

# THE VACCINE REACTION

*"When it happens to you or your child, the risks are 100%"*

Special Report

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## FLU VACCINE: *Missing the Mark*

On February 20, 2003, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) of the Food and Drug Administration (FDA) met to try to figure out which three strains of influenza to include in the flu vaccine produced for the 2003-2004 flu season in the US.<sup>1</sup> The FDA Committee members, as they do every year, came together to consider reports by the World Health Organization (WHO) of the type of flu being identified in persons being treated for respiratory infections around the world. What started out as a routine flu strain selection meeting ended up being part of the answer to why federal health agencies urged Americans to get vaccinated with a flu vaccine that did not protect against the most serious flu strain dominating the US flu season in 2003-2004.

A review of the FDA meeting transcript shows that there was little disagreement about selection of the first two strains of flu. The majority of the Committee concluded that the 2003-2004 flu vaccine should include A/Caledonia and B/Hong Kong, which were both in the previous year's vaccine. However, selection of the third strain was more difficult because there was strong evidence that a genetically mutated type A flu, known as A/Fujian, was emerging out of Asia and causing significant complications, including death.

The focus of the Committee's deliberations centered on the fact that epidemiological intelligence indicated that a mutated A/Fujian strain was rapidly moving from Asia through Europe and into Hawaii and the west coast of the US. Preliminary reports suggested that the close relative, A/Panama flu strain, present in the 2002-2003 flu vaccine formulation had little or no effect on A/Fujian. In fact, FDA and CDC flu experts repeatedly told the Committee that A/Fujian had two genetic mutations and was different enough from A/Panama that A/Panama may only offer minimal cross protection, if any.

At the February 20 FDA meeting, Nancy Cox, Ph.D., Chief, Influenza Branch, Centers for Disease Control (CDC), stated, "H3N2 viruses with amino acid changes at both 155 and 156 in site B (A/Fujian) tend to be poorly inhibited by antibodies to the vaccine virus, and low-reacting viruses with these changes have been detected in Asia, Europe and the Americas. I should also probably mention that our colleagues in the UK have similar findings in that at the WHO Collaborating Center in London they found that the most recent viruses that they had received from Europe are really quite poorly inhibited by antiserum to the Panama virus." (Cox was refer-

ring to the fact that the A/Panama vaccine would be ineffective in preventing the mutated A/Fujian strain of flu.)

As a result, the FDA Committee voted to defer the selection of the third flu strain until the WHO had made their recommendation three weeks later. When the Committee reconvened by phone on March 18, they learned that the WHO had decided to stay with A/Panama even though there was evidence that A/Fujian's two genetic mutations was preventing A/Panama from having much effect. When pressed, federal officials admitted that labs around the world were having trouble isolating and growing A/Fujian in eggs in a way that would allow mass vaccine production. Knowing that it takes about six months to ramp up flu vaccine production every year and concerned that further delay in strain selection would prevent a flu vaccine from being made available to the public by the fall, the majority of the Committee voted to go ahead and include A/Panama in the 2003-2004 flu vaccine.<sup>2</sup>

The March 18, 2003, VRBPAC meeting was the last for NVIC President, Barbara Loe Fisher, who had served on the Committee as the consumer voting member since 1999. She chose to abstain from the strain selection vote, saying, "I feel uncomfortable voting for inclusion of an A/Panama-like virus, when what may really be needed is an A/Fujian-like virus. So I am going to abstain and urge that the public be informed that next year's flu vaccine may not be protective against an emerging strain."

At the earlier February 20 meeting, Fisher questioned whether there were follow-up of cases of flu every year to determine if the vaccine was effective. Dr. Cox of the CDC answered, "There is no systematic follow-up to see, to document whether the general population who receives a flu vaccine is infected by a flu virus because it's an impossible task. I mean we have 80 million doses or 70 million doses given and it would be impossible to follow-up." Dr. Cox also pointed out that only about 20 percent of all flu-like illnesses are actually due to an influenza virus. "There are many other pathogens that cause respiratory illness," she said.

### **CDC Says All Children Should Get Flu Vaccine**

For decades, flu vaccine has only been recommended for those over 65 years old and anyone with a medical condition which places them at risk for suffering severe complications from the flu. However, in recent years the CDC has lowered the age to those over 50<sup>3</sup> and, in 2002, began to move toward recom-

mending universal use of a flu vaccine in all healthy children more than 6 months of age.<sup>4</sup> The CDC currently encourages two doses of flu vaccine for all healthy children 6 to 23 months of age for first-time vaccinees and an annual flu shot after that.<sup>5</sup> (In March 2003, influenza vaccine was incorporated into the Vaccines for Children program which provides federally-funded vaccines to poor and uninsured children.)<sup>6</sup>

In April 2003, as it did in 2002, the Advisory Committee on Immunization Practices (ACIP) of the CDC stated that “because young, otherwise healthy children are at increased risk for influenza-related hospitalizations, the ACIP continues to encourage influenza vaccination of children 6-23 months of age when feasible.” However, ACIP goes on to state that it “did not make a full recommendation for annual vaccination of this group because of several concerns that must be addressed before such a recommendation could be made. These concerns include increasing efforts to educate parents and providers regarding the impact of influenza....”<sup>5</sup>

### **FDA Approves Live Nasal Flu Vaccine**

Up until June 2003, the only flu vaccine that has been used in the US for the past three decades has been a killed or inactivated flu vaccine that is injected into the arm. However, on June 17, 2003, the FDA approved the first live virus flu vaccine, which is also the first vaccine designed to be sprayed up the nose.<sup>7</sup>

FluMist is manufactured by MedImmune Vaccines and distributed by Wyeth Vaccines and both companies invested heavily in the novel vaccine which they hoped would take over the majority of the flu vaccine market currently dominated by Aventis-Pasteur and Evans Vaccines, Ltd., makers of the killed flu vaccine. (MedImmune reportedly paid \$1.5 billion in 2002 to acquire Aviron,<sup>8</sup> which invented the live nasal flu vaccine. Wyeth had been a major producer of killed flu vaccine in the US but stopped making it in order to invest in and concentrate on FluMist.)<sup>9</sup>

When the FDA licensed FluMist in the summer of 2003, it limited its approval to use only in healthy persons between 5 and 49 years of age, even though most severe complications and deaths occur in those under 2 or over 65 who suffer from chronic illness. The vaccine’s most common side effects in pre-licensure clinical trials included flu symptoms (fever, runny nose, cough, body aches) and the vaccine is specifically not recommended for people with asthma or respiratory diseases because it worsened those conditions in clinical trials. Also, because it is a live virus vaccine and can transmit live flu vaccine virus to the immune-compromised, those persons coming into close contact with immune-compromised individuals cannot take the vaccine. FluMist is also contraindicated for pregnant women.<sup>10</sup>

The previous year, when the FDA’s Vaccines and Related Biological Products Advisory Committee met on December 20, 2002, to vote on whether FluMist should be licensed, NVIC’s Fisher voted “No” on the question of whether MedImmune had proved safety.<sup>11</sup> She said:

“The data are inadequate to support the safety of FluMist for individuals five to 64 years of age. The increased risk of asth-

ma in young children and the increased risk for some children in these studies for upper respiratory infections, musculoskeletal pain, otitis media and croup, as well as upper respiratory symptoms in adults, suggests that an unknown number of healthy, but perhaps genetically vulnerable individuals, across all age groups will not be able to handle this vaccine well, and this will, over the long term, also lead to the public perception that when you get the flu vaccine, you get the flu.<sup>11</sup>

“...The fact that live vaccine flu virus is shed in 80 percent of recipients poses an additional risk for our population at large, particularly for immune compromised individuals across all age groups. The outstanding questions about the true rate of transmission of vaccine strain viruses among children needs to be clarified, as does the retention of the attenuation of the shed viruses and the high frequency of nucleotide changes. Because this live virus nasal vaccine is not indicated for high risk health groups, which have historically been the targeted populations to receive the flu vaccine, it’s a very serious step to move to the use of a live virus vaccine for the majority of healthy individuals, and a standard for proof of safety must be very high. I don’t think that standard has yet been met by the data which have been presented so far.”<sup>11</sup>

### **MedImmune and Wyeth Launch Ad Campaign**

In the late summer of 2003, MedImmune and Wyeth launched the beginning of a three-year \$100 million media ad campaign targeting the potentially huge market of nearly 160 million Americans who are healthy and fall between the ages of 5 and 49.<sup>12</sup> The CDC estimates that only 13 percent of healthy people under 50, or about 17 million people, get flu shots every year.<sup>13</sup> Unlike the killed flu vaccine, which retails for about \$15, FluMist would cost consumers between \$46 and \$150 a dose.<sup>14</sup>

On September 10, 2003, MedImmune and Wyeth announced that Wal-Mart stores would offer FluMist.<sup>15</sup> MedImmune’s stock went up that day, reportedly having gained 48 percent in the previous 12 months. A MedImmune senior vice president said, “With the availability of FluMist at Wal-Mart pharmacies, healthy people will now have easier access to the first-available nasal flu vaccine while they are shopping in Wal-Mart stores.” It looked like FluMist was poised to be a blockbuster with MedImmune officials and some financial analysts predicting that FluMist would generate between \$120 million and \$140 million in sales.<sup>16</sup>

### **CDC Urges Widespread Use of Flu Vaccine**

On September 23, the CDC held a press conference to promote mass vaccination with flu vaccine.<sup>17</sup> “People have failed to appreciate how important and serious a disease influenza really is,” CDC head Julie Gerberding said. Another doctor added, “It is the single leading cause of death from any vaccine-preventable disease.”<sup>17</sup>

The head of the CDC’s National Immunization Program, Walter Orenstein, M.D., reported that the flu season which had just ended in Australia, New Zealand and other parts of the western hemisphere was “moderately severe” and was dominat-

ed by influenza A, which was “covered” in the vaccine being used this year. Emphasis was placed on encouraging healthy children to get vaccinated, as well as traditionally high-risk groups such as the elderly and those with chronic illnesses such as diabetes.

### ***IOM Says Flu Shots for Children Need More Study***

On October 6, the Institute of Medicine (IOM), National Academy of Sciences, released a report that said there is weak evidence that flu vaccine triggers neurological disorders.<sup>18</sup> However, the IOM Immunization Safety Review Committee also made it clear that inconsistencies in the scientific data and methodological problems with studies published so far prevented a more definitive conclusion.

The Committee agreed that there was a causal relationship between the 1976 swine flu vaccine and the paralytic disorder Guillain-Barré syndrome in vaccinated adults but that the majority of studies since do not link Guillain-Barré syndrome with flu vaccines. The Committee also said the “evidence favors a rejection of a causal relationship between influenza vaccines and relapse of multiple sclerosis in adults.”

However, the Committee cautioned that before federal officials recommend annual flu vaccinations for young children, the CDC should increase its monitoring, detection and evaluation of flu vaccine neurological complications. The Committee’s chair was quoted as saying, “Because flu vaccines are so widely used in adults, the possibility that neurological disorders might be related to vaccines must be given serious consideration.”

### ***FluMist Sales are Sluggish***

On October 17, Wal-Mart announced it would not sell FluMist in its stores because several state pharmacy boards raised questions about the legal ability of Wal-Mart’s pharmacists to administer the vaccine.<sup>19</sup> MedImmune’s stock started to fall by the middle of the afternoon.

By the end of October, it became apparent that relatively few of the four million doses of FluMist that MedImmune had produced were being purchased by hospitals, clinics or doctor’s offices. High cost, lack of insurance coverage, the need to keep FluMist frozen at all times, and people wary of safety concerns about squirting live flu virus up the nose were all cited as reasons.

Health care workers, fresh from their vaccine risk lesson with live smallpox vaccine virus transmission, rejected FluMist because of concerns about spreading the vaccine virus to immune compromised patients.<sup>20</sup> Some hospitals advised those who had used FluMist recently to avoid coming to the hospital to visit sick patients.<sup>21</sup>

### ***Fujian Flu Hits the US***

In November 2003, the media began reporting that a particularly nasty kind of flu was being seen in Texas and Colorado.<sup>22</sup> The CDC responded by issuing statements urging everyone to get their flu shots, with CDC director, Julie

Gerberding, M.D. saying, “This is very serious,” and pointing out that 36,000 flu-related deaths occur every year.<sup>23</sup> The year before, the CDC stated, “Epidemics of influenza typically occur during the winter months and are responsible for an average of approximately 20,000 deaths.”<sup>24</sup>

By early December, the media was reporting the flu-related deaths of several children. One 20-month old Colorado boy, whose death was widely reported, had been vaccinated.<sup>24</sup>

What followed was an explosion of publicity around the country about a possible severe flu epidemic and a higher-than-usual number of deaths, especially in children. There was a run on the inactivated, injectable flu vaccine and spot shortages began to be reported.<sup>25</sup> Part of the reason for the shortage became apparent when it was revealed that the two manufacturers of killed flu vaccine had cut their combined production of doses to about 83 million down from some 95 million. This was in response to the fact that at the end of 2002, about 12 million unused doses of flu vaccine had to be discarded even though during the 2002 flu season, the CDC had heavily promoted the idea that every American over 50 should get a flu shot and had encouraged healthy children to get vaccinated.<sup>26</sup>

But this year, with intense media coverage and a stream of statements from the CDC reporting flu deaths and pneumonia complications, the CDC had more success in convincing Americans that it was a good idea to get a flu shot. Predicting that the number of flu deaths could double to “70,000” this year, 27 public health officials admitted the current flu vaccine was not an exact match with the circulating strain but asserted that the vaccine “was a very close match” and would offer “cross protection.”<sup>27</sup>

Soon it became clear that a record number of adults and children were literally running to doctors and clinics to get vaccinated. MedImmune and Wyeth, seeing an opportunity to capitalize on the publicity, sent out a press release on December 5, 2003, claiming that its live virus nasal vaccine was more effective at preventing the current strain of flu that was circulating than the inactivated flu vaccine.<sup>28</sup>

### ***NVIC Calls for Full Public Disclosure***

Watching the CDC’s repeated calls for mass vaccination that prompted fearful Americans to line up in the rain and snow to get flu shots they thought would protect them, NVIC decided to set the record straight after MedImmune sent out the December 5 press release implying that their live nasal vaccine was more effective against the current flu (both the killed and live vaccines contain the exact same flu strains). On December 10, 2003, NVIC issued a press release calling on federal health officials and flu vaccine makers to be honest with the American people. NVIC also posted the press release with links to the February and March VRBPAC meeting transcripts on the NVIC Web site so members of the public could have access to them.<sup>29</sup>

In NVIC’s press release, Fisher said, “Public health officials knew last spring that it was highly likely that the A/Panama strain in the current vaccine was not going to protect against the mutated, more dangerous A/Fujian strain of flu. If there is

solid new evidence that the vaccine is protective against A/Fujian, then it should be released. If there is no such evidence, then it is not right to lead people to believe that if they get vaccinated now, they will be protected against it.”

That evening, Fisher appeared in an *ABC Evening News* report about the flu vaccine’s likely ineffectiveness against the most serious kind of flu that was generating the long lines at vaccine clinics. In the following week, national newspapers from *The Miami Sun-Herald*<sup>30</sup> to the *Pittsburgh Post-Gazette*<sup>31</sup> and *The Sacramento Bee*<sup>32</sup> reported the story.

### **DHHS Calls for New Manufacturing Methods**

Within a week of NVIC’s press release, DHHS Secretary Tommy Thompson held a press conference and announced that DHHS was requesting congressional appropriations of \$50 million for 2004 and \$100 million for 2005 to develop new technologies to more quickly make flu vaccines. He specifically suggested research would focus on using animal cell cultures instead of eggs for production.<sup>33</sup>

In response, NVIC’s Fisher told reporters that moving too quickly to the use of animal cell cultures could be dangerous: “Public health agencies have to make sure there is no contamination of the animal cell cultures with animal viruses as has occurred in the past with polio vaccines using monkey kidney cell cultures.” Fisher testified in Congress, at a September 10, 2003 hearing on SV40 contamination of oral polio vaccines, that past discussions in meetings of the FDA Advisory Committee had included proposals to use cancer cell substrates to produce vaccines as well as changing regulations to permit “allowable thresholds” of adventitious [extraneous] agent contamination. “There needs to be full public disclosure and debate about proposed use of animal tissue cultures or cancer cell substrates to make vaccines. It is not only possible, but probable, that there will be contamination of the vaccines with extraneous agents that could lead to cancer and other degenerative diseases,” she said.<sup>34</sup>

### **CDC Admits Flu Vaccine Failed**

At the same time, by mid-January 2004, CDC officials who were aggressively following up on reported flu deaths in children for the first time, reported a total of 93 flu-associated deaths among children nationwide. The CDC also reported that out of nearly 60,000 suspected cases of influenza worldwide that were tested for flu virus, *only 28 percent were positive*. Of these, about 99 percent were influenza A virus. Of the 518 influenza viruses collected by US labs, about 19 percent were similar to A/Panama and more than 80 percent were similar to the genetically-mutated A/Fujian.<sup>35</sup>

A preliminary assessment of flu vaccine effectiveness, conducted in Colorado, found that the flu vaccine this year was virtually ineffective against the A/Fujian strain that had panicked Americans standing in long lines for their flu shots. There was little, if any, cross protection with A/Panama. *Only 3 to 14 percent of those who got vaccinated were protected against the flu this year.*<sup>36</sup>

### **MedImmune Gives Away FluMist**

By mid-January 2004, with the flu season still in full swing and stocks of killed flu vaccine nearly depleted, MedImmune and Wyeth announced they had only sold about 400,000 doses of the more than four million doses of live virus nasal flu vaccine they had produced. Even after agreeing to sell doses to the federal government for \$20 each, less than half the \$46 wholesale price, fewer than 75,000 doses had been used. Instead of destroying the remaining stocks, the companies agreed to give away 250,000 doses to ease the flu vaccine shortages. A spokesman for Wyeth was quoted as saying the company was keeping “philanthropy with public health in mind.”<sup>37</sup>

But there were few takers, even when it was given away free. Instead of the \$120 to \$140 million in sales the companies had projected at the beginning of the flu season, they cut their revenue forecast to between \$55 and \$85 million. By the end of January, MedImmune and Wyeth were considering abandoning the manufacture and sale of FluMist and “getting out” of the market.<sup>38</sup>

### **Congress to Consider Bail Out of Flu Vaccine Makers**

On January 28, 2004, a bill was introduced by US Senators Bayh (D-IN), Landrieu (D-LA) and Emanuel (D-IL) to reimburse flu vaccine manufacturers when they produce more vaccine than is used by the public. Entitled the “Flu Protection Act of 2004,” the legislation requires the CDC to purchase back from the manufacturers unused doses of flu vaccine at the end of each season. It also requires the CDC to “conduct a public awareness campaign and education outreach efforts each year” and stress “the importance of receiving the influenza vaccine” and “the safety, efficacy and benefit of recommended vaccines for the public good.”<sup>39</sup>

### **A Look to the Future**

Once the CDC makes a final recommendation for “universal use” of flu vaccines in children, vaccine manufacturers will be protected against lawsuits for flu vaccine-induced injuries and deaths under the federal vaccine injury compensation program. The CDC’s “universal use” recommendation for flu vaccine is expected to be issued by the federal health agency’s Advisory Committee on Immunization Practices (ACIP) in 2004.<sup>40</sup> Soon after that announcement, state health officials and vaccine manufacturers are expected to lobby state legislatures to add flu vaccine to mandatory state vaccination laws for children. Every vaccine that the CDC has recommended for universal use in children in the past 20 years has been mandated by some or all states for school entry, including a second dose of measles vaccine; 4 doses of haemophilus influenzae b (HIB) vaccine; three doses of hepatitis B vaccine; one dose of chicken pox vaccine; and 4 doses of pneumococcal vaccine.<sup>41, 42</sup>

### **Who Will Pay?**

According to a 2003 Institute of Medicine (IOM) report, “Financing Vaccines in the 21st Century,” the US government

currently spends more than \$1 billion annually to purchase childhood vaccines from vaccine manufacturers at discounted government prices to give to poor and uninsured children under the federal Vaccines for Children (VFC) program. This represents about 55 percent of the total childhood vaccine market. After the CDC recommended all children should use chicken pox and pneumococcal vaccines and these vaccines were added to the VFC program, the VFC budget doubled from \$500 million to over \$1 billion between 2000 and 2002. The cost of giving children all CDC-recommended vaccines in private pediatrician's offices jumped from \$200 per child in 1997 to about \$600 in 2001.<sup>43</sup>

In their report, the IOM suggested that the "societal value" of a particular vaccine should be systematically measured and factored into national vaccine funding and insurance reimbursement policies. Maintaining that vaccines are not just for children anymore but "provide important protection across

the lifespan, from infancy to old age," the report says that "herd immunity" from mass vaccine use protects society and reduces medical costs associated with diseases; enhances the length and quality of life; and improves the productivity and social contributions of families who would otherwise be burdened by disease.

The IOM report being circulated on Capitol Hill recommends a combined mandate, subsidy and voucher plan that would *mandate* insurance benefit coverage for all CDC recommended vaccines in private and public health insurance plans; a universal government *subsidy* for reimbursement of private and public insurers and physician providers of CDC recommended vaccines; and a government *voucher* for uninsured children and adults. Americans enrolled in private health care insurance plans would end up paying vaccine manufacturers and doctors twice for annual flu vaccinations they may or may not want – both through their increasing health insurance premiums and federal taxes.

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## COMMENTARY

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Getting the flu has been a hit or miss proposition since influenza viruses have been circulating among humans. Some people seem to always get the flu every year while others never come down with it. In the great flu epidemic of 1918, some died and some never got sick at all. As with most viral or bacterial infections, if you get the flu you are more vulnerable to complications such as otitis media and pneumonia if you are already chronically ill or immune-compromised. But most healthy children and adults around the world who get the flu do not suffer complications and are left with natural immunity to the particular strain of flu they got. That may be the main reason why less than a quarter of the US population typically makes a special effort to get a flu shot every year.

However, getting the flu is becoming politically incorrect as the CDC is moving toward a cradle to the grave approach with flu vaccination. In the past few years federal officials (to the enthusiastic applause of vaccine manufacturers and doctors profiting from selling or giving flu vaccines) have begun widening the age limits at both ends of the age spectrum for annual flu vaccination.

The CDC started at the elderly end of the spectrum. Traditionally, those over 65 have been flu vaccine targets because many of the elderly are chronically ill or have impaired immunity. But the CDC lowered that age threshold to 50 several years ago. Now all healthy (and unhealthy) adults over 50 are candidates for annual flu shots according to the CDC.

Not satisfied with lowering the age for adults, in the past two years the CDC has started to soften up the public to accept the idea that all healthy children between the ages of 6 months and 23 months must get two flu vaccinations the first time they are vaccinated and an annual one after that. It means that future generations of Americans will have little or no immunological experience with type A or type B flu viruses that circulate every year and provide a natural, qualitatively superior and longer last-

ing immunity. So future generations of Americans will become flu vaccine dependent, presumably for the rest of their lives. It will be a national experiment that could have a far higher financial and long term health price tag than is currently appreciated.

When NVIC co-founder Kathi Williams and I began encouraging parents to become educated about diseases and vaccines nearly 22 years ago, the CDC was recommending that our children get 23 doses of 7 vaccines.<sup>47</sup> Today the CDC is telling us that our children need to get 37 doses of 11 vaccines and every state mandates most of them.<sup>41</sup> The addition of 2 doses of flu vaccine for infants will bring that total to 39 doses of 12 vaccines. And this, in the absence of long-term, case-controlled, methodologically-sound clinical studies and basic scientific research to evaluate the potential long term adverse effects on the developing brain and immune system of repeated vaccination in early childhood, as well as the possible life-long adverse effects of removing all natural immunity to diseases, such as influenza, in early childhood.

Before CDC officials add annual flu vaccinations to the recommended list of childhood vaccines, they should be required to explain to the public why so many already highly vaccinated American children are stuck on sick and suffering from chronic brain and immune system problems that cost Americans billions of dollars in health care and education every year. There aren't enough special education classrooms in the US to handle the learning disabled, hyperactive, autistic, asthmatic, epileptic, diabetic children, whose numbers have doubled in the past 20 years at precisely the same time the numbers of doses of required childhood vaccines has nearly doubled. Coincidence? Maybe. Or maybe not. Those officials in charge of the public health better look to themselves and get busy finding out why we have such a child health crisis in this country when nearly 95 percent of our children receive more vaccines than any other child population in the world.

## FLU VACCINE FACTS

- Flu vaccine, like all vaccines, only provides temporary immunity (if at all) and that immunity is qualitatively different from disease-induced immunity which provides longer lasting protection.<sup>44</sup>
- Flu vaccine contains three specific influenza viruses and does not protect against throat, respiratory, gastrointestinal and ear infections caused by bacteria and other kinds of viruses that cause flu-like symptoms. Only about 20 percent of all flu-like illnesses are actually influenza.<sup>1</sup>
- When the match between the vaccine and circulating viruses is close, the inactivated flu vaccine is thought to be 70 to 90 percent effective in giving temporary immunity to selected strains in healthy persons under 65 years old. For those over 65 years old, the efficacy rate drops to 30 to 40 percent, although it is considered to be 50 to 60 percent effective in preventing hospitalization or pneumonia and 80 percent effective in preventing death from flu caused by covered strains.<sup>5, 45</sup>
- The most common reactions to inactivated flu vaccine are fever, fatigue, painful joints, and headache. The most frequently reported serious reaction, which usually occurs within two weeks of vaccination, is Guillain-Barré syndrome, an immune mediated nerve disorder characterized by muscle weakness, numbness, pain and paralysis that can lead to death.
- According to vaccine manufacturers, contraindications for the inactivated flu vaccine are fever, an impaired immune system, egg or mercury allergy, history of Guillain-Barré syndrome.<sup>5, 45</sup>
- The CDC recommends inactivated flu vaccine for women more than 14 weeks pregnant even though most inactivated flu vaccines contain the mercury preservative, thimerosal.<sup>5, 45</sup> Mercury has been associated with brain damage and developmental delays in newborns whose mothers were exposed to high levels of mercury during pregnancy.<sup>46</sup>

A good indication of how the CDC disregards the precautionary principle when it comes to vaccine risks is its recommendation that all pregnant women get flu vaccine. Most flu vaccines given to adults contain mercury and CDC officials know quite well that scientific studies have demonstrated the brain damaging effects of mercury on the developing fetus. As far as flu vaccine safety goes, even the conservative Institute of Medicine (IOM) this year concluded that, before the CDC recommends annual flu vaccinations for young children, it should increase its monitoring, detection and evaluation of flu vaccine associated neurological complications. Despite recommendations since 1999 by the Environmental Protection Agency (EPA), FDA and IOM that mercury preservatives should be taken out of all vaccines, the CDC purchased flu vaccines containing mercury that were given to poor children under the Vaccines for Children program during the 2003-2004 flu season.

The flu vaccine fiasco this year demonstrated it is highly questionable as to whether the flu vaccine is going to offer even minimal protection against the flu you might or might not catch. And, since only 20 percent of all flu-like illness is really the flu, the odds are that the flu you think you have is not really the flu.

But one thing is clear: whether you line up to get a flu shot or not should be a matter of voluntary choice. Some families opt for boosting the natural functioning of their immune systems to resist influenza through breast feeding their infants and use of vitamin supplements, diet, exercise, chiropractic, homeopathy or other preventive health care options. Others would rather get the flu and attain a qualitatively superior and longer lasting immunity than the temporary immunity a vaccination offers. Some parents have concluded that their children are genetically vulnerable to vaccine complications and cannot in good conscience put their children's lives on the line for a flu vaccine that could leave their children crippled or dead.

Every American should have the right to freely choose the kind

of preventive health care they want for themselves and their children. No American should be forced to get a flu shot every year.

And yet, the stage is being carefully set for mass, mandatory vaccination of every American from the cradle to the grave. If private insurers are required to reimburse the insured for annual flu vaccinations; if federal taxes finance annual flu vaccinations for public health clinics; if Congress passes legislation that has the federal government reimbursing flu vaccine manufacturers every year for unused doses; if the CDC is required to launch an even more intensive annual nationwide flu vaccination campaign to make sure every child and adult gets a flu shot, then the next step is obvious: laws will be passed requiring Americans to buy and use flu vaccine. That will give the vaccine manufacturers a stable, predictable market. The government won't have to spend the money to bail out the vaccine manufacturers every year because the majority of Americans, who have voted with their feet and just said no to flu shots for the past 30 years, will no longer be able to say no.

If the flu vaccine is mandated to be used annually by every American, it will become the most profitable vaccine in the history of vaccination. Think about it: Mandated annual flu vaccination of 280 million Americans. Mandated insurance reimbursement for all flu vaccinations. Guaranteed market for flu vaccine manufacturers with no liability for vaccine injuries and deaths. At the end of the day, a stockholder's dream and a consumer's worst nightmare.

NVIC will monitor and report the unfolding story of the move by government, industry and organized medicine to make annual flu vaccinations mandatory for all Americans from the cradle to the grave. It is a story that may well be the ultimate example of exactly why America's hyperactive, oppressive mass vaccination program is losing the public trust.

Our mission continues: No forced vaccination. Not in America.

*For more information on influenza and the flu vaccine, go to:*

[www.nvic.org](http://www.nvic.org)  
[www.redflagsweekly.com](http://www.redflagsweekly.com)  
[www.cdc.gov](http://www.cdc.gov)

## References

1. Transcripts of the Vaccines and Related Biological Products Advisory Committee. February 20, 2003. U.S. Food and Drug Administration, Center for Biologics Evaluation and Research. < [www.nvic.org/Diseases/Influenza.htm](http://www.nvic.org/Diseases/Influenza.htm) >
2. Transcripts of the Vaccines and Related Biological Products Advisory Committee. March 18, 2003. U.S. Food and Drug Administration, Center for Biologics Evaluation and Research. < [www.nvic.org/Diseases/Influenza.htm](http://www.nvic.org/Diseases/Influenza.htm) >
3. *MMWR Recommendations and Reports*. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." April 14, 2000. Centers for Disease Control.
4. *MMWR Recommendations and Reports*. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." April 12, 2002. Centers for Disease Control.
5. *MMWR Recommendations and Reports*. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." April 25, 2003. Centers for Disease Control.
6. *MMWR Weekly*. "Notice to Readers: Expansion of Eligibility for Influenza Vaccine Through the Vaccines for Children Program." September 27, 2002. Centers for Disease Control.
7. Flumist Product Approval Information – Licensing Action. U.S. Food and Drug Administration, Center for Biologics Evaluation and Research. < [www.fda.gov/cber/products/inflmed061703.htm](http://www.fda.gov/cber/products/inflmed061703.htm) >
8. MedImmune, Inc. | Investors | News Releases. December 3, 2001. "MedImmune to Acquire Aviron in Exchange Offer Valued at \$1.5 Billion."
9. Wyeth: News & Announcements. November 19, 2002. "Wyeth Ceases Production of its Injectable Influenza Vaccine and Pneumococcal Polysaccharide Vaccine."
10. Influenza Virus Vaccine Live, Intranasal Flumist 2003-2004 Formula, Package Insert (Circular) June 16, 2003.
11. Transcripts of the Vaccines and Related Biological Products Advisory Committee. December 20, 2002. U.S. Food and Drug Administration, Center for Biologics Evaluation and Research.
12. MedImmune, Inc. | Investors | Strategic Alliances. < [www.medimmune.com/investors/stratall.asp](http://www.medimmune.com/investors/stratall.asp) >
13. CDC
14. Altman LK. February 25, 2004. "Spray flu vaccine is little used, even with shots scarce." *The New York Times*.
15. MedImmune, Inc. | Investors | News Releases. September 10, 2003. "Flumist Available in Pharmacies This Fall."
16. Higgins M. October 7, 2003. "MedImmune stock rallies on sales of Flumist vaccine." *The Washington Times*.
17. Brown D. September 24, 2003. "Officials urge wide use of flu vaccine." *The Washington Post*.
18. *The National Academies NEWS*. October 6, 2003. "Flu Vaccines Do Not Trigger Relapses in Multiple Sclerosis Patients." < [www4.nationalacademies.org/news.nsf/isbn/0309090865](http://www4.nationalacademies.org/news.nsf/isbn/0309090865) >
19. Clarke T, Pierson R. October 17, 2003. "Wal-Mart won't offer FluMist in '03." *Reuters*.
20. Greene L. November 5, 2003. "Hospitals are braced for FluMist." *St. Petersburg Times*.
21. Associated Press. December 5, 2003. "Hospitals urge people who had FluMist vaccine to stay away." *WJLA ABC 7 News*.
22. Associated Press. November 26, 2003. "Four Colorado children die from flu." *USA Today*.
23. Wyatt K. November 18, 2003. "CDC chief: Vaccine fails to match flu strain." *Chicago Sun-times*.
24. Crecente BD. December 6, 2003. "Flu virus attacks child despite vaccination." *Rocky Mountain News*.
25. December 8, 2003. "Fears escalate over flu outbreaks." *CBS News*. < [www.cbsnews.com/stories/2003/11/26/health/printable585700.shtml](http://www.cbsnews.com/stories/2003/11/26/health/printable585700.shtml) >
26. CDC Media Relations – Telebriefing Transcript. December 9, 2003. CDC News Conference: Influenza Update. Centers for Disease Control.
27. Graham J (*Chicago Tribune*). December 5, 2003. "70,000 deaths expected from especially widespread flu." *The Sun Herald*.
28. MedImmune, Inc. | Investors | News Releases. December 5, 2003. "New Data Suggest That a Live Attenuated Influenza Vaccine May Induce Immunity Against Currently Circulating Drifted A/Fujian-Like Influenza Strain."
29. NVIC Press Release. December 10, 2003. "Informed Consent Advocate Says Government and Industry Should Release Flu Vaccine Effectiveness Data." The National Vaccine Information Center. < [www.nvic.org/Diseases/Influenza.htm](http://www.nvic.org/Diseases/Influenza.htm) >
30. Tasker F, Borenstein S (Knight Ridder Newspapers). December 16, 2003. "Inherently difficult vaccine process, plus bad luck, create flu woes." *The Miami Herald*.
31. Srikameswaran A. December 19, 2003. "Vaccine shortage a question of timing." *The Pittsburgh Post-Gazette*.
32. Griffith D. December 14, 2003. "Flu vaccine injects a dose of confusion." *The Sacramento Bee*.
33. December 17, 2003. "Millions sought to upgrade flu vaccine production." *CNN Health*. [www.cnn.com/2003/HEALTH/12/16/sprj.flu03.vaccine](http://www.cnn.com/2003/HEALTH/12/16/sprj.flu03.vaccine)
34. Fisher BL September 10, 2003. "The SV40 Virus: Has Tainted Polio Vaccine Caused An Increase in Cancer?" U.S. House Government Reform Committee. < [www.nvic.org/Loe\\_Fisher/blfsv40testimony.htm](http://www.nvic.org/Loe_Fisher/blfsv40testimony.htm) >
35. *MMWR Weekly*. "Update: Influenza Activity." January 16, 2004. Centers for Disease Control.
36. *MMWR Weekly*. January 16, 2004. "Preliminary Assessment of the Effectiveness of the 2003-04 Inactivated Influenza Vaccine" – Colorado, December 2003. Centers for Disease Control.
37. Barbaro M. January 21, 2004. "Flumist offered free to public health agencies." *The Washington Post*.
38. January 2004. "Will FluMist survive another flu season?" *HealthScout*. < [www.healthscout.com/news/68/1503525/main.html](http://www.healthscout.com/news/68/1503525/main.html) >
39. Flu Protection Act of 2004. (S.2038; H.R.3758) 108th Congress.
40. National Immunization Program. October 15, 2003. "The ACIP Vote to Recommend Influenza Vaccination for Children Aged 6 to 23 months for influenza season 2004-05." Centers for Disease Control.
41. National Immunization Program. "2004 Childhood Immunization Schedule." Centers for Disease Control.
42. State Mandates on Immunization. < [www.immunize.org/laws/index.htm](http://www.immunize.org/laws/index.htm) >
43. Report Brief. "Financing Vaccines in the 21st Century: Assuring Access and Availability." Institute of Medicine. < [www.iom.edu/includes/dbfile.asp?id=14454](http://www.iom.edu/includes/dbfile.asp?id=14454) >
44. Cox RJ, et al. January 2004. "Influenza Virus: Immunity and Vaccination Strategies. Comparison of the Immune Response to Inactivated and Live, Attenuated Influenza Vaccines." *Scandinavian Journal of Immunology*.
45. Fluzone 2003-2004 Formula, Aventis Product information as of July 2003.
46. Steurwald U, et al. May 1, 2000. "Maternal seafood diet, methylmercury exposure, and neonatal neurological function." *Journal of Pediatrics*.
47. 1982 Red Book. Report of the Committee on Infectious Diseases. American Academy of Pediatrics.

## FOR MORE INFORMATION

A copy of this special report on the flu vaccine is provided on the Web site of the National Vaccine Information Center ([www.NVIC.org](http://www.NVIC.org)). At the NVIC Web site, you can access links to other vaccine and health information resources, as well as sign up to subscribe to NVIC's free Vaccine E-News Service or become a member of the National Vaccine Information Center.

## ABOUT THE EDITOR

**Barbara Loe Fisher** is co-founder and president of the National Vaccine Information Center. She is co-author of *DPT: A Shot in the Dark* (Harcourt Brace Jovanovich, 1985; Warner, 1986; Avery, 1991), a book which made an important contribution to public support for development of the purified pertussis vaccine licensed by the FDA for American babies in 1996. She is author of *The Consumer's Guide to Childhood Vaccines* (NVIC, 1997) and editor of *THE VACCINE REACTION* and *The Vaccine Hotline* newsletters.



During the 1980s, she helped lead a national grassroots effort to bring the issue of vaccine safety to public attention, including leading demonstrations at the Centers for Disease Control in Atlanta and at the White House in 1986. Later that year, Congress passed the National Childhood Vaccine Injury Act.

She served on the National Vaccine Advisory Committee for four years, where she was chair of the subcommittee on adverse events. She was appointed to the Vaccine Safety Forum at the Institute of Medicine in 1995, where she helped to coordinate five public workshops on vaccine safety. She served as the consumer voting member of the FDA Vaccines and Related Biological Products Advisory Committee from 1999 to 2003. She is a frequent public speaker at educational health conferences, where she defends the right to informed consent to medical interventions which can cause injury or death, including vaccination.

The mother of three children, in 1980 her two-and-a-half year old son reacted within four hours of his fourth DPT and polio vaccinations with a convulsion, collapse shock and state of unconsciousness. He was left with minimal brain dysfunction, including multiple learning disabilities and attention deficit disorder.

## About the National Vaccine Information Center

The National Vaccine Information Center (NVIC), founded in 1982 by parents of vaccine-injured children, is a 501(c)(3) non-profit, educational organization dedicated to preventing vaccine injuries and deaths through public education. NVIC promotes scientific research into the biological mechanisms of vaccine injury and death in order to identify biomarkers which place individuals at high risk for suffering vaccine reactions. NVIC advocates the institution of informed consent protections in mass vaccination laws and serves as a watchdog on vaccine research, development, regulation and promotion activities of public health agencies.

After launching the vaccine safety and informed consent movement in the US in the early 1980s, NVIC's co-founders worked with Congress to create the National Childhood Vaccine Injury Act of 1986. This historic law set up a vaccine injury compensation program and included vaccine safety provisions, such as mandatory recording and reporting of hospitalizations, injuries and deaths following vaccination.

In 1989, NVIC sponsored an International Scientific Workshop on Pertussis and Pertussis Vaccines and, in 1996, one of NVIC's major goals was realized when a purified pertussis vaccine was licensed for American babies after a decade and a half of advocacy work. NVIC held the First International Public Conference on Vaccination in 1997 and sponsored the Second and Third International Public Conferences on vaccination in 2000 and 2002 in Washington, DC.

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