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Dear Legislators and Public Health Officials in the State of Washington,

I have been asked to 1) comment on whether there are conflicts of interest at:

- the Washington State Department of Health (DOH) Office of Immunization and Child Profile (purchases, promotes, and distributes vaccines)
- the Vaccine Advisory Committee (VAC) (advises on vaccine purchases, uses, and promotion)
- and Washington Vaccine Association (WVA) (purchases nearly all vaccines sold or distributed in WA),

and 2) evaluate in particular whether the participation of Michele Roberts, chair-elect of the Association of Immunization Managers (AIM), a collaboration between all state, territorial and municipal immunization managers and Pharmaceutical Companies, poses an unmanageable and therefore unacceptable conflict of interest. Ms. Roberts serves as:

- a state health official and the DOH Director of the Office of Immunization and Child Profile
- a support staff member of the VAC
- a board member of the WVA

I have attached a statement of my qualifications to conduct this assessment.

As described in the 2017 Legislative Ethics Manual produced at the direction of the Washington State Legislative Ethics Board, state officials hold a public trust that obligates them to fulfill the responsibilities to which they were appointed with honesty and integrity. Paramount in that trust is the principle that public office is to be used to conduct the business of the state only in a manner that advances the public's interest. State officials are accountable to the people. The guiding principle of their service is that they are prohibited from having obligations or interests that are in conflict with their official duties, whether or not they are compensated for the outside interest.

To evaluate conflicts of interest of state officials, it is necessary to understand the psychology of conflict of interest and what social science research has taught us about relationships with third parties. There is an abundance of research in particular with regard to relationships of those in health care to pharmaceutical companies. The research shows that even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias. When they have a stake in the conclusion they reach, they tend to be biased in the way they

interpret information. A large body of research suggests that even though individuals (there are many studies on physicians) report that they are not biased by financial arrangements with pharmaceutical companies, they are.

Attempts to eliminate the bias by limiting gift size (as the Washington State Ethics Manual does), conducting educational initiatives, or mandating disclosure are unsuccessful because they rest on a faulty model of human behavior. The Pew Charitable Trusts Task Force on Medical Conflicts of Interest recognized that these attempts are inadequate. In studying certain kinds of financial relationships between physicians and industry, they observed that the totality of the evidence on conflicts of interest in health care suggests that can these relationships can undermine objectivity, integrity and credibility. Their recommendation and those of the Association of American Medical Colleges and the Institute of Medicine were that all medical schools adopt stringent policies to mitigate or eliminate these potentially damaging conflicts of interest.

Their recommendations are relevant to the question before us, whether relationships with vaccine manufacturers who participate side-by-side with state immunization program managers in AIM pose a major conflict of interest. In this regard, it is instructive to review the recommended best practices in conflicts of interest policies of the Pew Task Force. They **prohibited** pharmaceutical representatives involved in marketing from access to physicians and trainees in academic medical centers and affiliated hospitals and clinics while at the same time encouraging contact with scientists who could be objective. They **prohibited** health care professionals from accepting gifts and meals of any value from pharmaceutical companies.

In its memo of understanding for the organization, AIM explicitly acknowledges that representatives and lobbyists for the pharmaceutical companies will participate in the association and that health departments are to among other things

1. “respect the promotion of business objectives by pharmaceutical representatives (PRs)”
2. participate in all intended communication by the PRs
3. allow the PRs to meet with individuals in their departments, conduct educational seminars, and share information; and
4. allow the PRs to review any educational information about a vaccine developed by a health department to be reviewed before it is distributed.

Participation of state immunization managers in AIM creates the largest possible conflict of interest for them in their duty to conduct the business of the state only in a manner that advances the public’s interest. State immunization managers are directly working with pharmaceutical representatives who are there to further their business objectives, not the best interests of the people of the state of Washington. The research shows that pharmaceutical representatives do not present objective information about drug benefits and harms. Their goal is to maximize profits. The Pew Task Force recommended best practice was to PROHIBIT such

contact. **States (including Washington) should PROHIBIT public employees whose work in any way involves vaccines from joining AIM and/or participating in AIM activities.**

Worse yet, by participating in AIM, Washington state is agreeing to give pharmaceutical representatives access to other employees in the state immunization program and to even allow them to present unrestricted educational materials and seminars in which the information presented will not be objective, but self-serving.

Furthermore, in participating as a member of the Vaccine Advisory Committee, Michele Roberts has several major conflicts of interest identified in the Vaccine Advisory Committee Conflict of Interest Policy which at a minimum she needs to disclose (though the research would suggest disclosure is not sufficient):

- Through her membership in AIM, she has a relationship with an entity that benefits financially from the sale of vaccines. Please note that the state ethics manual did not require that she be compensated for there to be a conflict of interest.
- And as an officer of AIM she serves on the board or committees of an organization which is supported by vaccine manufacturers and which benefits financially thereby from the sale of vaccines.

Following the recommendations of the Pew Task Force, consideration should be given to PROHIBITING Michele Roberts and others who have major conflicts of interest from serving as the state immunization manager, as a member of any vaccine advisory committees, on the board of a vaccine purchasing associations, or any other position for which vaccine purchasing, distribution, and promotion may be unduly influenced by AIM.

I have noted my references below. Thank you for the opportunity to comment on this important issue for the state of Washington.

Sincerely,



Alvin H. Moss, MD

References

1. 2017 Legislative Ethics Manual.
http://leg.wa.gov/LEB/Documents/EthicsBoardManual_2017.pdf
2. Dana J, Loewenstein G. A social science perspective on gifts to physicians from industry. JAMA. 2003 Jul 9;290(2):252-255.

3. Korn D, Carlat D. Conflicts of interest in medical education: recommendations from the Pew task force on medical conflicts of interest. *JAMA*. 2013 Dec 11;310(22):2397-2398.
4. Association of Immunization Managers. Memo of Understanding. https://cdn.ymaws.com/www.immunizationmanagers.org/resource/resmgr/files/ph_arm_rep_programs.pdf
5. Vaccine Advisory Committee Conflict of Interest Policy. <https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthSystemResourcesandServices/Immunization/VaccineAdvisoryCommitteeVAC/MembershipPolicy/ConflictofInterestPolicy>

P.S. On January 29, 2019 an article in the *Washington Post* by Paige Winfield Cunningham provides confirmatory evidence of what I wrote in my letter on January 26, 2019. https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/01/29/the-health-202-coca-cola-emails-reveal-how-soda-industry-tries-to-influence-health-officials/5c4f65dd1b326b29c3778cf1/?fbclid=IwAR026EKIYmgtoCGkuAoQG-l-qIRHLT3D8CbC2VX9zezn41TPQyFzc6fMt2Y&utm_term=.c56405a31bc0

The article documents that a close working relationship between an industry that is seeking to further its business objectives and the CDC is capable of influencing CDC policy in a direction favorable to the industry and detrimental to population health. The *Washington Post* article cites a recently released article in the *Milbank Quarterly*, “Public meets Private: Conversations between Coca-Cola and the CDC” by Hessari et al. in which research is described highlighting the risks of corporate access to and influence on public health organizations. **Vaccine manufacturers have just the same access to state immunization officers including Washington’s Michele Roberts through AIM.** Like vaccine manufacturers, Coca-Cola has also given millions of dollars to the CDC Foundation. Because of the risks of industry influence compromising the CDC’s mission, the CDC released ethics guidelines in 2014 which the *Milbank Quarterly* article quotes, “partnering with the private entity presents a conflict of interest (real or perceived).” The *Milbank Quarterly* article concludes, “It is unacceptable for public health organizations to engage in partnerships with companies that have such a clear conflict of interest.” The same can be said of the state immunization officers working side by side in AIM with vaccine manufacturers’ pharmaceutical representatives who acknowledge that their participation in AIM is to promote their business objectives.

Alvin H. Moss, MD, FACP, FAAHPM

Statement of qualifications to speak on vaccines

I am a professor of medicine and physician-scientist at a land grant university school of medicine. My professional responsibilities include patient care, teaching, research and administration. I have published over 150 scientific articles in the peer-reviewed medical literature, and I serve on the editorial boards of the *Clinical Journal of the American Society of Nephrology* and the *Journal of Pain and Symptom Management*. These journals are the official journals of the American Society of Nephrology and the American Academy of Hospice and Palliative Medicine. I am a reviewer for the *New England Journal of Medicine*, *JAMA*, *the Annals of Internal Medicine*, and multiple other medical journals. I have received the highest research honor that my university confers, the Benedum Distinguished Scholar Award.

I am the Director of the Center for Health Ethics and Law at my university. I directed and taught the required course in medical ethics to medical students at my university for 25 years. I chaired the hospital ethics committee at the university hospital where I practice for 32 years and the West Virginia Network of Ethics Committees for 30 years. My interest in vaccine safety and vaccine injury was first prompted by ethical concerns of conflicts of interest in vaccine research and public policy. I view vaccines as pharmaceutical drugs and/or medicines, and I respect everyone's right to the informed consent (or informed refusal) of drugs and/or medicines. As a practicing physician I prescribe vaccines to my patients who choose to receive them after an informed consent discussion. Therefore, I am not ideologically pro-vaccine or anti-vaccine, but rather I am pro-health, pro-ethics, and pro-informed consent in vaccination (like any other medical procedure). I am ethically opposed to coercion of patients in health care.

I have testified three times in the last two years as an expert on vaccines. I testified two times before the West Virginia Legislature on vaccine-related issues: once to the West Virginia Senate Education Committee on March 18, 2007 (<https://www.youtube.com/watch?v=gDhv-MzHlHo>) ; and once to the West Virginia Joint Senate and House of Delegates Children and Families Committee on September 18, 2018 (<http://sg001-harmony.sliq.net/00289/Harmony/en/PowerBrowser/PowerBrowserV2/20180916/-1/28981> starting at 3:12:44). I testified as an expert witness on vaccines in Oakland County Circuit Court in Michigan in the case of Matheson vs Schmitt on January 22, 2018 (<https://www.facebook.com/115306698489462/posts/1669098553110261/>) .

As an expert witness on vaccines with an extensive background in medical ethics, I have testified to the importance of informed consent for vaccination which takes account of the benefits and burdens of vaccination. Good ethics starts with good facts. In my testimonies I have provided an ethical analysis of the facts available for vaccine safety including the influence of conflicts of interest in the research and the lack of "gold standard" research, that is, randomized double-blinded, placebo-controlled clinical trials. I chaired the conflicts of interest committee for West Virginia University Health Sciences Center and was the principal author of the health sciences center's policy on it which remains in effect.

I am a graduate of Harvard University and the University of Pennsylvania School of Medicine. The opinions in my testimony are my own and do not represent those of my employer.