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Citation

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THE CAPTIVE AUDIENCE:

A REVIEW OF PUBLIC INFORMATION ON THE SAFETY OF ***THE HEPATITIS B VACCINE****, ESPECIALLY AS IT IS BEING MANDATED FOR NEWBORNS AND YOUNG CHILDREN*

NATALIE KOTZER
THIRD YEAR PAPER
PROF. PETER BARTON HUTT

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INTRODUCTION

Ronnie received the hepatitis B (hepB) shot the day before Halloween. He almost died by Christmas. He was diagnosed with a rare and life-threatening form of arthritis. It was not long before Ronnie's parents suspected that the shot they gave to their son to protect him had exposed and would subject him to a life of chemotherapy, pain and suffering. While his arthritis is currently stabilized, Ronnie will need medication as long as he lives and his parents must live with the uncertainty as to whether their son's deterioration will continue.[1]

[1] *20/20: Who's Calling the Shots* (ABC television broadcast, Jan. 22, 1999) (ABC transcript number 1898).

At six years of age, Katherine lies in a bed in Skokie Illinois, unable to lift her head off her pillow or walk to the bathroom. Thirteen weeks before, this boundlessly energetic ice skater had a dream of going to the Olympics. While her mother did not want her vaccinated, her pediatrician advised her that it would be soon mandated. Katherine received the hepB vaccine. Now, she may never skate again. While her pediatrician, her state health department, the Centers for Disease Control (CDC) and the American Academy of Pediatrics (AAP) all recommended that Katherine be vaccinated, none of these entities will be required to help Katherine's mother carry her daughter up the stairs so that she can use the bathroom or pay for her medical care when her insurance runs out.[2]

Lyla Rose Belkin was a lively and alert five week old baby when her mother last held her in her arms. Her mother never imagined that her daughter would die within hours after receiving a hepB shot. Lyla had received her first hepB shot at 6 days old. Soon after her second shot, one month later, Lorna Belkin found her daughter pale and cold. At her final feeding that night, she was agitated and feisty. Sixteen hours after the vaccination, she fell asleep never to wake up again. The autopsy of her body ruled out choking as the cause of death and her swollen brain was the only abnormal finding. Lyla Belkin's death was attributed to Sudden Infant Death Syndrome (SIDS), a broad category or catch-all diagnosis when unexplainable childhood mortality takes away an otherwise healthy baby. The most abused diagnosis in pediatric pathology, SIDS is virtually un-

[2]Barbara Loe Fisher, Co-Founder & President, National Vaccine Information Center, Statement made to the Illinois Board of Health , in a hearing, titled, "Hearing on Immunization Rules and Proposed Changes" (March 26, 1998) [hereinafter Fisher Statement].

heard of when the infant is younger than one year of age.[3]

As Lyla's, Katherine's and Ronnie's parents agonize over what they could have done differently, their parental instincts keep on returning to the medical event which preceded the death of their children. While doctors scoffed at Michael Belkin's hypothesis of what may have caused the shocking death of his innocent and healthy daughter, Michael's internal voice found support in substantial research present on the Internet and Medline. He discovered that hepatitis B mainly infects intravenous drug users, homosexuals, prostitutes and promiscuous individuals because it is most commonly transmitted by blood, promiscuous behavior or dirty needles. As a result of self-motivated investigation, Michael Belkin and several similarly affected parents are beginning to question how a newborn baby could possibly contract hepatitis B if the mother was screened and tested negative, as Michael's wife was. Unless it is possible for a newborn child to have unprotected sex or share needles with an infected junkie, Michael learned that it is extremely unlikely for a newborn, like Lyla, to get the disease. Through the tribulations of experience, many parents, like Michael, wish that they had not followed the CDC's endorsement and state wide mandates of hepB vaccination in newborns and young children and had known that their children had a.001% chance risk of contracting the disease against which they had vaccinated their children. While these wishes come too late for protecting the health of their own children, these parents are determined to realize their wishes in the promising lives of other parents' children by questioning the safety of the hepB

[3]Michael Belkin, *Mindless Vaccination Bureaucracy,* at <http://www.909shot/com/belkin.html> [hereinafter Belkin].

vaccine.

Every day, in clinics and doctor office's nationwide, children are being vaccinated to protect them from disease. Parents trust that these immunizations and the health bureaucracy endorsing them will save their children's lives, not curtail or destroy them. Public health campaigns to control hepatitis B through mandatory childhood vaccination programs have instigated a vocal backlash from parents and victims who believe that the vaccine is causing more harm than science knows or public authorities will admit. Because of conflicting reports as to the actual incidence of hepatitis B in the United States and because the vaccine was developed for those engaging in high risk behaviors, including drug users and sexually promiscuous individuals, efforts to require administration of the vaccine to most, if not all, of the U.S. population has become controversial. The controversy has been intensified by an increasing number of adverse reactions, particularly autoimmune in nature, reported in connection with the vaccine and the increasing number of states which have mandated childhood vaccination as a condition for school admission. Recently, an alliance of 15,000 anti-vaccine activists and injured patients in France filed a lawsuit against the French government and vaccine manufacturers, accusing them of understating the risks and exaggerating the benefits of the vaccine for the average person. While health authorities in France, responding to concerns, have ended their mandatory hepatitis B vaccination program for eleven and twelve year old children, the CDC continues to call for the universal immunization of children up to eighteen years of age. Moreover, the U.S. federal health bureaucracy is currently devoting

much of its resources to expanding and enforcing its mass vaccination policies, rather than to effectively evaluating the adverse cases reported or genetic groups possibly at risk for responding adversely to the hepB vaccine.

If the vaccine is causing the adverse events which are being notoriously ascribed to it, then it had made a grave error in choosing to victimize Bohn Dunbar, brother of Bonnie Dunbar, professor of Cell Biology at Baylor College of Medicine in Texas. Contrary to being an anti-vaccine advocate, Dr. Dunbar has devoted and continues to devote her life's work to developing vaccines. She is a research scientist and medical professor who has a distinguished 25 year career in academic and laboratory science and has specialized in areas of autoimmunity and vaccine development. Honored in 1994 by the National Institutes of Health as the "First Margaret Pittman" lecturer for her pioneering work in contraceptive vaccine development, this pioneer has ignited a growing spark among a number of scientists to join consumer advocates, patient-rights groups and undiagnosed patients in a crusade against the hepB vaccine. Together they are searching for answers to questions looming over the vaccine's safety, which they contend is given to so many children in the dark without adequate study and understanding. Though a developer of contraceptive vaccines herself, Dr. Dunbar is a forceful critic. Her skepticism, like that of many others, was induced through personal experience with the vaccine's possible consequences.

Dr. Dunbar began investigating the safety of the hepB vaccine after both her brother and research assistant developed autoimmune and neurological dysfunctions following the hepatitis B vaccinations they were required to obtain. These

two individuals remain permanently debilitated from autoimmune side effects allegedly caused by this vaccine. Knowing her brother's complete health history, she watched her once active and healthy brother transform into someone she had never known. Following his hepB vaccination, he began suffering from serious rashes, joint pain, chronic fatigue, and multiple sclerosis like symptoms. He has now been affirmatively diagnosed with POTS (an autoimmune cardiovascular neurological problem). His problems have been attributed to the hepB vaccine by over ten different specialists of unquestionable medical authority. At about the same time, a twenty-one year old medical student beginning work in Dr. Dunbar's lab was required to receive the vaccine. She experienced fever and fatigue after her first injection. Three weeks following her second injection, she lost vision in one eye. While she regained most of her vision six months later, she had to revisit the hospital for two months after receiving the third dose of the vaccine. Assured by her doctor that she was given the safest of all vaccines, her aspirations for pursuing her life long dream of becoming a doctor have now grown dim as she remains completely blinded in one eye.[4]

An expert in this area, Dr. Dunbar was astonished by how two previously active and healthy individuals working in her laboratory developed autoimmune syndromes at the same prolonged immunological time frame following their booster injections to the hepB vaccine. These personal contacts with the health risks associated with the hepB vaccine have incited her to delve deeper into the trenches

[4]Dr. Bonnie Dunbar, Molecular Biologist, Baylor College of Medicine, Testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources Committee on Government Reform (May 18,1999), available at <http://www/house.gov/reform/cj/hearings/5.18.99/Dunbar.htm> [hereinafter Dunbar's Testimony].

of the vaccine's possible dangers. Consequently, Dr. Dunbar has been collecting data on the hepatitis B vaccine for the past few years, including investigating the more than 20,000 reports of adverse reactions filed with the FDA's Vaccine Adverse Event Reporting System (VAERS). During the course of her research, Dr. Dunbar has also been contacted by hundreds of doctors and patients around the world who have reported severe autoimmune and neurological complications to the hepatitis B vaccine in previously healthy children and adults, especially of Caucasian origin. Such reactions have included serious rashes, fever, joint pain, chronic fatigue, MS, lupus like symptoms, rheumatoid arthritis and neurological dysfunctions. Dr. Dunbar and other scientists hypothesize that genetic factors are implicated in the reactions reported to the vaccine. In investigating this hypothesis she, and many others following in her inquisitive path, have found that pre-licensure studies on the vaccine's safety were inadequate as have been the long term follow up clinical trials heretofore conducted. Moreover, all of the studies to date that have been touted for the vaccine's long term safety have been in genetic population groups and for a duration of time for which one would not expect to find the ominous autoimmune side effects allegedly caused by this vaccine. Interestingly, the side effects reported as a consequence of this vaccine are similar in nature, if not identical, to those pervading vaccine package warning inserts often not disclosed to patients.[5] Dr. Dunbar and others regard these findings, rather than the temporal relationship between the hepB vaccine and adverse reactions following its administration, to be an "amazing

[5] *Id.*

coincidence."

Although the stakes are always significant in vaccination disputes, the hepatitis B vaccine controversy has an added importance. The vaccine is the first to implement recombinant DNA technology so as to produce a vaccine containing a surface protein of the virus molecule it is administered to protect against. Patients who have the hepatitis B disease or respond adversely to the vaccine show similar reactions. New theories and experiments have been developed that could explain the autoimmune reactions purportedly caused by this virus or the viral protein used in the vaccine. Given the severe nature of reactions reported to this vaccine, their rarity in the population at large, and their increasing prevalence among specific genetic population groups vaccinated, Dr. Dunbar has proposed to study the mechanisms of post-vaccination autoimmune responses and to identify autoantibodies that might be held in common among vaccine recipients. She intends to determine possible diagnostic as well as therapeutic strategies for those likely to be or are already responding adversely to the hepB vaccine.[6]

Charging by Dr. Dunbar's side in this morally questionable national experiment is Barbara Loe Fisher, president of the National Vaccine Information

[6]Dr. Dunbar's Proposal to the NIH for funding. Proposal obtained from Dr. Dunbar, but is available at `http://webpages.netlink.co.nz/~ias/dunabar.htm>` citations omitted [hereinafter Dunbar's Proposal]. The studies outlined in her proposal would address her hypothesis that recombinant HBsAg (the surface protein of the HBV contained in the vaccine) can act as a molecular mimic to induce severe autoimmune reactions in genetically susceptible hepB vaccinated individuals or can generate anti-idiotypic antibodies with similar effects. Her research would also provide new insights into the predictability of adverse side reactions to the hepB vaccine in individuals of specific histocompatibility subtypes. Her studies would be unique in following the onset of human autoimmune disorders for the further identification of specific autoantibodies to "self" epitopes that could provide a mechanism for specific immunotherapy in patients who have been adversely affected by this vaccine or who are suffering from other autoimmune diseases.

Center (NVIC) child advocacy group. Her once healthy son was diagnosed with immune system dysfunction, multiple learning disabilities and attention deficit disorder soon after receiving the DPT (Diptheria-Pertussis-Tetanus) vaccine. Armed with federal statistics and personal stories of thousands of adverse reactions reportedly caused by this vaccine, Barbara Fisher and many of her supporters are demanding that parents be allowed to make a rational, informed, voluntary decision as to which diseases and vaccines parents will subject their children to in our country's battle against disease.

Public health authorities have yet to concede to this demand. Transcending this refusal, is the "catch 22" which lies at this controversy's core. Public health officials staunchly stand behind this weapon against disease, maintaining that it is one of the most innocuous and effective vaccines ever devised. Despite confrontations with regard to its safety, public health authorities find refuge in the popular rhetoric that "no confirmed reactions" have been found. However, no reactions could have been confirmed because no studies to detect them have been conducted. The abyss of scientific knowledge and research, insulating this vaccine from attack, has consequently enabled public health officials to dismiss the significance of reactions reported following the vaccine's administration as being just coincidentally, rather than causally, related. Following with this perspective, the NIH has rejected Dr. Dunbar's research proposals, requesting government funding and support, because epidemiological studies have not yet "proved" that a causal relationship exists between the vaccine and the adverse

events reported.[7] This lack of proof is very much the reason why Dr. Dunbar wants and needs to study this vaccine. Without government backing, she has been left to fund her research goals privately.

Clearly, individuals need to acknowledge the potential danger that this vaccine may pose before money will be spent or valid research conducted to assess its alleged side effects. Until molecular biologists and neuroimmunologists are given the chance and encouraged to precisely define the biological mechanism for response to vaccination and to develop pathological profiles to distinguish vaccine adverse events from other events, we will not be able to address causal relationships between vaccines and temporary or permanent health problems. Moreover, we will not be able to identify those who may be at risk for responding adversely. Because no follow-up studies have been completed which are long enough in duration to detect the specific types of responses this vaccine is purportedly causing and which can identify those individuals who may be genetically susceptible to responding adversely, scientific knowledge currently lacks an adequate understanding of the mechanisms by which our immune system responds to the hepatitis B surface antigen, a component of the vaccine and the virus itself. This lack of adequate study has become especially dangerous and worrisome given the vaccine's recent imposition on all newborns. The vaccine was never tested in newborns, no vaccines have ever been mandated at birth before and newborns have under developed immune systems which can be easily overwhelmed, shocked and perturbed so as not to be able to function properly

[7] Personal communication with Dr. Dunbar.

later in life.

This chasm of knowledge in the scientific compass guiding vaccine developers, medical providers, and policymakers and the refusal of public health officials to acknowledge what science does and does not know about the vaccine and its risks fuel a concern that the public is being misguided as to the vaccine's safety. Moreover, this controversy has suggested that adequate systems are not in place in America's mass vaccination infrastructure to properly evaluate and monitor reactogenicity to the hepatitis B vaccine. Clearly, it is as much a part of the fiduciary relationship of public health officials to prevent adverse events as it is to prevent the spread of diseases. Until such officials do respond appropriately, the sentiment that children are being involuntarily subjected to a national experiment will continue to permeate the public conscience, however only more profusely and intensely.

In saturating the vacuum of knowledge and understanding that cushions this vaccine from censure with the free exchange of information, consumer activist groups have become pivotal for stimulating public awareness and nourishing constructive change in our public health landscape. As long as vaccine injury remains a politically incorrect subject for open discussion and honest scientific investigation, an understanding of vaccine injury and deaths will continue to lie in the caskets of those it may have helped to bury and the public's confidence in our public health landscape will continue to ferment. Progress in adverse event reporting, scientific research and data collection can only be realized when efforts in these areas are made an official public health policy and

the information consequently accumulated are believed and truthfully disseminated among the public. Since vaccine coverage and efficacy depends on public confidence that routine immunizations are safe, there can only be losers in this politically charged debate if "opposing sides" do not learn to intelligently, truthfully and rationally coexist. In light of this reliance, the need to create allies between consumer advocacy groups and public health officials cannot be further emphasized. Clearly, the U.S. will never be able to win the battle against disease, when there is discord within its own army.

Neither Dr. Dunbar nor Barbara Loe Fisher advocate halting the hepatitis B immunization program, especially in certain defined genetic populations. What they do advocate, however, is that the least toxic and most technologically advanced vaccines be made available to Americans as a preventative health care choice, that vaccine risks be fully defined and communicated to the public and that individuals high with an increased risk for responding adversely be identified.[8] Currently available scientific evidence and reports of adverse events have undeniably demonstrated the importance of and need for studying hepB vaccine side effects in more detail, especially in the Caucasian population groups in which the vaccine is routinely, if not obligatorily, administered. Scientists, consumer activist groups, parents and the public, more broadly, are asking or rather pleading that the government stop, take a step back and study the long term effects of the hepB vaccine before they are told that it is their patriotic duty to sacrifice the lives of their children in the nation's war against disease.

[8]Opening Statement by Barbara Loe Fisher at the Institute of Medicine Vaccine Safety Forum, Workshop on Risk Communication and Vaccination, May 13, 1996 [hereinafter Risk Communication Workshop].

Parents who know and love their children most are asking that America listen to them as voices of children who cannot yet speak. Parents are responsible for their children's welfare and they, not the government or the vaccine manufacturers, will have to bear the burden if their children come home wounded or live with excruciating grief if they die.

The purpose of this paper is to provide an overview of the issues briefly introduced. Based on an evaluation of publicly available information and written from a consumer's perspective, this paper will present some of the known problems and most contested issues surrounding the safety of the hepB vaccine, as it affects U.S. citizens, as well as explore how they are playing out on this controversy's battlefield. As you read this paper and discover the possible ramifications of administering the hepatitis B vaccine, especially among infants and young children, it is important that you, the reader of this paper and archaeologist of facts, take a step back and review the artifacts with an open and objective mind. It is only within this purview that you will be able to appropriately ask yourself: should I be required to submit myself or my loved ones to this vaccine?

HEPATITIS B

THE VIRUS

Certain diseases are caused by pathogens, otherwise known as viruses, from the Latin word for "poison." Viruses cannot reproduce unless present within a host cell. Outside of a living cell, the virus exists as a macromolecular package, or virion. The virion contains a small amount of genetic material. The genetic material of the virion is surrounded by a protein capsule, or capsid. Many viruses, such as the hepatitis B virus (HBV), have a membranous envelope surrounding the capsid, which contains some virus specific proteins. The hepatitis B surface antigen (HBsAg) is one. This surface antigen is used in the vaccine and is thought to be related to the adverse side effects which this vaccine has been alleged to cause.

HBV is an infectious DNA virus of the hepadnavirus family in the Orthohepadnavirus genus.[9] The mature HBV virion is a 42 nm, spherical, double-layered dane particle containing a partially double stranded circular DNA molecule having 3200 nucleotides; only a small subpopulation of these heterogeneous dane particles constitute the infectious form of the virus (which does take other forms), and is present in the blood of some who have the disease.[10]

[9] Geo F. Brooks, Janet S. Butel, L.Nicholas Ornston, JAWETZ, MELNICK & ADELBERG'S MEDICAL MICROBIOLOGY(1995).

[10] Response sheet to the Hepatitis B virus and Hepatitis B Vaccine "Fact Sheets" distributed by the Public Health Alert System, prepared by Bonnie Dunbar, Ph.D., Professor, Department of Cell Biology, Baylor College of Medicine and Sheri M. Skinner, Ph.D., Department of Cell Biology and member of BCM Safety and Security Committee, Baylor College of Medicine. Response sheet obtained from Dr. Dunbar and can be requested from the National Vaccine Information Center [hereinafter Response Sheet]. Authors relied on several authorities in making their assertions; citations to these references are omitted here. Please refer to response

TREATMENT FOR HBV

There is no known cure for HBV. Thus, prevention of chronic infection is important because once a person is infected, there are few treatment options, all of which are very expensive. The FDA has only approved of two medications for the treatment of HBV infection, namely interferon-alpha and lamivudine. Interpheron alpha is administered through injections which have been reported to produce severe side effects. It is only used on patients with abnormal liver enzymes. In December of 1998, the FDA approved Lamivudine for treating chronic HBV in adults. This DNA polymerase inhibitor was originally used for treating HIV, and unlike interferon alpha, it is available in oral form and has fewer reported side effects. However, lamivudine poses a significant risk of viral mutations that could lead to drug resistance. [11] Additionally, its apparent effectiveness is diminishing. It is effective in only approximately 40% of patients with chronic HBV liver disease and not all HBV infected persons are candidates for treatment. While liver transplantation is an option for those infected patients suffering from advanced liver disease, the availability of organs is limited and an organ recipient must remain on immunity suppressing drugs for the rest of his life.[12]

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sheets for further inquiry.

[11] *The Safety of the Hepatitis B Vaccine,* American Medical Association, fact sheet available at < http://wwww.ama-assn.org/med-sci/98jan03.htm> [hereinafter AMA Fact Sheet].

[12] Harold S. Margolis, testimony before the U.S. Representatives Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 18, 1999), available at <http:www.cdc.gov./ncidod/diseases/hepatitis/margolis.htm> [hereinafter Margolis' Testimony].

CLINICAL FEATURES

Once exposed to HBV and the virus is transmitted, clinical features of HBV range from none (50% of cases) ◊ mild (30%) ◊ fulminant◊ death (0.2%). Physical symptoms may include profound fatigue (20% of cases), anorexia/gastric disturbance (50% of cases), jaundice (less than 20% of cases), myalgia (50% of cases) and rash (less than 20% of cases).[13] Other infected individuals may experience low grade fever, pain and swelling in the joints, headaches and a cough that may occur one or two weeks preceding an onset of jaundice and an enlargement and tenderness of the liver.

As outlined by Stevens and Lowe,[14] infection is estimated to be subclinical in 65% of patients, but HBV may cause clinical patterns of infection, which physicians diagnose and classify as acute or chronic hepatitis.

Acute hepatitis B is common among patients who recover from an hepB illness with jaundice, malaise, and anorexia. Many of such individuals develop lifelong immunity to the virus.[15] The clinical manifestations of acute hepatitis range from being subclinical in form to culminating into fulminant hepatitic failure (causing massive necrosis [death] of liver cells) in approximately 2% of cases.[16] According to *Harrison's Principles of Internal Medicine*, in cases of acute hepatitis B, "most patients do not require hospital care" and "95% of patients have a favorable course and recover completely" with the fatality ratio being "very low

[13] Response Sheet, *supra* note 10.
[14] Dunbar's Proposal, *supra* note 6.
[15] *Id.*
[16] *Id.*

(approximately 0.1%)" after experiencing three to four weeks of nausea, fatigue, headache, arthritis, jaundice and tender liver.[17] Those who recover completely from HBV acquire life-long immunity.[18] Dr. Worman, of Columbia University, estimates that while 90-95% of acutely infected adults recover without sequelae, about 5-10% of acutely infected adults become chronically infected.[19] In clarification of this statistic, Dr. Dunbar asserts that chronicity occurs in less than 5% of acute cases[20] and cautions against overstating the significance of those acute cases which are later re-diagnosed as constituting the "chronic" form. she explains that a chronic hepatitis diagnosis should not be perceived as an all or nothing diagnosis for a manifestation of HBV which is very dangerous. "Chronicity" is defined as a case in which the virus has not yet been cleared from the blood six months following exposure.[21] Thus, a diagnosis of "chronic" hepatitis does not necessarily entail the dangerous form usually associated with this manifestation of the disease.

According to Dr. Worman of Columbia University, the chances of becoming chronically infected is inversely related to age. He estimates that approximately 90% of infected neonates and 50% of infected young children will become chronically infected, in contrast to the 5% to 10% of immunocompetent adults he

[17] Barbara Loe Fisher, *When It Happens To You or Your child, the Risks Are 100%*, THE VACCINE REACTION (newsletter excerpts from *Hepatitis B Vaccine: The Untold Story*, National Vaccine Information Center). Available at < http://www.909shot.com/newsletterexcerpts.htm > [hereinafter *Happens To You*].

[18] *Id.*

[19] Howard Worman, M.D., *Hepatitis B*, available at < `http://cpmcnet.columbia.edu/dept/gi/hepB.html` > [hereinafter Worman].

[20] Response Sheet, *supra* note 10.

[21] Response Sheet, *supra* note 10.

suspects will be similarly infected with HBV.[22]

The natural history of chronic HBV infection will vary dramatically between individuals. Some individuals with chronic hepatitis will develop a condition commonly referred to as a chronic carrier state, whereby patients are still potentially infectious, but have no symptoms or abnormalities on laboratory testing. As with other statistics asserted with respect to this disease, authorities vary in their approximation of what proportion of HBV infected individuals become carriers of HBV. Moreover, it is important to note that of those who do become carriers of HBV, not all develop the chronic form. Some authorities estimate that only 1-5% of adults[23] exposed to the virus become "healthy carriers" while other authorities, such as the Public Health Alert System (PHAS), maintains that 6% to 10% of those who acquire HBV as adults will become carriers.[24] Although PHAS states that 15,000 to 20,000 new carriers develop annually in the U.S., it is important to understand that if this figure is accurate, it refers to "healthy carriers."[25] These people will have no symptoms and declining, but continuous infectiousness.[26] Moreover, most of these individuals will reach the end of their lives with little or no damage to their livers, despite the virus living there.[27] Only one-quarter of those carriers who do not recover completely

[22] Worman, *supra* note 19.

[23] Response Sheet, *supra* note 10.

[24] *Hepatitis B Vaccine Fact Sheet,* Public Health Alert System (PHAS), Harris County Health Department [hereinafter PHAS]. Fact sheet available upon request from the National Vaccine Information Center.

[25] Response sheet, *supra* note 10.

[26] Report by Dr. Sheri Skinner to the Baylor College of Medicine Safety Committee [hereinafter Skinner Report], available at <http://webpages.netlink.co.nz/~ias/dunbar.html>. Citations to references relied upon by Dr. Skinner are omitted. Please see the report for more information about these references.

[27] *Id.*

(fewer that 5% infected with the hepB virus) are in danger of developing life threatening liver disease later in life (hepatocellular carcinoma).[28] To support the prevalence of the carrier state, PHAS states that over 200 million HBV carriers are estimated worldwide.[29] While this generalized statistic appears weighty, only.037% of the above figure would be attributable to U.S. residents and such carriers would constitute only.029% of the U.S. population of over 260 million.[30] Thus, while several federal health authorities point to carrier state figures to support the need for the mass vaccination against the HBV, perhaps, as Bader points out, percentage figures indicating the approximate number of patients advancing to carrier state "should not be taught at all; instead, a notation of the fact should be made that chronicity varies widely depending upon a number of defined and undefined factors."[31]

In addition to possibly becoming a carrier of the HBV, individuals with chronic hepatitis B may develop clinically insignificant or minimal liver disease and never develop complications, while others may develop clinically apparent chronic hepatitis. Some chronic manifestations, though rare, may even progress into cirrhosis, which increases a person`s risk of developing hepatocellular carcinoma (primary liver cancer) later in life. This type of cancer is relatively rare in the United States, but it is the leading cause of cancer death in the world where

[28] Skinner Report, *supra* note 26.

[29] PHAS, *supra* note 24.

[30] Response Sheet, *supra* note 10. The Authors relied on figures given by Hollinger, F.B. et. Al., *Controlling hepatitis B virus transmission in North America, Proceedings of the International Conference on Prospects for Eradication of Hepatitis B Virus,* VACCINE, 8 (Suppl.), S-122-S-128 (1990). Hollinger's statement that "Over 75,000 carriers reside in the U.S." when applied to the statement that "over 200 million carriers are estimated worldwide" means that 75,000/200,000,000 or.037% of the world's carriers may be attributed to individuals comprising the U.S. population.

[31] Skinner Report, *supra* note 26.

HBV infection is endemic.[32] Generally, this rare type of cancer or other forms of life threatening liver complications occur in approximately one quarter of those with the chronic form of HBV.[33] While the fact sheet distributed by PHAS attributes 80% of hepatocellular carcinoma cases to individuals infected with HBV chronic infection,[34] this seemingly large percentage only amounts to approximately 0.2% of 1% of HBV cases occurring in the U.S. [35]

In sum, how do adults, specifically, respond to hepatitis B infection?[36]

λ

50% have low viral growth and an early system response and therefore, develop no symptoms. They resolve or defeat the virus and have lifelong immunity. [37]

λ

30% or more experience what they think is the flu, also go undiagnosed, resolve the virus and develop life long immunity.[38]

λ

Approximately 20% have higher viral growth and a later immune response so that they get sick enough to be diagnosed as having hepatitis B. However,

[32] `Worman, supra note 19.`
[33] Skinner Report, *supra* note 26.
[34] PHAS, *supra* note 24.
[35] Response Sheet, *supra* note 10.
[36] Skinner Report, *supra* note 26.
[37] *Id.*
[38] *Id.*

the vast majority of these individuals resolve the virus and obtain lifelong immunity.[39] Rarely do they become chronic carriers (less than 5%) of the virus.[40]

λ

About 2/10ths of 1% get sick, do not defeat the virus and die of liver complications.[41]

λ

Approximately 1-5% of adults[42] become so-called "healthy carriers." They have no symptoms but are still able to spread the virus.[43]

In sum, of the adults who are infected with the virus, almost 95% of them will recover, most with no symptoms at all and with lifelong immunity to the virus. Less than 5% will live essentially symptom free, but with declining and continuous infectiousness. About $1/4^{th}$ of this 5% will face life threatening liver complications decades later in life. About 1/5th of 1% of all infected adults will die soon after becoming infected with the virus.[44]

MORTALITY

[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*

The Centers for Disease Control, the American Medical Association (AMA), PHAS, and the Advisory Committee for Immunization Practices (ACIP) assert that approximately 4,000 to 5,000 people in the U.S. die each year from hepatitis B related chronic liver disease or liver cancer.[45] In clarifying this statement and depreciating its import, Dr. Dunbar and Dr. Skinner state that these statistics are representative of HBV related deaths in individuals whose immune systems were overwhelmed by the virus, were unable to fight the acute infection, and who died soon after infection (only $1/5^{th}$ of 1% of all infections) or of approximately one-quarter of chronically infected individuals who were also immunologically unable to rid themselves of the virus within six months of exposure and consequently died of cirrhosis or hepatoma some decade after being infected.[46] PHAS also states that 250,000 HBV related deaths are reported annually worldwide.[47] Dr. Dunbar and Dr. Skinner explain that even if accurate, the great majority of these deaths would have occurred among the chronically HBV infected population of the world. Based on the figures given by Hollinger et al. for carriers residing in the U.S., only.037% of the above figure could be attributed to U.S. Residents.[48]

Surely, generalized statistics may be useful for providing a quantitative assess-

[45] PHAS, *supra* note 24; CDC, Healthtouch, *Hepatitis B Vaccine & Hepatitis B Immune Globulin,* , available at < http://www.healthtouch.com/level/leaflets/cdc/cdc176.html> [hereinafter Healthtouch]; *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (*ACIP), Morbidity & Mortality Weekly Report (MMWR) 40(RR-13):1-19 (1991),available at <http://www.cdc/gov/ncidod/diseases/hepatitis/v40rr13.html> [hereinafter ACIP], citations omitted. See Source for references relied upon; AMA, *supra* note 11.

[46] Response Sheet, *supra* note 10.

[47] PHAS, *supra* note 24.

[48] Response Sheet, *supra* note 10.

ment of the risks which an individual exposed to the HBV faces. However, a more accurate understanding of this risk for U.S. citizens requires a more detailed and comprehensive assessment of qualitative factors, at least among different population groups within the U.S., by age of infection, gender, general health, behavioral proclivities, geographic location, and the general functioning of the group's immune system. Of course, a more particularized evaluation based on individual factors, including the specific functioning of an individual's immune system, would provide an even better estimate of the health risk posed to individuals confronted with the virus.

TRANSMISSION

Hepatitis B is not common in childhood and is not highly contagious. Unlike smallpox or the whooping cough and much like AIDS, hepatitis B is spread through the blood or bodily fluids like semen. Since inoculation of the virus is thought to occur through breaks in the skin or mucous membranes, many have characterized HBV as primarily an adult disease, affecting adults engaged in high-risk behaviors. According to *CDC Prevention Guidelines: A Guide to Action* (1997), a book written by federal public health officials at the U.S. Centers for Disease Control (CDC), "the sources of [hepatitis B] infection for most cases include intravenous drug use (28%), heterosexual contact with infected persons or multiple partners (22%) and homosexual activity (9%)."[49] Other populations

[49] *Happens to You,* note 17.

at risk, while to a lesser extent, include health care workers exposed to blood, patients requiring multiple blood transfusions, staff of custodial institutions and newborns born to infected mothers.[50]

In support of the disease's infectivity, the CDC and the PHAS have asserted that HBV is 100 times more infectious than HIV.[51] When asked to support this assertion, the CDC referred to a 1991 Morbidity and Mortality Weekly Report (MMWR), stating that the risk of HIV transmission was.3% while the risk of HBV transmission was 30%.[52] However, Dr. Dunbar and Dr. Skinner maintain that the CDC has failed to provide adequate documentation to substantiate these figures. Furthermore, this MMWR report, used by the CDC to validate its figures, relies largely upon anecdotal reports of HBV and HIV transmission instances (24 of the total 44 references were abstracts, letters, editorials or papers considered to be "anecdotal reports").[53] It is interesting to note that the CDC and other public health organizations have denigrated this type of evidence when offered to support a possible causal relationship between the hepatitis B vaccine and the adverse events reported to follow its administration – events that would trigger a more forthcoming response. Moreover, while this disease is infectious, as is HIV, and many public health fact sheets list bloodborne, sexual or perinatal routes as means for transmitting HBV, it is important not to overstate the ease by which HBV can be transmitted through these paths. Ex-

[50] *Id.*

[51] PHAS, *supra* note 24; CDC, *Hepatitis B and the Vaccine that Protects You,* available at <www.cdc.gov/nip/news/vacsafe/htm> [hereinafter CDC Fact Sheet] [Citations omitted; please see fact sheet for further inquiry into references relied upon].

[52] Response Sheet, *supra* note 10.

[53] *Id.*

posure to HBV through these routes does not necessarily result in transmission of the virus or result in its infection. Transmission ***may*** take place by these means only if the infectivity of the contaminated material is sufficient, which it frequently is not, and the recipient is sufficiently immunolgically compromised so as to be unable to neutralize infection. [54] Only 20% of the U.S. adult population encountering HBV are unable to mount a sufficient immune response.[55] In further support of the disease's infectivity, the CDC has asserted that 5% or more of U.S. individuals can be expected to be HBV infected.[56] Though grounded in scientific evidence, as opposed to anecdotal reports, some have nevertheless questioned the validity of this statement. This assertion was based on a study done by the National Center for Health Statistics, entitled the National Health and Nutrition Examination Survey (NHANES II). The values in these reports were estimates extrapolated from data of 14,488 persons who were chosen to be representative of the U.S. population. This small sample size (.000054% of the U.S. population) has led some to question the accuracy of what it has been purported to represent.[57] Even the CDC has alluded to the limits of relying upon such data. The *American Journal of Public Health*, which was written by physicians from the CDC, warned in reference to this statistic that "While these conclusions may be valid, they fail to provide a context that takes into account the sample size limitations of NHANES...".[58] Therefore,

[54] Response Sheet, *supra* note 10.
[55] *Id.*
[56] Dr. Waisbren, Sr., M.D., F.A.C.P.,F.I.D.S.A., *Universal Hepatitis B Vaccination: A Moratorium Should Be Placed on This Experiment*, available at <http://access1.net/via/VACCINE/hepbmoratorium.html>[hereinafter Moratorium].
[57] *Id.*
[58] *Id.*

as explained previously, generalized assertions and statistics, even if technically true and publicized by public health officials, should not necessarily be taken at face value without a more thorough understanding of the context from which they were derived and are to be applied.

HBV INFECTION IN INFANTS AND YOUNG CHILDREN

Hepatitis B is primarily an adult disease, is not highly contagious, is not deadly for most who contract it, and is not in an epidemic form in the U.S. (except among high risk groups). Nevertheless, as of 1991, the Immunization Practices Advisory Committee (ACIP) of the CDC recommended that all infants be injected with the first dose of the HBV vaccine at birth.[59] A similar recommendation was made by the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP).[60] Such recommendations were made despite the lack of knowledge about the health or completeness of a baby's immune and neurological systems at birth.[61]

In justifying the administration of the hepB vaccine among young infants and children, the ACIP's recommendations warn that in the "United States children become infected with HBV through a variety of means."[62] However, in a 1997 public hearing, Eric Mast, M.D., chief of the surveillance section of the hepatitis branch of the CDC, admitted that HBV is "not transmitted commonly by casual

[59] ACIP, *supra* note 45.
[60] Happens to You, *supra* note 17.
[61] *Id.*
[62] ACIP, *supra* note 45.

contact."[63] The ACIP also asserts that "horizontal transmission of HBV during the first five years of life occurs frequently in populations in which HBV infection is endemic."[64] However, HBV is not endemic in this country. Thus, perinatal transmission seems to be the only other viable means by which the HBV disease can be transmitted to babies born in the U.S. According to *Harrison's Principles of Internal Medicine* (1994), perinatal transmission of HBV occurs primarily in infants born to mothers carrying the HBsAg antigen and mothers with acute hepatitis B during the third trimester of pregnancy or during the early postpartum period. Although the precise mode of perinatal transmission is not known, epidemiological evidence suggests that most infections occur at the time of delivery and are not related to breast feeding.[65] Moreover, not all babies born to HBV infected mothers are consequently infected. According to the ACIP, the risk of perinatal HBV infection among infants born to HBV-infected mothers ranges from 10% to 85%, depending on the mother's hepatitis B antigen status.[66]

Despite the generalized statistics provided by federal health authorities which allude to the importance of vaccinating U.S. newborns against a life threatening risk of contracting HBV, *Harrison's Principles of Internal Medicine* (1994) states that perinatal transmission of hepatitis B is "uncommon in North American and western Europe."[67] Meheus' study of the prevalence of HBV markers

[63] Happens to You, *supra* note 17.
[64] ACIP, *supra* note 45.
[65] ISSELBACHER, BRAUNWALD, WILSON MARTIN, FAUCI, & KASPER, HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 1466 (13^{th} ed. 1994) [hereinafter Principles of Internal Medicine].
[66] ACIP, *supra* note 45.
[67] Principles of Internal Medicine, *supra* note 65.

by race, sex, and age in the U.S. from 1976-1980 supports this contention.[68]

Thus, "perinatal or childhood transmission of HBV is a minor contributor to the prevalence of HBV in this part of the world except in specific at-risk groups."[69] While federal health authorities mandate that all babies be vaccinated with the hepB vaccine, only some babies born to HBV infected mothers are at any real risk for contracting HBV.

To suggest that perinatal transmission of HBV in the U.S. is more significant than commonly believed, the ACIP states that approximately 150,000 infants are born to women who have immigrated to the U.S. from areas of the world where HBV infection is highly endemic.[70] However, the CDC fails to qualify this assertion by indicating what percent of these women transmit the virus to their infants or what percentage of infants born in the U.S. are born to such women so as to warrant the hepB vaccination of all U.S. infants. Moreover, infants born to HBsAg-positive immigrant mothers, like those born to infected American mothers, can be identified through prenatal screening programs for selective immunization. While the CDC does refer to an additional potential threats posed to children born to HBsAg-negative immigrant mothers, namely from "other HBV carriers in their families or communities,"[71] the CDC fails to point to evidence to substantiate this assertion or explicitly specify how the virus can be contracted from such individuals. Common scientific opinion maintains that one cannot contract or transmit the virus casually.

[68] Response Sheet, *supra* note 10.
[69] *Id.*
[70] ACIP, *supra* note 45.
[71] ACIP, *supra* note 45.

In further support of the mass vaccination of infants, especially newborns, PHAS states that as many as 90% of infants with perinatal HBV become carriers,[72] and 30% to 50% of children infected between the ages of one and five years become carriers.[73] Although these statistics seem to be potentially worrisome, the estimated figures of infants born to HBV infected mothers who consequently become carriers of the virus is low. In the 1988, a few years before the federal promulgation that newborns be hepB vaccinated, the estimated numbers of HBV carrier infants resulting from birth to HBV infected mothers by different ethnic/racial origins was, White:0.15%; Black 0.6%; Hispanic 0.5% and Asian: 2.0%.[74] Moreover, according to Hollinger et al. (1989), the prevalence of HBV markers for the HBV antigen in children under twelve years old was only 4.8%, despite the fact that 3.2% of infants were born to infected Caucasian mothers and 13.7% of infants were born to infected African-American mothers.[75] Furthermore, as the ACIP concedes, more than 90% of perinatal infections and their contribution to HBV carrier states in the U.S. can be prevented if HBsAg positive mothers are identified in advance and their infants are given the hepatitis B vaccine at birth.[76] In light of these studies and the single route by which HBV is likely to be transmitted to young U.S. children or infants, perinatal or childhood transmission of HBV was and is still a minor contributor to the prevalence of hepatitis B in the United States.

[72] PHAS, *supra* note 24.
[73] *Id.*
[74] Response Sheet, *supra* note 10.
[75] *Id.*
[76] ACIP, *supra* note 45.

INCIDENCE

As with other statistics pertaining to the HBV disease burden, the broad range of estimated cases of HBV in this country presents a problem in assessing the risks of contracting hepatitis B in the U.S so that the potential threat posed by the disease can be weighed against the benefits and risks of administering the vaccine in the United States. Despite disparate views, several public health officials maintain that acute and chronic consequences of hepatitis B infection are major health problems in the U.S. so as to warrant the mass administration of the hepB vaccine. The ACIP asserts that the reported incidence of acute hepatitis B increased by 37% from 1979 to 1989 and further alleges that an estimated 200,000-300,000 new hepatitis B infections occurred annually during the period between 1980 and 1991.[77] The CDC does not specify whether these assertions refer to infections which occurred in the United States. Other public health officials estimate that at a minimum, there are approximately 140,000 to 200,000 new infections of HBV annually in the United States.[78] In similar support of the prevalence of HBV in this Country, U.S. Hepatitis B vaccine maker SmithKline- Beecham (SKB) stated in its 1990 hepatitis B vaccine product insert that "the CDC estimates that there are approximately 0.5 to 1.0 million chronic carriers of the hepatitis B virus in the U.S. and that this pool of carriers grows by 2% to 3% (12,000 to 20,000 individuals) annually."[79] The CDC and

[77] ACIP, *supra* note 45.
[78] PHAS, *supra* note 24; CDC Fact Sheet, *supra* note 51; AMA Fact Sheet, *supra* note 11.
[79] Happens to You, *supra* note 17.

the AMA seem to be in agreement.[80]

Other scientific authorities, however, deem these statistics to be unsubstantiated and specious. In clarification, Dr. Dunbar and Dr. Skinner suggest that the estimated numbers of new HBV cases arising the U.S. annually are misleading, if not wholly inaccurate. Even if these numbers are true, it is important to note that they refer to all adults, with or without symptoms of the disease, who encountered the virus and responded in some way to it.[81] This is significant because almost 95% of the individuals counted in the statistics above will recover, most without experiencing any symptoms and all developing lifelong immunity to the virus.[82]

In addition to being misleading, such statistics are quite inconsistent with other data representing the incidence of infection in the U.S. during the same time period and indicating that HBV infection is not a major concern in this part of the world except among high risk groups. Historically, the U.S. has had one of the lowest rates of hepatitis B in the world even before a vaccine was in use (0.1% to 0.5% of the general population as compared to countries in the Far East and Africa where the disease affects 5-20% or more of the population).[83] Moreover, the rate of hepatitis B infection in the U.S. has only shown an increasing and consistent decline. In 1990, a year before the CDC recommended that all children be vaccinated with the hepatitis B vaccine, there were only 21,102 total cases, not cases arising just that year, of hepatitis B reported in the U.S.[84] In

[80] CDC Fact Sheet, *supra* note 51, AMA Fact Sheet, *supra* note 11.
[81] Response Sheet, *supra* note 10.
[82] *Id.*
[83] Happens to You, *supra* note 17.
[84] *Id.*

1991, the year in which the CDC promulgated the mass vaccination of children, there were only 18,0003 total cases of hepatitis B reported in the U.S. out of a total U.S. population of 248 million.[85] Moreover, the *Morbidity and Mortality Weekly Report* avers that there were less than 14,000 cases of HBV infection in 1992 nationwide.[86] In 1996, there were only 10,637 U.S. cases of hepatitis B reported, with a total of 279 cases reported in U.S. children under the age of 14.[87] As demonstrated by these statistics and further supported by the *Guide to Clinical Preventive Services*, in the United States "the greatest reported incidence [of hepatitis B] occurs in adults aged 20-39" and "the number of cases peaked in 1985 and has shown a continuous gradual decline since that time."[88] Despite the CDC`s contrary insinuations in the statistics which it has offered to justify the vaccine`s administration, the CDC has admitted to this apparent decline. In its October 31, 1997 *Morbidity and Mortality Weekly Report*, the CDC stated that "Hepatitis B continues to decline in most states, primarily because of a decrease in the number of cases among injecting drug users and, to a lesser extent, among both homosexuals and heterosexuals of both sexes."[89] This broad and inconsistent range of estimated HBV cases in the U.S. presents a problem for determining the risk posed to an U.S. individual exposed to HBV. This problem is compounded by three apparent additional problems: (a) the majority of HBV cases appear to be occur among I-V drug users, sexually promiscuous persons, and medical contacts who may not necessarily want to

[85] *Id.*
[86] Dunbar's Proposal to the NIH, *supra* note 6.
[87] Happens to You, *supra* note 17.
[88] *Id.*
[89] *Id.*

admit the source of their infection and therefore, fail to report their infection; (b) the genetic predisposition of most who are exposed to the hepatitis B virus who are able to fend it off without serious illness. Consequently, the numbers of reported cases may overstate the significance of the virus's potential for harm in those exposed to the virus; and (c) contraction of the disease by non-responders to the vaccine after vaccination. HepB vaccinated individuals may be contributing to the HBV disease burden by engaging in risky behavior thinking that they are immune from contracting the disease when they are not.[90]

Despite the variation in estimated cases of hepatitis B in the United States and these additional complexities, Dr. Dunbar has composed two tables evaluating the risk U.S. individuals face when exposed to the HBV virus. Table 1 provides a summary of the hepB infection status in the U.S. and table 2 estimates the risks of contracting HBV in the United States. Both tables use the higher figures of estimated cases cited by federal health authorities. As the following tables demonstrate, the incidence of the hepatitis B virus in the United States is low.

TABLE 1: SUMMARY OF HEPATITIS B STATUS IN THE UNITED STATES[91]

Values used:

U.S. population of 261,000,000;

HBV incidence: 170,000. This figure represents an average of the 140,000 to

[90] Dunbar's Proposal to the NIH, *supra* note 6.
[91] Response Sheet, *supra* note 10.

200,000 infected U.S. individuals as given in the Hepatitis B "Fact sheet," distributed by the Public Health Alert System[92] and posted online by the CDC[93] and AMA.[94]

	TOTAL	**HIGH-RISK GROUPS**[95]	**GENERAL POPULATION**
Total individuals infected per year: percentage of U.S. infected U.S. population	170,000 (0.065%) (Percentage of *total* U.S. population)	100,300 (.038%)	69,700 (.027%)
1. **ACUTE**[96]			
Subclinical (50%) (No Symptoms)	85,000 (.033%)	50,150 (0.019%)	34,850 (.013%)
Mild (30%) (Flu like Symptoms)	51,000 (.02%)	30,090 (.012%)	20,910 (.008%)
Severe (20%) (Hospitalized)	34,000 (0.013%)	20,060 (.008%)	13,940 (.005%)
Death from fulminant form (.2%)	68 (0.00003%)	40 (0.00002%)	28 (0.00001%)
2. **CHRONIC**[97]			
Healthy Carriers (1-5%)	1700-8500 (0.00065% - 0.003%)	1003-5015 (0.00038%-0.0019%)	697-3495 (.00027%-0.0013%)
Cirrhosis or Hepatoma deaths (may occur up to decades after infection) (.0025-.0125%)	425-2125 (0.00016%-0.0008%)	251-1254 (0.0001%-0.00048%)	175-871 (0.00007%-0.00033%)

[92] PHAS, *supra* note 24.

[93] CDC Fact Sheet, *supra* note 51.

[94] AMA Fact Sheet, *supra* note 11.

[95] High risk groups (sources of infection) include IV drug users (28%), heterosexual contact with infected persons or multiple partners (22%) and homosexual activity (9%). Response Sheet, *supra* note 10, citing data obtained from the CDC.

[96] *Id.* Blood chemistry of recovered patients returns to normal within six months.

[97] *Id.* Virus has not yet been cleared from the blood six months following exposure.

References for percentages, see footnote.[98]

[98] *See* references cited in Response Sheet, *supra* note 10.

TABLE 2: ESTIMATION OF THE RELATIVE RISK OF CONTRACTING HEPATITIS B IN THE UNITED STATES AND SUFFERING FROM SEVERE DISEASE OR DEATH AS A CONSEQUENCE

In table 2, Dunbar[99] has estimated the relative risk of severe death or disease from Hepatitis B in the U.S., given the worst and best incidence rates proffered by federal health authorities (namely 14,000 vs. 300,000 cases). Moreover, she has assumed that every individual has the same risk (that there is no difference in risk between the normal population and individuals comprising high risk categories, such as drug users). Clearly, the risk would be greatly reduced if the distinction between the normal population and high risk categories were established. Furthermore, the numbers might vary if it was possible to assess how many non-responders to the vaccine contract the virus and subsequently suffer from serious symptoms or die. Based on these considerations, Dr. Dunbar's best assessment of HBV risk is outlined in the table below:

Estimated Relative Risk of Severe Disease or Death from Hepatitis B in the United States

	Worst Case	**Best Case**	**% Infected**
CASES PER YEAR	300,000 (1% of total population)	14,000 (.005% of total population)	
CASES <u>RECOVERED</u>	**250,000+**	**11, 520+**	**83% +**
HEALTHY CARRIERS	15,000-30,000+	750-1400+	**10%+**
Fulminant hepatitis, cirrhosis and carcinoma or Death	**2500**	**116**	**.83%**

[99]Dunbar's Proposal, *supra* note 6.

Estimated Risk of serious illness or death (U.S. population of 265,000,000)	**.0009%**	**.000044%**	

In table 3, Dr. Skinner has compared the worst case scenario of living with hepatitis B as compared to suffering from an autoimmune disorder, possibly induced by the hepatitis B vaccine:

Table 3: SYMPTOMS, DURATION AND INFECTIOUSNESS OF LIVING WITH THE WORST CASE OF A HEPATITIS B INFECTION AS COMPARED TO AN AUTOIMMUNE DISEASE:

THE ILLNESS	**SYMPTOMS & DURATION**	**INFECTIOUSNESS**
HEPATITIS B – acute form	**Worst** Acute form: nausea, vomiting, low grade fever, constant fatigue, may develop jaundice which fades along with symptoms over approximately four weeks. Must stay home to recover for a few months. Fatigue can last up to a year. Blood chemistry returns to normal within six months. Mothers pass to babies if they become infected during third trimester.	Blood is infectious as long as viral antigen is in the bloodstream, generally for 3 months. Major danger is to sexual partner (20% to 70% of non-immune spouses will catch it from their infected mate). **Less than 1% of other family members are found to become infected.** Fetal infection probably occurs during the birth canal, or possibly through the placenta. Breast milk is an unlikely source.

HEPATITIS B — chronic form	Most do not have symptoms, but virus has not been cleared from the blood six months following exposure. Ten to thirty or more years later, about a quarter of these people will develop life threatening cirrhosis or even more rarely, liver cancer.	Blood ultimately becomes "relatively non-infectious," but the individual must still be careful.
Autoimmune disorders	**Depends on systems affected** **• Inflammation of blood vessels (vasculitis), joints (arthritis), can cause disabling pain.** **• Attack on the tissue of the nerves can cause blindness (optic neuritis).** **• Motor function impairment (multiple sclerosis, GBS and other neuropathies).** **• Problems with thinking and memory.** **• Temperature control problems** **• Disabling fatigue** **• Eventual failure of attacked organs (diabetes)** **• All disorders are frequently permanent, although some may experience periods of remission.**	Not infectious

THE HEPATITIS B VACCINE & ITS PROMULGATION

BASIC IMMUNOLOGY

Our immune system saves us from death by infection by initiating responses to destroy or eliminate invading organisms and toxic molecules produced by them. Because these immune reactions are destructive, it is essential that they be made only in response to molecules that are foreign to the host. Occasionally, the immune system will fail to distinguish foreign molecules from self molecules. This failure will cause it to react destructively against the host's own molecules, causing an autoimmune disease which can be fatal. Almost any macromolecule, as long as it is foreign to the recipient, can induce an immune response. Any substance capable of eliciting an immune response is referred to as antigen (*anti*body *gen*erator).[100]

There are two broad classes of immune responses: (1) antibody responses, and (2) cell-mediated immune responses. Antibody responses involve the induction of antibodies, small molecules of protein that attack the invading organism. These antibodies circulate in the bloodstream and permeate other bodily fluids. They bind specifically to a foreign substance, or an antigen, that induced them. By binding to antigens, antibodies inactivate viruses and bacterial toxins by

[100] MICHAEL ALBERTS, D. BRAY, J. LEWIS, K. ROBERTS, J.WATSON, MOLECULAR BIOLOGY OF THE CELL (3^{rd} ed. 1989).

blocking their ability to bind to receptors on host cells. Antibodies can also destroy invading microorganisms.[101] Some antibodies can even react with self molecules within the organism that produced the antibody so as to cause severe autoimmune diseases.[102]

Cell-mediated immune responses involve the production of specialized cells that react with foreign antigens on the surface of host cells. The cells responsible for immune specificity belong to a class of white blood cells, known as lymphocytes. Cell mediated immune responses involve a class of lymphocytes called T cells. T cells mediate immune responses against genetically foreign versions of cell-surface proteins called histocompatibility molecules. The major histocompatibility complex (MHC) is a complex of molecules which bind peptide antigens and present them to T cells for destruction or inactivation. In humans, the MHC is a cluster of genes. The most important cluster of such genes are called human leukocyte antigens (HLA) and they encode for proteins in this complex.[103]

THE VACCINE

A vaccine is a preparation of weakened or killed viruses or bacteria or highly purified components of such microorganisms, which may be administered to an individual to induce immunity against disease. Vaccination rests on the the-

[101] *Id.*
[102] *Id.*
[103] *Id.*

ory that periodically challenging and artificially stimulating the human immune system with small amounts of inactivated (killed) viruses and bacteria or attenuated (partially inactivated) live viruses will force it to produce antibodies that will confer immunity in the same way that a bout with the natural disease will. However, vaccines do not work in the body in the same way as a natural disease does. When bacteria or viruses enter the body and the disease progresses in a normal fashion, the immune system is stimulated to produce a type of natural immunity, which is often permanent. Vaccines, on the other hand, which are often directly injected into the blood or swallowed by mouth, provide, at best, artificial, temporary immunity. Some vaccines fail to provide any immunity at all.[104]

The hepatitis B vaccine (generally referred to as "the vaccine" in this paper) protects against infection with HBV by producing immunity or antibodies to the surface protein or outer coat of the hepB virus. This outer coat is called hepatitis B surface antigen, referred to as HBsAg. The first vaccine was produced by purifying this surface protein from the plasma of chronically infected persons. This plasma-derived hepatitis B vaccine was licensed by the U.S. in 1981 and was administered to high risk populations in the 1980's, until a genetically engineered, recombinant hepatitis B vaccine was developed. The plasma derived type is no longer produced in the United States and currently available vaccines are produced by recombinant DNA technology. These licensed vaccines are de-

[104]BARBARA LOE FISHER, THE CONSUMER'S GUIDE TO CHILDHOOD VACCINES (1997).

rived from hepatitis B surface antigens produced in yeast cells. A portion of the hepatitis B virus gene is cloned in yeast and the vaccine is produced from cultures of this recombinant yeast strain. Recombivax-HB, manufactured by Merck Sharp and Dohme (MSD), was licensed in 1986 and Engerix-B, manufactured by Smith-Kline Biologicals (SKB), was licensed in 1989. Another recombinant vaccine, Gen Hevac B, manufactured by the Pasteur Institute (PI), is licensed in France. Because the genetically engineered vaccine was developed only recently, there is still little known about it.[105]

The PHAS,[106] the AMA,[107] and the CDC[108] state that the recombinant vaccine does not contain live components of HBV and thus, protects against infection from the Hepatitis B virus (HBV). In support of the vaccine's safety and reliance upon such authorities, several public health authorities have inferred that the vaccine is innocuous because it cannot cause the HBV disease. True, the recombinant vaccine cannot cause the disease known as hepatitis B, as the live virus can. However, the recombinant vaccine does contain a protein that is found on the surface of the virus which initiates immune reactions to that surface.[109] Worthy of attention is the fact that the severe autoimmune effects allegedly induced by the HepB vaccine are the same as or similar to those reported as a consequence of (a) infection with HBV, (b) the plasma derived vaccine, and the (c) recombinant vaccine derived from a cloned HBV gene

[105]Grotto Y. Mandel, M Ephros, I. Ashkenazi and J. Shemer, *Major Adverse Reactions to Yeast-derived Hepatitis B Vaccines—a review*, VACCINE, Vol.16, no.4. pp.329-334 (1998).
[106]PHAS, *supra* note 24.
[107]AMA Fact Sheet, *supra* note 11.
[108]CDC Fact Sheet, *supra* note 51.
[109]Response sheet, *supra* note 10.

in yeast.[110] All three sources contain the HBsAg surface protein. As will be further discussed, the fact that the yeast derived vaccine has a different form of glycosylation than the native viral protein has suggested to some scientists that the autoimmune side effects allegedly caused by this vaccine are initiated by the peptide structure of the HBsAg protein.[111] Thus, while the hepatitis B vaccine cannot produce HBV as we know it, the protein which it contains can stimulate the immune system in a variety of ways, perhaps even to cause life-threatening autoimmune conditions, which are in some ways similar and even more detrimental than those caused by the disease itself.[112]

VACCINE RECOMMENDATIONS

CDC vaccine recommendations are made through a deliberative process involving advice and guidance from the Advisory Committee on Immunization Practices (ACIP). This federally chartered, scientific advisory committee provides the CDC and the Department of Health and Human Services (DHHS) with recommendations on how to decrease the incidence of disease through the use of vaccines and other biological products as well as how to improve the safety of these products' use.[113] Upon being finalized by the ACIP, a vaccination rec-

[110] Dunbar's Proposal to the NIH, *supra* note 6.
[111] *Id.*
[112] Response Sheet, *supra* note 10.
[113] Dr. Margolis' Testimony, *supra* note 12. The ACIP currently includes 12 voting members selected based on their infectious disease expertise, evaluation of vaccine performance and safety experience and immunization program knowledge. While members of the ACIP come from a diversity of backgrounds, ACIP meetings are attended by ex officio members who rep-

ommendation is submitted to the CDC for consideration. If the agency accepts the recommendations, the document is edited and published in the *Morbidity and Mortality Weekly Report* (MMWR) as an ACIP recommendation.[114]

The ACIP first published recommendations for the HBV vaccine in 1982. Epidemiological data at this time pointed to adult infections as contributing to almost all of the HBV disease burden in the U.S.[115] As a consequence, the ACIP recommended that high risk groups be vaccinated, such as health care workers and hospital staff, clients and staff of institutions for the developmentally disabled, hemodialysis patients, hemophiliacs, homosexuals, household and sexual contacts of HBV carriers, intravenous drug users, inmates of long-term correctional facilities, Alaskan Eskimos and infants born to women with chronic HBV infection. Vaccine use became more prevalent as federal health authorities promulgated its general safety and effectiveness and vaccine manufacturers found it to be inexpensive to produce. [116]

Beginning in 1990, the CDC, FDA, other governmental agencies, non-governmental investigators, and vaccine manufacturers provided new information pertaining

resent federal agencies, liaison members of professional societies, groups implementing vaccination programs, and the general public. All ACIP meetings are open to the public, providing time for public comment as well presentations of data from vaccine manufacturer representatives. Vaccine manufacturers are represented at ACIP meetings by the liaison representative from the Pharmaceutical Research and Manufacturers of America. Vaccine recommendations initially are drafted by a working group that includes ACIP members, ex officio and liaison representatives, vaccine manufacturers and CDC experts. Draft recommendations are sent to all ACIP members for comment, discussed during public meetings, finalized and adopted by vote of ACIP members.

[114] *Id.*

[115] *Id.*

[116] *Id.*

to the prevalence of the hepB virus and strategies for its eradication. Specifically, the ACIP was presented with data suggesting that the incidence of HBV had increased during the early 1980's, despite the availability of the vaccine. According to Dr. Margolis, perinatal and early childhood infections also contributed to a substantial proportion of the chronic hepatitis B disease burden in the United States at this time.[117] However, the ACIP attributed the apparent increase in the U.S. HBV disease burden to ineffectual efforts to vaccinate persons in the major risk groups for contracting the disease. For example, programs targeting drug users failed to sufficiently impel them to receive three doses of the vaccine.[118] Additionally, because health care workers were not often aware or informed of population groups at significant risk for contracting HBV, they did not successfully identify candidates for vaccination during routine health care visits.[119] Moreover, many sexual contacts of HBsAg carriers, identified in screening programs for blood donors, were not vaccinated.[120] Despite the regulations implemented to promote hepB vaccination and the ensuing decrease in the rate of health care worker HBV infection, the overall rate of HBV in the U.S. seemed to remain unaffected.[121] Consequently, government health authorities believed that regulations had to be developed to ensure implementation of vaccination programs among those occupationally and behaviorally at risk.[122] The ACIP did not believe that educational programs would sufficiently reduce

[117] *Id.*
[118] ACIP, *supra* note 45.
[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*

parenteral drug use and unprotected sexual activity, or fully eliminate other high–risk behaviors responsible for HBV transmission so as to affect the overall rate of HBV infection in the U.S.[123] Thus, in light of these considerations, the ACIP advanced in its June 1990, *Protection Against Viral Hepatitis* recommendations that "for the vaccine to have an impact on the incidence of hepatitis B, a comprehensive strategy must be developed that will provide hepatitis B vaccine to persons *before they engage in behaviors or occupations that place them at risk of infection*" (emphasis mine).[124] Similarly, in its 1991 recommendations, the ACIP stated that "since most HBV infections occur among adults, disease control could be accelerated by vaccinating emerging at-risk populations" and that "universal infant vaccination would eliminate the need for vaccinating adolescents and high-risk adults."[125] Since governmental efforts to vaccinate those contributing to the HBV burden in the U.S. had essentially failed, the ACIP decided to immunize young infants as "an alternative to high-risk group vaccination... and as a possible strategy to control transmission of the disease."[126] Thus, the CDC endorsed a strategy to eliminate HBV transmission among high-risk *adults* by immunizing *all infants*.

The comprehensive strategy recommended by the ACIP was developed and finally published in November 1991. According to Dr. Margolis, this strategy was subsequently endorsed by the American Medical Association (AMA), the American College of Obstetricians and Gynecologists, the American Academy

[123] *Id.*
[124] Margolis' Testimony, *supra* note 12.
[125] ACIP, *supra* note 45.
[126] Margolis' Testimony, *supra* note 12.

of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). The objective of the strategy was and is currently set "to eliminate transmission of HBV infection."[127] The components of this strategy consisted of 1) the prevention of perinatal HBV infection by screening all pregnant women and providing post-exposure immunization to at risk infants of chronically infected mothers; 2) routine hepatitis B vaccination of infants as part of the childhood immunization schedule; 3) routine vaccination of adolescents; and 4) vaccination of adolescents and adults in groups of increased risks for HBV infection.[128] Individuals in the last category include:

λ

Sexually active heterosexual adults with more than one sex partner in the past six months, or that have a history of sexually transmitted disease;

λ

Homosexual and bisexual men;

λ

Illicit injection drug users;

λ

Persons at occupational risk of infection;

[127] *Id.*
[128] *Id.*

λ

Hemodialysis patients;

λ

Sexual contacts of persons with chronic HBV infection;

λ

Client and staff of institutions for the developmentally disabled. [129]

The ACIP currently recommends that *everyone* younger than 18 years of age receive the hepatitis B vaccine. In contrast, the ACIP only specifically endorses the vaccine for adults over 18 who are *at risk* for contracting HBV.[130]

Although the following authorities are often cited as supporting the ACIP's recommendations, Dr. Skinner contacted the following individuals by phone and asked whether their organizations "recommended" any vaccines. They all replied in the negative. They recommend vaccination procedures, dependant upon the populations at risk and the best possible way to cover those populations. Furthermore, they neither test nor assert the safety or efficacy of any specific vaccine. When asked as to which authorities they depended upon to determine vaccine safety, they responded as indicated below:[131]

[129] CDC Fact Sheet, *supra* note 51.
[130] *Id.*
[131] Skinner Report, *supra* note 26.

Organization and Spokesperson	Their Authority on Safety
American College of Preventative Medicine (ACPM) : H.K. Keimowitz, Exec. Director (202) 466-2044	CDC, National Coalition for Adult Immunization
American Medical Association (AMA) Mr. Liznicki for Dr. J. Allen, M.D. (312) 464-4520	CDC, FDA
American Academy of Family Physicians (AAFP) Robert Graham, M.D. Exec. V.P. (816) 333-9700	Substance is on the market, therefore must have passed FDA inspection
American College of Physicians (ACP) G. Thomason, Scientific Policy Office (215) 351-2400 ext. 2847	Substance is on the market

The Federal Drug Administration's (FDA) stamp of approval should not be taken as the last word on the vaccine's safety. The FDA based its decision to approve the vaccine upon clinical trials and post-marketing surveillance studies in which patients and their doctors were asked to report possible adverse effects experienced in response to the vaccine within four to five days after each injection [four days for the Smith-Kline and five days for the Merck vaccine].[132] As this paper will later explain, the adverse events reported as being caused by hepB vaccination appear to be autoimmune in origin. Since such problems take weeks, if not months, to produce noticeable symptoms, these types of problems could not have been detected in these clinical and surveillance studies. Dr. Waisbren has also been especially critical of the FDA's current stance, or rather,

[132] *Id.*

course of inaction. In his testimony before the U.S. House of Representatives on May 18,1999, Dr. Waisbren inquired why the FDA has not been reacting to the numerous theories in the medical literature, proposing the means by which the vaccine may cause neurological complications.[133] Concerned that new vaccines being developed and marketed may cause similar adverse effects, he also questions why the FDA has not asked whether vaccines can exhibit molecular mimicry with human tissue, or whether a vaccine exhibits complimentarity with common viruses already lying within vaccinated patients. As will be explained, answers to these questions would address the hypothesized means by which the vaccine is believed to cause the adverse reactions reported.[134] Additionally, he wonders why the FDA has not demanded that HLA patterns of patients who have experienced adverse side effects be determined or that synthetic vaccines containing only immunogenic antigens be produced.[135] Concessions to these requests would be important and extremely beneficial in protecting individuals who may be at a heightened risk for responding adversely to the vaccine. As will be further discussed in this paper, many scientists believe that only a genetically susceptible subset of vaccinated individuals will develop adverse responses to the vaccine and that the protein derived from the hepatitis virus and used in the vaccine is implicated in this causal relationship.

While similarly cited in support of the vaccine's endorsement, the fact that the

[133] Burton A. Waisbren, Sr.., M.D., F.A.C.P., F.I.D.S.A., Testimony before the U.S. House of Representatives Subcommittee on Criminal Justice, Drug Policy and Human Resources (May 18, 1999) [hereinafter Waisbren Testimony], available at <http://www.house.gov.reform/cj/hearings/5.18.99/Waisbren.html>.

[134] *Id.*

[135] *Id.*

vaccine "is on the market"[136] may not be a legitimate source upon which to rely as evidence of the vaccine's safety. Placing a vaccine out on the market does allow for the testing of the vaccine's safety in population groups and under circumstances not studied in pre-licensure trials. However, this potentially useful and important resource of information cannot be relied upon as a valid source of the vaccine's safety if many of the adverse events reported by "market" participants are largely ignored or dismissed by the FDA and other federal health authorities. For instance, the Institute of Medicine (IOM), of the National Academy of Sciences (NAS), only began to examine reports of adverse effects associated with the hepB vaccines in 1992 after Congress directed them to, through DHHS.[137] DHHS finally responded when unheeded reports turned into public outcries. Parents could no longer contain their concern about their children's deteriorating health following their hepB immunization or their frustration with health authorities' failure to acknowledge the significance of their reports.

Conflicts of interest for these cited authorities may be another important issue for further research in attempting to adequately understand the vaccine's endorsement. It is well documented that committee members advising the CDC and members of organizations (such as the AAP and World Health Organization [WHO]) obtain substantial funding from pharmaceutical companies.[138] Additionally, the lobbyists who consult for the pharmaceutical companies are

[136] Skinner Report, *supra* note 26.
[137] *Id.*
[138] Dunbar's Testimony, *supra* note 4.

also many times the same lobbyists for medical health care providers.[139] Moreover, investigators who have carried out clinical trials on the vaccine's safety have benefited personally. Some have obtained laboratory funding for acting as consultants in promoting the vaccine and expert witnesses in legal conflicts. It appears that lack of government funding for independent research has forced many scientists into these ethical constraints. [140]

JUSTIFICATIONS FOR THE STRATEGY TO ELIMINATE HBV AMONG ADULTS AND HIGH RISK POPULATIONS BY IMMUNIZING ALL INFANTS AND CHILDREN

Even though hepatitis B is generally an adult disease, is not highly contagious, is not deadly for most who contract it, and is not in epidemic form in the United States (except for those in high risk groups, such as IV drug users), federal health authorities, such as the ACIP and the AAP, nevertheless recommended in 1991 that **all** infants be injected with the first dose of the hepatitis B vaccine at birth before being discharged from the hospital newborn nursery. This recommendation was given even though the only newborns at risk for contracting hepatitis B are those born to hepatitis B infected mothers and only a small percentage of babies born in the U.S. will grow up to be susceptible to contracting HBV. This recommendation is even more surprising since almost nothing is known about the health and integrity of a baby's immune and neurological systems at birth. One can assume that less is known about their responses to vaccines. Despite these facts, the ACIP, AMA and

[139] *Id.*
[140] *Id.*

CDC generally assert two main reasons why all infants should be vaccinated, as opposed to only those infants born to mothers who are infected with HBV.[141] The following justifications are still used today to promote the mass hepatitis B vaccination campaign for infants and young children. First, some authorities contend that children bear a large proportion of the U.S. HBV disease burden. Second, health authorities reason that vaccinating individuals at a young age could protect them if exposed to HBV infection later in life, since HBV infected or susceptible individuals failed to voluntarily participate in and comply with vaccination efforts that targeted them.

Disease burden attributable to young infants and children

In justifying the routine vaccination of all children and adolescents, some health authorities contend that children comprise a major portion of the HBV disease burden. The CDC asserts that before the routine infant hepatitis B immunization policy was instituted, approximately 30,000 infants and children were infected each year.[142] Moreover, they assert that one third of U.S. chronic HBV infections stem from infected infants and young children.[143] The CDC,[144] Dr. Margolis,[145] and the AMA[146] rely on such statistics to suggest that peri-

[141] *see* CDC Fact Sheet, *supra* note 51; ACIP, *supra* note 45; AMA Fact Sheet, *supra* note 11.
[142] CDC, *supra* note 51.
[143] *Id.*
[144] *Id.*
[145] Margolis' Testimony, *supra* note 12.
[146] AMA Fact Sheet, *supra* note 11.

natal and infancy infections contributed to a substantial proportion of the hepatitis B disease burden in the U.S., and would do so until this day, if not for the mass hepB vaccination policy. However, no scientific references are given to substantiate such assertions.[147] Moreover, this statistic is inconsistent when compared to other studies done and statistics presented, including those made by the CDC, before the federal policy to vaccinate all newborns and young infants was promulgated (for ease of reference, some of the studies and statistics previously mentioned in this paper will be repeated here). These alternative statistics indicate that newborns, infants and young children did not bear, nor were at risk of bearing, a great hepatitis disease burden in the U.S.

For example, Esteban assessed the risk of acquiring HBV in infancy and childhood. He found that for U.S. born mothers (for whom there is a low incidence of HBV infection), the published rates of perinatal transmission in 1988 by infected mothers was quite low.[148]

Origin	**HBsAg positive (%)**	**Number of Cases Studied**
White	0.15	901
Hispanic	0.5	513
Black, U.S. born	0.6	799
Asian, U.S. born	2	118
Other	0.5	78

[147] In support of the paragraph in which these statistics are contained, the CDC's web-page cites a paper authored in part by Dr. Margolis (1991) as a reference; however, it is not clear whether this source is cited as a reference for these assertions specifically, as opposed to only the sentence preceding its notation.

[148] Response Sheet, *supra* note 10.

Similarly, Hollinger et al. [149] found that the prevalence of HBV markers in children under 12 years of age was low – only 4.8% (including 3.2% of births to infected Caucasian mothers and 13.7% born to infected African American mothers). Mehaues' graph illustrating the prevalence of HBV markers by race, sex and age in the U.S. from 1976-1980 further supports the conclusions reached by Hollinger et al. and Esteban, that perinatal or childhood transmission of HBV was a minor contributor to HBV prevalence in this part of the world, except in specific high risk groups, in the period preceding the call for the mass vaccination of all infants and newborns.[150]

It is unlikely that the estimated 30,000 cases of HBV infected children are representative of cases that would otherwise arise in the U.S. if not for the mass vaccination policy, given other statistics offered to represent the same time period for which this figure was given. In 1990, a year before the CDC ordered that all children be vaccinated, there were a total of 21,102 cases of hepatitis B reported in the U.S. out of a total population of 248 million. In 1991, the year calling for the vaccination of all infants, there were only 18,003 total cases of HBV reported in the U.S. of a similar total U.S. population of 248 million.[151] According to October 31, 1997 MMWR published data by the CDC, there were 10,637 cases of hepatitis B reported in the U.S. in 1996, with 279 (.02%) cases reported in children under the age of 14.[152] Such statistics suggest that children bore an insignificant HBV disease burden. Consistent with the apparent

[149] *Id.*
[150] *Id.*
[151] Happens to You, *supra* note 17.
[152] *Id.*

decline in the incidence of HBV (as illustrated by these statistics), the *Guide to Clinical Preventive Services,* states that the "greatest reported incidence [of hepatitis B in the United States] occurs in adults aged 20-39" and the number of cases peaked in 1985 and has shown a continuous gradual decline since that time."[153] Even if one assumes that there were approximately 30,000 newborns or young infants infected in 1985, when the number of hepatitis B infections peaked so as to result in a significant HBV disease burden, one would still expect more than 279 reported cases of HBV in children under fourteen years of age in 1996[154], since children born in 1985 would only be eleven years old. While the inconsistencies could be attributed to a gross under-reporting of cases among infected children, if the estimated 30,000 cases of hepatitis B occurring in infants represent those actually reported, there is no reason to believe that reporting efforts would subsequently ebb to such a drastic extent, if at all.

Related to the significant disease burden justification offered by several federal health authorities and in further support of the federal endorsement of HBV vaccination in infants and newborns is the expressed concern that young children are at a heightened risk of suffering from chronic infections, complications, and death if they are exposed to and do contract the hepatitis B virus.[155] The *Guide to Clinical Preventive Services* (1996), written under the supervision of the U.S. Department of Health and Human Services (DHHS), states that the risk of developing a chronic hepatitis B infection is higher in infected infants

[153] *Id.*
[154] *Id.*
[155] *See* ACIP, *supra* note 45.

than in infected older adults and children.[156] While infections during infancy represent only 1-3% of HBV cases, DHHS asserts that "infections during infancy account for 20-30% of chronic infections."[157] In addition to heightening the concern with respect to the disease burden attributed to HBV infected infants and children, some have used these statistics to suggest that a large proportion of adults with chronic HBV became infected as young infants or as children, rather than by engaging in high risk behavior as teenagers or adults.[158] In support, the CDC and AMA allege that approximately 30% of people infected with HBV have no idea how they became infected.[159] Perhaps it is because they would prefer not to specify the means. Even if infants do account for 20-30% of all chronic infections, such statistics should be viewed in the context of the fact that chronicity occurs in less than 5% of all acute cases and results in a very small proportion of chronically infected individuals in the U.S. when compared to the U.S. population as a whole.[160] Thus, the fact that infants comprise 20% of a small percent of cases may not amount to a significant number of HBV infected infants so as to justify the mandatory vaccination of all infants. This is especially important in light of the fact that the only real way a child can be chronically infected is through mother-to-child transmission, a route highly "uncommon in North American and Western Europe."[161] Moreover, improved screening methods and a selective, rather than universal, immunization program

[156] Happens to You, *supra* note 17.
[157] *Id.*
[158] *See* AMA Fact Sheet, *supra* note 11; CDC Fact Sheet, *supra* note 51.
[159] *Id.*
[160] Response Sheet, *supra* note 10.
[161] Harrison's Principles of Internal Medicine, *supra* note 65.

can help prevent and reduce perinatal infection.

Although the ACIP states that each year, approximately 150,000 infants are being born to women who have immigrated to the United States from areas of the world where HBV infection is highly endemic,[162] the HBV risk posed to such infants cannot be adequately assessed nor relied upon as evidence of the need for immunizing all infants. As indicated in the preceding section, the ACIP fails to substantiate this assertion by indicating how many infants are subsequently infected or what percent of the total U.S. infant population these infants comprise, if in fact they are consequently infected. Moreover, even if this risk is substantial, foreign mothers, like those from the U.S., can be identified before the risk realizes and alternative strategies can also be formulated to identify and selectively immunize their infants.

In final support of the HBV disease burden borne by young infants, the AMA[163] and the CDC[164] aver that many cases of chronic infections suffered by infants and young children arise among children whose mothers were not infected with HBV and thus, cannot be protected by perinatal hepatitis B prevention programs. However, neither authority provides any scientific reference to substantiate such assertions or explains how such children may have otherwise contracted the HBV disease. The ACIP has claimed that horizontal transmission of HBV during the first five years of life occurs frequently in populations in which HBV is endemic.[165] HBV is currently not endemic in the United States and public

[162] ACIP, *supra* note 45.
[163] AMA Fact Sheet, *supra* note 11.
[164] CDC Fact Sheet, *supra* note 51.
[165] ACIP, *supra* note 45.

health authorities have not provided any examples or instances by which HBV infection can be transmitted horizontally in the United States through casual contact. Moreover, Barbara Fisher's research on HBV using medical textbooks, vaccine maker product inserts, published and unpublished CDC data and transcripts from government meetings have persuaded her that contrary to what some federal and state health officials are telling public and state legislators, HBV is not a disease that can be transmitted through casual contact.[166] Although the CDC currently operates a website that states that a person can get infected "by sharing personal items, such as a razor or toothbrush,"[167] in 1998 the CDC admitted to the fact that there is not even one documented case of HBV transmission from sharing toothbrushes or razors and ear piercing.[168] In the absence of such evidence, the likelihood that children born to HBsAg negative mothers, whether American or foreign, will acquire HBV and become infected is close to, if not, nil.

The vaccine's ability to provide immunity against the HBV when infants may engage in high risk behavior and become susceptible to infection

Since hepB vaccination of persons in high risk groups has generally not been a successful public health strategy,[169] the CDC and other health authorities contend that vaccinating babies and young children can offer them immunity to the HBV virus at a time when they may become susceptible to acquiring the

[166] Happens to You, *supra* note 17.
[167] Healthtouch, *supra* note 45.
[168] Happens to You, *supra* note 17.
[169] CDC Fact Sheet, *supra* note 51.

disease.[170] In support of this justification, the ACIP and other health authorities refer to clinical trials finding that U.S. licensed hepatitis B vaccines are 80% to 95% effective in preventing HBV infection and clinical hepatitis among susceptible children and adults.[171] In support of the vaccine's efficacy, the CDC also asserts that more than 95% of children and adolescents and more than 90% of young, healthy adults develop adequate antibody to three doses of the vaccine.[172] Furthermore, of those vaccine recipients who develop a protective antibody response, some authorities advance that such individuals become virtually 100% protected against clinical illness.[173] While these assertions seem encouraging, these public sources of information do not specify whether these conclusions were drawn from studies conducted among U.S. population groups, a factor that will be discussed to be highly relevant in adequately evaluating the safety and efficacy of the hepB vaccine.

Like other generalized statistics offered by such health authorities, the percentages cited above should not be taken at face value. First, these statistics may not be legitimate sources upon which to draw conclusions about the vaccine's effectiveness as it relates to specific population groups in the United States for whom the vaccine is mandated. For example, if 100 people are vaccinated and five contract the disease, the vaccine is declared to be 95% effective. However, if only ten of the 100 were actually exposed to the disease, then the vaccine was only 50% effective. This example demonstrates the importance of ana-

[170] *See* CDC Fact Sheet, *supra* note 51; AMA Fact Sheet, *supra* note 11; ACIP, *supra* note 45.
[171] ACIP, *supra* note 45.
[172] *See* CDC Fact Sheet, *supra* note 51.
[173] ACIP, *supra* note 45.

lyzing the risk of exposure for the population group for which these statistics are given. While the efficacy statistics cited by health officials are useful in identifying the vaccine's ability to protect hepB susceptible children against infection, these statistics are being advanced to support the vaccination of all newborns and young children, not just those at risk of contracting the hepB disease. Therefore, the significance of such statistics cannot be fully appreciated or undermined without considering the generally low rate of HBV exposure for U.S. newborns and young children and the undiscriminating recommendation, if not requirement, that all U.S. children and infants be hepB vaccinated and perhaps, consequently subjected to risk for responding adversely.

In addition, the general effectiveness of a vaccine does not necessarily justify its mass administration among infants and young children, when the duration of its acclaimed effectiveness has not been determined and will likely vary depending on the vaccine recipient.[174] In failing to recognize the importance of evaluating the population groups from which efficacy statistics were derived, health authorities are assuming that all vaccine recipients, regardless of race, culture, diet or any other circumstances respond to the vaccine the same. Since the length of protection offered by the vaccine is likely to vary in different recipients of the vaccine, an accurate assessment of the vaccine's efficacy for U.S. citizens will require an investigation into the length and nature of protection offered by the vaccine as it relates to different U.S. population and age groups, if not individuals, receiving the vaccine.[175]

[174] Response Sheet, *supra* note 10.
[175] *Id.*

In support of the vaccine's effectiveness in protecting children from HBV infection, Dr. Margolis and other governmental authorities, such as the ACIP, point to the success of ongoing hepatitis B immunization programs in other countries, countries in which the disease is endemic.[176] Specifically, Dr. Margolis has referred to the vaccine's efficacy in immunizing Alaska Native infants, who have relatively higher rates of HBV infection than found in much of the U.S. Previous studies showed that 8% to 13% of Alaska Native children were chronically infected with HBV and Alaska Natives had the highest rate of liver cancer in the United States.[177] Since 1983, all Alaska Native infants, beginning at birth, have been routinely vaccinated with the available U.S. licensed hepatitis B vaccines. A study conducted in 1993 found that among such children younger than eleven years of age, none had chronic HBV infection.[178] Other studies conducted among American Samoan children, children in Gambia and children in China have shown that routine hepatitis B immunizations in these population groups have lowered their HBV infection rates by more than 90%. There has also been a significant decrease in liver cancer in Taiwan since the vaccine's introduction.[179] According to Dr. Margolis, such studies "provide evidence that hepatitis B immunization will prevent liver cancer and chronic liver disease."[180]

The vaccine's ability to prevent liver cancer has not been denied. However, it is its ability to do so in particular U.S. populations, without significant risk

[176] *See* Margolis' Testimony, *supra* note 12; ACIP, *supra* note 45.
[177] *Id.*
[178] *Id.*
[179] *Id.*
[180] Margolis Testimony, *supra* note 12.

of adverse side-effects and for a specific period of time, which have been questioned. The evidence offered by Dr. Margolis and the CDC as to the vaccine's success in other countries is interesting in view of the fact that these studies were done in population groups that are genetically distinct from those in the U.S. This is an important fact not only for evaluating the vaccine's effectiveness, but also for assessing the vaccine's safety, as will be further discussed, and for which these statistics are offered in support. To date, Dr. Dunbar finds it to be an "amazing coincidence" that all of the studies touted for the vaccine's long-term safety and many of the studies cited in support of the vaccine's efficacy have been in genetic populations where one would not expect vaccine recipients' immune responses to the vaccine or the virus to be similar. It has long been established that the genetic response to the virus and the vaccine in Alaskan populations is distinct from those of other populations. [181] Therefore, the studies cited by Dr. Margolis, while persuasive, should be evaluated in the context of the genetic populations in which they were conducted. Since Caucasian populations are experiencing the most severe adverse reactions to the vaccine, separate epidemiology studies, whether for the vaccine's efficacy or safety, need to be carried out for Caucasian populations before one can truly assess the benefits or risks of administering the vaccine to them. Dr. Dunbar anticipates that a genetic inquiry into the large number of carriers and non-responders found

[181] Dr. Dunbar letter to Dr. Kane, author of articles published in the *Proceedings of the International Congress: Action towards Control of Hepatitis B as a community Health Risk*," heavily relied upon by federal health authorities. This symposium was made possible by an educational grant from SmithKline Beecham Biologicals, Rixernsart, Belgium. Dr. Kane is also the director of the hepatitis vaccine program at the World Health Organization (WHO). Letter obtained from Dr. Dunbar [hereinafter Kane Letter].

in foreign population studies would demonstrate that an epidemiological study in such distinct genetic populations would not be representative of responses by the Caucasian populations of England, France, Canada and the U.S. — the populations reporting the most severe adverse reactions to the vaccine and for which these foreign efficacy statistics are cited in refutation.[182]

The importance of particularizing generalized statistics of the vaccine's efficacy according to specific population groups being vaccinated is further amplified by the fact that immunological reactions against the hepatitis B virus as well as to the antigen used in the vaccine have been shown to have great genetic variability. Approximately 10% to 30% of vaccine recipients will not respond to the vaccine.[183] This response, or rather lack thereof, has been shown to be related to the genetics of the immune system[184] and numerous studies have showed a genetic predisposition by vaccine non-responders.[185] Moreover, some scientists have discovered significant histocompatibility genetic linkages among patients who are experiencing severe reactions following their receipt of the hepB vaccine as opposed to those who do not respond to this vaccine at all.[186] Just as the vaccine's efficacy varies according to different recipients of the vaccine, those reporting adverse events as a consequence of vaccination vary with respect to when they believe such adverse events were triggered – some occurring after the first, second or not until after the third injection.[187] Furthermore, for some

[182] *Id.*
[183] Response Sheet, *supra* note 10.
[184] *Id.*
[185] Information obtained from Dr. Dunbar.
[186] *Id.*
[187] Response sheet, *supra* note 10.

non-responders to the vaccine who underwent further boosters, these adverse reactions became even more severe.[188]

In light of such considerations, the vaccine's efficacy for U.S. citizens would be more accurately evaluated if particularized according to discrete U.S. population groups vaccinated. Even if the percentage of those who do not respond to the vaccine is relatively small when compared to the vaccinated population at large, the significance of these individuals must not be easily dismissed or glossed over in assessing the vaccine's efficacy. This is especially important when these statistics are advanced to support the vaccine's safety for particular groups of individuals for whom its risks may far outweigh its benefits. Moreover, without considering the particularities of the discrete genetic population groups in which the vaccine is being administered, health authorities may be overlooking significant evidence hiding in the genes of those who do not respond to the vaccine, which may help to explain why some individuals are responding adversely to it. Clearly, our ability to fully understand the vaccine's effects, both positive and negative, and the spectrum of responses to the vaccine, including those reporting life threatening adverse responses, will require further investigation into the genetic make-up of those vaccinated. Given the genetic basis of the immune response to HBsAg and the genetic relation of those reporting adverse events attributable to hepB immunization, genetic typing may also prove valuable for predicting the failure of the vaccine in some individuals who contribute to the U.S. HBV disease burden, by engaging in risky behavior thinking that they are

[188] *Id.*

protected from HBV infection when they are not, as well as for screening out individuals who may be at a heightened risk for responding adversely to the vaccine.

Even if the vaccine is shown to be effective in protecting specific population groups within the U.S. from HBV infection, a more accurate appraisal of the vaccine's efficacy must also take into account the length of time for which such protection is offered, especially since it relates to the justification given in support of the mass vaccination of all newborns and young infants. While the vaccine has been shown to generally protect against HBV infection, it does so "for an as yet undetermined length of time."[189] The 1998 Physician's Desk Reference[190] description of the Merck Recombivax HB vaccine states that the "the duration of the protective effect of Recombivax HB in health vaccinees is unknown at present and the need for booster doses is not yet defined."[191] The same can be said for Smith Kline Beecham's Engerix-B vaccine since it is essentially identical to Merck's vaccine. In contrast to those individuals who *may* respond to the vaccine and *may* become virtually protected against clinical illness for an *undetermined* length of time, those individuals whose immune systems' meet and neutralize the virus develop *life long immunity* to it (approximately 95% of all adults who are exposed to the virus). [192]

Of significance to the justification advanced for the vaccination of newborns and young infants is the assertion made in the *CDC Prevention Guidelines: A Guide*

[189] Response sheet, *supra* note 10.
[190] *Id.*
[191] *Id.*
[192] *Id.*

to Action (1997), that

> The duration of protection [of hepatitis B vaccine] and need for booster doses are not yet fully defined. Between 30% and 50% of persons who develop adequate antibody after three doses of vaccine will lose detectable antibody within seven years but protection against viremic infection and clinical disease appears to persist.[193]

In his recent statement before the U.S. House of Representatives Committee on Government Reform on May 18,1999, Dr. Margolis asserted that a "number of follow-up studies have shown that the initial 3-dose immunization series provides protection from HBV infection for years. These studies have followed more than 2,000 persons, vaccinated either as infants, children, or adults and the periods of follow-up have ranged from five to fifteen years."[194] While he avows that "all studies indicate that immunity is long-term, and may be lifelong,"[195] he fails to specify the population groups from which such statistics were derived and the duration of the vaccine's efficacy when administered to different population groups, accounting for factors such as race and age. In support of the vaccine's duration efficacy, Dr. Margolis theorizes that even though immunized people may lose antibody circulating in their blood, such individuals still can be protected from chronic HBV infection as immune cells of vaccinated individuals remember that they were vaccinated and consequently, rapidly produce antibodies when exposed to HBV.[196] Dr. Margolis, however, never claims that such immunologic memory lasts forever or at least as long as needed to confer protection for a vaccinated infant when the infant, if ever, becomes susceptible

[193] Happens to You, *supra* note 17.
[194] Margolis' Testimony, *supra* note 12.
[195] *Id.*
[196] *Id.*

to infection many years later. Thus, if immunity only lasts seven years or even as long as fifteen years,[197] and if teenage transmission of HBV is a concern, newborns vaccinated at birth or early infancy will require additional boosters, if not the entire vaccination protocol, at an age when they might be susceptible to acquiring HBV. In light of these considerations, it seems that the CDC has endorsed an ineffective, if not unwarranted, strategy to eliminate HBV transmission among adults at risk of contracting HBV by immunizing all infants who are currently not at a significant risk for contracting the disease, may never be at risk and may not be adequately protected by the vaccine administered during their early infancy if they ever are.

In sum, it is highly improbable that a U.S. newborn has any significant risk of contracting hepatitis B as a child, other than being born to an infected mother, because the disease is caused by a blood-borne virus. It is hard to believe that 30% of people who claim they have no idea how they acquired HBV were infected as infants and are not able to point to some time or situation in their sexual or drug history when they may have been exposed to the virus. Obviously, newborns are not likely to engage in intravenous drug use or promiscuous sex. Nor are they likely to suffer an accidental needle stick, as might a health care worker. Nevertheless, all newborns, not just those at risk of contracting HBV, have been commanded to receive the HBV vaccine before leaving the hospital. This obligation is justified, in part, on the assumption that all babies may grow up to be drug addicts or engage in promiscuous sexual behavior and that vacci-

[197] CDC Fact Sheet, *supra* note 51.

nating them now will protect them when they do engage in such risky behavior. However, the only way that U.S. born infants are likely to be exposed to the disease is by being born to an already infected mother. Given that serious doubts and perhaps dangerous concerns persist with respect to the vaccine's long term efficacy and its safety, public health efforts should be focused on reducing the HBV disease burden among those really at risk for contracting and transmitting the disease, rather than targeting those who are not given the choice to voluntarily participate or have the ability to resist the mass vaccination efforts that assault them. Innocent babies should not have to bear the burden of those who engaged in risky behavior and are irresponsible in protecting themselves or others from infection.

If the disease burden among children and young infants is as significant as some health authorities have asserted, then it may be better to focus our public health efforts and resources on improving universal screening procedures for all pregnant women to determine whether their babies should be vaccinated, on the basis of being HBsAg positive, engaging in high risk behavior, or emanating from a country in which the virus is endemic. The *Merck Manual* (1992), a major medical reference used by physicians, asserts that "postexposure vaccination is recommended for new born infants of hepatitis B positive mothers."[198] Perhaps as this reference suggests, all newborn infants should not be vaccinated, rather only those at risk of contracting HBV. Although selectively screening pregnant women for HBsAg has failed to identify a proportion of HBV infected

[198]Happens to You, *supra* note 17.

mothers,[199] the ACIP underscores that universal prenatal testing measures has the potential to identify an estimated 22,000 HBsAg-positive women and could consequently prevent at least 6,000 chronic HBV infections annually.[200] Given the failure of governmental authorities to substantiate claims as to how infants acquire the disease, other than by perinatal transmission, or bear a large HBV disease burden as a result, routine screening of all pregnant women for hepatitis B infection is one of the most important public health measures that can be taken to reduce the incidence of chronic hepatitis B cases in the U.S., especially if it is attributable to infections acquired in early infancy as some public health officials have contended.

REINFORCING SCREENING PROCEDURES AS AN ALTERNATIVE TO COMPELLING HEPB VACINNATION

Studies conducted in California, Connecticut, Kansas and the United States for the year of 1992-1993 found that although maternal HBsAg screening is well integrated into routine prenatal care, screening of pregnant women and reporting of results to health care providers is not complete in many geographic areas in the U.S. and there remains much room for improvement.[201] Inadequate immunoprophylaxis of infants born to HBsAg positive women is related to the failure of health practitioners to adequately document maternal screening results in the delivery room.[202] Additionally, the U.S. health care system's failure

[199] ACIP, *supra* note 45.
[200] *Id.*
[201] Maternal Hepatitis B Screening Practices, available at <http://ch.nus.sg/MEDNEWS/may94/7163_7.html> (citations omitted) [hereinafter Maternal Screening Practices].
[202] *Id.*

to adequately screen and treat infants exposed to HBV can be attributed to the selective practices of pediatricians. In focusing on ACIP's screening recommendations for certain racial and ethnic groups, many pediatricians may have been missing a substantial proportion of mothers who are HBsAg positive.[203] Deficiencies in screening programs are especially important, since the prevalence of chronic HBV infection among infants is higher among those born to women who have not been screened or who have not received prenatal care.[204] It is interesting that unlike the majority of states requiring that children be vaccinated, only a few states have enacted maternal HBsAg screening laws. Such state inaction is especially troublesome when national surveys have suggested that state laws improve HBsAg screening practices.[205] It makes one wonder why states are concentrating their efforts and resources on enacting laws which mandate that all young children be vaccinated against a disease which they are not generally at risk of contracting, rather than on improving universal screening measures which could identify those that are. If our goal is to prevent the spread of HBV, and preventing perinatal HBV transmission is necessary to accomplishing this goal, then we may better serve our aim by sustaining efforts to effectively screen HBV infected pregnant women, rather than by dispersing efforts and resources among different health policies. This is especially true when some of these policies may not only be unwarranted, but also potentially dangerous for a specific group of patients for whom the benefits of receiving the vaccine do not outweigh the risks of contracting HBV or responding adversely to the vaccine. Specifically, public

[203] *Id.*
[204] *Id.*
[205] *Id.*

health resources and efforts should be focused on better educating health care providers of the importance of screening all women for HBsAg and perhaps, enforcing such behavior through law. In addition, hospitals should develop policies to ensure that all women are screened for HBsAg before delivering their baby, prenatal screening is performed for women without previous HBsAg screening results, and that infants born to HBsAg positive women receive appropriate medical treatment and are reported to local health departments.[206] Hospital policies should also ensure that maternal screening results are documented in infants' medical records and conveyed to subsequent child care providers. Finally, legislators should be provided with information and support that could be used in drafting laws requiring that all pregnant women be screened, as opposed to mandating that all infants be vaccinated.[207]

RECOMMENDATIONS NOW MANDATED: CURRENT STATE AND LOCAL IMMUNIZATION LAWS

In an effort to reduce vaccine preventable diseases in the United States, state and local counties have passed immunization laws, following the questionably justified ACIP and AAP infant and childhood vaccination recommendations. State laws requiring immunization date from the early 1800s, when Massachusetts enacted a smallpox vaccination requirement for its residents. The 1960's and

[206] *Id.*
[207] *Id.*

1970's marked the modern era for school and licensed day care immunization laws, as states tried to eliminate measles in the United States.[208] Critics of the federal policy argue that before vaccines were introduced in the early 1900's, deaths and injuries from childhood diseases in technologically advanced countries, such as the U.S., were already declining because of better sanitation, nutrition and health care. Although vaccination measures have been credited for eradicating smallpox and eliminating polio from the Western Hemisphere, success deserving great applaud, there is a scientific question as to whether the success of some vaccines against certain diseases should be employed as a seal of approval so as to justify the administration of all vaccines against all diseases among all age groups –categories encompassing varying characteristics and proclivities. Moreover, human vaccination may not effectively eradicate some viruses and bacteria that also live in animals, such as HBV. More threatening is the fact that some viruses and bacteria are adaptable and can change their character in order to resist our efforts to eradicate them. One example is the way some bacteria have changed their character and become resistant to penicillin and other antibiotics. This may have been the case in the late 1980's when, after two decades of measles vaccination in the U.S., a more virulent type of measles was seen in an outbreak among children and adults.[209] HBV has threatened to do the same, as seen by lamivudine's decreasing effectiveness in

[208] David Satcher, M.D., Ph.D., Assistant Secretary for Health and Surgeon General, U.S. Public Health Service, Department of Health and Human Services, Statement before the U.S. House of Representatives Committee on Government Reform (Aug.3, 1999), available at <http://www.house/gov/reform/hearings/healthcare/99.08.03/satcher.html> [hereinafter Satcher].

[209] Alan Phillips, *Dispelling Vaccination Myths*: *a documented report,* available at <http://www.livelinks.com/sumeria/health/myth2.html> [hereinafter Dispelling Vaccination Myths].

treating HBV infection.[210]

All school and licensed day care immunization laws are state based. In the U.S., there are no federal laws mandating immunizations for school entry and day care attendance. The U.S. Supreme Court has affirmed the right of states to pass and enforce compulsory immunization statutes, and has upheld the constitutionality of state vaccination laws. While all fifty states have school immunization laws in effect, the specific vaccines, number of doses and vaccine schedules required vary by state.[211] Exemptions to immunization laws also vary by state. All states allow exemptions for medical reasons, forty-eight states will accept religious exemptions and approximately fifteen states will consider philosophical exemptions in some instances.[212]

So far at least forty-two states and the District of Columbia have laws requiring childhood inoculation in some form against HBV infection.[213] Although hepatitis B is not highly contagious in the general population, except in adults engaging in high risk behavior, and is not in epidemic form in the United States, many state health departments are treating hepatitis B like smallpox or polio. In fact, several state health departments and schools are requiring that children receive appropriate doses of the hepB vaccine before being admitted into school and others are threatening unvaccinated students with expulsion if they do not comply.

[210] AMA Fact Sheet, *supra* note 11.
[211] Satcher, *supra* note 208.
[212] The following states allow a philosophical exemption to vaccination in some instances: Arizona, California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Rhode Island, Utah, Vermont, Washington and Wisconsin. *See* NVIC, at <http://www.909shot.com/statemandates.html>.
[213] *Id.*

The low incidence of hepatitis B in some states preceding the spreading contagion of state mandates has led some parents to question why their state is following in this mass vaccination haul. For example, in Autumn of 1999, each kindergarten child in Ohio was obliged to receive the hepatitis B vaccine and the mandate is expected to eventually cover all students. Ohio already had a very low incidence of hepatitis B before the vaccine was mandated. Nearly two-thirds of Ohio's counties reported no new HBV cases in 1996 or 1997. Of the 120 new Ohioan hepatitis B cases reported in 1996, zero cases occurred in children under age ten. In 1997, only two of Ohio's ninety-four reported HBV cases occurred in children under age ten (one case in an infant, whose infection was presumably acquired from an infected mother). Moreover, more than 99% of Ohioans do not even carry the virus.[214] Similarly, in 1997, the Illinois Department of Health issued an order requiring that all 5^{th} and 6^{th} graders report on the first day of school with either proof that they have received three doses of the hepatitis B vaccine or else face expulsion. In 1996, 335 cases of HBV were reported in Illinois with only ten cases reported in children under fourteen years of age and only five like cases were reported in 1997.[215] These statistics have left many parents in Illinois to question why their state is commanding that more than two and a half million Illinois children receive three doses of the hepatitis B vaccine, at a cost of $40 per shot, to prevent five to ten cases of hepatitis B in children under the age of fourteen when hepatitis B is not highly contagious or in an epidemic form among the general population, and especially

[214] Kristine M. Severyn , *Hepatitis B vaccine for Ohio's Kindergartners Unnecessary, Wasteful*, CINCINNATI ENQUIRER, Friday, Jan. 15, 1999 [hereinafter Severyn].
[215] Fisher Statement, *supra* note 2.

not in this young age group.[216]

The validity of state mandated requirements has also been questioned in states with higher incidences of hepatitis B. For example, a Californian law became effective in July of 1999, which required that students entering the seventh grade obtain the three shot series. Without proof of immunization, students would not be allowed to attend school. Hepatitis B shots are also required for children attending childcare or entering kindergarten in California. In San Francisco, where there were approximately 3,000 intravenous drug users under the age of thirty, there were only twenty-three reported cases of hepatitis B in 1996 for this age group. The youngest victim was seventeen. While the number of hepatitis B cases may be higher, unreported cases would probably affect the incidence of HBV infection among drugs users and promiscuous individuals who would not want to admit the source of their infection, rather than represent the disease burden borne by young children under the auspices of parental and physician care.[217]

In furtherance of this mass vaccination effort, some states are enacting hepatitis B vaccine legislation to shield such bills from the public eye.[218] Other states are even using false and misleading information to ensure and encourage parental compliance. For example, in December of 1998, Tennessee was working on plans that would require children to be immunized against HBV before entering kindergarten. To fuel future compliance with this requirement,

[216] *Id.*

[217] *Hepatitis B Vaccines Debate Growing over Immunization of Young People*, HEPATITIS WEEKLY, Jan. 12, 1998.

[218] *See* Severyn, *supra* note 214.

Tennessee promulgated and publicized unsubstantiated and inaccurate justifications for vaccinating young infants and children. Specifically, it frightened parents with the assertion that HBV can be easily transmitted, simply by "sharing . . . household utensils like razors, toothbrushes, or silverware."[219] Moreover, the state reassured parents that the "vaccine is meant to be effective for at least thirteen years, so Tennesseans inoculated as kindergartners could still be protected when they reach their teens and are more likely to be sexually active."[220] As explained before, such justifications are unfounded and specious. The disease has not been shown to be casually transmitted through these means. Even if the vaccine is *meant* to provide long lasting immunity, its durational efficacy has not yet been determined.

In sum, many state health boards are treating hepatitis B like smallpox or polio and are thus, promulgating rules requiring its vaccine's use. Most states have even gone so far as to enact quarantines which exclude children from attending school in order to control the transmission of an infectious disease among a group not otherwise significantly infected. In targeting millions of innocent newborns and children for mandatory vaccination procedures, instead of specifically focusing on those suspected of carrying the disease, many parents believe and are declaring that their human rights and those of their children are being unnecessarily compromised, if not violated.[221] In fact, some parents who have refused to vaccinate their children have been charged with child neglect and

[219] *Pediatrics (HBV immunization) Tennessee T0 go Ahead with Mandatory Hepatitis B Vaccine*, HEPATITIS WEEKLY, Monday Dec. 7, 1998.
[220] *Id.*
[221] *See* Fisher Statement, *supra* note 2.

threatened that their children will be taken away if they do not comply with the state mandated vaccine. Without proof that their children have been vaccinated, some parents have been denied food stamps, welfare benefits and even health insurance. Traumatically, other parents have been coerced into vaccinating their children with the same vaccine they believe has possibly injured or killed another one of their children. Parents are not the only ones feeling state duress. Doctors have called the NVIC, wanting to give medical exemptions to children they thought were at a significant risk of reacting adversely to the vaccine; in fear of being harassed by state health officials, many failed to do so.[222] Moreover, despite their formal recognition, many school board officials have not accepted religious exemptions in practice. Traumatized and in constant fear that public health officials will take away their partially vaccinated children, parents no longer believe that they have a choice in the governance of their children's or in their own lives. While our human rights are defended by religious canons and our U.S. constitution, state mandated vaccination laws and efforts to enforce them have psychologically transported many American parents to some third world dictatorship, rather than making them feel grounded in "America, where respect for individual human life and freedom and the right to obey our conscience says everything about who are as a people and as a nation."[223]

[222] *Id.*
[223] *Id.*

ALLEGED SIDE EFFECTS OF AND ADVERSE REACTIONS TO THE HEPB

THE STANCE OF PUBLIC HEALTH AUTHORITIES

The growing number of states mandating the hepatitis B vaccine for newborns and young children intensifies the importance of assuring that the vaccine is safe. Otherwise, in mandating vaccination protocols without substantially testing and adequately addressing vaccine safety concerns, states may be, in effect, subjecting children and infants involuntarily to a national experiment. Despite this concern, many federal authorities and health practitioners share in Dr. Margolis' belief that the hepatitis B vaccines are "among the safest vaccines we have."[224] In support, the CDC and other health authorities advocate that the vaccine has been shown to be very safe with minimal side effects. Most health authorities cite pain at the injection site (3% to 29%) and/or mild fever (1% to 6%) as being the most common side effects of the vaccine.[225] However, they attribute even these mild side effects to the injection event and not to the hepatitis B vaccine, itself.

In support of the vaccine's safety, federal authorities point to results of pre-licensure studies, which did not detect severe adverse events and report local reactions to be greater in persons receiving the vaccine than in those receiving a placebo or another vaccine. [226] Additionally, mild side effects were not observed to occur more frequently among children receiving both the hepatitis B vaccine and the DTP vaccine, than among children only receiving the DTP vaccine. [227]

[224] Margolis' Testimony, *supra* note 12.
[225] *See* AMA, *supra* note 11; CDC Fact Sheet, *supra* note 51.
[226] CDC Fact Sheet, *supra* note 51, citing references dated 1980 and 1989, respectively.
[227] ACIP, *supra* note 45.

Dr. Margolis finds further support for the vaccine's safety in post-licensure studies which have similarly "not shown a scientific association between hepatitis B vaccination and severe neurological adverse events."[228]

Beyond clinical trials, the CDC,[229] AMA[230] and ACIP,[231] find support for the vaccine's safety in the fact that more than 20 million persons have received the hepB vaccine in the United States and more than 500 million persons have received it worldwide. In contrast to the prevalence of the vaccine's administration, the CDC considers serious side effects reported after receiving the hepatitis B vaccine to be "very uncommon."[232] Even though a low rate of anaphylaxis (hives, difficulty breathing, shock) has been observed in vaccine recipients based on reports to the Vaccine Adverse Event Reporting System (VAERS), the CDC estimates that the incidence of such reactions is low – namely one in 600,000 vaccine doses distributed.[233] In support, the CDC contends that only one case has been reported in 100,764 vaccinated children (ten to eleven years of age) with the recombinant hepB vaccine in British Columbia and no cases were observed in 166,757 children hepB vaccinated in New Zealand.[234] Though offering such statistics in similar support of the vaccine's safety, the ACIP concedes to the limitations of relying entirely on the data of these foreign studies. The large scale vaccination programs conducted for infants in Taiwan, Alaska and

[228] Margolis' testimony, *supra* note 12.
[229] *See* CDC Fact Sheet, *supra* note 51.
[230] *See* AMA Fact Sheet, *supra* note 11.
[231] *See* ACIP, *supra* note 45.
[232] CDC Fact Sheet, *supra* note 51.
[233] *Id.*
[234] *Id.*

New Zealand often used the plasma-derived hepatitis B vaccine, rather than the recombinant form, and more importantly, systematic surveillance for adverse reactions has been limited in these foreign populations.[235] Notwithstanding the purported low incidence of anaphylactic reactions as a consequence of the hepB vaccine, the CDC still warns of their life threatening nature and urges that further vaccination with the HepB vaccine be contraindicated in persons with a history of such reactions after receiving a previous dose of the vaccine.[236] Overall, however, federal health authorities find refuge from these safety concerns in the significant number of HBV doses administered worldwide as compared to the significantly fewer numbers of serious adverse reactions reported thereto. Such statistics, federal health authorities contend, suggest that the vaccine is coincidentally, if at all, related to reports of adverse reactions purportedly caused by this vaccine.

VIEWS OF VACCINE CRITICS

Health authorities are overlooking a biologically plausible underpinning for adverse reactions to the hepB vaccine and are disregarding positive rechallenges of such events in vaccine recipients

Contrary to the conclusions reached by many federal health authorities, scientists and patients have not found that " the hepatitis B vaccines have been shown to be very safe when given to infants, children or adults."[237] Both the

[235] ACIP, *supra* note 45.
[236] CDC Fact Sheet, *supra* note 51.
[237] *Id.*

published studies of reactions to viral infections, such as HBV, and the temporal relationship of the vaccine's administration with the onset of adverse events reported thereto strongly suggest to critics of the federal policy that these adverse events are related to the nature of the viral protein contained in the recombinant surface antigen, the principal component, of the vaccine.[238] Supporters of the mass vaccination of newborns and infants, like Dr. Susan Ellenberg, of the FDA, would more readily attribute causality to an adverse event following the administration of a vaccine if the event conforms to a specific clinical syndrome whose association with vaccination has strong *biological plausibility* and the event recurs on re-administration of the vaccine (*positive rechallenge*)[239] – the existence of both are subjects of disparate views and a polemic debate.

Many scientists believe that public health authorities are disregarding a biologically plausible mechanism by which the vaccine can induce the adverse events reported as following its administration. It is apparent that the hepatitis B virus (and the vaccine developed from the hepatitis B surface antigen) is unique from many other viruses and vaccines. In the late 1960's, patients with high titers of infectious HBV were found to have a specific antigen, associated with three types of particles. The antigen present on the outer part of one of the particles is referred to as the hepatitis B surface antigen (HBsAg) and its antibody is referred to as anti-HBsAg. Both the plasma and the recombinant

[238]Kane Letter, *supra* note 181.

[239]Susan S. Ellenberg, Director, Biostatistics & Epidemiology Division, Center for Biologics Evaluation and Research Food and Drug Administration, Department of Health and Human Services, Statement before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, U.S. House of Representatives, May 18, 1999 [hereinafter Ellenberg].

vaccine contain this antigen. While the recombinant vaccine cannot cause the disease of Hepatitis B as we know it, the vaccine does contain this protein found on the virus' surface, which initiates immune system reactions to that surface when an individual is exposed to the virus. Thus, while the recombinant vaccine cannot cause the HBV disease, the protein which it contains can stimulate the immune system so as to cause life threatening autoimmune conditions, similar to those manifesting in people suffering from HBV.[240]

It has long been established that viral infections, like that which causes the Hepatitis B virus, can be associated with autoimmune diseases. Experiments performed within the past sixty years on animals demonstrate that polypeptide chains of the types found in viruses that are homologous or nearly homologous with myelin can cause demyelination and that the viruses themselves can cause demyelination.[241] Some studies have showed that there are some HBsAg peptides (as used in the HBV vaccine and found in the HBV virus) that have strikingly similar regions to myelin proteins.[242] Moreover, the hepatitis B infection itself has been shown to cause autoimmunity, demyelination and other polyneuropathies, resembling the adverse reactions reported as a consequence of the vaccine.[243] Additionally, immune complexes containing HBsAg have been found in patients with acute and chronic hepatitis B and immune

[240] Response sheet, *supra* note 10.
[241] For a discussion of such research see <http://www.waisbrenclinic.com>, Dr. Waisbren , *How safe is universal hepatitis B vaccination* [hereinafter Waisbrenclinic], citing numerous scientific studies and reports [citations omitted].
[242] Dunbar's Proposal to the NIH, *supra* note 6.
[243] *See* Waisbrenclinic, *supra* note 241.

complex diseases leading to exrtrahepatic manifestations, which are similar to those reported by hepatitis B infected subjects. Reports of extrahepatic adverse reactions to the hepatitis B virus infection include the following reactions,[244]

Adverse reaction/Diagnosis	**Reference**
Systematic "Lupoid hepatitis," Systemic lupus erythamotsus	Borisova and Krel, 1992; Chng et al., 1993
Arthritis (polyarthritis, rheumatoid arthritis)	McCarty and Ormiste, 1973; Gocke, D., 1975; Duffy et al., 1976; Onion et al., 1971; Wands et al.,1975; Chistau and Helin, 1987; Morris and Stevens, 1978; Pease and Keat, 1985; Tsukada et al., 1987; Ytterberg, 1993.
Vascular Disorders (Vasculitis, polyarteritis, Erythema nodosum)	Gocke, D. 1975; Sarent et al., 1976; Duffy et al., 1976; Trepo et al., 1974; Michalak, 1977; Maggiore et al., 1983; Di Giusto and Bernhard, 1986; Tsukada et al., 1987; Rogerson and Nye, 1990.
Guillain Barre Syndrome	Neirmeijer and Gips, 1975; Penner et al., 1982; Tsukada et al., 1987; Tabor et al., 1987
Demyelinating disorders (optic neuritis, demyelinating neuropathy etc.)	Galli et al., 1986; Tsukada et al., 1987; Inoue et al., 1994; Achiron, 1994
Chronic Fatigue	Berelowitz et al., 1995
Glomerulonephritis	Venkataseshan et al., 1990

In the past thirty years many medical authorities have discussed and warned about possible neurological complications associated with hepatitis B vaccines, partly in recognition of the extrahepatic manifestations of the HBV disease and their possible relation to the HBV surface antigen used in the vaccine.[245]

[244] Dunbar's Proposal to the NIH, *supra* note 6.
[245] *See* Waisbrenclinic, *supra* note 241.

As early as 1974, in an article entitled "Hepatitis Vaccine: A note of caution," Zuckerman warned that autoimmunity could follow the administration of the hepatitis B vaccine because the disease [HBV] involved autoimmunity.[246] Moreover, he urged a "careful assessment of all vaccine effects on the immune system."[247] As late as 1988, just before the federal policy to vaccinate all newborns was promulgated, Hilleman, sometimes called the "father" of the hepatitis B vaccine,[248] cautioned:

> [T]he message from the hypothetical hepatitis B example is the administration of antigens or monoclonal bodies that directly or indirectly raise antibodies that attach to cell receptors **may carry large liabilities** even though they might provide a convenient means for preventing viral access to host cells.. **antibodies attached to cell receptors may invite the same kind of adverse response that are believed to be responsible for a variety of autoimmune disorders** (emphasis added).[249]

More recently in 1996, Burton A. Waisbren, M.D., a cell biologist and infectious disease specialist who is a founding member of the Infectious Disease Society of America and was the past President of the Infectious Disease Society of Milwaukee, pointed out in the Wisconsin Medical Journal that

> there is an increasing number of reports in the referred medical literature about demyelinizing diseases occurring after an individual has received the hepatitis B vaccination. . . since the hepatitis B virus itself has been reported to cause autoimmune problems, should we not be wary of giving antigens that seem to have triggered these problems?[250]

The following includes a representation of published reports of autoimmune type adverse events associated with the administration of the hepB vaccine: ***lupus*:** Tudela & Bonal (1992); Mamoux & Dunont (1994); Guiserix (1996);

[246] *Id.*
[247] *Id.*
[248] *Id.*
[249] *Id.*
[250] *Happens to You, supra* note 17.

arthritis, including polyarthritis and rheumatoid arthritis: Christan & Helin (1987); Hachulla et al. (1990); Rogerson & Nye (1990); Biasi et al. (1993), (1994); Vautier & Carty (1994); Hassan & Oldham (1994); Rheumatic Review (1994); Gross et al. (1995); Pope et al (1995); Cathebras et al. (1996); Soubrier et al. (1997); ***Guillain Barre Syndrome (GBS)*:** Shaw et al. (1998), Tuohy (1989); ***Vascular Disorders* (vasculitis, polyarteritis, erythema nodosum, cryoglobulinemia uveitis)**: DiGuisto and Bernhard (1986); Fried et al., 1987; Goolsby, 1989; Cockwell et al. (1990); Rogerson and Nye, (1990); Poullin & Gabriel (1994); Mathieu et al. (1996); Carmeli and De-Medina, 1993; Mathieu and Krivitsky (1996); Graniel et. al (1997); ***demyelinating disorders such as optic neuritis, Bell's Palsy, demyelinating neuropathy, transverse myelitis and multiple sclerosis***: Ribera and Dukta (1983); Shaw et al. (1988); WHO (1990); Reutens et al. (1990); Herroelen et al. (1991); Nadler (1993); Brezin et al. (1993); Mahassin et al. (1993); Kaplanski et al. (1995); Baglivo et al. (1996); Marsaudon & Barrault (1996); Berkman et al. (1996); Devin et al. (1996); Dunbar et al. (unpublished observations); Senejoux et al., (1996), Bonfils et al. (1996); Manna et al. (1996); Waisbren (1997); ***diabetes mellitus*:** Poutasi (1996); Classen (1996); ***Chronic fatigue***: Salit (1993); Delage et al. (1993) and **other diseases/symptoms**: Biron et al. (1988); Trevisani et al. (1993); Germanaud et al. (1995); Tartaglino et al. (1995); Macario et al. (1995) Senejoux et al. (1996); Noble et al. (1997).[251] Though not an all-inclusive illustration of what scientists conjectured prior and subsequent to the

[251] *Id. See also* Waisbrenclinic, *supra* note 241 for many other related references.

mass vaccination policy, such research and the cautionary statements elicited from them, at the very least, warranted a scrupulous follow up investigation of what was regarded by several to be highly suspect and potentially dangerous.

The majority, if not all, of the side effects reported to the recombinant hepatitis B vaccine are the same or similar to those reported as extrahepatic manifestations of the virus itself. Moreover, as Hauser et al. (1987) indicate in the text titled "Adverse Events of Childhood Vaccines," (1993), "the antibodies after infection with hepatitis B virus or after administration of plasma derived vaccine or recombinant vaccine are all alike in terms of their ability to elicit protective determinants that are active against all subtypes of the virus... " and that "the results of the trials of recombinant vaccine are much the same as those of trials of the plasma-derived vaccine." [252] Although these authors acknowledged that studies were not designed to assess serious adverse events, the authors expressed that "overall the number of examples of adverse neurological outcomes following receipt of hepatitis B vaccine are of concern, particularly those resulting in demyelinating neurologic disease."[253] The similarity between the adverse manifestations to HBV and both vaccines, despite the fact that the recombinant hepB vaccine involves a different form of glycosylation than the native viral protein, has suggested to some scientists that these reactions share a genetically influenced immune complex mediated pathogenesis.[254]

[252] Dunbar's Proposal to the NIH, *supra* note 6.
[253] *Id.*
[254] *Id.*

This hypothesis is further supported by substantial evidence of strong associations between

Moreover, experiments have shown that the HLA patterns of animals have been shown to influ

This is significant in light of the strong genetic association with the immune response to the he

A recent report presented at the National Rheumatology entitled, "An epidemic of rheumatoid

Moreover, in 1996, Montinari et al. published a study in Italy evaluating thirty children and ad

Montinari's work to identify genetic predispositions for reacting adversely to the hepatitis B va

Specifically, the results obtained by Alper et al. supported the authors' "hypothesis that the pr

Moreover, the authors concluded that the genetic markers they identified were most prevalent

Other studies have shown that amounts of antibody produced in response to HBsAg are geneti

Particularly interesting is the fact that there are genetic linkages among patients reporting seve

Therefore, these and other studies make evident that individuals are likely to have a genetic pr

consistent with the findings of Alper et. al., epidemiological study of the vaccine's safety in oth

The vast majority of individuals reporting adverse effects from the vaccine are describing similar symptoms, including rash, joint pain, chronic fatigue, neurological demyelinating disorders, neuritis and rheumatoid arthritis as well as lupus or multiple sclerosis type syndromes.[266] These severe side effects are asso-

[255] *Id; see also* Waisbrenclinic, *supra* note 241.
[256] Waisbrenclinic, *supra* note 241.
[257] Dunbar's Proposal to the NIH, *supra* note 6.
[258] Dr. Dunbar, Letter to Dr. Lashof , Committee chair of the Presidential Advisory Committee on Gulf War Veterans Illness [hereinafter Lashof Letter].
[259] Happens to You, *supra* note 17.
[260] Dunbar's Proposal to the NIH, *supra* note 6.
[261] Happens to You, *supra* note 17.
[262] *Id.*
[263] Dunbar's Proposal, *supra* note 6.
[264] *Id.*
[265] Personal communication from Dr. Dunbar.
[266] I. Grotto, Y. Mandel, M. Ephros, I. Ashkenazi and J. Shemer, *Major Adverse Reactions to Yeast-Derived Hepatitis B Vaccines – a* review, VACCINE, vol. 16, no.4, at 329-334 [hereinafter Grotto]; personal communication from Dr. Dunbar upon investigating reports to the Vaccine Adverse Event Reporting System and receiving personal reports from physicians

ciated with genetically driven autoimmune responses, much like those of which HBV infected individuals complain. New information has suggested means by which the peptide structure of the protein, used in the vaccine and derived from HBV, may initiate the primary autoimmune responses to the HBV virus and its vaccines.[267]

To explain the apparent adverse reactions to the vaccine, Dr. Dunbar and many scientists postulate that by a process called "molecular mimicry" the hepatitis B surface protein, used as an antigen in the recombinant vaccine (HBsAg), can provoke an autoimmune attack on a similar protein found in the nerves or other tissues of a genetically susceptible group of vaccine recipients.[268] The molecular mimicry theory suggests that pathogens, like viruses and bacteria, can trigger autoimmune diseases when a person's immune system makes a grave mistake. Confusing foreign proteins with the body's own proteins, the immune system's agents attack the body along with the pathogens they are intended to protect it against.[269] In a 1996 presentation at the Institute of Medicine Vaccine Safety Forum, Dr. Waisbren warned of "molecular mimicry" and the possible dangers associated with using genetically engineered hepatitis B vaccines containing polypeptide sequences that are present in human neurologic tissues, such as myelin. He hypothesized that through molecular mimicry, polypeptides can act as autoantigens and induce autoimmune demyelinating diseases of the brain,

and scientists all over the world.

[267] Dunbar's Proposal to the NIH, *supra* note 6.

[268] *Id.*

[269] For a more detailed explanation of how molecular mimicry works, see *Virus's Similarity to Body's Proteins May Explain Autoimmune Disease*, Science Times, New York Times Dec. 31, 1996 [hereinafter Times].

such as multiple sclerosis.[270] The theory that molecular mimicry between viral and self antigens could, in some instances, initiate autoimmunity has gained increasing acceptance in the past few years.[271] Although for a long time, some individuals did not believe that molecular mimicry was possible, recent research has shown otherwise.[272] Moreover, some scientists are even reporting that various other diseases, such as Lyme disease, the Herpesvirus or the Coxsackie virus, are inducing arthritis, Multiple Sclerosis like symptoms, and diabetes through such mimicry – much like the diseases and symptoms reported by those infected with the HBV virus or injected with the vaccine.[273]

Despite the skepticism of vaccine endorsers as to the biological plausibility of the molecular mimicry hypothesis, Dr. Dunbar and others find further support for questioning the vaccine's safety in the "positive rechallenges" of adverse reactions in vaccine recipients, confirmed upon re-administration of the vaccine. In addition to the dozens of publications tying the virus, as well as the vaccine, to autoimmune and other connective disease disorders, patient reports made to the Vaccine Adverse Event Reporting System (VAERS) provide further evidence that this viral antigen may be related to the autoimmune diseases it has been notoriously assigned to cause. Between October 1990 and September 1991, 700 hundred reports of adverse reactions to the hepatitis B vaccine were sent to

[270] Happens to You, *supra* note 17.
[271] *See* Waisbrenclinic, *supra* note 241 and numerous references cited; Dr. Dunbar's proposal to the NIH, *supra* note 6.
[272] *Id.*
[273] *A Shadow Falls on Hepatitis B Vaccination Effort,* SCIENCE, July 31, 1998, vol. 281, at 630-31[hereinafter Shadow Falls].

VAERS.[274] Sixteen percent of these reports were of damage presumed to be to the myelin of the nervous system. There were twenty-one cases of facial paralysis and six cases of Multiple Sclerosis (MS).[275] Eighty-two of the complications occurred in patients who received the plasma derived vaccine and eighteen occurred in those who received the recombinant vaccine. This difference can be explained by the fact that the recombinant vaccine had just been introduced into general use.[276]

More generally, for the twenty month period between November 1, 1990 and July 31, 1992, there were 4,227 reports of side effects from the hepatitis B vaccine made to the Vaccine Adverse Events Reporting System. Of this number, 383 were characterized as serious, fifty-seven as life threatening, 241 cases resulted in hospitalization, 108 individuals were disabled and 17 had died.[277] The FDA estimates that only ten percent of doctors report vaccine injuries and deaths.[278] Given that these reports were obtained during a time when the hepB vaccine was only recommended, as opposed to mandated, the numbers of actual injuries and deaths occurring today as a consequence of hepB vaccination are expected to soar in comparison.

Specifically, the numbers of adverse events reported in children responding to the vaccine has intensified the concern with respect to the vaccine's safety, especially in light of recent state mandates. While many adults in fear of adverse

[274] Waisbrenclinic, *supra* note 241, receiving data from VAERS through the Freedom of Information Act.
[275] *Id.*
[276] *Id.*
[277] *Id.*
[278] Dunbar's Testimony, *supra* note 4.

reactions have a choice to protect themselves from hepatitis B, or rather the vaccine, the state mandated and government endorsed hepatitis B vaccination schedule for infants and young children may be subjecting innocent children and infants to what some have called a "dangerous and scientifically unsubstantiated policy."[279] Independent analysis of raw computer data generated by the government operated Vaccine Adverse Event Reporting System (VAERS) confirms that in 1996, there were 872 serious adverse events reported to VAERS in children under fourteen years of age who had been injected with the hepatitis B vaccine. The children were either taken to the hospital or an emergency room, had life threatening health problems, were hospitalized or were left disabled following vaccination. Of these cases, 214 of the children had received the hepatitis B vaccine alone and the rest had received the hepatitis B vaccine in combination with other vaccines. In 1996, forty-eight children were reported to have died after they were injected with the hepatitis B vaccine, thirteen of whom had only received the hepatitis B vaccine before their deaths.[280] In infants who died under one month of age, most of the deaths were classified as SIDS.[281] Prior to this mass vaccination call, the syndrome of SIDS never struck infants this young and SIDS is officially defined as death occurring in infants older than one month of age.[282] More than 6000 children dying of SIDS every year.[283] Many wonder how many of these infants could have died as a result of hepB

[279] Happens to You, *supra* note 17.
[280] NVIC, *Hepatitis B Vaccine Reaction Reports Outnumber Reported Disease Cases in Children According to Vaccine Safety Group*, Press Release, Jan.27, 1999, available at <http://www/909shot.com/prhepb.html> [hereinafter NVIC Press Release].
[281] Philip Incao, M.D., Congressional Vaccine Testimony, available at <http://www.access1.net/via/Vaccine/Drincao/html> [hereinafter Incao].
[282] *Id.*
[283] *Id.*

vaccination. In contrast to reports of adverse side effects occurring in children following their hepB immunization, only 279 cases of hepatitis B disease were reported in children under age 14 in 1996 (*see* graph 1 appended at the end of this section, page 94a).[284] Of these, fifty-four occurred in the newborn to one year old age group in a population of 3.9 million babies born in the U.S. that year.[285]

Hepatitis B disease statistics obtained from eight states provide additional evidence for ques
Moreover, in 1997, New Hampshire reported one case of hepatitis B in children under five year
In that same year, however, there were a total of 106 VAERS reports of hepatitis B vaccine-rel
More generally, between July 1, 1990 and October 31, 1998 there were 24,775 hepatitis B vacci

As indicated previously, Dr. Dunbar has investigated the nature of the more than 20,000 reports of adverse reactions to the hepB vaccine made by patients to the VAERS. She has found that the vast majority of patients reporting vaccine associated complications are complaining of similar, if not identical symptoms (namely joint pain, rash, chronic fatigue, neurological disorders, neuritis, rheumatoid arthritis, lupus like syndrome and multiple sclerosis like symptoms).[290] Dr. Dunbar has divided the adverse events reported by patients and documented in medical journals as following this vaccine into three

[284] NVIC Press Release , *supra* note 280.
[285] Aimee Howd, *Investigative Report: Hepatitis B Vaccine: Ounce of Prevention, Pound of Misery*? INSIGHT, March 22, 1999 [hereinafter Howd].
[286] John Hanchette, *Safety of Controversial Hepatitis B Vaccine at Center of Debate*, available at `<http://www.909shot.com/hepbsafetygannette.html>` [hereinafter Hanchette].
[287] NVIC Press Release, *supra* note 280.
[288] *Id.*
[289] *Id.*
[290] Lashof Letter, *supra* note 258.

major classes of diagnoses: optic neuritis/multiple sclerosis; severe joint pain, frequently diagnosed as rheumatoid arthritis; severe fatigue, commonly diagnosed as chronic fatigue syndrome, post-viral fatigue syndrome, or myalgic encephalomyelitis.[291] Despite the difficulty physicians and scientists experience in precisely diagnosing the adverse events reported by vaccinated individuals, due to overlapping symptoms between such diseases and their syndromes, the reactions reported are nevertheless similar and predominantly range within these category types.[292] Over the past few years, Dr. Dunbar has also been in contact with numerous physicians and research scientists from several countries who have independently described thousands of identical severe reactions occurring in Caucasian recipients of the vaccine. It is apparent from these adverse reaction reports that the same types of adverse reactions are being reported for the plasma and recombinant forms of the vaccine. This is not surprising, however, as explained before, since the same recombinant DNA methods are used to produce both of these vaccines.[293]

Evidence in rebuttal to the AMA's, CDC's, and other health authorities' blanket assertion that "scientific data does not support an association between the hepatitis B vaccine and other neurological diseases" is not limited to the hundreds of thousands of adverse events reported to VAERS as following the administration of the hepatitis B vaccine or even the hundreds of similar documentations made in medical records and scientific journals. The Physician's

[291] Dunbar's Proposal to the NIH, *supra* note 6.
[292] *Id.*
[293] *Id.;* personal communication from Dr. Dunbar; Dunbar's letter to Dr. Kane, *supra* note 181.

Desk Reference and flyers that now accompany the vaccine warn of inflammatory, demyelinating and other disorders that may be caused or induced by the vaccine.

For example, in the 1998 Physician's Desk Reference, SmithKline Beecham included the following statement:

> WARNING: Multiple Sclerosis: In persons with multiple sclerosis, stimulation of the immune system may induce an exacerbation of the disease. Consequently, in persons with multiple sclerosis who have not been previously infected with hepatitis B as demonstrated by serological absence of immunity the benefit of immunization must be weighed against the risk of exacerbation of the disease.[294]

This reference further states that "[a]dditional adverse experiences have been reported with the commercial use of the Engerix-B vaccine. Those listed below are to serve as alerting information for physicians."[295] The list includes anaphylaxis, arthritis, GBS, transverse myelitis, optic neuritis, multiple sclerosis, visual disturbances, and the like.[296] Furthermore, because the FDA did not require drug companies to provide scientific evidence that the hepatitis B vaccine did not compromise the immune and neurological systems of children and adults over weeks, months or years post-vaccination, the length of time required for the type of adverse events being reported to manifest, Merck & Co. warned in their 1996 product insert that "as with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials."[297] Similarly, Smith Kline Beecham warned in 1993 that "it

[294] Dunbar's Proposal to the NIH, *supra* note 6.
[295] *Id.*
[296] Dunbar's Proposal to the NIH, *supra* note 6.
[297] Happens to You, *supra* note 17.

is possible that expanded commercial use of the vaccine could reveal rare adverse reactions."[298] In 1996, Merck further alluded to the possible threat the vaccine could pose to newborns in stating that " it is also not known whether the vaccine can cause fetal harm when administered to a pregnant women or can affect reproduction capacity" and because "it is not known whether the vaccine is excreted in human milk... caution should be exercised when the vaccine is administered to a nursing woman."[299] Furthermore, although doctors sometime administer the hepatitis B vaccine to children along with many other vaccines, Merck stated in its 1996 product insert that "specific data are not yet available for the simultaneous administration of RECOMBIVAX HB with other vaccines."[300]

The expanded, broad use of the hepB vaccines have provided data, meeting the expectations of these warnings. The vaccine manufacturers have warned of disorders, which are similar, if not identical, to those observed in vaccine recipients and post-marketing reports. If these post-marketing reports are not related to the hepatitis vaccine received by these individuals, then the population reporting such reactions is indeed a strange one when one considers the generally low attack rates of these diseases in the general population. Notwithstanding these reports and despite their own warnings, these same pharmaceutical companies continue to ignore or refute post-marketing data in line with the effects alluded to in their precautionary statements. Consequently, the public has been left to believe that such warnings were fueled by the motivations of vaccine manu-

[298] *Id.*
[299] *Id.*
[300] *Id.*

facturers to protect themselves from liability, rather than the individuals who would receive their vaccine. Moreover, in light of these warnings, or rather premonitions, and the refusal of vaccine manufacturers to acknowledge their realization in vaccine recipients, the public is also questioning the reliability and validity of studies being conducted, purportedly to assess the vaccine's safety. Due to inadequate governmental funding, most of these studies are being funded by these same manufacturers. With such considerations in mind, one is left to wonder whether the motivations that instigated the warnings of such entities have similarly sown the seeds of and continue to inspire and stimulate these projects and studies.

Public health authorities rely on inadequate studies

To devitalize the causal import of numerous reports and published data of adverse reactions following the hepatitis B vaccine's administration, the CDC and other health authorities point to studies which have allegedly not shown a scientific association between hepatitis B vaccination and severe neurological adverse events reported thereto.[301] In response and rebuttal to this assertion, many scientists argue that this statement cannot be said. The studies upon which federal authorities rely are outdated and several have been shown to be inadequate with respect to detecting the type of reactions allegedly caused by this vaccine and within the specific population groups thought to be adversely affected. For example, health officials have often cited studies for the proposition "that these [hepB vaccine related] side effects are reported no more frequently among those vaccinated than among persons not receiving the vaccine."[302] Of interest is the fact that the two references upon which this assertion often relies are Szmuneness (1980) and Francis (1982). Both of these references are dated more than ten years before the vaccine was generally administered to children and before the recombinant derived vaccine was in use. Similarly, the assertion that adverse events have not been observed more frequently among children receiving the hepB vaccine in conjunction with the DPT vaccine than among children only receiving the DTP vaccine does not do much to alleviate fears with

[301] *See* Margolis' Testimony, *supra* note 12; CDC Fact Sheet, *supra* note 51; AMA Fact Sheet, *supra* note 11.
[302] *See* CDC Fact Sheet, *supra* note 51.

respect to the vaccine's safety. The DTP vaccine has been said to adversely affect vaccinated children, such as by inducing brain inflammation, permanent brain dysfunction and SIDS.[303]

Moreover, clinical studies quoted in the Pediatric Desk Reference for both the Recombivax HB and Engerix B vaccines were based on studies conducted with observation periods during which one would not likely be able to detect the type of adverse events being reported as following hepB vaccination. In 1986, the FDA gave Merck & Co., and later SmithKline Beecham pharmaceuticals, licenses to market their genetically engineered hepatitis B vaccines in the United States. The FDA allowed both drug companies to use "safety" studies which only included a few thousand children, monitored for four or five days after vaccination.[304] As "proof" of their vaccine's safety, Merck & Co. stated in their 1993 product insert that "in a group of studies, 1636 doses of RECOMBIVAX HB were administered to 653 healthy infants and children (up to 10 years of age) who were monitored for five days after each dose."[305] The length of the short observation period in these studies is significant in light of the considerable body of scientific literature and reports establishing that the adverse effects allegedly triggered by the vaccine, such as polyarthritis, systemic vasculitis, lupus as well as symptoms of multiple sclerosis, are autoimmune in nature. An autoimmune response to an antigen does not normally manifest itself in such a short period of time, such as four to five days, and its detection usually takes longer than

[303] BARBARA LOE FISHER, THE CONSUMER'S GUIDE TO CHILDHOOD VACCINES (1997).
[304] Happens to You, *supra* note 17.
[305] *Id.*

thirty days. Therefore, it would be highly improbable for such clinical studies to have detected the type of autoimmune side effects allegedly caused by the vaccine. [306] Despite the short observation periods of such clinical studies, seventeen percent of all vaccinated individuals with the Merck vaccines still reported systematic complaints, including fatigue and weakness, fever, headache and arthralgia (joint pain)[307] – perhaps marking the genesis and initial developmental stages of what would later flourish into severe autoimmune disorders or diseases of the central nervous system.

Federal reliance upon pre and post-marketing studies for the conclusion that there is no causal association between the hepB vaccine and the adverse events reported as following its administration has been further questioned in light of the historic findings by the Institute of Medicine (IOM) in 1994. At the IOM, physicians and scientists reviewed the medical literature for evidence that vaccines, including the hepatitis B vaccine, can cause a variety of immune and neurological health problems. An independent committee of physician experts concluded that there were no case controlled observational studies or controlled clinical trials conducted on the hepatitis B vaccine either before or after licensure to scientifically evaluate persistent reports of adverse effects that the hepatitis B vaccine can cause, such as SIDS; Guillain Barre Syndrome (GBS); and other central demyelinating diseases, including transverse myelitis, optic neuritis, multiple sclerosis, and immune system dysfunctions, such as chronic arthritis. These are the very diseases being reported as a consequence of HepB

[306] NVIC Press Release, *supra*, note 280; personal communication from Dr. Dunbar.
[307] Happens to You, *supra* note 17.

vaccination.[308] In this report, titled "Adverse Events Associated with Childhood Vaccines," the IOM clearly states the following in the chapter on vaccines:

Conclusion on Biological events following immunization:1. Guillain Barre Syndrome: the evidence is **inadequate to accept or reject a causal relationship** between hepatitis B vaccine and GBS."
2. Other demyelinating Diseases: the evidence is **inadequate to accept or reject a relation** between hepatitis B vaccine and optic neuritis, ms, or transverse myelitis.
3. Arthritis: the evidence is **inadequate to accept or reject a causal relation** between the HepB vaccine and either acute or chronic arthropathy.
4. Anaphylaxis: none of the clinical trials reviewed by the committee **contained information** regarding hepatitis B vaccine and anaphylaxis.
5. SIDS: the evidence is **inadequate to accept or reject a causal relation** between hepatitis vaccine and SIDS.
6. Death: the evidence is **inadequate to accept or reject a causal relation** between hepatitis B vaccine and death from any cause other than those listed above.[309]

The Institute of Medicine further explicitly underscored the limited and inadequate nature of the pre- and post- licensure clinical studies; it stated that " it is important to note that individual trials usually involved a few hundred subjects for study. . . [and]. . . .when larger vaccination programs were monitored, observations of adverse events were necessarily less detailed and less accurately reported."[310] Moreover, they acknowledged that the studies that have been conducted "were not designed to assess serious, rare adverse events; the total number of recipients is too small and the follow up generally too short to detect rare or delayed serious adverse reactions."[311] Surprisingly, public health officials, have relied on these inadequate studies to refute reports of such adverse reactions.

[308] *Id.*
[309] Response Sheet, *supra* note 10.
[310] Happens to You, *supra* note 17.
[311] *Id.*

More generally, a significant conclusion of the IOM report was that almost no basic scientific research has been undertaken to define, at the cellular or molecular level, the biological mechanism of vaccine induced injury or death. The IOM closed its report by declaring that

> the lack of adequate data regarding many of the adverse events under study was of major concern to the committee... the committee encountered many gaps and limitations in knowledge bearing directly or indirectly on the safety of vaccines. These include inadequate understanding of the biologic mechanisms underlying adverse events following natural infection or immunization, insufficient or inconsistent information from case reports and case series, inadequate size or length of follow up of many population-based epidemiological studies... [312]

Despite IOM's conclusion, the CDC and several other public health authorities still maintain, that while reported, there is no confirmed scientific evidence that the hepatitis B vaccine causes chronic illness, including multiple sclerosis (MS), chronic fatigue syndrome (CFS), rheumatoid arthritis, and autoimmune disorders.[313] Not only have public health authorities relied upon surveillance studies which have been proven to be inadequate with respect to being able to detect the type of reactions possibly caused by the vaccine, but several health authorities have also relied upon many studies which were and continue to be conducted in population groups where one would not expect to find the severe side effects being reported by U.S. citizens as a consequence of the hepB vaccine. For example, in support of the vaccine's safety, the CDC refers to evidence of large scale hepatitis B immunization programs in Taiwan, Alaska and New Zealand which did not observe a "clear" association between hepB vaccination and the onset of adverse events.[314] It is astonishing that most, if not all, of the

[312] Happens to You, *supra* note 17.
[313] See CDC Fact Sheet, supra note 51; AMA Fact Sheet, supra note 11.
[314] CDC Fact Sheet, *supra* note 51.

studies that have been touted by federal agencies for long term safety have been in genetic populations where one could predict not to see the autoimmune side effects reported. Specifically, Dr. Dunbar is most interested in the hepB vaccine epidemiological studies performed in Alaska and New Zealand, both of which contain genetically unique populations groups.[315] This is particularly interesting in view of the long established scientific belief that the genetic responses to the hepatitis B virus and vaccine in these population groups are distinct from those of individuals comprising other ethnic and racial populations. Dr. Dunbar and others have been unable to obtain the specific data or experimental design of such studies from those directly involved in these experimentations. Consequently, Dr. Dunbar has persistently asked that federal health authorities supply her with the actual epidemiological data drawn from these studies on which they rely so heavily. Her requests have been ignored or denied. She anticipates that the large number of carriers and non-responders in this population would demonstrate that an epidemiological study in these genetic populations should not be extrapolated for use as being representative of responses by the Caucasian populations of England, France, Canada, and the U.S., who are reporting adverse reactions to the vaccine. Dr. Dunbar's colleagues have also informed her that that the majority of clinical trials conducted for this vaccine were carried out in Asia and Africa. Confirmation of such reports would be critical since scientific literature indicate that these populations also have immune responses that are genetically distinct from those of Caucasians. Since patients

[315] Personal communication from Dr. Dunbar.

reporting adverse events to the vaccine in the U.S. and abroad are primarily Caucasian in origin, one would not expect these population groups to respond similarly to the vaccine.[316] Thus, if epidemiology studies are relied upon and offered as evidence of the vaccine's safety, they must be specifically conducted for the populations for which they are asserted.

Reactions receiving heightened concern

Multiple Sclerosis

Notwithstanding the inadequacies of studies conducted to detect adverse events as a consequence of the hepB vaccine, vaccine manufacturers and federal authorities still continue to deny a causal relationship between the hepB vaccine and the onset of autoimmune and neurological disorders allegedly triggered by its administration. A disorder receiving heightened concern, initially in France and now in the U.S., is that the hepatitis B vaccine may cause Multiple Sclerosis (MS) or at least exacerbate it. Multiple Sclerosis is a disease of the central nervous system characterized by the destruction of the myelin sheath surrounding neurons so as to result in the formation of "plaques." MS is a progressive disease, usually fluctuating between exacerbating and remitting episodes. Most patients either die or experience permanent disability when remissions do not

[316] Dunbar's letter to Dr. Kane, *supra* note 181.

reach baseline levels. The cause of MS is unknown and the most widely held hypothesis is that it occurs, like diabetes, in patients with a *genetic* susceptibility. Some environmental factors may trigger "exacerbations." MS is three times more common in women than men and its diagnosis is usually made in young adults. [317]

As with other diseases allegedly caused or induced by this vaccine, the CDC and other federal authorities believe that unsubstantiated case reports and media attention fuel unwarranted concern with respect to this vaccine, rather than valid scientific studies. Despite the significance of IOM's conclusions, the CDC, AMA and ACIP still continue to maintain that the scientific evidence to date does not support the suspicion that HBV may cause MS or other similar demyelinating diseases affecting the nervous system. [318] In his statement before Congress in August of 1998, Dr. Margolis professed the conclusion reached by the National Multiple Sclerosis Society after analyzing French studies; he stated that according to the "view of the medical advisory board of the National Multiple Sclerosis Society, there is no current evidence of a link between hepatitis B vaccine and MS."[319] Apparently, the European Viral Hepatitis Prevention Board and the World Health Organization reached similar conclusions.[320]
The CDC and other federal public health authorities have relied upon some of the following reasons in dismissing a possible causal relationship between hepB

[317] CDC Fact Sheet, *supra* note 51.
[318] *See* AMA Fact Sheet, *supra* note 11; CDC Fact Sheet, *supra* note 51; ACIP, *supra* note 45; PHAS, *supra* note 24; Margolis' Testimony, *supra* note 12.
[319] Margolis' Testimony, *supra* note 12.
[320] *Id.*

vaccination and cases of MS which follow.

First, extensive pre-licensure clinical trials did not document such an effect.[321] Second, the CDC considers the hundreds of millions of immunized MS free persons as providing negative evidence for any possible causal link to the vaccine. Furthermore, the CDC has suggested that causation issues should be viewed within the framework of generalized vaccination efforts and success, rather than in the context of individual cases. In this purview, if vaccination causes MS, the CDC believes that it does so only rarely.[322]

Third, some studies in MS patients have shown that exacerbations of MS appeared to be more frequent after nonspecific viral illnesses, presumably caused by the generalized stimulation of the immune system that occurs with such infections, rather than being induced by the vaccine.[323] While there have been reports of exacerbations of MS following the immunization of persons who already had MS, the CDC and AMA contend that there is no evidence establishing that the vaccine has increased the rate of MS in otherwise healthy persons.[324] Furthermore, these authorities relegate U.S. and French findings of temporal associations between MS and the administration of the hepatitis B vaccine as being mere instances of expected coincidence, given the large number of vaccinations administered worldwide.[325] As with all case reports, the CDC denigrates such evidence as only constituting possible signals of a causal association, requiring confirmation by further controlled studies.

[321] ACIP, *supra* note 45.
[322] CDC Fact Sheet, *supra* note 51.
[323] CDC Fact Sheet, *supra* note 51.
[324] *Id.*
[325] *Id.*

Fourth, the CDC concedes that determining whether the hepatitis B vaccine actually causes an overall excess of MS in the vaccinated population as opposed to being just one of multiple possible triggers for MS in genetically susceptible individuals can only be evaluated in a population-based study, which has not yet been conducted.

Fifth, MS cases occurred before there was a hepatitis B vaccine.[326]

Sixth, the prevalence of MS is highest in Europe and North America where the prevalence of HBV infection is at its lowest.[327]

Seventh, natural HBV infection is not a risk factor for the development of MS.[328]

Finally, the CDC believes that the autoimmune nature of MS diminishes the plausibility of the "molecular mimicry" hypothesis, the leading theory explaining the possible biological mechanism by which the vaccine can drive the adverse reactions reported thereto. MS is autoimmune in origin, meaning that it involves a disease in which the person's antibodies attack the body's own myelin (a sheath that covers the nerves). The CDC contends that the molecular mimicry hypothesis requires that the hepatitis B vaccine be somehow similar to the three dimensional structure of the myelin in vaccinated individuals in order to provoke the formation of anti-myelin antibodies. According to the CDC, recent research using genetic sequencing (not yet published), has not shown such similarity between the hepatitis B vaccine and the myelin basic protein so as to be able to induce a MS response.[329]

[326] *Id.*
[327] PHAS, *supra* note 24.
[328] *Id.*
[329] CDC Fact Sheet, *supra* note 51.

In light of all this evidence, the CDC concludes that "while a potential association cannot currently be ruled out, such an association seems uncommon and the risk low. Given the risk and severity of hepatitis B disease, the benefit to risk ratio is heavily in favor of hepatitis B vaccination."[330]

Despite federal health officials' rejection of a causal relationship between the vaccine's administration and either the induction or exacerbation of MS, a number of published reports have linked the hepatitis B vaccine with ensuing episodes of MS, MS-like, or demyelinating polyneuropathies.[331] Moreover, in the 1998 Physician's Desk Reference, SmithKline Beecham included the following statement:

> WARNING: Multiple Sclerosis: In persons with multiple sclerosis, stimulation of the immune system may induce an exacerbation of the disease. Consequently, in persons with multiple sclerosis who have not been previously infected with hepatitis B as demonstrated by serological absence of immunity the benefit of immunization must be weighed against the risk of exacerbation of the disease.[332]

Furthermore, in 1997 individuals from the WHO, CDC, NIH, Walter Reed Army Institute of Research, various academic institutions, Pasteur Merieux Connaught (PMC), Pasteur Merieux MSD Joint Venture, Smith Kline Beecham, and Merck & Company, INC., met to discuss the safety of the hepatitis B vaccines, especially as they relate to MS. Dr. McFarland of the NIH affirmed that molecular mimicry is a possible etiologic factor of MS. In contrast to what the CDC contend, he explicitly emphasized that the theory of molecular mimicry does not require that the vaccine exactly match of the amino acid sequence

[330] *Id.*
[331] *See* Response Sheet, *supra* note 10, for citations to numerous studies.
[332] Dunbar's Proposal, *supra* note 6.

structure or have a similar spatial configuration to the myelin of vaccinated individuals.[333]

As with other studies offered by federal health authorities to deny a causal relationship between the vaccine and the adverse events reported, Dr. Dunbar has desperately attempted to get the data for the studies performed in France, relied upon by so many U.S. health authorities, such as the CDC and WHO, as establishing that there is no correlation between the vaccine and MS. Of no surprise, her efforts have proved futile. CDC members have admitted to Dr. Dunbar that they have never seen the data on which they so rely. In response to Dr. Dunbar's simple requests for such documentation, some federal health authorities told this vaccine developer that her views "belong in church and in anti-vaccine meetings."[334] Moreover, a French colleague of Dr. Dunbar has informed her that many French scientists believe the study to be a "joke," and that French scientists are under "gag orders" not to talk about it.[335] It is surprising that these studies continue to be cited and publicized, even though they are quite inconsistent with the findings of other respected French scientists and physicians. For instance, physician Philippe Jacubowicz, who heads an organization in Paris called REVHAB, has collected data on more than 600 cases of

[333]Study Group on Hepatitis B Vaccines Minutes, obtained from Dr. Dunbar. A meeting was held on March 21, 1997 in Georgia to discuss the available information on the possible association between the hepatitis B vaccine and multiple sclerosis and to consider plans for future epidemiological studies. Participants included individuals from the World Health Organization (WHO), Centers for Disease Control (CDC), National Institutes of Health (NIH), Walter Reed Army Institute of Research, various academic institutions, Pasteur Merieux Connaught (PMC), Pasteur Merieux MSD Joint Venture, Smith Kline Beecham, and Merck & Company [hereinafter Study Group].

[334]Dunbar's letter to Kane, *supra* note 181; personal communication with Dr. Dunbar.

[335]Personal Communication with Dr. Dunbar.

illnesses, many with MS like symptoms, in people who have received the hepatitis B vaccine.[336]

Similarly in the U.S., FDA officials have identified more than 111 MS cases in VAERS reports.[337] Consistent with the conclusions reached by other federal health authorities with respect to the vaccine's safety, the FDA maintains that a review of the medical records from these cases do not prove that they were actually caused by the hepB vaccine. This view is espoused despite the suggestion by other evidence that the actual number of possible MS like cases caused by the vaccine is significantly higher than what is reported to the FDA or documented in clinical trials and studies. Interestingly, it appears that the CDC, WHO, FDA and drug companies are dismissing many reported adverse reactions as "not being MS."[338] As with other blanket statements made by such officials, such assertions cannot be made. The term "multiple sclerosis" is in most cases not accurately diagnosed and many doctors do not even agree on the definition of this disease.[339] In the 1997 study group on hepatitis B vaccines, Dr. McFarland of the NIH spoke of the inherent difficulty associated with diagnosing MS. Since the "MS" disease includes many polyneuropathies, cases of MS can be dismissed or mis-diagnosed as being a specific polyneuropathy which it in fact encompasses. Dr. McFarland even suggested that scientists and physicians use "optic neuritis" as the initial demyelinating diagnostic event of MS in further studies.[340] While this condition may have heretofore been dismissed as not be-

[336] Shadow Falls, *supra* note 273.
[337] *Id.*
[338] Personal Communication from Dr. Dunbar.
[339] Personal letter from Dr. Dunbar.
[340] Study Group, *supra* note 333.

ing MS, Dr. McFarland recommended that this event be used "because it was relatively easy to diagnose and because a high proportion of these individuals would go on to develop MS."[341]

Accurately diagnosing or detecting a case of MS is further complicated by the fact that the course of MS is variable and often unpredictable and "MS" is essentially a diagnosis requiring two neurological episodes separated by time and space involving the central nervous system. Additionally, since there are no specific diagnostic tests for MS and many people have the active disease before any clinical symptoms become apparent, Dr. McFarland believes that clinical manifestations or reports of the disease represent only the "tip of the iceberg" of MS cases actually occurring or being documented in clinical studies, if any have in fact been appropriately done.[342] Therefore, while it may be more correct to speak of the adverse events possibly causally related to the vaccine collectively as polyneuropathies, since many of the reports are autoimmune reactions, including arthritic and demyelinating disorders, it is important to note that many of the cases dismissed as not being MS or not detected as MS in clinical studies may be indeed cases of MS attributable to hepB vaccination. Consequently, this consideration saps the force of many, if not all, of the reasons proffered by health authorities to deny a causal relationship between MS and the vaccine; the majority, if not all these reasons, depend on the accurate detection and diagnosis of MS by physicians and scientists, an ability demonstrated to be laden with complexities, inaccuracies and difficulties.

[341] *Id.*
[342] *Id.*

Federal health authorities' have attempted to evade the established complexity associated with accurately diagnosing cases of MS by finding refuge in clinical trials which have not documented a causal association between the hepatitis B vaccine and MS. Even if one puts this retreat, demonstrated to be laden with pitfalls, aside, this conclusion still cannot be relied upon in support of the vaccine's safety. As with other adverse events alleged to have been caused or triggered by the vaccine, no appropriate studies have been conducted or published to evaluate such a causal relationship.[343] IOM's landmark report acknowledged, that the "evidence is inadequate to accept or reject a causal relation" between the vaccine and demyelinating diseases, such as MS. However, the report did acknowledge that the "number of reports questioning the relation between one or the other of these [demyelinating] disorders of similar character suggests the need for systematic research."[344] Such research is especially needed since the IOM found that there were no case controlled observational studies or clinical trials conducted before or after the vaccine's licensure to scientifically evaluate persistent reports that the hepatitis B vaccine can cause multiple sclerosis.[345] The 1997 study group on hepatitis B vaccines reached a similar conclusion after discussing the available information on the possible association between the hepatitis B vaccine and MS and considering plans for future epidemiological studies. Specifically, they attributed the complications associated with planning a study to evaluate whether MS is caused or exacerbated by the hepatitis B vaccine to the clinical and epidemiological characteristics of MS,

[343] Response Sheet, *supra* note 10.
[344] Skinner Report, *supra* note 26.
[345] Happens to You, *supra* note 17.

its rare occurrence, and difficulties physicians confront in trying to define it or diagnose, as discussed earlier in this section. In light of these obstacles, they acknowledged that it would have been and continues to be very difficult to design a study with sufficient power to detect a difference in MS cases arising in hepB vaccinated populations as compared to controlled populations. However, participants did agree that future attempts to study MS as it relates to the vaccine's administration, should at least include the following parameters:

(a)

the observation time limit for such a study should be extended to 60 days from vaccination (as opposed to the four to five day limit previously used in many pre- and post- marketing surveillance studies);

(b)

optic neuritis would be useful as targeting the initial manifestation of MS related demyelination, since it is easily diagnosed and frequently heralds the development of MS (implicating many cases which may have been dismissed as not being MS); and

(c)

the control group should be matched for ethnic origins (and possibly geographical differences) because of the strong ethnic and genetic differences associ-

ated with the incidence of MS[346] (this recommendation is especially significant since many of the studies touted for the vaccine's long term safety and efficacy have been conducted primarily in population groups which are genetically distinct from the U.S. population groups reporting adverse reactions to the vaccine).

In addition to the questionable diagnoses and evaluations made by physicians and the inadequate or non-existent clinical trials relied upon by federal authorities, Dr. Dunbar diminishes a remaining reason advanced by several health authorities to dismiss a causal relationship between the vaccine and MS. Specifically, she regards PHAS' and the CDC's assertion that the prevalence of MS is highest in Europe and North America where the prevalence of HBV infection is lowest to be nothing more than a "red herring," if not misleading, unfounded and of no force.[347] In addition to the inherent difficulties associated with diagnosing MS, the apparent reduced incidence of MS and other demyelinating polyneuropathies outside the U.S. is likely to be due to lack of adequate medical facilities for accurate diagnoses. As the CDC has also conceded, systematic surveillance for adverse reactions has been limited in these populations.[348] Moreover, Dr. Dunbar and Skinner explain that while the initiation of polyneuropathic episodes (such as MS) among genetically predisposed populations (e.g., Caucasians of Northern European origin) could be expected to follow occasions of Hepatitis B *vaccination* in these same populations, they would not

[346]Study Group, *supra* note 333.
[347]Response Sheet, *supra* note 10.
[348]ACIP, *supra* note 45.

expect the generalized prevalence of officially diagnosed cases of MS to follow the generalized prevalence of *HBV infection.*[349] The capability of each individual to neutralize a viral infection, such as HBV, is a function of age, race, gender, general and immunological health, and genetic predisposition — all of which vary by geographic location and which may be different from those factors implicated in triggering or causing MS.[350] Superimposed upon all these variations in the way individuals exposed to the virus respond to it is the varying nature of the viral antigen implicated in the infection of each case.[351] Because viral constituents present in blood samples dictate the virus' level of infectivity, levels of infectivity among infected individuals vary widely as well. In light of these variations, the inconsistent and accidental contamination with blood samples (by which HBV can be transmitted) would not necessarily follow and should be distinguished from the purposeful and direct presentation of a consistently immunogenic bolus of a viral antigen to the immune system of a vaccine recipient (as presented by the hepatitis B vaccine, which may cause MS). In the first instance, contamination with blood samples varying widely in infectivity may not be sufficient to induce any transmission of infection or the induction of an autoimmune response in genetically predisposed patients. In the second, the immunization must induce some kind of reaction from any immune system genetically capable of reacting, whether the result is helpful or harmful.[352] In light of such circumstances, one would not expect cases of MS to necessarily

[349] Response sheet, *supra* note 10.
[350] *Id.* (citations omitted).
[351] *Id.* (citations omitted).
[352] Response Sheet, *supra* note 10.

follow the incidence of HBV in a population.

Sudden Infant Death Syndrome

Like MS, the possibility that the vaccine may be contributing to the prevalence of SIDS is receiving increasing attention, especially because of recent state mandates requiring that all newborns and young infants be routinely vaccinated against HBV. In addition to relying on studies conducted in genetically distinct population groups or those which have not yet been conducted to disconfirm the vaccine's potential harm, most of the studies relied upon to determine whether the benefits of administering the vaccine to infants outweigh its risks have concentrated on the adult population, not the population obliged to receive the vaccine. The CDC and other health authorities continue to deny any causal association between the hepatitis B vaccine and SIDS, despite IOM's findings that there is insufficient evidence to deny or confirm such an association.[353] In support of their refutation, the CDC refers to the National Center for Health Statistics, the primary federal organization responsible for the collection, analysis, and report of health statistics, which has shown a consistent decline in new born deaths since 1935 (in infants of one day to thirty days of age). The CDC and Dr. Margolis attribute this decline to great improvements in sanitation, health care and infectious disease control. While infants have been receiving the hepatitis B vaccine routinely since 1991, an examination of newborn death

[353]Response Sheet, *supra* note 10.

statistics reported during this time do not seem to show a rise, but have rather continued to slowly decline.[354] For example, in 1992, the first full year after the hepatitis B vaccine was first universally recommended for infants and when hepatitis B vaccination coverage was 8%, there were 4,800 SIDS deaths. In contrast, when coverage rose to 82% in 1996, the number of SIDS deaths actually decreased to 3,000 deaths. Dr. Margolis attributes this decline to changes made in sleeping positions for infants.[355] Dr. Margolis explained that if the hepatitis B vaccine were a major cause of SIDS, he would have expected an increase in SIDS, not a decrease. Furthermore, both Dr. Margolis and the CDC cast remaining doubts with respect to the vaccine's safety, as it affects newborns, to the forces of chance and coincidence. They avow that statistically, newborn death can occur within twenty-four hours of vaccination by coincidence alone since almost all infants are vaccinated during their first year of life and any infant with a medical illness or who dies is likely to have been vaccinated earlier in life.[356]

Although the statistics to which federal authorities point show a general decline in newborns deaths, classified as SIDS, such statistics do not exclude the possibility that the vaccine's administration among newborns may have decelerated the rate of this "slow" decline or is actually increasing SIDS deaths in infants of certain age groups. One study found the peak incidence of SIDS to occur at the ages of two and four months in the U.S., precisely when the first two

[354]CDC Fact Sheet, *supra* note 51; Dr. Margolis' Testimony, *supra* note 12.
[355]Dr. Margolis' Testimony, *supra* note 12.
[356]CDC Fact Sheet, *supra* note 51, citing views of the American Academy of Pediatrics (AAP) 1995; Dr. Margolis' Testimony, *supra* note 12.

routine immunizations are given.[357] Other studies have invalidated or at least questioned the reliability of studies claiming that there is no SIDS-vaccine relationship when they found that confounding effects skewed results in favor of the vaccine.[358] Moreover, without the vaccine's administration, the decline in SIDS deaths could have been much steeper, if not for the vaccine's side effects, so as to result in a fewer number of newborn SIDS deaths reported today. Furthermore, most of the studies evaluating the risks of the vaccine for newborn infants have been conducted among adult populations. While not much is known with respect to the adult response to the vaccine, as the IOM and many others have concluded, even less is known about the immunological reactions in infants, especially since they cannot communicate about the ailments from which they suffer. Additionally, in the event of deaths following vaccination, there is generally inadequate information collected by pathologists to adequately evaluate reactions in newborns.[359] Furthermore, VAERS data indicates that in infants who died under one month of age following their hepB vaccination, most of the deaths were classified as SIDS. Before the introduction of the vaccine, the syndrome had never struck infants so young and SIDS is officially defined as occurring in infants who are older than a month of age. In the mid 70's, Japan raised their vaccination age from two months to two years; their incidence of SIDS dropped dramatically.[360] With 6,000 children dying from "SIDS" each year, we must wonder how many of these deaths may have been caused by the

[357] Dispelling Vaccination Myths, *supra* note 209.
[358] *Id.*
[359] Dunbar's Testimony, *supra* note 4.
[360] Dispelling Vaccination Myths, *supra* note 209.

hepatitis B vaccine.[361]

In the absence of adequate studies and an understanding of the human response to the hepB vaccine, especially in newborns, we have no idea whether the potential threat posed by the vaccine to newborns is limited to causing short term severe consequences, such as SIDS, or rather whether it embraces long term debilitations, as well. Dr. Dunbar "would challenge any colleague, clinician or research scientist to claim that we have a basic understanding of the human newborn immune system."[362] In view of inadequate scientific and medical information on neonatal immunology, many, like Dr. Dunbar, find it to be remarkable that "newborn infants, especially those not at risk for the hepatitis B disease are being administered multiple injections of this vaccine and that there have been few, if any clinical trials to adequately evaluate the potential long term effects of neonatal immunization, especially as it relates to genetic diversity."[363] Such trials would be critical, especially in view of animal studies well establishing that the newborn system is very distinct from that of the adolescent or adult. In fact, newborn immune systems in animal models have been shown to be easily "perturbed to ensure that [they] cannot respond properly later in life."[364]

Long-term debilitations

[361] Incao, *supra* note 281.
[362] Dunbar's Testimony, *supra* note 4.
[363] *Id.*
[364] *Id.*

Evidence of the vaccine's possible harm towards and consequent need for further study in newborns should not be limited to an evaluation of its short-term effects, namely SIDS deaths. Perhaps, as newborn animal model studies have suggested, the vaccine may be in fact perturbing the ability of vaccinated newborns to respond properly later in life. Evidence of the vaccine's possible long-term harm should be viewed in the context of the overall health of U.S. children since efforts to vaccinate them have begun. Despite advancements in science and increases in adult longevity, the general health of U.S. children has declined significantly since the 1960's, when vaccines began to be widely used. In 1950 (before mass immunizations began), the U.S. had the third lowest infant mortality rate in the world. By 1986 and then in 1995, the U.S. had dropped to the 17^{th} and 23^{rd} place, respectively. Although now first in vaccine compliance through government mandates, as of 1999, the U.S. has dropped to the 24^{th} position in a rating of the overall health of children in different countries.[365] According to the National Health Interview Survey, conducted annually since 1957 by the National Center for Health Statistics, a shocking 31% of U.S. children have chronic health problems, 18% require special health care or related services, and 6.7% have a significant disability due to chronic or mental conditions.[366] Moreover, the rate of disability arising from chronic conditions in children has increased almost four times since 1960. The fact that respiratory allergies, asthma, and learning disabilities comprise the majority of such disabil-

[365] Letter testimony submitted to US Congress by a District Health Services Coordinator (Registered Professional Nurse), supported by the Missouri Central District School Nurse Association [hereinafter Nurse letter].

[366] *Id.*

ities[367] is significant in light of the fact that three controlled studies conducted in England and New Zealand comparing hepB immunized children to those who were not have shown that vaccinated children have significantly more asthma, ear infections, hospitalizations and inflammatory bowel disease.[368] Since vaccinations shift the balance of the immune system towards its chronically reacting side, vaccines may be contributing to the large scale and unprecedented increase in chronic conditions among children, becoming more widespread every day as we add more inoculations to an already crowded list. Such chronic conditions include allergies, asthma, diabetes and neurological dysfunctions, such as learning disabilities.

Barthelow Classen, M.D., CEO of Classen Immunotherapies Inc., has published an epidemiological study in the *New Zealand Medical Journal*, reporting a 60% increase in Type 1 diabetes (juvenile diabetes), from 1988 to 1991, following a massive campaign in New Zealand to vaccinate babies six weeks of age or older with the hepatitis B vaccine. His analysis of 100,000 New Zealand Children, prospectively followed since 1982, showed that the incidence of diabetes before the hepatitis B vaccination program began in 1988 was 11.2 cases per 100,000 children per year, while the incidence of diabetes following the hepatitis B vaccination campaign was 18.2 cases per 100,000 children per year.[369]

This report carries special import in light of the intensifying concern of U.S. diabetes experts who are currently seeing an alarming increase of type 1 diabetes among U.S. children and infants. The Children's Hospital Diabetes Clinic,

[367] Incao, *supra* note 281.
[368] *Id.*
[369] Happens to You, *supra* note 17.

for instance, perceived 1997 as being especially "alarming." More than 50% of newly diagnosed patients were under the age of three. Just recently, the clinic started treating its youngest patient, a six week old baby. As with SIDS, the disease never struck infants this young before. The medical profession first took note of the significant shift in the population of Type 1 Diabetes around 1993, right after the government first promulgated its policy that all newborns be vaccinated with the hepatitis B vaccine. While the medical profession first dismissed the rise as a fluke that would not persist, the numbers keep on growing. At this hospital alone, the diabetic population served has grown from 350 patients in 1990 to more than 800 in 1998. Where the clinic used to see a few newly diagnosed patients a year, they now see more than 100 cases.[370] Type 1 diabetes is genetic and millions of children can carry its genes without ever manifesting the disease. Something is needed to trigger the disease to onset its perils. Internationally and nationally, researchers are pointing to immunization schedules as the culprit and the hepB vaccine as an accomplice.[371]

Recently, a central district school nurse association has written to Congress, asking that the government consider its grave concerns about the hepatitis B vaccine. For the past few years, the nurses comprising this association have noted a significant increase in the number of children entering school with developmental disorders, learning disabilities, Attention Deficit Disorder and/or other serious chronic illnesses such as diabetes, asthma, and seizure disorders.

[370] Janice Kayser, *Children and Diabetes,* FREEMAN, Sept.26,1998 (Media clipping obtained from the NVIC).
[371] *Id.*

They see one common thread. According to these nurses, "they are the children who received the first trial hepatitis B injections as newborns in the early 1990s. As the hepatitis B compliance rate in newborns has gone up in their community, so has the percentage of damaged children."[372] Moreover, these nurses have asserted that while remaining constant in all preceding years, the census of ill children observed in health rooms has increased by 300% in the last four years. Their school district's confidential health statistics indicate that at least 20% of their children have significant neurological damage and/or some form of chronic illness and that the numbers of children with developmental disorders have steeply increased, as well.[373]

Championing the vaccine's possible side effects and the inadequate studies which have been conducted to assess them

Realistically, before public health officials stop HBV immunization, which could save many lives per year and a proper evaluation of the vaccine's benefits and risks can be made, strong evidence is needed that the vaccine causes significant side effects. However, before public health officials initiate a nationally mandated vaccination policy for any vaccine, they should have adequate long-term clinical trials and even stronger evidence that the vaccine has no significant severe side effects in any population, and especially in those in which it

[372] Nurse Letter, *supra* note 365.
[373] *Id.*

is mandated. To date, few studies have been carried out to determine the causes of the serious adverse events allegedly associated with the hepatitis B vaccine. Since the IOM report, none of the recommended studies have been funded by any of the drug companies and none have been reported in the literature.[374] While documentations in medical literature and patient reports do not "prove" that the vaccine is causally related to the adverse reactions reported following its administration, a plausible etiologic link warranting further study is strongly supported, at the very least, by the close temporal relationship between hepB vaccination and the onset of similar symptoms reported in vaccinated patients, the resemblance between the serious reactions to the hepatitis B vaccine and the extrahepatic manifestations of hepatitis B infection, and the possible immune complex mechanism driving the immune response to the vaccine and the virus. Among others, Dr. Dunbar is determined to investigate the possible etiologic link of adverse reactions reported as being caused by the hepB vaccine and her commitment to this endeavor must be applauded. Clearly, in order to establish the immune mediated nature of these phenomena, immune complexes containing HBsAg and antibodies must be identified and studied in recently vaccinated individuals of appropriate genetic and age populations. Dr. Dunbar is studying the immune responses to HBsAg in different individuals developing autoimmune responses, in part to test her hypothesis that subsets of patients having adverse reactions to the vaccine have similar and predictable gene sequences. Additionally, as a researcher and expert in cellular and molecular biology, Dr. Dunbar

[374] Computer searches conducted by Dunbar of the literature from 1966 to present; personal communication received by Dr. Dunbar from other scientists.

is investigating the possibility that molecular mimicry or other autoimmune mechanisms may be the means by which the genetically engineered hepatitis B vaccine "tricks" the immune systems of genetically susceptible individuals into attacking their own bodies so as to consequently cause debilitating autoimmune disorders. She hopes that in researching the long term prognosis for patients having adverse reactions to the vaccine, she will be able to develop a prophylactic strategy for identifying those likely to react adversely as well as specific therapeutic strategies for those who have already responded adversely to the hepB vaccine.[375]

A critic of the molecular mimicry hypothesis, Dr. Marrack has challenged anyone "to take T cells from a live person and show that they react to both self proteins and to a pathogen that mimics self," because "[t]hen you'd know that pathogen started that disease in that person. You'd catch the gun pointing at the right person." So far, according to Dr. Marrack "that experiment has not been done."[376] To meet Dr. Marrack's challenge and in furtherance and in need of her goals, Dr. Dunbar has applied to the National Institute of Health (NIH) for funding. Specifically, she requested that the NIH support her effort to investigate the scientific basis and genetic role of the adverse reactions being attributed to the vaccine, similar to those manifesting in HBV infected individuals. Consistent with the rhetoric professed by several federal health authorities in refutation of the vaccine's potential for harm, [377] the NIH has denied her pro-

[375]Personal Communication from Dr. Dunbar; Dunbar's Proposal to the NIH, *supra* note 6.
[376]Times, *supra* note 269.
[377]CDC Fact Sheets, *supra* note 51; *see* Margolis' Testimony, *supra* note 12; AMA Fact Sheet, *supra* note 11.

posal twice for lack of "epidemiological data" that the adverse reactions being reported are causally associated with the vaccine.[378] Dr. Marrack's comment, the NIH's refusal to fund Dr. Dunbar's studies, and federal health authorities' staunch reliance on the abyss of scientific knowledge insulating this vaccine from censure can all be perceived as casting doubt on the possible causal relationship between the vaccine and the reactions reported thereto or the possible mechanism by which the adverse reactions may be induced. Although potentially debilitating, these responses, however, only fortify and empower the case against the safety of the hepatitis B vaccine by pointing to the powerful catch-22 that pervades and lies at this controversy's core. Scientific evidence has not yet demonstrated a causal relationship between the vaccine and the induction of its reported side effects because no studies have been done to detect such a relationship. No studies have been done because federal health authorities and some scientists still do not believe or will not allow themselves to believe that such a relationship can exist.

In light of this catch-22, it is not surprising that government funds are not being allocated to study adverse reactions possibly caused by this vaccine as it relates to the genetics of those infected with the HBV virus and injected with the vaccine.[379] Moreover, at the recent Institute of Health meeting held at the National Academy of Sciences, it was apparent to Dr. Dunbar that the CDC and the FDA still did not have information pertaining to the role genetics can play in the adverse responses which are believed to be induced by the vaccine.

[378] Personal communication with Dr. Dunbar.
[379] Skinner Report, *supra* note 26.

Dr. Dunbar finds this absolutely remarkable, if not imaginable as a scientist, in light of the long established belief held by the scientific community that the immunological reactions to the hepatitis B virus and to HBsAg, as used in the vaccine, have great genetic variability.[380]

Although the AMA, the CDC, WHO, and other federal agencies continue to assert that no scientific evidence to date supports a causal association between hepatitis B vaccination and demyelinating diseases so as to warrant further study, interestingly, studies are nevertheless being organized in the Vaccine Safety Datalink project at the CDC because of "public concern" about the issue and the insufficient research on this specific topic.[381] Computerized medical records on approximately 5 million or 2% of the U.S. population are being used in this study. Results will probably be available in a year.[382] There are also at least six research projects underway attempting to examine whether a causal relationship exists between the hepatitis B vaccine and MS, at least two of which are funded by vaccine manufacturers.[383] Results will also become available soon. Despite their potential for great informational benefits, the experimental designs of these studies, like those which have preceded them, have been seriously questioned. It is apparent to Dr. Dunbar that new studies being done will not take genetic variability, of paramount importance, into account. The CDC study will be conducted in California, where investigators will not be able to ask about race. Dr. Dunbar has also been told that clinical trials will

[380]Personal Communication with Dr. Dunbar.
[381]CDC Fact Sheet, *supra* note 51.
[382]Margolis' Testimony, *supra* note 12.
[383]AMA Fact Sheet, *supra* note 11; Shadow Falls, *supra* note 273.

exclude anyone who has or has a family history of an autoimmune disease. This is especially worrisome because states are increasingly mandating that all children receive this vaccine when scientists are not performing appropriate studies to evaluate vaccine associated risks for those with a genetic predisposition to such diseases.[384] Surely, no one would agree that such genetically susceptible individuals are less worthy of protection or should be sacrificed in the crusade against halting HBV transmission among drug abusing or sexually promiscuous adults.

Clearly, one cannot evaluate the risk-benefit issue for each population examined unless there is, at the very least, a sufficient and forthcoming exchange of information with respect to the safety of this vaccine or adequate clinical investigations into what initially appears to be potential problems associated with a vaccine that later manifests in the lives of many individuals. Involuntary public human experiments do not suffice. The CDC's study, and others being conducted, must address not only "public" concerns, but also the concerns of physicians, immunologists, epidemiologists, and other basic scientists, such as those of the IOM and those participating in the study group on hepatitis B vaccines.[385] Moreover, such studies should consider as seriously the thousands of "anecdotal reports" of adverse events reported as a consequence of HepB vaccination as the CDC has done in comparing "anecdotal" reports of HBV and HIV transmission related events.[386] Furthermore, these studies should be carried out to determine the long-term prognosis for patients experiencing adverse

[384] Personal communication with Dr. Dunbar.
[385] Response Sheet, *supra* note 10.
[386] *Id.*

reactions to the vaccine so that a prophylactic strategy for identifying those likely to react adversely and therapeutic strategies for those who have already done so can be developed. Individuals who may have a family history of a disease must be included, so that risks can be evaluated for those with possible genetic predispositions. At the very least, such investigations could warn those populations who might have a greater risk for responding adversely to the vaccine. Immunologists and vaccinologists who have the ability to investigate the origins and mechanisms of such adverse events should be funded and allowed to do so. Just as we would not ask nor expect the tobacco industry to conduct unbiased investigation and research into the potential causal relationship between lung cancer and smoking, it is imperative that only individuals not affiliated with or receiving compensation from any of the vaccine manufacturers be involved in these studies. It is clear that the Institute of Medicine is in agreement with the points highlighted and summarized here. In its report, it published that "more research could be done on potential long term adverse effects from vaccines as well as the potential of vaccines to induce or worsen immune disorders."[387] Moreover, it asserted that "[t]he use of larger and better designed clinical trials conducted both before and after a vaccine's licensure for general use could also be considered to improve the rate of detection of rare adverse events" as well as "vaccine recall procedures." [388]

Consistent with the IOM's recommendations, Dr. Dunbar and other scientists are challenging the catch-22 which so powerfully pervades our public health pol-

[387] Dunbar's Letter to Kane, *supra* note 181.
[388] *Id.*

icy. She has obtained limited funding from private sources and will nevertheless undertake her proposed studies in collaboration with an immunogeneticist and a hepatitis virus expert at the University of Oklahoma. She and her collaborators have well-equipped laboratories for state of the art immunological and biochemical analyses and they have already collected blood samples throughout the country from those reporting adverse reactions to the vaccine. Although inadequate funding has slowed the progress of the unique studies which she has initiated, her efforts will persist. Clearly, her studies are critical to understanding the nature and cause of the adverse events being reported as following the hepatitis B vaccine's administration. This and other studies should be carried out to evaluate reports of severe adverse effects as a consequence of vaccination *before* this vaccine is used universally, if not mandated, in immunologically fragile infants who may not otherwise be at a significant risk for contracting or transmitting the HBV virus. In addition to Dr. Dunbar's study, laboratories not associated with drug companies are in the process of investigating etiologic links between the vaccine and rheumatoid arthritis.[389] Epidemiological studies specifically aimed at testing the existence of a relationship between the vaccine and the inducement or exacerbation of autoimmune disorders are being planned, as well.[390] In France, 150 physicians have petitioned the French Academy of Sciences to commission a study by investigators not connected to manufacturers of the vaccine. The Academy endorsed the call for a survey.[391] Scientists

[389]Skinner Report, *supra* note 26.
[390]Dr. Bonnie Dunbar, Dept.Cell. Biology, Baylor College of Medicine (personal communication).
[391]Skinner Report, *supra* note 26.

planning and carrying out these studies (both in the U.S. and abroad) report receiving two and three communications per day (via email, fax, letter, or telephone) from patients and medical personnel asking to contribute their own or their patients' data to the studies.[392] It looks like the quest for scientific truth is underway.

[392] *Id.*

ROLE OF THE VACCINE ADVERSE EVENT REPORTING SYSTEM IN ASS

THE VAERS SYSTEM

Until new scientific research is conducted and results are released, the National Childhood Vaccine Injury Act of 1986, specifically the Vaccine Adverse Event Reporting System (VAERS) which it created, will continue to play an important role in assessing the safety of this vaccine. This national system was designed to collect, manage and evaluate reports of possible adverse events related to vaccination. Initiated in 1990 and jointly managed by the CDC and FDA, VAERS has been instrumental in meaningfully assessing vaccine risks. Considered to be the "front line" of national vaccine safety supervision,[393] it is the only surveillance system that covers the entire U.S. population. Though potentially comprehensive, VAERS is a passive surveillance system, whose success relies on the contributions of physicians, health care providers, parents and vaccine manufacturers to submit reports of adverse reactions that occur during a period following vaccination. VAERS data are available to the public through the National Technical Information Service and also through requests made to the FDA's Freedom of Information office.[394] The criteria for reporting to VAERS are non-restrictive in that the VAERS system will accept and include

[393] Ellenberg, *supra* note 239.

[394] General Information and the VAERS form itself are available on the VAERS Internet web-site. The address is: http://www.fda/gov/cber/vaers.html.

any report, if submitted.

Vaccine manufacturers are required to report every potential adverse event of which they learn; however, they are not penalized for not doing so. Even if reported, documentations of adverse events following vaccination cannot conclusively establish causation, without an extensive follow-up of each serious event and death report made. Careful review, however, of such reports during months following a vaccine's licensure can uncover previously unexpected events or potential problems, only detectable when a vaccine is used in a more diverse population group than originally studied in clinical trials. Thus, this type of system is essential to the discovery of potential adverse consequences because as Dr. Ellenberg notes,

> It is the only surveillance system which covers the entire U.S. population and includes the largest number of case reports of events temporally associated with vaccination in the U.S. It provides timely availability of data from a geographically diverse population, allowing rapid detection of possible new, unusual or rare adverse events. Such detection generates hypotheses that may then be tested in other databases.[395]

Moreover, as an open forum of information for public purview and contribution, the VAERS system has tremendous potential to provide for a greater in-depth understanding of the nature and scope of vaccine associated adverse events. Despite its virtues, noble intentions and potential for success, VAERS is not without criticism. The VAERS system is perforated with problems and leaves much room for improvement. Supporters of the mass vaccination program criticize the VAERS system as being over-inclusive, while critics assert that it is under-inclusive of adverse events possibly induced by the hepB vaccine.

[395] Ellenberg, *supra* note 239.

PERSPECTIVES OF PUBLIC HEALTH AUTHORITIES

Supporters of the federal mass vaccination program do not believe that the number of side effects reported to VAERS establish a sufficient justification for questioning the administration of the hepB vaccine or its safety. The CDC lists at least three major limitations of relying upon VAERS data. First, VAERS accepts all reports of adverse health events which follow vaccination, regardless of the cause. Second, the same case may be reported to VAERS more than once when different people file the same report. For instance, a health care provider, a parent, and a manufacturer may all send VAERS the same report so as to result in several entries of the same case into the database. Additionally, the same report may also be filed separately for different vaccines administered at the same time. Third, the details and diagnosis of a given report may be incomplete or inaccurate depending on a person's access to complete clinical information.[396] Consistent with the stance taken by the CDC, Dr. Margolis believes that case reports of serious adverse events obtained through VAERS often do not represent true consequences of vaccination. While reports to VAERS, jointly managed by the FDA and the CDC, can provide valuable information about serious adverse events that may be associated with a vaccine, he believes that such data can only be used to generate hypotheses, rather than to determine whether a vaccine could actually cause an adverse event. While some patients may develop symptoms of illness subsequent to vaccination, Dr. Mar-

[396] CDC Fact Sheet, *supra* note 51.

golis relegates these symptoms to chance or the recognition of a patient's earlier illness that does not increase the overall risk of that illness occurring.[397] Similarly, Susan Ellenberg, director of the Biostatistics & Epidemiology Division of the Center for Biologics Evaluation and Research at the FDA, believes that "with virtually universal childhood immunization, beginning at birth or shortly thereafter, any adverse medical event in a child will 'follow' vaccination, and some of these will coincidentally follow within a few days of vaccination."[398] As indicated previously, Dr. Susan Ellenberg, of the FDA, would more readily attribute causality to an adverse reaction reported to an event, such as the administration of the hepB vaccine, if:

> 1) the event conforms to a specific clinical syndrome whose association with vaccination has strong *biological plausibility* (e.g. anaphylaxis) ;
> 2) a laboratory result confirms association (e.g., isolation of vaccine strain varicella vaccine from skin lesions of a patient with rash);
> 3) the event recurs on re-administration of vaccine (*positive rechallenge*); and
> 4) a controlled clinical trial or well-designed epidemiological study shows greater risk of adverse events occurring among vaccinated unvaccinated (control) groups.[399]

Dr. Ellenberg believes that few of the serious adverse events reported to VAERS meet any of the first three criteria and that any clinical trials conducted are almost always too small to provide useful information on causality for most rare events. Consistent with the opinions of many federal health authorities, Dr. Satcher, assistant secretary for the Health and Surgeon General (of the U.S. Public Health Service Department of Health and Human Services) believes

[397] Dr. Margolis' testimony, *supra* note 12.
[398] Ellenberg, *supra* note 239.
[399] *Id.*

that it "takes other studies to determine whether or not" reported data are indeed due to vaccines.[400] Nevertheless, he concedes that spontaneous report based surveillance programs, such as VAERS, perform "a critical function by *generating signals* of potential problems that *may warrant further, more detailed investigation*" (emphasis mine). [401]

VACCINE CRITICS CRITICIZE THE VAERS

Critics of the mass hepB vaccination mandates for children are not using VAERS data to conclusively establish a causal relationship between the hepB vaccine and adverse events reported as following its administration. Nor do they use such data as the only link of condemnation. Consonant with the views espoused by several federal vaccine advocates, the NVIC concedes that VAERS reports are simply reports of adverse events which occurred after vaccination. Without full medical record documentation and follow-up of each report, it is impossible to conclusively determine causation.[402]

However, despite such limitations, such reports can be helpful, as even vaccine advocates suggest, in determining the etiologic link of events reported. Critics of the federal vaccine policy are indeed, in Dr. Margolis' words, using VAERS data to "generate hypotheses"[403] and are asking that such data be appreciated for their significance as "generating signals" that "warrant detail investigation,"

[400] Satcher, *supra* note 208.
[401] *Id.*
[402] NVIC Press Release, *supra* note 280.
[403] Margolis' Testimony, *supra* note 12.

as Dr. Satcher has recommended.[404] As previously explained, many reports to VAERS of hepatitis B vaccine related adverse events contain similar symptoms that include fevers, rashes, vision problems, joint pain, muscle weakness, seizures and other autoimmune and neurological dysfunctions. Moreover, many of the deaths listed as SIDS cannot easily be written off as such since they include clinical manifestations that question the accuracy of the SIDS diagnosis. Such data has provoked scientists and physicians to delve deeper and determine whether some deaths and reactions may have been vaccine related. Additionally, the NVIC asserts that while children usually receive multiple vaccines on one day, such has not been the case with the administration of the hepatitis B vaccine. To temper causality complexities, many adults and children have only received the hepatitis B vaccine at the time of their hepB vaccination; therefore, many VAERS reports represent children who only received the hepatitis B vaccine prior to their reported hospitalization, injury or death. Thus, rather than relying on VAERS to provide a link of causal condemnation, NVIC and its supporters merely ask, as Dr. Ellenberg recommended, that "other types of studies" [405] be appropriately performed to determine whether or not the adverse events being reported are related to the vaccine.

As demonstrated in the preceding section of this paper, scientific research has proposed a "biologically plausible" mechanism by which the vaccine may induce adverse reactions in vaccinated patients (e.g., molecular mimicry). Additionally, reports of adverse events following vaccination allude to the existence

[404] Satcher, *supra* note 208.
[405] Ellenberg, *supra* note 239.

of "positive rechallenges," among those receiving the hepB vaccine, especially when one considers the rarity of such disorders in the general population and the cluster of such cases documented in those vaccinated. As adults, in addition to infants and children, continue to suddenly exhibit immune and neurological dysfunction following vaccination, it will be more difficult to convince such patients that they had an underlying genetic or metabolic disorder waiting to be expressed and whose manifestation happened to coincidentally coincide with the administration of the hepB vaccine. As a national sentinel system, VAERS should be used to warn practitioners, government officials and patients that a vaccine may be associated with some health problems, especially when many of the vaccine-related adverse event reports contain similar symptoms – as is the case with the hepatitis B vaccine. More importantly, federal officials should proceed with extra caution before requiring that individuals subject themselves to protocols lighted by possibly portentous signs that danger lies ahead.

Though supportive of VAERS for its enormous informational potential, critics of the federal vaccination policy are not without criticism of the VAERS system. The VAERS system, as currently structured, is highly inadequate to provide the necessary scientific information for which it was created. In analyzing raw computer data generated from VAERS, the NVIC has found that most of the hopes and expectations for increased reporting, better education and prevention of vaccine injuries have not been realized through this system. Specifically, the NVIC has found (1) that most health care providers fail to report such reactions; (2) a lag time exists between the onset of adverse events and the filing of

reports to document them; (3) reports are often filled with data entry errors; (4) reports are duplicated; (5) government officials fail to adequately follow-up reported serious injuries and deaths; (6) some vaccines are still on the market, despite their association with high numbers of adverse event reports.[406] Given these problems, critics of the mass administration of the vaccine believe that the adverse events reported only represent a small percentage of adverse reactions actually occurring in the U.S. as a consequence of the hepB vaccine, namely less than 10%.[407]

While VAERS permits physicians to report an adverse event as long as there is mere "suspicion" that the drug or vaccine may be related to an adverse effect, many have and do not. The success of the VAERS system and other similar passive programs depend on health care professionals' surveillance and voluntary reporting of adverse events following vaccination. Such surveillance, in turn, depends on pediatricians' variable levels of awareness and index of suspicion for such events—levels which have been shown to be deficient in many regards. David Kessler has provided several reasons why physicians do not report serious events to the FDA or the vaccine manufacturer following the administration of a vaccine shot. For example, when confronted with an unexpected outcome from treatment or the administration of a vaccine, many physicians do not consider the reaction to be vaccine induced, but rather consider the event to be related to some other factor or the biology of the vaccine recipient's make-up. Health care practitioner dismissal of possible vaccine related events may be a consequence

[406]Information distributed by the NVIC.
[407]NVIC Press Release, *supra* note 280.

of limited training in therapeutic decision making and clinical pharmacology. Additionally, physicians are not culturally inclined to notify the FDA about adverse events or product problems. Nor do they readily consider drug or device induced disease when confronted with unexpected outcomes; instead, they consider such reactions to be related to the course of the disease. Finally, physicians may be unclear as to what adverse reactions should be reported to the FDA.[408] The FDA has even conceded to the fact that the VAERS system is highly underrepresentative of the number of adverse events of which vaccine recipients actually suffer. FDA statistics indicate that the majority of VAERS reports are made by doctors. However, in 1993, a former FDA commissioner wrote in the *Journal of the American Medical Association* that one study showed that "only about 1 percent of serious events" attributable to drug reactions are reported to the FDA,[409] and other studies have estimated that physicians only report approximately 10% of events related to a vaccine's administration.[410] Moreover, the NVIC presents additional support for the proposition that reports made by doctors to VAERS represent only a small fraction of the vaccine-related injuries and deaths occurring in the U.S. every year. A 1994 NVIC study of 159 doctor offices in seven states found that only 28 out of 159 doctors (18%) surveyed indicated that they submit reports to the government (to any federal agency, such as the FDA, CDC or any health department) when a child suffers a serious health problem following their hepB immunization. In New York, only one

[408] David Kessler, M.D., *Introducing MEDWatch*, JAMA June 2, 1993, vol. 269, no.21, at 2765-2768.
[409] NVIC Press Release, *supra* note 280.
[410] Fisher Statement, *supra* note 2.

doctor out of 40 surveyed reported vaccine related adverse events to any governmental agency. This finding suggests that 97.5% of vaccine related deaths and disabilities go unreported in this greatly populated and vaccinated state. As found in New York, data obtained from the six other states surveyed revealed that few physicians, if at all, report, to any federal agency, whether it be the FDA, CDC, or a local health department.[411]

State	Doctors	Reporting
Arkansas	23	7
California	11	3
Georgia	21	9
Illinois	24	4
Maryland	26	2
New York	40	1
Texas	14	2

A survey of pediatric clinics in Arkansas further illustrates that the problems associated with physician reporting of vaccine related adverse events are not unique to these seven states and probably run rampantly nationwide. Many of the nurses surveyed in Arkansas had indicated that the doctors for whom they worked did not report adverse reactions to proper authorities, if at all, following a patient's vaccination. While a few did believe that adverse events were reported to a health department, a follow-up revealed that most state health department officers did not pass reports of adverse events received to the CDC or any other federal agency.[412] Although fewer than ten percent of all doctors obey the law and report serious health problems experienced by patients following their HepB vaccination, the federal government still receives between 12,000 and 14,000 reports of related hospitalizations, injuries and deaths every year. If this estimation represents less than 10% of what is actually occurring, then the number of adverse events occurring annually as a consequence of the hepB vaccine may exceed 100,000 cases. Thus, the 12,000 to 14,000 annual reports of hepB vaccine related injuries and deaths, often dismissed by federal health authorities as being rare occurrences, may be just the "tip of the iceberg," of what is awaiting to be unearthed by responsible investigation. Clearly, determining

[411] VAERS information obtained from the NVIC (1994 study results) (If the office indicated they report to any federal agency i.e. FDA, CDC, or health department, the report was counted).

[412] Survey obtained from the NVIC of nurses working in health clinics in Little Rock, Arkansas.

what fraction of these unreported events lead or have lead to permanent injury or death cannot be properly assessed without improvements in reporting efforts by health care practitioners.

Sadly, many physicians and medical students have not yet appreciated their instrumental role in maximizing the informational resource potential of the VAERS system. Indeed, many physicians have asked Dr. Dunbar "why should they look at it [the vaccine] or discuss it with their [patient's] parents," since it is recommended and mandated by government officials.[413] Others have said that their colleagues do not report adverse incidences related to hepB immunization because they "don't want to get involved."[414] They further tell her that they have been informed that this vaccine is the safest ever developed because it is a recombinant DNA vaccine and "therefore you can't get the disease."[415] Unfortunately, these health practitioners either misinterpreted or missed a significant aspect of immunology. As explained before, any peptide (a limited sequence of amino acids of a protein) or a full length or truncated protein (produced by purification from a biological source or using recombinant technology) when introduced into the body will be processed by the immune system, and depending on the nature of that protein, could result in long-term autoimmune reactions. Unfortunately, Dr. Dunbar believes that such details of immunology are not taught in medical schools. A senior member of a national health committee, involved in recommending school mandates for childhood vaccines, approached her after a speech she had given to the Institute of Medicine at the National Academy of Sciences. It was apparent that even he needed some brushing up on the basics of immunology, as he commended her on her speech and asked her for some guidance with respect to this aspect of immunology. Thus, it is essential that before we are able to tap into the wellspring of information which lies at VAERS' core and detect adverse events associated with the hepB vaccine, physicians must be better educated on the potential risks associated with this vaccine, its possible interactions with other vaccines and the increased risks that hepB vaccination could impose on already sick or genetically susceptible children.

Insufficient reporting efforts by health care professionals is far from being the only problem plaguing the VAERS system. Scientists attempting to delve deeper into what adverse events are actually reported face a daunting task. Dr. Dunbar first encountered VAERS, after observing two individuals in her laboratory develop serious medical problems following their hepB vaccination. These problems were similar, if not identical in nature, to those listed in the Physician's Desk Reference text as reported reactions to this vaccine and within a time frame predictable for consequential immunological reactions. After paying to obtain reports of similar adverse reactions from the FDA, under the Freedom of Information Act, Dr. Dunbar found herself buried by thousand of pages of documents listing thousands of hundreds of reports identical to those which she had filed. Despite the inadequacies of these reports, the information contained

[413] Dunbar's Testimony, *supra* note 4.
[414] *Id.*
[415] *Id.*

within them did demonstrate a unifying theme. The responses reported neurological damage, arthritis- like symptoms, and other immunological disorders which were not only similar to each other, but also similar, if not identical, to those alluded to in dozens of published medical journals warning of the vaccine's possible ability to cause severe immunological reactions. Although invited and incited by this correspondence to delve deeper into the reactions reported, it seemed as though Dr. Dunbar had extended her welcome. Finding enough information to warrant an extensive follow-up investigation of a causal relationship, her efforts to understand the nature of the events reported and their possible association to the vaccine were severely hampered by the limited data contained within the reports. [416]

While providing a plethora of data, Dr. Dunbar found these lists to be inadequate for the purposes for which they were admitted to the VAERS. Although a pioneering scientist in contraceptive vaccine development, she could not study the mechanisms by which the reported reactions could have occurred. The reports did not and still do not provide essential medical details (e.g., patient identity, genetic background, family history of autoimmune diseases, etc). Nor do they enable one to contact the physicians who reported these reactions. Moreover, there did not seem to be any follow-up action taken on the reactions which she attempted to examine. Consistently, no one had contacted her in response to the reactions she had herself filed. Overall, she found that the information provided by VAERS to be "inadequate and not accessible to those of us who are studying the serious adverse reaction events apparently related to this vaccine."[417]

Physicians and Scientists have not been able to maximize the potential of the VAERS system. Moreover, manufacturers have wielded it to their advantage. Though required to report adverse reactions attributed to their vaccines, manufacturers are not penalized for not doing so. As a consequence, VAERS's potential for success has been left in the grasp of parents who wish they had never entrusted their children's care in the hands of health care providers. Surely, parental reporting to VAERS can help compensate for so many of the inadequacies associated with physician reporting and record documentation. However, in order to be effective, parental efforts and strides must be taken seriously and sympathetically. Public confidence in health care systems, especially VAERS, has already been greatly compromised by the failure of public health authorities to appreciate parental contribution to the detection of adverse events following the vaccine's administration.

Feelings of bureaucratic incompetency overwhelm parents like Michael Belkin, who is left wondering how many other children died during the same time period when his five week old daughter, Lyla Rose, died. Though the world to him, Lyla's death was apparently not significant enough to be counted as a statistic by the FDA. The New York City Coroner called the VAERS to report Lyla's hepatitis B vaccine related infant death, but no one returned his phone call.

[416] *Id.*
[417] *Id.*

If such a reporting system does not return the calls of the N.Y. City Medical Examiner, one can only imagine how many other reports are ignored, as well. If the VAERS is supposed to be the emergency 911 number for disasters of tainted lots of vaccine that could poison thousands of other babies, then children may be in grave danger. Michael Belkin's experience and skepticism of the vaccine's safety is not unique. Several other parents, who similarly believe that their children were injured by the hepB vaccine, are questioning whether the VAERS provides a legitimate sample of data from which conclusions about the safety of the larger population can be made.[418]

Parents, like Mr. Belkin, or the public more broadly, are learning from experience and disappointment that they cannot rely on purportedly reassuring studies or statistics presented by the FDA or other governmental health authorities, which rely on the VAERS. For example, in a hepatitis B vaccine workshop at the National Academy of Sciences (NAS), which Mr. Belkin attended recently, the FDA declared that there were only 19 neonatal deaths reported to VAERS since 1991 allegedly related to the hepatitis B vaccine. He, like many other parents, have deemed the FDA and the "VAERS study data to be completely deceptive."[419] The fact that the "VAERS doesn't return coroner's calls" has led him to believe that "deaths and adverse effects from vaccination are woefully under-reported" and thus, to "conclude that the hepatitis B vaccine is safe because VAERS only reports 19 deaths is scientific fraud."[420] Pursuant to the forum, Mr. Belkin personally obtained raw data from the VAERS system and found 54 cases of SIDS to have been reported following the Hepatitis B vaccine in just the 18 months from January 1996 to May 1997, alone. Indeed, Michael left the NAS workshop with the impression that

> Merck and the CDC didn't know and didn't really want to know how many babies are being killed or injured by Hepatitis B vaccination. This is a bureaucratic vaccination program that is on auto-pilot flying into a mountain. The CDC bureaucrats have a vested interest in the status quo. If there were 17,000 reports of a dangerous disease in an 18 month period, the CDC would be all over the case. But when there are 17,000 reports of adverse reactions to a vaccine (as there were in the 1996-1997 data alone) the CDC advocates for 'public health'– the CDC dismisses it as a coincidence. [421]

Michael Belkin's opinions are representative of the views which are currently pervading the public conscience. A recent letter testimony submitted to Congress by a school nurse concerned about the safety of the hepatitis B vaccine similarly expressed the feelings that the

[418] Belkin, *supra* note 3.
[419] *Id.*
[420] *Id.*
[421] *Id.*

CDC and FDA have no idea what the long term effects will be on the newly developing neurological and immune systems of infants who are injected with this vaccine. They seem to be only concerned with denying the connection between these damaged children and the hepatitis B shot they received within a few hours of birth. [422]

If these voices echo the pain being felt in the hearts of many parents and more broadly, the public, then surely the critics of the federal vaccine policy are not to blame for the deteriorating public confidence in the vaccine or more generally, our public health systems. Time and time again, the public is pointing to the government as the culprit, as they repeatedly find it "red handed" with negligence.

IMPROVING THE VAERS SYSTEM AND THE REPORTING OF ADVERSE EVENTS

Underlying VAERS' unrealized success is a staunch presumption maintained by government officials and vaccine providers that the case reports of deaths and injuries following vaccination are only temporally, not causally related to hepB vaccination and that true vaccine adverse events are rare. By assuming rather than proving that a vaccine did not play a role in causing injuries, causation cannot be conclusively determined or even alluded to so as to warrant further investigation. In being driven by this presumption, Barbara Fisher believes that the Department of Health and Human Services has sadly contributed to the suffering of many vaccine victims through the federal compensation system in order to protect the status quo. In 1996, the Department proposed to add the hepatitis B vaccine to the Vaccine Injury Table (a table listing reactions to vaccines

[422] Nurse's Letter, *supra* note 365.

for which vaccine victims will be compensated). However, it cited "anaphylaxis within four hours" as the only adverse event presumed to be caused by the hepatitis B vaccine, in spite of IOM's conclusion that no scientific studies have ever been conducted to evaluate continuing reports and studies suggesting that the hepatitis B vaccine can cause arthritis, SIDS, GBS, myoptic neuritis, MS, transverse myelitis or other central demyelinating diseases. As a result of this non-causality presumption, health officials, much like those comprising DHHS, fail to fully investigate reports of hospitalizations, injuries and deaths following vaccination and have a standard, or at least release it to the public, for recalling lots of vaccines which are associated with high numbers of hospitalization, injury and death reports. Therefore, it is not surprising that several federal health authorities continue to aver that there is no need to conduct full investigations into individual reports of vaccine induced side effects or be concerned when high numbers of hospitalizations, injuries and deaths are connected to any one lot.

As long as this presumption underlies the VAERS system, VAERS will not enable public health authorities to realize the goals for which it was created, namely adequately monitoring adverse events related to vaccination, gaining knowledge about the nature, frequency, and severity of events following vaccination or being able to adequately recall vaccine lots which may be more reactive than others. [423]

The ramifications of this federally held presumption resonate beyond the ac-

[423] Barbara Loe Fisher, *Statement on HHS Proposed Changes in the Vaccine Injury Table and Qualified Aids and Interpretation of the National Childhood Vaccine Injury Act,* National Vaccine Information Center, May 1996, available upon request from the NVIC.

tual VAERS system and contribute to and exacerbate the problems associated with physician reporting, medical record documentation and follow-up investigations for each adverse event reported. As a result of this presumption, no publicity is generated by the government to inform the public that a federal vaccine injury compensation system exists. As a consequence, many doctors do not know about federal compensation programs, are afraid of costly lawsuits and thus, fail to report hepB vaccine related adverse events. Many American doctors who may be aware of the system still do not know that there is a Vaccine Adverse Event Reporting System; those that do are not likely to believe that a child's health problem reported by a parent following their child's vaccination could have been caused by the vaccine which the physician had just administered to the child. Thus, given that this presumption strings all the way through the U.S. health care system, it surely is not surprising that, at most, only 10 % of physicians ever report adverse events, and when they do, they report little, if any, vaccine related information patient's medical records.

Contemporaneous with such inadequacies, an unknown number of children are reacting poorly to vaccines. Many are suffering permanent injuries or even confronting death. Because their parents may never be told about the VAERS program by the government or by their physicians and their doctors may never recognize or do not want to admit that the vaccine they have administered is causally related to an adverse event of which a child complains, the cause and nature of the child's health problem is often misdiagnosed. Hence, the presumption initiated at the federal level does not halt at the health care

practitioner level either. As a consequence of its effect on physician ideology and concomitant ramification on their reporting and detection abilities, parents are not informed as to how they can identify whether their child has responded adversely to a vaccine or how they can monitor their child's health subsequent to vaccination. Most parents would not even suspect that a vaccine could have caused their child's sudden epileptic episode or death from "SIDS." Nor would they be culturally or intuitively receptive to investigating or questioning the safety of what their *health care provider* is administering to their child to protect their wellbeing. Moreover, the minority of parents who have actually taken the initiative to question and challenge the safety of the hepB vaccine, before it is administered to their child, are often treated with disrespect and hostility; as a reward for their courage, their emotions are only traumatized even more.[424] As this presumption finds reinforcement, many parents educated through the tribulations of experience, like Michael Belkin, are stamped with the impression that "the Drug Company/CDC/FDA alliance has really pulled the wool over the medical profession's eyes with the hepatitis B vaccine"[425] and perhaps, more broadly, over the public at large. Unless the thousands of reports

[424]In her testimony before the Government Reform Committee Hearing on Aug. 3, 1999, Tonya Nelson describes her traumatic experience when her newborn daughter died shortly following the hepB vaccination. The coroner and police treated her "like I [Tonya] had committed a crime. . . they questioned me over and over. It was not the kind of situation a mother should be in when her child had just died." Tonya was called 2 months later and told by the coroner that the cause of her daughter's death was the hepatitis B virus – which she could have only gotten from the vaccine. Sixteen weeks later, she received the death certificate in the mail and the cause of death was noted as "natural causes," otherwise known as "SIDS." When she called the coroner in shock, she had found out that he was asked to resign. A pathologist she was told to call told her to stop trying to find others to place the blame on and to go on with her life. Her doctor told her that she could not help her because malpractice insurance is too expensive. Her phone call messages left with the CDC were never returned. Many like Tonya continue to suffer, with gaping open wounds.

[425]Belkin, *supra* note 3.

of hospitalizations, injuries and deaths following vaccination are taken seriously by vaccine regulators, policymakers, and vaccine manufacturers, the casualties of mass vaccination policies will continue to grow and concomitantly feed into the public mistrust of our public health structures. If public apprehension and suspicion are engrained deep enough within the public conscience, the decay of trust in the American public health landscape may infiltrate other federal health policies so as to spoil legitimate and well warranted ones.

In sum, most of the hopes and dreams for increased reporting, better education, and prevention of vaccine deaths which fueled the creation of the VAERS system have not been realized, despite governmental, scientific, physician and parental efforts. VAERS has raised the red flag, warning us that patterns of similar health problems are occurring following the administration of one vaccine or a combination of vaccines. Such signals must be followed with rigorous scientific investigation. As the IOM concluded, there are "many gaps and limitations in knowledge bearing directly or indirectly on the safety of vaccines." [426] What is clear and cannot be denied is that there is a vacuum of scientific knowledge about how or whether the hepatitis B vaccine causes the adverse reactions reported thereto. This information gap makes "it far too easy for health officials to minimize vaccine risks and write off health problems following vaccination as simply 'coincidentally' occurring at the same time of vaccination or to suggest, without any empirical evidence whatsoever, that the child who

[426] Fisher Statement, *supra* note 2.

reacts is genetically defective."[427]

Indeed, adverse reporting and data collection systems will continue to be flawed as long as the presumption is maintained that case reports of deaths and injuries following hepB vaccination are only temporally, not causally, related to its administration. As Barbara Loe Fisher demonstrates, " if you don't believe they occur or occur only rarely, you wont look for them. If you don't look for them, you won't find them."[428] Clearly, "the success of detection methodologies are entirely dependent upon the willingness of those doing the detecting to believe in the plausibility of cause and effect and explore all possibilities."[429]

Those who oppose the mandatory hepB vaccination schedule for children are not asking that every adverse report be regarded as a causal consequence of hepB vaccination. However, they do believe that to further a goal of detecting actual adverse events rather than dismissing them, we must fundamentally transfigure the presumption which underlies our public health system. It may probably be better to prove that a vaccine did not play a role in an adverse event than to conveniently assume it did not. This change is especially significant where vaccination is mandated for otherwise healthy children. A proper functioning reporting and data collection system will require that this transformed presumption be carried at every step along the way of our public health system, from pre-licensing to post-marketing surveillance of vaccine related injury and from

[427] *Id.*

[428] Opening Statement by Barbara Loe Fisher, Institute of Medicine Vaccine Safety Forum, Workshop on "Detecting and Responding to Adverse Events Following Vaccination," Nov. 6,1995. Available upon request from the National Vaccine Information Center [hereinafter Detecting and Responding].

[429] *Id.*

federal health authority ideology to parental responsivity. A "new or old vaccine should be recognized as having the potential to cause health problems that have not yet been detected because of the limits of human intelligence, technology and funding." [430]

As previously explained, the detection of vaccine induced adverse reactions is inextricably linked to the acceptance of causal relationships by both reporters and data collectors. Consequently, efficient detection of adverse events depends on a high reporting rate by private physicians, public health clinics and emergency rooms of adverse events occurring within thirty days of vaccination. Medical schools should integrate into their curriculums courses on vaccine risks, benefits and side effects as well as ways in which physicians can act as partners with parents in preventing or responding to vaccine induced reactions. Education campaigns should be promoted to emphasize and inform physicians and the public about the importance of screening children at risk for responding adversely to the hepB vaccine, monitoring children after vaccination, seeking medical attention for vaccinees if vaccine related reactions do occur, and reporting adverse events following vaccination to the government. Moreover, health care practitioners must become more amenable to reporting such adverse events to VAERS, rather than merely dismissing them as coincidences. Perhaps physicians should be mandated to report vaccine adverse events and be penalized for not adhering to their responsibilities, much like the mandatory vaccination laws which exclude children from school if they do not comply. Clearly, we

[430] *Id.*

will never be able to detect and understand vaccine related adverse events if health care providers continue to erroneously determine or dismiss causality at the reporting level.

Once death, hospitalization or injury is reported following the administration of a vaccine, data collectors and federal health officials must also be ready to accept the possibility of a cause and effect relationship. According to Fisher, there should be a forty-eight hour on- site follow-up and investigation of the report. Adult patients should be interviewed, while parents of children patients should be questioned. Deaths labeled as SIDS, especially occurring when the infant is less than a month of age, should be considered "suspect" and thoroughly investigated. Additionally, a mechanism should be developed to monitor the outcome of possibly related vaccine serious events, such as seizures, with long term follow-ups being conducted after six months, a year and two years, to gather data on permanent damage – the type which is being reported as a consequence of this vaccine.[431] The mechanisms for detecting adverse events which occur within thirty days of vaccination are different from those which must be set up to detect health problems which have more subtle or delayed onsets; learning disabilities, for example, do not become measurable until children are old enough to attend school. Improved detection of reactions with delayed onsets will require retrospective evaluation of historical data as well as the creation of prospective studies which compare unvaccinated controls to vaccinated individuals over a period of ten to twenty years. While such studies would be

[431] *Id.*

expensive and logistically difficult, they may be necessary if we are to determine which vaccines are contributing to the development of immune and neurological damage in young children, often not becoming apparent until later in life.[432] Since today's children are our country's future, the expenditure of such efforts and resources are well worth the cost.

In addition to improving reporting and follow-up methodologies for adverse events which are possibly vaccine induced, federal health authorities must recognize and appreciate the value of the VAERS system as being another source of significant information for adequately detecting adverse events. Data obtained from the VAERS system are not only valuable for identifying patterns of classic vaccine reactions which warrant further investigation, but are also instrumental for identifying categories of children who should be screened out of mass vaccination programs and who may, otherwise, painfully pay for the politics which gamble with their lives.

[432] *Id.*

FRANCE HALTS THEIR HEPB VACCINATION MANDATE WHEN ALLEGED VICTIMS

In October 1998, France became the first country to suspend a government mandate requiring that school children receive the hepatitis B vaccine protocol. Faced with a potential public health disaster, this halt was taken in response to a plethora of reports of chronic arthritis, neurological disorders, symptoms resembling multiple sclerosis, autoimmune and other serious health problems following the administration of the hepB vaccine. One French physician has reportedly collected data on more than 600 people suffering from serious immune and neurological dysfunctions, many resembling multiple sclerosis, alleged to be induced by the hepB vaccine.[433] Consistent with a 1998 Canadian study published in *The Journal of Rheumatology* (1998:25:1687-93) by Pope et. Al., French data released in 1998 at the 62^{nd} Annual meeting of the American College of Rheumatology linked the vaccine to the development of autoimmune rheumatoid diseases, such as lupus and rheumatoid arthritis, in genetically susceptible individuals.[434]

Perhaps it was the force of lawsuits against vaccine manufacturers and the French government that spurred this sudden halt to the heretofore mandated childhood vaccine, rather than a over due concession to what was hypothesized and denied for years. Most interesting and perhaps, instrumental, in France's suspension of the vaccine's administration is the class action litigation currently occurring in France. As of July 1998, French attorneys representing 15,000

[433] NVIC, *Hep B Vaccine Victims in France Sue; France Suspends Hep B Vaccine Mandate*, available at < http: // www.909shot.com/hepbfrance.html>.
[434] *Id.*

French citizens and at least fifteen associations filed a lawsuit against the French government "accusing it of understating the vaccine's risks and exaggerating the benefits for the average person."[435] These plaintiffs are bringing suit against the entities they believe are responsible for the adverse reactions they have experienced following the receipt of the hepB vaccine. As a consequence of the mass hepatitis B vaccination campaign organized by the Minister of Health and vaccine producers, more than 20 million people have been vaccinated in France since 1994, either because they were obliged to do so or because, as the plaintiffs in this class action contend, they were "pressed into accepting the vaccination (either for themselves or for their children)."[436] Increasingly, these individuals have learned that the vaccine is not without serious risk, the magnitude of which is not yet known. Moreover, the plaintiffs in this class action, including private and public entities as well as physicians, believe that they have been victimized by government health authorities and pharmaceutical companies. Specifically, these plaintiffs assert that the defendants in this class action deliberately dramatized the prevalence of HBV in France by propagating false information on its mode of transmission and real magnitude. In addition, they assert that they were not told at the time they or their children were vaccinated, and still have not been informed, of the vaccine's possible serious side effects. Furthermore, these individuals allege that the vaccine has subjected them to and continues

[435] *Id.*

[436] This section of the paper is based from and recounts the facts and allegations contained in the complaint filed by the National League for Liberty in July 1998 against the French government and vaccine manufacturers for the administration of the hepB vaccine; this document is available at, < http://www.ctanet.fr/vaccination-information/plainte.html>. Citations have been omitted.

to expose them to physical threats that could have otherwise been avoided. The history of the vaccine's recommendation, promulgation and final halt in France, as recounted in these plaintiffs' complaint, and from which this section is based, is interesting for its striking resemblance to the chronology of events currently culminating in a controversy outbreak in the United States. Being one step ahead of the U.S., the chronology of events which took place in France is not only significant for its evidentiary value with respect to the vaccine's potential to harm, but also for its symbolic import of what may result and what is now gaining momentum throughout the U.S. as states and the federal government continue to urge, if not mandate, that children and newborns be vaccinated.[437]

THE PREVALENCE OF HEPATITIS B IN FRANCE

France is one of the countries of the world least affected by the Hepatitis B virus, with an incidence rate of approximately five to ten cases per 100,000 inhabitants. Moreover, there are only an estimated 100,000 chronic carriers and 8,000 new cases filed in France per year. The prevalence of the virus in France is 100 to 200 times less than in the regions most affected by the HBV disease, such as the Far East or Tropical Africa. The risk of a French individual acquiring a serious hepatitis B infection is about one in 50 million and as in the U.S., the disease is cured without sequelae in approximately 95% of cases. Furthermore,

[437] *Id.* The rest of this section is based on the plaintiffs' complaint. Footnotes to this complaint will no longer be cited.

it is estimated that there are only four to five deaths, seventy active chronic hepatitis cases, twenty-five cirrhosis cases and four liver cancers per year in all of France from serious cases of HBV. Additionally, it is estimated that the number of HBV related cases would be ten to fifty times lower if cited statistics focused on individuals for whom no risk factor prevails. Thus, as in the U.S., the risk of Hepatitis B in France is low for all and approaches a risk of "zero for children."

DECISION TO PROMOTE THE MASS VACCINATION POLICY IN FRANCE

Until 1994, the promulgation of the vaccine was targeted towards only those at risk for contracting the virus. Based on the recommendations of the WHO, Monsieur Douste – Blazy, the Minister of Health, launched a national vaccination campaign which propagated figures, claiming that there were 40,000 new cases of HBV infection each year and 300,000 chronic carriers of the virus in France. Similarly, Professor Jean-Francois Girard, Director General of Health, declared that, "We are seeing a slight increase in the prevalence of hepatitis B in France. This disease represents a major health problem." Plaintiffs in the class action believe that these figures were unfounded. Official sources of information in France, such as the Sentinel Network and the Courly Network, indicated that the incidence of hepatitis B in France between 1990 and 1994 was clearly abating. In charge of Sentinel Network, Dr. Antoine Flaugault stated in 1996 that "[t]he data do not reflect a current increase in the incidence of acute hepatitis B in the general population." Similarly, Professor Maurice Sepetjan

of the Lyon-Nord Faculty of Medicine noted that, "[w]e observe a very clear regression in cases of hepatitis B during the last 15 years."

Despite the especially low incidence of Hepatitis B in France and its apparent decline in 1994, French health authorities, nevertheless, instituted massive publicity campaigns to reinforce their recommendation that all newborns and adolescents be vaccinated. For example, a national vaccination campaign was launched in September of 1994, whereby reimbursement by social security was offered. In 1995, adolescents and infants became the object of a recommendation in the 1995 vaccination calendar drawn by the Vaccinations Technical Committee of the Senior Council of Public Hygiene in France. This recommendation was made despite the fact that only babies born to mothers with specific antigens are at risk for developing the disease and that screening mothers in the sixth month of pregnancy for specific hepatitis B antigens had been obligatory since 1992. The plaintiffs in this lawsuit contend that these campaigns marked "the passage from a policy of selective vaccination of individuals at risk to a policy of mass vaccination" for those who were not.

The timing of the mass vaccination campaign was significant in light of the serious side effects recorded years before the widespread vaccination call. In 1982, the CDC, the FDA and Merck Sharp and Dohme had created a surveillance committee for investigating possible side effects associated with the hepatitis B vaccination schedule. They found forty-one recorded cases of neurological side effects, of which nine were GBS and four myelitis, from a sample of 850,000 individuals vaccinated between June 1982 and May 1989. Additionally, believing

that a case of acute myelitis could be causally linked to the vaccine, Presse Medicale reported in December of 1993 that "[t]he possibility of an antigenic cross-reaction between the vaccine protein and a component of the nervous system has been suspected, the immunity system conflict becoming evident with repeated antigenic provocation. This could explain the numerous cases of neurological problems observed in unwell recipients of previous injections..." Moreover, a team headed by Professor Lyon-Caen, neurologist at Pitie Salpetriere Hospital, reported a dozen cases of multiple sclerosis or central nervous system demyelinating reactions in young adult patients weeks after they were injected with the vaccine. Consequently, Professors Lyon-Caen and other researchers explicitly warned physicians in medical journals not to immunize anyone with the hepB vaccine if they had MS or similar diseases. In a recent letter to patients, dated Jan. 28, 1995, Dr. Pertuiset, of the American Hospital in Paris, also warned that "[r]ecent observations have shown that in some cases there is a worrying chronological relationship between hepatitis B vaccination and the eruption of multiple sclerosis...." When questioned in April of 1996 about whether the hepatitis B vaccine could cause possible neurological effects, Professor Autret of the Tours University Hospital Centre responded, stating that "there is a sufficient temporal relationship for linking the advent of the demyelising attack on the administration of vaccines." Other medical journals also documented the possibility, if not likelihood, that the vaccine causes autoimmune diseases and pointed to the surface antigen of the virus used in the vaccine as being implicated. These warnings, contained in medical journals and similarly asserted

by medical practitioners and researchers, strongly suggested that demyelinating attacks, particularly auto-immune in nature, could be triggered in certain genetically predisposed patients following their hepB vaccination. As a sample of evidence pointing to a possibly dangerous specimen, further investigation into and caution with respect to administering the hepB vaccine should have been exercised.

PUBLIC CAMPAIGNS AND PROMULGATION OF THE VACCINE IN FRANCE

The possible alarm signals familiar to public authorities and pharmaceutical companies were left unheeded, or rather squelched by a perpetuating and an overpowering series of public campaigns, first initiated by Monsieur Philippe Doute-Blazy, and continued by his two successors at the Ministry of Health, which sirened the need for the country to be vaccinated against the HBV disease. As a means to spur French citizens into vaccinating themselves and their children, much of the publicity went so far so as to fuel misleading beliefs among the public. The pharmaceutical companies first directed their campaign at easy medical targets — mothers, individuals who would do anything for the safety of their child. In persuading them to vaccinate their children, pharmaceutical companies dramatized an increasing incidence of the hepB disease and made erroneous statements as to its possible modes of transmission. In furtherance of this effort, physicians were reminded of their powerful role in enforcing the government's recommendations, namely in their influence over patients' decisions to vaccinate themselves or their children. For instance, in 1995, the Minister

of Works and Social Affairs, associated with Social Security and the French Health Education Committee, spoke of "30,000 to 100,000 new cases" of HBV and emphasized that "[I]f doctors are widely in favour of hepatitis B vaccination its introduction into the system will counter public reluctance, particularly where adolescents are concerned. The purpose of the campaign is vaccination of adolescents and of infants from two months of age." These calls to physicians, though, need not have been heeded for the campaign to be effective. Publicity promulgating the need that everyone be vaccinated against HBV ran rampantly across the country. The importance of childhood vaccination was heard on numerous television and radio shows and could have been read on the 200,000 posters plastered around the country, two million hand outs administered to the general public or in instructive guides written for teachers and physicians. In 1995, the French government spent fifteen million francs publicizing the hepB vaccination campaign.

In particular, one of the most misleading statements propagated by this publicity campaign was that "hepatitis B is transmitted by saliva," a common misconception still heard in the U.S. today and which continues to play an influential role in the decisions of parents to vaccinate their children. This assertion, propagated by influential educational and health authorities, did and continues to encourage the mass vaccination of children by invoking fear in the hearts of parents that that their children can be infected through casual physical contact with others. In 1993, the French Health Education Committee and the Ministry of Health similarly fostered such ungrounded beliefs in asserting that "hepatitis

B is transmitted though blood, sexual secretions, saliva... in fact, the virus is present in all bodily fluids of an infected individual." Similarly, the High Seine General Council circulated a tract in 1994 and 1995, warning that "[h]epatitis B can be contracted from saliva." This statement was broadcasted on Fun Radio and the French Committee for Adolescents has eagerly promoted it. Moreover, the leaflets of vaccine manufacturers SmithKline Beecham (SKB) and Pasteur-Merieux (P-M) stated that "saliva [w]as a major vector for transmission of the virus." Knowing of the possible influence a physician may have on mothers decisions to vaccinate their children, SKB further warned in literature intended for doctors that hepatitis B is transmitted by tears, sweat, saliva and mother's milk.

It is surprising that health authorities and vaccine manufacturers continue to assert that saliva is a vector for transmitting and spreading the disease, despite strong evidence to the contrary. As early as 1995, a Guide to Vaccinations limited infective vectors to blood and sexual relations. In 1997, an INSERM report indicated that if there was any virus in the saliva it was at a level 1,000 times less than in the blood. Moreover, in 1998 Pasteur-Merieux and others admitted that the disease cannot be transmitted by the transferal of saliva alone, without skin abrasions or mucus. Furthermore, at a press conference on Jan.21,1998, Monsieur Kouchner, current public health minister, publicly affirmed the long held scientific belief that the hepatitis B virus is not transmitted through saliva. In light of contrary scientific evidence, plaintiffs in the class action assert that the government's aforementioned publicity disseminated misleading information

into the public. Consequently, they demand that public health officials and vaccine manufacturers be held responsible for ensuing vaccinations that resulted in injury. Plaintiff's find further support for culpability in the fact that Professor Bader, in charge of publicity at the Drug Agency in France, has not yet intervened to restate the facts. In creating a sense of obligation upon its citizens of what was really only recommended, plaintiffs in the class action allege that such publicity misguided its audience as to the necessity of vaccination and continues to do a great disservice to the public health it is obliged to promote.

To further propagate the mass vaccination campaign, vaccine producers systematically misinformed practitioners and the public, alike, as to the undesirable reactions possibly caused or induced by the hepB vaccine. Vaccine manufacturers shirked a duty owed to the public by strategically intensifying their vaccination campaign while cowardly refusing to bring to the playing field important and relevant information needed by parents for the careful balancing and weighing of factors comprising their decision to vaccinate themselves or their children. For example, as early as 1995 and 1996, side effects arising from the SKB and P-M vaccines were reported in the practitioner VIDAL, while no similar mention was found in the family 1998 VIDAL. School vaccination programs have also contributed to the public's ignorance with respect to the vaccine's safety or potential to be a health hazard. School health officials have failed to inform parents as to possible side effects resulting from the vaccine's administration. Moreover, French children are re-vaccinated every six years, without a follow-up evaluation being performed upon them to determine whether such children may

have responded adversely to the vaccine in the past. Furthermore, some teachers who have taken the initiative to provide parents with details of secondary effects possibly linked to the vaccine, perhaps so that they could look for them or make a more informed decision, have been severely penalized. Ironically, despite the potential for tremendous informational benefits, these public campaign efforts have attempted to keep parents uneducated, misinformed and in the dark.

As perhaps the only alternate source of reliable information, patients have entrusted the well-being of their children to the care of physicians, asking for meaningful and reliable guidance and advice with respect to this vaccine. However, being themselves misguided or unaware of significant facts, physicians have only exacerbated and perpetuated the public ignorance which plagues much of France. Despite noble intentions or as a result of ignorance, physicians may have also unwittingly placed themselves at risk for liability, or possibly reproach, for having endangered their patients lives. Until 1995, all the hepatitis B vaccines were represented as being completely harmless. The physician's VIDAL only mentioned the possibility of local reactions or of benign or short lived effects caused by the vaccine. More importantly, pharmaceutical companies professed a double standard by incongruously denying that risks could be caused by the vaccine while advising physicians administering the vaccine to exercise great caution. For example, on February 10, 1992, Dr. Marie Therese Nutini of Institute Pasteur Vaccines responded to a physician who had inquired about the correlation between ankylosing spondyarthritis and the hepatitis B vaccination, stating that

it is now admitted that stimulation of the immune system in any way cannot give rise to an auto-immune malady but it can reveal it or provoke an eruption. Here are the current recommendations in this type of pathology: contraindicate living vaccine viruses as far as possible; administer only those vaccines strictly necessary; after an eruption of the ailment wait a year/18 months before vaccinating. It is evident that: the risks/benefits of the vaccination should be carefully weighed; where it is possible check on existing antibody level may permit reduced vaccination; post vaccination checks will enable the response to the vaccine to be determined.

Despite the significance and usefulness of such advice, only one doctor was privileged with such information, after expressing concern and explicitly seeking guidance. Many wonder why the same was not sent to each practitioner to invite caution with respect to administering the vaccine. Moreover, the Vidal, the medical reference lying in every competent doctor's right hand, failed to mention any side effects for the Pasteur-Merieux vaccine until 1996. One can infer from Dr. Nutini's statements made in 1992, as well as from other evidence previously mentioned, that such adverse effects were clearly known or at least suggested to by clinical trials or physician reports before 1996. Similar to Dr. Nutini's response, Dr. Duterte of Smith-Kline Beecham responded to a physician's letter on Jan. 24, 1997, acknowledging that "[m]ultiple Sclerosis is one of the rare but possible undesirable effects of the hepatitis B vaccination mentioned in the VIDAL dictionary and in the instructions intended for patients attached to the packaging." But again, no attempt was made to publicize this information to all physicians administering the vaccine. This assertion is quite interesting, given that two months later,

this same company published an advertisement, accompanying an article entitled, " Doubt dispelled: vaccination programmes should be maintained." Finally, in 1998, Dr. Hamelin, Medical Director at Smith-Kline Beecham, did send a letter to all doctors, rather than just one seeking guidance; however, this time to allay fears rather than to urge caution. It read in part, "Neither in France nor in the rest of the world has any causal link been shown between hepatitis-B vaccination and the onset of demyelising diseases (multiple sclerosis , etc...) or other auto-immune diseases." Pasteur-Merieux sent a similar letter to all doctors as well. Contrary to what these companies have informed all physicians, doubts as to the vaccine's safety persist, especially as scientific evidence mounts to rebut what was distributed to dispel fears.

With the resurgence of "accidents" associated with the vaccine, the French Medicines Agency has launched a pharmacological inquiry into the possible undesirable effects attributed to the vaccine since its advent to the health market. In its first report on Dec. 15, 1994, the Agency indicated that it found 241 cases of undesirable neurological effects, approximately twenty-five of which were of the multiple sclerosis type. The National Pharmacovigilance Commission and the Medicines Agency, however, declared that this degree of risk did not exceed that which was expected to occur in the population studied. The French League for Liberty in Vaccination, however, believes that

this assertion is fallacious for the same reason similar studies conducted in the U.S. have been rejected. This study had compared the number of adverse reactions in non-vaccinated children over a fifty-two week span to children who had been vaccinated within a five week period, when problems associated with vaccination would probably not yet have manifested. Despite the inadequacy of this study, Professor Alexandre, director of the Medicines Agency, sent a letter in November of 1995 to every doctor asserting the theoretical impossibility of zero risk for any vaccine or drug and that any stimulation of the immune system necessarily entails the risk of inducing an eruption of adverse effects, such as multiple sclerosis in vaccinated patients who already have the disease. However, this letter failed to mention that in a report devoted to neurological accidents associated with the hepatitis B vaccine, his own Medicines Agency admitted to "demyelising attacks being capable of evoking a first eruption of multiple sclerosis" in individuals who did not suffer from such attacks previously. Like the Medicines Agency, the Department of the Director-General at the Ministry of Health was also optimistic about the vaccine's safety; on Dec. 13, 1996, it concluded that "[i]nvestigation of the neurological effects notified does not allow any new scientific considerations to be brought to bear on the causal link between the hepatitis B vaccination and multiple sclerosis... In the present state of knowledge the hepatitis-B vaccination remains of great importance and justifies the

continuance of vaccination programmes."

Several French public authorities have based their conclusions of non-causality on results obtained from a compilation of voluntary notifications made by practitioners to the French pharmacovigilance system, a system much like the U.S. VAERS system, since the vaccine was first commercialized in 1994. Given public ignorance as to the hepB vaccine's possible side effects and the aforementioned misleading publicity campaigns, one would not expect many health professionals to have made an association between the hepB vaccination and the onset of certain symptoms so as to report them as following or being caused by vaccination. Indeed, as in the U.S., reports actually made have been thought to only scratch the surface, representing only 10% of adverse events related to the vaccine. Many more reports are likely to be uncovered and detected as reliable scientific information is disseminated into the public, or at least among health practitioners.

Despite the abnegations by French health officials as to the vaccine's potential threat, several French authorities have recognized the limited and under-representative nature of this pharmacovigilance inquiry. As a consequence, some have concluded that it would be inappropriate to rely on physician reports of adverse events as evidence of non-causality.

Following in this perspective, Monsieur Bernard Kouchner, current Secretary of State at the Ministry of Health, underscored in Le Gen-

eraliste Review on March 17, 1998, that "If the known figures do not allow us to agree a relationship between the vaccination and the nervous system problems, neither do they allow us to dismiss any connection absolutely. . . if only because of our notifications which are voluntary, can never be regarded as exhaustive." As an example of an opinion probably held widely among the scientific community, the Medicines Agency urged the National Pharmacovigilance Commission to modify the list of undesirable effects associated with and the precautions to be used in the administration of all hepatitis B vaccines. As a result, the Agency stated,

> Exceptionally, cases of peripheral neuropathy, optic neuritis, or demyelising attack on the central nervous system have been reported in the week following vaccination, without causal link being established... In consequence, for those with multiple sclerosis, where the serology shows absence of immuni[z]ation against HBV, the benefit of this vaccination should be evaluated in relation to exposure to the virus and the risk of undesirable neurological effects.

Despite the implications of his own statement made one month earlier and the admissions made by other health authorities, Monsieur Kouchner announced that he would follow the advice of the Vaccinations Technical Committee and not challenge the vaccination campaign for young children. The timing of this pronouncement was interesting. At about the same time, the government had set forth the law which would compensate health care personnel adversely affected by the mandatory hepatitis B vaccine. By compensating individuals for hepB vaccine injury, this law and Kouchner's initial statement implicitly acknowledged that the vaccine could be responsible for the adverse effects reported thereto. The significance of this implication was shielded, however, by

a more forceful proposition suggested by the law and reinforced by Kouchner's later pronouncement that health is compensable, and thus, risk is justifiable. Notwithstanding the complications cited in the physician's VIDAL, implicitly and sometimes expressly alluded to by the vaccine manufacturers' own statements, neither the pharmaceutical companies nor public authorities halted the marketing or administration of the vaccine. Such inaction is especially surprising in light of the suggestion that populations low at risk for contracting the hepB virus could face a 300 times greater risk of suffering from a vaccine induced injury.

The scales of justice, on the other hand, are being implemented to carefully balance the benefits and risks of this vaccine. This system of mandating that some use a product, while simultaneously attaching no liability for its consequences has threateningly perpetuated what is already a grossly misinformed or rather uninformed system. Vaccine manufacturers have attempted to usurp the legal system to their advantage, as they have done with the public health conscience. In wielding "gag orders" as a leverage tool in vaccine damage legal settlements, vaccine manufacturers have attempted to prevent disclosure of information to the public about hepB vaccine health dangers. The Tribunals in France, however, have taken a step in demonstrating that they, and the public more broadly, will no longer allow pharmaceutical companies to maintain a captive market and be "immune" from accountability for the consequences of their products. Some courts have already announced decisions recognizing the link between hepB vaccination and the onset of pathology. For example, Nanterre

TGI held on April 4, 1997 that Pasteur's vaccines were entirely responsible for the plaintiff's ailments based on a medical certificate which read "Post- vaccination Guillain-Barre Syndrome admitted for rehabilitation." In June of 1998, a Nanterre court ruled that there was sufficient evidence to conclude that the Smith-Kline Beecham vaccine was associated with the manifestation of multiple sclerosis in two vaccinated individuals. The British drug maker SmithKline Beecham has appealed the ruling and a court order to pay roughly $23,000. Another ruling is pending in a case against French vaccine manufacturer P-M. Now, Kouchner has halted the mandatory law requiring that all children obtain the vaccine. Instead of relying on the lack of conclusive scientific data in order to dismiss causality, as many U.S. health authorities have done, Kouchner asserts that "it cannot be excluded that the vaccination might reveal or facilitate" central nervous system problems.[438] Despite the World Health Organization's assurance of the vaccine's "outstanding record of safety and efficiency,"[439] Kouchner's decision represents a new cautious approach to public health policy, consistent with an earlier statement he had made in 1998 as well as with the belief espoused in this paper, namely that we must transform the presumptions that underlie our public health infrastructure.

Perhaps Kouchner's regained faith in the art of strong possibilities was rekindled and is fueled by powerful reminders of what other scandals had in store for authorities similar to him in position. A former prime minister, Laurent Fabius and two other ministers are to stand trial for their roles in the scandal

[438] Article obtained from the NVIC, titled *France Suspends Hepatitis B Inoculations, supra* note 433.
[439] *Id.*

that left more than 500 people dead, when health officials knowingly provided AIDS tainted blood products to hemophiliacs. In 1997, authorities began investigating the role other health officials played in distributing potentially tainted growth hormones that may have killed 40 children afflicted with dwarfism in the mid-1980s. Although Kouchner's new refined attitude seems to be a move in the right direction, the WHO feared its ramifications. In October of 1998, the WHO expressed its concern that France's decision to halt the vaccine's obligatory administration would undermine WHO's 100-country inoculation program as well as the public confidence in this vaccine. Moreover, WHO fears that France's action, or rather the suggestion of causality which this country's refined view fosters, would induce other countries to suspend or delay the vaccine's introduction into mandatory immunization schedules.[440] As WHO feared, the French are teaching America what the threat of liability can do against those who have acted irresponsibly.

[440] *Id.*

CLOSING

WHAT DO AMERICANS WANT AND WHAT CAN WE EXPECT?

The fears of the World Health Organization are currently being realized in the U.S.. The legal revolt against the hepB vaccine in France is empowering, showing Americans what the dissemination of information can do to transform the preconceived biases percolating through the layers of our public health infrastructure and potentially contaminating the validity of and attitudes towards public health policy with respect to the safety of the hepB vaccine. Perhaps ignited by the "firestorm" of French lawsuits, the American public is making it clear that they want the government to "know we will no longer blindly follow their dictates. We will ask questions and use the legal system if we feel the need to be heard."[441]

Interestingly, the first boards of health consisted of volunteer citizen groups, composed of ordinary people, much like the parents who are concerned and expressing such views today. Immunization practice and essentially all public health laws in the U.S. have their historic roots in the 18^{th} and 19^{th} centuries, when unpredictable epidemics of highly contagious, dangerous diseases, such as yellow fever, typhoid, and smallpox, swept through a city and caused high

[441]Leah Janzen, *Parents Fight Needles,* WINNIPEG NEWS, Nov.7, 1998, at A1-A2 (obtained from the NVIC) [hereinafter Janzen]

mortality rates. Since port cities were hit especially hard when European immigrants disembarked from ships carrying smallpox into crowded cities, volunteer citizen communities were formed to quarantine such boats until those disembarking were certified to be free from contagious and infectious diseases.[442] At the turn of this century, the first mandatory vaccination regime was enacted to control small pox. Doctors usurped control over these citizen communities and funding from taxes planted the seeds for what would soon grow to be a massive public health infrastructure. It was not long before quarantine laws, initially established to protect society from infected individuals, expanded to include within their exclusive embrace citizens who were neither vaccinated or infectious. In 1918, an Illinois court upheld the right of a local board of health to exclude children from school for a period of two weeks during a smallpox epidemic, unless they already had smallpox or had been vaccinated. In 1922, a case involving the quarantine laws was brought before the Supreme Court. In response, the Supreme court said,

> while the powers given to health authorities are broad and far-reaching, they are not without their limitations. As we have said, while the courts will not pass upon the wisdom of the means adopted to restrict and suppress the spread of contagious and infectious diseases, they will interfere if the regulations are *arbitrary and unreasonable. A person cannot be quarantined upon mere suspicion that he may have a contagious and infectious disease* but the health authorities must have reliable information on which they have reasonable ground to believe that *the public health will be endangered by permitting the person to be at large. Where danger of an epidemic actually exists, health and quarantine regulations will always be sustained by the courts, but the health regulations are all sustained on the law of necessity*... Health authorities cannot promulgate and enforce rules which merely have a *tendency to prevent the spread of contagious and infectious diseases*, which are not founded upon an existing condition or upon a well-founded belief that a condition is threatened which will endanger

[442] Fisher Statement, *supra* note 2.

the public health (emphasis mine).

The significance of this decision is further amplified by the disease context in which it was professed. Hepatitis B is not like smallpox, a disease which could be transmitted as easily as by breathing the air of one's neighbor. There are not many young children or infants directly exchanging bodily fluids in the U.S., as is necessary to transmit the HBV disease. By mandating hepB vaccination as a pre-requisite for school entrance, state officials may be quarantining children on the *mere suspicion* that such children have the hepB disease - a conjecture that is highly suspect, unfounded and unreasonable. This disease is not highly contagious in this age group and the U.S. is not facing an HBV epidemic, either. Therefore, states are trying to promulgate and enforce rules that at most *merely have a tendency to prevent the spread of contagious and infectious diseases.* Not clearly grounded in necessity, this public health policy seems quite *arbitrary and unreasonable.*

The promulgation of traditional public health measures, such as education campaigns, may be more effective in protecting children from engaging in high risk behaviors than is vaccinating young children who will probably need to be vaccinated again when their behavior could actually put them at risk for contracting hepB. Moreover, improving methods of educating and screening pregnant women, IV drug users and prostitutes for vaccination could more effectively combat transmission among those really at risk, if that is our goal. If such efforts have been ineffectual in the past, care should be taken to alter strategies, not target groups.

One wonders why states have not mandated that every pregnant mother be tested for hepatitis B upon delivering her baby. While the civil rights of these women may be a concern, the civil rights of innocent babies who are not at risk for contracting the disease must not be asked to yield in sanction. This paper in no way denigrates programs attempting to reduce hepatitis B in populations of high risk, both in the U.S. and abroad. Nor does it suggest that we abruptly halt current vaccination programs in the U.S. However, it does ask that we enliven, and resuscitate the sacred principles of informed consent and personal choice, founding our Country's democracy and which have been cast aside, if not relegated to the subterranean of our current public health landscape and conscience. This request appears particularly reasonable in areas of the U.S. in which the incidence of hepatitis B is very low and for population groups who are not at risk for contracting or transmitting the disease. If our goal is to protect the public health, especially against the transmission of the disease, we must consider why we are subjecting millions of innocent newborns and children, not significantly endangered by the HBV disease, to a vaccine that may not only not protect them, but may also actually kill or handicap them.

In the last decade, many parents have stood on the sidelines in silence, helplessly and passively watching their children be victimized by what they think their health care system, and specifically the vaccine, induced. Out of necessity, many parents became investigators overnight as they sought to understand why their healthy child had needlessly become so sick. As their hope and faith

in the government and political process deteriorates in this trying search, so has the fortress which had once shielded their innermost voices and doubts from outward expression. With this new found freedom, parents have rallied a forceful cry against the only law in American "requiring a citizen to risk his life for his country"[443] since the repeal of the military draft in the 1970's. Unlike the eighteen year old men who were required to risk their lives, these eight hour or eight week old infants are incapable of voicing or formulating objections. So America is speaking for them, asking for a choice in this decision.

Recently, hepatitis B vaccine victims have asked Congress for improved health agency investigation and informed consent protections. In November of 1998, parents concerned about the safety of the hepatitis B vaccine asked a judge to shut down a voluntary program that would inoculate more than 18,000 Manitoba school children. Cynthia Devine, the attorney representing this group of parents, said that she would ask the judge to "suspend the program until more information about the situation in France can be distributed to parents."[444] Because the information provided to parents "didn't contain any balanced scientific evidence," she requested that the court "declare the existing forms null and void because they do not represent full and informed consent."[445] Apparently similar to the materials used to promulgate the vaccine in France, the consent form suggested that the program was obligatory rather than volun-

[443] NVIC, Opening Statement by Barbara Loe Fisher, Institute of Medicine Vaccine Safety Forum, Workshop on Risk Communication and Vaccination. Statement obtained from the NVIC.
[444] Janzen, *supra* note 442.
[445] *Id.*

tary.

More recently, a national poll of 1000 registered voters, taken by the Polling Company, revealed that two out of three (68%) Americans want the right to make informed, voluntary decisions about whether to subject heir children to hepB vaccination.[446] A plurality of Americans (45%) oppose state laws requiring that all five year olds receive the hepB vaccine as a pre-requisite for admission into kindergarten. When given information about risks associated with the hepatitis B vaccine, 59% of respondents were less likely to support mandatory vaccination laws. Moreover, only 25% of Americans believe that people, after receiving information about the risks and benefits of medical procedures, including the administration of drugs or vaccines, should then be *required to follow the orders* of their doctors or public health officials.[447] Barbara Fisher, of the NVIC, powerfully captured the sentiment of contemporary public opinion; in her statement to Congress last May, she asserted that "the lack of informed consent protections in mass vaccination programs is leading to fear and mistrust of the whole vaccination system. What we hear parents saying is: show us the science and give us a choice."[448] Indeed, Americans are demanding that they be given the right to balance the lofty risks and benefits of this vaccine and ultimately decide which preventative health care protocols will govern the lives of their children. Clearly, parents will no longer stand on the sidelines, entrust-

[446] NVIC Press Release, *supra* note 280.

[447] *Id.* Since the poll's margin of error was +/- 3.1% at the 95% confidence level , the same survey would probably lead to the same results if administered to a similar population in roughly 19 out of 20 cases.

[448] Testimony of Barbara Loe Fisher, Hearing of the Criminal Justice, Drug Policy and Human Resources Subcommittee of the House Government Reform, May 18, 1999 [hereinafter Fisher's Testimony].

ing this careful balance and the concomitant search for truth in the hands of health officials who have already decided the issue. By mandating that children be vaccinated without conducting adequate safety studies prior to the vaccine's administration, public health authorities have in effect forced parents to participate in a potentially dangerous national experiment in which their children are involuntary subjects.

The issue of personal choice is not only important for protecting the individual liberties upon which our democracy was founded. In demanding choice and in giving voice to the stories of their children, parents have taken the first step in transforming the issue of vaccine safety into a politically correct subject. By creating a climate for the free exchange of knowledge and information, parents are fostering public discussion about the vaccine's safety, instrumental for challenging the faulty presumptions which underlie our public health policies, retard the advancement of science, and undermine the public's confidence in a system designed to protect them. As Barbara Fisher asserts,

> If the universal a priori presumption continues to be that the children and adults who have died or suffered health problems following vaccination *would have* died, been brain injured, or become immune compromised even if no viral or bacterial antigen had been administered, then there will continue to be no incentive for clinicians and public health officials to spend any real time, money or energy detecting and responding to reports of deaths and injuries following vaccination. There will be no incentive for politicians to provide funding or government executives to make it a budget priority. There will be no incentive for researchers to commit the time and effort to conduct serious scientific investigations. There will be no answers because, it the name of disease control through mandatory vaccination, the hard questions about vaccine safety will be dismissed without serious examination. And we will continue to be bound by chains of ignorance – an ignorance that may come with a price so staggering that it could literally eventually compromise the biological integrity of the

human race.[449]

Without a human face and without a public voice, it is easy to dismiss the role of science in public policy. As Barbara Fisher powerfully puts it,

> when parents take the state mandated vaccine risk and it turns out that the risk for their child is 100%, everyone has been carefully pre-conditioned to accept the idea that the vaccine is not responsible. The doctor is not responsible. The vaccine manufacturer is not responsible. The government is not responsible. The genetically defective child is responsible.[450]

By challenging mandatory vaccination laws, parents are demonstrating their unwillingness to accept this attribution of responsibility or the casualties of our most precious resource. Beyond every vaccine adverse event statistic is a real child with real parents, emboldened to express their concern.

Despite the noble efforts of some courageous parents, many are still waiting to tell the public and health authorities of their story, which may provide the necessary answers to the questions we have been long asking. While critical to the advancement of science, their contribution will not propel its progression unless their voices are heard, and more importantly, respected. As Albert Einstein once wrote,

> The progress of science presupposes the possibility of unrestricted communication in all results and judgments—freedom of expression and instruction in all realms of intellectual endeavor. By freedom I understand social conditions of such a kind that the expression of opinions and assertions about general and particular matters of knowledge will not involve dangers or serious disadvantages for him who expresses them. This freedom of communication is indispensable for the development and extension of scientific knowledge.[451]

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[449] Opening Statement of Barbara Loe Fisher, Institute of Medicine Vaccine Safety Forum, Workshop on Risk Communication and vaccination, May 13, 1996.
[450] *Id.*
[451] *Id.*

Thus, science will remain at a standstill if the views of parents, scientists and organizations like the NVIC, are continually ignored and denigrated. The potential for growth in scientific understanding will continue to be stunted when parents who have contacted the NVIC are too traumatized by what has happened to their children or are too frightened by threats from state health and welfare officials to express their views. Some parents charged with child neglect have been told that their children will be taken away if they do not comply with the state mandated vaccine. In fear of public authorities, some physicians have expressed their reluctance to report adverse events as a consequence of the hepB vaccine or give a medical exemption for children they thought needed it. Some patients have been forced to go forward with the hepatitis B vaccine, even after they have experienced fevers, skin lesions, joint pain and other autoimmune and neurological symptoms. Many of these individuals are members of a single family.[452] Given the likely genetic predisposition in patients suffering from vaccine adverse events, public health authorities may be demanding that parents not only sacrifice one, but multiple family members in this crusade against hepatitis B. Thus, in Einstein's words, the "expression of opinions and assertions about general and particular matters of knowledge" regarding the public health and this vaccine have become of the type which "involve dangers or serious disadvantages for him who expresses them."[453] In an effort to protect the public health, many of the state mandated vaccine laws and the actions taken to enforce them have actually disrespected the individual human life and the invi-

[452] Fisher Statement, *supra* note 2.

[453] Opening Statement of Barbara Loe Fisher, Institute of Medicine Vaccine Safety Forum, Workshop on Risk Communication and vaccination, May 13, 1996.

olable rights of parents to listen to their hearts and conscience in order to make a valuable, rational voluntary decision. The essence of informed consent as it is applied throughout American health policy is based on the ethical principle that the person who must live with the consequences of a decision should make it. This ethical tenet is especially significant in this context, where parents will be the ones who will have to bear the burden when their child becomes another adversely affected vaccine statistic, sacrificed for the purported public good.

Clearly, public health policy requires participation by the public. The public would be more amenable to having their children vaccinated if more research on risk factors had been and will be visibly performed. Thus, parents are asking for more than that they be given the personal choice to balance the weights which may decide the lives of their children. They are asking that they be given the weights – that their consent be truly informed. The disclosure of necessary information preceding a child's vaccination must not only include identifying adverse events that might be causally associated with the hepB vaccine, but also detecting any predisposition that children in particular families may have that may heighten their risk for responding adversely to the vaccine. Even if remote, the real risks of serious diseases that may attend vaccinations must be scrupulously and comprehensively explained to the parents of such children. This type of disclosure will require a fundamental transformation and renovation of our public health policy system. Progress in scientific research will require a concerted effort by public health officials and the public, alike, to dismantle the decrepit and faulty presumptions which constitute the foundation of our public

health infrastructure. As indicated several times in this paper, "no confirmed reactions" has become the unified, standard rhetoric given by governmental and health officials in response to assertions that the vaccine may cause adverse reactions. Of course, there are no confirmed reactions; the kind of scientific studies that could reveal the link have not yet been done. The studies have not been conducted because the pleas of parents have been ignored, suppressed and depreciated. The success of detecting adverse events rests on the willingness of those to believe in the plausibility of finding a cause and effect relationship because "[i]f you don't believe they occur or occur only rarely, you won't look for them. If you don't look for them, you won't find them."[454] Thus, consonant with Kouchner's new found attitude, it may be better "to prove the vaccine did not play a role rather than to conveniently assume the vaccine did not play a role."[455] Moreover, causal relationships between vaccines and temporary or permanent debilitating health problems will remain unsolved unless molecular biologists and neuroimmunologists are given the chance and are encouraged to precisely define the biological mechanisms for responding to vaccinations. Inadequate long-term studies and the failure of scientists to study genetic and racial diversity among infants and children enrolled in vaccination schedules only exacerbates the vacuum of knowledge clogging our understanding of these mechanisms, as does the growing introduction of obligatory vaccines to an already crowded mandatory vaccination schedule.

[454] Opening Statement of Barbara Loe Fisher, Institute of Medicine Vaccine Safety Forum Workshop on Detecting and Responding to Adverse Events Following Vaccination, Nov. 6, 1995.

[455] *Id.*

As an official public health policy, results and implications drawn from future studies must be appreciated for their significant value. This building block will require that we strip our nations' tenacious intellectual, bureaucratic and economic commitment to vaccination as the only method for eradicating illness and the media's propagation of fear used to enforce it. The renovation of our public health edifice will require improved education for medical students, physicians and the public as to the possible risks associated with hepB vaccination as well as of the importance of screening children with high risk factors for responding adversely, monitoring children after vaccination and reporting related adverse events to the government. Obviously, physicians cannot warn patients with what they do not know. Few medical students have reason to question or right to choose what information they are taught. This attitude is reinforced when they begin their practice and have little time for continued education. In a sense, physicians have become captive by a system, much like their patients, which discourages them from independently acquiring information and forming their own opinions. Only better educated physicians can properly advise patients and their parents on how they can recognize and react to negative changes in their children's physical, mental, and emotional health following hepB vaccination. If causality continues to be erroneously determined by providers at the reporting level, vaccine adverse events will never be detected or understood.

Improving reporting protocols for adverse events will not sufficiently treat the malaise from which our public health policy suffers. The information contained within these reports must be adequately and appropriately evaluated for their

potential significance. A valuable database of vaccine adverse reported events should be created to retrospectively evaluate common denominators among cases reported. Such action would not only enable us to better identify high risk children, but also point us in new directions for vaccine adverse event research, particularly for the pathological profiles of vaccine injury and death.[456]

Once reported and adequately studied, data obtained from adverse reports and scientific research must be accepted, rather than readily dismissed for their cause-effect potential by the leading architects supervising and advising the reconstruction and maintenance of our public health policy infrastructure. Such top government and health care officials must demonstrate a commitment to making positive changes that will help vaccine injured children or rather prevent future children from being injured. The failure of researchers, vaccine manufacturers and health care officials to communicate what medical science does and does not know about vaccine risks has been perceived to be a fundamental betrayal of the public's trust, the pillars upon which our public health system relies.

Therefore, if public health authorities begin to acknowledge what parents have known for years in their hearts and which they are now expressing, parents will work with, rather than against, public health officials in remodeling and repairing our public health policy infrastructure. Otherwise, the integrity of the health system, which public health authorities have undeniably worked so hard to build, will only further erode. While doctors and scientists may deny a causal

[456] *Id.*

association, the mothers and fathers of our country will not, "[a]nd that simple fact will continue to haunt the mass vaccination program until the basic science research is done, credible vaccine safety evaluation systems are put in place, and parents believe that physicians are acting as caring partners with them in helping to prevent vaccine reactions."[457] Thus, public health authorities can be sure that organizations, like the NVIC, will enlist the help of parents of vaccine damaged children, or those not wanting their children to become vaccine statistics, in battling the politics of science. Americans have been placed in the dark for too long and now refuse to follow blindly. They ask for a glimmer of hope that the government is lighting the way in the search for scientific truth. If they do not find this spark, efforts to promulgate public health protocols will backfire as the public dares to start a holocaust of obstinence and revolt against public health policy. Indeed, their bonfire has already ignited a rampantly spreading blaze.

[457]Statement by Barbara Loe Fisher, National Institutes of Health Pertussis Conference, June 3-5, 1996, obtained from the NVIC.

GLOSSARY[458]

Amino acid: a class of organic molecules containing an amino group that can combine in linear arrays to form proteins in living organisms. They are the key components in all living organisms from which proteins are synthesized by the formation of peptide bonds. There are also several important amino acids that have no relation to proteins.

Anaphylaxis: a system or treatment that leads to damaging effects on the organism. Now reserved for inflammatory reactions and for what results in acute allergic reactions marked by shortness of breath, rash, wheezing, and hypotension.

Antibody: an immunoglobulin molecule that has a specific amino acid sequence by virtue of which it interacts only with the antigen that induced its synthesis in cells of the lymphoid series (especially plasma cells) or with antigen closely related to it. They are classified according to their ode of action.

Antigens: substances which are capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response, that is, with specific antibodies, or specifically sensitized T-lymphocytes, or both. Antigens may be soluble substances, such as toxins and foreign proteins, or particulates, such as bacteria and tissue cells; however, only the portion of the protein or polysaccharide molecule known as the antigenic determinant (epitope(s)) combines with antibody or a specific receptor on a lymphocyte.

Arthralgia: mild or severe pain in the joint(s).

Arthritis: inflammation of a joint(s) with swelling, redness, stiffness, tenderness, and pain, especially during movement. Chronic inflammation of the joints that occurs with chronic arthritis can eventually lead to crippling of the body including fusion of the joints, deformed bones, compression of the spinal cord, the inability to move and severe, constant pain.

Autoimmunity: a condition in which an individual's immune system reacts against his or her own tissues.

Bell's Palsy: Facial paralysis which occurs suddenly and is thought to involve swelling of the nerves. Although the precise cause is unknown, it is thought to be caused by a viral infection or immune system problem. Symptoms may begin with pain behind the ear followed by facial weakness and, within hours, can lead to partial or complete facial paralysis. Complete recovery within a few months occurs in many cases but some victims are left with permanent nerve damage including partial paralysis.

Chronic hepatitis B: an inflammatory disease of the liver caused by hepatitis B virus and lasting six months or more.

Chronic Fatigue Syndrome (CFS): a syndrome characterized by a wide range of immune and neurological system dysfunction including profound, chronic

[458]For definitions of other terms, one can refer to the on-line medical dictionary, available at <http://www.graylab.ac.uk/cgi-bin/omd?hepatitis+B>.

fatigue that can be disabling; joint and muscle pain and weakness; vision, balance and physical coordination problems; severe, chronic headaches; gastrointestinal symptoms; heart palpitations; inability to concentrate; loss of memory; deterioration of intellectual abilities; and personality changes. Some sufferers have abnormal immune system functioning or brain lesions. The cause of chronic fatigue syndrome is unknown, although some scientists theorize that it is caused by an infectious virus that attacks the immune system and the brain. The more than 70,000 Gulf War veterans who are reported to be suffering from "Gulf War Syndrome" are exhibiting symptoms identical to CFS. It is known that Gulf War veterans were given 17 different viral and bacterial vaccines, including ones that were experimental, before being exposed to environmental toxins in the Gulf.

Cirrhosis: sometimes used to refer to the chronic interstitial inflammation of any organ.

Dane particle: as the complete infective virion of hepatitis B, it is a 42nm spherical particle, containing a 27nm core antigen.

Demyelination: The myelin that sheaths many nerve fibers helps transmit neural impulses. If the myelin sheath is damaged through traumatic injury, metabolic disorders, toxic insult, viral or bacteria infection or vaccination, it can cause degeneration or demyelination. Two well known demyelinating diseases are multiple sclerosis and Guillain-Barre Syndrome. Demyelination is often irreversible, leading to permanent brain dysfunction or death.

Fulminant hepatitis: a severe and rapidly progressive form of hepatitis B accompanied by hepatocellular death and the signs and symptoms of hepatic failure. May be a complication of hepatitis B, C or D.

Glycosylation: the process of adding sugar units, such as by adding proteins.

Guillain Barre Syndrome (GBS): a rapidly progressing form of polyneuropathy that can be caused by infections, surgery or vaccination. It is thought to be the most frequently acquired inflammatory demyelinating neuropathy and the weight of evidence suggests that most cases are immune mediated. GBS is characterized by muscle weakness, numbness, pain and paralysis.

Hepatitis B:
a form of viral hepatitis, known as serum hepatitis, because it is commonly spread through contact with infected blood products (transfusion). May also be spread sexually or from mother to infant. Hepatitis B can cause much more severe infection than Hepatitis A. Infection with can result in an asymptomatic carrier state, a chronic infection or in the cirrhosis of the liver.

The virus is 42nm in diameter, with an outer sheath enclosing an inner 27nm core particle, containing the circular viral DNA. Aggregates of the envelope proteins are found in plasma and are referred to as hepatitis B surface antigen (HBsAg).

Hepatitis B antibodies: antibodies to the hepatitis b antigens, including antibodies to the surface and core of the dane particle and other antigens.

Hepatitis B antigens: antigens of the virion of the hepatitis b virus or the dane particle, its surface, its core and other associated antigens.

Hepatitis B immunization: the hepatitis B (hepB) vaccine is used to offer

protection against HBV infection, with 3 shots administered over the course of a half year. In the U.S., all infants receive the hepB vaccine. Two vaccines are available in the U.S. (engerix-b and recombivax-hb). The first dose of hepB is frequently given while the newborn is still in the hospital or when the infant first visits a doctor following birth. The second dose is given about 30 days after the initial dose. A booster dose is performed approximately six months later. Babies born to mothers testing positive for hepB receive hbig (hepB immune globulin), in addition, for prompt protection. Older children (11-12 years) are advised to receive a hepB booster, as are adults in high risk situations for contracting HBV.

Hepatitis B surface antigen (HBsAg): a serologic marker on the surface of the hepatitis B virus. The body will normally produce antibodies to the surface antigen as part of the normal immune response to infection. It is the presence of antibodies to the hepatitis B surface antigen that are detected in a positive hepatitis B blood test.

Hepatitis B virus: The type species of the genus Orthohepadnavirus that causes human hepatitis B and is also apparently a causal agent in human hepatocellular carcinoma. The dane particle is an intact hepatitis virion, named after its discoverer. Non-infectious, spherical and tubular particles are also seen in the serum.

Histocompatibility antigens: a group of antigens that includes both the major and minor histocompatibility antigens. The former are genetically determined by the major histocompatibility complex.

Homologous: corresponding in structure, position, or origin, such as an antigen and its specific antibody or the feathers of a bird.

Human leukocyte antigen: a genetic fingerprint on white blood cells and platelets, composed of proteins, that play a critical role in activating the body's immune system for responding to foreign organisms.

Immune system: the body system, made up of many organs and cells, that defends the body against infection, disease and foreign substances. Usually stimulated in specific ways.

Immunoglobulin: a specific protein substance that is produced by plasma cells to aid in fighting infection. Some proteins take part in various immune responses of the body to bacteria or foreign substances.

Immune complex: multimolecular antibody antigen complexes that may be soluble or insoluble depending upon their size and whether or not complements are present.

Immunogenetics: a subfield of genetics that uses both genetic and immunological analyses to study the genetics behind antibody formation and the immune response.

Inoculation: introduction of a material (usually a vaccine) into the tissues. It is also used to refer to a mode of entry for bacteria into the body.

Jaundice: Yellowing of the skin (and the white of the eyes) by a bile pigment. Frequently caused by a liver problem.

Lupus: An inflammatory connective tissue disorder that occurs predominantly in young women, but also occurs in children. Its precise cause is unknown,

but it is thought to be an autoimmune disorder. Symptoms include: fatigue, nausea, weight loss, arthritis, skin and mucous membrane lesions, sensitivity to light, headaches, epilepsy, lung, kidney and heart disorders.

Major Histocompatibility Complex (MHC): the set of gene loci specifying major histocompatibility antigens, for example, HLA in man.

Major histocompatibility antigen: a set of plasmalemmal glycoprotein antigens involved in rapid graft rejection and other immune phenomena.

Molecular Mimicry: a process in which structural properties of an introduced molecule imitate or stimulate molecules of the host.

Multiple Sclerosis (MS): a chronic demyelinating disease which is thought to be immune mediated or caused by an infection, but a definitive cause remains unknown. It is characterized by the breakdown of myelin and lesions throughout the brain.

Myalgia: pain in a muscle or muscles.

Myelin: the material making up the sheath that surrounds the nerve axons and by which transmission of signals throughout the body occurs.

Neuritis: inflammation of a nerve or noninflammatory lesions of the peripheral nervous system.

Neuropathy: Any functional disturbance or pathological change in the peripheral nervous system characterized by pain, weakness, and numbness, causing loss of sensation, muscle weakness, atrophy(wasting/shrinking) and paralysis.

Optic Neuritis: characterized by a rapid loss of vision over hours or days in one or both eyes caused by demyelination of the optic nerve fibers.

Pathogenesis: The origin and development of disease.

Peptide: a compound of two or more amino acids.

Rheumatoid arthritis: Chronic inflammatory disease in which there is destruction of the joints. Considered by some to be an autoimmune disorder in which immune complexes are formed in joints to excite inflammatory response.

Sequelae: a condition following as a consequence of a disease.

Transverse Myelitis: This is a clinical syndrome characterized by a sudden onset of signs of spinal cord disease and involves demyelination of the spinal cord. It can be associated with multiple sclerosis. It has been associated with viral infection, IV drug use and vaccination, but no definitive cause has been found. Symptoms begin with sudden local back pain, followed over several days by pain and weakness starting in the feet and moving upward. Bladder and bowel dysfunction and partial paralysis often follow. There is no treatment and many victims are left with significant disabilities.

Virion: a single virus particle, complete with coat.