ONE HUNDRED SEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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May 2, 2002

The Honorable Dan Burton
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Chairman:

I am writing to ask you to drop your threats to subpoena reams of patient information from the most important national database for monitoring vaccine safety, the Vaccine Safety Datalink (VSD) project. According to the Centers for Disease Control and Prevention, issuance of a subpoena could lead to the collapse of the VSD database, "destroying CDC's ability to scientifically test hypotheses relating to adverse events potentially associated with vaccines." It would also jeopardize the medical privacy of millions of Americans. Despite these risks, you and your staff have drawn up a draft subpoena. I urge you to reverse course and state clearly that you will not subpoena patient data from these medical records.

The database in question is the Vaccine Safety Datalink project, a federal effort established over a decade ago that now combines information from the medical records of eight large health maintenance organizations. HMO officials have expressed their concern that a subpoena would jeopardize the medical privacy of approximately 7.5 million Americans and would lead the HMOs to reconsider their participation in the project altogether.

The consequences of the loss of this database would be grave. It was the VSD project that demonstrated an association between rare cases of intestinal obstruction and the vaccine to prevent rotavirus infection, contributing to its withdrawal from the market. Studies using the VSD also helped make the measles-mumps-rubella, polio, and pneumococcal vaccines safer. In the future, according to CDC, the VSD will "be critical to our ability to monitor the safety of smallpox vaccinations in a timely and accurate manner." For these reasons, top public health officials and experts contacted by my staff uniformly expressed alarm at the possible collapse of the VSD.

A confrontation with CDC over the VSD is needless. In recognition of your interest in

confirming some of the results of VSD studies involving vaccines containing thimerosal, CDC and the HMOs have offered a way for independent investigators to analyze VSD data without compromising medical privacy. You should endorse this approach rather than continue to seek to subpoena the records themselves.

The rest of this letter explains my concerns in more detail.

The Vaccine Safety Datalink System

Understanding whether a particular vaccine is safe, and what side effects it may produce, begins with pre-licensure studies. While the size of these studies has increased in recent years, in some cases adverse outcomes are too rare to be detected before licensure. To identify quickly such rare events, public health officials rely on several mechanisms to monitor adverse effects after approval. The two largest and most important mechanisms are the Vaccine Adverse Event Reporting System (VAERS) and the VSD.

VAERS is a compilation of spontaneous reports of suspected adverse events from parents, health care providers, and pharmaceutical manufacturers. VAERS reports can be a signal that there may be a problem with a vaccine. However, because VAERS is a passive system, it rarely can answer the question of whether a vaccine is truly associated with a problem or at what rate the adverse effect is occurring.

In order to enhance the understanding of rare adverse effects of vaccines, CDC developed the VSD project in 1990. This project now utilizes the databases of eight large HMOs, pooling information from the medical records of approximately 7.5 million people, or 2.5% of the U.S. population. The records include diagnoses, laboratory test results, prescriptions, and immunizations, but do not include the names of patients. Even without the names, however, these data can be combined with information from publicly available sources to identify some patients. For this reason, the HMOs share information from medical records with CDC only after assurances that confidentiality will be strictly maintained.

The VSD yields an enormous benefit to the public health. Using this large and complex database, CDC can quickly design and implement sophisticated studies that take into account confounding factors and use proper control groups. The VSD allows public health officials not only to carry out planned research activities, but also to conduct timely investigations into adverse events.

One example of how the VSD enabled quick action to protect children is the case of the vaccine to prevent rotavirus infection, a cause of severe diarrhea in infants. In 1999, several cases of intestinal obstruction following rotavirus vaccination were reported to the VAERS system. While the number of cases were suggestive of a possible association, it was still unclear

whether these cases were coincidences or truly linked with the vaccine. Very quickly, CDC officials conducted a study using VSD data, which determined that this rare condition was associated with the rotavirus vaccine. The results contributed heavily to the manufacturer's decision to withdraw the vaccine from the market before more children could be injured.[1]

Over the last decade, public health officials and researchers have used the VSD to answer many vaccine-related questions. VSD studies, for example, have supported policy changes that have reduced adverse effects from the MMR vaccine,[2] maintained high levels of polio vaccination using a formulation that does not cause vaccine-associated polio,[3] and enhanced the safety of the pneumococcal vaccine schedule.[4] Other VSD research has examined theories of vaccine harm and failed to find empirical support for them. Such studies have provided evidence that childhood vaccines are not associated with diabetes,[5] that the MMR vaccine is not associated with inflammatory bowel disease[6] or aseptic meningitis,[7] and that the rubella vaccine is not

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[1]P. Kramarz, E. France, F. DeStefano et al., *Population-Based Study of Rotavirus Vaccination and Intussusception*, Pediatric Infectious Disease Journal, 410-6 (April 2001).

[2]R. Davis, E. Marcuse, S. Black, et al., *MMR2 Immunization at 4 to 5 years and 10 to 12 Years of Age: A Comparison of Adverse Clinical Events After Immunization in the Vaccine Safety Datalink Project*, Pediatrics, 767-71 (November 1997).

[3]R. Davis, T. Lieu, L. Mell, et al., *Impact of the Change in Polio Vaccination Schedule on Immunization Coverage Rates: A Study in Two Large Health Maintenance Organizations*, Pediatrics, 671-8 (April 2001).

[4]L. Jackson , P. Benson, V. Sneller, et al., *Safety of Revaccination with Pneumococcal Polysaccharide Vaccine*, Journal of the American Medical Association, 243-8 (Jan. 20, 1999).

[5]F. DeStefano, J. Mullooly, C. Okoro et al., *Childhood Vaccinations, Vaccination Timing, and Risk of Type 1 Diabetes Mellitus*, Pediatrics, E112 (December 2001).

[6]R. Davis, P. Kramarz, K. Bohlke, et al., *Measles-Mumps-Rubella and Other Measles-Containing Vaccines Do Not Increase the Risk for Inflammatory Bowel Disease: A Case-Control Study from the Vaccine Safety Datalink Project*, Archives of Pediatrics and Adolescent Medicine, 354-9 (March 2001).

[7]S. Black, H. Shinefield, P. Ray, et al., *Risk of Hospitalization Because of Aseptic Meningitis After Measles-Mumps-Rubella Vaccination in One- to Two-Year-Old Children: An Analysis of the Vaccine Safety Datalink (VSD) Project*, Pediatric Infectious Disease Journal, 500-3 (May 1997).

associated with chronic joint disease in adults.[8]

The VSD has played a significant role in making the current vaccine supply safer than ever. Your subpoena threats, however, represent a serious risk to the viability of the entire VSD system.

The Committee's Actions

On July 18, 2000, at a hearing entitled "Mercury In Medicine–Are We Taking Unnecessary Risks," Dr. Roger Bernier of CDC testified about the results of studies using VSD data to examine whether exposure to thimerosal in vaccines is associated with developmental delays. According to his testimony, an initial study suggested a connection between thimerosal and certain developmental symptoms. Subsequent studies in the VSD have not confirmed these findings, and further research is ongoing.[9]

On November 21, 2000, you sent a letter to CDC Director Jeffrey P. Koplan asking for VSD data "in both printed and electronic format."[10] After CDC refused, your staff has repeatedly threatened CDC officials with a subpoena for the raw data from the VSD, including asking for the name and address of the person who should receive the subpoena. Earlier this year, on February 21, 2002, your staff faxed to my staff a draft subpoena to CDC for "all records collected under the Vaccine Safety Datalink Project."[11]

In defending the subpoena threats, you have indicated that your interest in obtaining this medical information is to double check the results of the thimerosal study and to conduct independent analyses of vaccine safety. To accommodate this concern, CDC has developed a protocol to allow independent researchers access to VSD data through the National Center for Health Statistics (NCHS) under certain reasonable conditions. These conditions include: (1) the study is approved by the HMOs' Institutional Review Boards charged with assuring the protection of human subjects; (2) the study has a clear protocol; and (3) the study is conducted at NCHS, with the researchers able to leave with their results but not the raw data.

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[8]P. Ray, S. Black, H. Shinefield, et al., *Risk of Chronic Arthropathy Among Women After Rubella Vaccination*, Journal of the American Medical Association, 551-6 (Aug. 20, 1997).

[9]Institute of Medicine, *Thimerosal-Containing Vaccines and Neurodevelopmental Disorders* (Oct. 1, 2001).

[10]Letter from Chairman Dan Burton to Dr. Jeffrey P. Koplan (Nov. 21, 2000).

[11]Draft Subpoena Duces Tecum to Dr. Jeffrey P. Koplan (February 2002).

Despite this reasonable solution, which does not compromise patient confidentiality and would protect the future of the VSD, you have yet to abandon your subpoena threats.

The Threat to Medical Privacy and the VSD

Your draft subpoena asks CDC to "redact personal information, such as names, social security numbers, or other unique identifiers that would allow for the identification of individual patients."[12] However, even without names, social security numbers, and other unique identifiers, the VSD data can be used to identify individuals. The reason is that the dataset includes many non-unique variables, such as birthday, diagnosis, HMO, and date of immunization that can be patched together with information from publicly available sources to identify individuals. CDC explained:

> In order to assess the ease with which an individual could identify a patient's medical record, one of the VSD HMOs conducted an exercise. They imagined a scenario in which an HMO employee had access, via the internet, to the complete VSD database in its current format. If this employee knew that a co-worker was an HMO member, was able to learn the co-worker's birth date (e.g., through an office birthday party), and knew that the co-worker recently broke an arm and required medical attention, then that employee could find the co-worker's record in the VSD file easily. Once the co-worker's file was found, all of that person's medical history – such as information concerning other medical visits, diagnoses (including HIV and mental health status) and prescriptions filled - was available for review by this person. The Principal Investigator at one VSD HMO tested this scenario using his daughter. With her birth date and knowledge that she recently sprained an ankle, an HMO analyst was able to find her records in the VSD data. Such identification of individuals could have devastating consequences to the individual as well as to the HMO.[13]

CDC has informed my staff that the thimerosal study could not be replicated without identifying the diagnoses and medical records of many children who were excluded from the study for scientific reasons because of unrelated serious medical conditions. Identifying these records carries the risk of disclosure of confidential and sensitive medical information. If your desire is to verify the results of the VSD studies, then it is important to acknowledge the very important privacy interests at stake.

In addition to these privacy threats, a subpoena may threaten the viability of the VSD. Concern by participating HMOs was heightened last summer after a group called SAFE MINDS

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[12]Draft Subpoena Duces Tecum to Dr. Jeffrey P. Koplan (February 2002).

[13]Information sent to minority staff by Centers for Disease Control (Apr. 23, 2002).

filed a request under the Freedom of Information Act (FOIA) for raw VSD data. Researchers from the HMOs wrote to CDC urging the agency not to provide the medical records. Dr. Richard Platt and Dr. Tracy Lieu of Harvard Medical School, for example, sought "explicit assurance that health plans will have ongoing control over any new uses and distribution of their data."[14] These physicians explained that information at stake included HIV diagnoses and other identifiable information that would constitute a profound violation of medical privacy.

CDC responded to these concerns by denying the FOIA requests and then affording the VSD data the highest level of protection for privacy available under public health law.[15] However, representatives of SAFE MINDS claimed in the presence of my staff that a refusal by CDC would be met by a subpoena from you for the same information. Your subsequent subpoena threats led investigators at the participating HMOs to realize that even CDC's protection may not be able to guarantee the confidentiality of the records. As a direct result, according both to CDC and HMO officials, a subpoena may force the HMOs to reconsider their participation in the VSD. According to CDC, "If the currently participating HMOs withdrew from the Project because of lack of assurances of confidentiality, it is extremely unlikely that other HMOs would consider providing such complete and specific data to CDC, thus destroying CDC's ability to scientifically test hypotheses relating to adverse events potentially associated with vaccines."[16]

Because of medical privacy concerns, CDC is working on developing a new secure system that would allow public health officials to review rapidly the databases without ever having possession of highly confidential patient data. However, HMO officials have told my staff that a subpoena from you on existing data at CDC would even threaten their participation in this new system.

The logic is understandable: If millions of their patients lose their medical privacy, then they may lose confidence in their health plan. To convince patients that such a violation would never come to pass again, the HMOs may be forced to terminate the VSD project.

Reaction of Experts and Key Officials

Health officials and experts contacted by my staff uniformly expressed the belief that the

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[14]Letter from Dr. Richard Platt and Dr. Tracy Lieu to Dr. Robert Chen, (July 25, 2001).

[15]CDC has obtained protection under section 308(d) of the Public Health Service Act for Vaccine Safety Datalink data. This protection does not extend to a congressional subpoena, however.

[16]Information sent from CDC to minority staff (Apr. 23, 2002).

VSD is an essential tool to protect children. Dr. Georges Peter, chairman of the National Vaccine Advisory Committee, explained:

> The VSD program has been of vital importance in our continuing efforts to assess causal associations between adverse events in vaccine recipients and specific vaccines. One of the critical elements of the program is the large patient base which allows the investigators to assess possible associations between rare events and vaccines. Without the participation of large HMOs, the sensitivity of the program would be significantly limited and our nation's efforts to continue to enhance vaccine safety efforts would be very much compromised. These scientific studies are necessary for the children and parents who rely on safe and effective vaccines to prevent once common childhood diseases such as poliomyelitis, measles and meningitis."[17]

Dr. Neal Halsey, director of the Institute for Vaccine Safety at Johns Hopkins University, wrote:

> If the subpoena power of Congress is used in a misguided effort to find additional associations with thimerosal exposures, this will undermine the ability of CDC to undertake future research in the area of vaccine safety.[18]

Similarly, Dr. Lou Cooper, president of the American Academy of Pediatrics, noted:

> The Vaccine Safety Datalink (VSD) project has been our best instrument for studying longer term and low incidence consequences of immunization. It is a unique tool, and I am not sure how we could replace it. Any threat to the confidentiality of these data, which are in fact patient medical records, would violate the trust relationships between patients and their doctors and would force the HMOs to withdraw from the program, an irreplaceable loss in our effort to insure vaccine safety. The precedent set by such an action would be a major setback to research on vaccine safety and would have a chilling impact on other vitally needed public health research.[19]

Bioterrorism and the Future of the VSD

CDC officials have said that the loss of the VSD would compromise the agency's ability to protect the American people from future bioterrorist threats. According to CDC:

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[17]E-mail communication from Dr. Georges Peter to minority staff (Apr. 23, 2002).

[18]E-mail communication from Dr. Neal Halsey to minority staff (Apr. 23, 2002).

[19]E-mail communication from Dr. Louis Cooper to minority staff (Apr. 24, 2002).

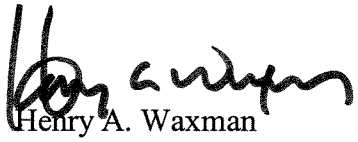
A study is underway within the VSD to more accurately estimate the number of persons likely to suffer complications from smallpox vaccination. Should the decision be made for its broader use in the U.S., the VSD will be critical to our ability to monitor the safety of smallpox vaccinations in a timely and accurate manner. The VSD can also serve as a valuable tool for monitoring other bioterrorism threats that might result in unusual syndromes, vaccine-derived or otherwise.[20]

The loss of the VSD would also undermine other research priorities. CDC officials told my staff that concerns over your subpoena threaten to derail a number of research projects, including some on developmental delay, another topic you have pursued in committee hearings.

Conclusion

I know you are deeply interested in the safety of immunizations. Indeed, I understand that the reason you are threatening to subpoena the VSD data is that you believe the data may contain important information about the risks of vaccines. But in fact, the issuance of a subpoena would have the opposite effect, jeopardizing the VSD system and thereby reducing vaccine safety. I urge you to reconsider your actions.

Sincerely,



Henry A. Waxman
Ranking Minority Member

cc: Members of the Committee on Government Reform

[20]E-mail communication from CDC to minority staff (Apr. 24, 2002).