

**Final resolution after Congress Session II on March 13, 2014
DISAPPROVED – The ACOFP continues to support childhood immunization.**

Resolution 10 – End Administration of Live Intranasal Influenza Mist Vaccine in United States

WHEREAS, influenza vaccines are effective in children older than two but little evidence is available showing efficacy for children under two; and

WHEREAS, no vaccine safety comparisons have been carried out, emphasizing the need for standardization of methods and presentation of vaccine safety data in future studies; and

WHEREAS, in children under the age of two, the efficacy of inactivated vaccine has been found comparable to placebo, and it has not been possible to analyze the safety of vaccines from studies due to the lack of standardization; and

WHEREAS, minimal data exists on the safety of inactivated vaccines, the most commonly used vaccine in young children; and

WHEREAS, evidence of the efficacy of live intranasal vaccine is incomplete; and

WHEREAS, the Food and Drug Administration (FDA) has mandated manufacturers to include in package information that the live intranasal vaccine has not been proven to be safe from carcinogenic potential, mutagenic potential, or impairment of fertility; and

WHEREAS, no studies or data exist for whether live influenza mist can cause fetal harm when administered to pregnant women or women who may become pregnant in the future; now, therefore be it

RESOLVED, that the American College of Osteopathic Family Physicians (ACOFP) acknowledges the dangers of live intranasal influenza vaccines and lobbies to have it withdrawn from the marketplace by the FDA; and be it further

RESOLVED, that if continued immunization in children is to be recommended as public health policy, the ACOFP lobbies the FDA Vaccine and Related Biological Products Advisory Committee to perform studies on influenza vaccine types, assessing quality outcomes for efficacy and safety in general usage.

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References:

1. <http://www.cdc.gov/flu/about/viruses/change.htm> retrieved 09/28/2013, Center for Disease Control and Prevention, How the Flu Virus Can Change: “Drift” and “Shift”
2. <http://www.bcm.edu/molvir/influenza> retrieved on 09/28/2013, Baylor College of Medicine, Department of Molecular Virology and Microbiology, Influenza Virus (Flu), The Agent
3. <http://www.cdc.gov/flu/professionals/vaccination/virusqa.htm> Retrieved on 09/28/2013 Center for Disease Control and Prevention; Selecting the Viruses in the Seasonal Influenza Vaccine
4. www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm294307.pdf retrieved 09/28/2013 Highlights of Prescribing Information package insert for FluMist Quadrivalent, Intranasal Spray, 2013-2014 formula, Mediimmune, July 2013
5. Study AV006: Years 1 and 2 – Clinical endpoint efficacy study against culture-confirmed influenza in children aged 15-71 months of age., Retrieved on 09/29/2013 from www.fda.gov/ohrms/dockets/ac/01/briefing/3769b1_01.doc
hrisAnna M. Mink M.D., Wasima N. Rida, Ph.D., Antonia Geber, M.D., presentation to Vaccines and Related Biological Products Advisory Committee of the FDA meeting July 26,27, 2001 ,
6. <http://www.cdc.gov/flu/professionals/acip/clinical.htm> retrieved on 09/29/2013, Clinical Signs and Symptoms of Influenza, Diagnosis
7. <http://www.fiercevaccines.com/special-reports/flumist> retrieved on 09/29/2013 FluMist January 17, 2013, Free Weekly Vaccines Industry Newsletter
8. <http://summaries.cochrane.org/CD001269/vaccines-to-prevent-influenza-in-healthy-adults>, Retrieved on 09/ 28, 2013 Published Online: June 4, 2013 Cochrane Studies , Jefferson T, Di Pietrantonj C, Rivetti A, Bawazeer GA, Al-Ansary LA, Ferroni E Published Online: June 4, 2013
9. <http://summaries.cochrane.org/CD004879/vaccines-for-preventing-influenza-in-healthy-children> retrieved 09/28/2013, Cochrane Summaries Jefferson T, Rivetti A, Di Pietrantonj C, Demicheli V, Ferroni E Published Online: August 15, 2012
10. [.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm080754.htm](http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm080754.htm)
Retrieved on 09/29/2013 Questions about Recommendations and Adverse Side Effects