**Barbara Loe Fisher, Co-founder & President National Vaccine Information Center**
**FDA Vaccines & Related Biological Products Advisory Committee Meeting May 7, 2010**

On March 22, FDA officials adhered to the precautionary principle and recommended that doctors suspend use of Rotarix vaccine after a private lab identified DNA from a pig virus in Rotarix vaccine and the manufacturer confirmed the seed stock was contaminated too.

As of yesterday, we know that DNA from two pig viruses, one of which has been linked to a wasting disease in baby pigs, has been identified in Rotateq vaccine. In addition to pig virus DNA that is not supposed to be in RotaTeq, the private lab reportedly also identified DNA fragments from a virus similar to monkey retrovirus in Rotateq.

However, as yet no action has been taken by the FDA to, again, appropriately adhere to the precautionary principle by recommending that doctors suspend use of RotaTeq vaccine until the agency finds out where the contamination came from, whether it poses a health hazard and why it was not detected by the manufacturer until now.

The FDA approved manufacturing process for RotaTeq and Rotarix allows use of African Green Monkey kidney cells, cow serum and a pig pancreatic enzyme, which presents opportunities for adventitious agent contamination with, for example, the prion that causes mad cow disease or DNA from viruses that infect pigs and monkeys. If vaccine safety screening technology used by the FDA and vaccine manufacturers is not state of-the-art, the public cannot rely upon assurances that vaccines have met the government's legal requirement for proof of purity.

The most troubling question that remains is how DNA from an animal virus could have contaminated original seed stocks of Rotarix and evaded testing prior to the vaccine's licensure in 2008, which means that every dose of Rotarix given to more than one million children since 2008 was contaminated. Were RotaTeq vaccine seed stocks contaminated with PCV1 and PCV2 DNA as well? And why does RotaTeq vaccine have allowable thresholds of residual monkey viral DNA? And could there be other animal viruses DNA in rotavirus vaccines that still has not been detected with currently used technology?

A February 2010 FDA document listing non-binding recommendations for vaccine makers states that vaccines should be free of adventitious agents because residual DNA might be a risk for causing cancer or being infectious. Parents being told by federal health officials to give their babies three doses of live rotavirus vaccine before six months of age expect those vaccines and others to be free from adventitious agent contamination because the FDA legally requires vaccine manufacturers to adhere to binding regulations rather offering companies non-binding recommendations.

The National Vaccine Information Center urges the FDA to (1) recommend the suspension of the use of RotaTeq vaccine until more is known about whether PCV1 and PCV2 contamination is a hazard to human health over time and Merck can guarantee RotaTeq is adventitious agent free; (2) institute a legal requirement for vaccine manufacturers to immediately notify the FDA of any and all potential contamination issues; and (3) raise the legal standards for testing of vaccines for adventitious agent contamination prior to licensure.

**Statement on Advanced Analytical Methods in the Characterization of Cell Substrates**
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As has been mentioned today, contamination of vaccines with animal viruses is not new. In the 1950's and early 1960's, polio vaccines given to millions of children and adults used monkey kidney tissue cells contaminated with simian virus 40. A 1973 prospective study of more than 50,000 pregnancies concluded that inactivated polio vaccines given to pregnant women in that study between 1959 and 1965 were associated with excess malignancies and brain tumors in children born to those mothers. If there continues to be a dispute in the 21st century about whether monkey viruses or monkey viral DNA in vaccines can, in fact, cause cancer in humans, there is no dispute that polio vaccines were contaminated with a monkey virus.

Vaccine manufacturers are allowed to use cell material that comes from the bodies of mammals, including humans, monkeys, cows, pigs, dogs and rodents, as well as cells from birds and insects, to make either experimental or currently licensed vaccines. There is always the risk of adventitious agent contamination that can escape detection.

The discussion last November in this Committee involving a vaccine manufacturer seeking a license to use caterpillar cells, which have the potential to be infected with insect viruses that are hard to detect, to make influenza vaccine is indicative of how important the contamination issue is becoming as hundreds of vaccines using novel cell substrates are being developed. Drug companies are experimenting with dog kidney and human fetal retinal cells, even though these cell lines have been documented to cause tumors in animals, and there have been discussions in this Committee during the past decade about using cancer cells to make vaccines, even though there has been a long standing prohibition on their use due to risk for adventitious agent contamination.

The recent detection of DNA fragments from a bird virus in measles vaccine by the same private lab that identified pig viral DNA in rotavirus vaccine, brings to mind detection in 1995 by Swiss scientists of reverse transcriptase from an avian retrovirus in influenza vaccines, as well as the live measles and mumps vaccines, using chicken cells for production. Reverse transcriptase activity has been associated with the presence of retroviruses that can permanently alter the genes of the cells they infect.

This is no small matter when the CDC now recommends that every American get an annual flu shot from 6 months of age throughout life, even during pregnancy when the genetic and biological integrity of the unborn child developing in the womb may be exquisitely vulnerable to the effects of adventitious agent contamination of vaccines.

The contamination of seed stocks of rotavirus vaccine with animal virus DNA that was not detected pre or post-licensure is an important wake up call for industry and government. The National Vaccine Information Center urges the FDA to (1) explore with vaccine manufacturers technology that does not rely on utilization of mammal, bird, insect or other living cells that can

be contaminated with adventitious agents posing a risk to human health; and (2) institute stronger legal requirements for proof that vaccine cell substrates and other materials used for production of seed stocks are free from adventitious agent contamination and remain free throughout the manufacturing process before lots are released for public use; and (3) while vaccines are being thoroughly re-tested for adventitious agent contamination, the FDA should institute stricter labeling standards to fully and clearly inform the public using vaccines about residual adventitious agent content in all vaccines.