

## COMMENTARY -

### **Universal hepatitis B Vaccination: Is it a Sword of Damocles Hanging Over the Head of the American People?**

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#### INTRODUCTION

“Spontaneous reporting by the alert and competent doctor will, in the foreseeable future, remain the most important source of new leads about drugs.”<sup>1</sup>

In 1985, a young nurse presented herself with classic early symptoms of a central nervous system demyelinating disease. The symptoms started one month after she received a hepatitis B vaccination.<sup>2</sup> Her case reminded me of a patient I had seen in 1980 who developed a progressive multiple sclerosis-like disease shortly after he had received a swine flu vaccination in 1976.<sup>3</sup> Surprisingly, I saw two other patients in 1986 and 1987 whose cases almost exactly mirrored that of the young nurse, and in each instance symptoms started one month after they received a hepatitis B vaccination.<sup>2</sup> In 1988, Shaw et. al. reported on a post-release surveillance study of hepatitis B vaccine.<sup>4</sup> Thirty-eight neurologic complications that followed hepatitis B vaccination were found in what was essentially a voluntary reporting system. They discounted most of these cases by using the dubious rationalization developed by the government to deny that central nervous system damage had occurred after the swine flu vaccination.<sup>4,5</sup> This rationalization states that if the rate of a complication reported after a vaccine via a voluntary reporting system is less than the spontaneous occurrence of that complication as determined by a 100% reporting system in Olmsted County, Minnesota, then the reported complication is due to chance.<sup>4</sup>

Since 1985, many cases have been found in which the hepatitis B vaccines have been followed by demyelinating or autoimmune diseases. (Table 1) These cases, plus the recommendations of the National Ad Hoc Advisory Committee on Immunization, the Center for Disease Control and Prevention (CDC), and the American Academy of Pediatrics, that promote the universal vaccination of infants, have prompted this commentary.<sup>5,6,7,8</sup>

The thrust of this commentary is not to prove the incidence of occurrence of adverse effects of this vaccine, nor to denigrate its usefulness in high-risk patients. It is rather to ask, in view of the above, whether it is conscionable or wise to administer hepatitis B vaccine to all infants, with the informed consent suggested by the American Academy of Pediatrics (which is used by most of the hospitals in the Milwaukee area), which reads "no serious reactions have been linked to this vaccine."<sup>5,6</sup>

To help the reader answer this question, information will be summarized with regard to: Why, based on animal studies and experiences with other vaccines, complications from hepatitis B vaccine should be expected; what should have been learned from the swine flu vaccine experience; the reports of damage apparently due to the hepatitis B vaccination; the

probable mechanisms by which hepatitis B vaccine causes neurologic damage; how and why the push for universal vaccinations came about; and the steps that will be necessary to address the serious problems posed by this and other future vaccines.

**1. Animal experimentation that should have alerted manufacturers and government agencies to the dangers of neurologic and autoimmune complications from hepatitis B vaccine.**

Stohlman and Weiner in 1981 showed that the mouse DNA virus JHM causes acute and chronic demyelination.<sup>9</sup> They suggested with supporting data, that an antibody mediated the chronic disease. This was because during the course of the disease no active virus was found.

Buchmeir, et al, in 1984 found in their model system of JHM infection in mice that "antibody response to precisely defined regions on a viral glucoprotein may induce profound changes in the pathogenesis of the infection".<sup>10</sup> Dal Canto, et al, in 1982 reviewed experimental models of virus-induced demyelination.<sup>11</sup> They cite the work of Lindsley and others that demonstrated that a specific MHC class 1 antigen from the host must coexist in affected animal.<sup>12,13</sup> This suggests that the antigenic make up of the recipient will be a factor in the development of an autoimmune demyelination.

**2. Experiences and authoritative discussions that suggest viruses, including the hepatitis B virus, can cause demyelination and autoimmunity in humans and that vaccines have the same propensity. This information should have forewarned pharmaceutical companies and government agencies about the demyelinating and autoimmunity dangers of hepatitis B vaccine.**

In 1983, Roos reviewed the literature regarding viral diseases that can cause chronic central nervous system demyelination in humans.<sup>14</sup> He stated, "We know that viruses can cause demyelinating disease in animals" and cited 106 articles to this effect. There is specific information regarding the relationship of hepatitis B virus itself and the development of a chronic autoimmune hepatitis.<sup>14</sup> In 1975, this fact caused Zuckerman to warn against assuming that a viral vaccine would not cause a similar reaction.<sup>15</sup> Berger, et al's, finding of antibodies to hepatitis B in a case of severe Guillain-Barre syndrome, an admittedly demyelinating autoimmune disease, emphasized the importance of this warning since in their case a natural infection seemed to have set up this autoimmune process.<sup>16</sup> An article by Miller and Stanton in The Quarterly Journal of Medicine in 1954 reviews the neurological sequelae of prophylactic inoculation up to that time.<sup>17</sup> They cite 144 articles on the subject which, taken as a whole, should leave no doubt that neurologic complications were a well-recognized complication of vaccination as early as 1954. Their article is well worth reading if one has any skepticism regarding the occurrence of severe neurologic complication after both passive and active immunizations with bacterial or viral vaccines and antisera. Miller and Stanton's remarks in the introduction of the paper also seem as relevant today as they were in 1954. "Finally, it must be admitted that, in the heat of the emotional battle provoked for and against prophylactic inoculation, there has been a tendency on the part of the medical profession to turn a blind eye to unfortunate individual

complications of procedures which have indisputable social value."<sup>17</sup> One of the most ironic citations in the article is that of Guillain-Barre who in 1919, reported a fatal case of the syndrome which now bears their name.<sup>18</sup> The patient had received an inoculation of antiserum. The reader is asked to remember their names because as the subject has unfolded, the Guillain-Barre syndrome, which will be discussed in detail in a later section, turns out to be the bellwether or more serious complication of vaccines.

In 1967, Miller, et al, reported on multiple sclerosis and vaccinations [19]. They detailed nine cases in which development of or exacerbation of multiple sclerosis followed a smallpox, yellow fever, tuberculosis and typhoid vaccination.<sup>19</sup> They cited other authors who had reported similar findings in.<sup>20,21,22</sup> They mentioned that there might be a latent period between the vaccination and the onset of symptoms. One of the explanations they offered was, "It is possible that the bacterial proteins injected in the course of the vaccination against typhoid fever and yellow fever may also belong to the class of intermediate antigens shared by microorganisms and cerebral white matter." Thus, we see that the concept now termed "molecular mimicry," which will be mentioned later, is based on pre-existing scientific information.

In 1971, Wells reported in the British Medical Journal, nine cases of central nervous system disease that followed influenza vaccination.<sup>23</sup>

In 1973, Rabin, in a letter published in the Journal of the American Medical Association discussed the problems and politics involved in gaining recognition of the fact that central nervous system disease can follow vaccination. He then reported a convincing case of retrobulbar neuritis that followed influenza vaccination.<sup>24</sup>

In 1973, Adams, et al, reported a case of severe demyelination occurring years after primary smallpox vaccination.<sup>25</sup> This report and that of Wells lend doubt regarding the efficacy of surveillance after viral vaccinations that only takes into account reactions occurring a few weeks after vaccination.<sup>23,25</sup>

In 1974, Bellanti discussed the adverse effects of viral vaccines. In one division of his paper he discussed adverse effects of viral vaccines which are seen in normal hosts and which appear to be related to the nature of the viral antigen.<sup>26</sup>

In 1980, Owen, et al, reported a case of multiple sclerosis that was exacerbated after hepatitis. He reviewed reports in the medical literature, which suggested that nonspecific immune stimulation such as that caused by virus infections, skin tests and vaccines can cause exacerbation of demyelinating disease.<sup>27</sup>

The fact that vaccines and viral infection could be involved in autoimmune diseases other than those presenting by demyelination has been brought out by Keane, et al.<sup>28</sup> He reported a case of Richter's syndrome that followed a typhoid vaccination. Gocke, et al, reported an associated case of polyarteritis and the Australian antigen.<sup>29</sup> A review by Schattner and Rager-Zisman in 1990 discussed fully the topic of virus-induced autoimmunity.<sup>30</sup>

As early as the 1970s specific warnings appeared about the potential dangers of hepatitis B vaccine and the dangers of relying on a voluntary reporting of adverse reactions. In 1975, Zuckerman published a paper in *Nature* entitled, "Hepatitis B Vaccine: a note of Caution".<sup>15</sup> He noted the finding of Neurath that antigen determinants related to human plasma are constituents of hepatitis B surface antigen.<sup>31</sup> These antigens are the active principles of hepatitis vaccines, whether made from serum or by yeasts. He postulated that anti-immunity evoked by these antigens might cause the chronicity of hepatitis B. His final statement was to the effect that studies of hepatitis B vaccine should include careful assessment of their effects on the immune system. As far as can be determined, this admonition still has not been followed since there have not been published studies regarding whether hepatitis B vaccine causes an increase in antimyelin T-cell clones. These studies, which are easily within the capabilities of pharmaceutical companies, have not been reported.<sup>32</sup>

In 1971, Finney, who was the statistician involved in the infamous thalidomide incident, wrote an article entitled, "Statistical Aspects of Monitoring for Dangers in Drug Therapy."<sup>33</sup> This authoritative article seems to have been ignored entirely by those who set out to promote the safety of hepatitis B vaccine via epidemiologic methods that relied on voluntary reporting of toxicity.<sup>4</sup> Finney stated that a special United Kingdom inquiry showed that only 14% of women on the pill who died from thrombosis or embolism had been reported independently to the committee responsible for monitoring its safety.<sup>33</sup>

**3. Why the development of the Guillain-Barre syndrome after the swine flu vaccination in 1976 and 1977 should have forewarned manufacturers and government agencies about the probable development of central nervous system demyelination after hepatitis B vaccination.<sup>34</sup> How the same techniques used unsuccessfully to rationalize and deny central nervous system complications after the swine flu episode are now being used to do the same thing with reports of central nervous system complications from the hepatitis B vaccine.<sup>4,34</sup>**

The swine flu vaccine debacle will be discussed in some detail since the self-serving rationalizations that the government evoked after the event has been pivotal in the way virus vaccines are promoted to this day.

Morris was the first to report central nervous system demyelination that occurred after the swine flu injection.<sup>35</sup> His statement that, "In some instances, at least the inducing factor in Guillain-Barre syndrome also served as the inducing factor in multiple sclerosis", appears to have been supported by the additional clinical observations of multiple sclerosis-type illness that developed after the swine flu vaccination.<sup>3,35</sup> I saw and reported five cases of demyelinating disease that occurred after the swine flu vaccination without knowing of Dr. Morris' observations.<sup>3</sup> By 1982, Dr. Morris and I had personally seen 35 cases of central nervous system disease that appeared to result from the swine flu injection.<sup>36</sup>

By this time, the Justice Department, in association with the CDC and the Public Health Service was faced with a surge of lawsuits claiming neurologic damage from the swine flu injection. These eventually amounted to claims of over three billion dollars.<sup>37</sup>

The claims were against the United States government because in order to get the pharmaceutical companies to participate in the swine flu program, a law had been passed in which the government agreed to assume liability for damage done by the vaccine.<sup>34</sup> The full extent of the swine flu vaccine litigation damage control program mounted by the government will probably never be known, but in essence a decision was made to settle complaints of damage due to Guillain-Barre syndrome and to fight all other complaints in federal courts. This decision was buttressed by a group of experts that was impaneled by the government.<sup>38</sup> The following assertions were made: Any complications that occurred more than six weeks after vaccination could not have been due to the swine flu vaccine: Guillain-Barre syndrome was rigidly defined in a way that rejected cases that in any way deviated from that definition; and a distinction was made between the peripheral nerve damage that admittedly occurred in Guillain-Barre syndrome and any central nervous system damage. This distinction cannot be justified scientifically because of the known similarities between myelin of the central nervous systems and the peripheral nervous system and because of known clinical associations between the two syndromes.<sup>39,40,41</sup>

Finally, the government attorneys brought up epidemiology theories that emanated from the Mayo Clinic which claimed that if the incidence of a complication was not any higher than occurred in the 100% actuarial system used in Olmsted County, Minnesota, then the incidence of the complication occurred by chance. These epidemiologic arguments are patently transparent knowing that only a small portion of adverse reactions to a drug are reported.<sup>33</sup> Further, their incidence cannot be compared to incidences derived from a 100% reporting system connected to the Mayo Clinic in a single county in Minnesota.<sup>42</sup> Poser's comment regarding dependence upon this type of epidemiological statistics to establish causal relationships are probably most to the point.<sup>43,44</sup> He said in 1983, "The dependence upon epidemiological statistics to establish causal relationships appears to be a new dimension in our clinicopathological tradition. It sweeps aside the experience of clinicians and neuropathologists, it denigrates the work of the experimentalists, and it substitutes calculations of probabilities for the recognition that variability in the manifestations of disease reflects the diversity of humanity's genetic attributes."<sup>43,44</sup> The government approach to swine flu litigation started to fall apart when Dr. Goldfield (who first brought the swine flu problem to the attention of the government) was allowed to see all the case reports of reactions that had been turned over by the CDC to the Justice Department.<sup>45</sup> He found many cases of central nervous system toxicity that had not been accepted by the CDC. He reported this fact to an attorney who was suing in a case of multiple sclerosis. The Justice Department refused to provide these records and was subsequently sanctioned by Federal Judge Harold Baker as follows: "The order of the court is that the government is in willful, deliberate, continuous disobedience to the order of the court for discovery. This discovery order is relevant on the issue to which the discovery is directed, that is causation. And the appropriate sanction in this case is that the issue of causation is taken as decided against the government. That the swine flu vaccination was a proximate cause of the nonphysical condition of the plaintiff."<sup>46</sup> After this sanction the government settled the case with the promise that the settlement remain secret. Several other lawsuits of this type were then lost by the government usually with a federal judge's support.<sup>47</sup> The data regarding how many of the three billion dollars worth of cases are still pending or were settled would have to be obtained through the Freedom of Information Act since as in the Johnson case,

the settlements probably were kept a secret. However, in a deposition, Dr. Arnason, an expert, who often testifies for the defense in trials against the government, stated in a legal deposition that the Justice Department now settles for CNS cases as well as for the Guillain-Barre syndrome cases following swine flu vaccination. An example of the types of awards made appeared in the Medical World News in April 1981. A Federal court awarded Dr. Katherine Wolfe 2.9 million dollars for central nervous system damages caused by the swine flu vaccine.

The foregoing swine flu incidents are dwelt upon here because both the Center for Disease Control and Prevention and the manufacturer of hepatitis B vaccine applied the same reasoning in regard to the cases of toxicity appearing after the hepatitis B vaccine was released.<sup>4</sup> They agreed that Guillain-Barre disease might occur more frequently than they would expect in vaccinated populations, but they chose to rationalize the reported cases of central nervous system diseases and autoimmune diseases as occurring by chance or that there is no evidence to support causality. Their main arguments have been that central nervous system complications that were reported by physicians via the voluntary reporting system represented all cases that occurred.<sup>4</sup> The fallacy of comparing voluntarily reported complications with those delineated by 100% accurate reporting systems such as are in place in a single county of Minnesota has been commented upon by many qualified person.<sup>43,44</sup> This type of comparison fails to take into account Retailiau's authoritative remark to the effect that, "wide spread underreporting of illness and death in the passive phase of this type of surveillance system impairs the ability to draw conclusions about reactions to vaccines from the reports of illness is received".<sup>48</sup> Kaplan admits in a paper that came from the Center for Disease Control and Prevention that, "as in any national surveillance system we are aware that not all cases of Guillain-Barre syndrome diagnosed by participating neurologists are reported on a case report".<sup>49</sup> This type of comparison also fails to take into account the authoritative report of Finney which pointed out that usually only 15% of adverse reactions are voluntarily reported.<sup>33</sup>

The discussion in this section strongly suggests that when the Guillain-Barre syndrome turned up as occurring after the hepatitis B vaccine the swine flu experience should have alerted both pharmaceutical companies and government agencies to the fact that central nervous system demyelination would also turn up. It also points out the fallacy of rationalizing the central nervous system reports of demyelination by the same type of reasoning that failed so miserably in the swine flu incident.

#### **4. Reports that have appeared in the literature and in the VAERS (Vaccine Adverse Experience Reports) reporting system that show that demyelinating and autoimmune diseases have occurred after the hepatitis B vaccination.**

On September 8, 1983, a letter appeared in the New England Journal of Medicine in which Dr. Ribera and Dr. Dutka of the San Diego Naval Hospital reported on a case of polyneuropathy that followed a vaccination with hepatitis B vaccine.<sup>50</sup> They stated, "Since inflammatory polyradiculopathy has occurred after many different types of vaccines, this may be an interaction of a nonspecific immunologic stimulus with unidentified factors present in the vaccine."<sup>50</sup>

In March 1985, Snider and Gogate, in a letter to JAMA reported a case of a possible systemic reaction to hepatitis B vaccine in which there was polyneuropathy.<sup>51</sup> They felt that, "large scale epidemiologic studies are needed".

In 1988 Biron, et al, reported a case of myasthenia gravis that occurred after hepatitis B vaccination.<sup>52</sup>

In 1988 Shaw, et al, published the results of a postmarketing surveillance study based on physicians reports of complication due to hepatitis B vaccine. They used Kurland, et al, as the statistical monitor. They found even by this generally discredited method of analysis 41 cases in which hepatitis B vaccinations were followed by serious neurologic adverse event.<sup>4</sup> These events included: convulsions (five cases), Bell's palsy (10 cases), Guillain-Barre syndrome (nine cases), lumbar radiculopathy (five cases), brachial plexus neuropathy (three cases), optic neuritis (five cases), and transverse myelitis (four cases).

In 1987, Fried, Conen, Conzelman and Stienemann reported in the Lancet a case of uveitis that occurred after hepatitis B vaccination.<sup>53</sup> They pointed out that immune complex disease did occur during the natural hepatitis B infection and that it was reasonable to suppose that this would happen after vaccination with the same antigen that the patient was exposed to in the natural infection.<sup>54,55</sup>

In 1990 the first case of multiple sclerosis that had ever been seen in an Alaskan child occurred after the 8-year-old child had received hepatitis B vaccine.<sup>56</sup>

I saw my first case of chronic severe central nervous system disease that appeared after a hepatitis B vaccine in 1985.<sup>2</sup> I reported this to the Center for Disease Control and Prevention and to Merck, Sharpe & Dohme, but it was never acknowledged. A complete case report was turned down for publication by JAMA. To my surprise I saw a second identical case the next year and a third case a year later. Case reports of these patients were not accepted for publication by the Lancet in 1990 or by the Wisconsin State Medical Journal in 1991. Six months after these rejections, the Lancet did publish a report by Herroelen and his colleagues in Belgium of 2 cases of demyelination that followed hepatitis B vaccination.<sup>57</sup> Dr. Herroelen by personal communication now states that he has seen over 30 cases with this complication.

In 1992, I was able to share briefly with my colleagues my experiences of posthepatitis B vaccination which by that time had grown to 6 cases of bizarre neurologic disease that appeared like atypical multiple sclerosis which had surfaced in my consultation practice. Only two of these had presented themselves with any knowledge that hepatitis B vaccine might be the cause of their illness.

In 1993, Nadler reported a case of multiple sclerosis that followed the hepatitis B vaccination that was identical to three of the cases I mentioned in my report.<sup>58</sup>

By mid-1993, through the Freedom of Information Act, a printout was obtained regarding adverse neurological reactions that had been reported to VAERS, the Vaccine

Adverse Experience Reports, the agency contracted by the government to accept adverse reaction reports.<sup>59</sup> When this printout was culled to reject reports that did not seem relevant, there were 257 instances in which reporting physicians had felt an adverse immunological reaction had taken place. The cases reported to VAERS were broken down as follows: convulsions (five cases), Bell's palsy (ten cases), Guillain-Barre (nine cases), lumbar neuropathy (five cases), brachial plexus neuropathy (three cases), optic neuritis (five cases), and transverse myelitis (four cases). (Table 1). As a result of my letter to the Infectious Disease News, I have heard of 5 additional cases of severe neurologic damage that follow hepatitis B vaccination. They are for the most part, strikingly similar to the cases I have seen. These cases are not included on Table 1, which summarizes experiences published for the most part by VAERS and others.

Table 1 summarizes 310 cases in which professional observers have concluded that hepatitis B vaccine has caused serious nervous system or autoimmune complications. If we apply Finney's statistics to this value, the cases of this type probably run into the thousands since we can expect to know of only fifteen percent of adverse reactions based simply on voluntary reporting.<sup>33</sup>

## **5. Some of the mechanisms by which hepatitis B vaccine could have caused both demyelination and autoimmunity.**

The first and most likely mechanism through which hepatitis B vaccine could have caused neurologic damage has been termed molecular mimicry. Put simply, this concept, which was first named by Damian in 1964, is that proteins that are presented to the body defenses by either bacteria, viruses, vaccines or drugs, will evoke an autoimmune reaction if the polypeptides that constitute their antigenic sites are homologous or almost homologous to polypeptides present in the body tissue itself.<sup>60</sup> In 1980, Panitch suggested that antibodies to measles and to myelin basic protein were directed against similar antigenic and other autoimmune diseases.<sup>61</sup> A crucial finding in regard to this being the probable mechanism by which hepatitis B vaccine caused demyelination were that of Oldstone and Fujinami, who showed that the hepatitis B capsular antigen, the antigen in the hepatitis B vaccine, contained polypeptide sequences that were homologous or near homologous with myelin.<sup>62,63</sup> While the techniques and computer programs to make these comparisons are readily available, as far as can be determined polypeptide constituent studies that compare vaccine polypeptides with those in human myelin have not been undertaken by vaccine manufacturers.

Another mechanism by which chronic disease could be caused by hepatitis B vaccine was first suggested with Zuckerman.<sup>15</sup> He pointed out that since much of the pathology induced in hepatitis B infection is mediated by immunologic mechanisms, that inducing immunity to hepatitis virus had theoretical risks.

A third mechanism by which hepatitis B vaccine was suggested to cause chronic disease was reported by Hilleman, the scientist most responsible for its development.<sup>65,66</sup> He states in a discussion regarding the quest for an AIDS vaccine that, "the message from the hepatitis B example is that the administration of antigens. . . that directly or indirectly

raise antibodies that attach to host cell receptors may carry large liabilities." He suggests that these liabilities may be responsible for a variety of autoimmune disorders. It is strange that he never mentions this information in his many discussions regarding hepatitis B vaccine.<sup>64,65,66</sup>

Hellstrom and her associates have suggested another mechanism by which hepatitis B vaccine might cause damage. They point out that the pre-S2 antigen (which is in hepatitis B vaccine) may be a pathogenic factor in the development of chronic autoimmune liver disease that follows hepatitis B infection and they suggest that it may not be a suitable component of hepatitis B vaccine.<sup>67</sup>

The concept that much of hepatitis B vaccine toxicity is due to more generalized phenomenon that allows autoimmune pathology to be evoked is suggested by the wide variety of the reported autoimmune reactions that have been noted after its use. These include multiple sclerosis, myasthenia gravis, Guillain-Barre syndrome, optic neuritis, encephalitis and uveitis. (Table 1)

Which of the mechanisms mentioned above causes demyelinating diseases after vaccination remains to be positively determined. However, the reasonable theories discussed in this regard should have given pause to those who claim no serious toxicity has resulted from the vaccine while they now push for universal vaccination against hepatitis B.<sup>5,6,7,8</sup>

## **6. The push for universal hepatitis B vaccination - An "off-label (not officially accepted by the FDA) use."**

In view of what has been discussed, it is a source of wonderment that members of the Center for Disease Control and Prevention, the American Medical Association, State Medical Societies, the American Academy of Pediatrics and many other public health agencies have endorsed the idea that hepatitis B vaccine should be given to every newborn in the United States.<sup>5,6,7,8</sup> How has this come about in spite of the fact that the Federal Food and Drug Administration has not approved of this use and that this has to be considered "an off-label use?" An important factor in this regard is undoubtedly the fact that the market for hepatitis B vaccine can run into billions of dollars. Merck, Sharpe & Dohme, is said to have sold 240 million dollars worth of this vaccine in 1992.<sup>68</sup> Imaginative and effective promotional methods have been developed by the American pharmaceutical industry. They have hired scientists who publish articles in prestigious journals about vaccines, but all too often fail to mention their dangers. They often fail to mention the authors' connection to the manufacturer of the vaccine.<sup>65,69,70,72</sup> They also hire scientists who just prior to their employment were in charge of monitoring the safety of their vaccines regulatory agency as government employees.<sup>70</sup> In addition, the scientists of the Center for Disease Control and Prevention also promote universal vaccination in articles and appearances before State Medical Society Committees. For instance, Dr. Harold Margolis of the Center for Disease Control and Prevention appeared before a committee of the State Medical Society of Wisconsin in 1992. After his presentation the committee endorsed universal hepatitis B vaccination of all infants. This was in spite of the fact that the present vaccines are only

approved by the FDA for use in groups who are at special risk of getting hepatitis B (see present package insert of hepatitis B vaccine). Does this mean every baby in the United States regardless of environment or social status is a special risk for getting hepatitis B? One wonders how many pediatricians in this country are aware that they are taking the risky step of ordering an "off label" use of a drug when they allow babies under their care to be vaccinated. Parents are usually shown the brochure put out by the American Academy of Pediatrics that states "no serious reactions have been linked to this vaccine and most children have no associated side effects."<sup>6</sup> This brochure patently ignores the information detailed in the preceding section of this discussion.

Another example of a possibly too-close relationship between the CDC and industry was the inclusion of Dr. Guess, a statistician with Merck, Sharpe & Dohme and formerly with the CDC, as the co-author of the paper which concluded that hepatitis B vaccine did not cause serious CNS neurologic damage.<sup>4</sup>

Whether the promotional methods mentioned are ethical and desirable will have to be decided by the profession and perhaps the courts. In this connection, The New England Journal of Medicine, have taken an initial step in this direction by new conflict of interest policies regarding articles that appear in their journals.<sup>72</sup> A recent discussion of this problem in the distinguished medical journal Science has highlighted the importance and controversial nature of the "conflict of interest problem".<sup>73</sup>

## **7. What should be done?**

In view of the facts presented that show that viruses, and in particular hepatitis B virus, cause demyelinating and nervous system damage in both animals and humans; that these types of damages occur in humans after administration of the hepatitis B vaccine; that this damage has been discounted by the manufacturers and government agencies by the use of questionable and discredited epidemiologic methods, and that there are several very logical theoretic mechanisms by which this damage could occur, what can and should be done to meet the problems posed by the vaccine? First, synthetic vaccines should be developed that evoke resistance to the target virus but that do not contain any polypeptide sequences present in human tissue.<sup>74</sup> As many as three sequential polypeptides can evoke an antigenic response as shown by Aw and this should be taken into account.<sup>75</sup> Computerized programs can determine these homologies and are readily available.<sup>63</sup> The age of synthetic vaccine production has arrived. The technology and expertise to produce vaccines devoid of polypeptides homologous with human tissue are available.<sup>76,77,78</sup> Further, meticulous studies regarding antigenic components that are encephalogenic add another avenue to screen potentially dangerous antigens from vaccines.

Secondly, modern methods of case finding should be instituted to determine the rate at which the vaccine causes untoward results. Underreporting cannot continue to be ignored. The machinery for this critical need was put into force in the national Childhood Vaccine Injury Act of 1986.<sup>79</sup> Hepatitis B vaccine should be included in this governmentally mandated program for pertussis, measles, mumps and polio. If this is done, complete records of all that receive the hepatitis B vaccine will be available since this act

requires the administrator of the vaccine to record the name of all individuals who are vaccinated. With this information a complete follow-up can be obtained since each person who receives the vaccine can be contacted as to whether or not it caused immediate or long-term toxicity. The second provision of the act that states that the government must assume financial responsibility for untoward vaccine reactions has already proved unworkable since the money set aside to cover claims was soon exhausted.<sup>80</sup> This provision would remove the impetus for pharmaceutical companies to insure the safety of their own vaccines. If it is utilized in regard to hepatitis B vaccine, we can expect a replay of the billions of dollars of claims against the government that resulted from similar swine flu legislation and which are now occurring with pertussis vaccine.

When the rate of serious vaccine complications has been determined by an accurate surveillance system the rate at which hepatitis B might be expected to attack various subgroups of population must be determined. Surely the risk for a baby from a middle class family must be less than that for a baby born into the many disastrous situations that occur in many of our large cities. Then, when individuals can be told the probability of them getting hepatitis B and the probability of them getting a serious complication from the vaccine, they can decide whether they or their children should take the vaccination.

### **SUMMARY**

Specific reasonable suggestions have been made in regard to the problems that have been discussed. At this point, because of the involvement and commitment of agencies and manufacturers who appear to have vested interest in hepatitis B vaccine, these problems might not be fully addressed until the victims have had their day in court. It is hoped that some remedial actions can be taken before this occurs.

**TABLE 1**  
**NEUROLOGIC AND AUTOIMMUNE DISEASES ATTRIBUTED TO THE**  
**HEPATITIS B VACCINATION**

<u>AUTHOR</u>	<u>REF#</u>	<u>COMPLICATIONS</u>	<u>NO. OF CASES</u>
Shaw, et al	4	Convulsion	5
		Bell's Palsy	10
		Guillain-Barre	9
		Lumbar Neuropathy	5
		Brachial plexus neuropathy	3
		Optic Neuritis	5
		Transverse Myelitis	4
Ribera	51	Polyneuropathy	1
Snider	52	Polyneuropathy	1
Biron, et al	53	Myasthenia Gravis*	1
Herroelen	58	Demyelination	2
Waisbren	3	Demyelination	5
Nadler	59	Demyelination	1
Fried	54	Uveitis*	1
VAERs up to Jan, 1993	57	Neuropathy	102
		Facial Paralysis	38
		Paralysis - note stated	3
		Multiple Sclerosis	13
		Guillain-Barre	31
		Polyneuritis	2
		Optic Neuritis	16
		Myelitis	12
		Peripheral Neuritis	37
Encephalitis	3		
<b>TOTAL</b>			<b>310</b>

\*Autoimmune disease

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