutrition," by Dr. W. J. McCormick, M.D., Toronto, Canada.[1]

The CHAIRMAN. You may proceed to give a résumé of it.

Mr. MILLER. I appreciate this courtesy, Mr. Chairman, and in the interests of time, along with my statement I should like permission to include in the record the following abstracts or articles and one booklet which give different viewpoints on the vaccination question.

Specifically, I list a booklet on polio by Dr. Benjamin P. Sandler, selected pages on vaccination and polio by Dr. Alonzo J. Shadman, and an article by Dr. W. J. McCormick, M.D., of Toronto, Canada, and other articles and letters by Dr. Ratner, Dr. Meyer, et cetera, as I have listed on page 17 of my written report.

The CHAIRMAN. Very well. They may be included in the record. I note, however, that the reference to Dr. Sandler is in the form of a booklet. It has additional information, including certain tables. I don't believe we would be able to include the entire booklet in the record, but we will receive it for the files for the benefit of the committee.

Mr. MILLER. The reason I mentioned that particular booklet first, Mr. Chairman, is because of the unique nature of the testimony that it contains. The booklet is entitled "Diet Prevents Polio," and it is the burden of the author's thesis that a blood sugar level which can be controlled by the diet can prevent polio without any vaccination—he is not opposed to vaccination as he states in the book, but he presents his interesting theory that diet alone can render immunity to polio. And I feel that the entire book is necessary for the members of the committee who might wish to examine this rather unusual thesis.

The CHAIRMAN. It will be available for all members of the committee.

(The documents referred to follow:)

[Reprinted from the Journal of the American Medical Association, Jan. 21, 1956]

POLIOMYELITIS VACCINE

To the EDITOR:

During the week of November 14, 1955, at meetings of the American Public Health Association in Kasas City, the U.S. Public Health Service released two reports on poliomyelitis. One report on November 15 presented by Dr. Langmuir's group from the Poliomyelitis Surveillance Committee stressed the great effectiveness of one inoculation of the Salk vaccine used in 1955, namely, a 50- to 80-percent reduction in paralytic poliomyelitis. The other report on November 17, presented by Dr. Scheele, stressed the safety of the current Salk vaccine. The widespread national publicity that followed these reports naturally led the public and medical profession at large to believe that we now had a safe and highly effective vaccine. However, what was not made sufficiently clear in the reports and the press stories that covered the country was that the first report, stressing excellent effectiveness, referred to an earlier model of a Salk vaccine and that the second report, stressing current safety, referred to a later model. The effectiveness report on the earlier model was based on results achieved in children, the bulk of whom received vaccines that were manufactured prior to the development of the postinoculation poliomyelitis cases first reported on April 27. Such vaccines were admittedly the product of a process in which there were "fundamental weaknesses in the safety testing procedures" (Scheele, Aug. 25), which did not have the benefit of the more sensitive cortisone-treated monkey tests (formally required on September 10) and which did not have the advantage of crucial filtration procedures that followed the recognition of "the absolute need for removal of particles within which virus may be protected from inactivation by formaldehyde" (Scheele, Nov. 17).

There is substantial evidence (Bulletin of the American Association of Public Health Physicians, November 1955) indicating that manufacturers' vaccine, other than Cutter's, had varying amounts of live virus in it and that what is

[1] In committee files.

being measured for effectiveness is not Salk's killed virus vaccine but a live virus vaccine labeled Salk—obviously powerful but also more dangerous. At any rate, it should be evident that the Salk vaccine, for which great effectiveness is claimed on the basis of one inoculation, is a product that is no longer on the market nor in the hands of physicians (we hope) and that was the product of an inadequate manufacturing process and inadequate and relatively less sensitive safety tests. The report on November 17, dealing with the current Salk vaccine's safety, is the interim report of the Public Health Service Technical Committee on Poliomyelitis Vaccine as published in the Journal, December 10, 1955. The publication of this report is intended to guide and to keep physicians informed of developments in the Salk vaccine program. The report itself has one striking peculiarity. Though it deals with dated decisions made at specific meetings held since May 26, not one single date is listed in the document. Not even is the date of the issuance of the interim report given. It is as if we are dealing with a timeless document that purports to give both active and retroactive reassurance.

Though the intention of this omission of dates is only knowable to the committee, the confusion leading from this omission is knowable to the reader. I will attempt to indicate the extent to which the report has been informative as to the nature of a safer Salk vaccine and, in the practical order, the extent to which his report adds to the current confusion. The summary highlights in the clarification of a safer Salk vaccine are as follows: (1) "the absolute need for * * * suitably spaced filtration procedures" (this provision made its first appearance in the minimal requirements as amended November 11, 1955) and (2) "a safety-test program * * * strengthened by improving sampling procedures * * * and by increasing the sensitivity of the monkey safety tests" (the test utilizing the cortisone-treated monkey made its first appearance in the minimum requirements as amended on September 10, and as reamended on November 11).

However, is this the vaccine that is in the hands of physicians and health departments? The interim report itself and the statement of Dr. Scheele, reported in Washington News in the Journal, December 3, leads us to believe that it is. In the latter news story, it is stated that "production of the Salk poliomyelitis vaccine, which has been lagging * * * will start picking up sometime in December and probably will reach a normal rate by February. Reason for the lag * * * is the major changes made last May in vaccine production and testing requirements and the continuing refinements since that date * * * [the] modifications were incorporated formally into minimum standards for producing and testing the vaccine on November 11 * * *."

However, it should be clear that the new requirements of last May subsequently resulted in steady production throughout the summer and did not cause the delay in the late fall production referred to above. It should also be remembered, as confirmatory, that in May it was recognized that the new requirements would only halt vaccine production temporarily. Therefore, the delay in production seems to be associated with the minimum requirements amended November 11. In an attempt to confirm this and to discover whether the vaccine in my possession (vaccine with an expiration date of April 6 and 7) conformed to the November 11 minimum requirements for safe production, inquiry was made of the manufacturer, a manufacturer who incidentally happens to be at present the leading producer of the Salk vaccine. The answer was disquieting. Not only did the vaccine in my possession not conform to the November 11 requirements but the more than 1 million cubic centimeters of vaccine issued by the same manufacturer the week of December 12 also did not conform to the November 11 requirements, insofar as it excluded a crucial filtration step required during the inactivation process. Furthermore, the manufacturer's representative stated that no such vaccine can be expected from them, and presumably other companies, until the end of January, though in the meantime they would continue to release vaccine already in process not conforming to these requirements.

The Salk vaccine, then, which we were encouraged to believe is both highly effective and safe on the basis of recent reports, turns out to be, when highly effective, a vaccine that is no longer on the market and, when safe, a vaccine that has yet to make its appearance and clinically prove its effectiveness. Yet, in the face of this paradox, the public is being urged from all directions, except

that of the practicing physician, to get their inoculations immediately. This, in spite of the fact that there is a shortage of vaccine and that the vaccine available is inferior if not obsolete. To complete the picture, other things should be said. All physicians hope and pray that we now have a safe and effective vaccine. This hope, however, should not rob us of our objective and critical faculties. When we have a safe and effective vaccine, we want to know it and not base it on slender, infirm, and contradictory criteria.

Categorically, the following remarks can be said, and I again refer the reader for further amplification to the Bulletin of the American Association of Public Health Physicians: 1. The epidemiological techniques of the poliomyelitis surveillance unit for the determination of clinical safety of the vaccine have proved and remain inadquate. This is highlighted in part by the U.S. Public Health Service in their finding of live virus in a seventh lot of Cutter vaccine, which previously was exonerated on epidemiological grounds. 2. The reporting of poliomyelitis cases associated with the vaccine has proved to be incomplete. The fact that poliomyelitis surveillance unit has dropped the reporting of crucial satellite cases is a case in point. 3. The fact that millions of children have been inoculated without overt and obvious harm is not a criterion for the safety of the vaccine. To begin with, even when a readily detectable live virus Salk vaccine was used in Idaho, only 1 out of over 1,600 children came down with poliomyelitis. This means that had the 7 million children, estimated to have received their first shot in the National Foundation for Infantile Paralysis program, been inoculated with a readily detectable live virus Salk vaccine, 6,996,000 would not have come down with poliomyelitis anyway. The careful surveillance that is necessary to assess safety in a vaccine with lesser amounts of live virus is obvious.

The Idaho data simply confirms the fact that poliomyelitis is a low-incidence disease and that there is a high degree of acquired immunity and many natural factors preventing the occurrence of the disease (as contrasted to an "infection") in the Nation at large. In Salk vaccines with lesser amounts of live virus, the crux of the danger lies in the production of carrier states and the development of satellite cases, which the U.S. Public Health Service has not been surveying since the middle of the summer and which were incompletely surveyed prior to this period. 4. Everyone should recognize that 1955 was a low poliomyelitis year independently of the use of the Salk vaccine, which was only given to 9 million children. The slight contribution that an unsafe Salk vaccine may have made to the reduction of paralytic poliomyelitis in 1955 is counterbalanced by the known contribution it made to the increase in paralytic poliomyelitis in 1955. 5. Physicians should recognize one peculiar aspect of the experts' recent decision to stick to a three-shot schedule for some for 1956 protection rather than one shot for many. Logic would dictate that, with the shortage of vaccine, it is better to have a 50- to 80-percent reduction of paralytic poliomyelitis in three times the number of people than to have an additional 20- to 50-percent protection in one-third the number. Presumably, experts are not convinced of the rough studies proving a high degree of effectiveness after one injection of the transferability of these statistics based on a replaced and suspect vaccine. 6. The medical profession should recall, in the light of the findings pertaining to safety in the interim report, that during the summer the promoters of the vaccine continued to urge mass inoculations in spite of recognized ignorance on their part. They were in the dark as to what had gone wrong with the Cutter vaccine, which had passed all established safety tests existing at the time. They also urged mass inoculation despite the fact that one of the two major producers of the vaccine since the field trials of 1954 had begun to find live virus in the vaccine back in May, by using testing procedures more stringent than those required by the Government, the reasons for which were unknown to the pharmaceutical house and the Government. Neither the public nor the medical profession was informed of these justified uncertainties, nor is it certain that we are yet being adequately informed. 7. Finally, we should recognize that only one side of the ledger is being presented by the promoters of this vaccine. The price that has been paid and the risks that have been taken for the dubious results that have been obtained are not mentioned. The price that we have paid, and are continuing to pay, goes far beyond those known vaccinated children who have come down with poliomyelitis.

HERBERT RATNER, M.D.,
Health Commissioner, Oak Park, Ill.

The Present Status of Polio Vaccines

(Presented before the Section on Preventive Medicine and Public Health at the 120th annual meeting of the ISMS in Chicago, May 26, 1960.)

[Note.—This panel discussion was edited from a transcript. Opinions presented are those of the panel members and do not necessarily represent those of the society]

Moderator: Herbert Ratner, M.D., director of public health, Oak Park, and associate clinical professor of preventive medicine and public health, Stritch School of Medicine, Chicago.

Panelists: Herald R. Cox, Sc. D., Pearl River, N.Y.; Bernard G. Greenberg, Ph. D., Chapel Hill, N.C.; Herman Kleinman, M.D., Minneapolis; Paul Meier, Ph. D., Chicago.

PART I[1]

Dr. Herbert Ratner. In this panel we are first going to discuss the Salk vaccine, later the live virus vaccine. None of us have any commitments or allegiances except to the truth. Dr. Cox, of course, is from a pharmaceutical house, but he is not here to sell you his vaccine. He happens to be one of the world's leading authorities on live virus vaccines, as well as killed vaccines. His reputation for integrity is exceptional and unchallenged. He has devoted 14 years to the development of the live polio virus vaccine specifically. He is here to share his knowledge with you. You will have full freedom to question and to dispute. Dr. Cox is director of virus research at Lederle, and is at present, president elect of the Society of American Bacteriologists.

Dr. Kleinman is an epidemiologist from the Minnesota Department of Health. He is intimately connected with that department's pioneering field studies on Cox live polio virus vaccine. Yesterday, he landed from Russia, where he was an official delegate of the U.S. Public Health Service at a conference on polio virus vaccines. He was coauthor in 1957 with Dr. Leonard Schuman of a paper entitled, "The Efficacy of Polimyelitis Vaccine with Special Reference to Its Use in Minnesota 1955–1956," wherein they concluded that "analysis has revealed (that) the use of two doses of Salk poliomyelitis vaccine * * * (was) 83 percent protective against paralytic poliomyelitis."

Professor Meier is a biostatistician from the University of Chicago. In the field of polio, he is best known for his analysis "Safety Testing of Poliomyelitis Vaccine" (Science, May 31, 1957), which suggested that a searching study of the entire Salk vaccine program by an appropriate body be conducted. Despite the attempt of the editors to initiate a debate on the crucial issue of safety testing, proponents of Salk vaccine remained silent.

Professor Greenberg is head of the department of biostatistics of the University of North Carolina School of Public Health and former chairman of the Committee on Evaluation and Standards of the American Public Health Association. In the past he has presented several papers on methodologic problems in the determination of the efficacy of the Salk vaccine.

The reason for this panel on the present status of polio vaccines is best expressed by a quote from Dr. Alexander Langmuir. He is in charge of polio surveillance for the USPHS, and has been an ardent proponent of the Salk vaccine even prior to the Francis report of 1955. In a symposium on polio in New Jersey last month he stated that a current resurgence of the disease, particularly the paralytic form, provides "cause for immediate concern" and that the upward polio trend in the United States during the past 2 years

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"has been a sobering experience for overenthusiastic health officers and epidemiologists alike."

In the fall of 1955 Dr. Langmuir had predicted that by 1957 there would be less than 100 cases of paralytic polio in the United States. As you know, 4 years and 300 million doses of Salk vaccine later, we had in 1959 approximately 6,000 cases of paralytic polio, 1,000 of which were in persons who had received 3, 4, and more shorts of the Salk vaccine. So you see, expectancy of the Salk vaccine has not lived up to actuality, and Dr. Langmuir was right when he said the figures of 1959 were sobering.

In preparation for the discussion, it was thought best to review some basic facts of polio: incidence, natural history, the disease, and immunity, all important to the understanding of the vaccine problem. Table 1 presents current data on incindence of paralytic polio. Figure 1 presents the natural variations in incidence of polio and infectious hepatitis. Both diseases were in a natural decline when the Salk vaccine was introduced in 1955. Since the wide acceptance of the Salk vaccine was based primarily on the sharp decline in polio incidence, it is important to keep in mind that infectious hepatitis equally declined following the Salk vaccine.

Figure 2 shows what the incindence of paralytic polio would have been from 1951 through 1959 if the figures were corrected for the radical changes in diagnostic criteria since the introduction of the Salk vaccine. Dr. Greenberg will discuss some of these changes later. The solid columns in figure 2 represent a conservative estimate of what the incidence of paralytic polio would have been in former years if the diagnostic criteria of 1959 had been used. This permits a more accurate comparison. It also helps us evaluate the progress or lack of progress made since the introduction of the Salk vaccine.

Table 1.—*Paralytic polio cases in the United States in 1957, 1958, 1959, including paralytic polio cases in Salk vaccines*

	Total	Increase over 1957 (percent)	Salk vaccinated			
			1 or more doses	3 doses	4 doses	3 or more doses
1957	[1] 2,158		[2] 658			[2] 206
1958	[1] 3,122	45	[3] 571	[3] 237	[3] 10	[3] 247
1959	[1] 5,694	164	[4] 1,870	[4] 750	[4] 178	[4] 928

[1] National Office of Vital Statistics figures: Morbidity and Mortality. USPHS vol. 8, No. 52, Jan. 8, 1960.

[2] Polio surveillance figures: Thrupp, Lauri D., et al.: Poliomyelitis in the United States, 1957. Public Health Reports 74:535–545, June 1959.

[3] Polio surveillance figures: Polio Surveillance Unit Report No. 160, Dec. 5, 1958. These figures are only through Nov. 20, 1958. Also omitted are cases of paralytic polio among 179 cases for which age and/or vaccination status are unknown. The true figures are higher.

[4] Polio surveillance figures: Polio Surveillance Report No. 197, May 16, 1960.

Note.—These figures do not include cases of paralytic polio among 237 cases for which PSU did not receive any separate reports, in 184 cases in which the vaccine status was unknown, and in an unknown number of cases whose original diagnosis was changed as a result of "a 60-day followup report which included a verification of the diagnosis, (and) an estimate of the severity of residual paralysis." "The paralytic category [now] includes 4,783 cases with residual paralysis at 60 days plus 689 cases with a preliminary diagnosis of paralytic poliomyelitis for which no followup data were received." That the switch from paralytic cases to nonparalytic cases on the basis of the absence of residual paralysis in those with 3 or 4 doses of Salk vaccine is considerable may be gathered by comparing the final report on 1959 (Report 197), which includes followup data through Feb. 29, 1960, with the preliminary report in an earlier PSU Report No. 193, which includes followup data through Jan. 11, 1960. This should be understood in the light of Dr. Langmuir's remark to State epidemiologist in his letter of Sept. 29, 1959, that, "In the final analysis, even a small number of corrections may make crucial differences in the evaluation of effectiveness of vaccine. A revoked diagnosis or a switch of diagnosis from paralytic to nonparalytic, or vice versa, in only 5 to 10 percent of cases could change basic conclusions remarkably."