



**MedImmune, Inc.**

**MedImmune Oral Testimony  
Congressional Hearing on Government Reform**

**By Dr. Jim Young  
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Good morning. My name is Dr. Jim Young, and I am the President of Research and Development at MedImmune, Inc, a biotechnology company headquartered in Gaithersburg, MD. Today's topic is of particular interest to me, not only because of my association with MedImmune, but also because I happen to be a flu virologist by scientific training. As you may know, MedImmune manufactures the new intranasal influenza vaccine, FluMist, which was licensed by the FDA in June 2003. FluMist, in addition to being the first intranasal influenza vaccine available in the U.S., is a live attenuated vaccine that provides immunity both systemically and in the nasal passages – the usual point of entry for influenza virus. Today I would like to share with you our opinion on what the most recent flu season has taught us about the United States' ability to protect its citizens against the flu and, most importantly, about the country's ability to be prepared in a pandemic situation. Our thoughts are based upon our experience with FluMist in its first year of commercial availability.

After 30 years of development, costing approximately \$1 billion, and three FDA Advisory Committee meetings, FluMist was finally licensed for the very limited population of healthy individuals age 5 to 49 years. Because FluMist licensure occurred late in the influenza manufacturing cycle, we planned for a limited launch and manufactured at risk about a quarter of our total production capacity of 20 million doses of vaccine. Our manufacturing for the current influenza season was virtually flawless, making approximately 5 million doses of FluMist available to the consumer as early as September, well ahead of this year's early influenza season. Of these 5 million doses, about 65,000 doses were donated by our business partner Wyeth to college campus vaccination programs. Further, up to 3 million doses were made available for purchase by CDC at the discounted price of \$20 a dose - a price at which, I might add, would require us to sell more than 8 million doses just to break even financially. Unfortunately,

close to 4 million of the 5 million doses made remain unused to date, and will be destroyed at the end of this year's influenza season. Thus, in spite of MedImmune's best efforts to work proactively and cooperatively with public health authorities to bring to market the first innovation in influenza prevention in more than 50 years, there were 4 million lost vaccination opportunities in this year's influenza season, which hit early and hard, and challenged the U.S. vaccine supply and distribution systems. As such, as we analyze our initial "very disappointing" experience as a flu manufacturer, one of the options we are considering is whether we should remain in the vaccines business, or whether we should "cut our losses and get out now" rather than face the overwhelmingly difficult regulatory landscape of bringing new and more effective vaccines to market. On our part, to simply achieve parity with the approved labeling of the old-line, inactivated vaccines, we must spend at least an additional \$200 million to achieve safety and efficacy standards the other vaccines were never required to achieve (or have ever independently proven for that matter). This double standard is more than enough reason to cause new manufacturers pause before entering the vaccine business, and our very public experience this flu season will most certainly have a chilling effect on others who are considering entry into the business.

What were some of the factors that contributed to the lost opportunities for vaccination?

First, demand for influenza vaccine is strongly influenced by policies set by federal health authorities. Current influenza vaccine recommendations primarily target persons who are less than 2 years of age, more than 50 years of age, or who have underlying medical conditions that put them at high-risk for complications due to influenza.

However, the burden of influenza illness is significant in healthy persons who fall outside these targeted age groups, and in otherwise healthy unvaccinated school-age children who serve as vectors for transmission of influenza to their families and to high-risk

individuals with whom they are in contact. In fact, if you look at the flu season thus far from October 2003 through February 3, 2004, 121 influenza-associated deaths among children less than 18 years of age had been reported to CDC. Forty-nine of the children (or 40%) were 5 to 17 years of age, and 95 of the children (or 79%) had no underlying medical conditions. Therefore, MedImmune believes that the existing narrowly targeted influenza vaccine recommendations are woefully inadequate and must be expanded, and that influenza vaccine should be universally recommended for all Americans. This would further the objectives of influenza prevention, ensure continued development of new innovative vaccines, and ensure availability of adequate vaccine supplies for annual and pandemic influenza seasons. Specifically, a universal recommendation will drive the demand for routine annual vaccination, which will in turn provide the impetus on the part of vaccine manufacturers to increase their production capacity to meet routine demand. This increased capacity will enable manufacturers to better respond to influenza not only on an annual basis, but also in the event of a pandemic, which would severely challenge existing vaccine capacity and the vaccine delivery infrastructure. Recommendations by public health authorities are necessary, but not sufficient to ensure adequate vaccination of the American public -- federal authorities need to make the public aware of the significant burden of influenza in all populations (both healthy and high-risk), and must enthusiastically endorse new innovative vaccines as they become licensed and available.

Another factor that contributed to lost opportunities for vaccination in the current influenza season was the misperception that FluMist would CAUSE the flu rather than prevent it as it had just been approved by the FDA to do - driven in part by erroneous information provided by public health authorities in public statements and on government web sites that clearly stated "that FluMist can cause the flu." While the statement on the

web site was ultimately changed, it was not changed until AFTER the media ran with the erroneous information. These statements created damaging misperceptions of FluMist and its benefits AND almost certainly reduced the number of people protected against this year's flu epidemic that included the virulent mismatched Fujian strain. "Accurate" educational materials from our public health officials are paramount to successfully sharing the benefits of vaccination to the general public and achieving broad immunization against the flu.

How is MedImmune contributing to efforts to prepare for a pandemic threat?

- First and foremost, we have already made a considerable investment – to the tune of \$1 billion - to overcome the extraordinarily high regulatory hurdles facing new vaccines in order to make available an important new option for influenza vaccination.
- Second, should we ultimately choose to remain in the flu vaccine manufacturing business, we will undertake the financial burden of spending hundreds of millions of *additional* dollars to hopefully expand our indication to include persons younger than 5 and older than 49 years – which if we successful in doing, will in turn hopefully increase the demand for FluMist that will then justify increasing our manufacturing output to capacity.
- Third, we are working proactively with federal authorities to develop and test a FluMist vaccine for use in a pandemic situation.
- And fourth, we have worked closely with the World Health Organization to make MedImmune's intellectual property in the area of reverse genetic engineering available for development and testing of inactivated pandemic vaccines.

So in conclusion, the core of my message to you today is that in 2004, in the wealthiest and most powerful country on earth with the world's best healthcare system, it should be unacceptable to all of us that more than 100 American children and countless elderly have recently died from a completely preventable disease. Importantly, this year is not unique. EVERY year 36,000 Americans die as a result of the flu. The best way for us to be prepared to prevent this from happening in the future – as well as to help make sure we are prepared to deal with a pandemic situation – is to have the current flu vaccination recommendations expanded to include all Americans, and especially expanded to include that all healthy children be vaccinated against the flu.

Thank you for this opportunity to speak with you today.