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Vaccines and Autism Revisited

TO THE EDITOR: In his Perspective article on a possible connection between vaccines and autism, Offit (May 15 issue)¹ speculates about my daughter, Hannah, and repeats inaccuracies from a March *New York Times* opinion piece that was officially corrected by the *Times* and our April 5 letter.

By omitting critical information from my March 6, 2008, statement, Offit misrepresents my position. I said, "Many in the autism community and their champions believe that the result in this case may well signify a landmark decision as it pertains to children developing autism following vaccinations. This still remains to be seen, but currently there are almost 5,000 other cases pending."

Offit's remarks about Hannah's case are not evidence-based. He has no access to my daughter's personal medical records, legal documents, or affidavits. In contrast, physicians from the Department of Health and Human Services (DHHS) who studied this information recommended that the government concede Hannah's case. The clinical history Offit presents contains significant inaccuracies, and the resulting conclusions are consequently flawed.

Offit confuses issues by comparing Hannah's case with unrelated decisions in "vaccine court." The Office of the Secretary of DHHS, through the Department of Justice, conceded Hannah's case. There was no courtroom hearing and no decision from the "unusual vaccine court."

Offit is frequently cited regarding the "biologically plausible" theory that simultaneous administration of multiple vaccines is safe. His opinion is unsupported by clinical trials, much less investigations in potentially susceptible subpopulations.

Despite the high frequency of mitochondrial dysfunction in autistic children,² studies have not established primary or secondary roles. To explore this question, we need an immunization database for children with metabolic disorders to establish safety guidelines³ and improve vaccine safety for minority subgroups of children.

I agree with the statement of Bernadine Healy, former director of the National Institutes of Health, who said, "I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show. . . . If you know that susceptible group, you can save those children. If you turn your back on the notion there is a susceptible group . . . what can I say?"⁴ Also commendable is the new 5-year research plan of the National Vaccine Advisory Committee, which will entail the study of minority subpopulations, including patients with mitochondrial disorders.⁵

A strong, safe vaccination program is a cornerstone of public health. Misrepresenting *Hannah Poling v. HHS* to the medical profession does not improve confidence in the immunization program or advance science toward an understanding of how and why regressive encephalopathy with autistic features follows vaccination in susceptible children.

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Dr. Poling is the father of Hannah Poling and reports receiving consulting or lecture fees from Pfizer, Eisai, Ortho-McNeil, Biogen, Teva, Immunex, and Allergan. No other potential conflict of interest relevant to this letter was reported.

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THE AUTHOR REPLIES: Poling implies that by omitting his phrase “many in the autism community and their champions,” I unfairly attributed the notion that vaccines might cause autism to him alone. However, Dr. Poling’s public announcement of the DHHS concession to the press and his subsequent appearances on national television and at autism conferences suggest that he is, at the very least, a vocal centerpiece of that community.

Poling claims that I didn’t have access to his daughter’s medical records. My information was based on a verbatim transcript of the DHHS concession, which stated that his daughter had had frequent ear infections and a series of viral infections early in life. These infections, which are a far greater immunologic challenge than attenuated or inactivated vaccines, are not in dispute.

Poling states that my assertion that the administration of multiple vaccines is safe is an “opinion . . . unsupported by clinical trials.” But studies of concomitant use, which are required by the Food and Drug Administration before licensure to show that new vaccines do not affect the safety or immunogenicity of existing vaccines or vice versa, have clearly shown that multiple vaccines can be administered safely.

Poling agrees with Healy that “you should [n]ever turn your back on any scientific hypothesis because you’re afraid of what it might show.”

However, scientists have not been afraid to test the hypothesis that vaccines might cause autism. Far from it: the ill-founded notion that the measles–mumps–rubella (MMR) vaccine caused autism was tested in 10 epidemiologic studies. Unfortunately, the public airing of that hypothesis caused thousands of parents to avoid the MMR; many children were hospitalized and several died from measles as a result.¹⁻⁴ Now, Poling and Healy are standard-bearers for the poorly conceived hypothesis that children receive too many vaccines too early. As a consequence, some parents are choosing to delay, withhold, or separate vaccines. The problem here is not a failure of scientists to consider hypotheses; rather, it is a failure of the media and the public to distinguish hypotheses from scientific evidence.

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More on Microembolism and Foam Sclerotherapy

TO THE EDITOR: Ceulen et al. (April 3 issue)¹ found intracardiac gas emboli in all patients treated with polidocanol foam (air-to-liquid ratio, 4:1), noting the potential for microembolism. We corroborate this observation in a series of 45 patients treated with proprietary very-low-nitrogen (<0.8%) polidocanol microfoam (Varisolve) generated through a sterile canister system controlling bubble size. In our unpublished series, intracardiac gas emboli were detected in all patients.

An ongoing, multicenter investigational-new-drug (IND) trial involving patients with great-saphenous-vein incompetence and right-to-left cardiac shunts is investigating the clinical significance of gas emboli with the proprietary very-low-nitrogen microfoam. On pretreatment screening, the prevalence of right-to-left shunt was unexpectedly high (40%). During treatment, 36

patients had cerebral emboli, detected by transcranial Doppler studies, and underwent extensive monitoring, including diffusion-weighted magnetic resonance imaging (MRI) at 24 hours and 28 days. No cerebral lesions were detected, and no abnormalities were noted on perimetry or assessment of cardiac markers.² The study will continue until 50 patients with cerebral emboli have been studied.

In contrast, the risk associated with physician-compounded room-air foams is difficult to quantify in the absence of specific data on the potential for cerebral infarction.

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