On September 10, 2004, a report co-authored by Mark Blaxill and Barbara Loe Fisher entitled "From Safety Last to Children First: A White Paper on Vaccine Safety" was submitted to Julie Gerberding, M.D., Director, Centers for Disease Control. The report was written in dissent to the official summary of the June 3-4, 2004 deliberations of a Blue Ribbon Panel on Vaccine Safety, whose members were appointed by Dr. Gerberding to discuss critical vaccine safety concerns being discussed in public forums.

The Centers for Disease Control has never formally responded to Blaxil and Fisher's report and it was not made part of a published summary of the June 3-4, 2004 meeting in Atlanta.

In November 2007, the Age of Autism, founded by Dan Olmsted and Mark Blaxill, published this report in eight installments under the title "The Atlanta Manifesto" with special introductions written by Blaxill and Fisher at www.ageofautism.com

November 7, 2007

"Congratulations! You've Been Named to a Blue Ribbon Panel."

by Mark Blaxill

On one of those rare days that my wife and I were actually sitting down at our dinner table for a normal dinner, the phone rang. It was a Wednesday night and Elise answered the phone. She got one of those expressions on her face that meant, "This is not your average call." Her voice turned animated and friendly as she seemed to respond to charm with even more charm. As she turned to hand me the phone, her eyebrows rose.

"It's for you dear. It's the CDC."

I soon found myself speaking to a charming young woman, an aide to CDC Director Julie Gerberding, whose name I can't remember. She was calling to invite me to serve on a "Blue Ribbon Panel on Vaccine Safety" as a "consumer representative." I would be joining high-ranking representatives from the CDC, the Advisory Committee on Immunization Practices, various universities and other federal agencies. Dr. Louis Cooper, past President of the American Academy of Pediatrics would be the chairman. I had had a hint that something like this might be in the works, having spent some time in Washington DC in the previous few months. One of our friends in Congress had mentioned that he hoped to secure an invitation for a SafeMinds representative to a vaccine safety meeting and I had raised my hand. "I'd be delighted to attend", I said to Gerberding's aide. "When does the meeting start?"

"Tomorrow morning at 9:00 AM. It's in Atlanta."

After 25 years in the consulting business, I was used to making last minute travel plans, but this was a bit less notice than I had bargained for. And I had a conflict, an important client meeting on Thursday that I couldn't postpone. But I learned that the meeting would continue through Friday, so I accepted the invitation along with Gerberding's aide's gracious apologies for the late notice. The Blue Ribbon Panel meeting was scheduled on June 3-4, 2004 and after booking the first flight from Boston Logan Airport down to Atlanta, I was able to make it in just a few minutes after the panel reconvened, on Friday morning just a bit after 9.

As I quickly learned, the Blue Ribbon Panel on Vaccine Safety was one of these fascinating exercises in bureaucratic judo, in which a federal agency under attack does its best to neutralize the threat by turning the attacker's energy back on itself, all the while appearing to respond openly and thoughtfully to criticism. In this particular instance, the attack came from two public health professors at John Hopkins, Neal Halsey and Daniel Salmon, who wrote a paper proposing a

change in vaccine safety management. Their rather sensible suggestion was to separate the management of vaccine promotion from vaccine safety assessment, both of which resided within the National Immunization Program (NIP) at CDC. As Halsey and Salmon noted, “This dual role of the NIP to promote immunizations and conduct safety evaluations creates the potential for real and perceived conflicts of interest.”

Faced with this fairly obvious, but threatening point, the Blue Ribbon Panel was the judo move. The CDC called together a bunch of their close friends and asked them to discuss what to do about vaccine safety. Realizing that Congressional oversight wouldn’t let THEM get away with a panel consisting solely of insiders, they invited a few token outsiders. Barbara Loe Fisher, who has long played a lonely role as the nation’s conscience on vaccine safety was invited, as well as some autism organization representatives: Peter Bell from Cure Autism Now and Rob Beck from the Autism Society of America. As Lou Cooper explained, the role of the panel was to offer “a reflection of our individual and collective wisdom”, not to make recommendations. Lou Cooper would take charge of writing up these “reflections.” Under the cover of this relatively friendly document (in case anyone from Congress asked), and after it was all over, the CDC would go ahead and do whatever it wanted to do in the first place.

Based on the timing of my invitation, I surmised that I was not on the top of CDC’s list of friendly panelists. Or maybe they just misplaced my invitation. In any event, as I walked into the hotel conference room late, I took a seat next to Barbara and joined into the discussion. And I must say, it ended up being quite an interesting day.

In response to a question about how the CDC was doing on vaccine safety, I started out doing my best to shake the group up a bit. Apologizing in advance for being “the skunk at the garden party”, I said I thought the CDC was doing a terrible job. And not just on vaccine safety management, but on the larger question of childhood health. They were too busy protecting their sacred programs, I argued, and nothing at all to deal with the crisis in childhood health in America. There were other voices for change in the room as well. Barbara was forceful and deeply knowledgeable on the issues and Peter Bell was similarly supportive on the issues of childhood health. Some of the invitees from the transportation world (in which the FAA promotes air travel and the NTSB deal with airplane safety) thought it was pretty obvious that you needed to separate the functions of promotion and safety management. The voices for change were clearly a minority in the crowd, but despite the wide range of opinions, everyone was professional and polite and Lou Cooper was a gracious host and moderator. But I did notice getting at least one nasty look from one of the ACIP crowd.

Then it was over. Lou Cooper promised to write up a summary report and send it around. When I got the draft a couple of weeks later, it was pretty obvious that the judo move was working. All of the frank conversation, all of the sharp

commentary and the fundamental criticisms were nowhere to be found. Instead, the clear coherent call for change from the outsiders in the room was scattered in bits and fragments throughout the document. The “collective wisdom” of the establishment dominated the tone and reporting. According to Cooper’s summary, the CDC was doing a great job on vaccine safety and everyone on the Blue Ribbon Panel wanted to protect their “good work” from “outside influences.” It was as if a number of us were never there.

I can’t say I was surprised, nor particularly disappointed. But I was definitely annoyed that the voice of dissent had been so thoroughly suppressed. I wondered what I could do about it and I called up Barbara. We both agreed that the least we could do was to actually say something, and we proceeded to write down our dissenting view. They could (and would) ignore what we had to say, but at least we would speak to the void in our own voice, rather than through a filter.

After a month or so of hard work, we wrote the paper called “From Safety Last to Children First: A White Paper on Vaccine Safety.” We let Lou Cooper know what we were doing. We mailed a copy to Julie Gerberding. And that was truly speaking to the void. We never received a response of any kind from CDC. Just Lou Cooper (obviously not happy) asking us not to call it a “minority report” and letting us know it would not be a part of the official record of the meeting. Simply “that they own their response and may distribute it as they wish.”

So what we wish to do, after three years in bureaucratic limbo, is to share our “parent representative report” with the readers of the Age of Autism. The issues we raise haven’t gone away, quite the contrary. We hope you find it thought provoking.

As to the real and perceived conflicts of interest in vaccine safety management, not much happened after all this effort. Gerberding made a cosmetic change by moving the vaccine safety function out of NIP and into another area within CDC. And the Blue Ribbon Panel remained even more obscure than most such efforts. Even Halsey and Salmon noticed the silence. “Both the CDC and FDA responded to our published commentary and recognized the perceived conflict of interest. The CDC then convened a blue-ribbon panel to review the vaccine safety program and where it should be located. But instead of an open debate with the medical and public health communities, the CDC held a closed-door meeting. Neither the transcript of the meeting nor the panel's report has been made public. This is hardly an auspicious beginning to resolve this issue and build confidence in vaccine safety.”

November 7, 2007

One More Time for Old Time's Sake

by Barbara Loe Fisher

When I received my invitation in the summer of 2004 to participate in a Blue Ribbon Panel on Vaccine Safety, I was curious to see who else would be participating. When I saw that Lou Cooper would be the moderator, I knew we would need to dust off our radar to distinguish between what appeared to be happening and what was really happening because Lou is both a gentleman and a magician. He and I first squared off in a debate on the Regis Philbin Show in 1986 when Kathie Lee was still engaged to Frank Gifford and Lou was still insisting that DPT vaccine was really, really, really safe.

But the invitation to the Blue Ribbon Panel meeting also came at a time when I was re-evaluating the 20 years I had worked with public health officials and other "vaccine stakeholders" in collaborative efforts. The latest two year effort was floundering badly despite its promising beginning. I found myself wondering if there was any use flying to Atlanta for another one but I wanted to go because Mark Blaxill was going to be there.

When parents of DPT vaccine injured children organized in the early 1980's under the banner of Dissatisfied Parents Together (DPT) one of the first actions that Merck, Lederle, Wyeth and Lederle took was to threaten to leave the nation without any DPT, MMR or polio vaccine unless they got total liability protection from Congress. The drug companies and the American Academy of Pediatrics pushed very hard for an "exclusive remedy" – no more lawsuits against negligent doctors or drug companies for any reason. They said it was necessary "to protect the vaccine supply." Congress believed them and pledged to pass a federal vaccine injury compensation program to do just that.

Congressional leaders asked our fledgling parent organization to come to the table and fight for the rights of families during creation of the National Childhood Vaccine Injury Act eventually signed into law by President Reagan in 1986. Negotiations on behalf of parents were primarily handled by DPT's first president, environmental lawyer Jeff Schwarz, whose daughter had been brain damaged and eventually died from a reaction to DPT vaccine. We insisted that any law creating a compensation program must first contain safety provisions that would help prevent vaccine injuries and deaths from occurring in the first place. We got them: mandatory reporting, recording and information for parents.

We also insisted that a parent's right to go to court must be protected if federal compensation was denied or – very importantly - if it could be shown that the

drug company engaged in criminal fraud or gross negligence in the testing and manufacturing of the vaccine. Parents prevailed on this point, too, but it came at a high price in terms of compensation caps and certain criteria limitations being placed on those filing vaccine injury claims.

Even so, we never believed that Congress would go back on its promise to parents to ensure that the federal vaccine injury compensation program would be a fair, expedited, less traumatic and less expensive alternative to a vaccine injury lawsuit. That promise has been broken as Congress has looked the other way over the years and allowed the federal compensation system to be turned into a cruel joke, a poor imitation of a jury trial. The lawsuits in the 1980's may have often left vaccine victims with next to nothing after most cases were settled on the courthouse steps by drug company lawyers with deep pockets. But today, government officials fight nearly every vaccine injury claim and, despite the $2 billion already paid out to families, two out of three vaccine victims are turned away empty handed.

This was my first lesson in the politics of mass vaccination.

It was during those four years of negotiations between 1982 and 1986 with government, industry and doctors that I was introduced to the major players in the mass vaccination business. I watched officials in the Departments of Health and Human Services and Justice steadfastly oppose a federal compensation program. CDC officials, especially, did not want to admit publicly that vaccines they recommended for universal use can harm children because they have adopted a utilitarian "for the greater good" position to dismiss the significance of vaccine casualties and persuade state governments to mandate every new vaccine they recommend.

The CDC's stance then and now is: vaccines are entirely safe and effective and if a child's health deteriorates after vaccination, it is the child and not the vaccines at fault.

For the past 25 years, this stubborn "see no evil, hear no evil, speak no evil" position taken by government health agencies when it comes to discussing vaccine risks has made it almost impossible for them to accept the urgent call by parents of vaccine injured children for the institution of safety and informed consent protections in the mass vaccination system. Between 1988 and 2005, I sat at the table with officials from government, the pharmaceutical industry and medical organizations as a member of the National Vaccine Advisory Committee (1988-1991), where I was the chair of the subcommittee on vaccine adverse events; the Institute of Medicine Vaccine Safety Forum (1995-1998), where I helped to produce four published reports on vaccine safety research and policy reform priorities; the FDA Vaccines and Related Biological Products Advisory

Committee (1999-2002), where I voted on the scientific evidence that new vaccines had been proven safe and effective; and the Vaccine Policy Analysis Collaborative, a participatory democracy experiment initiated by the Centers for Disease Control (2002-2005) which almost succeeded until it was sabotaged by industry.

I came to the table again and again because I believe that those who are public critics of government policy should be willing to engage those who make government policy in the hope both parties can better understand one another and find common ground to effect positive change. What I learned from long years of sitting at the table with fellow citizens working in government, who saw my vaccine safety advocacy work as a threat to the public health even as I viewed their denial and inaction as a threat to the public health, is that fear and mistrust dominated almost all of our deliberations. Even when we successfully transcended that fear and mistrust and connected on a personal level as mothers or fathers, daughters or sons, idealists or skeptics, doctors or lay experts, citizen activists or government workers, there was always the institutional position that interfered with our being able to permanently bridge the divide. Tragically, too often that divide was encouraged by those paid by industry whenever it looked like vaccine safety advocates and government health officials might work things out.

Parent pleas to government health officials to acknowledge vaccine risks and do the real science were rejected in favor of holding the line and creating more spin to deny vaccine risks. So, after 25 years, there is still no basic science research into the biological mechanisms for vaccine injury and death or pathological profiles and genetic/biological high risk markers to separate out what is and is not vaccine induced; there are still no methodologically sound epidemiological studies comparing the health of vaccinated and unvaccinated persons to determine background rates for learning disabilities, ADD/ADHD, seizures, autism, asthma, diabetes and other chronic illness in vaccinated and unvaccinated populations. And as we face an escalating autism epidemic that is claiming 1 in 150 or even 1 in 100 of our highly vaccinated children, we still do not know with any scientific certainty the full extent of what injecting children 48 doses of 14 vaccines by age six does to individual and public health.

I came to the Blue Ribbon Panel meeting in 2004 knowing all of the players and remembering the long years we had been doing this familiar dance. For me, the highlight of the coming together again was watching a young father of a daughter with vaccine-induced autism, the brilliant Mark Blaxill, remind them that they continue to ignore our pleas for credible science at their peril. It was a feeling of gratitude, relief, hope and exhilaration, the kind that soldiers dug in the trenches must feel when the cavalry reinforcements arrive. I still wonder what it felt like for everyone else in the room to witness the old and new generations of parents of

vaccine injured children united in a common cause that was little changed, a harbinger of things to come.

The Atlanta Manifesto:
Safety Last to Children First

by Mark Blaxill and Barbara Loe Fisher

Safe Minds and the National Vaccine Information Center (NVIC) are pleased to have an opportunity to present a case for change in our nation's public health strategy. We are grateful to Dr. Julie Gerberding and her staff for reaching out for a range of views on this subject. As parents and citizens, we have joined this discussion feeling the weight of great responsibility on our shoulders, because we see an urgent need for change in public health policy and practice. The health of the children of our country is deteriorating. Yet rather than facing this reality, our public health leadership has turned away from the challenge in order to defend entrenched practices and controversial policies, some of which may have contributed to these adverse trends. Accordingly, we want to make a strong and clear statement: the public health agenda in our country requires comprehensive reform.

The authors represented our respective organizations -- National Vaccine Information Center and Safe Minds -- as invited participants to the Blue Ribbon Panel on Vaccine Safety on June 3-4, 2004, in Atlanta. We appreciated receiving our invitations to attend. We also respect and acknowledge the efforts of the chair, Dr. Louis Cooper, to summarize the discussion in his Summary Report. Given the mix of the participants, many of whom have close ties to the past CDC leadership and/or personal involvement in setting the recent course of U.S. public health policy and practice, we did not expect that the Summary Report would convey our sense of urgency and concern. Although the Summary Report represented a good faith effort to report on the Blue Ribbon Panel's proceedings, it did not provide a coherent reporting of the case for comprehensive change. Accordingly, our two organizations have joined together to author this White Paper on Vaccine Safety, entitled, "From Safety Last to Children First."

We should note at the outset that our most fundamental dissent from the larger group is the framing of the agenda itself. We are far less concerned with focusing on vaccination than we are concerned with focusing on better health outcomes for America's children. Although our organizations have frequently (and unfairly) been described as "anti-vaccine," we share the view that vaccine programs to manage infectious diseases can be a valuable part of strategies to advance the mission of childhood health. These diseases, however, reflect only a fraction of the adverse health outcomes facing children today and a decreasing fraction of these. So although the focus of the agenda for the Blue Ribbon Panel reflects the misplaced emphasis on infectious diseases, we choose not to restrict our Response to the Summary Report to the agenda as defined. Instead we will

address the case for change based on some core principles and a hopeful vision of the future.

We share a sense of hope that America's public health focus can be reformed to serve the health needs of children and families in the 21st century. A forward-looking focus for public health practice would embrace:

1) **A mission of securing positive health outcomes** for children and families;

2) **A commitment to a total health perspective**, including chronic as well as infectious disease, developmental disability as well as episodic illness, and quality of life as well as the absence of disease;

3) **A recognition of the crisis of the chronic disease epidemics among children**, including autism, learning disabilities, attention deficits and other neuro-developmental disorders as well as asthma, allergy, juvenile-onset diabetes and other autoimmune disorders;

4) **A vaccine policy that treats all citizens,** including parents, as intelligent participants in the health choices they make for themselves, their children and their communities and requires true informed consent for participation in vaccine programs;

5) **An operating philosophy that sets a goal of zero vaccine adverse reactions** and treats each reaction respectfully, indeed as a resource for diagnosis and prevention of future vaccine adverse reactions, especially those that lead to chronic adverse health outcomes;

6) **A governance model for vaccine policy-making based on true public accountability**, characterized by public inclusion, openness to scientific criticism and a willingness to accept past shortfalls as an opportunity for learning, growth and change.

We believe that this positive focus is notably absent in public health policy and practice today. Consequently, we share a grave concern that the past approach of public health authorities requires comprehensive and fundamental reform. In contrast to our vision of hope, we see a current approach that is fixated on:

1) **A mission of fighting a war on disease** that disregards the secondary and tertiary consequences of war and views innocent children as inevitable casualties;

2) **A commitment to an unprecedented expansion** in the childhood vaccine program , with inadequate, if any, consideration given to the cumulative and interactive effects of this strategy;

3) **A consistent posture of hyping the risk of infectious disease**, a communication model that relies on fear, hyperbole and incomplete information;

4) **A vaccine program concerned largely with herding "the public"** into a state of compliance, reflecting a view of citizens as a monolithic entity in need of instruction rather than engagement;

5) **An operating ethos in vaccine safety management of utilitarianism**, one that allows for "acceptable losses", based on an approach that places "safety last" in funding priorities;

6) **A pattern of governance** in which many decision-makers have direct financial and/or career conflicts of interest that produce biases to program expansion and the defense of past policy decisions.

The continued pursuit of the current approach has created an adversarial environment that jeopardizes the health of America's children and the long-term well-being of our nation. Within the CDC, a defensive bureaucracy finds it increasingly difficult to reconcile past ideological and policy commitments with the emerging realities. Parent organizations, faced by institutional complacency (with respect to epidemic childhood illnesses like autism) and defensiveness (with respect to the examination of plausible environmental and biological hypotheses), are forced into confrontations they do not enjoy, consuming time they do not have. Pediatric organizations, long resigned to becoming instruments of state policy by allowing their members to become a toll gate for vaccine administration in well child visits, have come adrift from the service mission that motivates most pediatricians, securing positive health outcomes for children, not maximizing their office visits. Vaccine manufacturers, prisoners of their extraordinary corporate profit rates, pursue short term profit enhancement with too little regard for the adverse effects to which inappropriate usage of their products may contribute. In the meantime, as a nation we have too many sick children and no shared view about how they got that way.

This all must change.

From Waging a War on Disease to Securing Childhood Health

For those who join high level discussions of vaccine policy for the first time, it is quite surprising to see many CDC officials wearing uniforms. By embracing a military identity, these officials emphasize their unique prerogatives. That they possess the authority: to deploy the coercive powers of the state as they see fit; to deprive citizens of their liberty in the name of the greater good; and to enforce what they consider to be necessary human sacrifices as they do battle with dangerous microbes and viruses. The language of conflict — the "war on disease," "combating the causes of epidemic," "fighting emerging infections" — is closely connected to the language of military power and, of course, "Disease Control." History teaches us that when government officials are determined to fight a war, any war, truth can be the first casualty.

Although the CDC hosts multiple centers for disease prevention, a clear organizational focus on chronic childhood disease and disability and on overall childhood health is absent. The Center for Chronic Disease Prevention focuses almost exclusively on adult conditions, while the Center for Birth Defects and Developmental Disabilities (NCBDDD) focuses its attention on a selective set of childhood conditions, a set that excludes autoimmune conditions. The NCBDDD has meanwhile demonstrated puzzling complacency in its approach to developmental disorders such as autism. Effectively, the CDC's largest institutional commitment to childhood health lies within the National Immunization Program, a group with an exclusive focus on preventing infectious diseases through mandated mass vaccinations. For most American families, the childhood immunization program represents the public face of the CDC and its most concrete intervention in our everyday lives. We exaggerate only a bit when we say the war on infectious disease as implemented by the NIP is America 's primary childhood health initiative.

In the war on infectious disease, the CDC measures progress by its surveillance of "notifiable diseases." There are now more than 60 such notifiable infectious diseases and the CDC reports these diseases on a weekly basis for each state and territory, with annual breakdowns that itemize case counts by age group, including children. By contrast, no such chronic disease and disability surveillance exists for children, with the sole exception of some rudimentary asthma data. As to clear childhood health crises such as the epidemic of autistic spectrum disorders (ASDs), the CDC only says, "We do not know if ASDs are becoming more common in the United States ."

Clearly, our public health officials possess *asymmetric* information with respect to the total health of children and how it is changing. This asymmetry results in part from institutional inertia, in part from limited funding and in part from different perceived relevance of such timely reporting for intervention purposes. Whether

or not this asymmetry was ever deliberate, it has resulted in clear ignorance regarding chronic disease. And although one might attempt to excuse such ignorance as an historical legacy, at some point such ignorance becomes willful: a conscious choice to forego the acquisition of unwelcome knowledge; an attempt to preserve plausible deniability in the face of disturbing news. In a parent, such denials would amount to negligence. Indeed, diligent, concerned parents have become the most vocal critics of our public health officials' performance in the area of childhood health.

Yet while parents may know a great deal about their own children, they inevitably possess a limited view of populations, enhanced perhaps, but quite possibly distorted, by shared group experiences in advocacy groups. Scientists typically rely on more rigorous surveillance and research to provide reliable trend and incidence data. Yet scientists and other "experts" will only know what basic surveillance tells them or what they seek to know through sponsored research. When basic surveillance and critical research is lacking, scientists become less reliable sources than parents, absent primary information sources of any kind.

As parents, we therefore often look to front line health professionals such as therapists and nurses for their perspective. These professionals have a broader perspective on childhood health than either parents or scientists. Among such health care professionals, the message is clear: something new and terrible is happening to America 's children. Consider, for example, a quote from a representative of school nurses in Missouri, testifying before Congress in 2000.

> *"The elementary grades are overwhelmed with children who have symptoms of neurological and/or immune system damage: epilepsy, seizure disorders, various kinds of palsies, autism, mental retardation, learning disabilities, juvenile-onset diabetes, asthma, vision/hearing loss, and a multitude of new conduct/behavior disorders …*
>
> *We (nurses, principals and teachers) have talked many times about the possible cause(s) of the continuing increase in pervasive developmental disorders (PDD), such as autism. From the literature we have found, we should expect a rate for PDD of about 2-5 in 10,000. In our community the rate in Kindergarten, 1st and 2nd grade is more like 1 in 150. The teaching staff is overwhelmed ….*
>
> *We are all now faced with a moral dilemma: will we protect the "sacred cow of conventional vaccine philosophy" or will we stand up and speak out for the "health and well being of innocent children"? We choose children. We wonder, which will our government choose?*
>
> *— Patti White, RN Missouri Central District School Nurse Association. Statement to the Subcommittee on Criminal Justice, Drug Policy, and Human. Resources of the Committee on Government Reform U.S. House of Representatives*

In the year 2000, there were 122 cases of AIDS reported in children under five years of age, 37 cases of measles, 57 cases of mumps, 10 cases of rubella, 43 cases of hepatitis B, less than 3,000 cases of pertussis, and zero cases of tetanus, diphtheria and 9 other notifiable diseases. By contrast, California — with over 10% of the U.S. population -- reported over 6,700 new cases of PDD/autistic disorder, by extrapolation a national reporting rate of 70,000 children annually. Over 800,000 children under five reported an episode of asthma. New juvenile-onset diabetes cases probably numbered in the thousands (unfortunately, no reliable surveillance exists).

We do not presume to judge the *relative* significance of these diseases to childhood health, however we do submit that chronic diseases are in no way *less* harmful to children. We would also note that the vast majority of children *recover* from a case of childhood infectious disease (as parents looking back on our childhood, most of us remember uneventful recoveries from these diseases as children).

We represent a growing constituency of parents of children who developed normally and then acquired a chronic developmental disorder early in childhood. Our children will never fully recover. Although we recognize the risk of childhood disease, we would gladly trade a few episodes of vaccine-preventable, infectious disease in our children for the disabilities they will live with for the rest of their lives. Tragically, our ranks have swelled dramatically. Indeed, the numbers suggest that the weight of the modern public health agenda should revolve around families like ours. The problem we represent therefore is new. It has, moreover, emerged and grown in parallel with the growth in the number of required childhood vaccines. So although we recognize the risk of jumping to premature conclusions regarding causality, we also deplore complacency and defensiveness in any form. It is time, indeed long past time, for our public health officials to reset their priorities and turn their attention to the health issues of greatest consequence for children in the 21st century.

From Expansion of Vaccine Interventions to a Commitment to a Total Health Perspective

The Blue Ribbon Panel was convened to consider a proposal to separate vaccine risk management from risk assessment [at the CDC]. We concur with the spirit of this proposal and believe that independence in vaccine safety assessment is overdue. The National Immunization Program has long confused vaccine safety with vaccine promotion. But we also see a deeper force driving the problems with vaccine safety, a force that goes beyond simple questions of organization and governance. The longstanding commitment of our public health leadership to expansion of the mandatory vaccination programs places pressure on the watchdogs of safety to make vaccine risk assessment friendly not just for current programs, but also for new vaccines. Dr. Robert Chen, the official most responsible for vaccine safety over the last decade has openly confessed to this bias in print.

> *"Given the current increasingly "anti-vaccine" milieu, it is hard to imagine that the full potential of new vaccines will be harnessed. To avoid this impending tragedy, we need to critically examine the factors influencing this change in public sentiments."*
>
> — Dr. Robert Chen, Vaccine Safety and Development Branch, National Immunization Program, CDC, "Vaccine Risks: real, perceived and unknown", Vaccine, 1999.

Dr. Chen sets forth here the central fallacy of modern vaccine policy: if some vaccine interventions have done some good, then more interventions will do more good. His conclusion that the failure to expand the vaccine program would be a "tragedy" reflects this a priori assumption, shared by so many, that we have only just begun to harness the potential for strategies of increased intervention. Numerous careers, major research programs and large-scale commercial investments have been bet on the promise of public acceptance of unlimited vaccine interventions. Much is at stake.

In just a few short years, we have seen the effects of this strategy. Through the 1970s, the childhood immunization schedule consisted of interventions against a short list of diseases: smallpox, polio, diphtheria, pertussis and tetanus. Today, the CDC's "universal use" list for children has expanded to include vaccines against measles, mumps, rubella, hepatitis B, haemophilus influenza B, varicella, pneumococcal and influenza. Before they reach their second birthday, a child born today will receive 32 separate vaccine doses when following the CDC's recommended schedule. With these additions, we have embarked on a public health strategy that constitutes a radical shift in the way our species experiences its environment and a radical shift in the way the human immune and

neurological systems develop during the first critical months of life. In a quite literal sense, we have entered unexplored territory.

As the childhood vaccine program has expanded, it has also changed character. The earliest vaccines—polio, diphtheria, smallpox—protected against highly infectious and frequently fatal diseases, diseases to which infants were also highly vulnerable. The new additions to the vaccine program have not targeted similar attributes or shared the same benefits. These new targets are often less dangerous to children (chickenpox or rubella), less infectious (haemophilus influenza B or pneumococcal) or otherwise less prevalent among children (hepatitis B).

Although the original vaccines had demonstrable preventive benefits, their risks were also meaningful. Dramatic, sometimes fatal, adverse events associated with neurological damage have been documented, most notably with whole cell pertussis vaccine, but also with oral polio vaccines. The re-introduction of smallpox vaccine after September 11, 2001 was curtailed due to unacceptable rates of adverse events, including cardiac events that led to death. One distinguishing feature of these events, however, was their clear cause-and-effect relationship with single vaccine exposures.

As the vaccine program has expanded, we face new safety concerns. In addition to the ongoing risk of single vaccine adverse events, we need to recognize new exposure risks, either from the cumulative effect of vaccine ingredients or from the unintended consequence of interactions between vaccine and other environmental antigens and the potential for accidents in a complex, closely-coupled system like the developing immune system.

Vaccine mercury exposure provides a dramatic example of the cumulative effect risk. Exposing the developing brain to mercury was never a good idea, but the introduction of two new vaccines in the early 1990s (not to mention the increasing practice of antenatal Rho D immunization) tripled the earliest exposure rates. These additions effectively compounded acknowledged mercury risks to pregnant mothers from seafood consumption and dental amalgams. In the case of mercury, we see the dark side of the "more is better", expansionist bias: if some mercury exposure is bad, then more is unquestionably worse. Yet now the CDC has recommended new childhood mercury exposures via influenza vaccines, when evidence continues to accumulate underscoring the danger of these exposures.

More complex, but no less concerning, is the issue of interactive effects. We simply do not know what the risks of these 39 doses of 12 vaccines might be for human health when combined together in developing infants. In the face of this recent escalation in intervention, common sense would suggest a testing discipline involving more than assessments of each new vaccine, or even

combination vaccine, on its own, but rather involving comprehensive assessments of the old strategy vs. the new strategy in their entirety. Such comprehensive testing has been dismissed as too expensive, or even absurd. But it has never been attempted.

So as parents, we are faced with a puzzling paradox. We want our children to be healthy, but they are not, even though we have done what we have been told to do by public health officials and pediatricians. We see families around us in similar distress, with asthma inhalers and epi pens as common in schools today as peanut butter and jelly sandwiches were in our day. We are concerned about a radical strategy of intervention that has never been tested for safety and yet we watch as responsible government officials behave defensively and with more regard for their beliefs and careers than for the future of our children. We want to believe in the integrity of our public health system, yet we cannot, because we fear that excessive specialization and bureaucratic inertia has led us away from the only focus that matters: the overall health and well-being of our children. We believe it is time to call a halt to the expansionist momentum and revisit basic strategic premises. We strongly encourage the CDC to move away from strategies focused on the parts to a strategy focused on a total health perspective. This may be difficult, but it is necessary if we are going to answer the question: why are so many children chronically ill today?

From Hyping the Risk of Infectious Disease to Facing the Reality of Chronic Disease Epidemics

As the vaccine program expands and the complex assessment of marginal cost and benefits becomes more critical, the integrity of the analyses surrounding these assessments matters even more. A prior commitment to a strategy of program expansion casts suspicion on the CDC's internal analysis when the institutional proponents of the expansion strategy control the interpretation and dissemination of information and analysis. The obvious concern is that benefits may be overstated and that risks will be suppressed.

We see pervasive evidence of bias among CDC's analysts that lends credence to such concerns. Hepatitis B vaccine policy serves as useful first case in point.

CDC officials display a bias toward vaccine interventions. When the mandatory hepatitis B vaccination was added to the childhood immunization schedule in 1991, this new initiative was the outcome of years of policy discussions. CDC infectious disease specialists took a public advocacy stance in favor of "worldwide elimination of hepatitis B transmission," claiming "we have the way, we need the will." Oddly, for a disease transmitted primarily through promiscuous sexual activity and intravenous drug use, the strategy they chose was universal infant immunization, including a first dose immediately at birth. Yet claims supporting the wisdom of this "way" have been called into question by recent research showing that infant hepatitis B immunization provides protection for five years at most.

CDC models exaggerate the incidence of infectious disease. Promoting a short-lived intervention in populations far removed from the main source of the infection is odd enough, but the CDC felt obliged to defend the urgency of such an unusual choice by overstating the overall risks of this (largely adult) disease. Until the late 1990s, annual infections by hepatitis B virus (HBV) in the U.S. were routinely quoted at more than 300,000 despite the fact that CDC's own surveillance numbers showed far fewer cases, less than 10% of the quoted cases, and these case counts fell rapidly through the 1990s

CDC models overstate childhood disease risk to justify vaccine interventions. Defenders of the universal hepatitis B vaccine birth dose policy estimated that 25,000 HBV infections occurred annually in children prior to the introduction of the vaccine. These calculations have not been challenged but are full of holes: surveillance reports of childhood infections have never reached even 1% of these modeled levels; the models that produce high infection estimates require large rates of horizontal transmission, transmissions that have never been reliably described; and distinctions between perinatal transmission (where mothers could reasonably be offered a choice between vaccine exposure and maternal HBV testing) and childhood transmission (where vaccines provide unique benefits)

have never been established. In evaluating a policy that requires annual immunizations of millions of newborns, rigor and accuracy in making such distinctions are critical, but such scrutiny has been forsaken in favor of salesmanship and hype.

We have by now become familiar with the fear-mongering that makes infectious disease a reliable news item. From the infamous swine flu to the West Nile virus, we have grown accustomed to seeing the threat of deadly infection on the front page and the evening news. Even with more legitimate threats like SARS, the reality of these threats consistently fails to meet the hype, yet spreading the fear of infection remains a reliable tactic. By contrast, chronic diseases--perhaps because they are judged to be less preventable, a matter for families to accept rather than a prevention opportunity — receive nowhere near the same attention or priority. Autism rates have increase tenfold but the CDC has not yet declared a public health crisis. Similar to the case of hepatitis B, autism provides a second case example of CDC policy bias.

CDC surveillance designs fail to specify chronic disease variants. The featured activity in CDC's autism surveillance activities is the Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP). Although only a single publication has been produced so far as an output of this effort, this publication revealed the manifold weaknesses of the program. The MADDSP approach fails to distinguish between the sub-categories of the Pervasive Developmental Disorders (PDDs) — autistic disorder, PDD not otherwise specified and Asperger's syndrome — an approach that makes it impossible to compare results of MADDSP with other studies around the world. MADDSP researchers place children in diagnostic categories based only on a records review and do not require standardized diagnostic interviews. Diagnostic precision is essential to effective surveillance (can you imagine hepatitis reports that fail to distinguish between viruses A, B and C?) yet the MADDSP program has abandoned any effort to institute such precision. Even so, the CDC now offers their approach as the model for other states to follow. Lack of diagnostic precision may provide a deliberate refuge for analysts who are not interested in obtaining good facts, but makes for poor health policy in the long run.

CDC studies avoid the assessment of chronic disease trends. When CDC studies have embraced a more rigorous approach to PDD classifications, they have still failed to report accurately on time trends. The autism prevalence researchers in Brick Township, NJ provided accurate estimates of autism rates in a well-defined study population. Yet they suppressed important evidence on changes in autism rates over time, reporting rates by only two large age groups. More disturbing, these authors failed to publish autism rates by birth year, rates that would have demonstrated clear and compelling evidence of an increasing time trend in autism rates. Safe Minds has obtained these rates, and they contradict the CDC authors' claims that "prevalence rates for the two [time periods] were not different." We cannot help but wonder how the surveillance

disciplines, so well developed in infectious diseases, break down so completely in chronic diseases like autism. Yet they do.

When increasing trends are acknowledged they are dismissed with speculation. When discussing the undeniable increases in reported autism rates, CDC officials profess little concern and offer unsupported hypotheses that attempt to play down the likelihood of any real increase. The NCBDD web site on autism offers the following account.

"The studies that have looked at how common ASDs are often used different ways to identify children with ASDs, and it is possible that researchers have just gotten better at identifying these children. It is also possible that professionals know more about ASDs now and are therefore more likely to diagnose them correctly. Also, a wider range of people are now being classified as having ASDs, including people with very good language and thinking skills in some areas who have unusual ways of interacting or behaving."

In the face of the spectacular rise in reported autism rates, speculations like these cry out for scientific support. Yet there is no scientific evidence of any kind that supports a single one of these speculations. How is such carelessness allowed?

Taken together, these tendencies form a pernicious pattern of misinformation and deception. The favored diseases and interventions are supported, while the inconvenient trends and anomalies are suppressed. Responsible public health management demands a clear-eyed view of the current health reality, one based on high-quality data, sound analysis and rigorous logic. It is time to start facing this reality without further delay.

From Herding the Public to Informed Consent

The rising complexity of vaccine risks and benefits makes the assessment of risk far more sensitive to the assessment of such complex trade-offs. But when the guardians of vaccine safety [at the CDC] play a dual role as advocates of program expansion, the potential for bias, conflict of interest and bureaucratic error in these assessments rise when there are no mechanisms in place for self-correction. When advocates of vaccine programs can also exercise the coercive power of the state to enforce their decisions through vaccine mandates, the risks of catastrophic failure multiply.

In an open society, we typically rely on the free choices of informed citizens as the corrective mechanism for dealing with complex trade-offs. We express our freedom in two ways, through the free market (for economic trade-offs) or free elections (for policy making). In either domain, we know from long experience that assigning decision rights to centralized state authorities can produce lasting inefficiencies and/or inappropriate concentrations of power. Checks and balances on such power are essential to prevent the abuse of power by the state and secure improved outcomes for society.

Vaccine programs introduce special problems in an open society. Mass vaccination programs for infectious disease prevention are based on the premise that herd immunity is the only way to manage infectious diseases. Achieving herd immunity requires widespread compliance, indeed significantly greater compliance than either free markets or free elections require for success. Vaccination coverage rates sufficient to provide herd immunity have been estimated to be in the 80-95% range depending on the disease. Achieving such high compliance rates in large populations demands extraordinary efforts. Compounding this difficulty, public health officials have increasingly defined success as compliance rates approaching 100%, a shift from a goal of herd immunity to a goal of local elimination, even global eradication, of most diseases for which vaccines have been developed. With such aggressive targets the exercise of economic choice ("I don't want to receive that service") or the declaration of dissent ("I don't support that policy") runs in direct opposition to the interests of the bureaucracy in meeting its performance goals.

In order to reach these rising compliance targets, vaccine program sponsors ask for and typically receive exemptions from normal checks and balances on state power. These exemptions are justified because the prevention of disease is seen as an area in which the interests of the collective override the rights of the individual. Consequently, manufacturers receive exemptions from product liability laws. Citizens face powerful sanctions if they fail to comply with state recommendations -- children can be denied entry to school, parents can be declared negligent, and pediatricians can deny service to families when they

choose not to vaccinate. Program managers are protected from accountability to external parties in numerous ways.

These exemptions can end up producing an unhealthy relationship between citizens and central authorities. In the eyes of the officials, a diverse and autonomous citizenry becomes a monolithic and (ideally) submissive "public." The public must be convinced of the virtues of compliance so that the herd can maintain its immunity and remain safe from disease. The more submissive the herd, the greater the opportunity for heroic achievements in disease elimination and the less the need to apply coercive measures to dissenting citizens.

Yet the childhood immunization program is the only medical intervention capable of producing injury or death that the state imposes on healthy children. Vaccines are also the only privately manufactured product whose universal consumption is made a prerequisite for participation in public services. These extraordinary exemptions from our normal democratic system of checks and balances and free markets demand extraordinary, and constant, scrutiny. Vaccine program management must not only work when safety is secured, it must also be robust in the face of safety failures.

But how robust can our system of vaccine safety management ever be? If one assumes that program managers are always diligent, competent and correct in their assessments and that the programs themselves unambiguously and universally safe, then these exemptions from our standards of openness are a small price to pay for results. But when there is a possibility of negligence, incompetence, or even well-intentioned error, these protections run the risk of perpetuating and exacerbating truly catastrophic failures. In their book, The Virus and the Vaccine, Deborah Bookchin and Jim Schumacher elaborated the dangers:

> *"The decisions of our health policy makers, even when well intentioned are not always well informed. And sometimes those decisions are not even well intentioned. Sometimes they are based on bias or inadequate scientific evidence. Sometimes they are biased by the close relationship between the pharmaceutical industry and the government health officials who are charged with regulating that industry. Moreover, sometimes even the best scientists can make mistakes. The safest medical products can have unforeseen side effects. Things do occasionally go wrong, sometimes dreadfully wrong, during even the most noble of scientific endeavors."*

And when things do go wrong, the inevitably defensive reactions can creep down a slippery slope from the prevention of unnecessary panic to the dissemination of propaganda and the suppression of dissent. The resources available to health officials to mount defenses in the face of failure are extensive. Prestigious

journals can relax their standards in support of questionable research; at-risk constituencies can mobilize resources to attack discomforting facts; funding agencies can deny resources for investigations into possible failures; and conscientious scientists can face disincentives (even sanctions) when they pursue unpopular investigations.

One powerful bulwark against such breakdowns is the right of informed consent. Informed consent requires and empowers each citizen to make choices for themselves and their families based on their independent assessment of risks and benefits. Informed consent thereby provides a counterbalancing force against overreaching activities of the state and provides incentives for manufacturers to improve the safety and effectiveness of their products:

- **In the absence of an ability** to choose between vaccine formulations, combinations and producers, citizens can at least exercise choice with respect to timing and receipt of specific vaccinations;
- **In the absence of meaningful product guarantees or warrantie**s, citizens can request and expect the provision of scientific information regarding attributed risks and benefits of vaccines;
- **In the absence of clear scientific knowledge** regarding the immunological mechanisms, failure modes and adverse exposure consequences, citizens can seek, consider and act on information from multiple sources, reserving the right to critically review official interpretations of vaccine benefits and risks and freely act upon the information they have obtained.

Today, parents who wish to make a different choice with respect to their children's vaccinations face numerous obstacles. They can claim a medical exemption if their child has suffered a "severe vaccine reaction" that must meet restrictive CDC standards as a contraindication to further vaccination and are able to find a doctor willing to write a medical exemption to vaccination. They can, in most states, claim exemption based on sincerely held religious beliefs. In eighteen states, they can exercise their right to a philosophical or conscientious belief exemption to vaccination. But everywhere these rights might be exercised, they are, practically speaking, nearly impossible to obtain (in the case of medical exemptions), under challenge (religious exemptions) or available only to a small number of parents who are aware of their rights.

In real life, when parents resist their pediatrician's advice, they risk sanctions of varying severity, up to and including loss of medical care, health insurance and even custody. Pediatricians or nurses can and do notify Child Welfare authorities when parents resist vaccination and the parents can be charged with child medical neglect. Parents can postpone the age at vaccination, but in doing so

they forego access to most child-care and educational services. Indeed, with respect to the universal hepatitis B birth dose, they often find that vaccination takes place in hospital nurseries without their knowledge, preceding consent. The provision of true informed consent, which has defined the ethical practice of modern medicine and is so essential as a counterweight to state power, remains a distant promise for most American parents.

From Safety Last to a Quest for Zero Vaccine Adverse Events

Members of our organizations (SafeMinds and the National Vaccine Information Center) recall private conversations during which National Immunization Program officials revealed their underlying utilitarian philosophy: parents of vaccine injured children, calling for reform of the vaccination system, were described as "selfish"; adverse events were described as "acceptable losses"; while adverse events resulting in injuries and death were dismissed as either coincidences or the inevitable by-products of the pursuit of the "greater good." Dr. Robert Chen, the man most responsible for setting the tone and direction of NIP safety practices for over a decade, described the end result of a utilitarianism mindset on safety management at NIP in 1999:

> **"[W]e have been relatively slow in appreciating the importance the public now places on vaccines safety. In fact, much of our resource allocations still unfortunately reflect safety last rather than safety first…Furthermore…we have not been as interested in preventing vaccine-induced illnesses as we are with vaccine-preventable diseases."**

The fact that Chen would make this concession in print suggests strongly that not only does this "safety last" mindset exist, but that it is more severe and pervasive than he and others acknowledge. Indeed, it affects all aspects of safety management in the childhood immunization program. A partial list of "safety last" examples would include the following.

- **The CDC has long acknowledged** the central problem with the Vaccine Adverse Event Reporting Systems (VAERS): that the reporting of vaccine adverse events will necessarily be reduced under a passive reporting system. Estimates of the underreporting vary (a common estimate is that only 5-10% of adverse events are reported), yet there are only limited efforts in place to promote and encourage the reporting of these events as mandated by Congress (under PL 99-5500).

- **When observed, adverse events are routinely dismissed** by pediatricians as unrelated to vaccination, with the tacit support and encouragement of NIP officials. Adverse event reports are frequently met with the assertion that the timing of onset of seizure disorders, sudden infant death syndrome, hospitalizations and other vaccine injuries are only coincidentally related to vaccination.

- **When faced with adverse event claims**, families of vaccine injured children in the Vaccine Injury Compensation Program (VICP) often find themselves the target of active suppression of those claims, as even straightforward events are routinely opposed in an adversarial process.

Expert witnesses for the CDC called to testify in VICP award proceedings routinely deny the very existence of vaccine adverse events.

- **More broadly, the Vaccine Injury Compensation Program**, originally conceived as a means for rapid compensation for families suffering from vaccine injury, has approached the management of compensation with a stubborn reluctance to grant awards. The result of this reluctance is that only a fraction of the hundreds of millions of dollars set aside in the vaccine injury trust fund has ever been paid out.

- **In the meantime, vaccine manufacturers** have received widespread protection from product liability claims, an exemption that substantially reduces the normal marketplace incentives on manufacturers to ensure the safety of their products.

- **This unusual liability exemption stands in stark contrast** to disturbing examples of longstanding product contamination, including the recent discoveries of connections between contaminated polio vaccines and highly carcinogenic simian virus (SV40) detected in many human cancers.

- **More complex safety concerns** have faced even greater neglect, as safety testing of the new expanded-program strategies, e.g., comparing exposed populations to zero exposure populations, has never been attempted.

- **When high profile safety investigations** have taken place, these investigations have been carried out by interested parties. In the case of three thimerosal studies in Denmark, for example, the primary authors for all of them were directly employed by a vaccine manufacturer (or its affiliates) that held direct profit interests in the products involved

These problems have all been compounded as the safety management agenda has shifted from evaluating narrowly defined events, such as a seizure response to a dose of whole cell pertussis in DPT vaccines, to assessing adverse effects rooted in cumulative exposures to vaccine elements (e.g., thimerosal exposure from three separate childhood vaccines in combination with prenatal mercury exposures from maternal dental amalgams or seafood ingestion) or the interactive effects of multiple antigen vaccines and/or multiple vaccines given in close succession. Co-factors, which could also play a role in vaccine adverse events suffered by an individual, such as coinciding viral or bacterial infection at the time of vaccination; simultaneous exposure to environmental toxins, such as pesticides or toxic mold; or predisposing genetic factors due to biodiversity in an ethnically diverse population, are never factored in. Vaccine safety administrators are ill prepared even to acknowledge the possibility of such effects, let alone evaluate them.

One consequence of combining mandatory vaccination policies with exempting manufacturers from product liability has been the absence of free market competitive pressures to raise quality performance. As the quality revolution in management swept through the business world in the latter part of the 20th century, most competitive industries have embraced quality disciplines that have not yet penetrated the NIP. One of the leading quality management experts, Philip Crosby, in his influential book, Quality is Free (1980), succinctly described one of the core lessons of quality management.

"The first step is to examine and adopt the attitude of defect prevention. This attitude is called symbolically, Zero Defects. Zero Defects is…a standard that management can convey to employees to help them decide to do the job right the first time…Most people talk about an AQL, an acceptable quality level. An AQL really means a commitment before the job to produce imperfect material… Consider the AQL you would accept on the products you buy. Would you accept in advance an automobile that you knew in advance was 15% defective?…How about the nurses that care for newborn babies? Would an AQL of 3% on mishandling be too rigid?…The only proper performance standard is Zero Defects. Why settle for less? People accept the performance standards you give them."

The pursuit of zero defects in vaccine safety would demand a performance standard of zero adverse reactions. Such a goal need not be immediately attainable, but the relentless focus on continuous improvement toward that goal would mean that no disabling injuries or deaths would be viewed as acceptable. Instead, every adverse reaction would be managed as an opportunity for analysis of the root causes of vaccine failures. Instead of encouraging reclassification of adverse events as coincidental events, severe reactions would be treated with respect, compassion and curiosity. And instead of fighting injured families as greedy opportunists, compensation programs would be restored to their original role, as an occasion to provide justice and deserved financial support. But as Philip Crosby describes it, embracing Zero Defects (Zero Adverse Reactions in this context) requires adopting a new attitude, one that several panel participants noted would require sweeping cultural changes in all aspects of vaccine safety management. Culture change can only come from the top. This brings us to the conditions and context for leadership on vaccine programs and safety, in other words, vaccine governance.

From Conflicts of Interest to True Public Accountability

Public institutions have the responsibility to carry out public affairs with governance mechanisms that keep decisions free of conflicts of interest and resultant self-dealing by interested parties. As our society has evolved, the influence of well-organized and well-funded interest groups has made avoiding such conflicts of interest progressively more difficult. In the area of vaccine safety, we see serious conflicts between the promotion and management of the childhood immunization program and the exercise of diligence and care in the safety monitoring of the program.

These conflicts play out in numerous ways. Indeed, despite many years of effort by dedicated consumer advocates, we fear that vaccine program governance has deteriorated to a point where the most economically interested parties have effectively collaborated to dominate decision-making in ways that maximize their direct benefits, while marginalizing the legitimate concerns and life-altering experiences of dissatisfied customers of the vaccine programs. These parties—vaccine manufacturers, health maintenance organizations (HMOs), pediatrician groups and government public health officials--have demonstrable interests in favor of expanding vaccine administration and mandates while constraining vaccine safety initiatives and in some cases suppressing unwelcome vaccine risk findings. To illustrate this governance dilemma, we review the interlocking interests of these four parties briefly.

Vaccine manufacturers. Maintaining a successful vaccine program requires the participation of a viable base of vaccine suppliers. These suppliers deserve the opportunity to make competitive, market returns, consistent with their risks and investments. Increasingly, however, the "market" for vaccine suppliers has become a regulated state oligopoly, not really a market at all, but rather a highly managed public-private partnership with guaranteed returns and minimal financial risks. Large, stable and growing markets are guaranteed by official decree. Product liability is more limited than for any other manufactured product. New firm entry is highly constrained and only a small set of competitors share the market, with only a small set of competitive formulations granted market access at any point in time. Public health officials, in their quest to serve their suppliers, have effectively become supplier advocates, consistently acquiescing in decisions that benefit vaccine manufacturers and disadvantage consumers.

The extraordinary profitability of pharmaceutical manufacturing (the 2001 profits of the top 10 pharmaceutical manufacturers exceeded the profits of the rest of the Fortune 500 combined) can make vaccines appear unattractive as a business: indeed drug manufacturers have long complained about the poor relative profitability of their vaccine divisions. But as the vaccine program has expanded and most childhood vaccines produced by manufacturers have been

added to the CDC's "universal use" and state mandatory vaccination requirements, this performance profile has shifted. New, patent protected products with high prices and healthy margins have replaced older vaccine formulations in the product mix. While decisions to endorse and promote the strategic expansion of childhood vaccines (vaccines with increasingly small incremental consumer benefits) have provided large financial benefits to these companies, the management of safety concerns has consistently placed manufacturers' interests ahead of those of consumers.

Despite demonstrable health threats, recalls of dangerous vaccine products are a rare event. Remarkably, polio vaccines contaminated with highly carcinogenic viruses were never recalled and have now been associated with widespread cancer incidence. Similarly, longstanding calls to recall vaccines containing the highly neurotoxic element, mercury, have gone unheeded, with unknown developmental consequences in the millions of children exposed after the risks of mercury exposure were first identified. Even now, new flu vaccine formulations containing mercury have received CDC endorsement. Meanwhile, sensitive safety investigations into vaccine failures have been entrusted, in some cases, to vaccine manufacturers themselves and, in others, to researchers with close financial ties to manufacturing companies. Not surprisingly, the research results of such investigations routinely find no adverse consequences of vaccine exposure.

Health maintenance organizations. HMOs face the unique challenge of maintaining profitability in the face of skyrocketing health care costs and pressure from their own customers, primarily private companies seeking to minimize the cost of providing health care benefits. In pursuit of their profit goals, these insurers have clear interests in minimizing the cost of their service obligations and reducing the variability of their patient risk profiles, while also projecting an image of responsive service and high quality care to their patients. Because of the known turnover in their patient bases, HMO investments in health and prevention require relatively short payback periods; by extension, long-term risk reduction and chronic disease prevention is unlikely to receive HMO financial support.

By contrast, childhood vaccinations provide a strong economic benefit to HMOs: they provide visible services to young families; the unit of service delivery (the well child visit) is highly predictable, routinized and therefore low cost at the delivery level; and they prevent less structured (and potentially higher cost) care delivery in the case of children infected with a childhood disease. Another economic goal of HMOs lies in restricting the cumulative number of well child visits, one reason why combination vaccines have proven popular. The potential adverse consequences of an expanded childhood vaccine program (and expanded vaccine combinations) are either out of their services scope (e.g.,

autism and other developmental disabilities) or beyond their preventive planning horizon (e.g., asthma, diabetes, cancer).

With respect to vaccine safety, HMOs can, and in some cases do, provide important information resources for safety management. Given the value of their patient data, HMOs have an interest in maintaining control over their private databases. Pooled databases like the Vaccine Safety Datalink provide information resources of extraordinary potential societal value; yet by increasing the transparency around health outcomes across different participating HMOs, information sharing also threatens the autonomy of these organizations. The public interest lies clearly in full and prompt reporting of health outcomes, especially as they relate to vaccine safety, but HMOs have resisted the expansion of public health claims on their data resources. They typically fall back on claims of patient confidentiality to restrict outside access, but these claims are rarely in the interests of their patients, instead they are largely a mechanism to retain autonomy and control. As a consequence, resources for vaccine safety reporting have remained highly restricted, non-standardized, inaccessible and unreliable for assessing health outcomes.

Pediatricians. One consequence of the cost squeeze in health insurance has been that pediatricians, like most primary care physicians, have become captives of a new economic model of primary care delivery: high volume, low touch, and increasingly structured around compensation rules for specific diagnosis codes rather than time spent with children. Most pediatricians enter the field of pediatric medicine out of a desire to serve children. Increasingly, they are becoming captives of the compensation rules regarding allowable services. One of these allowable routines is the well child visit, a repeatable and tightly defined procedure that is little more than a tollgate for vaccine administration. The economics of pediatric practice have become increasingly dependent on these tolls, and the well child toll has become a critical component of a pediatrician's annual income.

By contrast, as the front line of vaccine adverse effect reporting, pediatricians have incentives to avoid adverse event reporting. When faced with a possible vaccine adverse event, each pediatrician has discretion in associating the event with the vaccine, although the National Childhood Vaccine Injury Act obligated the pediatrician simply to report the event and not make a causation determination at the provider level. Pediatricians have a personal stake in the success of the vaccine program and, more important, an emotional stake in the absence of causal relationship between vaccination and injured children. No pediatrician wants to believe that their personal interventions have caused harm to their young patients.

At the same time, the report of an adverse event takes time and effort while also causing the pediatrician to fear litigious behavior on the part of parents, even though the 1986 Vaccine Injury Act protected pediatricians from most vaccine

injury lawsuits. For all these reasons, pediatricians view reporting vaccine reactions as a risk rather than a benefit. Not surprisingly, the groups that represent pediatricians seek to minimize the concerns over adverse events and preserve the confidence of parents in the childhood immunization program and its associated well child visit.

Public health officials. Public health officials in positions of vaccine policy leadership typically have sustained long careers in the field and have participated in the long trail of policy choices that has produced the current expansive strategy. These career officials draw meaning from this legacy of work and often reveal their search for meaning by seeking other ways to expand their mission, either through heroic efforts at disease eradication ("Worldwide elimination of hepatitis B transmission: we have the way we need the will") or global collaborations to spread vaccine successes to new countries. They certainly have little appetite for seeking evidence that might constrain this mission or, what would be far worse, to demonstrate that it might have inflicted more harm than good.

As the regulatory hub for the field vaccine development, these officials interact regularly with interested parties in the vaccine program: the vaccine manufacturers, the HMO industry representatives and pediatrician groups. After many years of collaboration in this community (what Eisenhower might have called the vaccine development complex), public health officials can easily lose their objectivity as they are caught in the web of their connections with industry professionals: they may become friends with their industry colleagues--certainly they often develop mutual respect as colleagues--as they also maintain a range of professional and social contacts across the community. Those who may question or criticize their mission are threatening and unwelcome. Frequently, these outsiders are dismissed with epithets: they (indeed we) are derided as "anti-vaccine", "not scholarly" or "junk scientists and charlatans."

Effective dismissal, however, requires a larger scale denial of resources for which these officials serve as gate-keeper: they deny funding for legitimate vaccine injury hypotheses; they deny independent access to vaccine safety data resources; they forego deep investigations into adverse consequences; they work to deny exemptions and informed consent provisions in vaccine laws; and they effectively deny meaningful access and participation in vaccine research-setting priorities and policy-making to the interested and injured parties

Missing from this governance system are the only parties without a real conflict of interest, the real customers of the childhood immunization program: parents and children. As parent organizations, we represent a part of that most vital constituency, not the whole constituency, but a vital part nevertheless. And we are calling for a clear break from the practice of business as usual. It is time that the public health officials became more accountable to the parents, whose

children's lives are on the line, than to the industry, which profits from government mandates and protections.

Conclusion

We conclude this white paper with a distress call, not because we are alarmist by natures, but because we share a concern that the default path of vaccine development and safety management will not lead us closer to the hopeful future we described at the beginning of this report. Instead, we fear that the more likely direction will turn sharply toward an even more extreme approach to childhood public health strategy.

- **The mission will continue to creep away from mere overemphasis** on infectious disease prevention and management to a pursuit of disease eradication, a far more radical and quixotic goal;

- **The strategy will continue to overreach,** from a step-wise expansion of the U.S. vaccine program expansion to a global escalation of vaccine interventions across diseases and geographies;

- **The communication approach** will grow increasingly strident, shifting from the mere hyping of infectious disease risk to promoting an ambience of fear, hijacking the threat of terrorism to lend legitimacy to the creeping mission;

- **The style of engagement with families** will become more coercive, moving from an emphasis on herding the public with public relations to imposing forced vaccination with all the necessary suppression of dissent and infringement on civil liberties that would be required to institute such coercive measures;

- **The operational oversight of vaccine safety will degenerate**, from the current utilitarian stance, which merely devalues adverse reactions, to a more Orwellian posture in which adverse event denial becomes the prevailing mode of management;

- **The program governance standards will decline further**, from a half-hearted attempt to manage conflict of interest to a full embrace of governance by and for the vaccine development complex, as continued engagement with increasingly restive (and non-compliant) parent groups becomes less and less appealing.

We believe you have an historic opportunity to signal a new day in childhood public health management. To do this, we suggest you take the following ten simple steps.

1. **Declare autism a national emergency.** It is the proverbial "canary in a coal mine" for a host of chronic neurological and immune system disorders.

2. **Launch a full-scale investigation** into all potential environmental causes of autism and related disorders, including mercury and vaccines.

3. **Extend the investigation** to address the broader increases in immune and neurological dysfunction in children, including learning disabilities, attention deficit disorders, asthma and diabetes.

4. **Design and launch a comprehensive surveillance system** aimed at quantifying the incidence rates, trends and costs to society for chronic diseases and disabilities in American children.

5. **Re-structure CDC vaccine program funding priorities** to commit funds for independent research into the biological mechanisms of vaccine injury and death, including research into genetic and other biological factors which put some individuals at greater risk than others for suffering vaccine adverse events.

6. **Launch a comprehensive audit of the safety** of the newly expanded vaccine program, comparing the incidence of chronic disease and disability in high, low and zero vaccine exposure populations.

7. **Maintain and expand independent researcher access to government** vaccine risk assessment data resources such as the Vaccine Safety Datalink and the Vaccine Adverse Event Reporting System.

8. **Remove vaccine risk assessment and vaccine safety oversight responsibilities from CDC and FDA** and place them in a separate federal agency, with accountability to the general public, including parent groups.

9. **Charge the new federal agency with responsibility** to investigate vaccine adverse reactions and provide necessary resources for a comprehensive re-assessment of long-term health outcomes of alternative childhood vaccination strategies.

10. **Reconstitute the current leadership** of the NIP to include outside scientists with no previous involvement in vaccine development, regulation, policy-making or promotion.

We appreciate the opportunity to submit this report and hope that we will have an occasion to review it with you in person in the near future.

Respectfully submitted,

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