May 14, 2020

Secretary Alex M. Azar II
Secretary of Health and Human Services
Office of the Secretary
330 C St SW
Washington, DC 20416

RE: National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Notice of Proposed Rulemaking

OPEN LETTER TO THE SECRETARY

Dear Secretary Azar,

I am writing to specifically respond to the American Academy of Orthopaedic position statement titled Rotator Cuff Tendinopathy, Adhesive Capsulitis, and Arthritis Can Not be Caused by Vaccine Administration [https://www.aaos.org/about/bylaws-policies/statements--resolutions/position-statements/] in June of 2019. It is important to understand that these statements do not necessarily reflect the majority opinion of the society and are simply the opinions of the authors. In fact, the following disclaimer is provided on their website: "*AAOS Position Statements usually deal with a socio-economic issue and are designed for audiences beyond orthopaedic surgery. They are developed as educational tools based on the opinions of the authors. **They are not a product of a systematic review**. Readers are encouraged to consider the information presented and reach their own conclusions."*

Disappointingly, the authors are not listed, nor are their conflicts of interests or other disclosures. Further disconcerting is the claim that there is "no scientific evidence that demonstrates that vaccination administration can injure the shoulder". Clearly, the authors failed to conduct an adequate review and failed to cite Bodor, or Arias in their list of references. I have previously summarized the evidence in my prior letter including these two studies. While the scientific literature is largely observational and not experimental in nature, the body of work represents the best available evidence. Many, if not the majority, of medical decisions are based on observational data alone, as many conditions and treatments do not lend themselves to experimental randomized trials.

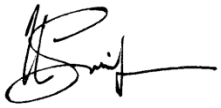
Additionally, the authors of this statement only comment and express concern about the temporal relationship criteria for supporting causation, ignoring the many other criteria I noted in my original letter. Finally, they fail to cite or provide any experimental evidence of their own to support the notion vaccines do not cause shoulder injuries. The authors of the position statement suggest a post-marketing surveillance study of the Hepatitis A vaccine failed to find a difference in shoulder problems before and after surgery (Black, Steven, et al. "A post-licensure evaluation of the safety of inactivated hepatitis A vaccine (VAQTA®, Merck) in children and

adults." *Vaccine* 22.5-6 (2004): 766-772.). Unfortunately, the study is grossly underpowered to detect differences in a rare condition such as SIRVA as its incidence is likely less than 1/50000-1/100000. A study of millions of participants would be needed to be adequately powered for statistical purposes. Therefore this particular study simply cannot inform us on the topic of SIRVA.

A final example of the poor quality of this position statement is evidenced by citation of Trollmo [Trollmo, C., Carlsten, H., & Tarkowski, A. (1990). Intra-articular immunization induces strong systemic immune response in humans. *Clinical & Experimental Immunology*, *82*(2), 384-389.] The authors suggest this is an animal study; clearly the title itself suggests it is not. Further, in my original letter I describe how this study supports the theory of vaccinations having the capability of causing joint injury. They suggest the Trollmo experiment "did not lead to any harm". In the article, the authors of the study note all six volunteers that received intra-articular knee or wrist injection of the vaccine experienced joint swelling and stiffness within 2-4 hours. They do not comment on pain, and simply state these findings disappeared "within some days". This is hardly strong clinical evidence for 'no harm'. The study only had follow up of 14 days and was experimental in nature, not clinical and not focused on describing clinical symptoms of patients. In fact, the study finds that antigen injected into the joint induces a significantly higher immune response than that of subcutaneous injection.

Based on these assessments, I (an active Fellow of the AAOS) reject the conclusions of this position statement.

Sincerely,



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All opinions expressed are solely my own and do not represent or reflect the views of the Johns Hopkins University or the Johns Hopkins Health System