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SPECIAL ARTICLE

The Process of Public Policy Formulation: The Case of Thimerosal in Vaccines

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ABBREVIATIONS. FDA, Food and Drug Administration; AAP, American Academy of Pediatrics; PHS, Public Health Service; EPA, Environmental Protection Agency; CDC, Centers for Disease Control and Prevention; NVPO, National Vaccine Program Office; AAFP, American Academy of Family Physicians; CBER, Center for Biologics Evaluation and Research; WHO, World Health Organization; ATSDR, Agency for Toxic Substances and Disease Registry; COID, Committee on Infectious Diseases; ACIP, Advisory Committee on Immunization Practices; IAG, Interagency Vaccine Group; NVAC, National Vaccine Advisory Committee.

Effective immunization programs have markedly diminished the incidence of vaccine-preventable diseases. As a result, there now exists in society a lower awareness of the actual risks associated with the diseases themselves and a greater prominence of the potential risks of adverse effects associated with vaccines.

Concern regarding public reactions to new vaccine safety issues may place pressure on policymakers and/or health care providers to act quickly in response to new information. However, this concern must be tempered by the necessary caution required to assess the intended and unintended risks and benefits of any action undertaken. The interplay of these potentially competing demands is well illustrated by the recent safety concern involving the use of thimerosal in vaccines.

EMERGENCE OF THIMEROSAL AS A CONCERN

Thimerosal is a mercury-containing compound that has been widely used as an antimicrobial agent in vaccines for over 60 years. Human exposure to mercury may have potentially significant health consequences. By mid-1999, the Food and Drug Administration (FDA) had discovered that children could be exposed to an amount of mercury from vaccines that exceeded 1 of 3 existing federal safety thresholds. After this realization, the organized medical and public health communities in the United States became involved in a series of urgent and intense discussions to determine an appropriate response to the issue. This manuscript describes and analyzes the process that led to the July 7, 1999, joint American Academy of Pediatrics (AAP)/US Public Health Service (PHS) statement on thimerosal,[1] with the goal of suggesting improvements for managing similar vaccine safety concerns in the future.

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METHODS

We conducted structured interviews with over 15 individuals involved in the discussions and negotiations leading to the joint AAP/PHS statement on thimerosal. The individuals represented both the governmental agencies and nongovernmental organizations involved, including the FDA, the Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention (CDC), the National Vaccine Program Office (NVPO), the AAP, and the American Academy of Family Physicians (AAFP). Interviews were conducted through face-to-face meetings or by telephone between January and April 2001. Table 1 lists the individuals interviewed who allowed their identities to be published.

TABLE 1. List of Individuals Interviewed for Thimerosal Study

Name	Organization and Title
Jon S. Abramson, MD	Chair, COID, AAP
Joel J. Alpert, MD	Past President, AAP
Leslie K. Ball, MD	Division of Vaccines and Related Products Applications Office of Vaccine Research and Review, CBER, FDA
Roger H. Bernier, PhD, MPH	Associate Director for Science National Immunization Program, CDC
Louis Z. Cooper, MD	Vice President, AAP
William M. Egan, PhD	Deputy Director Office of Vaccine Research and Review, CBER, FDA
Lynn R. Goldman, MD	Former Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, EPA
Neal A. Halsey, MD	Past Chair Committee on Infectious Diseases, AAP; Director Institute for Vaccine Safety
Karen M. Hendricks, JD	Department of Government Liaison, AAP
John F. Modlin, MD	Chair Advisory Committee on Immunizations
Martin G. Myers, MD	Director, NVPO
Walter A. Orenstein, MD	Director, National Immunization Program, CDC
David Satcher, MD, PhD	US Surgeon General, Assistant Secretary for Health
Richard Zimmerman, MD	American Academy of Family Physicians Liaison to ACIP

INITIAL CONTROVERSY AND ACTIONS

The development and implementation of immunization policy in the United States is a cooperative effort among many entities in the public and private sectors (Table 2).

The concern over thimerosal in vaccines originated from a confluence of independent events, 1 informal and 1 formal, within the FDA. In the spring of 1998, some individuals within the FDA's Center for Biologics Evaluation and Research (CBER) began to informally consider the increased number of recommended vaccines and the amount of substances, such as mercury, contained in them to which vaccine recipients were exposed. Available literature to help quantify their concern was limited.

The formal identification of thimerosal as a concern arose through the FDA's efforts to comply with the Food and Drug Administration Modernization Act.[2] As mandated by Congress, Section 413(a) of the Act required the FDA to compile a list of drugs and foods that contain "intentionally introduced" mercury compounds and to provide a quantitative and qualitative analysis of these compounds within 2 years of the Act's enactment.

FDA's Reassessment of the Risk From Thimerosal

The FDA's previous formal review of thimerosal in biological products had occurred in 1976. The convergence of concerns over mercury in vaccines that occurred within the CBER beginning in April 1998 prompted the agency to reassess the risks of thimerosal.[3]

One of the steps of this risk assessment was to investigate the potential exposure of humans to thimerosal in vaccines. Based on the information submitted by industry and FDA internal data, the CBER determined that thimerosal was present in over 30 licensed vaccines in the United States.[4,5] The amount of mercury by weight present in each of these vaccines was calculated. The CBER then referred to the recommended childhood immunization schedule to determine the amount of mercury to which young children may be exposed. Of the vaccines that a child could receive in the first 2 years of life, those that contained thimerosal were the 2 available formulations of the hepatitis B vaccine and some formulations of the diphtheria-tetanus-acellular pertussis and *Haemophilus influenzae* type b vaccines. Looking at cumulative exposure over the first 6 months of life, an infant 6 months old who received all recommended vaccine doses on schedule could be exposed to up to 187.5 μg of mercury.

Another step in the risk assessment process was to determine whether thimerosal actually constituted a true health risk; that is, whether there were data demonstrating that this amount of mercury could be potentially harmful to children. To identify whether there were any known health risks from exposure to thimerosal, the CBER conducted a literature review and queried the Vaccine Adverse Event Reporting System, a national surveillance system for voluntarily reported adverse events associated with vaccines. The CBER found that at low doses, thimerosal has been associated with rare hypersensitivity reactions, such as persistent skin sensitization at the site of vaccination. At very high doses (ie, 1000 times higher than levels found in vaccines), thimerosal has been reported to cause neurologic and renal toxicity.

An early assessment of the health risks of all forms of mercury by the World Health Organization (WHO) found that insufficient information was available to perform risk calculations for human exposure to ethyl mercury compounds, the type of mercury contained in thimerosal.[6] However, the WHO did note that the limited data available suggested that ethyl mercury was probably less hazardous than methyl mercury, because it is metabolized faster in the body.

The WHO and 3 US governmental agencies—the FDA, the EPA, and the Agency for Toxic Substances and Disease Registry (ATSDR)—had developed independent guidelines for safe exposure to methyl mercury (Table 3).[7–10] Because no guidelines exist for ethyl mercury exposure, the FDA used the guidelines for safe exposure to methyl mercury as a guide for determining whether the mercury (ethyl) dose from thimerosal in vaccines approached a level of concern or health risk.

The existence of 3 differing US federal guidelines for methyl mercury was a source of confusion and contention in determining the appropriate response

TABLE 2. Organizations Involved in US Immunization Policy

United States government agencies
NVPO coordinates each element of the immunization process. Facilitates collaboration among federal agencies via the Interagency Vaccine Group (IAG).
CDC, through its National Immunization Program (NIP), provides national direction and leadership to aid state and local health agencies in planning and implementing immunization programs.
FDA is responsible for the licensure of new vaccines, ensuring that new vaccines meet requirements for safety, purity, potency, immunogenicity, and efficacy.
United States government advisory committees
NVAC advises and makes recommendations to the NVPO on ways to achieve optimal prevention of human infectious diseases through vaccine development.
ACIP provides advice and guidance to the Secretary and Assistant Secretary for Health, and the CDC on the most effective means to prevent vaccine-preventable diseases.
Private sector organizations
AAP mainly through its Committee on Infectious Diseases (COID).
AAFP

Most of these committees and organizations have liaison representatives on each other's committees. The national recommended childhood immunization schedule is issued jointly by the ACIP, the AAP, and the AAFP in January of each year.

TABLE 3. Methyl Mercury Guidelines

Agency	Guideline Value for Daily Consumption (μg/kg/day)	Guideline "Type"
EPA	0.1	Reference dose
ATSDR	0.3	Minimal risk level
FDA	0.4	Tolerable daily intake
WHO	0.47	Provisional daily tolerable intake*

* Converted from a weekly tolerable intake level.

to concern regarding thimerosal in vaccines. Each agency developed their guidelines for different purposes. The most conservative of these guidelines was the level established by the EPA to serve as a warning of mercury in the environment to trigger additional investigation. The ATSDR guideline is set below levels that might cause an adverse health impact in those most sensitive to a particular substance. The FDA guidelines were developed as safe limits for long-term consumption of food contaminated with mercury, particularly fish, which is the main exposure route of humans to methyl mercury. No guidelines were available to assess the risk of exposure in bolus doses by intramuscular injection.

Nevertheless, the existing methyl mercury guidelines were the best information available at the time for assessing risk from ethyl mercury exposure. The CBER calculated exposure limits for each of these guidelines based on the average weight at various percentiles in female infants between birth and 26 weeks of age (Table 4). Based on these calculations, the CBER determined that potential exposure to mercury from the recommended childhood vaccines in the first 6 months of life could exceed the EPA methyl mercury guideline, but not the ATSDR, FDA, or WHO guidelines. However, the CBER was unable to determine with certainty whether exposure to thimerosal in vaccines was harmful.

In April 1999, results from the preliminary risk assessment were discussed at an internal FDA meeting, and participants realized that there was a clear need for additional data. The CBER began to consult with toxicologists both within the FDA and at the National Center for Environmental Health, and several vaccine researchers, including Neal Halsey, MD, Director of the Institute for Vaccine Safety at Johns Hopkins University. The FDA also initiated discussions with vaccine manufacturers regarding the need to develop thimerosal-free vaccines.[3]

Origin of the Crisis

Dr Halsey was invited by the FDA to an internal meeting in mid-June 1999 where he was asked to provide feedback on the results of their preliminary risk assessment regarding thimerosal. On learning of the FDA data, and personally verifying the calculations of the levels of mercury to which children could be exposed, he believed that the issue warranted serious concern and urgent action. At the time, Dr Halsey was soon to complete his term as Chair of the AAP Committee on Infectious Diseases (COID). Dr Halsey previously worked within the CDC's immunization program and had been a member of the Advisory Committee on Immunization Practices (ACIP). As such, he had extensive experience and professional relationships within the US immunization policymaking arena. Beginning around June 24, 1999, Dr Halsey informed many of these contacts of his concern regarding the potential health effects of thimerosal and the results of the FDA's preliminary risk assessment. After notifying the Director of the CDC's National Immunization Program, Dr Halsey met with CDC personnel at the National Immunization Conference on June 25. He also informed several other individuals, including the incoming Chair of the COID, the Chair of the ACIP, and a member of the AAP Board of Directors. In addition to his concern regarding the potential health effects of mercury exposure in infants, Dr Halsey expressed the need for urgent action on the issue because the FDA was planning to send a letter to vaccine manufacturers in the beginning of July 1999 regarding the need to remove thimerosal from vaccines, at which point the information about thimerosal would become public. He believed that publicity surrounding this issue, without action on the part of the PHS and/or the AAP, could result in long-term damage to public confidence in the national immunization system.

TABLE 4. Calculated Exposure Limits for Methyl Mercury

Agency	Percentile Body Weight		
	5th	50th	95th
EPA	65μg	89μg	106μg
ATSDR	194μg	266μg	319μg
FDA	259μg	354μg	425μg
WHO	305μg	417μg	501μg

After Dr Halsey informed these initial contacts of his concerns regarding thimerosal, conversations began to occur among the parties. The Interagency Vaccine Group (IAG) held a conference call on June 28 and reviewed the information from the FDA's preliminary risk assessment. After this call, the IAG formed a special workgroup to address the thimerosal issue. CDC immunization officials also conferred with the AAP, vaccine companies, and internal CDC toxicologists.

Significant differences of opinion surfaced regarding the accuracy of the exposure and risk-assessment information concerning thimerosal, its importance, and the need for any immediate discussion or action.

To quickly bring representatives of several organizations involved in immunization policymaking together to discuss the issue, a meeting was organized by Dr Halsey and Dr Cooper for June 30, 1999, at the AAP offices in Washington, DC. The selection of the venue for this meeting was deliberate. The initial course of action for the government normally would have been for the ACIP and the National Vaccine Advisory Committee (NVAC) to meet to discuss the issue. However, governmental advisory boards are required by the Federal Advisory Committee Act to provide adequate public notice of meetings and publish meeting agendas in the *Federal Register*. Given how quickly some individuals believed a meeting should occur, it was not possible to officially convene these advisory bodies in such a short time frame. By having an informal meeting at the offices of the AAP, a frank discussion of the scientific and biological veracity of all available information could take place without delay. As a result, however, this meeting precluded the formal involvement of the ACIP and the NVAC.

Drs Cooper and Halsey developed a list of invitees, which included representatives of the CDC, FDA, EPA, AAP, vaccine manufacturers, and toxicologic consultants. An initial goal of the meeting was

to achieve consensus on a course of action, as many believed that public presentation of differing views would likely confuse practitioners and parents, and potentially undermine confidence in the national immunization system.

At the meeting, FDA representatives shared the results of their preliminary risk assessment, outlining what was known and unknown about the issue and describing the difficulties in determining whether the level of mercury in vaccines should be of concern. Because of the complexities in interpreting the data regarding the potential risk of harm from thimerosal, there was disagreement among the parties present as to its significance. Disagreements existed between organizations, within organizations, and among the toxicologists present at the meeting. Some participants believed strongly that the potential threat to health from thimerosal was significant; others believed that there was no clear evidence that thimerosal was harmful, particularly when compared with the clear health risks of delaying childhood vaccines. The 2 AAP committees represented at the meeting, the COID and the Committee on Environmental Health, were in sharp disagreement on this point. There was also a varied sense of exigency, with some participants believing that urgent action was required, whereas others thought the process should slow down to include other parties in the discussion and address perceived significant gaps in the scientific data. Actions proposed by participants at the meeting ranged from immediately stopping administration of all vaccines containing thimerosal to children under 6 months of age to encouraging vaccine manufacturers to expedite the elimination of thimerosal from vaccines.

An overriding concern expressed by all parties at the meeting was the need to maintain the public's trust in the US immunization system by striking the appropriate balance between acknowledgment of the potential risk of harm from thimerosal and the actual risk of harm from not immunizing against vaccine-preventable diseases.

The Path to Compromise Between the AAP and the PHS

It became clear during the June 30, 1999 meeting that no consensus would be reached that day regarding an appropriate course of action. Sharp disagreements regarding the clinical significance of thimerosal exposure were not resolved. Specific individuals who felt most strongly regarding the potential health risk of thimerosal exposure stated that they would independently make public statements if their respective organizations did not support their contentions. The meeting concluded with all participants agreeing that no statement would be released by any individual or organization until after the July 4th weekend, and that discussions between the PHS and the AAP would continue in an attempt to achieve a unified public statement. Leadership in both the AAP and the PHS believed that releasing a joint public statement was crucial for preserving the public's trust in the immunization system.

PHS officials in the CDC and elsewhere believed that vaccine manufacturers should be encouraged to expedite the elimination of thimerosal from vaccines, but did not want to make any changes to the childhood immunization schedule. However, CDC officials also felt strongly that it would be in the best interests of the national immunization system and the public's trust for a statement to be developed jointly with the AAP. This prompted David Satcher, MD, PhD, the US Surgeon General and Assistant Secretary for Health, to be involved in the negotiations.

After the June 30 meeting, there was significant debate within the AAP as to the appropriate course of action to be taken. Over the next several days, there was constant reconsideration and revision of positions taken among both individuals and committees.

On review of available information and opinions, the AAP Board of Directors decided to put forth the position in their negotiations with the PHS that the birth dose of the hepatitis B vaccine be temporarily delayed. They considered the risk of disease to be low except for infants of HBsAg-positive mothers. The Board of Directors believed that hospitals should already have procedures in place to determine the hepatitis B status of mothers and treat the infants of HBsAg-positive status mothers appropriately.

Other parties were informally involved in the discussions leading to the joint statement. The AAFP did not think the issue warranted such urgency and believed that the health effects data for methyl mercury on which the EPA guidelines were based were questionable.

Many conference calls, meetings, and sharing of draft statements occurred within and between the AAP and the PHS over the course of the July 4, 1999 holiday weekend. The Surgeon General held several discussions with the AAP president to negotiate a compromise position. Although they were extremely concerned about both the short- and long-term consequences of delaying administration of the hepatitis B vaccine, PHS officials agreed to the recommendation to present a unified position to the public.

The joint statement was officially released in the late afternoon of July 7, 1999,[11] and was published in the *MMWR Morbidity and Mortality Weekly Report* on July 9, 1999.[1]

DISCUSSION AND RECOMMENDATIONS

First and foremost, it is clear that all parties involved in this process acted in the manner they believed was in the best interest of children in the United States. Even parties that differed most strongly never doubted the intent or purpose of those with whom they disagreed.

Only 2 weeks transpired between the time that leaders of the major national organizations involved in US immunization policy learned about the issue of thimerosal in vaccines and the release of the joint AAP/PHS statement. During that time, these individuals and their organizations worked diligently to develop a response that they believed balanced the potential risk from exposure to thimerosal with the actual risk of vaccine-preventable disease and would

ensure continued public confidence in the nations' immunization system. Considering the complexity of the information available and the gaps in information relevant to specific concerns, it is not surprising there was significant disagreement regarding the potential risk associated with thimerosal. To some, the process could be considered a success, in that compromise was reached and the "crisis" was addressed. However, others have publicly criticized the process, noting that the recommendation to delay the birth dose of hepatitis B vaccine confused practitioners and put infants at risk for hepatitis B infection.[12] One well-known vaccine expert went so far as to say that the process was a "model of how not to reach public health decisions."[13]

Communicating Initial Concerns and the Relationships Among Government Agencies

Ideally, members of the NVPO's IAG would have first learned of the thimerosal issue from FDA officials, who would have informed the group of its review of the thimerosal content in vaccines. In this case, however, an individual outside of the government was the first to inform many of these agencies. How soon the FDA should have done so is a matter of controversy, as is how much information should have been gathered before informing other parties. The FDA was reluctant to raise an issue with the IAG when there were so many uncertainties surrounding the potential health risks involved. In addition, the FDA must be sensitive to proprietary issues related to any product under its review.

The IAG is designed to facilitate collaboration among federal agencies working with vaccine issues through regular meetings and other activities. To do so, the IAG must achieve a better balance between ensuring that members are informed of emerging issues, and allowing agencies to gather enough data to adequately inform other parties before the information is released to the public. For such interagency groups to be effective, there must be confidence among the participating parties that their missions all benefit from coordinated and shared efforts with each other. Thus, the organizing entity must be seen as independent and impartial relative to its constituents. One aspect of this issue is to ensure that the budget and reporting authority of the NVPO are not under the influence or control, perceived or otherwise, of any constituent agency. Currently, the NVPO budget passes administratively through the CDC.

We recommend that serious consideration be given by the Office of the Secretary for Health and Human Services to increase the perception of the independence of the NVPO, including moving the office out of Atlanta and altering the method of budget allocation

The Washington, DC Meeting of June 30, 1999

The meeting that occurred at the AAP offices in Washington, DC, on June 30, 1999, was a key event in facilitating the discussions leading to the joint statement. Both the convening of this type of meeting and the rapidity in which it was organized was highly unusual for the AAP, yet the pattern of action was reflective of the wishes of the Board of Directors.

There are questions as to the appropriateness of who was, or was not, invited. One concern expressed from many sources was the presence of vaccine industry representatives at the meeting. The meeting occurred near the time of the vaccine safety hearings in Congress, and in a political environment in which allegations of collusion between industry and immunization policymakers had been made. Some participants at the meeting believed that having industry representatives at a closed meeting could have bolstered this allegation. Their participation may also have inhibited the candor of some meeting participants.

Yet, the role of the vaccine manufacturing industry to a healthy immunization system cannot be overstated. Vaccine manufacturers possess a unique knowledge of vaccine product development and production, and their participation in different aspects of immunization policy is important.

Another concern is that some parties did not participate in this meeting (or later deliberations), such as the AAFP or representatives of hospitals that would be affected by the change in the newborn hepatitis B recommendation.

In addition, the full membership of the 2 federal immunization advisory committees, the ACIP and the NVAC, did not actively participate in the initial thimerosal deliberations because of the perceived restrictions of the Federal Advisory Committee Act on conducting meetings on very short notice. The CDC and the NVPO have reviewed the regulations more closely and have found that provisions do exist for convening meetings on an emergency basis.[14]

Consideration of Unintended Consequences

The decision to delay the birth dose of hepatitis B vaccine was not taken lightly by any party to the process. Balancing the uncertain risk of thimerosal exposure with the known risk of vertical transmission of hepatitis B disease was difficult for many. However, in some deliberations leading to the joint AAP/PHS statement, consideration of the potential impact of delaying the birth dose of the hepatitis B vaccine did not receive sufficient attention. For some in favor of stopping the birth dose of hepatitis B vaccine, there was little acknowledgment of the potentially significant ramifications of changing the policies of birthing hospitals across the nation, the mechanisms for disseminating this policy change to these hospitals, or the adequacy of hospital procedures for determining the hepatitis B status of mothers. There seemed to be little effort made to examine the existing literature on the impact of changes in immunization recommendations and the lag times for the adoption of recommendations.[15,16] Furthermore, there was an undeserved confidence placed by some authorities in the ability of hospitals to consistently screen all mothers for hepatitis B status before delivery, although previous studies had shown frequent failures of such screening programs.[17–19]

Several analyses of the impact of the joint statement on infant hepatitis B vaccination practices are

just now beginning to be published.[20–23] These analyses have shown that some hospitals stopped vaccinating all newborns with hepatitis B vaccine, including those born to HBsAg-positive mothers.[21,23] One possible factor is the lack of information or understanding of the recommendation by hospitals and physicians.[23] Because of the absence of appropriate safeguards for testing and reporting the hepatitis B status of mothers, this change in policy has inadvertently led to the death of at least 1 infant from hepatitis B.[20] Studies have also shown that many hospitals have not reinstated policies to administer newborn doses of the hepatitis B vaccine despite the availability of thimerosal-free vaccine.[20–23] The importance of administering the first dose of hepatitis B vaccine at birth is illustrated by a recent study that showed that children who received the first dose at birth were more likely to complete the full hepatitis B vaccination series.[24]

In times of rapid decision-making regarding immunization policy, we recommend that all parties involved seek to analyze the short- and long-term intended and unintended consequences of their proposed actions. This type of analysis could take the form of the formalized and structured risk assessment process used by other government agencies, such as the EPA.

Media Pressure

One of the major issues driving concern and urgency among almost all parties was the manner in which the media would portray the issue. Concern over the accuracy of media coverage in general, and for vaccine issues in particular, is well founded.[25] However, an overriding issue is the question of how much should concern over media coverage drive the time frame of decision processes for public or individual health issues. Those entrusted with policy-making authority must balance concern over the risk of exaggerated public perception regarding safety issues with concern over the responsibility to ensure that accurate information be transmitted to the public.

Functions of the FDA

The FDA ensures the safety and efficacy of products before they are approved for use and regularly evaluates the manufacturing process of pharmaceuticals, providing a constant standard of products available to consumers. However, the case of thimerosal illustrates an inherent limitation to current FDA processes. In the 1940s when thimerosal was approved for use in this country, there were limited modalities available to assess for the toxicity of given substances. Interestingly, there is no authority for the FDA to periodically reevaluate approved vaccine additives with increasingly modern methods.

This is in contrast to some other federal agencies, such as the EPA. In 1988, legislation was passed requiring that pesticides be reevaluated by the EPA every 10 years. Because no such process has been legislated for the FDA, additives like thimerosal do not undergo periodic evaluation. In addition, for a product containing mercury, the effect of most concern is on nervous system function. At this time, the FDA has no testing mechanism for developmental neurotoxicity of the products it evaluates.

In addition, the FDA does not have a regular mechanism to identify the cumulative amount of thimerosal, which children would receive over the course of the recommended immunization schedule. Each vaccine was approved for use as an independent agent and thus the amount of thimerosal contained in each individual vaccine raised no concern. It was only when the cumulative amount from all the vaccines contained in the recommended immunization schedule was calculated that concern arose.

We recommend that Congress should consider legislation to allow the FDA the authority to perform periodic evaluation of approved vaccine additives. In addition, we suggest that 1) the FDA incorporate developmental neurotoxicity testing mechanisms into its evaluative efforts, and 2) the FDA develop a mechanism for ongoing determinations of the cumulative amount of additives to which individuals may be exposed as a result of specific federal recommendations.

The Existence of Differing Federal Safety Standards

One of the more vexing issues to all parties involved was the existence of differing federal standards for exposure to mercury from the EPA, the FDA, and the ATSDR. Although each agency had a different purpose in establishing a specific safety threshold, the fact that there was no clear federal consensus on this issue was confusing. This variation allowed different parties to the discussion to champion one agency's threshold over another to support their own contentions.

We recommend federal agencies that have created differing safety thresholds for exposure to specific substances work to develop a single federal consensus on safe exposure levels or, alternatively, determine under which circumstances the different guidelines are to be used. Where more than 1 federal standard is necessary, each agency should be charged with stating explicitly the rationale for determining a different safety level.

The Process Within the AAP

The AAP is an organization consistently recognized for its devotion to the furthering of the health and well-being of children. Without question, the internal debate that took place within the AAP on this issue involved genuine disagreement on the course of action that would be of greatest benefit to the children of the United States.

The AAP Board of Directors frequently looks to its committees for advice and information regarding specific issues on which it must set policy. However, the perception exists that the normal course of deliberations within the committee structure was usurped in some fashion. Rather than the Board of Directors hearing official reports on this issue from certain committees, specific individuals were able to dominate the process, although they may have represented minority opinions.

We believe the deliberative committee structure of the AAP is very valuable. We recommend that all attempts be made to maintain use of this structure in times of crisis. This will help ensure that the consensus voice of expert committees, rather than specific individuals, are able to help guide the AAP Board of Directors regarding policy deliberations.

The Perception of a Process Under Siege

Recent congressional hearings have focused on a variety of immunization issues. The tone of these hearings has often been confrontational and intimidating. At one point efforts have even been made to subpoena personal financial information of those involved in immunization policy decision-making and in the preparation or review of documents from the Institute of Medicine. Many dedicated citizens are now reticent to participate in such committees for fear of being subpoenaed and having their integrity publicly questioned and challenged. Such public accusations, even if unfounded, have the potential to cause significant personal and professional harm, thereby deterring involvement of leading experts in the field.

New hearings on childhood vaccines were to begin soon after the June 30, 1999, meeting at the AAP offices. As such, concern over the manner in which any action or deliberation might be perceived in this type of environment cast a pall of concern and even fear over many individuals. Indeed, this was perceived as a course of action under siege by a Congressional hearing process not operating in the best interests of the nation's immunization system or our nation's children. This perception also added to the development of a crisis atmosphere and the imperative to act in rapid fashion.

Limitations of Study

We interviewed many, but not all, of the parties involved in this process. As such, we believe we have constructed an accurate overall chronology and assessment of the events that took place in late June and early July 1999. However, there exists the possibility that some information may not have been captured. In addition, these interviews were conducted almost 2 years after this process took place. Therefore, there may be recall bias influencing some of the information we received.

CONCLUSION

The process that resulted in the change in immunization recommendations as a result of concern related to thimerosal was complex and multifaceted. Although there are still significant differences of opinion regarding the appropriateness of the actions taken, the immunization system in the United States remains healthy and intact.

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