February 25, 2019

Dr. Jose R. Romero, MD
Chair, Advisory Committee on Immunization Practices (ACIP)
University of Arkansas for Medical Sciences and Arkansas Children's Hospital
1 Children's Way
Little Rock, AR 722202-3591

Dear Chairman Romero and ACIP Members:

I write on behalf of Children's Health Defense (CHD), a non-profit organization devoted to public health. We have carefully followed your work to evaluate and recommend vaccines to the American public, and particularly to children. We are aware that you may recommend Merck's human papillomavirus (HPV) vaccine, Gardasil 9, to women and men aged 27-45 at your upcoming meeting on February 27-28, 2019. Your recommendation will thus expose over 80 million adults to the possibility of vaccination by Gardasil 9.[1]

CHD would consider this a reckless recommendation based on all the information available to us. If you and the other ACIP members proceed with this recommendation, CHD will seek to hold you accountable for endangering this population with a product that has little proven efficacy in this age group but which likely puts them at higher risk of developing cancers and other grave conditions, including autoimmune diseases, Alzheimer's and dementia. In fact, CHD believes that Merck would not dare to seek a Gardasil 9 recommendation for this age group except for the prospect of complete liability protection under the 1986 National Childhood Vaccine Injury Act that your ACIP recommendation may create.

I briefly outline some of the reasons why such a recommendation would be dangerous.

Merck Failed to Use Inert Placebo Controls for Gardasil and Gardasil 9

Despite Gardasil's novelty, Merck failed to test its vaccine against a true inert placebo control in the licensing clinical studies, as World Health Organization and American Medical Association guidelines recommend. In most of its clinical trials, Merck dosed its control groups not with an inert formula, but with a highly toxic aluminum adjuvant. Merck thereby masked the differences, including safety signals, it would have observed if it had compared Gardasil to an inert placebo. Merck then used the fraudulent gimmick of comparing Gardasil 9 to its precursor Gardasil, again masking differences it would have otherwise observed against a true placebo. Although in one trial study Gardasil 9 used a small group of 306 subjects who purportedly received saline solution, even these clinical trials subjects had previously received three doses of Gardasil, so they

[1] https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf

were not Gardasil-naive. Merck's failure to use real placebo controls in the Gardasil and Gardasil 9 clinical trials should preclude any ACIP recommendation for these products.

Untested Ingredients

Merck tested Gardasil and Gardasil 9 only in their entirety; Merck never tested their distinct ingredients individually for human safety. These ingredients include the aluminum-containing adjuvant amorphous aluminum hydroxyphosphate sulfate (AAHS), polysorbate 80, sodium borate, and an undisclosed adjuvant, residual free HPV L1 DNA fragments. Merck included these DNA fragments as a second adjuvant without any idea about their long-term impact on the human body. The amount of AAHS in Gardasil 9, at 500 micrograms, is more than double the amount in Gardasil, raising the question whether Gardasil 9's heavy reliance on the Gardasil trials for comparison is justifiable. Leading scientists and multiple studies associate injected aluminum with autism, Alzheimer's, dementia, Parkinson's, autoimmune diseases, POTS, and Crohn's disease in humans, as well as behavioral abnormalities in animals. None of these injuries could have been detected in Merck's rigged clinical trials.

Polysorbate 80 and sodium borate–which is banned for use in food products due to its health hazards–are associated with infertility in animal experiments. The Gardasil 9 product insert acknowledges that the vaccine is untested for its effects on human fertility. Gardasil and Gardasil 9 clinical trials showed high spontaneous miscarriage rates of 25% and 27.4% respectively, more than double background rates in the relevant age range, raising serious questions about effects on fertility. In addition, the injection of free genetically modified DNA fragments raises serious safety concerns. Merck's failure to adequately test Gardasil and Gardasil 9's ingredients separately for human safety should preclude any ACIP recommendation.

Disease Enhancement

The Gardasil clinical trials, upon which the Gardasil 9 clinical trials rely, demonstrate in Study 013 that women who were PCR positive and seropositive for vaccine-relevant HPV types at the time of vaccination were up to 44.6% more likely to develop cervical intraepithelial neoplasms (CIN) at stage 2 or 3 or worse than women who had not been exposed to the relevant HPV types before vaccination. (Table 17, May 2006 VRBPAC Background Document) In other words, vaccinating women who had previously been exposed to HPV vaccine types and who had current HPV infections with relevant types *increased their risk of developing cervical lesions or cancer* by 44.6%. Women with either HPV antibodies or HPV infections from HPV vaccine types at the time of vaccination *had an elevated risk* to develop CIN 2/3 or cancer of 33.7%. (Table 19, May 2006 VRBPAC Background Document). Vaccinated individuals previously exposed to HPV therefore have an extraordinarily high risk of developing cervical lesions or cancer. This is precisely the cohort to whom Merck and ACIP are now proposing to recommend the vaccine, purportedly to prevent cancer. For this reason, we consider such a recommendation to be not just reckless, but also potentially fraudulent and grossly negligent.

Destroying the opportunity to observe risk enhancement further, Merck vaccinated the control group in Gardasil Study 013 at the end of the clinical trial period. Going forward, Merck was thus able to compare only "earlier vaccinated" against "later vaccinated" subjects, instead of observing the long-term distinctions between vaccinated subjects and true controls.

The FDA approved the safety of Gardasil 9 for women and men aged 27 through 45 on October 5, 2018, by "extrapolation from cross-study comparisons" across Gardasil and Gardasil 9 formulations based on "the extensive safety database of Gardasil in younger age groups."[2] By this flimflam, Merck achieved the appearance of Gardasil and Gardasil 9 safety by obscuring danger, not eliminating it.

Table 6 in Gardasil 9's product insert specifically *excludes* clinical trial subjects who were PCR positive and seropositive.[3] Yet the product insert acknowledges in Section 14.2 that *48% of subjects aged 16-26 were PCR or seropositive*.[4] It stands to reason that the intended older population of women and men aged 27 to 45 have even higher rates of PCR and seropositive results because of sexual activity over a longer time period. Merck's Gardasil clinical trial data strongly suggest that a Gardasil 9 recommendation for adults 27-45 may put at least 50% of this population at enhanced cancer risk. Women and men who suffer HPV-related cancers after receiving this vaccine may have legal claims against your Committee for recommending this risky, yet massively profitable, product for use in this age group for the advertised purpose of cancer prevention.

Remarkably, neither the CDC nor professional medical associations are requiring screening before HPV vaccination in this older age group. Recent preliminary epidemiological evidence from England, Scotland and Wales–countries with high HPV vaccine uptake–suggests that cervical cancer rates among young women in their 20's have gone up, not down, since the introduction of the HPV vaccines.[5] HPV vaccines, it appears, rather than preventing cancer, may be causing it. We don't know if the real rise in cervical cancer is because of vaccines, failure to do cervical screening, or other factors. Gardasil 9's product insert notes that Merck never evaluated its potential to cause cancer or genetic mutation.[6] Merck's failure to adequately investigate the risk of disease enhancement in this age group should preclude any ACIP recommendation.

HPV Type Replacement

With over 200 known types of human papilloma viruses, and approximately 12-18 known oncogenic types, scientists and public health officials have long been concerned about the possibility of HPV type replacement with more virulent and carcinogenic types following HPV vaccination. While CDC scientists concluded in 2016 that there is "no clear indication that type replacement

[2] https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM622941.pdf.
[3] https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf.
[4] *Id.*
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5821696/.
[6] https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf.

is occurring,"[7] an independent analysis disputes that claim.[8] We don't know what will happen when potentially more virulent HPV types become prevalent once Gardasil 9 reduces the circulation of the five newly-added HPV types. Merck's failure to adequately investigate the risk of HPV type replacement should preclude any ACIP recommendation.

Gardasil 9 Recommendation for Men Aged 27-45

The Gardasil 9 product insert states that "[e]ffectiveness…in men 27 through 45 years of age is *inferred* from efficacy data in women…and supported by immunogenicity data from a clinical trial in which *150* men, 27 through 45 years of age, received a 3-dose regimen."[9] (emphasis added) It is breathtaking to imagine that ACIP members would recommend a vaccine to approximately 40 million men–none of whom have cervices–based on clinical trials for cervical cancer, that included only 150 men in the target age range. This proposal is particularly alarming given the robust danger signals emanating from Gardasil programs worldwide. Merck's failure to adequately investigate Gardasil 9 in men in this age range should preclude any ACIP recommendation.

Gardasil and Gardasil 9's Overall Risk Profiles

People have reported Gardasil and Gardasil 9 to cause death and serious adverse events at a rate higher than for any other ACIP-recommended vaccine. Since 2006, when Gardasil came on the U.S. market, people have reported over 450 deaths and over 61,000 serious medical conditions from HPV vaccines to VAERS.[10] While this includes GSK's HPV vaccine Cervarix as well, Gardasil has always had the lion's share of the U.S. market. An HHS-funded study established that the voluntary VAERS system captures *less than 1% of vaccine injuries* and deaths.[11]

61,060 HPV Vaccine Adverse Event Reports were received from 2006 to Jan. 14, 2019.

Death	**464**
Life Threatening	**965**
Permanent Disability	**2885**
Hospitalizations	**6080**
Emergency Room Visits	**15,403**

[7] http://pediatrics.aappublications.org/content/137/3/e20151968.

[8] https://jameslyonsweiler.com/2018/05/18/biased-cochrane-report-ignores-flaws-in-hpv-vaccine-studies-and-studies-of-hpv-type-replacement/.

[9] https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf.

[10] https://childrenshealthdefense.org/wp-content/uploads/02-26-19-Medalert-Charts-Combined-2-pages.pdf. As of December 14, 2018, VAERS reported 60,714 serious injuries and 458 deaths from HPV vaccines. See detailed information on reverse side.

[11] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf .

Autoimmune Diseases

Table 9 of Merck's package insert discloses the extraordinary revelation that 2.3% of the clinical trial subjects given the Gardasil vaccine and 2.3% of the young women given injections of Gardasil's neurotoxic aluminum adjuvant experienced serious autoimmune diseases. Since cervical cancer kills 2.3 of every 100,000 American women, the chances of getting autoimmune disease from the vaccine, even if it works, are 1,000 times the chances of being saved from a death from cervical cancer. Based upon this extrapolation alone, the vaccine presents an unconscionable risk – but the true risks are actually far worse than this.

Fifty Percent Injury Rate

During Gardasil's clinical trials, an extraordinary 49.5% of the subjects receiving Gardasil reported serious medical conditions within seven months of the start of the clinical trials. Because Merck did not use a true placebo in its clinical trials, its researchers were able to dismiss these injuries as sad coincidences. (They employed the term "new medical conditions," rather than classifying these injuries as "adverse events.")[12] This explains why scientists have identified HPV vaccines as the most dangerous given to this age group, causing 65.9% of all serious adverse reports, including 62% of deaths, 66% of life-threatening reactions, and 80% of all permanent disabilities.[13] Gardasil was the primary HPV vaccine in use. Merck's failure to adequately investigate the post-licensure injuries and deaths from Gardasil and Gardasil 9 should preclude any ACIP recommendation.

Your appointment to this committee creates myriad opportunities for you, including power, prestige and financial rewards. It is well-known and well-documented that a vast majority of ACIP Committee members receive hefty grants from vaccine manufacturers and pharmaceutical companies in the years following their service. A grave responsibility accompanies these benefits. The public relies on your Committee to make recommendations that assure that our vaccine program is safe. Since 1986, ACIP's role has been particularly important since the vaccine companies have virtually no liability for injuries caused by their vaccine products and no economic incentive to either assure or investigate vaccine safety. Sadly, since 1986, this Committee has devolved into a rubber stamp for vaccines that carry inadequately researched potential risks. This Committee has recommended approximately 45 additional vaccine doses since the passage of the 1986 National Childhood Vaccine Injury Act. Not one of these vaccines has been properly safety

[12] 49.5% NMCs Day 1 thru Month 7:
NB Miller, "Clinical Review of Biologics License Application for Human Papillomavirus 6,11,16,18,L1 Virus Like Particle Vaccine (*S. cerevisiae*) (STN 125126 GARDASIL), manufactured by Merck, Inc.," at 393-94 (Table 3020, June 8, 2006, archived at http://wayback.archive-it.org/7993/20161024002027/http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111287.pdf

[13] L. Tomljenovic and C.A. Shaw, "Adverse Reactions to Human Papillomavirus Vaccines, Table 17.1, page 164, using at VAERS data through 9/12/13, in Shoenfeld et al, Vaccines and Autoimmunity (Wiley Blackwell), 2015.

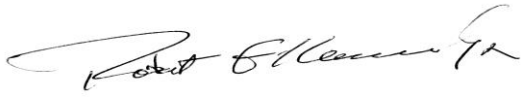
tested against a true inert placebo. The risk profile for these products is therefore completely unknown.

Thanks to your recommendations, the vaccine industry has mushroomed from about $1 billion to $50 billion in that period, and children are not getting healthier. In fact, chronic disease in vaccinated children has risen from 12.4% to 54% under your watch. Your careful consideration of vaccine safety and efficacy is oftentimes the only thing that stands between public health and the four pharmaceutical companies that make all our vaccines. I remind you that all four of these companies are convicted felons that have paid over $35 billion in recent years for deceiving regulators, lying to the public, bribing doctors and engaging in other fraudulent practices to sell their pharmaceutical products. In those instances, they were caught and convicted only because plaintiff's tort lawyers could sue them. Since tort lawyers cannot sue these companies for defectively designed vaccines, only you can protect the public from these deceitful practices and dangerous products.

I attach Informed Consent Action Network's (ICAN's) recent correspondence with the Secretary of the Department of Health and Human Services (HHS) of December 31, 2018, outlining ACIP's failure to recommend vaccines that use rigorous methods in clinical trials, large sample sizes, true placebo controls and extended observation periods for potential injury.[14] I also include the Stipulation of District Court Judge Jesse M. Furman of the Southern District of New York, acknowledging that HHS (including ACIP) has failed completely to uphold its legal responsibilities to report on its efforts to make childhood vaccines safer.[15] This Stipulation proves that ACIP has been an abject failure in its role of assuring a safe vaccine supply. Instead, it has become a tool wielded by the industry to mandate a parade of lucrative vaccines that are ineffective, untested and unsafe. Your collusion with industry to obscure vaccine risks and recommend untested and unnecessarily risky products may violate U.S. and Georgia racketeering statutes and tort laws.

I urge you to carefully consider all the information above before making any Gardasil 9 recommendation.

Sincerely yours,



Robert F. Kennedy, Jr.

[14] https://icandecide.org/wp-content/uploads/whitepapers/ICAN%20Reply%20-%20December%2031%2C%202018.pdf
[15] https://icandecide.org/wp-content/uploads/whitepapers/Stipulated%20Order%20copy.pdf