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Association of American Physicians and Surgeons, Inc.
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STATEMENT

of the

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS

on

VACCINES: PUBLIC SAFETY AND PERSONAL CHOICE

before the

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT
U.S. HOUSE OF REPRESENTATIVES

submitted by

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Aug. 3, 1999

The Association of American Physicians and Surgeons (AAPS), founded in 1943 to protect the sanctity of the patient-physician relationship, is dedicated to the Oath of Hippocrates and represents physicians in all specialties nationwide.

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Introduction

The Association of American Physicians and Surgeons (AAPS) recognizes that vaccines, in the past, have prevented many serious illnesses. But it is simply a fact that every insurance policy has a premium. Every medical intervention carries both risks and potential benefits. The risk:benefit calculation is different for each individual patient, and can only be made by the patient (or the patient's guardian) in consultation with the

attending physician.

It is the right of every patient to refuse a medical intervention, even if recommended by the attending physician, and it is the duty of the physician to advise according to his or her own best judgment. Informed consent is a prerequisite for ethical medical treatment (or for research), as is internationally recognized in the Nuremberg Code.

In many venues, these principles are being violated, particularly for children and infants. "Recommendations" by the Advisory Committee on Immunization Practices are often transformed into mandates by state health departments, with or without the specific agreement by the legislature, and in turn, by school districts that require this medical treatment as a condition of attendance. If children do not receive all the mandated vaccines, because of their beliefs or individual medical circumstances, they may be deprived of their liberty to associate with others or of their supposed "right" to a public education. Parents may give "consent" to the vaccine under duress, such as the threat of having their children taken from them.

There is also increasing concern about the safety and efficacy of the vaccines so mandated. According to data for 1996, serious adverse events after the hepatitis B vaccine -- including 48 deaths -- are reported three times as frequently as cases of hepatitis B in children under the age of 14.

After reviewing the evidence independently, we suspect that adverse reactions to many vaccines are vastly underreported, as formal long-term studies of vaccine safety have not been completed. We are convinced that there is indeed genuine cause for concern, and have enclosed the letter outlining our questions to Dr. Harold Margolis of the CDC, one of the principal advocates of mandatory universal immunization against hepatitis B.

The rotavirus vaccine is another case in point. One day it was considered a "must," and the main issue for discussion was how to force HMOs to pay for it. Then, on July 16, CDC spokesman Barbara Reynolds told *The New York Times* that "no one should now be giving this vaccine to anyone." Despite the occurrence of intussuception in clinical trials, at a rate about 30 times that previously reported by the CDC, physicians were not warned to watch for this complication, which can be fatal in the absence of prompt treatment.

AAPS has called for an immediate moratorium on mandatory hepatitis B vaccines for schoolchildren. While Health and Human Services recently announced it would no longer recommend the vaccine for newborns, we are asking Secretary Shalala to further ask state health departments to place an immediate moratorium on all mandatory vaccines, particularly hepatitis B, pending further research about their effectiveness and dangerous adverse effects.

The following outlines our concerns about federal vaccine policy:

- The source of mandates
- The erosion of medical ethics
- Reversal of public health policy
- Lack of informed consent
- Vaccine risk and adverse effects
- Risks versus benefits

The Source of Mandates

By means of vaccine policy (1), the federal government is effectively making critical medical decisions for an entire generation of American children. The mechanism is a public-private partnership. "Recommendations" issue from the Advisory Committee on Immunization Practices, a small group whose members have incestuous ties (2) with agencies that stand to gain power, or manufacturers that stand to gain enormous profits, from the policy that is made. Even if such members recuse themselves from specific votes, they are permitted to participate in discussions and thus influence the decision.

ACIP recommendations frequently become mandatory through actions of state legislatures, or through state health departments to which legislatures have delegated such authority. State policy is generally enforced by school districts, which set requirements for school attendance. Some children, as reported by ABC's 20/20, are being home schooled because they have not received all the required vaccines.

Mandatory Vaccine Policy Results in An Inversion of Medical Ethics

Mandates have a profound effect on medical practice. Once a vaccine is mandated for children, the manufacturer and the physician administering the vaccine are substantially relieved of liability for adverse effects (3). The relationship of patient and physician is shattered: in administering the vaccine, the physician is serving as the agent of the state. To the extent that the physician simply complies, without making an independent evaluation of the appropriateness of the vaccine for each patient, he is abdicating his responsibility under the Oath of Hippocrates to "prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone." Instead, he is applying the new population-based ethic in which the interests of the individual patient may be sacrificed to the "needs of society."

If a physician advises against a mandated vaccine, he faces increased legal liability if the patient is infected with the disease. In addition, he may risk his very livelihood if he is dependent upon income from "health plans" that use vaccine compliance as a measure of "quality."

It is perhaps not surprising, although still reprehensible, that physicians sometimes behave in a very callous manner toward parents who question the need for certain vaccines. I have even heard reports of physicians threatening to call Child Protective Services to remove the child from parental custody if a parent refused a vaccine even after the child had screamed inconsolably for hours after each of the first two doses.

Reversal of Public Health Policy

The federal policy of mandating vaccines marks a monumental change in the concept of public health. Traditionally, public health authorities restricted the liberties of individuals only in case of a clear and present danger to public health. For example, individuals infected with a transmissible disease were quarantined.

Today, a child may be deprived of his liberty to associate with others, or even of his supposed right to a public education, simply because of being unimmunized. Yet, if a child is uninfected, his unprotected status is not a threat to anyone else. On the other hand, immunization of a child who is already infected (or who becomes infected in spite of the vaccine) is of no protective value to anyone.

This represents a reversal of the earlier policy of preventing exposure to infectious agents. In fact, it takes

exposure as to contaminated needles or promiscuity as a given, while begging the question of whether protection against hepatitis B has any overall effect on morbidity or mortality in a population that also exposes itself to worse hazards.

With hepatitis B vaccine, the case for mandatory immunization with few exemptions is far less persuasive than with smallpox or polio vaccines, which protected against highly lethal or disabling, easily transmissible diseases. Most physicians probably recommended immunizing most patients against these diseases, while defending their authority to give contrary advice (4).

In contrast, an informed and conscientious physician might frequently advise against hepatitis B vaccine, especially in newborns, unless a baby is at unusual risk because of an infected mother or household contact or membership in a population in which disease is common.

Lack of Informed Consent

AAPS awaits the release of full information concerning the licensure of hepatitis B vaccine and the mandate for newborn immunizations, as requested under the Freedom of Information Act by the National Vaccine Information Center. It is imperative that independent scientists have the opportunity to review the raw data. In the meantime, physicians are still morally obligated to seek informed consent and to provide full and honest disclosure of the risks and uncertainties of the vaccine, in comparison with the risks of the disease.

Information given to parents about this vaccine often does not meet the requirement for full disclosure. For example, it may state that "getting the disease is far more likely to cause serious illness than getting the vaccine" (5). This may be literally true, but it is seriously misleading if the risk of getting the disease is nearly zero (as is true for most American newborns). It may also be legalistically true that "no serious reactions have been known to occur due to the hepatitis B recombinant vaccine" (6). However, relevant studies have not been done to investigate whether the temporal association of vaccine with serious side effects is purely coincidental or not.

Vaccine Risks and Adverse Effects

The Vaccine Adverse Event Reporting System (VAERS), established by the CDC and the FDA, contains about 25,000 reports of adverse reactions associated with hepatitis B vaccine, or to a vaccine cocktail that included hepatitis B. (A copy of this data base is available on request from snavely@primenet.com. Compressed, the file is about 8 megabytes and may take half an hour to download.) About one-third of the reactions were serious enough to result in an emergency room visit or hospitalization, and there were 440 deaths, including about 180 attributed to Sudden Infant Death Syndrome or SIDS.

More than 20 million persons are said to have received the vaccine in the United States (7). Thus, there are about 4 serious reported reactions for every 10,000 persons receiving the vaccine. If only one-tenth of the reactions are reported to VAERS, as is often assumed, there are about 4 serious adverse events for every 1,000 persons receiving vaccine. This is not an unreasonable estimate of the degree of underreporting with a passive reporting system (also see below). Moreover, Congress heard testimony concerning medical students who were told not to report suspected adverse events (8).

Dr. Harold Margolis, a CDC hepatitis expert, told Congress that the incidence of SIDS has decreased at the same time that infant immunization rates have increased (9). In other contexts, the Back to Sleep

campaign is credited with a dramatic fall in SIDS, but the presence of findings such as brain edema in healthy infants who die very soon after receiving hepatitis B vaccine is worrisome. It is possible that the decrease might have been greater without hepatitis B immunizations.

Data in VAERS are too limited to answer such questions as this: Does SIDS occur on the day after hepatitis B vaccine with a greater-than-expected frequency? Does it occur at a younger- than-expected age? Are the autopsy findings different in babies who just received the vaccine (in other words, was SIDS truly the cause of death)?

The CDC admits that the results of ongoing studies on a potential association of hepatitis B vaccine and demyelinating diseases such as multiple sclerosis are not yet available. Post- marketing surveillance in the first three years after licensure showed that Guillain Barré syndrome was reported significantly more often than expected, with a relative risk between 1.3 and 2.8. Of possibly greater interest is the fact that the observed number of convulsions was only 6 to 20 percent of the expected number, suggesting underreporting by a factor of 5 to 17. If optic neuritis and transverse myelitis were underreported by this amount, complete ascertainment probably would have demonstrated a significant increase in the vaccinated population (10).

The question of an association between apparent increases in behavioral disorders (such as autism and attention deficit/ hyperactivity disorder) and the increasing number of childhood vaccines has been raised, primarily by parents, but I am not aware of appropriate studies addressing the issue.

Asthma and insulin-dependent diabetes mellitus, causes of lifelong morbidity and frequent premature death, have increased substantially, with childhood asthma nearly doubling (11), since the introduction of many new, mandatory vaccines. There is no explanation for this increase. The temporal association, although not probative, is suggestive and demands intense investigation. Instead of following up on earlier, foreign studies suggesting a greater-than- chance association, the CDC, through vaccine mandates, is obliterating the control group (unvaccinated children).

Dr. Barthelow Classen testified concerning his studies, which suggest that hepatitis B and other vaccines could increase the incidence of diabetes mellitus (12, 13). Of note, VAERS contains more than 4,000 reports of abdominal symptoms that could have been due to pancreatitis, which was probably not specifically sought and thus missed if present.

Risk vs. Benefit

For each individual, the risk of a serious adverse vaccine reaction (not known but possibly as high as 4 per 1,000) must be weighed against the risk of disease. (Note that a risk as low as 1 per 1,000,000 may be cause for regulatory action in the case of involuntary risks, and 1 in 10,000 for voluntary risks.)

In the United States, seroprevalence for hepatitis B surface antigen, a sign of a chronic carrier state, is between 0.1 and 0.5 percent (1 to 5 per 1,000) in normal populations, compared with up to 20 percent in the Far East and some tropical countries, and 30 percent in needle-using drug addicts or persons with Down's syndrome, leukemia, or chronic renal disease requiring dialysis, among others (14).

Thus, for a member of the "normal" population, the risk of serious adverse reaction to the vaccine is probably of the same order of magnitude as the lifetime risk of becoming a chronic carrier for hepatitis B.

Although the carrier state may disqualify the individual from certain occupations, only a small percentage of carriers develop chronic active hepatitis, cirrhosis, or liver cancer.

Overall, the annual incidence of hepatitis B in the U.S. is currently about 4 per 100,000 (15). The risk for most young children is far less. In 1996, the number of deaths from viral hepatitis (of all types) reported in children under the age of 14 was 11, and in children under the age of 1 year was 1 (16). The number of reported cases of hepatitis B in children under age 14 was 85 in 1993 (17) and 279 in 1996, according to CDC figures, or between 2 and 6 per million.

There may be a genetic predisposition to adverse effects. Although much of the vaccine testing was done in Alaskan natives and Asians, adverse events in the United States have been predominantly among Caucasians (8). Nearly 80 percent of adverse events associated with hepatitis B vaccine alone involve women, who are more susceptible to autoimmune reactions. This female predominance deserves serious study, not off-hand dismissal ("nurses tend to overreport," said a CDC official) (18).

Universal immunization could lead to disproportionate injury to susceptible populations, who might also be the least affected by the disease one is trying to prevent.

Conclusions

Public policy regarding vaccines is fundamentally flawed. It is permeated by conflicts of interest. It is based on poor scientific methodology (including studies that are too small, too short, and too limited in populations represented), which is, moreover, insulated from independent criticism. The evidence is far too poor to warrant overriding the independent judgments of patients, parents, and attending physicians, even if this were ethically or legally acceptable. Indeed, evidence is accumulating that serious adverse reactions are being ignored. Although this statement has focused on hepatitis B vaccine, similar questions should be raised about others as well.

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