



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

May 26, 2020

Re: Request for studies to support denial of petition concerning baker's yeast-recombinant technology in vaccines

Dear Dr. Obukhanych:

This letter is in response to your request sent on April 22, 2020, to the Washington State Department of Health (DOH) for additional information on studies regarding the safety of yeast recombinant vaccines. Specifically you requested, “*all studies you believe ACIP has relied upon to determine that none of the pathological manifestations of non-IgE-mediated gastrointestinal food allergy (such as chronic diarrhea/constipation, delayed gastric emptying, gastroesophageal reflux/projectile vomiting, irritable bowel and gut pain) are related to the use of yeast-recombinant vaccines*”.

I cannot speculate on studies the Advisory Committee on Immunization Practices (ACIP) has relied upon and can only speak to research I have conducted on this issue to respond to your inquiry. As you know, certain vaccines are made in yeast cells. Although the vaccine is purified away from the yeast cells during the vaccine production process, residuals of the yeast protein remain in the final product. Vaccines produced using yeast have an excellent safety record and have been used for decades in the United States. Based on review of the literature, there do not appear to be studies which demonstrate a relationship between the administration of vaccines produced with yeast and development of gastrointestinal food allergies to subsequent dietary yeast consumption or development of inflammatory bowel diseases. A review by the Institute of Medicine found no evidence of harm other than rare instances of hypersensitivity reactions including anaphylaxis related to Hepatitis B vaccine.¹ Similarly, another study concluded yeast-associated anaphylaxis after Hepatitis B vaccine in sensitized patients appears to be a rare event.² A third study found that yeast-derived vaccine is safe, even in subjects with pre-existing anti-yeast IgE antibodies.³ Likewise, authors from a fourth study concluded that yeast proteins in recombinant Hepatitis B vaccines do not cause type I or type III allergic reactions.⁴ A fifth study concluded that adverse reactions were not more frequent in persons with rises in yeast antibody titers.⁵

¹ Stratton, K., Ford, A., Rusch, E., Clayton, E. W., Committee to Review Adverse Effects of Vaccines, & Institute of Medicine (Eds.). (2011). *Adverse Effects of Vaccines: Evidence and Causality*. National Academies Press (US).

² DiMiceli, L., Pool, V., Kelso, J. M., Shadomy, S. V., Iskander, J., & V.A.E.R.S. Team (2006). Vaccination of yeast sensitive individuals: review of safety data in the US vaccine adverse event reporting system (VAERS). *Vaccine*, 24(6), 703–707. <https://doi.org/10.1016/j.vaccine.2005.07.069>

³ Pêtre, J., Van Wijnendaele, F., De Neys, B., Conrath, K., Van Opstal, O., Hauser, P., Rutgers, T., Cabezon, T., Capiou, C., & Harford, N. (1987). Development of a hepatitis B vaccine from transformed yeast cells. *Postgraduate medical journal*, 63 Suppl 2, 73–81.

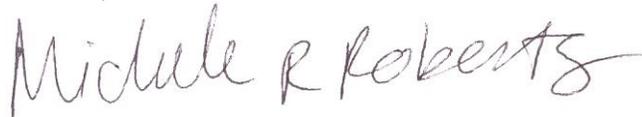
⁴ Wiedermann, G., Scheiner, O., Ambrosch, F., Kraft, D., Kollaritsch, H., Kremsner, P., Hauser, P., Simoen, E., André, F. E., & Safary, A. (1988). Lack of induction of IgE and IgG antibodies to yeast in humans immunized with recombinant hepatitis B vaccines. *International archives of allergy and applied immunology*, 85(1), 130–132. <https://doi.org/10.1159/000234489>

⁵ Zajac, B. A., West, D. J., McAleer, W. J., & Scolnick, E. M. (1986). Overview of clinical studies with hepatitis B vaccine made by recombinant DNA. *The Journal of infection*, 13 Suppl A, 39–45. [https://doi.org/10.1016/s0163-4453\(86\)92668-x](https://doi.org/10.1016/s0163-4453(86)92668-x)

Based on this and other safety data, vaccine providers follow Center for Disease Control guidance for screening patients to determine if there are any contraindications or precautions to vaccines for patients with severe yeast allergies. Patients with severe allergic reactions, including anaphylaxis, should not receive hepatitis B, HPV, and PCV13 vaccines. Vaccine Information Statements are required before any vaccine is administered. This information is provided to patients to raise awareness about contraindications and precautions that should be considered before vaccines are given, and possible side effects of each vaccine.

The Department of Health will continue to base vaccine guidance and information on current recommendations from the ACIP. These recommendations are developed by a group of public health and medical experts and issued as official federal guidance for the use of vaccines in the United States. ACIP members use an evidence-based approach, called [Grading of Recommendations, Assessment, Development and Evaluation \(GRADE\)](#), to analyze data for vaccines. The key factors in GRADE include an evaluation of benefits and risk, the quantity and quality of evidence supporting the evaluation, health economics, and the values and preferences of the patients affected.

Sincerely,

A handwritten signature in cursive script that reads "Michele R Roberts".

Michele Roberts, MPH, MCHES

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cc: Michelle Davis, State Board of Health
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