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## **Risks of FluMist Vaccine**

### **An Investigation By Dr. Sherri Tenpenny**

"MedImmune, the manufacturer of FluMist, recently announced that it signed an agreement that makes FluMist, the new intranasal influenza vaccine, readily available to people as they shop at Wal-Mart, the worlds biggest retailer." [1]

As the physician in charge of a bustling Integrative medical clinic, questions about vaccines frequently arise. After reading about the MedImmune-Walmart joint venture, I felt compelled to warn our patients and our internet subscribers of the potentially serious complications that may come from direct and passive exposure to this new vaccine. I also wanted to give a "heads up" to everyone regarding the onslaught of advertising that is about to besiege them.

Hundreds of TV and print advertisements have been designed to persuade everyone into taking the FluMist plunge. The campaign will be the "most intense, direct-to-consumer marketing campaign ever waged for a vaccine," costing an estimated \$25 million over the next 2.5 months [2]. In addition, Wyeth, MedImmune's partner, plans a three-year, \$100 million campaign to encourage use of the nasal flu vaccine among physicians.[3]

The television arm of the blitz campaign will focus on the "inconveniences" that your family, friends and co-workers will endure if you don't get the flu shot and subsequently contract the flu. Print advertisements and magazine articles apparently will use scare tactics—similar to those that were used while promoting the smallpox vaccine—which warned of the high possibility of a "bioterror attack using the flu virus." [4]

Apparently, the goal seems to center around frightening—or inducing enough guilt—that everyone would begin to demand the vaccine as soon as it is available. And at nearly \$70 a dose, this will be a financial

bonanza for MedImmune and Wyeth, who are expecting the vaccine to become the blockbuster new drug that will push MedImmune's revenues to more than \$1billion/year. [5]

However, there are many reasons for caution. FluMist contains live (attenuated) influenza viruses that replicate in the nasopharynx of the vaccine recipient. The most common side effects include "cough, runny nose/nasal congestion, irritability, headaches, chills, muscle aches and fever > 100° F." [6] These symptoms are nearly identical to those the flu vaccine is designed to prevent. [7]

A cause for significant concern is the vaccine's most prevalent side effects: "runny nose" and "nasal congestion." It has been documented that the live viruses from the vaccine can be shed (and potentially spread into the community) from recipient children for up to 21 days, [8] and even longer from adults. [9] Viral shedding also puts breastfeeding infants at risk if the mother has been given FluMist. [10]

In addition to shedding via nasal secretions, the virus can be dispersed through sneezing. What is the normal physiological response when an irritant enters the nasal passages? A sneeze...sometimes a big sneeze...sometimes several big sneezes. Therefore, the risk for shedding—and spreading—live viruses throughout a school, church, workplace, or store — especially one which is administering the vaccine.

In the section of the FlumMist package insert labeled "PRECAUTIONS," the manufacturer states the following warning:

"FluMist® recipients should avoid close contact with immunocompromised individuals for at least 21 days."

The warning is specifically directed toward those living in the same household with an immunocompromised person, but the on-going release of live viruses throughout the community may be a significant risk to everyone who has a weak, or weakened, immune system.

The number of immunocompromised people in the United States is enormous:

It is estimated that at least 10%, or more than 28 million people have eczema. [11]

More than 8.5 million people have cancer. [12]

There are reported to be 850,000 individuals with diagnosed and undiagnosed HIV infection or AIDS [13] and

Based on 2001 data, there were 184,000 organ recipients [14]

An even more extensive list of at-risk people includes the untold millions on drugs called corticosteroids. Prednisone®, Medrol®, and a variety of similar medications are given to both adults and children.

These drugs are prescribed for dozens of conditions including asthma; allergies; eczema; emphysema; Crohn's disease; multiple sclerosis; herniated spinal discs; acute muscular pain syndromes; and all types of rheumatoid and autoimmune diseases. As much as 60% of the entire population could be considered to be "chemically immunosuppressed."

It is important to realize that FluMist is CONTRAINDICATED for people who are immunocompromised. People who receive FluMist and are living with an immunocompromised person put their loved ones at risk.

Will this make stores that administer the vaccines—like Walmart and the other pharmaceutical chain stores that have announced they will carry FluMist [15]—risky places to shop for large segments of the population? What measures will be taken in these stores to ensure that the virus will not become commingled with food? What hand washing policy is going to be enforced in the stores for all Walmart employees and customers who have received FluMist? These are reasonable questions that deserve answers.

The target market for FluMist is "healthy children and adults, ages 5 to 49 yrs." Some believe that by vaccinating these people, a type of "herd immunity" will occur that will protect the very young and the elderly who are excluded from getting this vaccine. However, it is these very "at-risk" populations who may suffer the most from the flu by being exposed to people who are given FluMist.

According to information presented at the May, 2003 National Influenza Summit,[16] approximately 85% of Americans between the ages of 20 and 50 go unvaccinated, and nearly 66% between the ages of 50 and 64 do not receive the flu vaccine. Have there been "raging

epidemics" across the country due to lack of flu vaccinations? It appears that the massive campaign to vaccinate everyone this year appears may be motivated, in part, by economics.

The viruses suspected to be the most likely cause for the flu this season were negligibly different from the strains used in last year's flu vaccine. Therefore, the influenza vaccine produced for the 2003- 2004 season is identical in composition to the one used last year. This marks only the second time that the same strains have been used during two consecutive flu seasons.[17] Consider that antibodies from other viral vaccines—such as MMR, polio and chickenpox vaccines—last at least 3 years, and in some instances, up to 15 years. If the viruses used in the vaccine are the same as last year, why is this year's vaccine even necessary?

An ever greater concern about FluMist is the contents within the vaccine. Each 0.5ml of the formula contains 10<sup>6.5-7.5</sup> particles of live, attenuated influenza virus. That means that between 10 million and 100 million viral particles will be forcefully injected into the nostrils when administered. The viral strain was developed by serial passage through "specific pathogen-free primary chick kidney cells" and then grown in "specific pathogen-free eggs." That means that the culture media was free of pathogens that were specifically tested for, but not a culture that was necessarily "pathogen-free." The risk that the vaccine may contain contaminant avian retroviruses still remains. In addition, a stabilizing buffer containing potassium phosphate, sucrose (table sugar) and nearly 0.5 mg of monosodium glutamate (MSG) is added to each dose. [18]

One of the most troubling concerns over the injection of this "chemical soup" is the potential for the viruses to enter directly into the brain. At the top of the nasal passages is a paper-thin bone called the cribriform plate. The olfactory nerves pass through this bone and line the nasal passages, carrying messenger molecules to the brain that are identified as "smells" familiar to us. The olfactory tract has long been recognized as a direct pathway to the brain. Intranasal injection of certain viruses has resulted in a serious brain infection called encephalitis, presumably by direct infection of the olfactory neurons that carried the viruses to the brain.[19] Time will tell whether the live viruses in FluMist will

become linked to cases of encephalitis.

The pharmaceutical companies do not necessarily always do a reasonable job of considering the "down side" when they are pushing new drugs or new vaccines. FluMist has the potential for causing the worst, most severe flu epidemic seen in years. Parents tell their young children not to put things up their noses because they might cause them harm. It would be wise to consider that advice for adults. With all the risks involved, one should be extremely cautious about what one allows to be sprayed in one's nose.

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