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REPORT BY THE

Comptroller General

OF THE UNITED STATES

Discussion Of Selected Issues Affecting Federal Immunization Activities

The Department of Health and Human Services provides financial grants and other services to State and local health departments to provide childhood disease and flu immunizations. This report discusses certain issues raised by a number of Senators concerning immunization program effectiveness, liability, adverse vaccine reactions, and vaccine supply. Some issues remain unresolved. Further, the report contains recommendations that the Department improve program management and the measurement of program effect.

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JUNE 6, 1980

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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The Honorable Abraham A. Ribicoff, Chairman
Senate Committee on Governmental Affairs

The Honorable Harrison A. Williams, Chairman
Senate Committee on Labor and Human Resources

The Honorable Edward M. Kennedy
United States Senate

The Honorable Jacob K. Javits
United States Senate

The Honorable Richard S. Schweiker
United States Senate

In response to your January 3, 1978, letter, we are providing information on the Department of Health, Education, and Welfare's (HEW's) 1/ immunization programs. This report addresses issues you raised about HEW's childhood disease and flu immunization programs, such as program effectiveness, liability, adverse vaccine reactions, and vaccine supply. We are reporting separately on the Food and Drug Administration's effectiveness in regulating biological products.

In summary, we found that:

--HEW believes, and cites reported disease incidence statistics to show, that Federal immunization activities have had a significant influence in reducing childhood disease levels. Although Federal programs have obviously helped reduce disease levels, we believe that reported disease incidence statistics (1) have limitations as indicators of the actual rate of disease increase or decline and (2) do not distinguish between the effects of Federal and non-Federal efforts. We identified opportunities for HEW to

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1/On May 4, 1980, a separate Department of Education was created. The part of HEW responsible for the activities discussed in this report became the Department of Health and Human Services. This Department is referred to as HEW throughout this report.

improve (1) immunization program management and (2) evaluation of program effectiveness. HEW could (1) provide clear guidelines for program coordination and agency interaction, (2) clarify liability issues, (3) help establish uniformity in the content and enforcement of State immunization laws, and (4) make funding requests more predictable and consistent. HEW is making some program improvements as a result of lessons learned during the swine flu program. (See app. I, pp. 4 to 14.)

--Although alternatives are being considered, a comprehensive policy that stipulates the circumstances under which the Federal Government will assume liability for public immunization programs does not yet exist. Liability issues confronting public programs are still developing, particularly with respect to the individual and collective liability of vaccine manufacturers, Federal agencies, and other health care providers who participate in public immunization programs. (See app. I, pp. 17 to 21.)

--The adequacy of the duty-to-warn process may ultimately be decided by the courts. Although many health care providers stated that the process is adequate, we noted instances where pertinent data were excluded from vaccine information forms and where recommended administrative procedures were not followed. (See app. I, pp. 22 to 25.)

--Current adverse reaction monitoring systems have limited value in showing the risks associated with vaccination. Better systems are needed and could be developed, but their additional costs should be weighed against their potential benefits. (See app. I, pp. 26 to 29.)

--Current vaccine supplies seem adequate, and manufacturers contend that they will continue providing vaccine. However, the number of vaccine manufacturers has decreased in recent years, and potential liability and technical problems could threaten continued production. HEW has considered some alternatives for ensuring future vaccine supplies, but has not adopted any contingency plans. (See app. I, pp. 30 to 35.)

Accordingly, we recommend that the Secretary of HEW:

--Direct the Director, Center for Disease Control (CDC), to undertake studies to test the reliability of disease reporting and measure the variability and extent of non-Federal immunization resources. Such studies could help HEW (1) more accurately assess Federal immunization program effectiveness and (2) better determine Federal support needed for immunization activities.

--Establish policies and procedures to improve future immunization program coordination, including (1) interagency working agreements, (2) guidelines for interagency immunization information flow, and (3) regularly scheduled meetings, such as have been held periodically in the past, to obtain the advice and counsel of key agency officials, manufacturers, State and local health care providers, insurers, the public, and others having legitimate concern about immunization policies and programs.

--Direct the Director, CDC, to develop methods to help standardize varying State mandatory immunization laws and to help improve their enforcement, such as (1) developing a model State law and (2) continuing to emphasize the importance of consistent State laws and enforcement through publicity and personal contact with State and local officials.

--Request whatever Federal funding is needed to attain and maintain desired immunization goals for all childhood diseases. Funding for any new vaccine programs should be in addition to these programs.

--Expedite data gathering to determine the potential costs and other effects of the proposed liability alternatives. These should be weighed against the risks of the current liability arrangement to provide a basis for choosing the best alternative. Whichever approach is taken, Federal liability policy should be made clear to all program participants.

--Establish a systematic procedure to obtain, consider, and act on comments on "Important Information Statement" content from interested experts within and outside HEW and the Federal Government to assure that participants' views are fully considered.

--Direct the Director of CDC and the Commissioner of the Food and Drug Administration to measure the reliability of existing vaccine reaction monitoring systems and determine the feasibility of improving the reliability of existing systems.

--Place the authority and responsibility for reaction data collection and dissemination with one agency or clearly divide and coordinate the responsibility. The information should be routinely shared with other interested parties.

We have discussed these findings with your staff in several briefings since January 1978. Appendixes I to III include details on our findings.

By letter dated March 4, 1980, HEW commented on a draft of this report (see app. IV) and concurred with most of our recommendations. HEW did not concur with our recommendations that it: (1) conduct studies to test the reliability of disease reporting and to measure the variability and extent of non-Federal immunization resources and (2) request whatever Federal funding is shown to be needed to attain and maintain desired immunization levels. Although HEW said it did not agree with the first recommendation, HEW is taking actions which in our opinion should accomplish the recommendation's intent. Concerning the second recommendation, HEW said that the administration and the Congress must continue to set priorities based on existing problems and budgetary constraints. We believe that the administration and the Congress should have the best information available with which to make these decisions, and that HEW can and should improve the information it provides on the need for Federal immunization programs and the extent of resources required to adequately achieve program goals.

As arranged with the Senate Committee on Governmental Affairs, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of the report. At that time we will send copies to interested parties and make copies available to others upon request.

Comptroller General
of the United States

Contents

ABBREVIATIONS

BoB	Bureau of Biologics
CDC	Center for Disease Control
DTP	diphtheria, tetanus, and pertussis
FDA	Food and Drug Administration
HEW	Department of Health, Education, and Welfare
NIAID	National Institute of Allergy and Infectious Diseases

DISCUSSION OF SELECTED ISSUES AFFECTING FEDERAL IMMUNIZATION ACTIVITIES

INTRODUCTION

The Department of Health, Education, and Welfare (HEW) 1/ has issued no comprehensive national immunization policy. However, its implicit immunization policy is to reduce the morbidity and mortality of immunizable diseases by maximizing immunization rates. This policy encompasses a series of Federal immunization related activities that have evolved since the early 1950s. The key activities have been

--providing financial grants and other services to State and local health authorities for prevention and control of childhood diseases and flu as authorized by legislation passed in the 1950s, 1960s, and 1970s;

--licensing, purchasing, and stockpiling vaccines to assure safe and adequate supplies;

--making annual recommendations on vaccine usage; and

--conducting surveillance for disease trends and vaccine reactions.

HEW manages national immunization programs against flu and seven preventable childhood diseases--polio, measles, rubella, diphtheria, tetanus, pertussis, and mumps--primarily under the authority of section 317 of the Public Health Service Act (42 U.S.C. 247b). Federal funding for immunization programs began in 1955 with the passage of the Poliomyelitis Vaccination Assistance Act (Public Law 84-377) which provided $53.6 million over a 2-year period to States and communities for administration of inactivated (Salk) polio vaccine. In 1963, Federal financial assistance was again used to provide live, attenuated (Sabin) oral polio and combined diphtheria, tetanus, and pertussis (DTP) vaccine to States and communities. Measles and rubella immunization programs were first

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1/On May 4, 1980, a separate Department of Education was created. The part of HEW responsible for the activities discussed in this report became the Department of Health and Human Services. This Department is referred to as HEW throughout this report.

funded in 1965 and 1969, respectively. Mumps vaccination began in 1975 as part of the measles, mumps, and rubella combined vaccine, but was not specifically funded as part of the national immunization program until 1977. According to a Center for Disease Control (CDC) official, mumps was not included earlier because of fund limitations and its low priority among other diseases.

In April 1977, HEW announced a new childhood disease immunization initiative which calls for a coordinated involvement of Federal, State, and local governments, industry, labor, voluntary organizations, health care providers, and individual families. Its major goals are to (1) raise immunization levels to at least 90 percent by October 1979 for children under age 15 and (2) establish a permanent system to provide comprehensive immunization services for the about 3 million children born in the United States each year.

In October 1978, HEW also launched an intensified immunization program designed to eradicate indigenous measles cases in the United States by October 1, 1982. This initiative is not intended to eliminate the disease entirely from the world as was done with smallpox, but is intended to eliminate all U.S. measles cases.

To date, HEW has conducted three flu immunization programs, the swine flu program during the 1976-77 flu season and two smaller programs during the 1978-79 and 1979-80 flu seasons. The swine flu immunization program attempted to immunize the entire U.S. population, while the 1978-79 and 1979-80 flu programs were designed to immunize only those persons at the highest risk of serious complications or death from flu. We reported on the effectiveness of HEW's swine flu program in a June 27, 1977, report to the Congress, "The Swine Flu Program: An Unprecedented Venture in Preventive Medicine" (HRD-77-115). Also, on April 6, 1979, we testified on HEW's 1978-79 flu program before the Subcommittee on Health and Scientific Research, Senate Committee on Labor and Human Resources. (See app. III.) We did not review the 1979-80 flu program.

Three agencies are primarily responsible for HEW's immunization programs--CDC, the Food and Drug Administration's (FDA's) Bureau of Biologics (BoB), and the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID). Their primary activities in national immunization programs are as follows:

--CDC provides funding through immunization project grants to State and local governments and negotiates Federal contracts for purchases of vaccine for distribution to grantees. It also provides leadership, technical assistance, training, and advisory personnel to State and local programs and collects and analyzes surveillance data to monitor disease trends, detect outbreaks, identify vaccine-related adverse reactions, and assess national immunization levels.

--BoB licenses vaccine manufacturers, regulates vaccine production, tests vaccine lots, and regulates some aspects of distribution.

--NIAID supports disease research, research and development on immunizing agents, and administers some vaccine clinical trials.

CDC grant funds awarded annually to State and local governments for the childhood immunization program have ranged from about $5 million to $23 million between 1963 and 1978. (See app. II.) Grant funds under the new initiatives in 1977 and 1978 totaled $17 million and $23 million, respectively. Immunization grants for the swine flu and the 1978-79 flu programs totaled $26 million and $5.1 million, respectively. 1/

For fiscal year 1979, HEW requested $50 million for its immunization grant programs--$35 million for childhood diseases and $15 million for flu. HEW received $35 million for the childhood program (Public Laws 95-482 and 96-38) and $6.4 million for the flu program (Public Law 95-482).

SCOPE OF REVIEW

We made our review at the Office of the Secretary, HEW and at CDC; BoB, FDA; NIAID, National Institutes of Health; and other agencies. During our review, we had extensive coordination with the Office of Technology Assessment which was evaluating selected Federal vaccine and immunization policies. We also obtained information at 5 State and 10 local health departments. We reviewed legislation, examined records and files, and interviewed agency officials. In addition, we contacted six vaccine manufacturers--three that are currently producing and three that have stopped production.

1/HEW purchased swine flu vaccine in addition to providing project grant funds. The 1978-79 flu program grants included funds for purchasing vaccine.

OPPORTUNITIES FOR IMPROVING AND BETTER ASSESSING PROGRAM EFFECTIVENESS

HEW believes, and cites reported disease incidence statistics to show, that Federal immunization activities have had a significant influence in reducing childhood disease levels. Although Federal programs have obviously helped reduce disease levels, we believe that reported disease incidence statistics (1) show trends but are not conclusive for measuring the effect of Federal programs and (2) do not distinguish between the effects of Federal and non-Federal efforts. We identified opportunities for HEW to improve (1) immunization program management and (2) evaluation of program effectiveness. HEW is making some program improvements as a result of lessons learned during the swine flu program.

Limitations of statistics as program effectiveness measures

The reported disease incidence statistics, which HEW uses to identify trends and as its primary program effect indicators, have limitations as indicators of the actual rate of disease increase or decline. In addition, the statistics do not show the extent to which changes are attributable to Federal programs. Trends are developed largely from voluntary reports of disease cases, and estimates of reporting extent are inconsistent and vary widely. The extent that voluntary disease reports represent actual disease cases has not been adequately determined.

HEW officials believe the Federal role in immunization programs has had a significant effect in reducing disease levels. According to recent HEW reports, childhood diseases are at, or near, record low levels since 1963. During the first 18 weeks of 1979, reported measles cases were the lowest number ever recorded for the same period in any year. Similarly, reported polio, mumps, and diphtheria cases were at their lowest levels since 1963. Also, reported rubella, tetanus, and pertussis cases were below 1977 levels. (See app. II.) During this period, HEW encouraged immunization activities and provided personnel, funding, and vaccine for public programs. At the same time, State, local, and volunteer resources supported public programs, and private physicians provided many immunizations.

To illustrate the importance of the Federal role in immunization programs, HEW graphs the relationship between measles incidence and dollars as shown on the following page. This graph shows an inverse relationship between Federal funding and measles incidence. That is, as Federal funding increases, measles incidence decreases or vice versa. Thus, Federal funding would appear to have a significant effect on controlling the disease. However, it is difficult to adequately measure the effectiveness of the Federal activities because of problems in disease reporting and unknown variations in State and local funding and volunteer resources, and the interrelationships between the Federal and non-Federal efforts.

Disease reporting problems

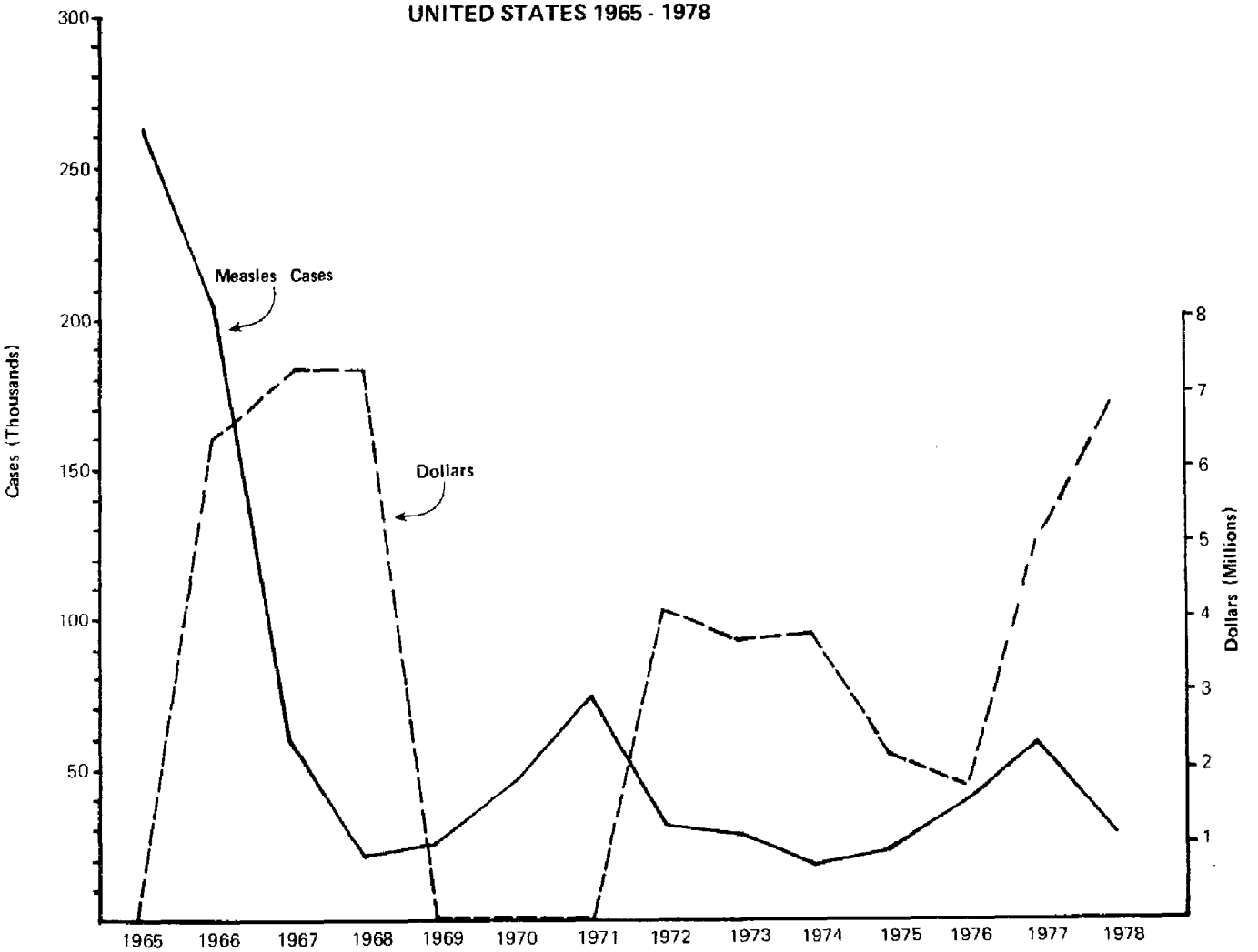
HEW relies on private physicians, State and local health officials, and others to report disease cases. The accuracy and completeness of disease reporting can vary over time and by reporting source and can be affected by disease incidence and severity, extent of publicity, errors in diagnosis, and ease of reporting. According to various estimates, the completeness of reporting for common diseases, such as measles, varies from less than 1 percent to over 80 percent of total actual cases. Also, recent intensive disease case identification activities, undertaken as part of the measles immunization program, have shown that many measles cases were previously unreported.

HEW officials acknowledge that the extent of disease reporting does vary, but have stated that the variance will balance out over time and that disease incidence trends are, therefore, reliable indicators of program success. They add that better disease incidence data can be obtained only through additional, very costly, data collection methods. However, HEW has not made any concerted effort to determine the extent that reported disease rates represent actual disease rates. Occasional studies and estimates have produced inconsistent and widely varying results, as described above.

Unknown influence of other immunization resources

Besides the data problems, HEW's measles statistics and trend data do not consider the effects of potential changes in State and local, volunteer, and private immunization

MEASLES CASES* AND FEDERAL GRANT FUNDS** OBLIGATED FOR MEASLES CONTROL PROGRAMS BY YEAR UNITED STATES 1965 - 1978



*Calendar Year
**Fiscal Year
HEW, PHS, CDC, BSS, IM

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APPENDIX I

resources as the Federal funds change. That is, increases or decreases in Federal funding could be wholly or partially offset by increases and decreases in these other immunization resources. HEW does not routinely collect data on the extent of these resources that are available each year and, consequently, has little information on how they effect changes in disease levels.

Changes in all public immunization resources--Federal, State and local, and volunteer--should directly affect the total number of public immunizations given each year. Therefore, we used changes in the total number of yearly public immunizations to estimate the effects of changes in public resources. CDC obtains information on total public immunizations from voluntary reports of State and local health departments. It has not determined the extent these reports represent actual immunizations. We compared changes in total public immunizations to changes in Federal funding between 1973 and 1978 1/ and found that, overall, changes in Federal funding appear to stimulate similar changes in public immunizations. (See graph on p. 8.) However, at times the percentage change in public immunizations varies in opposite directions to the percentage change in Federal funding which could indicate that changes in Federal funds may be somewhat offset by changes in other public resources. The significance of either of these effects depends on the extent that the data collected represent actual immunizations.

Similarly, to demonstrate the effects of private immunization resources, we estimated the number of private immunizations given each year by subtracting total public immunizations from net total vaccine doses distributed. CDC obtains information on net doses distributed from the vaccine manufacturers. The statistics represent total doses distributed less doses returned unused. They equate to total immunizations given except for wastage, duplicate vaccinations, and doses that are unused and stored at public and private health care centers. We compared changes in this estimate of private doses distributed to changes in Federal funding. (See graph on the following page.) We found that private doses also increased and decreased with changes in

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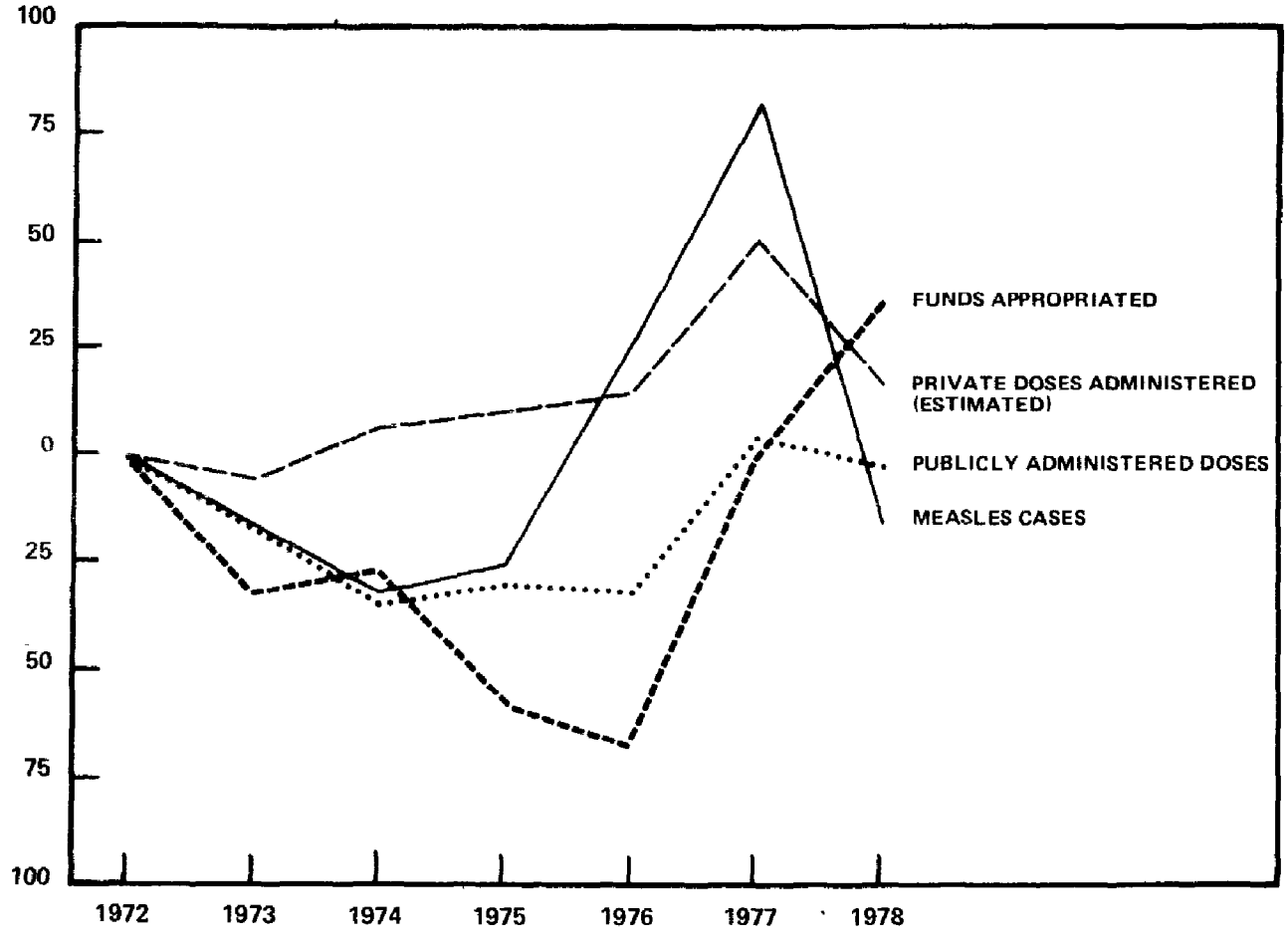
1/We assume that increases or decreases in Federal funds correspond to increases or decreases in immunizations supported by Federal resources.

FEDERAL FUNDS APPROPRIATED, AND MEASLES CASES



Federal funding, but to a lesser extent than public immunizations. If changes in the number of private doses given are assumed to occur 1 year after changes in Federal funding, 1/ a strong inverse relationship exists which indicates that private resources offset changes in Federal funding. Again, although Federal funds may stimulate some increase or decrease in private resources, these resources could be offsetting the Federal funding changes to a greater degree than other public resources. The significance of either effect depends on the reliability of the data.

Opportunities for program improvement

To improve the effectiveness of Federal immunization activities, HEW should

--provide clear guidelines for program coordination and agency interaction,

--clarify liability issues,

--help establish uniformity in the content and enforcement of State immunization laws, and

--make funding requests more predictable and consistent.

Program coordination and implementation

Successfully carrying out immunization activities requires cooperation among various Federal and State agencies and private organizations. Key participants are CDC, FDA, the National Institutes of Health, the Department of Defense, State and local health departments, vaccine manufacturers, insurance carriers, and various private professional groups. Interrelationships among the key groups involved in immunization programs have developed over the years on an ad hoc basis and seem to function adequately; however, they need good rapport among organization leaders. Clear definition of the respective roles and responsibilities among these

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1/Some time lag occurs between the time Federal funds are approved and the time these funds begin to affect potential vaccinees. The 1-year time span arbitrarily selected for this analysis seems to be a reasonable time to expect to see such an effect.

groups could help preserve the effective relationships and provide stability for future programs.

State and local health departments have primary responsibility for health within their jurisdiction. However, in administering immunization programs they enlist the participation of other State agencies, private practitioners, and special interest groups. Also, other Federal agencies that have responsibilities for health services are involved with immunization programs.

HEW obtains input from some of these groups through its Advisory Committee on Immunization Practices, whose members recommend various immunization policy alternatives. Furthermore, to improve coordination during the 1977 childhood initiative and the 1978-79 flu program, HEW held several immunization conferences and workshops that were attended by representatives from a wide range of governmental and nongovernmental groups. Also, HEW established a small, temporary task force to help coordinate interagency activities of the childhood program. This task force terminated on September 30, 1979.

Despite these positive actions to improve coordination, HEW has not established a systematic way to unite the processes of individual agencies or to assure input and debate on policy questions from all groups that have legitimate concerns about immunization policy and programs. Conferences and workshops are held at the discretion of the Secretary of HEW and are not regularly scheduled. Intra- and interagency information flow mechanisms depend largely on the responsible agency officials with few guidelines or interagency working agreements.

Regularly scheduled meetings and better information flow guidelines do not of themselves assure that good coordination will occur because responsible officials' interrelationships will continue to be the most important factor. However, such actions at least could help assure that, when responsible officials change, contacts among agencies will continue and that agencies continue to have access to important information about each others' immunization activities.

Unresolved liability issues are potential threats to Federal immunization program effectiveness

HEW's study groups on policy have concluded that if solutions for public immunization program liability issues are not found: (1) vaccine recipients will refuse to participate in immunization programs, thereby increasing the unimmunized population, (2) health care providers will not participate in administering vaccine, and (3) the few remaining manufacturers may be driven from a commitment to produce vaccine. Questions remain unresolved about who should bear the economic burden for vaccine-related injuries--vaccinees, health care providers, the Government, or vaccine manufacturers--especially where no negligence is involved. According to some HEW study groups, these issues pose serious threats to future immunization programs. The issues are discussed in more detail on pages 17 to 22.

Lack of uniformity in content and enforcement of State immunization laws limits immunization program effectiveness

Varying State mandatory immunization laws and lack of their enforcement inhibit immunization program effectiveness. Standardization in their content and improved enforcement of these laws could be useful.

By May 25, 1979, all States had passed legislation which required immunization against childhood diseases for public school children. While State laws seem to be becoming more uniform, current requirements vary among States and generally do not include all seven childhood diseases. For example, 34 States' regulations exclude one or more diseases, such as mumps, rubella, or pertussis. In addition, some States do not have immunization laws which cover private schools, licensed child care facilities, or all children who are enrolled in public schools. A February 1979 CDC survey of State immunization laws found that 10 States have laws which do not apply to either private schools or child care facilities and that 25 State laws apply only to new students entering school.

Dose requirements for full immunizations also differ between many States and HEW. For example, HEW recommends five DTP and four polio vaccinations for children by the time they reach school age (age 4 to 6). However, many

States require four or less DTP vaccinations and three polio vaccinations. Furthermore, there is no common agreement between States and HEW on the maximum age at which rubella immunizations should be given.

State compulsory immunization laws are enforced to varying degrees throughout the States. According to a 1978 CDC telephone survey, State immunization laws were not being fully enforced in about one-third of the immunization projects CDC supports. Also, immunization laws in four of five States we contacted were not being fully enforced. State and county health officers told us that public school officials were admitting school-entry-level children without the required vaccinations.

Inconsistent and unpredictable funding may limit program effectiveness

An HEW work group reported in 1977 that continuous and predictable Federal financial support is essential for successful immunization programs. Yet, HEW funding for childhood immunization programs has been generally inconsistent since 1963. Funding has also caused delays and uncertainty in HEW's flu programs. (See app. III.) Erratic HEW funding inhibits the ability of health care providers to plan, staff, promote, implement, and maintain successful immunization programs. Some State and local health officials stated that they cannot operate programs which would maximize immunization rates and minimize disease levels without consistent and predictable Federal support. According to a CDC immunization program operations official, many States had been reluctant to hire adequate staffs because of the fluctuations and uncertainty of Federal immunization support.

Since 1963, when measles vaccine became available, annual Federal support for the measles immunization program has fluctuated from no funds to $7.3 million. The program received

--no funds from 1963 through 1965,

--$6.4 million in 1966 and $7.3 million in 1967 and 1968,

--no funds from 1969 through 1971, and

--various amounts ranging from $5.1 million in 1972 to $1.7 million in 1976 and $6.9 million in 1978.

Funding for other childhood disease programs has also been erratic, but to a lesser degree than for measles. Total funding has ranged from about $5 million to $23 million over the same time. (See app. II.)

The extent of Federal support for these programs has been determined by HEW's funding requests and by its disease-specific strategy for allocating funds. HEW has usually received all the funds it requests for childhood disease immunization programs. These requests have varied considerably, but their adequacy is unknown because, as previously discussed, the reliability of the information HEW uses to determine the need for funds is uncertain. Beginning in 1963, HEW allocated nearly all the immunization funds it received to programs for one childhood disease at a time--first polio, then measles, and finally rubella. In 1972, HEW began allocating funds to support immunization programs for all childhood diseases except mumps, but total funding decreased from about $17 million in 1972 to about $5 million in 1976. With the childhood immunization initiative in 1977, immunization funding again increased and HEW allocated program funds for all the childhood diseases, including mumps.

According to a 1977 HEW report, childhood disease incidence had increased in recent years. Two reasons cited were (1) a decline in total direct Federal support and (2) HEW's disease-specific strategy for allocating grant support. HEW officials concluded that the wide fluctuation in reported disease levels since 1963 was partially attributable to erratic Federal funding practices. However, as mentioned earlier, we cannot draw a correlation between Federal funding and disease levels because the data needed for assessing program effectiveness are either unreliable or unavailable. (See pp. 4 to 9.)

Improvements resulting from the swine flu program

Based on its experiences during the swine flu program, HEW has made changes to improve the management and operation of current immunization programs. Lessons learned and HEW efforts to apply them are:

--Immunization policy decisions should include input from all participants who have legitimate concerns

in immunization programs. HEW learned that some groups felt excluded from the decisionmaking and information-sharing processes of the swine flu program. As a result, in late 1976, HEW initiated a series of conferences and workshops to obtain information and advice from various constituencies to help formulate national immunization policy. One study group found that current systems worked well for decisions relating to biomedical expertise; but groups concerned with law, economics, insurance, social issues, and public education were underrepresented. In developing recent "Important Information Statements," 1/ HEW solicited views and comments from various groups within and outside HEW. Groups that commented on the statements included congressional subcommittee staff members, representatives of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Association of State and Territorial Health Officials, immunization project directors, and county health officers.

--Liability issues need long-range solutions to assure participation in Federal immunization programs by vaccine manufacturers, health professionals, and the public. Since the swine flu program, HEW has convened several study groups to develop policy guidance for these and other issues which affect national immunization programs.

--Flu immunization programs should have key decision points for reevaluating the merits of continuing the program. HEW developed a time-phased approach for future flu programs. Proper application of this approach could save many needless vaccinations and later vaccine-associated illnesses and the costs associatad with each. (See app. III.)

Conclusions and recommendations

Statistics on the reported incidence of disease do not allow accurate assessment of the effect of Federal immunization activities. Establishing and implementing procedures

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1/Statements prepared by HEW and given to potential vaccinees through State and local health departments. The statements discuss risks and benefits of vaccination against childhood diseases and flu.

to collect more extensive disease incidence data could be significantly more costly than current voluntary reporting, according to HEW officials, and if their estimates are correct, would not yield significantly different program effectiveness conclusions. However, studies to test the reliability of disease reporting and measure the variability and extent of non-Federal immunization resources could help HEW (1) more accurately assess Federal immunization program effectiveness and (2) better determine the Federal support needed for immunization activities. Such studies or tests could be performed periodically using sampling techniques that could minimize additional costs. Accordingly, we recommend that the Secretary of HEW direct the Director of CDC to undertake studies to test the reliability of disease reporting and measure the variability and extent of non-Federal immunization resources.

In any case, the chances for success of Federal programs could be enhanced if HEW (1) promoted a more systematic way to unite the processes of individual agencies and to assure input and debate on policy questions from all groups that have legitimate concerns about immunization policy and programs, (2) clarified liability issues (see pp. 17 to 22), (3) helped establish uniformity in the content and enforcement of State immunization laws, and (4) made funding requests and allocations more predictable and consistent.

Accordingly, to improve future immunization program coordination, we recommend that the Secretary of HEW establish policies and procedures addressing

--interagency working agreements;

--guidelines for interagency immunization information flow; and

--regularly scheduled meetings such as have been held periodically in the past to obtain the advice and counsel of key agency officials, manufacturers, State and local health care providers, insurers, the public, and others having legitimate concerns about immunization policies and programs.

In addition, to better achieve uniformity in State laws and enforcement, HEW should provide States some guidance. We

recommend that the Secretary direct the Director of CDC to develop methods to help standardize State laws and to help improve their enforcement, such as (1) developing a model State law and (2) continuing to emphasize the importance of consistent State laws and enforcement through publicity and personal contact with State and local officials.

Annual funding for each disease should be more predictable now that immunization programs include all currently immunizable childhood diseases. We recommend that the Secretary request whatever Federal funding is shown to be needed to attain and maintain desired immunization levels for all childhood diseases. Funding for any new vaccine programs should be in addition to these programs.

Agency comments and our evaluation

HEW, in commenting on a draft of this report, said it did not concur with our recommendation that HEW undertake studies to test the reliability of disease reporting and measure the variability and extent of non-Federal immunization resources. (See app. IV, pp. 54 and 55.) HEW stated, however, that it has undertaken a pilot test of a more active disease surveillance method to evaluate the extent of disease reporting in the area tested. In addition, HEW said it is exploring ways to make an existing data system better identify the extent of Federal, State, and local expenditures for public health programs. These actions in our opinion are consistent with the intent of our recommendation.

HEW agreed that immunization program coordination is essential and said it was considering means of ensuring that currently functioning interrelationships continue to work adequately. HEW commented that formal meetings to consider the views of non-Federal organizations and individuals would be held when needed because it would be needlessly costly to require regularly scheduled meetings for that purpose. (See app. IV, p. 55.)

We believe that regularly scheduled meetings would formalize the process of obtaining input from all interested parties and would better ensure that such parties periodically have the opportunity to participate with Federal personnel in discussing policy and program needs. Such meetings, if not held too frequently, need not be too costly.

HEW concurred with our recommendation to develop methods to help standardize State laws and enforcement and informed us of actions it is taking or considering. (See app. IV, pp. 55 and 56.)

HEW did not concur with our recommendation that it request whatever Federal funding is shown to be needed to attain and maintain desired childhood immunization levels. (See app. IV, p. 56.)

Implementing this recommendation depends upon HEW obtaining the best information it can on the size of the problem and the extent of Federal resources needed to achieve specific goals. The recommendation is not broad or open-ended as HEW suggests because we are not proposing that HEW request as much money as possible, rather we are recommending that HEW request only as much as a documented demonstration of need will justify. Only in this way--with reliable, well-documented information on need, performance, and estimated costs to achieve specific objectives--can the Congress make informed decisions about competing and highly desirable health and human resource goals.

LIABILITY ISSUES REMAIN UNRESOLVED

Although alternatives are being considered, a comprehensive liability policy for public immunization programs does not yet exist. Liability issues confronting public immunization programs are still developing. Questions that need answers include:

--Who is obligated to provide vaccine risk-benefit information to vaccine recipients?

--What is adequate information, and is it being provided?

--Who should bear the economic burden of a vaccine-related injury when a safe and effective vaccine is administered?

Vaccine is being administered in public programs, but manufacturers, health care providers, and government officials are uncertain whether current liability arrangements will continue to work for future programs.

Uncertain responsibility for risk-benefit information

Past court decisions have held manufacturers responsible for warning potential vaccine recipients of the risks and benefits associated with the vaccine (duty-to-warn). However, because they have no control over public program vaccine administration, the manufacturers try to shift their duty-to-warn responsibility to the vaccine purchaser. For HEW's current childhood immunization and flu programs, the manufacturers supply vaccine through a contractual agreement whereby the manufacturer remains responsible for negligence in vaccine production and HEW purports to assume the duty-to-warn responsibility. HEW, in turn, through immunization grants, directs its grantees to carry out the duty-to-warn function. Whether these assumptions and shifts of responsibility are adequate to determine liability has yet to be tested in court. Therefore, the extent of Federal, State, or manufacturer responsibility or liability is uncertain.

The manufacturers we interviewed said that current liability arrangements are sufficient for them to obtain insurance and to continue to supply vaccine, but they are uncertain whether the contractual duty-to-warn delegation adequately protects them from the costs of related liability suits.

Adequacy of duty-to-warn process is uncertain

Questions about the accuracy and completeness of HEW and manufacturer adverse reaction data and the adequacy of their dissemination make the adequacy of the duty-to-warn process uncertain. (See pp. 22 to 26.) The determination of whether the duty-to-warn process adequately informs potential vaccinees of vaccine risks and benefits or protects the Government, manufacturers, and health care providers from costly liability suits will probably be made by the courts.

Proper placement of economic burden for adverse reactions without negligence is uncertain

When vaccine is properly prepared and administered and vaccinees are properly informed of risks and benefits, who should bear the economic burden of an adverse reaction to a

vaccination? Where no negligence is found, vaccinees may have to bear the cost of such reactions. Adverse reactions are expected in immunization programs. 1/ The Federal Government's promotion of vaccination, particularly to the point of encouraging mandatory immunization laws for school entry, raises a moral question of whether someone who benefits not only himself but also society by assuming the physical risk of vaccination should have to absorb all costs associated with an adverse reaction to the vaccine in a no-fault situation.

In this regard HEW decided to compensate only Guillian-Barre victims who had the swine flu shot. HEW assumed no fault for the unexpected Guillian-Barre reactions, but it did assume responsibility to compensate victims for those reactions which appear to have resulted from participation in the federally sponsored swine flu program. The issue could again become a problem for future immunization programs. Yet, a Federal liability policy that would compensate no-fault public program vaccine reaction victims may also have to consider no-fault reaction victims receiving vaccine in private settings.

Adverse judgments could threaten continued vaccine availability

Significant court decisions against persons administering vaccine or vaccine manufacturers could cause vaccine not to be available for use in public programs.

Before the 1976 swine flu legislation (Public Law 94-380) provided for an exclusive remedy against the Federal Government for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine, some State and local program participants had problems either in obtaining adequate liability insurance coverage

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1/HEW officials state that most reactions to vaccines are mild and expected. More severe reactions are rare and not always predictable based upon the limited number of people exposed to the vaccine during clinical trials. They further note that no drug or treatment regimen is risk-free. However, the risk of serious adverse reactions to vaccines is far less than the risk of developing severe complications as a result of contracting the disease.

or in assuming liability. However, swine flu legislation did not apply to other programs, and again in HEW's 1978-79 flu program, some State and local public health officials were reluctant to participate in the program because of fear of suit for an adverse reaction even though there was no negligence on their part. These concerns have not yet been a serious problem for childhood disease immunization program participants. However, court decisions holding the participants liable for inadequate vaccine risk-benefit information whether or not their own actions are negligent could inhibit their participation in future programs.

Similarly, if the courts hold manufacturers responsible for the duty-to-warn in public programs, the real or potential liability costs to them or their insurers may be such that the manufacturers would be unable or unwilling to supply vaccine for public programs. The vaccine manufacturers we interviewed did not perceive liability costs to be an immediate threat to their vaccine production, but they said the future is unpredictable in that regard. Vaccine is currently available for public immunization programs, but the liability arrangement does not preclude adverse decisions from occurring which could disrupt vaccine availability.

HEW is seeking a liability solution that would assure vaccine availability

The 1976 swine flu program legislation required HEW to conduct

> "a study of the scope and extent of liability for personal injuries or death arising out of immunization programs and of alternative approaches to providing protection against such liability (including a compensation system) for such injuries" (Public Law 94-380, section 3).

HEW was also required to recommend legislative changes needed, if appropriate.

In May 1978 HEW issued its liability report to the Congress--"Liability Arising Out of Immunization Programs--Final Report to Congress." The report analyzed liability alternatives with respect to the following objectives:

1. To ensure that adequate vaccine supplies continue to be manufactured, distributed, and administered.

2. To permit implementation of a rational and consistent national immunization policy.

3. To treat all program participants fairly.

4. To identify the full risks and costs associated with immunization programs.

5. To minimize societal costs of side effects.

6. To ensure that broader policy implications are foreseeable.

HEW did not recommend any liability alternatives, because it considered available data insufficient to make a fully informed decision and because instituting a new approach would likely involve significant startup costs. Also, once a new approach is begun, it might be difficult to change. A June 29, 1979, HEW report to the Congress reiterated that insufficient data are available to recommend any changes in present liability arrangements. Before recommending final liability policy changes, HEW is trying to obtain reliable data on the costs of adverse reactions and the potential effect of policy changes on other Federal activities.

Conclusions and recommendations

The Government could approach the liability problem in one of two general ways, both of which involve risk. First, the Government could deny claims and allow the courts to determine whether the Government is liable. If program participants have to assume some of the liability under these court decisions, they may be discouraged from further participation in federally sponsored immunization programs. This could significantly affect future public program vaccine supply and administration. Second, the Government could pursue a comprehensive compensation system for settling claims similar to that used to settle Guillian-Barre claims in the swine flu program. This would reduce the need for claimants to file suits against the Government or program participants. This approach could entail substantial costs to the Government and might encourage a broad policy of having the Government assume similar liability for other Federal programs.

We recommend that the Secretary of HEW expedite data gathering to determine the potential costs and other effects of the various proposed liability alternatives. These then

should be weighed against the risks of the current liability arrangement and the best alternative chosen. Whichever approach is taken, Federal liability policy should be made clear to all program participants.

Agency comments

HEW concurred with our recommendation and informed us of actions it is taking or plans to take. (See app. IV, p. 56.)

THE DUTY-TO-WARN PROCESS

The adequacy of the duty-to-warn process in Federal vaccination programs may ultimately be decided by the courts. Many health care providers interviewed said the duty-to-warn process, while not perfect, is adequate for informing vaccinees of the relative risks and benefits of the vaccine. However, some potential risk information is not included on important information statements, and the statements are not always administered as prescribed by HEW. The significance of these content and administration problems is difficult to assess and involves medical, social, and legal issues.

Information provided to vaccinees

HEW's important information statements used to provide risk and benefit information to potential vaccinees are incomplete in that (1) some known risks associated with vaccines are not included and (2) the reliability of vaccine-associated reaction statistics is uncertain. However, HEW officials said that these statements provide vaccinees adequate warning because they show the relative risks and benefits of vaccination.

The important information form for rubella excludes at least one known possible reaction to the vaccine. The rubella statement does not mention the possibility of contracting peripheral neuritis, 1/ even though it is a known reaction

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1/Inflamation of the terminal nerves or end organs, which according to a CDC study occurs once in every 10,000 vaccinations.

to the vaccine. CDC's Immunization Program director told us that this reaction was not included because it is (1) a difficult term for the lay person to understand and (2) closely related to other reactions described on the form. Also, the measles vaccination important information form does not mention the possibility of death occurring following vaccination. A 1977 CDC study estimated that 20 deaths might occur following 100 million measles vaccinations, and 1 death might occur following the same number of polio vaccinations. The forms for polio show death as a possible reaction. CDC's Immunization Program director said that the cause and effect relationship between vaccine and death is not as clearly established medically for measles as it is for polio.

Risk information reported in the important information statements is based partially on clinical trials and on reporting systems of uncertain reliability which may cause over or understatement of reactions. 1/ (See pp. 26 to 30.)

Since the swine flu program, CDC has developed important information statements using comments it solicits on the content and language from organizations and individuals within and outside HEW. However, no systematic procedure exists for deciding who should comment, or for obtaining the comments and recording their disposition. Developing forms to advise vaccinees of potential vaccine risks while also encouraging potential vaccinees to get vaccinated are inherently conflicting responsibilities. Because of the appearance of this conflict and the forms' importance in adequately advising vaccinees of vaccine benefits and risks or in protecting the Government from liability suits, the development of information forms should be as thorough and open to constructive comment as possible.

Information dissemination

Manufacturers and Federal and State governments have little assurance that vaccinees are properly warned of vaccine risks and benefits. Duty-to-warn requirements are delegated from vaccine manufacturers to the Federal Government to immunization project officials and are administered

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1/Risk information is also obtained from special investigations and literature reviews.

by local clinics or participating private physicians. HEW gives immunization projects written guidelines for performing the duty-to-warn, but neither HEW nor the States contacted routinely monitor the duty-to-warn process. As a result, administration of the process varies nationwide, and no assurance exists that important information statements are read and understood or signed by the appropriate party.

CDC and one State contacted had done one-time studies to determine (1) compliance with duty-to-warn requirements and (2) the vaccinees' understanding of important information statement content. Study results were mixed. Some project officials were adequately performing duty-to-warn requirements while others were not, and some vaccinees read and understood information statement content while others did not. The CDC study recommended establishing a monitoring system at the State level.

Problems with reading and understanding the forms

Even though vaccinees are required to sign the information statements or an accompanying card, we observed, local officials told us, and a CDC study showed that potential vaccinees may not read or understand the significance of the statements. Possible explanations for this are (1) apparent public disinterest in the content of the forms, (2) inadequate attempts by service providers to explain the importance of the forms, and (3) language barriers.

For example, in one State, the Director of the Bureau of Communicable Disease Control said that, although signature cards are signed as required, he doubted that many of the parents whose children are vaccinated in public clinics read the important information statements. We observed in another State that, in a 30-minute period, 15 children were vaccinated in a public clinic, but only one of the accompanying adults read an important information statement. The statements were available in the vaccination area, but none of the clinic personnel were attempting to have them read. Nevertheless, the adults were signing signature cards indicating they had read and understood the statement.

CDC's field test of the childhood immunization information statements showed that, for about 20 to 30 percent of the vaccinees, their parents or guardians did not read the

entire statement. Another 12 to 25 percent answered "don't know" when asked questions about the disease, the vaccine, and the number of doses and precautions. Sixty-five percent answered "yes" or "don't know" when asked if injectable polio vaccine caused paralysis. Properly constituted injectable polio vaccine is not thought to cause paralytic reactions; however, paralytic polio has been associated with oral polio vaccine.

Problems getting appropriate signatures

Problems also exist in securing signatures from appropriate parties on the important information forms (or signature cards). In one State, the signature cards can be signed by any adult accompanying a child. Some State officials said that sometimes getting signatures for children coming to public clinics is difficult because the children are not always accompanied by their parents or guardian.

Several State officials complained about having to get signatures for each childhood disease vaccine given rather than by series. They claim that such a procedure is excessive. An HEW Indian Health Service official told us that getting necessary adult signatures for each vaccine given to Indian children on reservations posed a logistical problem. When children arrive at Indian Health Service clinics for their immunizations, they are not always accompanied by a parent or guardian. In some cases clinic staff travel many miles on a reservation to obtain the appropriate signatures.

Conclusions and recommendations

Aside from the issue of having more reliable adverse reaction information, HEW could better assure adequate "Important Information Statement" content by establishing a systematic procedure to obtain, consider, and act on comments on the content from interested experts within and outside HEW and the Federal Government. Accordingly, we recommend that the Secretary of HEW establish such a procedure to assure that the views of appropriate participants are fully considered.

Improving form administration is more difficult. Current HEW guidelines for form administration appear adequate. A monitoring system, as recommended by the CDC study, could provide useful information on whether the duty-to-warn process

is being adequately administered. However, such a system's costs may outweigh its benefits and still would not assure compliance with duty-to-warn requirements in every case. Once responsibility for duty-to-warn administration is made clear by the courts or national policy, more specific administrative controls can be determined.

Agency comments

HEW concurred with our recommendation and has taken appropriate corrective action. (See app. IV, p. 57.)

ADVERSE REACTION INFORMATION

HEW's vaccine reaction monitoring systems have limited value in showing the risks associated with vaccination. Further, reaction reports are not routinely shared among organizations that could use them. Better reporting systems could be developed, but the increased costs of such systems would have to be weighed against the systems' potential for improving the safety of current immunization practices.

Limited value of adverse reaction monitoring systems

HEW's systems for collecting adverse reaction data do not assure that complete and valid information on the rates and types of adverse reactions are obtained. The systems rely largely on voluntary reporting, 1/ and the reactions reported are linked to vaccines temporally and statistically rather than directly through conclusive medical evidence.

Reaction reports are not routinely shared between organizations that could use them. Both CDC and BoB collect adverse reaction information--CDC primarily from State health departments as part of its overall disease surveillance and control responsibilities and BoB primarily from manufacturers because of its product regulation responsibilities. The two agencies share information, when one feels the other has a need for it or when one requests a report from the other.

1/Reaction reports are supplemented by special investigations and medical literature reviews.

Limitations in data collected

HEW's primary sources of current vaccine reaction information--monitoring systems and clinical trials--provide information with inherent limitations. In addition, adverse reaction rates were calculated using "ball park" estimates of the number of vaccinations given.

Passive reaction monitoring--Until recently neither CDC nor BoB had procedures for systematically collecting and analyzing data on adverse reactions to vaccines. Historically, the agencies relied largely on voluntary reports and studies for adverse reaction data. Reactions could have been reported by vaccinees, private physicians, State and local health departments, or vaccine manufacturers. In addition, HEW made more intensive investigations and studies for a few specific vaccine reactions. However, for the most part, HEW had little assurance that the data obtained through this largely passive approach were valid and complete, because often reactions were not reported or reported reactions might simply be unrelated illnesses following a vaccination. The extent and quality of reporting was unknown.

In 1978 CDC required its immunization grantees to establish adverse reaction data collection systems. Also, BoB has recently proposed regulations that would require manufacturers to furnish BoB any adverse reaction reports they receive. 1/ However, these systems still rely on voluntary reporting by vaccinees and immunization providers in both the public and private settings and may not provide complete and accurate data on the actual numbers and types of vaccine reactions. The present CDC system is designed to provide estimates on the number of reactions and identify unusual clusters that can serve as a basis for more intensive study. According to CDC officials, present problems in obtaining complete and accurate reports stem from a low level of concern about adverse reactions to vaccines that have been in use for a long time. In addition, they point out that obtaining data on reactions that occur as infrequently as 1:100,000 participants is extremely costly and can be quite difficult, particularly when the adverse reaction occurs after a lengthy lapse of time.

1/Vaccine manufacturers are currently required to hold, for possible reviews by BoB during its periodic inspections, any reaction reports they receive.

Clinical trials--Current clinical trials of flu vaccines include active followup on vaccinees, but the number of people tested is too small to assure that reactions of remote probability are observed. For example, the Guillian-Barre syndrome associated with the 1976 swine flu vaccine occurred once in every 100,000 cases, whereas only about 5,000 people participated in the trials. Guillian-Barre was not identified as a possible adverse reaction. Also, clinical trial data for some vaccines, such as DTP, were developed years ago without using a control group. Therefore, the rates of common reactions following these vaccines are based on estimates.

Unreliable data on vaccine doses administered--HEW compares the number of reactions obtained from its various sources to the number of vaccine doses distributed to determine adverse reaction rates. Reliable data are not available on the actual number of total vaccinations. Using doses distributed tends to understate reaction rates, because not all vaccine distributed is administered. However, CDC officials said the degree of change would be insignificant if actual doses administered were used in the calculation.

Reporting period may restrict reaction data received--The reporting period for adverse reactions noted on the important information statements may restrict the number of reactions reported. HEW established a 4-week reporting period on these statements. According to CDC's Immunization Program director, most adverse reactions occur within this period. However, some adverse reactions can occur more than 4 weeks after vaccination. In fact, the rubella and DTP important information statements report that reactions may occur 2 to 10 weeks after vaccination. By establishing an adverse reaction reporting period of 4 weeks, HEW may artificially restrict its own adverse reaction data base.

Adverse reaction reports are not routinely shared among health organizations

HEW could better coordinate the adverse reaction data gathering and dissemination functions of CDC and BoB by giving one agency full responsibility. Adverse reaction reports are collected by both agencies and are not routinely shared between the two or among other health organizations. No standard procedures exist to assure that reaction data are

channeled where needed. Reports are shared when requested and when an official receiving a report feels other agency officials have a need for it. This system is based largely on chance and individual judgment and provides no assurance that all reports are channeled to the appropriate agency. Officials from CDC and BoB stated that data on severe unexpected reactions are shared. However, we examined 10 adverse reaction reports made to CDC, and about 4 weeks after the date of the last report, none of the reports had been furnished to BoB. BoB's Director, Division of Bacterial Products, said BoB followup investigations should have been done on at least one of the reports.

The cost/benefit of better reporting systems is uncertain

HEW might be able to provide more complete and reliable adverse reaction data by developing a more active monitoring system. However, such a system would require (1) systematic and intensive studies to identify adverse reactions following vaccinations and (2) significantly more funds and personnel. Even with the increased investment, a more active system still could not assure detection of all reactions, and would have much the same problem as the current system in proving more than a temporal or statistical association between the vaccine and a subsequent illness.

CDC officials recognize that the present system could be improved, but they do not know whether a more active system would cause any change in immunization practices. A 1977 CDC study reported that firm conclusions about vaccine reaction rates and types are not possible because of the limitations in reaction reporting. The report noted that currently available knowledge about reactions to vaccine represents, at best, rough estimates. However, CDC officials believe that reaction data currently included in important information statements and elsewhere are generally adequate because they are based on the collective and extensive experience of immunization health experts--both within and outside HEW--and on the results of clinical trials and surveillance systems.

Conclusions and recommendations

HEW makes recommendations and provides leadership and support for administering millions of doses of vaccine annually, based on its data which show that vaccination

benefits outweigh the risks. However, the degree of vaccine associated risk is not clear because of limitations in existing adverse reaction reporting systems.

More active data collection could provide greater assurance that vaccine reactions are identified. However, data collection on a large scale would be more costly than the current system, and the extent to which a more active system would add to present vaccine reaction knowledge is unknown.

We believe that HEW should know the extent of the reliability of its reaction monitoring systems. We recommend that the Secretary of HEW, before developing new, more costly monitoring systems, direct the Director, CDC, and the Commissioner, FDA, to

--measure the reliability of existing systems and

--determine the feasibility of improving the reliability of existing systems through more active data collection.

Also, although both CDC and BoB need reaction information, we recommend that the Secretary either place the authority and responsibility for reaction data collection and dissemination with one agency or clearly divide the responsibility. Information obtained should be routinely shared with other interested parties.

Agency comments

HEW concurred with our recommendations and informed us of the actions it is taking or plans to take. (See app. IV, pp. 57 and 58.)

POTENTIAL VACCINE AVAILABILITY CONCERNS

Current vaccine supplies seem adequate, and manufacturers contend that they will continue producing vaccine. However, the number of vaccine manufacturers has decreased in recent years, and potential liability and technical problems could threaten continued vaccine production. Although HEW has considered some alternatives for ensuring adequate future vaccine supply, it has adopted no contingency plans.

Current supply appears adequate

While temporary shortages have occurred occasionally in some immunization projects, vaccine supplies appear adequate nationally. HEW, State, and local officials said the temporary shortages resulted from various contracting and technical production problems and did not impair overall immunization programs. In areas where shortages occurred, officials were able to borrow vaccine from other areas until supply resumed. HEW officials and manufacturer representatives have stated that vaccine is produced in sufficient quantity to meet all domestic demand.

Although we found no cases other than minor vaccine supply disruptions where vaccine supply did not meet demand, available information is inadequate to determine conclusively that the supply is sufficient. For example, the actual amount of vaccine produced each year is unknown. Manufacturers provide HEW statistics on the net number of doses distributed each year, but the manufacturers told us they produce more vaccine than they distribute. One manufacturer's representative said his company stockpiles a 2-year vaccine supply. Another said his company maintains a 1-1/2-year supply. We were unable to verify the extent of supply because manufacturers consider the total amount of vaccine they produce or store and their plant capacity to be trade secrets. Similarly, the actual demand for vaccine is unknown. State and manufacturing representatives told us that vaccine forecasts are rough estimates based on various factors, such as annual immunization status reports, annual birth rates, vaccine usage in previous years, and the number of disease-susceptible individuals.

In attempting to determine the adequacy of vaccine supply, we compared the amount of vaccine distributed to an estimated number of doses needed to vaccinate the unimmunized population. We estimated the doses needed by using the 1974 U.S. Immunization Survey reports and HEW's recommended immunization schedules. Our analysis showed that enough vaccine was distributed from 1974 to 1978 to provide the minimum recommended vaccinations for children and young adults for all diseases except mumps. 1/ However, we do not

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1/Mumps was specifically funded as part of HEW's immunization program in 1977.

know the extent that distributed vaccine was unused or used for revaccinations. For example, in most States children entering school for the first time are required to have certain vaccinations. Those who have no previous immunization records may be required to be revaccinated.

Continued availability could be threatened by production or liability problems

Continued vaccine availability depends on a few manufacturers. A disruption in these manufacturers' production processes could adversely affect supply. In addition, potential increased costs associated with liability for vaccine production and administration could cause both manufacturers and local public health officials to become reluctant to participate in public programs.

Only a few manufacturers still produce vaccines

The future of domestic vaccine supply depends on the continued willingness and ability of a few companies to produce adequate quantities of vaccine. Only five domestic companies currently produce childhood disease vaccines. One domestic manufacturer produces measles, mumps, and rubella vaccines, and another produces live polio vaccine. Inactivated polio vaccine, which is used infrequently in this country, is produced in the United States by a Canadian-owned company. Diphtheria, tetanus, and pertussis vaccines are produced by three domestic manufacturers, three State health departments, and two foreign manufacturers.

HEW's National Immunization Work Group which met subsequent to the swine flu program on March 15, 1977, reported that the number of vaccine manufacturers has decreased during the past 15 years as follows:

Type of vaccine	From	To
Live polio	3	1
Measles	6	1
Rubella	4	1
Mumps	2	1
DTP	7	a/5

a/Does not include the three States which manufacture DTP vaccine primarily for their own use.

Most of the manufacturer representatives we interviewed said that decreasing profit margins were the primary reasons vaccine manufacturers have left the business. They said:

--Government regulations create a standard product which leads to national pricing at decreasing margins because of competitive bidding.

--Effective vaccines given once and providing lifelong immunity make the potential market size decrease rapidly, and the size of the market determines the number of companies that can or should participate in the field.

--Profits do not support the research and development costs essential to keep up in the industry.

In addition, one manufacturer's representative said his company decided its research and development moneys could achieve more health benefits in other areas.

According to an HEW study, manufacturers have not supported such views with presentations of data on costs and profits from the sale of vaccine and how costs associated with liability for vaccine-related side effects compare with similar costs for other drugs.

Potential production problems

Any of various production and distribution problems could disrupt vaccine supplies for several months--particularly when only one manufacturer is producing the vaccine. Vaccine manufacturing is a complex process requiring the combination of natural raw materials, a reliance on biological processes, and the technical competence and capability to properly use the materials and test the results. One manufacturer representative said that manufacturing competence and capability must be maintained because restarting production once it has been stopped is very difficult despite well-documented manufacturing processes.

The Director of FDA's Bureau of Biologics stated that even experienced manufacturers sometimes have technical problems that put them out of production for several months. Manufacturer representatives said that lack of certain raw materials, failure of the delivery system, contamination of the seed virus, economic problems, or other unknown factors

could disrupt supply. For example, both HEW officials and manufacturer representatives told us that foreign country bans on the export of Rhesus monkeys have caused a shortage of monkeys available for premarket tests of live-polio vaccine. The shortage could disrupt vaccine supply. HEW and manufacturer officials said Rhesus monkey breeding colonies have been and are being established to help alleviate the problem.

Liability problems

Vaccine manufacturers could become reluctant to produce vaccine if they must absorb large settlement costs of future liability suits. Similarly, State and local health officials may become reluctant to administer vaccine. So far, neither of these potential problems has caused significant disruption in vaccine availability, although we noted that liability concerns caused some reluctance by State and local officials to participate in HEW's 1978-79 flu program. (See app. III, pp. 46 and 47.)

Contingency plans have been considered by HEW

The active vaccine manufacturers we interviewed assured us they plan to continue production. However, because of the uncertainties in future commercial vaccine supply, HEW has considered several supply alternatives. For various reasons no alternative plan has been chosen, and HEW immunization program officials stated that it will take a crisis in vaccine availability before the Government develops alternative sources of supply. Some of the alternatives considered are:

--Purchasing vaccines from foreign manufacturers. Although some HEW officials consider this a viable alternative, others have raised concerns about the quality and continuing availability of vaccine if foreign manufacturers are used.

--Developing a Federal capacity to produce vaccines. The Government currently has the statutory authority to produce vaccines for its own use or, when supplies are unavailable from private sources, for public and private agencies and individuals engaged in the field of medicine (42 U.S.C. 263). Under present regulation it

would take from 2 to 5 years to develop vaccine manufacturing capability. HEW perceives that this is not a realistic alternative because of the Government's lack of experience in and lack of personnel and facilities for large-scale vaccine production.

--Enlarging CDC's stockpile of vaccines. Present CDC stockpiles of childhood disease vaccines could be expanded. One manufacturer told us that current Federal regulations regarding vaccine shelf-life limit the amount of vaccine that can be stored.

Any such contingency plans would be confronted with the issues of immunization policy and liability previously described.

Conclusions

Although we found no evidence of major vaccine supply shortages in public immunization programs, future vaccine supply is uncertain. Relief of that uncertainty, including adoption of any contingency plans, depends on resolution of immunization and liability issues described earlier in this report.

Federal Immunization Grant Funds Obligated to the States and Reported Morbidity Levels for Childhood Diseases in the United States from 1963 to 1978

Year (note a)	Total Federal appropriation for all childhood diseases	Measles		Mumps		Rubella		Polio		DPT			
		Total allocated	Number of cases	Total allocated	Number of cases	Total allocated	Number of cases	Total allocated	Number of cases	Total allocated	Number of diptheria cases	Number of tetanus cases	Number of pertussis cases
	(millions)	(millions)		(millions)		(millions)		(millions)		(millions)			
1963	$ 8.7	$ -	385,156	$ -	(b)	$ -	(b)	$ 7.0	449	$ 1.7	314	325	17,135
1964	10.2	-	458,083	-	(b)	-	(b)	8.2	122	2.0	293	289	13,005
1965	8.0	-	261,904	-	(b)	-	(b)	6.4	72	1.6	164	300	6,799
1966	8.0	6.4	204,136	-	(b)	-	46,975	1.2	113	0.4	209	235	7,717
1967	9.1	7.3	62,705	-	(b)	-	46,888	1.4	41	0.4	219	263	9,718
1968	9.1	7.3	22,231	-	152,209	-	49,371	1.3	53	0.5	260	178	4,810
1969	9.6	-	25,826	-	90,918	9.6	57,686	-	20	-	241	185	3,285
1970	16.0	-	47,351	-	104,953	16.0	56,552	-	33	-	435	148	4,249
1971	16.0	-	75,290	-	124,939	16.0	45,086	-	21	-	215	116	3,036
1972	17.0	5.1	32,275	-	74,215	8.5	25,507	2.6	31	0.8	152	128	3,287
1973	10.0	3.5	26,690	-	69,612	3.5	27,804	2.5	8	0.5	228	101	1,759
1974	10.6	3.7	22,094	-	59,128	3.7	11,917	2.7	7	0.5	272	101	2,402
1975	6.2	2.2	24,374	-	59,647	2.2	16,652	1.5	8	0.3	307	102	1,738
1976	5.0	1.7	41,126	-	38,492	1.7	12,491	1.3	14	0.3	128	75	1,010
1977	17.0	5.1	57,345	2.6	21,436	4.2	20,395	3.4	18	1.7	84	87	2,177
1978	23.0	6.9	c/26,795	3.4	c/16,681	5.8	c/17,772	4.6	c/4	2.3	77	82	1,999

a/ Funding for childhood immunizable diseases is allocated by fiscal year, and the number of disease cases is reported by calendar year.

b/ Not available.

c/ Preliminary data.

APPENDIX II

APPENDIX III

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

FOR RELEASE ON DELIVERY
EXPECTED AT 10:00 a.m. EST
FRIDAY, APRIL 6, 1979

STATEMENT OF
PHILIP A. BERNSTEIN, DEPUTY DIRECTOR
HUMAN RESOURCES DIVISION
BEFORE THE
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
ON THE
1978-79 FLU PROGRAM

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear here today to discuss our review of the 1978-79 flu program. As requested by the Subcommittee, we examined the program's management and effectiveness and determined from available records the current status of liability claims against the Federal Government arising out of all Federal immunization programs, particularly the swine flu program.

We reviewed the activities of the Office of the Secretary, Center for Disease Control (CDC), and National Institutes of Health in the Department of Health, Education, and Welfare (HEW), and the activities of the Department of Justice. We also interviewed, by telephone, 12 State and 6 county health officials regarding their individual programs.

APPENDIX III

BACKGROUND

On March 23, 1978, the President proposed to the Congress an ongoing Federal flu immunization program administered by HEW to supplement existing flu immunization activities and to begin during the 1978-79 flu season. Through this program, HEW planned to increase the number of high-risk individuals immunized from 20 to 40 percent of the total estimated 42 million high-risk population during 1978-79, and to about 60 percent by 1980. HEW's basic objective was to reduce excess mortality among the high-risk group. The proposed budget for the 1978-79 program was $15 million; immunizations were to begin in August and to be completed by late November.

However, congressional concerns were expressed about the need for a Federal flu program, liability, and HEW's ability to plan and implement a safe and effective program. Because funding was delayed, in July 1978, HEW revised the budget request to $8.2 million for a 1978-79 flu program. Congress funded the program at the requested level on August 25, 1978 (Public Law 95-355) and the President signed the legislation on September 8, 1978. Immunizations began in late October 1978 and HEW encouraged immunization projects to continue through January 1979.

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PROGRAM RESULTS

The effectiveness of the 1978-79 flu program in preventing excess mortality among high-risk individuals is unknown. Its effectiveness in vaccinating the target population was minimal because of a variety of problems associated with the virus itself and with program management.

The Russian flu strain expected to be predominant during the 1978-79 flu season was not, and a slightly different strain called Brazil flu became predominant. The 1978-79 flu strains in total primarily attacked individuals under age 26. Only a small portion of those over age 65 and the chronically ill over age 26 were attacked. These latter two groups comprise the majority of the high-risk population. Those who were attacked, experienced a relatively mild illness. Therefore, this season's flu caused no measurable excess mortality. In In addition, although the Russian flu vaccine used during the program is expected to provide some protection against Brazilian flu, the level of protection provided is uncertain. Consequently, it is difficult to conclude that the vaccine was effective in preventing excess mortality.

As of February 28, 1979, immunization projects reported administering about 1 million of the 3.5 million doses of vaccine that HEW had planned to be administered under the

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1978-79 flu program. Problems which contributed to the failure to administer the number of vaccinations planned include:

--uncertainties about the nature and behavior of flu viruses,

--incomplete predictions of vaccine acceptability,

--uncertain and late program funding,

--ignored program implementation schedules, and

--unresolved liability problems.

Solutions to these problems are needed before HEW can plan and implement an effective flu program.

Uncertainties about the nature and behavior of flu viruses

Flu is not as predictable and controllable through immunization as some other common diseases such as measles or polio. Unlike the more stable organisms which cause these common diseases, flu viruses constantly change and current scientific knowledge is inadequate to predict with certainty (1) the antigenic content of the coming year's flu virus, (2) the level and severity of the disease caused by the virus, and (3) the group of individuals most likely to be affected. As a result, HEW's predictions can and do create controversy about the need for and implementation of a flu program. For the 1978-79 flu program this controversy affected its acceptance by the public and health professionals.

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adult population completed in February 1978 which showed that about 50 percent would want to be immunized if a nationwide program were recommended, and (2) its success in motivating a large portion of the high-risk population to be vaccinated in the swine flu program. The CDC survey, however, did not specifically assess the attitudes of high-risk people. While they were probably included in the survey, their specific responses to the question on willingness to be immunized were not separately analyzed.

Uncertain and late program funding

Most flu program grantees attributed the small number of people vaccinated during the program to a number of factors affected by uncertain and late funding. These factors included key program components such as vaccine availability, project readiness to proceed, delivery schedules, and public information programs. Although HEW encouraged potential grantees to develop program plans and procedures in anticipation of funding legislation, some grantees which planned to participate cancelled their efforts because of late funding. According to CDC, flu immunizations should be completed by late November for optimal program effectiveness. The 1978-79 flu program was originally planned to meet this schedule. However, by the end of November, fewer than 600,000 doses had been administered.

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Like the swine flu program, this year's flu program shows how risky predicting flu virus behavior can be. Not only did the predicted Russian flu not become predominant as expected, but also the predicted population group to be most seriously affected was attacked infrequently. HEW had predicted, based on past experience, that the 1978-79 flu would be most severe in the chronically ill and those over 65 years of age. However, the population attacked most frequently were people under 26 years of age, and the disease consequences were generally mild in those attacked. More scientific knowledge about the flu virus is needed to improve the reliability of predictions for each coming flu season. Such knowledge is also needed to facilitate planning for the best way to control excess flu mortality.

Incomplete predictions of vaccine acceptibility

Although the 1978-79 flu program was targeted at high-risk individuals, many of whom would normally be under the care of a private physician, the potential demand for vaccine by this group through public programs was never assessed. Several State officials said that the most significant factor regarding the program's failure to meet immunization goals was the lack of response by the high-risk group.

HEW assumed that high-risk people would desire vaccination based largely on (1) a CDC survey of the general

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According to an HEW official, using normal operating funds, HEW began planning for the flu program before it was funded, in anticipation that an appropriation would be forthcoming. He said that starting a flu program before the peak flu season would have been impossible had HEW waited to begin until funds were appropriated. Key activities carried out in advance of the appropriation included:

--Surveying immunization grantees to determine
  (1) if they would participate in the proposed program and
  (2) the extent of their participation based on various possible funding dates. Surveys were conducted on February 7 and 24, May 4, July 21 and August 17, 1978.
--Developing grant guidelines and furnishing them to immunization grantees by June 1, 1978.
--Obtaining comments and advice from advisory committees, States, and other organizations on the information form explaining the benefits and risks of vaccination.
--Developing vaccine contract proposals (RFPs) and furnishing them to vaccine manufacturers before June 1, 1978. The RFPs did not contain vaccine

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potency specifications because these did not become available until July, 1978.

--Arranging for adequate vaccine production by the manufacturers.

--Conducting preliminary reviews of most grant applications. CDC encouraged grantees to submit applications early, and by the time the Congress appropriated funds for the program 37 applications had been received and reviewed. Eleven applications were received after the appropriation.

HEW was required by the legislation to obligate all funds for the 1978-79 flu program by September 30, 1978. By then HEW reported obligating $6.7 of the $8.2 million appropriated as follows:

--$5.1 million for grants to 48 immunization projects for vaccine procurement and program implementation,

--$0.5 million for CDC direct operations, and

--$1.1 million for NIH participation in vaccine clinical trials.

HEW officials said that the $1.5 million unobligated was returned to the Treasury.

Ideally, according to CDC and grantee schedules, funds should be available to grantees by mid-June or early July to allow enough lead time to prepare a program. However, 1978-79 flu program grantees could not make firm plans or

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commitments until funds were appropriated in early September and grants were received at the end of September. Thus, although vaccine became available in early October, few projects scheduled active vaccination programs before November. In addition, some States reported that the delay in program implementation reduced the demand for vaccine by health professionals and the public and caused conflicts with ongoing children's immunization programs.

Ignored program implementation schedules

HEW continued efforts to get funding and to promote the flu program after a point in time when its potential effectiveness was severely limited. A reduced program to immunize about 40 percent of the original goal was utimately funded.

As recommended by our report on the swine flu program (The Swine Flu Program: An Unprecedented Venture in Preventive Medicine, HRD-77-115, June 27, 1977), CDC has established a timephased plan for dealing with pandemic influenza which includes specific decision points. CDC did not characterize the 1978-79 flu as a pandemic flu but did have decision points incorporated in its program plan. CDC and several States reported in May 1978 that if grant funds were unavailable by early summer, immunization projects might be unable to develop adequate programs. At that time, CDC reported that if grant funds were

not available by July 20, 1978, the advisability of proceeding with the program should be reconsidered.

On July 26, 1978, the Director, CDC, recommended to the Assistant Secretary for Health that the 1978-79 flu program be revised from an active vaccine administration program, and be limited to improving surveillance operations across the country and planning for administering vaccine the following year. However, the Secretary, HEW, chose to proceed with the program anyway because (1) it would provide vaccine for poor people in the high-risk groups who would otherwise be unable to obtain it, and (2) he saw it as an opportunity to establish an ongoing flu immunization program.

Unresolved liability problems

Liability problems which became an issue for public vaccination programs during the swine flu program, continued to plague the 1978-79 flu program. This was reported as a major factor in the States' inability to meet immunization targets, because some public health officials were reluctant to participate in the program.

Before the program was funded, a representative of the Association of State and Territorial Health Officers testified in April 1978, before the Health Subcommittee of the House Interstate and Foreign Commerce Committee,

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that the liability issue was the main cause of State (or grantee) objection to the program. He said the program should not go forward until the liability issue had been solved. After the program had been implemented, several immunization project health officials told us that some public health officials in their projects either did not participate in the program or did so reluctantly because of concerns about liability.

Much of the liability problem for project participants seems to stem from concerns about the Guillain-Barre Syndrome and the numbers of claims arising from the swine flu program. Under the swine flu program, the Federal Government assumed all liability, but could seek recovery where negligence could be shown on the part of program participants. Responsibility for liability in the 1978-79 flu program is unclear where no negligence is involved. Project participants were responsible for their actions in administering the vaccine, and for informing vaccinees of the potential benefits and risks of vaccination.

STATUS OF LIABILITY CLAIMS

Since 1963, Public Health Service records show that 3,721 vaccine-related claims have been made against the Federal Government through the Public Health Service, of

which 3,694 are swine flu claims. The other 27 claims by type of vaccine are as follows:

Polio	19
Flu	3
Smallpox	3
Typhus/Typhoid	1
Measles	1

Disposition of claims

As of March 23, 1979, claims filed relating to the Swine Flu program totaled $3,351,065,780.

--No claims have been settled through the courts.

--20 claims have been settled out of court for a total of $117,483. 575 claims have been withdrawn or denied leaving 3,099 claims pending.

--1,045 claims totaling $952,549,318 relate to Guillain-Barre Syndrome.

Public Health Service records indicate that the Federal Government has paid only one non-swine flu vaccine claimant, who won a suit against the Government over paralysis sustained from live polio vaccine. The original claim against the Government was for $7,000,000. In 1975, the plaintiff was awarded $1,029,973 in damages and an additional $3,201 in allowable costs.

Presently, 10 non-swine flu claims are pending, totaling $44,050,000. The earliest pending claim was filed during fiscal year 1976.

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The Federal Government's approach to vaccine-related suits

The Chief of the Torts Section, Civil Division of the Department of Justice, said that making public the approaches being taken by the Government to resolve swine flu claims might adversely affect the Government's negotiating position. For other vaccine-related claims, the Government is assuming no fault or obligation to compensate. When trying to settle claims out of court, the Torts Section Chief told us that the Department handles each case based on criteria relevant to that case. Some of the criteria used include: nature of adverse reaction, law of the relevant jurisdiction, prognosis, and health insurance coverage.

SUMMARY OF OBSERVATIONS

Existing knowledge about flu is inadequate to assure that an effective federally funded flu program can be planned and implemented. Each year HEW must decide based on uncertain information

--what the flu strain will be, the level and severity of disease it will cause, and the group of individuals most at risk,

--whether a program can be developed and funded for timely implementation, and

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--if the public and health care providers will participate.

Planning a program around such uncertainty is a gamble at best. The program could result in decreased flu morbidity and mortality or it could be costly, ineffective, and detrimental to public confidence in the Federal Government's ability to provide leadership in preventive health care.

We recognize that HEW may need to seek Congressional funding based on incomplete information about the nature and behavior of the expected flu. However, based on our work, we believe that the Secretary, HEW, should give greater consideration to the following factors in determing the role of the Federal Government and the amount of funds which should be spent:

(1) The extent and severity of flu expected,

(2) the extent of demand measured in the target population, and

(3) the capability of existing public and private settings to meet that demand.

Also, the Secretary should establish a time-phased approach to the program similar to that already established for dealing with potential flu pandemics. This approach includes meaningful decision points but should also include cutoff

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dates if unexpected problems occur which cannot be adequately resolved.

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Mr. Chairman, this concludes my statement. We shall be happy to answer any questions that you may have.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

REFER TO:

OFFICE OF THE INSPECTOR GENERAL

MAR 4 1980

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Answers To Selected Questions On Federal Immunization Activities." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Bryan Mitchell
for Richard B. Lowe III
Acting Inspector General

Enclosure

GAO note: Page references in this appendix may not correspond to page numbers in the final report.

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COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE COMPTROLLER GENERAL'S DRAFT REPORT ENTITLED "ANSWERS TO SELECTED QUESTIONS ON FEDERAL IMMUNIZATION ACTIVITIES"

General Comments

In the past few years, there have been several reviews of immunization programs. These include national work groups called together by this Department, special meetings called by the Surgeon General or the Secretary, Congressional hearings, and investigations by the Congressional Office of Technology Assessment (OTA) and the General Accounting Office (GAO). This investigation represents GAO's third investigation of Federal immunization programs in the past 3 years. This review was undertaken during a period when unprecedented advances were being made in the field of childhood immunizations. Between 1977 and 1979, the number of doses of vaccine administered in the public sector has risen strikingly, immunization records have been reviewed on more than 28 million school children, and immunization levels of children have risen to unprecedented levels. Immunization laws governing school entry are now in existence in all 50 States and the immunization levels of children entering school are currently in excess of 90 percent against measles, rubella, polio, and DTP. Additionally, 5 of the 7 vaccine preventable diseases of childhood were at alltime lows in 1979.

Except for a discussion of current disease reporting inadequacies, this latest review by GAO touches on no problem areas not covered by other reports and offers no new or realistic suggestions for program improvement. This, and previous reviews, address issues of ensuring adequate supplies of vaccine, vaccine-associated liability, problems of achieving and maintaining adequate levels of immunization, the need to monitor adverse reactions to vaccines, and the need for a stable level of Federal support for immunization programs.

In general, the current GAO report does not recognize the unquestionable positive impact on health that immunization programs have had. While some caution must be exercised in interpreting the data available on the reported incidence of some of the vaccine-preventable diseases of childhood, no one can reasonably deny that there have been enormous decreases in the occurrence of most of these diseases and that these decreases have been brought about by immunization. There is also overwhelming evidence that public programs have played an important part in these achievements and that significant improvements have followed increases in Federal support of these programs.

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The issue which GAO discusses in the report which has not been fully covered by other reports is summarized in the following quote:

"Limitations in program accomplishment measures preclude verification of HEW's conclusion that Federal immunization activities have had a significant influence in reducing childhood disease levels" (page 6).

This statement has two parts. The first is that the number of reported cases is an unreliable indicator of the occurrence of disease. We strongly disagree with this assertion. Although reporting is admittedly not complete for all vaccine-preventable diseases of childhood, surveillance systems clearly provide an accurate reflection of trends in disease occurrence.

It is difficult to imagine that the significant changes in reported measles and rubella cases over past years have been caused by variations in physician reporting habits. This conclusion is supported by the fact that trends in measles deaths have closely paralleled trends in measles cases, and mortality reporting is not affected by the same variations in physician compliance as disease reporting. A similar check exists with rubella, since increases in cases of rubella can be related to increases in cases of congenital rubella syndrome. For paralytic polio, moreover, reporting is believed to be nearly complete.

As the overall level of measles declines and as the Department embarks upon a campaign to eliminate the spread of measles in the United States, it is recognized that improvements in the thoroughness and timeliness of reporting of measles cases by practicing physicians and others are needed. A major component of the measles elimination strategy is to institute active surveillance systems which do not rely solely on voluntary reports by private physicians. School and day-care center nurses and teachers are being encouraged to report suspected cases of measles. Selected physicians and other health care providers likely to see persons with measles are being contacted regularly rather than waiting for them to take the initiative in reporting cases. A pilot evaluation of this approach was recently undertaken in 10 Western and Midwestern States. This included thousands of phone calls, generally weekly, to physicians and hospitals. They found very few cases of measles that were not being reported through the usual channels.

The second point made is that it is difficult to distinguish between the effects of Federal and non-Federal efforts in the immunization program. This is true. One study has attempted to distinguish between the effect of Federal intervention and that taking place as a result of private sector and other activities (Albritton RB: Cost-benefits of

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measles eradication: Effects of a Federal intervention. Policy Analysis 4:1-21, Winter 1978). This study concluded "This analysis shows massive public benefits derived from Federal support of measles immunization. A ratio of $10.34 in benefits to every $1.00 in costs since 1966..." Admittedly, such an analysis is quite difficult because of the very important role of the Federal Government in stimulating activity in the private and public sector in addition to any direct assistance it provides. The leadership and publicity attendant on national immunization programs have always been regarded as a key element in stimulating the private sector, voluntary organizations, and the community to achieve high levels of immunization in the community. While there may be local campaigns in the absence of a national program, there has never been a concerted national effort reaching all citizens except those organized and led by HEW. Since HEW campaigns depend on cooperation of all groups, it is not surprising that one cannot precisely separate them or determine differential effectiveness.

The enormous progress made during the Childhood Immunization Initiative of 1977-1979 in finding and immunizing children, and in reducing the occurrence of vaccine preventable diseases, also attests to the importance of the Federal role. Federal funding and commitment were high during these years. This progress and that noted by GAO with reference to the impact of Federal funding for measles immunization in the late 1960's and again in the early 1970's, present a strong case for the significant impact of Federal funding.

GAO Recommendation

"Direct the Director, Center for Disease Control (CDC), to undertake studies to test the reliability of disease reporting and measure the variability and extent of non-Federal immunization resources. Such studies could provide assurance of the validity of HEW's conclusions regarding program effectiveness and could help HEW better determine the extent of Federal support needed for immunization activities."

Department Comment

We do not concur that studies of the type suggested by GAO can be justified. Both CDC and the State health departments are continually trying to assess and improve surveillance systems. As indicated in the General Comments, active efforts are currently underway to assess and strengthen measles reporting as part of the campaign to eliminate indigenous measles from the United States. Further special studies to provide significantly better information on disease trends would be very costly and of limited benefit. Studies to "measure the variability and extent of non-Federal immunization resources" will be explored, although they would be expensive and add a considerable

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reporting burden on health care providers and health agencies. We are currently exploring means of improving the existing National Public Health Program Reporting System established under the Health Incentives Formula Grant Program to expand its usefulness in assessing Federal, State, and local expenditures for public health programs, including immunization programs.

GAO Recommendation

"Establish policies and procedures to improve future immunization program coordination including: (1) Interagency working agreements, (2) guidelines for interagency immunization information flow, and (3) regularly scheduled meetings such as have been held periodically in the past to obtain the advice and counsel of key agency officials, manufacturers, State and local health care providers, insurers, the public, and others having legitimate concern about immunization policies and programs."

Department Comment

We concur that immunization program coordination is essential. We are presently considering means of ensuring that currently functioning interrelationships continue to work adequately. The options include formation of an interagency work group, development of a formal memorandum of understanding between Federal agencies and guidelines for information flow. Formal meetings of non-Federal organizations and individuals, supplementing the various advisory groups already constituted in the Department, will be held when needed; we believe it would be needlessly costly to require regularly scheduled meetings for this purpose.

GAO Recommendation

"Direct the Director, CDC, to develop methods to help standardize State laws and enforcement such as (1) develop a model State law and (2) continuing to emphasize the importance of consistent State laws and enforcement through publicity and personal contact with State and local officials."

Department Comment

We concur. CDC is already working actively in this area. Its program guidelines for immunization project grants currently require inclusion of "a plan to ensure that every effort will be made to obtain compliance with existing compulsory school and day care immunization laws/regulations." Recognizing that passage of immunization requirements is a constitutional prerogative of the States, CDC is

urging the maximal expansion of these laws and rigid enforcement of them and has provided data which demonstrate the effectiveness of various laws. This has been manifested in articles in CDC's Morbidity and Mortality Weekly Report, in letters and comments provided to State health departments and, in at least one instance, statements delivered before a State legislature. CDC is presently considering the possibility of drafting a model law.

GAO Recommendation

"Request whatever Federal funding is shown to be needed to attain and maintain desired immunization goals for all childhood diseases. Funding for any new vaccine programs should be in addition to these programs."

Department Comment

We do not concur. Unpredictability and variability of Federal funding have been a major problem in the past, but have improved lately. Nonetheless, it must be recognized that the Administration and Congress must continue to set priorities based on existing problems and budgetary constraints. It is impractical to concur with such a broad, open-ended recommendation because: (1) We are often faced with lack of total agreement on desirable goals; (2) various strategies can be employed to reach agreed-upon goals; (3) legitimate differences can exist on the appropriate role of various levels of government, the private sector, and private individuals, and (4) part of the Department's role is to make resource decisions that cannot always maximize every goal among competing and highly desirable goals in health and human resources.

GAO Recommendation

Expedite data gathering to determine the potential costs and other potential effects of the various proposed liability alternatives. These then should be weighed against the risks of the current liability arrangement and the best alternative chosen. Whichever approach is taken, Federal liability policy should be made clear to all program participants."

Department Comment

We concur. Data on potential costs of vaccine-associated injuries have been obtained and our Office of General Counsel is presently making estimates on the possible costs of a compensation system. Statements of policy will be widely disseminated.

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GAO Recommendation

"Establish a systematic procedure to obtain, consider and act on comments on important information statement content from interested experts within and outside HEW and the Federal Government to assure that appropriate participants' views are fully considered."

Department Comment

We concur. A system has been established. A wide variety of viewpoints is sought and considered in the development of these statements, although final responsibility for the content of these statements rests with the Department.

GAO Recommendation

"Direct the Direc , CDC, and the Commissioner, Food and Drug Administration (FDA), to test the reliability of existing vaccine reaction monitoring systems.

"Place the authority and responsibility for reaction data collection and dissemination with one agency, or clearly divide and coordinate with other interested parties."

Department Comment

We concur. CDC's adverse reaction system for all vaccines provided in public programs is only now becoming fully operational. Its adequacy will be monitored. Summaries of information obtained will be produced regularly and shared widely.

FDA currently tests the reliability of its reaction monitoring system by having FDA scientific personnel review vaccine manufacturers' reports of adverse reactions during annual inspections. Each manufacturer is required to maintain a file on adverse reactions. It should be noted that the cost of obtaining adverse reaction data is very high if that reaction occurs at a rate of fewer than 1:100,000 participants or if it occurs after a lengthy period of time has elapsed.

Both the Bureau of Biologics and CDC are taking steps to determine the feasibility of improving the reliability of its existing systems through more active data collection. For example, the Bureau of Biologics is conducting a pilot program with a major manufacturer to obtain all of its reported adverse reactions. In addition, there have been, and will continue to be, discussions held with both organizations

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and representatives of the medical community, academic community, and with regulated industry to attempt to obtain a consensus concerning the feasibility of improving the reliability of existing systems through more active data collection.

Improved coordination of reaction monitoring is one aspect of our considerations regarding the establishment of a formal interagency work group or developing memorandums of understanding between agencies.

Technical Comments:

Throughout the report there are references to the "Administrator, FDA." These should be changed to "Commissioner of Food and Drugs."

Page 11, last paragraph

This statement should be modified to indicate that most reactions to vaccines are mild and expected. More severe reactions are rare and not always predictable based upon the limited number of people exposed to the vaccine during clinical trials. It should further be noted that no drug or treatment regimen is risk-free. However, the risks of serious adverse reactions to vaccines are far less than the risks of developing severe complications as a result of contracting the disease.

Page 29, second paragraph, first sentence

The 1976 swine flu legislation (Public Law 94-380) applied solely to the swine flu program and did not extend Federal liability to non-negligent injuries associated with other flu vaccines or vaccines in general. Some clarification of this point is needed.

Page 41, paragraph 2, first sentence

The comment about all vaccine reactions data being obtained through passive reporting systems is not correct. The Food and Drug Administration has had contracts in effect for quite some time to collect and analyze data relative to adverse reactions to vaccines for specific diseases. For example, the Bureau of Biologics has a contract for maintenance of a registry of cases of Subacute Sclerosing Panencephalitis (SSPE) associated with measles or possibly measles vaccines. In addition, reports received through "passive" reporting systems at CDC and FDA result in intensive, "active" investigations. The identification of the occurrence of Guillain Barre Syndrome through the passive surveillance system established during the swine flu program was followed by an active investigation which identified the true risk. Similar investigations of abscesses following DTP vaccination have recently been undertaken.

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Pages 41-42

The section on Passive reaction monitoring should point out that obtaining data on reactions that occur as infrequently as 1:100,000 participants is extremely costly and can be quite difficult, particularly when the adverse reaction occurs after a lengthy lapse of time.

Page 52, paragraph 1, last sentence

Change to read "HEW and manufacturer officials said Rhesus monkey breeding colonies have been and are being established to help alleviate the problem."

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