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COMMUNICABLE DISEASE AND IMMUNIZATION
PROGRAMS

GOVERNMENT

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HEARING
BEFORE THE

SUBCOMMITTEE ON
PUBLIC HEALTH AND WELFARE
OF THE

COMMITTEE ON
INTERSTATE AND FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES

NINETY-FIRST CONGRESS

SECOND SESSION

ON

H.R. 15961

A BILL TO AMEND SECTION 351 OF THE PUBLIC HEALTH
SERVICE ACT SO AS TO CLARIFY THE INTENT TO INCLUDE
VACCINES, BLOOD, BLOOD COMPONENTS, AND ALLER-
GENIC PRODUCTS AMONG THE BIOLOGICAL PRODUCTS
WHICH MUST MEET THE LICENSING REQUIREMENTS OF
THIS SECTION

AND

H.R. 12067, H.R. 11913, H.R. 12116, H.R. 12153,
H.R. 13482, H.R. 16168, and S. 2264

BILLS TO AMEND THE PUBLIC HEALTH SERVICE ACT TO
PROVIDE AUTHORIZATION FOR GRANTS FOR COMMUNI-
CABLE DISEASE CONTROL AND VACCINATION ASSISTANCE

MARCH 13, 1970

Serial No. 91-44

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COMMUNICABLE DISEASE AND IMMUNIZATION PROGRAMS

FRIDAY, MARCH 13, 1970

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

The subcommittee met at 10 a.m., pursuant to notice, in room 2123, Rayburn House Office Building, Hon. Paul G. Rogers presiding (Hon. John Jarman, chairman).

Mr. ROGERS. The subcommittee will come to order.

The hearings today are on H.R. 15961, introduced by Chairman Staggers at the request of the Department of Health, Education, and Welfare, to specifically list certain products as licensable biologicals; and H.R. 12067, H.R. 11913, H.R. 12116, H.R. 12153, H.R. 13482, H.R. 16168, and S. 2264, similar bills to provide assistance to the States and political subdivisions to deal with communicable diseases, such as tuberculosis, venereal disease, rubella, measles, poliomyelitis, diphtheria, tetanus, whooping cough, or Rh disease or any other disease representing a major public health problem.

At this point in the record, there will be placed the text of the bills and the agency reports thereon.

(The text of H.R. 15961, H.R. 11913, H.R. 12067, H.R. 12116, H.R. 12153, H.R. 13482, S. 2264, and H.R. 16168, and departmental reports thereon follow:)

[H.R. 15961, 91st Cong., 2d Sess., introduced by Mr. Staggers (for himself and Mr. Springer) on February 17, 1970]

A BILL To amend section 351 of the Public Health Service Act so as to clarify the intent to include vaccines, blood, blood components, and allergenic products among the biological products which must meet the licensing requirements of this section

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 351 of the Public Health Service Act is amended by inserting after "antitoxin," each time such word occurs, the following: "vaccine, blood, blood component or derivative, allergenic product,".

[H.R. 11913, H.R. 12067, H.R. 12116, and H.R. 12153, 91st Cong., 1st Sess., introduced by Mr. Rogers of Florida on June 5, 1969; Mr. Staggers on June 11, 1969; Mr. Rosenthal (for himself, Mr. Addabbo, Mr. Biaggi, Mr. Bingham, Mr. Carey, Mr. Farbstein, Mr. Gilbert, Mr. Halpern, Mr. Koch, Mr. Podell, Mr. Powell, Mr. Ryan, and Mr. Scheuer on June 12, 1969; and Mr. Rosenthal (for himself, Mr. Brasco, and Mr. Murphy of New York) on June 16, 1969, respectively, are identical¹ as follows:]

A BILL To amend the Public Health Service Act to provide authorization for grants for communicable disease control

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Communicable Disease Control Amendments of 1969".

GRANTS FOR COMMUNICABLE DISEASE CONTROL

SEC. 2. Section 361 of the Public Health Service Act (42 U.S.C. 264) is amended by inserting at the end thereof the following new subsection:

"(e) (1) There are hereby authorized to be appropriated \$60,000,000 for the fiscal year ending June 30, 1970, and \$75,000,000 for the fiscal year ending June 30, 1971, and \$90,000,000 for the fiscal year ending June 30, 1972, to enable the Secretary to make grants to States and, with the approval of the State health authority, to political subdivisions or instrumentalities of the States under this subsection. In the award of such grants the Secretary, in accordance with appropriate regulations, shall give consideration to the relative extent of the communicable disease problems and to the levels of performance in preventing and controlling such diseases. Such grants may be used to pay that portion of the cost of communicable disease control programs which is reasonably attributable to (A) purchase of vaccines or other agents needed to protect those portions of the population determined to be epidemiologically important to the control or prevention of communicable diseases and (B) salaries and related expenses of additional State and local health personnel needed for planning, organizational, promotional, and other epidemiologic activities in connection with such programs, including studies to determine the communicable disease control needs of communities and the means of best meeting such needs and personnel and related expenses needed to maintain additional epidemiologic and laboratory surveillance occasioned by such programs.

"(2) For the purposes of this subsection—

"(A) a 'communicable disease control program' means a program which is designed and conducted so as to contribute to a nationwide effort against tuberculosis, venereal disease, rubella, measles, poliomyelitis, diphtheria, tetanus, whooping cough and other communicable diseases which are transmitted from State to State, are amenable to reduction, and which are determined by the Secretary on the recommendation of the National Advisory Health Council to be of national significance, and

"(B) the term 'State' includes the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

"(3) Payments under this subsection may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of underpayments, or overpayments, in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of this subsection.

"(4) The Secretary, at the request of a recipient of a grant under this subsection, may reduce the money grant to such recipient by the fair market value of any supplies (including vaccines and other preventive agents), or equipment furnished to such recipient and by the amount of the pay, allowances, traveling expenses, and any other costs in connection with the detail of an officer or employee to the recipient when the furnishing of such supplies or equipment, or of the detail of such officer or employee (as the case may be), is for the convenience of and at the request of such recipient and for the purpose of carrying out the program with respect to which the grant under this subsection is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies, equipment, or personal services on which the reduction of such grant is based, but such amount shall be deemed a

¹ H.R. 12153 differs in that it requests \$75,000,000 for each fiscal year after the fiscal year ending June 30, 1971.

part of the grant to such recipient and shall, for the purposes of paragraph (3) of the subsection, be deemed to have been paid to such agency.

"(5) Nothing in this subsection shall limit or otherwise restrict the use of funds which are granted to a State or to a political subdivision of a State under other provisions of this Act or other Federal law and which are available for the conduct of communicable disease control programs from being used in connection with programs assisted through grants under this subsection.

"(6) Under this subsection, the Secretary shall be required to submit an annual report on performance in preventing and controlling communicable diseases."

[H.R. 13482, 91st Cong., 1st Sess., introduced by Mr. Gallagher on August 12, 1969]

A BILL Vaccination Assistance Act of 1969

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Vaccination Assistance Act of 1969."

SEC. 2. Effective July 1, 1969, subsection (a) of section 317 of the Public Health Service Act is amended to read as follows:

"(a) There are hereby authorized to be appropriated \$15,000,000 for the fiscal year ending June 30, 1970, and for each of the next four fiscal years, to enable the Secretary to make grants to the States and, with the approval of the State health authority, to political subdivisions of instrumentalities of the States under this section. Amounts appropriated pursuant to this section for any fiscal year ending prior to July 1, 1975, shall be available for making such grants during the fiscal year for which appropriated and the succeeding fiscal year. Such grants may be used to pay that portion of the cost of immunization programs against poliomyelitis, diphtheria, whooping cough, tetanus, measles, and rubella which is reasonably attributable to (1) purchase of vaccines needed to protect such groups of children as may be described in regulations of the Secretary upon his finding that they are not normally served by school vaccination programs, and (2) salaries and related expenses of additional State and local health personnel needed for planning, organizational, and promotional activities in connection with such programs, including studies to determine the immunization needs of communities and the means of best meeting such needs, and personnel and related expenses needed to maintain additional epidemiologic and laboratory surveillance occasioned by such programs. Such grants may also be used to pay similar costs in connection with immunization programs against any other disease which the Secretary finds represents a major public health problem in terms of high mortality, morbidity, disability, or epidemic potential and to be susceptible of practical elimination as a public health problem through immunization with vaccines or other preventive agents which may become available in the future."

[H.R. 16168, 91st Cong., 1st Sess., introduced by Mr. Burton of California on February 25, 1970, and S. 2264, 91st Cong., 1st Sess., passed the Senate, October 20, 1969, and referred to the Committee on Interstate and Foreign Commerce October 21, 1969, are identical as follows:]

AN ACT To amend the Public Health Service Act to provide authorization for grants for communicable disease control and vaccination assistance

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Communicable Disease Control and Vaccination Assistance Amendments of 1969".

GRANTS FOR COMMUNICABLE DISEASE CONTROL AND VACCINATION ASSISTANCE

SEC. 2. Section 361 of the Public Health Service Act (42 U.S.C. 264) is amended by inserting at the end thereof the following new subsection:

"(c)(1) There are hereby authorized to be appropriated \$60,000,000 for the fiscal year ending June 30, 1970, \$75,000,000 for the fiscal year ending June 30, 1971, and \$75,000,000 for the fiscal year ending June 30, 1972, to enable the Secretary to make grants to States, and, with the approval of the State health authority, to political subdivisions or instrumentalities of the States under this subsection. In the award of such grants the Secretary, in accordance with appropriate regulations, shall give consideration to the relative extent of the com-

municable disease and vaccination problems and to the levels of performance in preventing and controlling diseases for which assistance is available under this subsection. Such grants may be used to pay that portion of the cost of communicable disease control or vaccination programs which is reasonably attributable to (A) purchase of vaccines or other agents needed to protect those portions of the population determined to be important to the control or prevention of such diseases and (B) salaries and related expenses of additional State and local health personnel needed for planning, organizational, promotional, epidemiologic, and other activities in connection with such programs, including studies to determine the communicable disease control and immunization needs of communities and the means of best meeting such needs and personnel and related expenses needed to maintain additional epidemiologic and laboratory surveillance occasioned by such programs.

"(2) For the purposes of this subsection—

"(A) a 'communicable disease control or vaccination program' means a program which is designed and conducted so as to contribute to a nationwide effort against tuberculosis, venereal disease, rubella, measles, poliomyelitis, diphtheria, tetanus, whooping cough, or Rh disease, or any other disease which the Secretary finds represents a major public health problem in terms of high mortality, morbidity, disability, or epidemic potential and to be susceptible of practical elimination as a public health problem through immunization with vaccines or other preventive agents which may become available in the future, and

"(B) the term 'State' includes the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

"(3) Payments under this subsection may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of underpayments, or overpayments, in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of this subsection.

"(4) The Secretary, at the request of a recipient of a grant under this subsection, may reduce the money grant to such recipient by the fair market value of any supplies (including vaccines and other preventive agents), or equipment furnished to such recipient and by the amount of the pay, allowances, traveling expenses, and any other costs in connection with the detail of an officer or employee to the recipient when the furnishing of such supplies or equipment, or of the detail of such officer or employee (as the case may be), is for the convenience of and at the request of such recipient and for the purpose of carrying out the program with respect to which the grant under this subsection is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies, equipment, or personal services on which the reduction of such grant is based, but such amount shall be deemed a part of the grant to such recipient and shall, for the purposes of paragraph (3) of the subsection, be deemed to have been paid to such agency.

"(5) Nothing in this subsection shall limit or otherwise restrict the use of funds which are granted to a State or to a political subdivision of a State under other provisions of this Act or other Federal law and which are available for the conduct of communicable disease control or vaccination programs from being used in connection with programs assisted through grants under this subsection.

"(6) Under this subsection, the Secretary shall be required to submit an annual report on performance in preventing and controlling diseases covered by this subsection.

"(7) Nothing in this subsection shall be construed to require any State or any political subdivision or instrumentality of a State to have a communicable disease control or vaccination program which would require any person who objects to such treatment to be treated, or to have any child or ward of his treated."

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., October 23, 1969.

HON. HARLEY O. STAGGERS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Rayburn House Office Building,
Washington, D.C.*

DEAR MR. CHAIRMAN: This is in response to your requests of June 11 and 13, 1969, for our views on H.R. 11913 and H.R. 12067, two bills "To amend the

Public Health Service Act to provide authorization for grants for communicable disease control."

In our opinion, new legislative authority in this field is neither necessary nor desirable. All of the program purposes included in H.R. 11913 and H.R. 12067 are now covered by the grant authorizations in Section 314 of the PHS Act, the Partnership-for-Health program. Formula grants under Section 314(d) may be used for the whole range of public health services, including the prevention and control of communicable diseases. Similarly, project grants under Section 314(e) are available and have been utilized for communicable disease control. The current program of support for a nationwide rubella immunization program funded through Section 314(e) is an example of the application of non-categorical funds to a communicable disease problem.

In summary, the re-establishment of categorical grant programs in the field of communicable disease control is unnecessary, would complicate and confuse existing non-categorical grant authorizations, and runs counter to the President's efforts to consolidate and simplify grant programs to achieve greater effectiveness and increased flexibility in the allocation of Federal resources.

Sincerely,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., November 18, 1969.

HON. HARLEY O. STAGGERS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Rayburn House Office Building, Washington, D.C.*

DEAR MR. CHAIRMAN: This is in response to your request of October 23, 1969, for our views on S. 2264, as passed by the Senate, a bill "To amend the Public Health Service Act to provide authorization for grants for communicable disease control and vaccination assistance."

In our opinion, new legislative authority in this field is neither necessary nor desirable. All of the program purposes included in S. 2264 are now covered by the grant authorizations in section 314 of the Public Health Service Act, the Partnership-for-Health program. Formula grants under section 314(d) may be used for the whole range of public health services, including the prevention and control of communicable diseases. Similarly, project grants under section 314(e) are available and have been utilized for communicable disease control. The current program of support for a nationwide rubella immunization program funded through section 314(e) is an example of the application of non-categorical funds to a communicable disease problem.

In summary, the reestablishment of categorical grant programs in the field of communicable disease control is unnecessary, would complicate and confuse existing noncategorical grant authorizations, and runs counter to the President's efforts to consolidate and simplify grant programs to achieve greater effectiveness and increased flexibility in the allocation of Federal resources.

Sincerely yours,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., February 27, 1970.

HON. HARLEY O. STAGGERS,
*Chairman, Committee on Interstate and Foreign Commerce, House of Representatives,
Rayburn House Office Building, Washington, D.C.*

DEAR MR. CHAIRMAN: This is in response to your request of February 19, 1970 for the views of the Bureau of the Budget on H.R. 15961, a bill "To amend section 351 of the Public Health Service Act so as to clarify the intent to include vaccines, blood, blood components, and allergenic products among the biological products which must meet the licensing requirements of this section."

H.R. 15961 is the same as a bill submitted by the Secretary of Health, Education, and Welfare in order to clarify the Department's authority to regulate

certain biological products under section 351 of the Public Health Service Act. Accordingly, we recommend the enactment of H.R. 15961.

Sincerely,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., March 13, 1970.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce
House of Representatives
Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of February 19, 1970, for a report on H.R. 15961, a bill "To amend section 351 of the Public Health Service Act so as to clarify the intent to include vaccines, blood, blood components, and allergenic products among the biological products which must meet the licensing requirements of this section."

This bill embodies the provisions of a draft bill submitted to the Speaker of the House of Representatives by this Department on February 12, 1970. The details of the bill are explained in a letter of the same date to the Speaker, a copy of which is enclosed for your convenience.

For the reasons stated in the enclosed letter, we urge enactment of the bill.

Sincerely,

ROBERT H. FINCH, *Secretary.*

Enclosure.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., February 12, 1970.

HON. JOHN W. MCCORMACK,
Speaker of the House of Representatives,
Washington, D.C.

DEAR MR. SPEAKER: We are enclosing for the consideration of the Congress a draft bill "To amend section 351 of the Public Health Service Act so as to clarify the intent to include vaccines, blood, blood components, and allergenic products among the biological products which must meet licensing requirements of this section."

The enclosed draft bill would amend section 351 of the Public Health Service Act by specifically including the following products in the list of licensable biologicals: "vaccine, blood, blood component or derivative, allergenic product,"

This amendment is in the nature of emergency legislation necessitated by a recent decision of the United States Court of Appeals, Fifth Circuit, (*Blank v. United States*, 400 F. 2d 302 (5th Cir. 1968)) which held (reversing, in part, a conviction handed down by the United States District Court for Northern District of Texas) that the products known as Citrated Whole Blood (Human) (now named Whole Blood (Human)) and Packed Red Blood Cells (Human) are not biological products within the meaning of section 351 of the Public Health Service Act and are therefore not subject to regulation thereunder. The rationale of the Court was that, at the time the predecessor of section 351 was enacted (1902), the product and processes involved in blood transfusion were unknown and therefore not within the intent of Congress. This reasoning would also cast doubt on the authority of the Secretary to issue standards for and otherwise regulate allergenic products. Unfortunately, this Department did not become aware that this specific point of the *Blank* decision had been affirmed until after the time for seeking review by the Supreme Court had expired. This decision, while a governing precedent in the Fifth Circuit, is to be contrasted with an arguably similar case, involving blood plasma, in the Second Circuit (*United States v. Steinschreiber*, 218 F. 2d 426 [S.D.N.Y. 1962], 219 F. Supp. 373 [S.D.N.Y. 1963], affirmed per curiam, 326 F. 2d 759 [2d Cir. 1964]). While we believe our interpretation to be correct, vindication by the courts is likely to require several years, a period too long to have the authority of the Secretary to regulate under section 351 left under a cloud, and the uniform application of this section geographically impaired.

As an interim measure, we have amended the good manufacturing practice regulations for drugs under the Federal Food, Drug, and Cosmetic Act (21 CFR part 133) so as to incorporate by reference the standards for manufacturing, processing, packing and holding these biological products that were issued under section 351 of the Public Health Service Act, set forth in Part 73 of 42 CFR. (See the Federal Register, Vol. 34 No. 194, October 9, 1969, page 15645). The draft bill presented here is proposed in the interest of public-health protection and uniformity of the law throughout the United States, and as a legislative clarification in line with what we believe to be the correct interpretation.

As noted above, in addition to blood, blood components, and allergenic products, we are also proposing to add "vaccine" to the list of products subject to licensing to remove any doubt as to the coverage thereof, though the *Blank* decision does not directly bear on vaccines. "Vaccine" is a general term which covers products intended to stimulate the body to provide its own protection. Its inclusion with the others constitutes a minor remedial clarifying modification of the list of biological products now subject to licensure, and is consistent with the intent of the original "Virus-Toxin Law" of 1902 to protect the public health through the control of biological products.

We therefore believe that the public interest requires prompt enactment of the present proposal.

We would appreciate your referring this draft bill to the appropriate Committee for consideration.

We are advised by the Bureau of the Budget that there is no objection to the submission of this proposed legislation to the Congress from the standpoint of the Administration's program.

Sincerely,

ROBERT H. FINCH, *Secretary.*

A BILL To amend section 351 of the Public Health Service Act so as to clarify the intent to include vaccines, blood, blood components, and allergenic products among the biological products which must meet the licensing requirements of this section

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 351 of the Public Health Service Act is amended by inserting, after "antitoxin," each time such word occurs, the following: "vaccine, blood, blood component or derivative, allergenic product,".

U.S. DEPARTMENT OF THE INTERIOR,
OFFICE OF THE SECRETARY,
Washington, D.C., February 10, 1970

HON. HARLEY O. STAGGERS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: Your Committee has requested the views of this Department on H.R. 11913, a bill "To amend the Public Health Service Act to provide authorization for grants for communicable disease control."

While we endorse the objectives of this legislation, we defer to the views of the Department of Health, Education, and Welfare as to the need for and advisability of its enactment.

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

Sincerely yours,

WALTER J. HICKEL,
Secretary of the Interior.

Mr. ROGERS. Our first witness this morning is Dr. Robert Q. Marston, Director of the National Institutes of Health, and I understand Dr. Roderick Murray will be with you as the Director of the Division of Biologics Standards.

Dr. Marston and Dr. Murray, the committee welcomes you. We are delighted to see you again. We will be pleased to receive your testimony at this point.

STATEMENT OF DR. ROBERT Q. MARSTON, DIRECTOR, NATIONAL INSTITUTE OF HEALTH, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY DR. RODERICK MURRAY, DIRECTOR, DIVISION OF BIOLOGICS STANDARDS

Dr. MARSTON. I thank you, Mr. Chairman, and members of the committee.

I am happy to appear before this committee today to testify on behalf of H.R. 15961, which would provide needed modernization of section 351 of the Public Health Service Act, through which the Federal Government regulates the licensing and distribution of biological products.

The change we are proposing is a small but important one. H.R. 15961 would amend section 351 to include additional products as subject to licensing requirements of this section—specifically vaccines, human blood used for transfusions, blood components, and allergenic products. This is necessary in order to update the language to reflect some of the changes in knowledge, thought, and terminology which have occurred during the more than half century since the statute was enacted.

VACCINES

Since the enactment in 1902 of the virus-toxin law, there has been no substantial change in the designations of the products intended to be covered under that law. The 1902 law designated several categories of products, one of which was the term "virus". Section 351 today retains, without any modification or amplification, this same "virus" product category designation, although through many years the meaning of this word has changed from that of a toxic substance to the now identifiable causative agent of certain diseases. Since the enactment of the 1902 law, the sciences of microbiology and immunology have advanced extensively so that there are now known variations of infectious living micro-organisms which formerly were referred to only as viruses; for example, rickettsiae, bacteria, and others.

All products containing material derived from any of these various infectious agents require the same assurances of being prepared by meeting the manufacturing standards called for in section 351. However, the now obsolete use of the word "virus" creates an ambiguity that hampers the effectiveness of the administration of the statute.

It would clarify, simplify, and modernize the statutory language to conform with the present state of the sciences and the present usage of terms to include the now universally used word "vaccine" to indicate the intent to include any product containing or made from or with a minute living cause of an infectious disease, including filterable viruses, now referred to as "viruses, bacteria, rickettsiae, fungi, and protozoa".

BLOOD AND BLOOD COMPONENTS

The Virus-Toxin Law of 1902 (the 1944 revision of which occurred when public health laws were consolidated), and the present Section

351 of the Public Health Service Act, each include specifically the category of "therapeutic serum" as products subject to licensing control. However, none of them state specifically that blood for transfusion to humans, blood components, or byproducts of blood are included in the "therapeutic serum" category. Beginning in the thirties, and increasing enormously during and after the Second World War, the processing and shipment of human blood and its components became a widely used procedure. The Public Health Service has held the view that blood for transfusion, blood components, and blood byproducts such as albumin, fibrinogen, et cetera, used in the treatment, cure, and prevention of diseases of man are subject to control under the Public Health Service Act as products "analogous" to a therapeutic serum.

It would appear incontrovertible that these products pose the same kind of potential threat to the public health as the other biologicals specifically enumerated in the original licensing control statute. In addition, one constituent of whole blood is the serum which is in itself therapeutic. Processors of all of these blood products have been required to qualify for license to permit their shipment for interstate sale for use in the treatment of diseases of man in accordance with the basic intent of section 351 of the Public Health Service Act.

Although there have not been many formal challenges of this interpretation, a recent decision of the U.S. Court of Appeals, Fifth Circuit, held that the products known as citrated whole blood (human)—now named whole blood (human)—and packed red blood cells (human)—now named red blood cells (human)—are not biological products within the meaning of section 351 of the Public Health Service Act and are therefore not subject to regulation thereunder. In *Blank v. United States*, 400 F. 2d 302 (5th Cir. 1968), the circuit court reversed the lower court which convicted the appellant of, among other things, false labeling and marking of the blood products. The rationale was that, at the time the predecessor of section 351 was enacted (1902), the product and processes involved in blood transfusion were unknown and therefore not within the intent of Congress.

This decision, while a governing precedent in the Fifth Circuit, is to be contrasted with an arguably similar case in the Second Circuit (*United States v. Steinschreiber*, 218 F. Supp. 426 (S.D.N.Y. 1962), 219 F. Supp. 373 (S.D.N.Y. 1963), affirmed per curiam, 326 F. 2d 759 (2d Cir. 1964)) which upheld the Government's interpretation. While we believe our interpretation to be correct, vindication by the courts is likely to require several years. This is too long a period to have the authority of the Secretary to regulate under section 351 left under a cloud, and the geographically uniform application of this section impaired.

As an interim measure, we have amended the good manufacturing practice regulations for drugs under the Federal Food, Drug, and Cosmetic Act (21 CFR pt. 133) so as to incorporate by reference the standards for manufacturing these biological products that were issued under section 351 of the Public Health Service Act. This bill is proposed in the interest of public health protection and uniformity of the law throughout the United States. It provides a legislative clarification in line with what we believe to be the correct interpretation.

ALLERGENIC PRODUCTS

The Public Health Service holds the view in consonance with current scientific and medical thought that allergenic products are basically immunological agents in that their effect is based upon a specific immune process. This action is considered analogous to that of the action of toxins with their counterpart antitoxins, and thus they have been viewed as subject to licensing control under section 351 of the Public Health Service Act.

We don't know of any formal challenges to this interpretation. However, in *Blank* cited above, the appellant court opinion makes reference to pollen extracts (subject to license as an allergenic product) in a manner that implies that such products are not subject to control under section 351 of the Public Health Service Act. The appellate judge in discussing the element of injection as a factor in determining whether the statute applies, stated:

Injection is a meaningful element of analogy but its impact is not great. If it were of much force, there would be brought within the ambit of the statute thousands of drugs having not even remote relation in any other attributes to other products named in the statute—anesthetics, vitamins, pollen extract, and narcotics, to name only a few. Thus, the judge assumed pollen extracts are not controlled under section 351, but they have been for many years and such control has been accepted as beneficial with respect to safety, purity, and potency of such products by practicing allergists.

The control of pollen extracts and other allergenic products is not based upon the elements of injection alone, just as control of all the other biological products is not based upon the injection element alone. Some allergenic products are actually applied to the surface of the skin as in the so-called "patch test."

The principal basis for control of allergenic products is the presence of an immunological process, just as for blood and blood products the principal factor is that blood contains a therapeutic serum.

The U.S. Court of Appeals' statement quoted above will undoubtedly result in confusion which would be avoided by including including specific language clarifying that allergenic products are included in section 351 control.

While the changes in section 351 proposed by this bill may appear relatively minor, we urge their enactment. They will do much to assure that biologic products available to the American people will, in fact, meet the requirements demanded of them by current medical thinking.

I will be glad to answer any questionst hat the committee may have on these matters.

Mr. ROGERS. Thank you, Dr. Marston.

Mr. Preyer?

Mr. PREYER. No questions; thank you.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. I think the distinguished doctor has made a very good statement here.

I feel that it is important that the substance be included within the purview of the law. I agree with the witness.

That is all I have to say, Mr. Chairman.

Mr. ROGERS. Dr. Marston, do we have control of intra-operations in the sale of blood?

Dr. MARSTON. No, sir: we don't.

Dr. MURRAY, would you like to expand on that?

Dr. MURRAY. Well, the restriction is to interstate shipments. This is in line with the policy of the Government of the United States in its execution of many other responsibilities.

Approximately 80 percent of the blood used for transfusion in this country is obtained from institutions holding Federal licenses for interstate shipment. What is done intrastate is rather small and would require for no additional purpose an expenditure of tremendous effort in inspection and testing.

Furthermore, most of these blood banks are very small and in hospitals. They are widely scattered and follow the guidelines applicable to federally licensed blood banks in general.

Mr. ROGERS. You feel there is no problem, then?

Dr. MURRAY. I feel there is no problem.

Mr. ROGERS. As I understood your testimony, there was another circuit court case that said you did have the authority other than the Fifth Circuit.

Dr. MURRAY. Yes, sir.

Mr. ROGERS. Why was not the Fifth Circuit decisions appealed?

Dr. MARSTON. The Department of Health, Education, and Welfare was not aware of this action until it was too late for us to appeal to the Supreme Court.

Mr. ROGERS. What do you mean, was not aware of? I don't understand that.

Dr. MARSTON. The action occurred in 1968, as I recall, and by the time that we knew of the implications of this action of the Fifth Circuit Court of Appeals, the time for appealing that decision had passed. We began in 1969 trying to correct this through the legislative route.

Dr. MURRAY. That is correct.

Mr. ROGERS. How are you notified of adverse decisions? Generally, I would have thought that you would have testified or your people would have testified and be in close touch.

Did the Justice Department bring the case?

Dr. MURRAY. No; we were not informed. It is my understanding that the Justice Department which follows these cases was incorrectly informed and they believed that the case was still pending when in fact it had been decided. By the time it was known, it was too late.

Mr. ROGERS. That is incredible. The Justice Department didn't know it?

Dr. MURRAY. That is what I am told.

Mr. ROGERS. I would like for us to send a letter to the Justice Department from the committee asking for an explanation of what happened and why they didn't know it. This could have great adverse effects, I would think. Suppose that it takes time for the Congress to enact this, it would put you in a very bad position, I presume, and it could affect many people, could it not?

Dr. MARSTON. Yes, sir.

Mr. ROGERS. That is ludicrous that the Justice Department does not even know when their own cases are decided. We will check it.

(The following letter was received for the record:)

DEPARTMENT OF JUSTICE,
OFFICE OF THE ATTORNEY GENERAL,
Washington, D.C., April 22, 1970.

HON. JOHN JARMAN,
*Chairman, Subcommittee on Public Health and Welfare,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: This is in response to your letter of April 9, 1970, to the Attorney General, enclosing a transcript of a hearing held before the Subcommittee on Public Health and Welfare on H.R. 15961 and other bills on March 13, 1970. In your letter, you request an explanation of the failure of the Department of Justice to notify the Department of Health, Education and Welfare of the adverse decision in *Blank v. United States*, 400 F. 2d 302 (5th Cir. 1968), and a description of the means by which we advise interested Government departments and agencies of the results of such cases.

By explicit instructions set forth in Title 6 of the *United States Attorneys' Manual*, the various United States Attorneys are under long-standing directions to transmit immediately to the Department of Justice decisions of the United States district courts and courts of appeals in which the Government or one of its officers or agencies is a party, including opinions and dates of judgments. Should a court of appeals decision be adverse to the Government, the United States Attorney is required to transmit a copy of the opinion to the Department promptly by air mail so that immediate consideration may be given to the filing of a petition for rehearing or to the seeking of review in the Supreme Court. In the October 27, 1967, issue of the *United States Attorneys Bulletin*, volume 15, number 22, page 668, a bi-weekly informational bulletin distributed to all United States Attorneys, the Criminal Division reminded the United States Attorneys that they must give the Division prompt notifications of all decisions reversing convictions. For your convenience, I am enclosing a copy of this Bulletin item and an extract from Title 6 of the *United States Attorneys' Manual* governing notification to the Department of decisions of the courts of appeals.

Upon receipt from the United States Attorney of the report of an adverse court of appeals decision or an appealable adverse district court decision, the appropriate division of the Department notifies the interested agency, where such exists, and solicits its views. Frequently, the agency is already aware of the decision through the efforts of its own legal staff or field office, including direct contact with the United States Attorney.

In the *Blank* case, the United States Attorney's office neglected to advise the Department of the decision of the Court of Appeals for the Fifth Circuit, on September 6, 1968, reversing the conviction. This was an oversight on the part of the Assistant United States Attorney who handled the appeal. It should be noted that in March, 1968, the Criminal Division contacted the United States Attorney's office concerning the status of the *Blank* case appeal, and, in September, 1968, the Division made inquiry of the statistical unit in the Department which gathers case data on the basis of monthly reports from all United States Attorneys, receiving the advice that the unit's records showed the *Blank* case appeal as still pending.

When it is realized that criminal appeals alone number more than 2000 per year, it is perhaps not surprising that an occasional incident such as this occurs. In an effort to eliminate them, approximately six months ago the Criminal Division entered into a cooperative arrangement with the clerks of most of the courts of appeals, including the Fifth Circuit, whereby they now transmit directly to the Division's Appellate Section, as well as to the appropriate United States Attorneys, all decisions in criminal cases.

I trust that this is the information which you desire.

Sincerely,

WILL WILSON,
Assistant Attorney General.

Enclosures.

CRIMINAL DIVISION

Assistant Attorney General Fred M. Vinson, Jr.

SPECIAL NOTICES

Appellate briefs

In order to insure that the Department is aware of current problems in Criminal Division cases and in order for the Department to render possible aid, you are reminded that two copies of all briefs and printed records in these cases should be forwarded to the Department as soon as available. See Title 6 of the United States

Attorneys Manual at page 8.2. It is not necessary to send more than two copies of a brief, nor is it necessary to write a letter with the routine briefs; in fact, some offices use a form to transmit briefs, records or opinions. However, it is important that the Department receive two copies of the brief for appellant and two copies of the Government's response as soon as possible.

Decisions adverse to the Government

In order to enable the Department to obtain the advice of the Solicitor General in seeking review of decisions adverse to the Government, you are reminded that you should *promptly* (within one or two days if possible) notify the Appellate Section of all final decisions by district judges dismissing indictments and of all decisions by appellate courts reversing convictions as well as of any other decision adverse to the Government where we can seek review, e.g., forfeitures, immigration matters, suppression of evidence in narcotic cases under 18 U.S.C. 1404, etc. You should send a full copy of the opinion and your specific recommendations together with any pertinent papers. See Title 6 of the United States Attorneys Manual, pages 1-4, 6, 8.2, 8.6-9, and 11-16. Since a notice of appeal is jurisdictional, the failure promptly to notify the Department or file a protective notice of appeal means that the Government loses by default. Early notification is necessary to enable the Department to suggest either a rehearing or to enable the Criminal Division to write a memorandum to the Solicitor General outlining the pertinent facts and law.

TITLE 6: APPEALS

REVIEW OF COURTS OF APPEALS' DECISIONS BY SUPREME COURT

PROMPT NOTICE OF DECISIONS BY COURT OF APPEALS

When a case is decided by a court of appeals, the United States Attorney shall immediately transmit a copy of the opinion to the Department, giving the date of the judgment. If the decision is adverse to the Government, a copy of the opinion shall be transmitted to the Department promptly by air mail so that immediate consideration may be given to the filing of a petition for rehearing or to the seeking of review in the Supreme Court; and the United States Attorney shall promptly make such recommendations or suggestions for further proceedings as he may wish, in order to aid the Department in determining what further steps should be taken. When the decision is favorable, to the Government a copy of the opinion of the court of appeals, as well as copies of other appropriate papers, shall be forwarded promptly to enable the Department to prepare an immediate response in the event that a petition for certiorari is filed in the Supreme Court by the other side.

Mr. ROGERS. Now, what about the liaison between you and Justice? Who is responsible for seeing that Justice advises you? Do we have any setup for this or do we just hope that somebody else tells us in time?

Dr. MURRAY. It is generally accomplished through the Office of the General Counsel of the Department.

Mr. ROGERS. I wonder if you would have the General Counsel furnish us an explanation of this from HEW's viewpoint.

Dr. MARSTON. Yes, sir.

(The following letter was received for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE GENERAL COUNSEL,
Washington, D.C., April 3, 1970.

Re: H.R. 15961—Statement of Dr. Robert Marston and Dr. Roderick Murray,
March 13, 1970.

Hon. PAUL G. ROGERS,
House of Representatives,
Washington, D.C.

DEAR MR. ROGERS: This is in response to your request that this office furnish you with a description of our liaison with the Department of Justice, and advise

you why there was a failure to seek review of the Circuit Court decision in *Blank v. United States*, 400 F. 2d 302 (5th Cir. 1968).

There is a very close liaison between this office and the Department of Justice with respect to litigation affecting Department of Health, Education, and Welfare programs. In the ordinary course, we are promptly advised by the Department of Justice of the status of such litigation up to and including the final disposition of the case. Unfortunately, however, we were not so advised of the Circuit Court's decision in *Blank*.

We first became aware of the *Blank* decision early in January 1969, when a trade newsletter reported that the decision had been rendered on September 6, 1968. The report was confirmed by the Department of Justice. Since the 90 day period for seeking review had expired, recourse to the Supreme Court was not available. Under these circumstances, it was concluded that prompt remedial legislation was required.

Sincerely yours,

ROBERT C. MARDIAN,
General Counsel.

Mr. ROGERS. Because we may need to take some action along this line if this is typical of the handling of the cases by Justice for the Department.

I think you have made a very strong case for something to be done. I don't think there will be any questions on that. I am surprised that there is lack of knowledge of what happened on the case so that it could not be appealed. But we will get that from Justice and the General Counsel.

Thank you very much.

Dr. MARSTON. Thank you.

Mr. ROGERS. Just one moment. I believe Dr. Carter has some additional questions.

Mr. CARTER. Of course, under your purview, are vaccines, blood, blood components and derivatives and allergenic products. At the present time, you will inspect these different substances and approve them before they are permitted to go into interstate commerce; is that correct?

Dr. MARSTON. Dr. Carter, we will continue to do what we have been doing in the past as far as these are concerned.

Mr. CARTER. It just makes it absolutely legal.

Dr. MARSTON. Yes; it does two things; It updates the law and meets an emergency that arose as a result of the *Blank* case.

Dr. MURRAY. If I might add to that just one thing.

We have continued as though the state of things had not changed. This has been welcomed by almost all of the institutions that are concerned. We have taken the position among ourselves that we would continue to do this until this was challenged.

Mr. CARTER. That is all, Mr. Chairman.

Thank you.

Mr. ROGERS. You mean you are going to function even though it is not lawful?

Dr. MARSTON. We are using a modification of the regulations under the Federal Food, Drug, and Cosmetic Act as an interim authority for continuing our activities in this area.

Mr. ROGERS. I think you need to do something but I would hope that it would be done within the operation of the law.

Dr. MARSTON. Yes, sir.

Mr. CARTER. Mr. Chairman, I feel it is pretty necessary for them

to continue as they are. Of course, there is a difference in opinions rendered by the courts and certainly in the absence of a definite opinion I think it is necessary to protect the public health of the country for them to continue as they see fit.

Mr. ROGERS. Yes.

I understand they have to modify the general manufacturing process to cover this.

Dr. MARSTON. Yes, sir. We are working under regulations which have been amended so as to incorporate by reference the standards for manufacturing these biological products that were issued under section 351 of the Public Health Service Act.

Mr. ROGERS. Thank you very much.

Dr. MARSTON. Thank you.

Mr. ROGERS. Our next witness will be Mr. Irving Lewis, Deputy Administrator of the Health Services Administration, and Dr. David Sencer, director of the Communicable Disease Center, Atlanta, Ga.

Mr. Lewis and Dr. Sencer, if you will, take the chairs here in front of us.

We are pleased to see you and we will be glad to receive your testimony at this time.

STATEMENT OF IRVING LEWIS, DEPUTY ADMINISTRATOR, HEALTH SERVICES ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY DR. DAVID SENCER, DIRECTOR, COMMUNICABLE DISEASE CENTER, ATLANTA, GA.

Mr. LEWIS. Mr. Chairman and members of the committee: I am happy to appear before you this morning to present the views of our Department on several bills relating to immunization and communicable disease control programs.

While my comments are directed primarily toward the provisions of the House bills, H.R. 11913, H.R. 12067 and H.R. 12116, they are also applicable to the Senate-passed bill. Although S. 2264 differs in a number of particulars from the House bills, its basic approach and provisions are the same.

The only significant differences in the provisions of the House bills relate to the duration of the grant authorization and to the level of annual appropriations authorized. H.R. 11913 proposes a 3-year program with appropriations authorizations of \$60 million for fiscal year 1970; \$75 million for 1971; and \$90 million for 1972. Both H.R. 12067 and H.R. 12113, on the other hand, would establish a continuing grant program with appropriations authorizations of \$60 million for fiscal year 1970 and \$75 million for "each fiscal year thereafter."

All of the bills would add to section 361 of the Public Health Service Act, which is a section dealing essentially with communicable disease control, a new subsection authorizing project grants to States and their political subdivisions to pay certain costs related to programs for the prevention and control of communicable diseases, including including both immunization programs and programs directed toward other communicable diseases (such as tuberculosis and venereal diseases) for which no comparable immunizing agents are available.

The present language of the bills does not make entirely clear the intended role of these project grants in the total structures of grants authorized by the Public Health Service Act for the establishment or support of public health services. Some of the provisions of the bills suggest that what is intended is a new supplementary or standby authorization for use only in connection with intensive nationwide communicable disease programs. Other provisions, however, imply that—in addition to these special program purposes—grants could also be made under this new authority for regular ongoing communicable disease activities of State and local health agencies.

In our opinion, new legislative authority in this field is neither necessary nor desirable, regardless of which of these alternative interpretations reflects the intended purpose of these bills. All of the program purposes covered by these bills are now covered by the grant authorizations in section 314 of the Public Health Service Act, commonly known as the partnership for health grants. Let me note at this point, Mr. Chairman, that we have recently proposed legislation—the “Health Services Improvement Act of 1970”—that would extend these existing grant authorities for 3 additional years and clearly focus them on improving the organization and delivery of health services. Although this proposal, H.R. 15960, would incorporate these authorities in a revised title IX of the act, for convenience I shall refer to them in this statement by their present section numbers.

Formula grants under section 314(d) may be used for the whole range of public health services, including the prevention and control of communicable diseases. Similarly, special project grants under section 314(e) may be, and will continue to be, made for continuing as well as short-term activities in communicable disease control. Our current and projected 1970 and 1971 grant funds under this subsection, for example, include funds for supporting a nationwide rubella immunization program.

Even if the purpose of the pending bills were limited to special or supplemental communicable disease programs, therefore, we see no need for additional legislative authority. And if these bills are also intended to authorize project grants for regular on-going communicable disease activities, we believe their enactment would not only be unnecessary but would represent a step backward in the development of a rational Federal grant structure.

In view of the key role played by this committee in recent years in the consolidation of many separate categorical grant programs into one formula grant authorization and one project grant authorization, I shall not undertake at this time any detailed restatement of the advantages of grant consolidation. In our opinion, however, such consolidations are essential to effective health planning and coordination at the State and local level. They assure the basic foundation for an effective-Federal-State partnership in financing public health services and provide the statutory flexibility that is needed in the allocation of limited Federal resources among a wide variety of State and local health needs. To provide a new and separate authorization for communicable disease project grants, while still continuing the availability of grants under section 314(e) would result in overlapping and duplication of grant authorizations.

We recognize that there is a renewed interest in many quarters in categorical grant authorizations—I might say, Mr. Chairman, this renewed interest does not apply only to the area of communicable diseases, but various other diseases—and that this interest has increased during the current period of severe budgetary constraints. It is understandable that, when a period of restricted budgets follows shortly after the consolidation of categorical grant authorizations, the difficulties in obtaining grant funds for particular programs will be attributed in part to the grant consolidation, itself. This line of reasoning, however, fails to recognize the nature of current budgetary limitations.

The principal constraints today—including those initiated by the congress as well as by the executive branch—are those aimed at controlling total expenditures during the fiscal year. This means that the ultimate availability of Federal dollars through the budgetary process for any particular purpose cannot be assured by categorical authorizations and appropriations.

Budget requests for categorical grants are vulnerable to reduction, as well as those for broader grant programs. And all appropriated funds, with a few statutory exceptions, are still subject to expenditure constraints and total expenditure ceilings in order to keep total Federal outlays within the prescribed limits. Under these circumstances, categorical grant authorizations provide little, if any, advantage in the competition for Federal dollars. Their principal effect is to increase the difficulty for States and localities of allocating a limited number of dollars to the most pressing needs.

In addition to these general budgetary considerations, which apply to all program authorizations, I should like to add a special comment with respect to a budgetary revision by President Nixon, and which was eventually enacted in the appropriations bill for this year, Mr. Chairman. It has particular reference to grants for communicable disease control activities, because the renewed interest in categorical grants for such activities appears to be in some measure—I think this may be a mild statement, Mr. Chairman—a reaction to this budgetary revision proposal.

Under the provisions of section 314(d) the States are able to distribute their formula grant funds among various health programs according to their own judgments as to relative needs and priorities, without regard to the former categorical restrictions. Under section 314(e) project grants are also available to help support a wide range of State and local health services, including the control of communicable diseases, when such services are part of new or innovative programs or constitute activities of special regional or national significance. In implementing this new grant legislation, we have envisioned that certain categorical programs such as tuberculosis, cancer, and venereal disease control would, over time, be shifted from project grant to formula grant support as they matured and became widely accepted in practice. Such a shift would serve not only to correct certain rigidities in the Federal grant structure carried over, in part, from previous categorical grant authorizations, but also to support the partnership for health concept that Federal aid should strengthen rather than inhibit the authority of State and

local health agencies in the planning and control of their various health programs and activities.

President Nixon's amendment to the fiscal year 1970 budget represents a significant attempt to translate this concept into reality. That is, the President amended the budget submitted to the Congress by the outgoing administration so as to transfer \$18 million from project to formula grants. Tuberculosis control has been identified as the program which will be most directly affected by this change in funding mechanisms.

To assure that this shift in funding mechanisms will not precipitously terminate any tuberculosis project, the Health Services and Mental Health Administration of this Department has provided transitional support with section 314(e) project grant funds during the current fiscal year. This will give the States an effective change-over in the sources of funding with minimum impact on existing tuberculosis control programs.

Additionally, let me emphasize that tuberculosis, as well as other disease or health projects which have been developed to meet demonstrated special needs, and which have been approved by the State health planning agency, will continue to be eligible to compete for section 314(e) funds as they have in the past.

In summary, Mr. Chairman, we strongly support the basic concepts underlying the grant consolidation represented by the provisions of section 314 of the Public Health Service Act. We believe that such consolidated grant authorizations improve the Federal grant structure from the standpoint of the Federal Government and are essential to the maintenance and strengthening of a Federal-State-local partnership in the planning and support of health services. These present grant authorizations embrace all of the program purposes contemplated in the pending bills, including the support of intensive immunization programs to control such diseases as rubella. In our opinion, the establishment or reestablishment of categorical grant programs in this field of public health is unnecessary, would complicate and confuse existing grant authorizations, and offers no realistic prospect for fiscal security during periods of severe budgetary and fiscal constraints. We would therefore recommend against the enactment of this proposed legislation.

Mr. Chairman, that completes my prepared statement.

Dr. Sencer, who, as you know, is in charge of the Communicable Disease Center, is here with me to answer specifically detailed questions which you might have with respect to the various programs.

Mr. ROGERS. Thank you.

Mr. Preyer?

Mr. PREYER. Thank you, Mr. Chairman.

I think you explained very well the problem arising from, as you put it, the renewed interest in many quarters in categorical grant authorizations.

You are saying that that renewed interest comes basically from the desire to make sure that these programs get some funds and the reason they are not getting the funds is not that it is not a categorical grant authorization but it is because of expenditure constraints.

Let me put it this way. What are the "quarters" you referred to when you say "a renewed interest in many quarters in categorical grant authorizations?" What "quarters?"

Mr. LEWIS. I would say by quarters, individuals or associations, whether they be in the health area or whether they be in the political structure, in the executive branch, outside the executive branch. I don't mean the word pejoratively, Mr. Preyer. There is an interest in heart disease; people interested in the national American Heart Association; people interested in respiratory diseases and tuberculosis control. As individual categorical programs are combined into a larger framework and as there is not enough money to go around to meet all needs, there is a renewed interest, and I do not question for a moment that it is a legitimate interest. There is a renewed interest in having a categorical grant in order to achieve that particular purpose.

Mr. PREYER. They seek these because they fear the loss of funds for their programs?

Mr. LEWIS. Yes. I do not mean that in the sense of just loss of funds for the program but whether or not the program purpose in which they are interested will be satisfactorily carried out within the framework of the larger grant authorization.

Mr. PREYER. As far as the loss of funds part of it goes, you are saying to these people what you really ought to be doing is cracking down on these expenditure constraints rather than trying to do away with the larger project grants. Is that about what you are saying?

Mr. LEWIS. I think I am saying two things, Mr. Chairman.

One, that expenditure constraints in the last several years, starting with the previous administration, expenditure constraints on the total Federal budget have been imposed both by the Congress and by the President in such a fashion that the nature of an authorization for appropriations which in the past was the vehicle to go ahead, authorization as opposed to expenditure, that the nature of the authorization is, itself, not an assurance that the appropriation can be spent.

I am not advocating that groups debate with the Congress or with the President what the total of the expenditure constraints should be. I am highlighting the nature of that phenomenon, which is new in the Federal budgetary system for us and the way we formulate our programs.

The second thing I am saying, Mr. Chairman, is that there is another objective which is also being pursued with respect to the relationship between the Federal Government, the State and the local government and the whole private sector and that is the improvement of the way in which grants are made and the delegations, if I may use that word, to State and local communities to have more flexibility in the way they program their funds.

Therefore, pressure, if I may use that word, on how funds should be expended to achieve particular program purposes has to be applied at all levels, including the State and the local level. And where a particular purpose is of an overriding national significance, the National Government should retain a programing capability for that particular purpose. Within the project grant program, for example, of the partnership for health, we are programing specific amounts of money for the nationwide rubella immunization program; we are also programing a specific amount of money for the venereal disease program.

We have taken the position that from a national standpoint the tuberculosis control program, in large measure the funding of which

previously had been in the project grants, can be moved into the formula grants, however, our retaining some amount of money in the project grants to assure that the most pressing needs and highest priority ones which aren't met through formula grants and State and local funds will still be able to be met.

Mr. PREYER. I think your first point is a good one, that appropriation does not automatically mean to go ahead. We can approve all we want to but if these expenditures constraints are exercised further up the line some place, we don't get anywhere. I think you have pointed this out very clearly.

Thank you.

I think these are good points you make.

Mr. ROGERS. What are the diseases that you consider communicable, Doctor, that you try to control?

Dr. SENCER. There are many diseases that we try to control through a variety of methods. The diseases we are attempting to control through immunization would be diphtheria, whooping cough, tetanus, polio, measles, German measles.

There are many communicable diseases that are controlled in a variety of fashions. Many of the hospital-acquired infections of communicable diseases, we attempt to control by better education of hospital staffs.

There are communicable diseases that are transmitted through food. Control is carried out through regulations which are set for the interstate shipment of food, such as the inspection of meat by the Department of Agriculture.

There are diseases which we do not know how to control, communicable diseases such as hepatitis. We can prevent hepatitis in people who have been exposed through the use of a gamma globulin.

Two of the major communicable diseases, of course, are tuberculosis and the venereal diseases, of which there are really two primary ones—gonorrhea and syphilis.

Tuberculosis is better controlled through adequate treatment of people who are known to have TB, and preventive treatment of those who have been exposed.

Syphilis is best controlled at the present time through treatment of active cases of syphilis and investigations of their contacts with prophylactic treatment of people who have been exposed. While gonorrhea can be treated, we do not yet have the technology of control. We are working on methods by which we can do a better job of screening population groups to determine who needs treatment.

Mr. ROGERS. Thank you.

Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

There has been an increase in venereal disease in the past few years; is that correct?

Dr. SENCER. Yes, Dr. Carter; there has been an increase in gonorrhea in the past several years, quite a striking increase.

We think that the increase in infectious syphilis has been stopped. In the last 2 years, it has been slightly down hill. We attribute this to better epidemiology, better case-finding by State and local health departments.

Mr. CARTER. Don't you think the efficacy of penicillin has helped to diminish syphilis greatly?

Dr. SENCER. Yes; syphilis is very easily treated if the people who are infected can be brought to treatment.

Mr. CARTER. It is now but at one time it was very difficult, was it not?

Mr. LEWIS. You mean to bring to treatment?

Mr. CARTER. Years ago, it was rather difficult when we used salversan and arsenicals. That has been a major triumph of the Health Department. As a medical student and as an intern, I saw many cases of syphilis and as a young physician. At the present time, however, we don't see so much of it. It is not so much in evidence as it was at one time.

Of course, there has not been a corresponding decrease in gonorrhea. Perhaps it has gone down some because we do have more effective drugs in the treatment of that.

In your rubella, the development of your rubella vaccine, how effective has it been?

Dr. SENCER. In measles, the vaccine we have now been using since 1964 is an extremely effective vaccine for the individual who receives it. There has been a striking decrease in the amount of measles that has been reported in the country although we are concerned that this year the incidence of measles is up somewhat over last year.

Mr. CARTER. At the present time you give them a small amount of the viral agent that causes measles and then usually give gamma globulin with it? Is that the present method?

Dr. SENCER. No; the vaccine that we originally used for measles did require gamma globulin to prevent some of the higher fevers. There are vaccines in which they have further diminished the strength of the virus. They have attenuated the virus so that we now are using what they refer to as a further attenuated measles virus vaccine which does not require gamma globulin and does not produce the higher fever in the children.

Mr. CARTER. How effective is your treatment for German measles?

Dr. SENCER. The vaccine is extremely effective in preventing clinical cases of German measles. It has been well-field-tested and it has been used in the general practice now since last spring.

We estimate there have been some 4 million children who have been immunized through public programs. We are not sure how many have been immunized in the private sector.

The vaccine, if it is going to be effective for preventing birth defects in unborn children, is going to have to be administered to large numbers of children to build up immunity in our population.

At the present time, we do not recommend that women of child-bearing age receive the vaccine unless we can be assured that they will not become pregnant for at least 2 months following the administration of the vaccine. Because it is a live virus vaccine and it does get into the blood stream, we do not know whether this attenuated virus could cause any damage to the fetus. So, we are not recommending that women who could become pregnant receive the vaccine.

We are concentrating on immunizing all the children so that there is no place for the virus to reside and infect the pregnant woman.

Mr. CARTER. Have you noticed a decrease in the number of birth defects since the use of German measles vaccine?

Dr. SENCER. No. Birth defects are not a reportable situation so that we don't have a good count. We have been establishing in several communities some pilot projects of how we can maintain surveillance of all types of birth defects.

We have a program in metropolitan areas where all of the hospitals, where all the medical societies and all the counties are reporting all their birth defects so that we can begin to find out what is really the background of birth defects. This program has now been instituted in Los Angeles and we hope that in Seattle another program will come about.

Mr. CARTER. You are unable to report on the effectiveness of it?

Dr. SENCER. No, sir; it is too early to report on the effectiveness.

Mr. CARTER. You know, most birth certificates have on them that it is a normal or abnormal birth and if there are any birth defects I should think from that you could get—

Dr. SENCER. This gives us a crude indication, but so many birth defects are not detected until the child is a month old or 2 months old and this never then gets back to the birth certificate. It is filed, as you know, immediately.

Mr. CARTER. With German measles they are rather marked.

Dr. SENCER. If it is severe, but we have found after the 1964 epidemic that the more you look, the more defects you find turning up in children later on in life, for example, in general heart defects that are not detectable at birth. The severe rubella syndrome is detectable when you get the cataracts and the deafness.

Mr. CARTER. Of course, you get other bizarre effects. I remember an encephalic I delivered at one time.

Mr. ROGERS. Did you say syphilis has gone down?

Dr. SENCER. Syphilis is down slightly in the past few years. We don't think it is a major victory but it has stopped increasing. It is down slightly. I am referring to infectious syphilis.

Mr. ROGERS. How late are your figures?

Dr. SENCER. We have them for calendar year 1969.

Mr. ROGERS. Through 1969?

Dr. SENCER. Yes, sir.

Mr. ROGERS. What are the reported cases of syphilis for 1969?

Dr. SENCER. 19,181.

Mr. ROGERS. What was it in 1968?

Dr. SENCER. In 1968, 19,019; in 1967, 21,053; in 1966, 21,414.

Mr. ROGERS. What funds do you devote to syphilis?

Dr. SENCER. At the present time, in grant funds there are \$7.2 million of 314(e) funds going to State and local health departments.

Mr. ROGERS. These are project funds?

Dr. SENCER. These are project funds.

Mr. ROGERS. It is not nationwide then; it is simply to zero in on communities, or what?

Dr. SENCER. Just about every State in the Union receives money.

Grants are awarded either to the State health department or to local health departments where the problem exists.

I think there are three States in which there are no funds.

Within the States, these projects are so written that the funds target in on areas where venereal disease is concentrated, which are usually the major cities.

Mr. ROGERS. This is for the present budget you are speaking of?

Dr. SENCER. This is the 1970 budget.

Mr. ROGERS. Is it a decrease or increase?

Dr. SENCER. This is stable from last year.

Mr. ROGERS. Has there been any change in cost of running the program because of inflation or cost of living?

Dr. SENCER. Yes, sir.

Mr. ROGERS. In effect, it is a decrease.

Dr. SENCER. The effect is a decrease; yes, sir.

Mr. ROGERS. Gonorrhea. Has that gone up or down?

Dr. SENCER. Gonorrhea has gone up.

Mr. ROGERS. Give us the figures on gonorrhea.

Dr. SENCER. In 1969, 531,000 reported cases.

In 1965, in contrast, there were 324,000.

Mr. ROGERS. Up since 1965?

Dr. SENCER. Yes, sir. It has been a steadily increasing disease.

Mr. ROGERS. Dramatically so.

Dr. SENCER. Yes, sir.

Mr. ROGERS. Is it localized in any area of the country?

Dr. SENCER. Again, if you say localized, it is an urban problem. As I mentioned before, we are not sure that we have the technology of control. We have the technology of treatment. If we can find the people who are infected, we can adequately treat them.

Mr. ROGERS. What funds are you spending on the control of gonorrhea?

Dr. SENCER. There are no grant funds specifically for the control of gonorrhea.

Mr. ROGERS. No funds?

Dr. SENCER. There are no grant funds, sir. We do utilize some of our own appropriated in-house money for research and for demonstrations. We have several contracts with State and local health departments trying to find out what the best methodology of control would be.

Mr. ROGERS. How much are you spending on research and demonstration projects?

Dr. SENCER. We have around \$300,000 in contracts, and then we have, I would estimate, around \$300,000 of our own direct operation money in the laboratory doing laboratory research.

Mr. ROGERS. How many research projects are there in total?

Dr. SENCER. I think there are around 24 contracts, sir.

Mr. ROGERS. Twenty-four?

Dr. SENCER. Yes, sir. I could supply the list for the record if you would like it.

Mr. ROGERS. I think we would like to have it.

(The following information was received for the record:)

STATES WITH GONORRHEA CONTRACTS—FISCAL YEAR 1970

Alabama:

Montgomery
Birmingham
Mobile
Tuscaloosa
Dothan
Selma

Baltimore

Chatham County, Ga. (Savannah)

Chicago

Columbus, Ohio

District of Columbia

Florida:

Fort Lauderdale
Jacksonville
Tampa

Houston

Kentucky:

Lexington
Louisville
Harlan County
Leslie County
Letcher County

Louisiana: (New Orleans)

Memphis

Monterey County, Calif.: (Salinas)

New Haven

Norfolk

St. Clair County, Michigan

St. Louis

San Francisco

San Joaquin County, Calif.: (Stockton)

Seattle

Mr. ROGERS. Is there any time element with these?

Dr. SENCER. The first 2 years of these contracts we have been trying to accumulate data base to find out what we are doing. We now in the laboratory have two promising leads. One is a blood test that can screen people for infections. The other is a new method of culturing the organism to find out if people are actually infected.

In the coming year, our contracts will be devoted to field testing these two approaches to control. I would not say that the blood test that we have is anything comparable to the blood test that we have for syphilis. You might say that we are back in the days of the Wasserman test for syphilis of 20 years ago in gonorrhea, but we do have something that we can put in the field.

Mr. ROGERS. Now, have you been spending any funds prior to this on the treatment of gonorrhea?

Dr. SENCER. No sir.

Our priority in project grants has been on infectious syphilis because we feel we have the technology for control there. Our priorities on gonorrhea have been in terms of research and demonstration.

Mr. ROGERS. So you are not giving any aid to States or communities to meet the problem of gonorrhea?

Dr. SENCER. No, sir.

Mr. ROGERS. Yet, there has been a dramatic increase?

Dr. SENCER. Yes, sir.

Mr. ROGERS. Do you plan to give some help to the States or the communities in this area, half a million people, up from 300,000 in 1965?

Dr. SENCER. We have no specific plans. It would be a question of having an effective control program, Mr. Chairman.

Mr. ROGERS. I thought you said there was treatment that could be given.

Dr. SENCER. Yes, we have an effective treatment.

Mr. ROGERS. Does that not stop the spread of it if you catch the people and give them proper treatment?

Dr. SENCER. Yes; if you find the people.

Mr. ROGERS. At least that is known technique.

Dr. SENCER. Yes, sir.

Mr. ROGERS. You don't propose to do anything about it?

Dr. SENCER. Pencillin given in adequate dosage is very adequate treatment. It is not quite as simple as syphilis where a single visit to the clinic will adequately treat syphilis. There have to be at least three visits to the clinic to adequately treat gonorrhea.

It is not the cost of providing the penicillin but it is the personnel necessary to find the people who are infected, to manage the laboratories, to do the additional culture examinations that are necessary, and which the health departments do not have.

Mr. ROGERS. So they really need help. Is that what you are telling me?

Dr. SENCER. They could use additional support to provide additional personnel to help bring people to treatment.

Mr. ROGERS. Now, what happens to persons if they get gonorrhea and they are not treated? Do they ever have blindness?

Dr. SENCER. No; gonorrhea will not cause blindness in adults, but it will cause kidney disease through causing strictures where people will get infections, bladder infections, renal infections. In women, it can cause sterility.

Mr. ROGERS. They have to be hospitalized eventually, probably.

Dr. SENCER. Many people who have untreated gonorrhea will require hospitalization; yes, sir.

Mr. ROGERS. Now, at what level does this disease have to reach before you are going to propose something to be done? Does it have to reach a million, a million and a half, 2, 3 million?

Dr. SENCER. I think we would be willing to propose additional effort if we felt that we could effectively utilize additional personnel.

Mr. ROGERS. You told me that is what they needed was personnel. I don't mean to embarrass you but I am startled that you don't have any program to meet one of the most rapidly rising communicable diseases in the country. You are the people in the communicable health disease and in HEW and you do not even have a program for it. Here it has gone up from 1965, 200,000 cases, a dramatic rise. I would hope you would review this and let this committee know if you are going to do something about it. If not, we may have to have specific legislation, category legislation, and rather than just communicable disease, to specify this communicable disease if we can't get any program going.

Dr. SENCER. We will be glad to provide you with a program.

Mr. ROGERS. I would want to have that.

(The following information was received for the record:)

GONORRHEA CONTROL

A national program for the control of gonorrhea is not feasible at this time because of certain deficiencies in diagnostic techniques and program methodology. The Communicable Disease Center is now engaged, however, in studies and demonstrations aimed at correcting these deficiencies.

Two major factors contributing to the increase in gonorrhea are: 1) the inadequacy of the treatment now being provided to many people who have gonorrhea, and 2) the difficulty of diagnosing the disease in asymptomatic but infectious females. To deal with the first of these problems an intensified physician education program can be undertaken to assure that effective treatment is given, thereby lessening spread of the disease from patients. Concurrently, a number of diagnostic techniques are being field tested which give promise of providing an effective means of diagnosing gonorrhea in females. It is planned, in 1972, to redirect current study projects in two major demonstrations. One project would involve a large

scale test of a saturation program which would combine treatment of all reported cases; the use of new culture media techniques in diagnosis in situations where women are being examined such as Family Planning, Maternal and Child Health, and cancer screening clinics; and intensive physician education. Complementing the saturation program, an epidemiologic project will be undertaken to evaluate specific approaches to case investigation and follow-up of contacts. From these two demonstrations practical experience and knowledge will be gained upon which a nationwide program might be developed.

Mr. ROGERS. Now tell me about typhoid fever. Is it up or down?

Dr. SENCER. Typhoid fever in this country is what we would consider a very minor health problem. The control of typhoid fever has been achieved through improved environmental sanitation. You can equate the number of miles of sewer lines with the decrease in typhoid fever. There will be an occasional outbreak of typhoid with a few cases which will come to light.

The last outbreak within the continental United States was in Missouri.

I think you are probably referring to the outbreak aboard the—I can never pronounce the name of the cruise ship—

Mr. ROGERS. I think it stopped in Port Everglades in Florida.

Dr. SENCER. As you know, there was an outbreak aboard the ship. Our staff cooperated with the Canadian Government.

Mr. ROGERS. Are there any other facts about typhoid? Do you give vaccinations?

Dr. SENCER. Typhoid vaccine is not recommended for use in the United States any more.

Mr. ROGERS. There is no requirement for it?

Dr. SENCER. No requirement at all. For foreign we travel, really don't recommend typhoid vaccine. We recommend that people be careful of the water they drink rather than take the vaccine.

Mr. ROGERS. So you approach this on a project grant basis?

Dr. SENCER. There is no support to State or local health departments for typhoid fever control. We provide technical assistance. If there is an outbreak, we will send our epidemiologists to help them control it.

Mr. ROGERS. Who provides the funds for controlling?

Dr. SENCER. This is from our communicable diseases direct appropriation to the center.

Mr. ROGERS. You use your funds to control it?

Dr. SENCER. Yes, sir.

Mr. ROGERS. How much funds are given to you for this purpose?

Dr. SENCER. There are no specific funds for typhoid fever control. Our overall budget is \$38 million this year which is for direct operations.

Mr. ROGERS. Of which you have how much leeway to operate on? I presume you have fixed costs. Suppose an emergency comes up, how much money can you devote to it?

Dr. SENCER. Our budget is almost completely in personnel and the supporting services, maintenance of laboratories and so on. So, if an emergency comes up—

Mr. ROGERS. It is really a matter of providing personnel.

Dr. SENCER. We provide the personnel.

Mr. ROGERS. But not paying for additional costs.

Dr. SENCER. No.

Mr. ROGERS. What do you do? Do you try to get a project grant approval up here?

Dr. SENCER. We scrounge.

Mr. ROGERS. That is what I want to know.

Dr. SENCER. A few years ago, there was a 1-year appropriation to establish an epidemic reserve. This was for polio vaccine in the early days or oral polio vaccine. We did at that time provide a polio vaccine on an emergency basis to state or local health departments if they had an outbreak. Since that time, there have been no funds set aside for epidemic reserve.

Mr. ROGERS. Excuse me.

Dr. SENCER. There have been no funds provided for this epidemic stockpile since this one-time appropriation.

Mr. ROGERS. You just don't have any funds for it?

Dr. SENCER. No, sir.

Mr. ROGERS. If an epidemic breaks out, you have no present funds to meet it; is that what you are telling us?

Dr. SENCER. We have funds to provide personnel services and laboratory support but in terms of vaccine, no, sir.

Mr. ROGERS. Have you requested any?

Dr. SENCER. We have in the past; yes, sir.

Mr. ROGERS. Has the Department approved them?

Mr. LEWIS. I have no specific recollection. We have not approved any because we have none but I have no specific recollection.

Mr. ROGERS. Don't you think you should have some funds available for emergency epidemics?

Mr. LEWIS. I think we should. I don't think we are the only source that has to have funds available for emergencies.

Mr. ROGERS. What have you done on your part? I think we should have some, should we not, in case an epidemic breaks out?

Let us know the Department's position on this, will you?

Mr. LEWIS. On funds for epidemic reserve?

Mr. ROGERS. Yes.

(The following information was received for the record:)

EPIDEMIC RESERVE FUND

One possible approach to the strengthening of protective measures against communicable diseases would be the appropriation of an "epidemic reserve fund" to permit the establishment of a national stockpile of vaccines and other biological agents for use in the event of major epidemic outbreaks in one or more areas. A partial precedent for such a reserve fund can be found in the \$1 million fund established in 1962 for polio vaccine. This fund was provided through a one-time appropriation, limited to the purchase of polio vaccine, and designed for the special purpose of implementing the intensive nation-wide immunization program authorized by the Vaccination Assistance Act.

In the light of the current situation, including the rubella program already in progress, there is no apparent need for a national vaccine stockpile or epidemic reserve fund related, as in the case of the 1962 fund, to a single disease. A case could be made, however, for a reserve fund to permit the maintenance of a stockpile of vaccines or preventive agents to protect against epidemic outbreaks of three diseases—polio, measles, and diphtheria. The outbreaks of measles and diphtheria during the past year and declining levels of immunity against these diseases as well as polio among the urban poor point to possibilities of epidemic outbreaks of any of these three diseases which could justify the maintenance of some reserve supply of vaccines.

While a national emergency fund would offer some program advantages in dealing with possible epidemics of one or more of these diseases, our Department

has not proposed such a fund because of its belief that the need for such a reserve fund is not sufficiently acute to warrant its cost in a period when stringent Federal budgets require that limited financial resources be directed toward the highest priority needs. We estimate that an appropriation of approximately \$2 million would be required for the establishment of a vaccine stock pile through an epidemic reserve fund, and we believe that such an outlay for a reserve fund is not warranted when the needs in other program areas are so urgent. It should also be noted that State and local health agencies have resources, including Federal grant funds, which can be mobilized for intensive immunization programs in the event of any serious epidemic outbreak.

Mr. ROGERS. Do you have any program to deal with botulism poisoning?

Dr. SENCER. Yes, sir. After the white fish epidemic in Tennessee, when botulism type E first became a problem, we did purchase about \$500 worth of botulism antitoxin which contained type E which is not commercially available in this country.

Mr. ROGERS. \$500 worth?

Dr. SENCER. Yes, sir.

Mr. ROGERS. How many would that serve?

Dr. SENCER. That was around 25 doses.

Mr. ROGERS. Twenty-five doses?

Dr. SENCER. Yes, sir. You have to recognize that type E botulism is a very rare situation and we do provide—I should not say this in front of Mr. Lewis but we do intend, toward the end of the fiscal year, to look to see if we have any funds left over, and have been continuing to replenish this small supply of botulism antitoxin.

Mr. ROGERS. What about the other kind?

Dr. SENCER. A and D is commercially available.

Mr. ROGERS. But you have no funds to purchase it?

Dr. SENCER. No, sir.

Mr. ROGERS. It does not do any good to have it available if you can't purchase it.

On your part, there is no fund to help the State Department and cities. On your part, there are no funds to help them?

Dr. SENCER. No, sir.

Mr. ROGERS. Tell me about tetanus.

Is it up or down? What is the problem?

Dr. SENCER. Tetanus is at a low level at the present time. There are two problems in tetanus: One is the problem of neonatal tetanus where children are born outside the hospital in less than ideal circumstances and develop tetanus at an early age as a result of infection of their umbilical cord.

I see the State health officer from Texas is here. I hate to have to say this but most of the cases of neonatal tetanus do occur in Texas.

The other problem of tetanus is older people who were born before the routine use of immunizing agents in childhood and particularly women who have not been in the military. We see not an increasing amount but a concentration of cases of tetanus in people who are older, particularly women.

Mr. ROGERS. How many reported cases of tetanus are there?

Dr. SENCER. 174, sir, in 1969.

Mr. ROGERS. Is this up or down?

Dr. SENCER. It is comparable to the previous year. It has been a continuing downward trend, slowly downward.

Mr. ROGERS. Do you make any funds available for this?

Dr. SENCER. In the past when the Vaccination Assistance Act was in effect, we did provide funds for immunizing against diphtheria, whooping cough, and tetanus which is a combined vaccine. There are funds available through the Children's Bureau which could be used through the local health departments for this purpose.

Mr. ROGERS. Are there now?

Dr. SENCER. There are funds that could be used.

Mr. ROGERS. That is their partnership funds?

Dr. SENCER. No. This is the Children's Bureau funds.

Mr. ROGERS. How much is available there?

Mr. LEWIS. The maternal health formula grant total is \$50 million.

I don't know how much is purchased for drugs and biologicals.

Mr. ROGERS. Let us know that figure.

Dr. SENCER. Yes; we will, if we can get you a figure.

(The following information was received for the record:)

AVAILABILITY OF MATERNAL AND CHILD HEALTH GRANT FUNDS FOR TETANUS IMMUNIZATION

States use their maternal and child health services funds authorized by title V of the Social Security Act to extend and improve, especially in rural areas and in areas suffering from severe economic distress, services for reducing infant mortality and otherwise promoting the health of mothers and children. The 1970 appropriation for grants to States for maternal and child health services was \$50 million, the same amount as for 1969 and 1968.

All State maternal and child health programs use part of their funds for immunizations against preventable diseases. During 1968, the latest year for which data are available, 4,020,000 children received immunizations against tetanus under the maternal and child health program.

States are required to report expenditures under the program in broad categories only. For 1968 States reported expenditures of Federal, State, and local maternal and child health funds of \$2,825,000 for drugs and biologicals. The proportion used for tetanus vaccine is unknown.

Mr. ROGERS. What about polio?

Dr. SENCER. Polio is down. It is at the lowest level it has been in history in this country. Last year, there were only 17 cases of paralytic polio reported.

In general, there are fairly adequate immunization levels. I say in general. We do know there are probably areas of low levels of immunization where we could have outbreaks of polio today.

Mr. ROGERS. Do you propose to have a program to immunize against polio?

Dr. SENCER. Again, we did put national emphasis on polio in the early days of vaccines. It has now been accepted as a routine part of medical practice.

We as professionals in disease control are continuing to emphasize to physicians and health departments that they should include this in their programs of preventive medicine.

Mr. ROGERS. The young people who are born every year should be immunized, should they not?

Dr. SENCER. Yes, sir; we feel they should be immunized by the time they are 18 months of age.

Mr. ROGERS. What assurances do you have that this is being done?

Dr. SENCER. We have as a Federal Government no assurance that it is being done. There are many States which require immunization as a prerequisite to school entrance so that we feel at the time of

school most children are getting immunized. Our concern is, though, that the preschool children, particularly those who are not receiving medical care, the people who are dependent upon emergency service rather than routine service, are not getting the preventive services and this is where the danger of polio outbreak lies.

Mr. ROGERS. Have you done any study to find out how many people this probably encompasses?

Dr. SENCER. Yes, sir. Each year, we contract with the Bureau of the Census.

Mr. ROGERS. How many people do you feel are not being immunized that should be?

Dr. SENCER. I have a table that we could supply for the record.

Mr. ROGERS. I wish you would.

(The following table was received for the record:)

*Number of persons under age 20 who have not received polio vaccine, United States—
1969*

Age group:	Without vaccine
<1-----	1, 687, 000
1-4-----	1, 463, 000
5-19-----	1, 900, 000
<20-----	5, 050, 000

Source: U.S. Immunization Survey—1969.

Mr. ROGERS. What about mumps? Is that up or down?

Dr. SENCER. Mumps is a very poorly reported disease. I would not put too much reliance on the figures. There has been recently a vaccine which has been introduced—

Mr. ROGERS. People can be vaccinated against that?

Dr. SENCER. At the present time; yes. We are hopeful in the next 2 or 3 years there will be a vaccine that will incorporate measles, German measles, and mumps in one immunization. We feel this will be the most appropriate approach to mumps.

Mr. ROGERS. Have the cases of mumps gone up or down?

Dr. SENCER. Mumps is a disease that goes up and down every 2 years. Last year it was down. The previous year it was up. You can see that there has not been much impact of the mumps vaccine. There has been no Federal program for mumps control. We feel that in children it is a fairly innocuous disease. Most efforts have been put on immunizing children as they get to puberty so that they don't develop mumps later in life and become sterile.

Mr. ROGERS. So you have no program as such?

Dr. SENCER. No, sir.

Mr. ROGERS. Whooping cough?

Dr. SENCER. Whooping cough is prevented by the same vaccine that is used for tetanus and diphtheria. Again, there is no program for whooping cough control at the present time.

Dr. Murray's staff at the Division of Biologic Standards, as well as ours, is concerned about some changing patterns in the epidemiology of whooping cough. Perhaps there is going to be need to develop something to keep on immunizing people later in life. The vaccine is such that you don't like to immunize much above the age of 5 because you get quite severe reactions.

We are hopeful that there may be something that can be done so that you can continue to maintain immunity throughout life.

Mr. ROGERS. So it has been going up?

Dr. SENCER. There has been a slight increase in the last few years. This is something that we attribute perhaps more to something going on with the disease than lack of effort to control it.

Mr. CARTER. Mr. Chairman, may I ask a question on that?

Mr. ROGERS. Yes.

Mr. CARTER. Is it not given quite often, as you mentioned, with diphtheria, DPT, so-called?

Dr. SENCER. Yes, sir.

Mr. CARTER. It is given to quite younger than 5 years?

Dr. SENCER. Yes. I said we were not using it past the age of 5. They take the pertussis vaccine out of the diphtheria—tetanus combination because of the reaction it causes.

Mr. CARTER. Usually it is given in the first month or so?

Dr. SENCER. Hopefully in good practice it is given earlier because whooping cough is a very severe disease in infants.

Mr. CARTER. Thank you, Mr. Chairman.

Mr. ROGERS. Measles, I believe, has gone up.

Dr. SENCER. Yes, sir.

Mr. ROGERS. And German measles has gone up; is that correct?

Dr. SENCER. German measles has gone up because there has been renewed interest in the disease. We know that when there is something that can be done for a disease we get better reporting. When there is nothing that a physician can do about a disease, he sees little reason to report it. But today, with a good vaccine, we are seeing an increase in the reporting. We attribute the increase in German measles to much better reporting.

Mr. ROGERS. Nevertheless, it is an increase, as far as we know.

Dr. SENCER. No. It is an artificial increase.

Mr. ROGERS. How do you know that? Do you have doctors report that have never reported cases to you?

Dr. SENCER. Yes, sir. In rubella, we do have a program in which we are supporting programs of not only vaccination but surveillance and the epidemiology of rubella. We have our personnel assigned to work with State and local health departments who are looking into just this sort of situation.

We do have physicians saying; "Yes: I was seeing rubella last year but I did not report it."

This year, after we have been encouraging them to report, we are getting better reporting.

Mr. ROGERS. How about regular measles?

Dr. SENCER. This is an actual increase, sir.

Mr. ROGERS. Pardon?

Dr. SENCER. This is an increase. This is not due to better reporting.

Mr. ROGERS. Why is it they would report measles and not rubella?

Dr. SENCER. Before we had a measles vaccine.

Mr. ROGERS. Don't you classify them both as measles?

Dr. SENCER. They are different diseases.

Mr. ROGERS. I understand that. You mean you ask them to report measles but you did not ask them to report German measles? Is that what you are telling us?

Dr. SENCER. No, sir. Before there was a measles vaccine there were 400,000 cases of measles reported a year. But we do know there were 4

million cases of measles a year. It was just not reported. Now, when there are 26,000 cases reported, we believe that is an accurate count.

Dr. Carter might like to speak to this but when you know that you can get something accomplished in controlling it—

Mr. ROGERS. By reporting.

Dr. SENCER (continuing). By reporting it, you get better reporting. It is human nature.

Mr. ROGERS. Let me ask you this: What are the increases in measles, percentage of increase?

Dr. SENCER. The percentage of increase, I don't have the percentage but I can figure it.

Mr. ROGERS. Tell us what the increased cases are.

Dr. SENCER. In calendar year 1968, there were 22,000 cases; in calendar year 1969, there were 26,000 cases.

Mr. ROGERS. What this year?

Mr. LEWIS. We don't have that here.

Mr. ROGERS. I understand on February 28 the issue of Morbidity and Mortality showed an increase in measles from 634 cases to 1,186 cases this year in a comparable week. That is a 100-percent increase.

Dr. SENCER. Yes, sir. We are concerned about this.

Mr. ROGERS. I would think so if it is a 100-percent increase, if this is typical.

What are you doing for a program for measles?

Dr. SENCER. There are no Federal funds going for the purchase of measles vaccine this year.

Mr. ROGERS. None, and a 100-percent increase this year over last?

Mr. CARTER. Mr. Chairman, would you yield?

Mr. ROGERS. Certainly.

Mr. CARTER. Measles is a severe disease but the effect of it has been lessened in the past few years through giving the person exposed immune globulin. In most cases, it aborts it and it is not very severe. At least, that has been my experience. It is, of course, and remains a serious disease.

I feel with increased number of vaccinations in our country it will go down.

Do the distinguished gentlemen agree?

Dr. SENCER. We are not seeing any difference in the severity of the disease today, Dr. Carter.

Mr. CARTER. It is handled much better, I think.

Dr. SENCER. Yes; the medical services today—if a child gets good medical care—

Mr. CARTER. Have you observed the use of immune globulin in the case of exposure to measles?

Dr. SENCER. Yes. But the places we are seeing measles occur today are in people who are not receiving good medical care. These are people in the inner cities where it is difficult to get to medical care. There is very little immune globulin being provided in these areas.

Mr. CARTER. But it is a wonderful medicine.

Dr. SENCER. If it is given soon enough after exposure it is effective.

Mr. CARTER. Yes, sir. I have used it. I have used it on my own son. It just aborted it. He was not sick very much. That is the usual case where it is used early as I understand it.

Thank you, Mr. Chairman.

Mr. ROGERS. So that, there is a 100 percent increase this year over last?

Dr. SENCER. Yes, sir.

Mr. ROGERS. At least from the tables we have. But you have no program on that.

Mr. LEWIS. For the purchase of the vaccine.

Mr. ROGERS. What program do you have?

Mr. LEWIS. The organization, the staff that has worked with the State and local health departments in the measles programs is still intact and working on the rubella programs. We are rendering the same organizational assistance but not the purchase of vaccines, Mr. Chairman. The organization which was set up under the measles program which was to fund both organization and the purchase of vaccine, the organization remains intact.

Mr. ROGERS. Are you funding the support of personnel from the State in this program?

Dr. SENCER. For the German measles program; yes, sir.

Mr. ROGERS. I am talking about regular measles where there is a 100 percent increase.

Dr. SENCER. The personnel that the States can employ under the 314(e) project grants for rubella programs can work on other diseases. The funds under the 314(e) grants cannot be used to purchase measles vaccine.

Mr. ROGERS. Should they not be able to get this vaccine if there is a 100 percent increase?

Dr. SENCER. There is a need for increased emphasis on immunization of children who are not receiving it at the present time.

Mr. ROGERS. Of course. This is the thing that I am impressed with by the testimony so far.

Mr. CARTER. Is it not quite expensive?

Dr. SENCER. Yes; measles vaccine is considerably more expensive than DPT, for example.

Mr. ROGERS. So that probably we won't get it if it is more expensive, so they probably need some help. This is my concern. Here we have a disease that is up 100-percent. Yet, you tell me you don't need this bill; we need everything through partnership and we should not give special help in this area, but the facts are not developing this way from the testimony. I am concerned.

Let me go to another one.

Over here in the Senate when they were having testimony there the Surgeon General was asked, "Well, but is it not rare or unusual for a person with an active case of tuberculosis to be working in a restaurant or a place that serves food?"

You know what the Surgeon General said?

"No; I do not think that you would find anyone with an active tuberculosis working in a restaurant."

You know what happened here on the Hill?

Dr. SENCER. Yes, sir.

Mr. ROGERS. Now, somewhere there is an insensitivity to this whole problem and it goes again to the problem of health cost. We all talk about rising health costs. Yet, we are not doing anything to prevent people from getting sick when we could to prevent raising health costs.

The best way I know to prevent rising health cost is prevention of disease. Would you agree with that?

Mr. LEWIS. That is part of it, Mr. Chairman.

Mr. ROGERS. A major part. If you can keep somebody from getting sick, that is the best part.

Mr. LEWIS. If there is complete knowledge and capability to organize everybody so that they don't get sick.

Mr. ROGERS. Yes; you have been able to do it, but we are not doing it like we ought to. You come in and the Department—and I am not talking personally; I am talking about the Department—comes in and tells us we don't need a program where we have measles going up 100 percent. We have TB. What program do you have for TB?

Dr. SENCER. The tuberculosis programs are being supported just about in all parts of the country at the present time.

Mr. ROGERS. What?

Dr. SENCER. There are programs for the support of tuberculosis control in all parts of the country at the present time.

Mr. ROGERS. How much of your funds are you allocating?

Dr. SENCER. This is complicated this year, sir, because of the transition from support under 314(e) to support under 314(d). The level of effort as of June 30, 1969, was \$20 million. As Mr. Lewis said in his testimony, there is going to be that much money made available—

Mr. ROGERS. Are these project grants?

Dr. SENCER. That was totally in project grants; yes, sir.

Mr. CARTER. Would the distinguished chairman yield for a question on this?

Mr. ROGERS. Yes.

Mr. CARTER. Let us see about the progress of this disease, tuberculosis.

Is it true that it has gradually gone down throughout the years even though we do have sporadic outbreaks in certain areas? Has there not been a great decrease in that?

Dr. SENCER. Yes; there has been a steady decrease in tuberculosis since the turn of the century.

Mr. CARTER. But more especially since the development of streptomycin, INH and PABA and other drugs.

Dr. SENCER. Yes. Each introduction of a new drug has shown a dramatic decrease first in deaths and then an accelerated decrease in the morbidity. However, from 1960 until 1967, it was decreasing at a rate of 3.3 percent per year.

In 1968, a decrease of 6.6 percent.

In 1969, there was a decrease of 9.3 percent.

In the past 3 years, we have accelerated the decrease.

Mr. CARTER. Is it not true that many of our States that have regional hospitals have begun to phase out some of their hospitals because of the decrease in tuberculosis?

Dr. SENCER. That is right. Hospitals have been closing, and treatment has been shifting to general hospitals, Dr. Carter.

There has been at the same time an increased demand on health department services because people are not staying in hospitals as long but they need to continue on medication for 1 to 2 years.

Mr. CARTER. I think that this part is well taken, that we have shown a diminution in the occurrence of this disease.

Dr. SENCER. At the present time, there are around 10 percent of the preschool children who have not received any polio vaccine.

Mr. ROGERS. What would that be in round figures?

Dr. SENCER. That would be 2 million.

Mr. ROGERS. It would be 2 million that have not been vaccinated?

Dr. SENCER. That is right; prior to school entrance.

Mr. LEWIS. Each year?

Dr. SENCER. No; that is as of today. There are 2 million children who have not received any polio vaccine.

Mr. ROGERS. This increases each year, I presume.

Dr. SENCER. They are picked up as they get to school.

Mr. ROGERS. Hopefully.

Dr. SENCER. Hopefully; yes, sir.

Mr. ROGERS. Do all the schools require this?

Dr. SENCER. Not all the schools but there is quite a jump in levels of immunization at the time of school entrance.

Mr. ROGERS. How many schoolchildren are not being immunized, would you say?

Dr. SENCER. Under the age of 20, 4.7 percent have received no polio vaccine.

Mr. ROGERS. What is that in numbers?

Dr. SENCER. Four million.

Mr. ROGERS. Four million?

Dr. SENCER. Yes; under the age of 20.

Mr. ROGERS. Right now we have 6 million people who should be immunized.

Dr. SENCER. This would be inclusive, sir.

Mr. ROGERS. Includes them all?

Dr. SENCER. Yes.

Mr. ROGERS. So, 4 million total of those under 20 who are not immunized. Would that be correct?

Dr. SENCER. That is right, sir.

Mr. ROGERS. These are people then who could develop polio that we could prevent if we immunized them?

Dr. SENCER. Yes, sir.

Mr. ROGERS. What happens when you get polio?

Dr. SENCER. It can range from no disability to death. Fortunately, most cases of polio have little residual. However, as you know, you can have people who have to spend their lives in respirators, crippled.

Mr. ROGERS. An additional cost for the public in those instances, too, isn't it?

Dr. SENCER. Yes.

Mr. ROGERS. Now, what program do you have to immunize the 4 million who are not presently immunized?

Dr. SENCER. Again, there are no specific funds that are being awarded under the partnership for health for polio immunization. These are allowable costs, again under the maternal child health grants of the Children's Bureau and also some of the neighborhood health center programs. This would be something that could be incorporated; into their program if they desired.

Mr. ROGERS. Would you let us know the plans that you have or the Federal Government has to aid in this program?

Dr. SENCER. Yes, sir.

(The following information was received for the record:)

POLIO IMMUNIZATION

Our Department is aware that the levels of protection against polio have fallen off, particularly in central city poverty areas, since the intensive nation-wide effort in the mid-1960's. Data from the 1969 immunization indicate that only 55 percent of the children age 1-4 living in urban poverty areas are adequately immunized. Thus a polio epidemic potential has been building up in these areas. Special program efforts to reduce these hazards are clearly required, and the Communicable Disease Center has been working with State and local health officials to develop adequate protective measures. These efforts have not been confined to the polio immunization problem, however, since similar deficiencies in levels of protection against measles and other communicable diseases have been found in the same poverty areas.

The feasibility of immunizing large numbers of susceptibles in concentrated urban ghetto areas has been demonstrated—provided that local priority is established and adequate resources are available. Utilizing personnel from the Communicable Disease Center, State and local health departments, State and local medical societies, indigenous personnel and other voluntary help, San Antonio, Texas, conducted a community-wide program which provided polio and measles immunization simultaneously. Houston, Texas, administered 76,000 polio immunizations in an eight square block area of a low socioeconomic area with the cooperation of neighborhood health center personnel and 52 organized community groups. The use of neighborhood health center facilities and mobile vaccination vans contributed greatly to the success of this program. In Chicago, temporary clinic facilities were established in housing projects and indigenous personnel from the area were used to elicit response for immunizations. This program immunized a total of 350,000 lower socioeconomic residents and was successful in terminating a disease epidemic.

Intensive immunization activities such as those above could be included in ongoing State or local programs with little difficulty. State or local projects could program intensive immunization activities into one-half or one-third of their total ghetto population at 2 or 3-year intervals. This would probably maintain sufficient immunity to prevent any serious epidemics from occurring.

We believe that earmarked Federal aid for immunization programs should be directed primarily toward intensive nationwide programs—such as those for polio and measles in recent years and the current rubella program—and that ongoing State and local programs, including intensive follow-up efforts in special problem areas, should be financed through State and local funds. Available State and local funds for this purpose include, of course, Federal grant funds for the general support of public health services—including grants pursuant to section 314 of the Public Health Service Act and maternal and child health grants under Title V of the Social Security Act. Although these grant funds are not earmarked for specific disease programs, they provide significant support for many programs, including immunization programs. For example, during the 1968 fiscal year (the last year for which program data are available), 2,946,000 children were immunized against polio under the Maternal and Child Health grant program.

Dr. SENCER. However, I must say that throughout our country I feel that health services, not through your efforts but on the local level, are not as good perhaps as they once were. At one time, I know in most States each county had a county health officer, medical officer, and they required examinations for all food handlers. I am afraid there has been a relaxation of this. Instead of one medical officer per county, we have one per region, perhaps. I am afraid they are not requiring the same standards for food handlers and others. There is less awareness on their part of the problems and less amount of work on their part going toward eradication of these diseases. I regret it.

And it is reflected in occurrences such as we have had here on Capitol Hill.

I thank the distinguished Chairman.

Mr. ROGERS. Now let me ask you: What has happened to TB? Have you had any increased cases this year?

Dr. SENCER. No, sir. Tuberculosis is not reported month to month as other diseases. At the present time, we only get annual reporting of tuberculosis from the county as a whole. We have some special projects set up in some communities trying to see if there are better methods of getting more current information.

Mr. ROGERS. So, we really don't know.

Dr. SENCER. We don't know.

Mr. ROGERS. I would say our experience in Washington would lead me to believe that it perhaps is going up.

Would you have that same feeling after these tests you have taken here?

Dr. SENCER. I don't think I would say it is going up over the country. We do know that with increasing urbanization, tuberculosis is becoming more and more of a city problem, a big city problem. And we are going to see blips, if you will, in the occurrence of tuberculosis.

Mr. ROGERS. What did your tests show on Capitol Hill?

Dr. SENCER. We tested almost 13,000 people. Twenty-five percent of them, roughly, speaking, were tuberculin positive.

Mr. ROGERS. Susceptible to the disease?

Dr. SENCER. This indicates they have been infected with organisms that cause the disease. It does not mean that they have the disease.

Mr. CARTER. Or are allergic to it.

Dr. SENCER. I don't want to get into a professional argument with Dr. Carter.

Mr. ROGERS. Let me ask you this: What do you have to do once you are infected as you say or allergic to it? What happens to trigger it to make you get it?

Dr. SENCER. To make you get the disease?

Mr. ROGERS. Yes.

Dr. SENCER. We wish we knew, sir.

Mr. ROGERS. A run down condition, you get too tired, you get a cold, or what?

Dr. SENCER. I think we would sort of categorize it as stress, the various things that happen to a person that are stressful will lead to a development of the disease.

Mr. ROGERS. So that 25 percent of people here on the Hill that you tested could have this?

Dr. SENCER. Could develop it in the future; yes, sir.

Mr. ROGERS. If there is enough stress in their living, and so forth?

Dr. SENCER. I am sure there are other factors.

Mr. CARTER. Positive reaction means that they have been exposed to it, that they have been infected. More than likely, they have been cured of the disease.

Out of the total number examined here, out of that 25 percent, how many positive X-rays did you get?

Dr. SENCER. There were 150 people who had repeat films because of pulmonary abnormality.

Mr. CARTER. Did these 150 show activity?

Dr. SENCER. No, sir. We have four people who currently are under diagnostic study.

Mr. CARTER. Four out of 25 percent and the total number of positives were how many?

Dr. SENCER. 2,340.

Mr. CARTER. 2,340. Four have shown activity. So that is really a very small percentage of active tuberculosis, though it is too much, any of it is too much in a place of food handling.

Dr. SENCER. We know from studies that 85 percent of all tuberculosis that is going to develop in the future are from people who currently have a positive skin test. So that this is the group that we are concerned about in providing preventive treatment so that they don't become a case some time in the next 40 years.

Mr. ROGERS. Do we have a sufficient program going on in this Nation to prevent people who are susceptible from getting tuberculosis?

Dr. SENCER. At the present time, I would say that we have a program which, with the resources available—I am not talking about financial resources——

Mr. ROGERS. I understand the resources and this gets into a money deal. I understand that.

Dr. SENCER. It is personnel as well as money, sir. It is how many people are there to provide the services that the people need. We estimate this past year 1 million people were provided with preventive treatment as a result of the project grants that we made available to State and local health departments. Ideally, we would say all 24 million people in the country who are infected should receive treatment.

Mr. ROGERS. How many infected? 24 million, you estimate?

Dr. SENCER. Our estimate is 24 million.

Mr. ROGERS. You treated how many? 1 million?

Dr. SENCER. Between 750,000 and 1 million.

Mr. ROGERS. So we have 23 million——

Dr. SENCER. Still to go.

Mr. ROGERS. Who are susceptible to TB, that we know by giving them some help we could prevent it: is that correct?

Dr. SENCER. Yes.

Mr. ROGERS. What do you do to prevent it? Give them pills?

Dr. SENCER. Yes, sir. These pills, when taken for a year, will prevent 80 percent of the TB that is going to develop.

Mr. ROGERS. Once you have developed an active case of TB, how much do you suppose it costs to get over it? It depends, I know, on the degree and the severity.

Dr. SENCER. Ideally a person with active TB should be hospitalized for a minimum of around 3 months.

Mr. ROGERS. What would that cost, do you suppose?

Dr. SENCER. Between \$25 and \$50 a day.

Mr. ROGERS. I would say that is a minimum figure.

Dr. SENCER. Hospitalization for TB, if it is in a tuberculosis hospital and not a general hospital, is more reasonable.

Mr. ROGERS. A place run by the State?

So the total cost is borne by the public for the most part?

Dr. SENCER. Yes. But then you have to realize the person will be out of work, will be nonproductive for possibly 6 to 9 months, and there will be at least a year's outpatient services necessary for that person.

Mr. ROGERS. So, we have a potential here of 23 million people—I am sure they all won't get it, but it is potential—that could cost either them or the taxpayers hospitalization for 6 months, did you say?

Dr. SENCER. Three months.

Mr. ROGERS. Three to six months I presume it would take?

Dr. SENCER. Yes, sir.

Mr. ROGERS. At least \$30 a day. How much is that?

Dr. SENCER. \$2,700 for 3 months.

Mr. ROGERS. \$2,700. That is just hospitalization.

Dr. SENCER. Yes, sir.

Mr. ROGERS. Times 23 million—

Dr. SENCER. All 23 million will not develop tuberculosis.

Mr. ROGERS (continuing). I understand that, but it is a potential.

Dr. SENCER. It is a potential, yes, sir.

Mr. ROGERS. Think what cost could be. I realize all of them won't get it. But we know we could do something about it if we would go out and give these tests to find out if they are susceptible and give them these pills. That would help bring down health costs in in this Nation

Mr. CARTER. Mr. Chairman, I agree with you that is quite true. We are not using the tuberculin test throughout the country as much as we should. I would like to know if you are doing as many tuberculin tests as you did a few years ago.

Dr. SENCER. We are doing more tuberculin tests than we did a few years ago. Much of the tuberculin testing at the present time is being concentrated on two groups. One, on contacts of cases of tuberculosis and the other on school children.

Mr. CARTER. That has been done, of course, for years. I would say in my State there is not as much done as there was a few years ago.

Mr. ROGERS. You are right.

Mr. CARTER. I know I am right as far as my State is concerned, and I regret that this is true.

Of course, it has always been routine to check contacts, has it not, either by skin tests or by the patch test. Now, I would like to ask you a question. What percent of the tuberculin positive people have actually had the disease?

Dr. SENCER. The current feeling, sir, is that all people who have the positive skin test are infected.

Mr. CARTER. Have they recovered?

Dr. SENCER. The disease, if they have had the disease, has not been a recognizable occurrence that has led them to medical care where they have had the X-ray to determine that they had the disease. Most of the people who have a positive tuberculin test have no X-ray evidence of any pulmonary disease.

It has been shown in large numbers of autopsies that if you do serial sections through the lung you will find a small nodule where there is still living tuberculi that does cause disease.

Mr. CARTER. All people who have had TB, or practically all of them, show a positive tuberculin test?

Dr. SENCER. Yes, sir.

Mr. CARTER. How many of those people that show positive tuberculin will come down with the disease in the future?

Dr. SENCER. We have some studies that we have been conducting with the Navy that would indicate that with a fresh infection, a new infection, the risk will be around 1 in 400.

Mr. CARTER. One-fourth percent?

Dr. SENCER. One-fourth percent.

Mr. CARTER. One-fourth percent of the 23 million will possibly come down with it?

Dr. SENCER. Yes, sir.

Mr. LEWIS. Over time.

Mr. CARTER. Thank you.

Thank you Mr. Chairman.

Mr. ROGERS. Now, projecting those figures you gave me, there is a potential of the 23 million. Suppose they all did eventually develop it, and I realize, I am sure they won't, but the potential is there.

With hospitalization alone at a low figure of \$30, it would amount to \$62 billion, not million, but \$62 billion. Now, if 1 percent of them developed it, that is \$621 million. And if a fourth of 1 percent developed it, it is \$155 million.

Now, you are sure a fourth are going to develop it almost, aren't you?

Dr. SENCER. Yes, sir.

Mr. ROGERS. So this is a cost right here, and this is at \$30 a day, which is not realistic, of \$155 million just for hospitalization. That does not count the treatment of the doctors later or anything else. This is a \$155 million potential that could be averted in hospital cost to people.

Now, I understand that you are giving some funds to treat a million people out of the 24 million. So, you are treating one twenty-fourth or about 4 percent.

Dr. SENCER. Yes, sir.

Mr. ROGERS. So you know there are people who are going to have this that we are not even reaching. I would hope that the Department would relook at this to see what can be done to increase this program.

Here we have the technique, we ought to do something. I don't see a sufficient effort. Rather, I see a response to legislation to get at this problem simply negative.

Mr. CARTER. Mr. Chairman, I would recommend in this case that more—well, it is going to take more funding, but more emphasis be placed on enlarging the number of public health officers throughout our States.

Of course, I know it is difficult to keep them in the Public Health Service, but we should do something to upgrade this division of the medical profession and increase the number and increase their effectiveness toward examination of people who can spread this disease, foodhandlers particularly.

I should think that a regular examination of school children would be extremely valuable. It is not necessary to use the old tuberculin test which we used and which is a little bit painful. Of course, it is percentage-wise the one which tells us most. But the patches can easily

be used. I just hope that we don't lose the effectiveness of health officers throughout the country. They have in the past rendered a great service, and we need more of them.

Thank you, Mr. Chairman.

Mr. ROGERS. Now, what did your study show at the White House? How many were susceptible there at the White House?

Dr. SENCER. Approximately the same percentage, sir. We tuberculin-tested 811. There were 22 percent who were positives.

Mr. ROGERS. How many would that be?

Dr. SENCER. It was 150.

Mr. ROGERS. Any active cases?

Dr. SENCER. We did not find any active cases. There are two people who are under further investigation.

Mr. ROGERS. Two are possible cases?

Dr. SENCER. Yes, sir.

Mr. ROGERS. But you don't know yet for sure?

Dr. SENCER. No, sir.

Mr. ROGERS. When will you know?

Dr. SENCER. Because of the characteristics of the tubercle bacillus it may be up to 2 months before we know it. It takes that long to culture the organism.

Mr. ROGERS. Will you let the committee know?

Dr. SENCER. Yes, sir; we will.

Mr. ROGERS. Do you know if they require health tests for people who work in restaurants over the Nation?

Dr. SENCER. This varies tremendously from community to community. This is usually dependent on local health codes. In the past there was a great deal of emphasis placed on food-handler examinations. We have to recognize that tuberculosis is an airborne disease. You catch it from breathing it and not from eating it.

Mr. CARTER. I believe you are going wrong there. There is bovine tuberculosis, isn't there? Actually we can get it from contact, I would think, and from eating food.

Dr. SENCER. Food handlers in general come from the lower socioeconomic groups. They are a fairly transient group that is more likely to have tuberculosis. So we feel that this is a group that the health department should be concerned about, not because they are food handlers, but because they are coming from high-risk groups.

Mr. ROGERS. Do we have any program to try to encourage this, to check it? What about in the District of Columbia?

Dr. SENCER. The District of Columbia, with the resources that have been available to them have been concentrating on people who are known to have tuberculosis, trying to make sure that they provide adequate services to those people and to their contacts.

Mr. ROGERS. But they do not screen the people working in the food establishments?

Dr. SENCER. With their resources, they are not able to routinely screen all people who work in food-handling establishments.

Mr. CARTER. This is bad, Mr. Chairman. Every food handler should have a tuberculin test.

Mr. ROGERS. Can we do anything about that? Do we have any authority to get into this field?

Dr. SENCER. There is no authority to get into the field. Again I would have to say it is a matter of resources. With the resources that have been available to the District they have had to place this emphasis on people who are in need of treatment and the reason that the Communicable Disease Center assisted here on Capitol Hill, rather than the District Health Department, is that their people were busy testing in the schools.

Mr. ROGERS. Don't you have any project grant money that could go to that?

Dr. SENCER. There is a project grant to the District of Columbia, yes, sir.

Mr. ROGERS. But it is not doing the job.

Dr. SENCER. Again, sir, this is just a matter of priorities. The District with the funds that have been made available to them have put it on things that have a greater priority.

Mr. ROGERS. In other words, food-handlers they don't give much priority to?

Dr. SENCER. If you have to equate between providing services to a person that you know to be infectious and screening, you have to provide your services to the person whom you know to be ill.

Mr. ROGERS. You mean they only have enough money to provide the one-fourth of 1 percent care?

Dr. SENCER. They are providing as good clinic services as possible to people who are known to have tuberculosis, to contacts of cases of tuberculosis, and to the schools.

Mr. ROGERS. How do they know how many food-handlers have it or don't, if they don't screen them? There may be many active cases like we found on the Hill.

Dr. SENCER. With the resources available to the District of Columbia today if they decided to screen food-handlers, they would have to stop providing services to the people who are known to have tuberculosis.

Mr. ROGERS. Here is what I mean. If you know there is a problem in a communicable disease, why does not the Communicable Disease Center and HEW work on some program to get additional funds?

You are telling me you don't need these funds, you don't need this bill. Why don't we do something?

Mr. CARTER. Mr. Chairman, this applies, I believe, to the District. Some States have these programs going on and they require that food-handlers be checked both for tuberculosis and venereal diseases.

Mr. ROGERS. I should think it would be essential.

Mr. CARTER. Absolutely.

Mr. ROGERS. Let me ask you this. Could you furnish to the committee a rundown of all States that require health certificates for food-handlers? I realize some of this is done on a community level, but I should think the State health officers would know whether the communities have it or not or if they don't know, certainly we ought to know.

(The following information was received for the record.)

HEALTH EXAMINATION LEGISLATION OR REGULATIONS FOR FOOD HANDLERS

State	Law/or regulation	Health certificate
Alabama	No (local option)	
Alaska	do	
Limited local areas	Ordinance	Yes.
Arizona	Legislation	Yes.
Arkansas	No (local option)	
Limited local areas	Ordinance	Yes.
California	Legislation	Yes.
Colorado	No (local option)	
Denver	Ordinance	Yes.
Connecticut	No (local option)	
Delaware	Regulation	Yes.
District of Columbia	No (local option)	
Florida	Statute (local option)	
Miami-Dade	Ordinance	Yes.
Tampa-Hillsborough	do	Yes.
Georgia	Regulation	Yes.
Hawaii	Legislation	Yes.
Idaho	No (local option)	
Illinois	do	
Chicago	Regulation	Yes.
Indiana	No (local option)	
Iowa	do	
Some local areas	Ordinance	Yes.
Kansas	No (local option)	
Kansas City	Ordinance	Yes.
Topeka	do	Yes.
Wichita	do	Yes.
Some other local areas	do	Yes.
Kentucky	No (local option)	
Louisiana	Regulation	Yes.
Maine	Legislation	Yes.
Maryland	No (local option)	
Prince Georges and Montgomery Counties	Ordinance	Yes.
Massachusetts	No (local option)	
Limited local areas	Ordinance	Yes.
Michigan	No (local option)	
Detroit	Ordinance	Yes.
Minnesota	No (local option)	
Minneapolis	Regulation	Yes.
Bloomington	do	Yes.
Mississippi	do	Yes.
Missouri	No (local option)	
Jefferson City	Ordinance	Yes.
Montana	No (local option)	
Limited local areas	Ordinance	Yes.
Nebraska	No (local option)	
Omaha-Douglas	Regulation	Yes.
Lincoln-Lancaster	do	Yes.
Nevada	No (local option)	
Reno-Clark	Ordinance	Yes.
New Hampshire	No (local option)	
New Jersey	do	
Jersey City	Regulation	
Newark	do	
New Mexico	Legislation	Yes.
New York	No (local option)	
Buffalo	Ordinance	Yes.
Rochester	do	Yes.
North Carolina	Regulation	Yes.
North Dakota	No (local option)	
Limited local areas	Ordinance	Yes.
Ohio	Legislation	Yes.
Oklahoma	No (local option)	
Oklahoma City	Ordinance	Yes.
Oregon	No (local option)	
Limited local areas	Ordinance	Yes.
Pennsylvania	No (local option)	
Philadelphia	Ordinance	Yes.
Pittsburgh	do	Yes.
Rhode Island	No (local option)	
Limited local areas	Ordinance	Yes.
South Carolina	No (local option)	

HEALTH EXAMINATION LEGISLATION OR REGULATIONS FOR FOOD HANDLERS—Continued

State	Law/or regulation	Health certificate
South Dakota	do.	
Sioux Falls	Ordinance	Yes.
Tennessee	No (local option)	
Limited local areas	Ordinance	Yes.
Texas	No (local option)	
El Paso	Ordinance	Yes.
Fort Worth	do.	Yes.
Houston	do.	Yes.
San Antonio	do.	Yes.
Utah	No (local option)	
Limited local areas	Ordinance	Yes.
Vermont	No (local option)	
Virginia	do.	
Norfolk	Ordinance	Yes.
Washington	Legislation	Yes.
West Virginia	No (local option)	
44 counties	Ordinance	Yes.
Wisconsin	No (local option)	
Milwaukee	Ordinance	Yes.
Wyoming	No (local option)	
Limited local areas	Ordinance	Yes.

¹ Not required by any local jurisdictions.

² Food Handlers repealed August 1969.

³ Local health officers may require individual certification to continue employment.

Mr. CARTER. Mr. Chairman, there is another question. I believe you stated that you did examine the schoolchildren in the District. I would like to know how many were given tuberculin tests last year and what your percentage of positives was.

Dr. SENCER. I will have to supply that for the record.

(The following information was received for the record:)

WASHINGTON, D.C., SCHOOL CHILDREN TUBERCULIN TESTING PROGRAM, SCHOOL YEAR 1968-69

	Number tested	Reactors	Rate
Kindergarten	7,185	32	0.4
1st grade	10,583	40	.4
Total	17,768	72	1.4

¹ Comparable to national average.

Note: Total enrollment in kindergarten and 1st grade, 28,059; percent of participation, 63.

Mr. ROGERS. I understand in this measles program where you are trying to vaccinate children, Massachusetts told me, at least I heard, that they can vaccinate the first, second, and third grades, but they don't have any money to go up further.

Dr. SENCER. This year with the funds available, we have placed priority on children who are entering into the school situation because they are the ones who spread that back into the community and to their parents.

Mr. ROGERS. Let me have once more the amount of funds going into the German measles program?

Mr. LEWIS. There is a total of \$25.6 million for the German measles in fiscal year 1970, the first startup year.

Mr. ROGERS. How many will that cover?

Mr. LEWIS. Approximately, my recollection is 8 to 10 million children.

Mr. ROGERS. How many are there that should be vaccinated?

Mr. LEWIS. Over time—

Mr. ROGERS. I mean right now.

Dr. SENCER. Forty-five million, sir.

Mr. ROGERS. Forty-five million, and we are doing—

Dr. SENCER. We will be able to provide vaccine for 10 million.

Mr. ROGERS. What does it cost to take care of a mentally retarded child, would you estimate?

Dr. SENCER. The estimates that have been worked out from the 1964 epidemic of German measles where there were from 20 to 30 thousand children born with the rubella defects, Dr. Cooper at the New York University Medical School estimates \$2.6 billion in lifetime costs for these children.

Mr. ROGERS. \$2.6 billion?

Dr. SENCER. Yes, sir.

Mr. ROGERS. That is just for one epidemic?

Dr. SENCER. That is for the results of the 1964 epidemic, yes, sir.

Mr. ROGERS. One epidemic?

Dr. SENCER. Yes, sir.

Mr. ROGERS. Have you requested additional funds to try to touch the 45 million?

Dr. SENCER. There are funds in the 1971 budget, \$16 million, which will continue to vaccinate children. You have to realize that the vaccine has just been licensed this year. Supplies have been limited. We have been buying it. I have just been told that another company has been licensed so there should be additional supplies available.

Mr. ROGERS. If we had sufficient funds, I expect the company would produce them, would it not, or subcontract to other companies to produce them?

Dr. SENCER. They cannot subcontract, sir, because of the licensure. I think that they are producing as fast as the technology allows. It is not an easy vaccine to produce.

Mr. ROGERS. They are producing as much as can be produced?

Dr. SENCER. Yes, sir; without going into capital investment—

Mr. ROGERS. I understand, but I am saying if we really put emphasis on getting these people vaccinated, it might require capital investment, it might require some costs. I just don't think we grasp yet the importance of preventive medicine.

I am not trying to particularize it, I am talking about the Department. I am shocked that they come up and oppose a bill like this and give us the business, "Well, we are going to give it all in partnership."

I am basically in favor of the partnership approach. I understand that. But this is not the answer when we have epidemics that are breaking out. You can't plan those too well. We are not even planning for giving tests on TB that we can, though, we are just not doing it. Something needs to be done. I hope this legislation will give impetus to getting something done.

Do you have any questions, Mr. Preyer?

Mr. PREYER. No questions.

Mr. ROGERS. Thank you.

I hope the Department will review its position on this and let the committee know if we can't do more on this communicable disease.

Mr. LEWIS. Mr. Chairman, may I say that with respect to the rubella program, it has been the Department's position all the time from the outset that it would do the maximum, that funds as such would not be a limiting factor, and it is still our understanding that even if we put additional funds in right now, given the necessity for production and organization of a program on a nationwide basis, we could not necessarily reach more children.

Mr. ROGERS. Why is that?

Mr. LEWIS. Because it takes an organization, it takes production of vaccine to do it.

Mr. ROGERS. I thought you said you had your organization going.

Mr. LEWIS. Yes. I am talking about the organization in the entire country.

Mr. ROGERS. You mean you can vaccinate in the first, second, and third, but not in the fourth and fifth grades. I thought in every school you could do that.

Mr. LEWIS. Dr. Sencer would agree we would not be in a position to get 45 million children immediately.

Mr. ROGERS. Certainly we could do better than the 10, could we not? I realize you may not cover 45 million in 1 year, but certainly you can do better than 10. I just don't think we are trying to get at it.

Tuberculosis—I would have thought probably there was no case of TB up here. I never heard about it. All of a sudden we have had a couple of deaths.

Dr. SENCER. There have been two reported deaths.

Mr. ROGERS. There are four active cases and a fourth of the people susceptible. This is frightening to me and shocking when we in this country have the technique to do something about it.

I intend to discuss this with the Secretary to see if we cannot put some emphasis on that and give you some help in the Communicable Disease Center. That is what we need to do: to put to work the knowledge that we have as of this present day. I do appreciate your coming up. I realize these decisions are not all yours by any means, but I do think the problem is well out of hand for what we could do if we were to address ourselves to it.

Thank you for being here. I appreciate your patience.

Mr. LEWIS. Thank you, Mr. Chairman.

Mr. ROGERS. Our next witness is Dr. Robert J. Anderson, the medical director of the American Thoracic Society, appearing for the National Tuberculosis and Respiratory Disease Association.

Dr. Anderson, I am delighted to see you. I am sorry that we have taken so long. We will make your statement a part of the record, without objection. If you would proceed to let the committee have your thoughts.

STATEMENT OF DR. ROBERT J. ANDERSON, ON BEHALF OF THE NATIONAL TUBERCULOSIS AND RESPIRATORY DISEASE ASSOCIATION

Dr. ANDERSON. Mr. Chairman and members of the committee, if I may, I would like to read this statement and add some things that I am prompted to add by the discussion which has taken place this morning.

First, Mr. Preyer, we are one of many "quarters" that feels that communicable diseases are not necessarily approached best by the comprehensive health program.

The National Tuberculosis and Respiratory Disease Association, along with its State and local associations, has as its primary goal the eradication of tuberculosis and the control of respiratory diseases in the United States. In view of recent trends in financing of tuberculosis under the comprehensive health program, we believe that progress toward eradication of that disease will be seriously impeded by remaining under that program. Therefore we support legislation now being considered by this committee to provide authorization for specific grants for communicable disease control.

Because tuberculosis control programs are carried out in the framework of the health system of the country and that systems must therefore be strong and effective, our organization supported the Comprehensive Health Planning and Public Health Service Amendments of 1966, now section 314 of the Public Health Service Act. The underlying concepts of this legislation are directed at the development of stronger, more effective State and local health services and programs.

However, on that occasion, and since then, we have stated our conviction that Federal money for tuberculosis control must be distributed through the project grants mechanism and must be adequate in amount in order to accomplish an acceleration in tuberculosis control. These were also the conclusions of the Surgeon General's Task Force on Tuberculosis in 1963. I am providing the committee with a copy of that report.¹

As a result of the task force's recommendations, project grants specifically for tuberculosis control were subsequently adopted by the Public Health Service as the main method for furnishing Federal support to this disease program. Although funding never reached the level suggested by that task force, these project grants brought about outstanding improvements in tuberculosis control in nearly the entire country—improvements which are documented in the reports from areas receiving those grants.

In the meantime, the comprehensive health features of section 314 of the Public Health Service Act have become operative. Under the law, almost any kind of health program that a State or locality might carry out is eligible for support by the 314(d) formula mechanism. Innovative activities and those determined to be of national significance are also eligible for project grants through the federally administered 314(e) program. However, our observations of tuberculosis control funding force us to conclude that implementation of communicable disease control, and especially tuberculosis control, is not soundly approached by the provisions of section 314.

First, most tuberculosis control programs are not eligible for 314(e) support because they are not innovative. Secondly, the formula used for allotment of 314(d) funds is based on population and per capita income which does not relate well to the variations in the tuberculosis problem. Furthermore, the States with large tuberculosis problems are forced to make choices within the constraints of these formula funds between tuberculosis control activities and other health services

¹ The report referred to is entitled "The Future of Tuberculosis Control" a report to the Surgeon General of the Public Health Service by a task force on tuberculosis control—Public Health Service publication No. 1119, a copy of which may be found in the committee files.

to fund an effective tuberculosis control program in such States will take a large proportion of their formula funds. Thus the systems of (d) and (e) grants are not suitable to assure the maintenance of communicable disease control, an activity which is basic to protection of the public health.

The features of H.R. 11913 and H.R. 12067 being considered here today augment 314(d) and 314(e) by assuring programs for prevention and control of tuberculosis and other communicable diseases. We believe the legislation will achieve that objective for the following reasons:

First, it sets up a separate authorization for tuberculosis and other communicable diseases, thus enabling the Congress to make certain that the primary and elemental public health function of communicable disease control is carried out. Because the grants are solely for communicable disease, State and local authorities are not forced into the distressing position of making a Solomon's choice between these essential programs and the innovative and other important health activities that are eligible for 314 funding. In short, the legislation sets a national policy that communicable disease prevention and control is fundamental to public health.

Second, it recognizes that the techniques for the control of tuberculosis and many other communicable diseases are known and simply need to be applied for the public to benefit.

Third, the legislation recognizes that the spread of communicable disease is potentiated by our people's extreme mobility and that the control of these diseases is a function which, if not performed well in each State and locality, has great impact for other States and localities. In this regard, it is also enables States to survey and assess their communicable disease problems.

Fourth, the legislation provides that the awarding of grants shall give consideration to the relative extent of the communicable disease problem and to the level of performance in preventing and controlling such diseases. Tuberculosis is a health problem which varies considerably from State to State and even more so, within States. For 1968 data, there was a 22-fold difference in death rates and an eightfold difference in case rates between the lowest and highest ranking State. Attachment 1 of the appended NTRDA release shows the range in State rates. Obviously, if the Congress wants to reduce the incidence of tuberculosis, it must get support and programs to where the problem is. A formula based on population and per capita income such as governs 314(d) simply does not do so.

As I understand these legislative proposals, they provide that grants be made in such a way that the record of performance in preventing or controlling such diseases must be considered and rewarded. This means to us that operational workloads for activities that are important and critical in preventing or controlling diseases, the sorts of things you were talking about earlier, be taken into consideration in the awarding and supporting of these grants. Such considerations might include the number of contacts of TB and VD cases who were examined, the number of identified cases who complete their courses of drugs for preventive and definitive treatment of tuberculosis.

This record of performance should be documented in the report which the Secretary is required to submit annually, we presume to the Congress. This report will enable the Congress and the public to see what has been accomplished with the funds they have provided. Mr. Lewis said that the comprehensive health program was focused on the organization and delivery of health services.

We think equally important is to get the technical methods of control instituted around the country where they are needed.

However, I should like to see the legislation more explicit in two regards than it is in its present wording.

First, there should be authority for grants for eradication-type, intensive, short-term, one-time campaigns in areas whose entitlement on the basis of extent of the disease problem would not provide funds adequate for such campaigns.

Second, although the legislation provides clearly that grants be available on entitlement based on extent of the problem, and that payment be in consideration of performance, there is need for an intermediate step in the award process which might be spelled out in the legislation. We believe that there should be a requirement that a State or political subdivision requesting a project grant submit a plan of operation to HEW for review and final approval. Such a plan should include definitive descriptive information on administrative, organizational, budgetary and technical aspects of operations, as well as a definition of the population groups to be served. Agreement between HEW and the State or political subdivision on this plan should relate to the performance factors that would be the basis for final payment and to the reports required of the recipient.

Intensive specialized control programs will have significant effects on the tuberculosis problem. In 1968, under such programs, new active cases of tuberculosis reported in the United States—42,758—dropped 6.3 percent, the largest annual percent decline in the preceding 5 years. Dr. Sencer told you this morning that last year this decline increased even further. Now, we attribute this important improvement to the fact that there has been an intensive control program directed and organized by the Public Health Service and the States on a project grant basis, directing known control efforts into certain areas.

This started in 1963, as I mentioned, and is now just beginning to have its impact. If we have problems with funding of TB control, we can see nothing but the total effort diminishing.

Mr. ROGERS. Are they pulling away funding in this area?

Dr. ANDERSON. I think it is inevitable that it would happen under the present comprehensive health legislation, Mr. Rogers, because the formula (d) moneys, as I point out, are distributed on the basis of population and per capita income and don't take into account the problem or the techniques that are going to be used to approach it.

In spite of this progress, we expect that the eradication of tuberculosis will be slow and difficult—truly as the word signifies—a pulling out of the roots. We still have about 25 million people who have been infected with the tubercle bacillus, a large number of whom may break down, which means most likely in those 25 million

people there are living tubercle bacilli in their bodies which continue to excrete a little protein which is responsible for the positive skin tests. As long as there are living tubercle bacilli in a person's body, that person is under danger of developing a life-threatening process. He has a little process which may be indistinguishable in X-rays, but they are picked up by the skin test on the arm. We think that while we have this number of people at risk it is essential that we apply preventive treatment widely enough that the number of such events will be reduced, just as you apparently feel, Mr. Chairman.

The legislative proposals before you will make it possible to continue such efforts. The tuberculosis control situation is now precarious in many localities, due to termination of 314(e) project support. We are beginning to get reports as to the precariousness of this situation in the States. We hope therefore, that the Congress will enact communicable disease grants legislation in order that progress in the tuberculosis eradication campaign, and in control of all communicable disease, will not be halted.

(The attachments accompanying Dr. Anderson's statement follow:)

NATIONAL TUBERCULOSIS AND RESPIRATORY DISEASE ASSOCIATION,
New York, N.Y. May 6, 1969.

From: L. B. Clayton, M.D. and M. Brautigam

To: Constituent and Affiliated Associations

Subject: New active cases and deaths, by state, 1967; provisional 1968 cases.

Cases in big cities, 1967

State health departments reported a total of 45,647 new active tuberculosis cases in the United States in 1967. The case rate of 23.1 per 100,000 population represents a decline of 5 per cent from the 1966 rate of 24.4. This annual reduction has been surpassed only once since 1960. Provisional figures for 1968 indicate a greater decrease in both the number of cases and the case rate.

Seventeen states, each with more than 1,000 new cases in 1967, had a combined total of 34,614 cases, constituting 76 per cent of all cases reported in the country. Case rates among the states ranged from 45.7 per 100,000 population in Hawaii to 5.5 in Iowa. The District of Columbia, which is classes as a city, had a case rate of 52.4 per 100,000 population in 1967.

Although the annual incidence of tuberculosis is a useful indicator of tuberculosis trends, it does not reflect the complete tuberculosis problem, i.e., the total cases under treatment or supervision. At the end of 1967, the Public Health Service estimated a total of 315,000 such cases on current health department registers throughout the country, approximately seven times the number of new active cases reported during the year.

Tuberculosis deaths numbered 6,901 in 1967 with a death rate of 3.5 per 100,000 population, a decline of 10 per cent over the previous year's rate of 3.9. The 1968 death rate is estimated at 3.3 per 100,000 population. Mortality rates ranged from 6.7 in Alabama to 0.3 in Utah, the lowest death rate ever recorded in any state.

Fifteen states and the District of Columbia had both case and death rates above the national average.

Cities with 250,000 or more residents accounted for 17,268 new active tuberculosis cases or 38 per cent of the 45,647 reported in the United States during 1967. Nine of these cities had case rates more than twice the U.S. average of 23.1.

NEW ACTIVE TUBERCULOSIS CASES AND DEATHS WITH RATES PER 100,000 POPULATION, BY STATE:
1967 (FINAL) AND 1968 (PROVISIONAL)

State	1968 provisional, new active cases		1967 final, new active cases		1967 final, tuberculosis deaths	
	Number	Rate	Number	Rate	Number	Rate
United States.....	42,758	21.4	45,647	23.1	6,901	3.5
Alabama.....	1,338	37.5	1,379	38.9	239	6.7
Alaska.....	112	40.4	110	40.4	10	3.7
Arizona.....	471	28.2	436	26.5	101	6.1
Arkansas.....	564	28.0	497	24.9	81	4.1
California.....	3,754	19.5	4,171	22.1	487	2.6
Colorado.....	1,232	11.3	256	12.7	52	2.6
Connecticut.....	368	12.4	411	14.1	75	2.6
Delaware.....	100	18.7	122	23.3	22	4.2
District of Columbia.....	420	51.9	423	52.4	87	10.8
Florida.....	1,620	26.3	1,601	26.5	199	3.3
Georgia.....	1,074	23.4	1,223	27.1	140	3.1
Hawaii.....	300	38.6	348	45.7	16	2.1
Idaho.....	63	8.9	55	7.8	11	1.6
Illinois.....	3,006	27.4	2,999	27.6	379	3.5
Indiana.....	1,006	19.9	1,069	21.3	175	3.5
Iowa.....	118	4.3	150	5.5	40	1.5
Kansas.....	226	9.8	223	9.8	43	1.9
Kentucky.....	1,037	32.1	1,071	33.4	189	5.9
Louisiana.....	910	24.4	966	26.3	187	5.1
Maine.....	100	10.2	120	12.2	25	2.5
Maryland.....	1,118	29.8	1,187	32.2	181	4.9
Massachusetts.....	908	16.7	910	16.8	198	3.7
Michigan.....	1,816	20.8	1,930	22.4	224	2.6
Minnesota.....	300	8.2	394	10.9	53	1.5
Mississippi.....	548	23.4	616	26.3	80	3.4
Missouri.....	815	17.6	882	19.2	172	3.7
Montana.....	102	14.7	109	15.6	17	2.4
Nebraska.....	120	8.4	121	8.4	14	1.0
Nevada.....	93	20.5	147	33.4	13	3.0
New Hampshire.....	43	6.1	44	6.4	9	1.3
New Jersey.....	1,327	18.7	1,455	20.9	261	3.4
New Mexico.....	193	19.0	248	24.5	41	4.1
New York.....	4,750	26.2	5,069	28.2	771	4.2
North Carolina.....	1,222	23.8	1,247	24.6	163	3.3
North Dakota.....	45	7.2	49	7.8	9	1.2
Ohio.....	1,258	11.9	1,548	14.7	339	3.1
Oklahoma.....	437	17.4	442	17.6	102	4.0
Oregon.....	290	14.4	322	16.3	39	2.7
Pennsylvania.....	2,429	20.7	2,736	23.4	494	4.2
Rhode Island.....	121	13.3	148	16.5	30	3.3
South Carolina.....	645	24.0	716	26.9	100	3.8
South Dakota.....	104	15.8	119	17.8	11	1.6
Tennessee.....	1,104	27.8	1,199	30.4	208	5.3
Texas.....	3,108	28.3	3,209	29.6	375	3.5
Utah.....	74	7.2	65	6.4	3	0.3
Vermont.....	30	7.1	44	10.6	20	4.8
Virginia.....	1,454	31.6	1,521	33.5	168	3.7
Washington.....	566	17.3	507	15.8	76	2.4
West Virginia.....	442	24.5	539	29.8	85	4.7
Wisconsin.....	453	10.8	463	11.0	80	1.9
Wyoming.....	24	7.6	31	9.7	7	2.2
Puerto Rico ²	741	27.2	1,191	44.2	(³)	(³)

¹ Excludes 95 military cases.

² Not included in totals.

³ Not available.

Source: Tuberculosis Branch, National Communicable Disease Center, PHS, and National Center for Health Statistics, PHS.

NEW ACTIVE TUBERCULOSIS CASES AND RATES PER 100,000 POPULATION IN CITIES WITH 250,000 OR MORE POPULATION, 1967

City	New active cases	
	Number	Rate per 100,000
Total, 56 cities.....	17,268	38.5
Akron, Ohio.....	42	14.0
Albuquerque, N. Mex.....	39	16.7
Atlanta (Fulton Co.), Ga. ¹	276	45.7
Baltimore, Md.....	683	75.1
Birmingham, Ala.....	200	56.9
Boston, Mass.....	276	41.9
Buffalo, N.Y.....	215	46.2
Chicago, Ill.....	1,989	56.0
Cincinnati, Ohio.....	143	28.6
Cleveland, Ohio.....	289	35.1
Columbus, Ohio.....	88	16.1
Dallas, Tex.....	242	28.8
Dayton, Ohio.....	91	34.0
Denver, Colo.....	88	18.4
Detroit, Mich.....	951	59.4
El Paso, Tex.....	96	30.2
Fort Worth, Tex.....	104	26.2
Honolulu, Hawaii.....	183	50.4
Houston, Tex.....	562	47.3
Indianapolis (Marion Co.), Ind. ¹	294	38.6
Jersey City, N.J.....	115	42.5
Kansas City, Mo.....	143	28.2
Long Beach, Calif.....	52	13.6
Los Angeles, Calif.....	851	30.1
Louisville (Jefferson Co.), Ky. ¹	192	28.6
Memphis (Shelby Co.), Tenn. ¹	162	22.1
Miami (Dade Co.), Fla. ¹	348	32.0
Milwaukee, Wis.....	173	22.4
Minneapolis, Minn.....	73	15.8
Nashville (Davidson Co.), Tenn. ¹	155	34.0
Newark, N.J.....	296	74.3
New Orleans, La.....	224	32.9
New York, N.Y.....	3,542	43.6
Norfolk, Va.....	126	40.7
Oakland, Calif.....	84	22.0
Oklahoma City, Okla.....	74	19.2
Omaha (Douglas Co.), Nebr. ¹	59	14.8
Philadelphia, Pa.....	942	45.1
Phoenix (Maricopa Co.), Ariz. ¹	157	17.6
Pittsburgh, Pa.....	253	45.6
Portland, Oreg.....	118	30.7
Rochester, N.Y.....	90	29.4
Sacramento, Calif.....	124	44.9
St. Louis, Mo.....	281	44.8
St. Paul, Minn.....	62	19.8
San Antonio, Tex.....	295	42.1
San Diego, Calif.....	133	19.8
San Francisco, Calif.....	368	49.2
San Jose, Calif.....	72	18.7
Seattle, Wash.....	142	24.5
Tampa, Fla.....	68	21.5
Toledo, Ohio.....	63	16.0
Tucson, Ariz.....	55	22.0
Tulsa, Okla.....	63	21.3
Washington, D.C.....	423	52.4
Wichita, Kans.....	39	13.6

¹ Since details for principal city were not available, data shown are for county.

Source: Tuberculosis Branch, National Communicable Disease Center, PHS.

Mr. ROGERS. Thank you very much, Dr. Anderson. I appreciate very much your testimony. It has been very helpful and it has pointed up some of the things that I thought were true.

Mr. Preyer?

Mr. PREYER. I would just like to thank Dr. Anderson for helping to continue my medical education on this committee. This is a very interesting and helpful statement.

Dr. ANDERSON. Thank you, sir.

Mr. ROGERS. Thank you so much, Doctor. I would just like to note that I don't know why they don't use this process of going in where the rate is heavy in some places. I notice in Hawaii you pointed out it is 45.7 percent per 100,000 to 5.5 per hundred thousand in Iowa.

In the District of Columbia, it is 52.4 percent per 100,000. Now, this is very easy, I would think, to begin to get at this problem if they will put the funds where the problem is. I think that is what you are saying.

Dr. ANDERSON. That is what I am saying. If I may say, on the District of Columbia, for example, under the formula for formula (d) grants the District of Columbia would get about a \$63,000 increase out of the formula money. Out of the project money there has been devoted about \$600,000. As you have learned, even that amount has been inadequate to really cope with the problem now.

Mr. ROGERS. Thank you, Doctor.

Our next and last witness this morning is Dr. James A. Peavy, commissioner of health from the Texas State Department of Health, who is appearing for the Association of State and Territorial Health Officers.

Dr. Peavy, it is good so see you again. We are grateful for your being here, because it is an important problem and certainly you and those of the association you represent are very much on top of this problem, I am sure. We are pleased to receive your testimony.

STATEMENT OF DR. JAMES E. PEAVY, ON BEHALF OF THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS

Dr. PEAVY. Thank you very much. It is an honor to be here.

Mr. Chairman, I do want to express not only my personal appreciation, but that of the association for your recognition of the importance of preventive measures. Your statements were very timely and we feel exactly the same way. I cannot visualize, with the rising costs of medical care, letting programs that we know are effective go by the wayside and continue the increased cost of treatment but not put emphasis on preventive treatment.

I am James Peavy, and I serve as commissioner of health of the Texas State Department of Public Health. I am the immediate past president of the Association of State and Territorial Health Officers, and the testimony I present today is on behalf of that association.

First of all, I want to express the support of our association for S. 2264, H.R. 11913, H.R. 12067, and related measures. We strongly endorse the financial assistance for preventing and controlling tuberculosis, venereal diseases, and other communicable diseases.

COMPREHENSIVE HEALTH PLANNING

As this committee knows, the Association of State and Territorial Health Officers has been a leading supporter of the legislation that authorizes financial assistance for comprehensive health planning and formula and project grants for health services under section 314 of the Public Health Service Act. When this legislation was originally considered, it was our hope that section 314(d) of the Public Health

Service Act would be funded at a level that would permit the States to meet their most urgent public health needs. Unfortunately, this hope has not been realized. You will recall that the Department of Health, Education, and Welfare proposed the following appropriations for formula grants in recommending the enactment of this legislation to the Congress:

1968	-----	\$170, 500, 000
1969	-----	230, 700, 000
1970	-----	292, 600, 000
1971	-----	297, 000, 000
1972	-----	300, 000, 000

Our own recommendations were even higher. Last year we were funded at a level of \$62½ million. However, only \$90 million has been approved for section 314(d) grants for 1970. The same level of funding is proposed in the 1971 budget of President Nixon. The Association of State and Territorial Health Officers continues to urge that the authorization for appropriations and the actual appropriations under 314(d) be increased substantially, and we strongly support the concept of the legislation that is identified as the "partnership for health." But we are faced with a conflict in theory and practice. Simply stated, Federal support for health programs in the States at present has the broadest legislative authority but no money. We cannot ignore pressing health problems while we wait for additional funding under section 314(d). Consequently, we urge the enactment of the legislation before the subcommittee.

TUBERCULOSIS

In 1963, the Surgeon General's Task Force on Tuberculosis recommended a 10-year program to combat and control tuberculosis, as Dr. Anderson so ably pointed out. This was some 10 years after drugs were discovered that made specific chemotherapy for the disease possible. Significant reductions were made in the number of new active cases of tuberculosis and in the number of deaths due to tuberculosis.

Despite this progress, the Department of Health, Education, and Welfare in 1969 proposed that the \$18 million of project grants for the control of tuberculosis under section 314(e) of the Public Health Service Act be discontinued. At the same time, the Department recommended that a corresponding dollar figure, \$18 million, be added to formula grants under section 314(d) and be used for combating tuberculosis, venereal disease, and alcoholism.

The problem caused by this decision of the Department is no minor matter. By shifting the \$18 million from project to formula grants, the allocation on a State-by-State basis was radically changed. The project grants were distributed with consideration given to the relative extent of the tuberculosis problem. The formula grants, however, by law are allocated among the States on the basis of population and per capita income. The States with a significant tuberculosis problem, therefore, for the most part have greatly reduced funds for the control of tuberculosis.

The discovery of active cases of tuberculosis on the environs of the Congress and two deaths attributed to this infectious disease is evi-

dence "close to home" of the importance of continuing public health programs to combat tuberculosis and other preventable diseases.

VENEREAL DISEASE

The venereal diseases are another pressing public health problem that is in need of attention at the Federal level. While it is true that there has been a gradual decline in the number of cases of syphilis, there has been a dramatic rise in the incidence of gonorrhea:

Year:	Newly reported cases of gonorrhea
1958.....	232, 513
1960.....	258, 933
1962.....	263, 708
1964.....	300, 667
1966.....	351, 738
1968.....	431, 380

IMMUNIZATION

Despite the fact that we have preventive agents for diphtheria, measles, polio, rubella and tetanus, these diseases continue to take a needless toll in death and disability. Diphtheria has increased in each of the last 4 years, 1965 through 1968, from 164 to 209, to 219 and to 243. We still have 22,000 cases of measles reported and this is an understatement since the reporting is less than complete. German measles is another communicable disease that can be prevented with a vaccine. A vaccine has recently been licensed. Only 50,000 cases of German measles are reported each year, but the actual incidence is estimated to be approximately 2.5 million. This disease causes mild discomfort, but in a pregnant woman carries the risk of death and a lifetime of disability to the unborn child. The National Nutrition Survey as well as the Office of Economic Opportunity—and I might add that my own State's nutrition survey has confirmed this—reports that less than one-half of the preschool children in poverty areas are adequately immunized against polio, measles and other preventable diseases. Seventy-five percent of these immunizations are done by health departments. If we are to eliminate the possibility of an epidemic in these ghetto areas, we must provide national leadership and a national commitment against them.

Rh DISEASE

S. 2264 would also extend the authority of the Federal Government to assist in financing control programs in the field of Rh disease. Our association endorses this additional coverage.

The Association of State and Territorial Health Officers is honored by this opportunity to present testimony. We urge enactment of the legislation before the subcommittee to combat diseases that can be prevented.

I will be happy to answer any questions you might have.

(The attachment to Dr. Peavy's statement follows:)

REPORTED CASES AND DEATHS OF CERTAIN NOTIFIABLE DISEASES

Disease	Cases		Deaths	
	1965	1968 ¹	1965	1967 ¹
Diphtheria.....	164	243	18	32
Measles.....	261,904	22,527	276	81
Polio.....	72	57	16	16
Rubella.....	46,975	48,433		
Tetanus.....	300	159	181	144
Tuberculosis.....	49,016	42,758	7,934	6,901
Syphilis.....	112,842	² 98,195	2,434	2,381
Gonorrhea.....	324,925	² 431,380	9	11

¹ Preliminary.² Fiscal year figures.

Source: Public Health Service.

Mr. ROGERS. Thank you very much, Dr. Peavy. Your statement is most helpful.

Mr. Preyer?

Mr. PREYER. No questions, Mr. Chairman.

Your statement will be very helpful, Dr. Peavy.

Mr. ROGERS. On your suggestion of including the Rh problem, what is the control or prevention there? I don't think it is a prevention, it is a control, isn't it? Or is there prevention?

Dr. PEAVY. I would say both. As you know, if you have a mother that has an Rh negative—this is a determination of the antibodies in the mother's blood, it is a hemoglobin determination—if the baby is born with a positive Rh and these two are incompatible with each other, the next child the mother has could be born with very severe defects.

There is a method of immunizing after you get the newborn child. If the mother is immunized within 72 hours, she can have another child without having the defects that may result because of the Rh factor.

Mr. ROGERS. A simple immunization?

Dr. PEAVY. Yes, sir, a simple immunization.

Mr. ROGERS. I would be glad to have from the association some suggested funding in these areas that you think are most critical and submit it for the record. I think it would be helpful.

Dr. PEAVY. We will be happy to do so.

(The following information was received for the record:)

Suggested annual funding levels of Federal support necessary for communicable and preventable disease control programs throughout the States and territories

	<i>In millions</i>
Vaccination assistance programs.....	\$35
Tuberculosis control programs.....	25
Venereal disease control programs.....	20
Rh factor control.....	2

Mr. ROGERS. We appreciate your efforts and support of the organization. We are always impressed with the work you and your association do.

Dr. PEAVY. Thank you very much.

Mr. ROGERS. This will conclude our hearing. The subcommittee stands adjourned.

(The following statement was received for the record:)

STATEMENT OF FRED T. KUSZMAUL, ASSISTANT DIRECTOR, NATIONAL CHILD
WELFARE COMMISSION, THE AMERICAN LEGION

The American Legion appreciates the opportunity to express its views on the bills pending before you which would provide authorization for grants for communicable disease control.

The American Legion through its child welfare program is vitally interested in the control and eradication of communicable diseases which affect children and young people. Since 1956, we have had an especial interest in the problem of infectious venereal disease among our youth. On a number of occasions, we have requested the Congress to provide additional funds for the venereal disease control and seemingly when additional funds for this purpose were made available to the states, the incidence of gonorrhea and syphilis was reduced.

Several years ago we felt the nation was well on its way toward eradication of syphilis and toward substantial reductions in gonorrhea. In recent months, however, we have been shocked to learn of the increase in the incidence of gonorrhea to epidemic stages in many localities. Although nationally the incidence for syphilis is down, the rate in some localities is also up for that disease.

The American Legion is not opposed to the Partnership for Health concept, but it would appear there is an element of competitiveness at the state and local levels of government in the use of funds for communicable disease control resulting in a reduction of control programs in some of the not-too-popular communicable diseases such as tuberculosis and venereal disease. The greatest progress against these diseases has been made under a system of federal project grants. During the early 1950's when the U.S. Public Health Service relinquished responsibility for venereal disease control to the states, it was only a matter of a few years until syphilis was practically out of control.

Failure of some states and localities to participate in certain communicable disease control programs seriously limits the effectiveness of neighboring states or localities to control the infectious spread of these diseases. None of the communicable diseases can be permanently eliminated from any locality or state unless they are eliminated in other areas.

There is strong evidence of the need to provide additional funds for measles and rubella vaccination programs. Substantial numbers of children have not been vaccinated for either of these diseases, yet a rubella epidemic is forecast for 1970-71. If such an epidemic occurs, the number of children born with serious birth defects will be substantial and the cost of their treatment and care will far exceed the cost of a vaccination program. We strongly urge funds for the continuation of the vaccination program.

Several years ago, we were greatly heartened by the Surgeon General's announcement of a ten-year program to insure the eradication of syphilis. Although the timetable for this effort may have been altered by cut-backs in venereal disease control programs, we are convinced if funds are restored for this activity that the goal is certainly attainable.

Federal project grants for prevention and eradication of communicable diseases may be justified as desirable for the following reasons:

1. There is a need for a national coordinated effort to control communicable diseases rather than a spotty State and local activity which occurs usually only after an epidemic.
2. Communicable diseases pose a serious problem of interstate and international transmission.
3. Present control techniques have established their effectiveness in bringing about substantial reductions in communicable diseases.

We strongly urge the subcommittee to take favorable action upon the "Communicable Disease Control Amendments of 1969" as an important and necessary supplement to the Partnership for Health.

(Whereupon, at 12:35 p.m., the committee adjourned.)

