Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

**VIA ELECTRONIC FILING**

October 28, 2020

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Commissioner Stephen M. Hahn, M.D.
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**AND THE FOOD AND DRUG ADMINISTRATION**

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| **PETITION FOR ADMINISTRATIVE ACTION TO INCLUDE DISCLOSURES IN THE PACKAGE INSERT OF ALL ACELLULAR PERTUSSIS VACCINES** | **:** | **Docket No. _____** |

# CITIZEN PETITION

This petition for administrative action is submitted on behalf of Informed Consent Action Network[1] ("**Petitioner**") pursuant to 21 CFR § 10.35 and related relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request that the Commissioner of Food and Drugs (the "**Commissioner**") require that manufacturers of acellular pertussis-containing vaccines meet the requests in the "Action Requested" section below.

## A. Action Requested

1. It is hereby requested that all manufacturers of acellular pertussis-containing vaccines be required to amend the package inserts of these products to disclose that they do not prevent infection and transmission of pertussis.

[1] Including, but not limited to, on behalf of its members that work for the Petitioner.

## B. Statement of Grounds

2. Pertussis, commonly known as whooping cough, is caused by the bacterium *Bordetella pertussis* ("**pertussis**"). Pertussis in adults is generally mild and can, if necessary, be treated with antibiotics. However, pertussis can cause serious illness in newborns and infants infected with this bacterium.

3. Vaccines licensed in the United States for pertussis are referred to as acellular pertussis vaccines ("**aP vaccines**"). Currently licensed aP vaccines, with year of licensure, are: Infanrix (1997), Daptacel (2002), Pediarix (2002), Adacel (2005), Boostrix (2005), Kinrix (2008), Pentacel (2008), Quadracel (2015), and Vaxelis (2018).[2]

4. Individuals receiving aP vaccines may be protected from symptoms resulting from pertussis, but these vaccines do not prevent infection and transmission of pertussis.

5. As recently explained by research scientists from over a dozen major universities, as well as the World Association of Infectious Diseases and Immunological Disorders (WAidid) and the Vaccine Study Group of the European Society of Clinical Microbiology and Infectious Diseases (EVASG), in an article titled *Pertussis Prevention: Reasons for Resurgence, and Differences in the Current Acellular Pertussis Vaccines*, published in the journal *Frontiers in Immunology: Vaccines and Molecular Therapeutics*:

> Natural infection evokes both mucosal and systemic immune responses, while aPVs induce only a systemic immune response. As *B*. pertussis is a mucosal pathogen and only exceptionally causes infection outside the respiratory tract, this difference is of particular importance in pertussis control. Mucosal immunity is essential to prevent colonization and transmission of *B. pertussis* organisms. Consequently, preventive measures such as aPVs that do not induce a valid mucosal response can prevent disease but cannot avoid infection and transmission. …
>
> aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of B. pertussis and do not exert any herd immunity effect.[3]

6. Also see the following studies: PNAS (2014) https://www.ncbi.nlm.nih.gov/pubmed/24277828 ("[W]e have confirmed that, as in humans, aP [pertussis] vaccines provide excellent protection against severe disease in baboons. However, aP [pertussis] vaccines do not prevent colonization following direct challenge or infection by transmission."); Vaccine (2018) https://www.ncbi.nlm.nih.gov/pubmed/29180031 ("neither DTP, nor DTaP or Tdap prevent asymptomatic infection and silent transmission of the [pertussis] pathogen … in contrast to prior infection [with pertussis], current pertussis vaccines do not prevent asymptomatic infection.").

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[2] https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

[3] https://www.frontiersin.org/articles/10.3389/fimmu.2019.01344/full.

7. This means that individuals administered aP vaccines can still become infected with and transmit pertussis while remaining asymptomatic or paucisymptomatic.[4] For example, a grandmother who received an aP vaccine and was exposed to someone with pertussis may assume that she is not susceptible to infection and cannot transmit pertussis to her grandchild because she received this product. This grandmother, and all other consumers, should therefore be informed in the package insert of all aP vaccines that *while this product may reduce their symptoms, it does not prevent them from becoming infected with and transmitting pertussis.*

8. The undersigned therefore respectfully urges that the action requested above be adopted forthwith.

## C. Environmental Impact

9. The undersigned hereby states that the relief requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

## D. Economic Impact

10. Economic impact information will be submitted upon request of the commissioner.

## E. Certification

11. The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

[4] The genome of the pertussis bacteria is estimated to have approximately 3,000 genes, many of which encode surface or secreted proteins. All aP vaccines used in the United States contain only 5 of these antigens, and hence can only generate antibodies to 5 of the thousands of antigens on the surface of or secreted by the pertussis bacteria. By generating antibodies to only 5 of the surface antigens and secreted toxins of the pertussis bacteria, the result is that individuals may have few or no symptoms if infected with pertussis *but* will still become colonized with and silently transmit pertussis. It appears that this defective immunity remains even after an individual receiving aP vaccines becomes infected with pertussis virus. The body of such a person will continue to generate a vigorous immune response only to the 5 antigens, but not to other pertussis antigens. This defective immune response appears to remain irrespective of how many times a person that received this product is infected with pertussis and appears to be caused by what is known as "linked epitope suppression" which locks in the initial immune response created by the 5 select antigens. Due to "linked epitope suppression," the generation of antibodies to the 5 epitopes in the aP vaccine suppresses the creation of antibodies to a broader range of other epitopes that comprise the pertussis bacteria.

12. The Petitioner therefore respectfully urges that this request be granted forthwith.

Respectfully submitted,

*/s/ Aaron Siri*
Aaron Siri
Elizabeth Brehm
Jessica Wallace
SIRI & GLIMSTAD LLP
200 Park Avenue
17th Floor
New York, NY 10166
Telephone: (212) 532-1091
Facsimile: (646) 417-5967
Email: aaron@sirillp.com