Dunbar's testimony to Congress concerning Hepatitis B on May 18, 1999

Bonnie S. Dunbar, PhD
Department of Cell Biology
Baylor College of Medicine, One Baylor Plaza
Houston, Texas 77030
Email: blixen@texada.net

Good morning and thank you for this opportunity to discuss these critical health care issues. My name is Bonnie Dunbar, and I am a research scientist and medical and graduate student professor who has worked in the areas of autoimmunity and vaccine development for over twenty five years (the past 17 years at Baylor College of Medicine in Houston, Texas).

I have been honored by the National Institutes of Health as the first Margaret Pittman lecturer for my pioneering work in vaccine development. This honor was special for me because Dr. Pittman's contributions were instrumental in early aspects of vaccine development and because I understand the impact that some vaccines have had, and will continue to have, on our society. My ongoing research in the area of vaccine development continues to be a major commitment. I have worked extensively with the U.S. Agency for International Development and the World Health Organization programs and have a life long commitment to carrying out research to understand, and hopefully, to help solving problems associated with world population as well as disease problems.

As I have been invited to speak to this distinguished subcommittee, it is important to discuss my experience with the clearly apparent severe adverse effects of the Hepatitis B vaccine. About five years ago, I had two individuals working in my laboratory who were required to take the Hepatitis B vaccine. Both of those individuals developed severe and apparently permanent adverse reactions as a result of the vaccine. Both of them were completely healthy and very athletic before this vaccine and have now suffered severe, debilitating autoimmune side effects from the vaccine. I have studied the complete medical history of my brother, Dr. Bohn Dunbar, who developed seriously chronic joint and muscle pain, fatigue, and multiple sclerosis-like symptoms. And now he has further been diagnosed with POTS (an autoimmune, cardiovascular, and neurological problem) and subsequently with chronic inflammatory, demyelinating polyneuropathy. His problems have been attributed to the Hepatitis B vaccine by over a dozen different specialists around the United States of unquestionable medical expertise. He has now been rated permanently and totally impaired at greater than 90%. His health care has already cost the state of Texas about a half million dollars in the Texas Worker's Compensation Program to date, and that figure will continue to rise given the severity of his health condition.

My other student went partially blind following her first booster injection, a medical condition that was markedly exacerbated by her second booster that resulted in hospitalization. Personal communications are that her eyesight is continuing to deteriorate. Because she is in medical school she has been, understandably in my opinion, afraid to pursue investigation into her medical problems because of her concern that they might affect her medical career.

I am extremely sensitive to the need to evaluate the risk vs. benefits of any vaccine. Because of my experience in this area, it became intuitively clear to me that these two active, healthy individuals working in my laboratory developed autoimmune syndromes within a predictable immunological time frame following their booster injections of the Hepatitis B vaccine. After carrying out extensive literature research on the nature of this virus and this vaccine, it became intuitively obvious to me that there is a significant scientific probability that the vaccine is the cause of those adverse reactions. Both the published studies of reactions to viral infection and the temporal relationship of vaccine administration to adverse events suggest strongly that these adverse reactions are related to the nature of the viral protein, the recombinant surface antigen of which is the principal component of the vaccine.

I have been in contact with numerous physicians and research scientists from several countries who have independently described identical severe reactions to the vaccine in thousands of Caucasians. Their observations have been, for the most part, denied or ignored by the public health systems, as is evidenced by the serious charges against healthcare officials and pharmaceutical companies brought recently in France. The reversal of the vaccine mandate for children in France was not based on lack of documentation. I have now been contacted personally by hundreds or more individuals (including parents of infants and children) who have reported deaths, severe health problems and life long disabilities, resulting in major medical costs following the administration of this vaccine. It appears that the adverse events related to this vaccine are within a gene pool that is capable of genetic definition. I respectfully submit that rigorous scientific studies into the possibility that the vaccine can cause severe autoimmune disorders is necessary.

The following points specifically address the issues listed in my invitation to speak to this committee.

1. The Food & Drug Administration has set up a system for reporting adverse reactions to the vaccine. How does this system work? What is being done to study these adverse reactions.

My first experience with this reporting system followed my observation of the two individuals in my laboratory who developed serious medical problems within a time frame predictable for immunological reactions. After seeing that these reactions were listed in the Physicians' Desk Reference text as reported reactions to this vaccine, I learned about the VAER's reporting system. When I first called the FDA about this, I was told by an individual that "this vaccine is a problem and it is a big one." I was initially sent some information on reports of reactions that were similar, if not identical, to those of these two individuals. I attempted to initiate a dialogue with individuals at the FDA but

doi: 10.1588/medver.2004.01.00008

was simply told that I could obtain the information under the Freedom of Information Act. I subsequently paid to obtain copies of these documents; and I was overwhelmed by the thousand of pages of documents I received listing thousands of reports, hundreds of which were identical to the reports I had filed for the two individuals working in my laboratory. Unfortunately, the details on these lists were insufficient for studies to critically evaluate the mechanisms by which these reactions occur.

There was no response to my subsequent correspondence with members of this branch of the FDA. (I am aware that the cutbacks in FDA funding may have played a role in this issue.) It became apparent that the essential medical details (e.g., patient identity, genetic background, family history of autoimmune diseases, etc.) are not provided by this reporting system and that there is no way to contact physicians reporting these reactions. *This information is, therefore, inadequate and not accessible to those of us who are studying the serious adverse reaction events apparently related to this vaccine. It was also apparent that there is no follow-up on these reactions since the two patients I reported were never contacted to evaluate their deteriorating health conditions.*

What was obvious from the information I obtained from the VAERS reports were that there are thousands of reports listing such conditions as neurological damage, arthritis symptoms, and other serious immunological disorders. These are the same types of medical conditions that, in my extensively detailed investigation of the literature, have been published in dozens of medical journals that cite the correlation of this vaccine and severe immunological reactions. (Table of references to be provided at time of hearing). The fact that this reporting system is "passive", i.e., not mandatory, also suggests that only some fraction of adverse events (estimated by FDA officials as 1-10%). In summary it is my opinion that the VAERS system, as currently structured, is highly inadequate to collect scientifically useful information.

I have now been in direct contact with hundreds of severely ill patients (as well as with physicians who have hundreds more patients) having developed adverse reactions to this Hepatitis B vaccine. I feel that it is critical to investigate the early onset effects as well as subsequent development of autoimmune adverse reactions in the hope that we might find more directed treatments to avert the long term effects in those already afflicted with these problems. I believe this is possible in view of new technologies for treatment of autoimmune diseases that are targeted to the identification of specific autoantibodies to defined epitopes.

2. Do the benefits of administering the vaccine to infants outweigh the risks?

To date my studies have concentrated on the adult population. Sadly, even less is known about immunological reactions in infants, especially since they cannot communicate, as can older children or adults, their severe pain, fatigue, or other neurological or physical disturbances. In the event of deaths following vaccination, there is generally inadequate information collected by pathologists to adequately evaluate these reactions.

I would challenge any colleague, clinician or research scientist to claim that we have a basic understanding of the human newborn immune system. It is well established in studies in animal models that the newborn immune system is very distinct from the adolescent or adult. In fact, the immune system of newborns in animal models can easily be perturbed to ensure that it cannot respond properly later in life.

In contrast, it is highly improbable in the U.S. that a newborn has any significant risk of contracting Hepatitis B as a child because the disease is caused by a blood-borne virus. 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 medical worker. About the only way they are likely to be exposed to the disease is by being born to an already infected mother.

In view of this lack of scientific and medical information of neonatal immunology, it is remarkable to me that newborn infants, especially those not at risk for the Hepatitis B disease itself are being administrated 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.

3. What process does the CDC employ to make a recommendation for a vaccine: What role do pharmaceutical companies play in that process? Do conflicts of interest exist?

As I am not an expert on public health policy, I am not familiar with all of the nuances of policies for recommending vaccine mandates. It is well documented, however, that committee members advising the CDC and members of organizations (such as the American Academy of Pediatrics, and the World Health Organization) obtain substantial funding from pharmaceutical companies. Furthermore, it is well documented that investigators who have carried out clinical trials on this vaccine also benefit personally and obtain laboratory funding as consultants promoting the vaccine and as expert witness in legal conflicts. It is also documented that lobbyists who consult for pharmaceutical companies are the same lobbyists for medical health care providers. I leave it up to this distinguished committee to investigate and evaluate the seriousness of these apparent conflicts of interest.

However, it is also apparent to me that the lack of government funding specified for independent scientists to evaluate adverse vaccine reactions is a major reason for scientists to seek funding for experiments dictated by pharmaceutical companies.

4. What disclosure is required before the vaccine is given? Is it adequate?

It is apparent to me, as it is to many others who have been investigating this issue, that adequate long-term follow-up information was not collected in clinical trials for this vaccine. This is particularly true with respect to the Caucasian population. One might therefore ask: "Is there is sufficient information concerning risks of this vaccine to be disclosed?" The ominous lists of potential reactions listed in the vaccine inserts appear not to be given to patients by their physicians. The physician-patient relationship is fiduciary. That is why the lawyer representing my brother, who had an adverse reaction to this vaccine, made a claim of fraud, a claim which this lawyer says has a strong basis in the Restatement of Torts.

doi: 10.1588/medver.2004.01.00008

Many physicians and medical students have told me that, if this vaccine is recommended and mandated by government officials, "why should they look at it or discuss it with their patients?" Others have said that their colleagues do not report these incidences because they "don't want to get involved." They further tell me 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." Unfortunately, they have clearly missed a major point of basic immunology. 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 cDNA 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.

Sadly, in basic science courses in medical schools, many of these details of immunology (a medical research field that has exploded over the last decade) are not taught. I have taught in the basic science curriculum for over 15 years so I am well aware of this limitation. In fact, I recently was invited to speak at the Institute of Medicine at the National Academy of Sciences on this subject. I was quite shocked when a senior member of a national health committee (involved in recommending mandates for childhood vaccines) came up to me and said: "Very interesting talk. I know you teach beginning medical students. Could you recommend me a basic immunology textbook? I think I need to catch up on some of this immunology stuff."

In summary, it is essential in my opinion that physicians be better educated on the potential risks of this vaccine, as well as the interactions with other vaccines and the increased risks of vaccinations of sick children. It is also critically important to conduct the research necessary so that they will have better information to identify people at risk for adverse reaction. In any event early diagnoses of these reactions will result in more effective therapies.

My colleagues and I have submitted proposals to investigate the scientific bases for these vaccine adverse reactions. Many of these reactions are similar to those reactions from individuals having the virus itself. It is also apparent that there are major histocompatability, genetic linkages among patients who are having the severe reactions. It has already been shown that as many as 10 to 30% have been reported as not developing antibodies when they are vaccinated and, therefore, they may not to be protected from the disease. This non-responsiveness may be attributed to the individual histocompatability genes.

We have proposed to carry out research to determine the long-term prognosis for patients having such adverse reactions for two purposes: (1) Developing a prophylactic strategy of identifying those likely to react adversely so they can avoid the vaccine if at risk; and (2) developing a therapeutic strategy by early and more effective identification of those who have had adverse reactions with the hope of developing more specific therapies. I and my collaborators have well equipped laboratories for state of the art immunological and biochemical analyses and we have already collected blood samples throughout the period of these adverse reactions. We therefore, have unique samples to begin to scientifically pinpoint the reasons for the adverse reactions. We have significant preliminary evidence that may explain these responses and we will continue to seek funding to continue these studies. We have obtained some limited funding from private sources but as yet there are no government funds allocated for studying adverse reactions to this vaccine, so the progress of these studies is slow.

It is apparent that the Hepatitis B virus (and vaccine developed from the Hepatitis B surface antigen) is very unique from many other viruses and vaccines. New theories and experiments (i.e. molecular mimicry and anti-idiotypic antibodies) have been developed which could explain reasons for autoimmune reactions caused by this virus or the viral protein used in the vaccine. (The December 26, 1996, New York Time's article which summarizes studies on "molecular mimicry" theories for viruses causing autoimmune diseases may be right on point.) The fact that there are dozens of publications on the correlation of this virus as well as the vaccine with autoimmune and other connective tissue disorders provides strong evidence for the correlation of this viral antigen causing autoimmune diseases.

In summary, no one, especially myself, would ever assert that the Hepatitis B virus is not causing serious health problems in the world. However, if this, or any other vaccine, by nature of the protein or parts of the protein (native or produced from a cDNA as a recombinant protein), has the ability to adversely effect the immune system of large numbers of individuals resulting in severe adverse reactions (even if restricted to some genetic populations), then the public reaction to *all* vaccines, including those that clearly *don't* have related adverse reactions will be doomed in the public's eye. That includes the development of vaccines to evolving airborne viruses that might become a serious threat to the world population. Thanks to the success of the Government funded Human Genome Project and advances in computer programs, it may soon be possible to evaluate potential molecular structure to predict these problems with vaccine in advance or early in vaccine development.

I will conclude by relating an observation. In my research on vaccines that have been used for the humane control of animal populations, I have had the opportunity to observe first hand African elephant family behavior. Whenever a baby cries, the entire herd of up to a hundred will immediately trumpet, and charge with great flurry to surround the infant elephant. When it is apparent that there is no danger, they will one by one touch trunks with that infant, ensuring that he is okay before going about their business. They would certainly never allow a single baby or family member to be exposed to unknown danger.

I ask you in your task of investigating our public health system that as do our friends the elephants, listen to the cries of babies (and family members) that might have been adversely affected by this vaccine or who may be at risk. Please demand adequate scientific documentation and medical information to make responsible decisions concerning mandating vaccines for children. In addition to your investigation on the adverse reactions of this vaccine I would urge you to help to provide research funds which are currently not available to study the serious adverse reactions of this vaccine as well as other vaccines.

Thank you for the opportunity to appear before this distinguished subcommittee. I will be glad to answer any of your questions or provide you with additional information you may request.

Sincerely, Bonnie S. Dunbar, Ph.D., Professor

doi: 10.1588/medver.2004.01.00008