December 2, 2022

Kent Heckenlively
(b) (6)

Re: Citizen Petitions (Docket Numbers FDA-2017-P-4500 and FDA-2019-P-1130)

Sent via email to: (b) (6)

Dear Mr. Heckenlively,[1]

This letter responds both to your citizen petition that was received by FDA's Dockets Management Staff on July 27, 2017 (Docket number FDA-2017-P-4500; 2017 Petition) and to your citizen petition that was received by FDA's Dockets Management Staff on March 8, 2019 (Docket number FDA-2019-P-1130; 2019 Petition). In the 2017 Petition, you asked the "Food and Drug Administration and the Centers for Disease Control (the Agency) to exercise regulatory discretion and issue Regulations to implement a Five Year Moratorium on all Childhood Vaccinations" (2017 Petition at 1) and to take certain other actions. The Food and Drug Administration (FDA or we) sent you an interim response to the 2017 Petition on January 23, 2018. In the 2019 Petition, you asked the:

> Food and Drug Administration and the Centers for Disease Control (the Agency) to exercise regulatory discretion and issue Regulations to implement an immediate Suspension of all current vaccine drug approvals under the regulations pertaining to vaccine drug biologics…and permanently ban all childhood vaccinations until the safety and efficacy provisions of the [National Childhood Vaccine Injury Act] are faithfully and fully implemented

(2019 Petition at 1; footnote omitted) and to take certain other actions. This letter responds to both the 2017 Petition and the 2019 Petition (the Petitions) in full.

In this letter, as a preliminary matter, we first clarify the relationship between the FDA and the Centers for Disease Control and Prevention (CDC), and the roles and responsibilities of each of these agencies with regard to vaccines. Second, we discuss the safety of licensed vaccines. We then turn to the requests contained in the following sections of the 2017 Petition: *Actions Requested* (2017 Petition at 1-2) and *Exhibit A: Vaccination Moratorium Regulation* (2017 Petition at 17). Next, we consider the requests contained in the corresponding sections of the 2019 Petition: *Actions Requested* (2019 Petition at 2-3) and *Exhibit A: Vaccination Suspension Regulation* (2019 Petition at 18). We consider each of your requests in light of the legal

[1] Other "[s]ignatories on behalf of the Petitioners" are Rima E. Laibow and Ralph Fucetola. 2017 Petition at 13-14, 2019 Petition at 17.

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standards for FDA action, and provide our conclusions based on the facts, the science, and the law.

This letter responds to the Petitions in full. We have carefully reviewed the Petitions, comments submitted to the docket, and other information available to the Agency.[2] Based on our review and consideration of these materials, and for the reasons described below, we deny the Petitions. Here is an outline of our response:

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[2] We received nearly 1,800 comments to the dockets for the Petitions, and reviewed the comments received. Some comments raised specific concerns relating to vaccine safety that were not raised in the Petitions (e.g., inadvertent exposure to simian virus 40 (SV40) in inactivated poliovirus vaccine in the 1950s before discovery of this virus). However, none of the comments with specific concerns raised new issues that the Agency has not already carefully considered. To the extent that some comments raised concerns relating to the safety of thimerosal-containing vaccines, we note that the Agency responded in 2008 to a citizen petition from the Coalition for Mercury-free Drugs (CoMeD) that raised similar concerns; we are incorporating the CoMeD citizen petition response (available under Docket Number FDA-2007-P-0232 at www.regulations.gov) by reference into this response. Insofar as additional studies have been published about the safety of thimerosal-containing vaccines since the time of that citizen petition response, we note that FDA's assessment of the topic, based on the scientific data and information currently available, remains unchanged.

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I. Preliminary Matter: FDA Is Responding to the Petitions Solely on FDA's Behalf

You submitted the Petitions to FDA. However, at several points in the Petitions, including the following, you address both FDA and the Centers for Disease Control and Prevention (CDC):

- "In the Matter of Childhood Vaccine Moratorium Generic Docket FDA-S-2013-0610-0001 Before the United States Food and Drug Administration And Centers for Disease Control" (2017 Petition at 1);
- "[T]he undersigned hereby Petition the Food and Drug Administration and the Centers for Disease Control (the Agency)" (2017 Petition at 1; 2019 Petition at 1);
- "The Centers for Disease Control, under the aegis of the Food and Drug Administration" (2017 Petition at 3); and
- "In the Matter of Suspension of Vaccine Drug Approvals Generic Docket FDA-S-2013-0610-0001 Before the United States Food and Drug Administration and Centers for Disease Control" (2019 Petition at 1).

Contrary to your assertion, CDC is not "under the aegis of" FDA. 2017 Petition at 3. FDA and CDC are separate organizations, sister operating divisions within the U.S. Department of Health and Human Services (HHS).[3] Both operating divisions do, however, have a role to play in monitoring the safety of vaccines.[4]

FDA is a federal regulatory agency tasked with, among other things, "ensur[ing] that…human…drugs, biological products, and medical devices are safe and effective."[5] By statute, vaccines are biological products.[6] FDA regulates vaccines under provisions of the Public

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[3] HHS, "HHS Agencies & Offices." Available at https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html (accessed Mar. 24, 2020).

[4] HHS, "The Journey of Your Child's Vaccine." Available at https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html (accessed Mar. 24, 2020).

[5] HHS, "HHS Agencies & Offices." https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html (accessed Mar. 24, 2020).

[6] "The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings" (emphasis added). 42 U.S.C. § 262(i)(1).

Health Service Act (PHS Act)[7] and the Federal Food, Drug, and Cosmetic Act (FD&C Act).[8] FDA regulates clinical trials of vaccines; licenses (approves) each vaccine based on a demonstration that the product is safe, pure, and potent, and that its benefits outweigh its risks; inspects vaccine manufacturing facilities to ensure the quality and safety of the vaccines produced; and reviews the safety, purity, and potency of every lot of vaccine before the vaccine may be released onto the market. FDA is also one of the federal government agencies that monitor vaccine safety once vaccines are marketed.[9]

CDC is a federal agency tasked with, among other things, "protect[ing] the public health of the nation by providing leadership and direction in the prevention and control of diseases and other preventable conditions, and responding to public health emergencies."[10] CDC's Immunization Safety Office (ISO) identifies possible vaccine side effects and conducts studies to determine whether health problems are caused by vaccines.[11, 12] ISO participates in the continuous monitoring of the safety and effectiveness of vaccines.[13] CDC uses many strategies to assess vaccine safety, to identify health problems possibly related to vaccines, and to conduct studies that help determine whether a health problem is caused by a specific vaccine.[14] CDC also works with other federal government agencies and other stakeholders to determine the appropriate public health response to vaccine safety concerns and to communicate the benefits and risks of vaccines.[15] One of the federal government entities that works with CDC is FDA's Center for Biologics Evaluation and Research (CBER).[16] More about CDC's Vaccine Safety Monitoring activities can be found on CDC's website.[17] CDC also plays a key role in the development of the recommended vaccine schedule for children and adults (discussed in section III.A.1.a below).

This letter represents FDA's response to the 2017 Petition and the 2019 Petition; it is not a response on behalf of CDC or any other federal entity. For requests intended for CDC, you should contact CDC directly.

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[7] Public Health Service Act, as amended, codified at 42 U.S.C. §§ 201 *et seq*.
[8] Federal Food, Drug, and Cosmetic Act, as amended, codified at 21 U.S.C. §§ 301 *et seq*.
[9] FDA, "Vaccine Product Approval Process." Available at https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm (accessed Mar. 24, 2020).
[10] HHS, "HHS Agencies & Offices." Available at https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html (accessed Mar. 24, 2020).
[11] CDC, "Vaccine Safety: About ISO." Available at https://www.cdc.gov/vaccinesafety/iso.html (accessed Apr. 8, 2020).
[12] CDC, "Vaccine Safety: Research." Available at https://www.cdc.gov/vaccinesafety/research/index.html (accessed Apr. 8, 2020).
[13] CDC, "Vaccine Safety: About ISO." Available at https://www.cdc.gov/vaccinesafety/iso.html (accessed Apr. 8, 2020).
[14] *Id*.
[15] *Id*.
[16] CDC, "Vaccine Safety: Vaccine Safety Partners." Available at https://www.cdc.gov/vaccinesafety/ensuringsafety/partners/index.html (accessed Mar. 24, 2020).
[17] CDC, "Vaccine Safety: Vaccine Safety Monitoring." Available at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html (accessed Mar. 24, 2020).

II. Licensed Vaccines, Including Pediatric Vaccines, Are Safe

A. Vaccines Are Shown to Be Safe at the Time of Licensure

FDA has a stringent regulatory process for licensing vaccines that serves as a model for other countries.[18, 19]

The PHS Act authorizes FDA to license biological products, including vaccines, if they have been demonstrated to be "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i). Prior to approval by FDA, vaccines are extensively tested in non-clinical studies and in humans. FDA's regulations describe some of the extensive data and information that each sponsor of a vaccine must submit to FDA in order to demonstrate the product's safety before FDA will consider licensing the vaccine. FDA requires that the sponsor's application include, among other things, data derived from nonclinical laboratory and clinical studies showing the product's safety, purity, and potency; a full description of manufacturing methods for the product; data establishing the product's stability through the dating period; and a representative sample of the product and summaries of results of tests performed on the lot(s) represented by the sample. 21 CFR § 601.2(a).

As is evident from the language of the PHS Act and FDA's regulations, the licensure process for a vaccine requires the sponsor to establish, through carefully controlled laboratory and clinical trials, as well as through other data, that the product is safe and effective for each of its intended uses. FDA's multidisciplinary review teams then rigorously review the sponsor's laboratory and clinical data, as well as other information, to help assess whether the safety, purity, and potency of a vaccine has been demonstrated.[20] Only when FDA's high standards are met is a vaccine licensed.

FDA regulations explicitly state that "[a]pproval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products" (emphasis added). 21 CFR § 601.2(d). Therefore, the manufacturers of vaccines that have been licensed in the U.S. have necessarily demonstrated the safety of the vaccines within the meaning of the applicable statutory and regulatory provisions before the vaccines were licensed and allowed to be marketed.

For more information on FDA's thorough process for evaluating the safety of vaccines, see Appendix I of this letter, *Aspects of the Vaccine Licensure Process*.

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[18] CDC, "Ensuring the Safety of Vaccines in the United States." Available at https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf (accessed Mar. 24, 2020).

[19] FDA, "Vaccine Safety Questions and Answers." Available at https://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm133806.htm (accessed Mar. 24, 2020).

[20] FDA, "Vaccines." Available at https://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm (accessed Mar. 24, 2020).

B. Vaccine Safety Continues to Be Monitored Post-Licensure

FDA's oversight of vaccine safety continues after licensure of the product. Once the licensed product is on the market, post-marketing surveillance of vaccine safety is conducted in order to detect any rare, serious, or unexpected adverse events, as well as to monitor vaccine lots. FDA employs multiple tools and databases to evaluate the safety of these vaccines. A vaccine approved for marketing may also be required to undergo additional studies to further evaluate the vaccine and to address specific questions about the vaccine's safety, effectiveness, or possible side effects.[21]

For more information on post-licensure safety monitoring of vaccines, see Appendix II of this letter, *Aspects of Vaccine Postmarketing Safety Monitoring*.

III. The 2017 Petition

In this response to the 2017 Petition, we begin with *Exhibit A: Vaccination Moratorium Regulation*, addressing the requests you make there for substantive action by FDA. 2017 Petition at 17. We then address the first two items in *Actions Requested*, which we believe constitute a request for FDA to take certain procedural actions relating to the regulation you propose. 2017 Petition at 1. Finally, we address the last two items contained in *Actions Requested*. 2017 Petition at 2.

A. Your Requests Relating to a Moratorium

In the 2017 Petition, you request that FDA "[i]mpose a five year moratorium on all childhood vaccines from birth to age eighteen, with 'Not for Childhood Vaccination' placed on all vaccine labels by suspending the existing vaccine approvals as to minors." 2017 Petition at 17. This statement appears to contain requests for three separate substantive FDA actions. We address each of these in turn below.

1. Your Request That FDA Impose a Moratorium on All Pediatric Vaccinations

In the 2017 Petition, you request that FDA "[i]mpose a five year moratorium on all childhood vaccines from birth to age eighteen." 2017 Petition at 17. We interpret this, read along with other portions of the 2017 Petition, to be a request for a five-year moratorium on childhood vaccinations, i.e., the administration to children of vaccines approved for pediatric use. FDA declines your request because it is outside the scope of FDA's authority to impose such a moratorium.

FDA does not make recommendations regarding the use of vaccines. Likewise, FDA does not impose any childhood vaccination requirements. We discuss each of these facts below.

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[21] *Id*.

a. FDA Does Not Issue Vaccination Recommendations

FDA approves vaccines and their labeling, but does not make recommendations regarding the use of vaccines. The federal entity responsible for issuing recommendations on the use and timing of vaccines is CDC.

The Advisory Committee on Immunization Practices (ACIP), working with the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians, develops immunization schedules, which are recommendations for the routine administration of vaccines to children and adults in the civilian population in the U.S.[22, 23] The immunization schedules include recommendations on the ages at which individuals should receive particular vaccines, as well as on the number of doses and the dosing intervals for each vaccine. Using an evidence-based framework,[24, 25] ACIP considers available data on the safety and effectiveness of a vaccine before developing or changing a recommendation for its use.[26] If the CDC Director approves ACIP's recommendations, these recommendations become part of the United States official childhood immunization schedule.[27]

Note that the immunization schedule constitutes a set of recommendations, not requirements. As explained further below, states may enact and enforce immunization laws and regulations that contain vaccine requirements.

FDA does not provide vaccination recommendations, and it is outside the scope of FDA's authority to revise the immunization schedule for children.

b. FDA Does Not Impose Vaccination Requirements

While the vaccine schedule recommendations are issued by the federal government, it is the states that enact and enforce immunization laws and regulations under the authority of their state constitutions.[28] All states, the District of Columbia, and U.S. territories require children attending childcare facilities and schools to be vaccinated against certain communicable

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[22] CDC, "Advisory Committee on Immunization Practices (ACIP): Recommendations." Available at https://www.cdc.gov/vaccines/acip/recommendations.html (accessed Mar. 24, 2020).
[23] CDC, "Immunization Schedules: Child Immunization Schedule (birth to 18 years)." Available at https://www.cdc.gov/vaccines/schedules/hcp/index.html (accessed Mar. 24, 2020).
[24] CDC, "Advisory Committee on Immunization Practices (ACIP): Evidence Based Recommendations." Available at https://www.cdc.gov/vaccines/acip/recs/index.html (accessed Mar. 24, 2020).
[25] CDC, "Advisory Committee on Immunization Practices (ACIP): About GRADE." Available at https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html (accessed Mar. 24, 2020).
[26] CDC, "Vaccines for Your Children: The Journey of Your Child's Vaccine." Available at https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html (accessed Apr. 8, 2020).
[27] *Id.*
[28] FDA, Vaccine Safety Questions and Answers." Available at https://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm133806.htm (accessed Mar. 24, 2020).

diseases.[29] State laws also often include vaccination requirements for college students as well as healthcare workers and patients in certain facilities.[30]

FDA has not promulgated any regulations that mandate the use of vaccines, and it would be outside the scope of FDA's statutory authority to require vaccinations. It is also outside the scope of FDA's authority to control the development or enforcement of State immunization laws and regulations.

In light of the above facts, FDA denies the request to impose a moratorium on all childhood vaccinations, as such an action is outside the scope of FDA's authority.

2. Your Request That FDA Require Changes to the Labeling of Licensed Pediatric Vaccines

You request that FDA require the statement "'Not for Childhood Vaccination' [be] placed on all vaccine labels." 2017 Petition at 17.

As discussed in Section II above, every U.S.-licensed vaccine, including every pediatric vaccine, was found to be safe, pure, and potent at the time of approval, and was labeled accordingly.

We have thoroughly reviewed the Petitions and the information cited in the Petitions, including the bar chart entitled "*Study Shows Vaccinated Children Are Sicker Than Vaccine-Free Children*" (2017 Petition at 2) and the data on which it appears to be based.

FDA concludes that no labeling change is warranted for any pediatric vaccines at this time because there is no scientifically sound evidence to support your contention that vaccinated children are less healthy than unvaccinated ones. Your contention is contradicted by an extensive body of published scientific literature. This point is discussed further in section III.C.

For these reasons, we deny your request for FDA to require changes to the labeling of licensed, marketed pediatric vaccines.

3. Your Request That FDA Suspend Approvals for Childhood Use of Pediatric Vaccines

Referring to "all childhood vaccines," you also request that FDA "suspend[] the existing vaccine approvals as to minors." 2017 Petition at 17.

FDA's authority to suspend an existing vaccine license is laid out in FDA's regulations: "Whenever the Commissioner has reasonable grounds to believe that any of the grounds for revocation of a license exist and that by reason thereof there is a danger to health, the Commissioner may notify the licensed manufacturer that the biologics license is suspended." 21

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[29] CDC, "SchoolVaxView: Requirements and Exemptions." Available at https://www.cdc.gov/vaccines/imz-managers/coverage/schoolvaxview/requirements/index.html (accessed Mar. 24, 2020).

[30] CDC, "Public Health Professionals Gateway: Public Health Law: Vaccination Laws." Available at https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html (accessed Mar. 24, 2020).

CFR § 601.6(a). The regulations lay out multiple possible grounds for the revocation of a license; for purposes of this letter, the one most relevant to your concerns is that "[t]he licensed product is not safe and effective for all of its intended uses or is misbranded with respect to any such use." 21 CFR § 601.5(b)(1)(vi).

As described in Section II and Appendix I of this letter, all U.S.-licensed vaccines on the market today have gone through FDA's stringent approval process. All are subject to standards of safety, purity, and potency and were found to be safe and effective for their intended uses. In the absence of data or information suggesting otherwise, FDA considers that all of the pediatric vaccines that are currently licensed and on the market remain safe and effective.

In the 2017 Petition, you do not provide data or information that would constitute reasonable grounds to believe that any licensed, marketed pediatric vaccine "is not safe and effective for all of its intended uses" (or that any other grounds for license revocation exist under 21 CFR § 601.5(b)(1)). Therefore, we deny your request to suspend approvals for childhood use of pediatric vaccines.

B. Your Request That FDA Suspend or Repeal the National Childhood Vaccine Injury Act

In the 2017 Petition, you request that FDA "[s]uspend (pending repeal) the 1986 National Childhood Vaccine Injury Act and return vaccine injuries to the Constitutionally-mandated, traditional civil justice system." 2017 Petition at 17.

1. The National Childhood Vaccine Injury Act

We believe you are referring, in particular, to those provisions of the National Childhood Vaccine Injury Act of 1986[31] (NCVIA) that amended the Public Health Service Act to establish the National Vaccine Injury Compensation Program[32] (VICP) "to ensure that those who bear the burden of rare serious adverse events possibly caused by vaccines are compensated."[33] The VICP was created to compensate those injured by certain vaccines[34] on a no-fault basis; it provides an optional alternative to the traditional tort system for resolving vaccine injury

[31] The National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743, 3755; codified at 42 U.S.C. § 201 *et seq*.

[32] The National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743, 3758; codified at 42 U.S.C. § 300aa-10 *et seq*.

[33] *Priorities for the National Vaccine Plan*, Committee on Review of Priorities in the National Vaccine Plan, Board on Population Health and Public Health Practice, Institute of Medicine of the National Academy of Sciences, 2010. Washington (DC): National Academies Press (US); 2010. Introduction. Available at: https://www.ncbi.nlm.nih.gov/books/NBK220055/ (accessed Mar. 24, 2020).

[34] The 21st Century Cures Act, enacted on December 13, 2016, made several amendments to the NCVIA, including expanding the VICP's coverage to include new categories of vaccines. Section 3093(c) of Pub. L. 114-255, 130 Stat. 1033, 1152; codified at 42 U.S.C. §§ 300aa-14(e)(3), 300aa-11(f), and 300aa-11(b)(2).

petitions.[35] Therefore, there is no need to "return vaccine injuries to the Constitutionally-mandated, traditional civil justice system" (2017 Petition at 17), because disputes regarding such injuries have not been barred from that system.

The VICP is administered by the Health Resources & Services Administration (HRSA), an operating division within HHS. For more information about VICP, you may wish to refer to HRSA's website.[36] Please note that FDA is not responding to the Petitions on behalf of HRSA.

2. FDA Does Not Have the Authority to Suspend or Repeal Any Statute

The NCVIA is a statute, enacted by Congress, and the VICP was established by that statute. As statutory law, it can only be changed by Congress (or be found invalid in the context of a lawsuit brought in the federal court system). Agencies in the Executive Branch, such as FDA, do not have the authority to suspend or repeal statutes. Therefore, we deny this request because it is not within the scope of FDA's authority to suspend or repeal the NCVIA.

C. Your Request That FDA Conduct Studies of Vaccinated and Unvaccinated Children

You request that FDA "[p]erform large scale studies of vaccinated and un-vaccinated children." 2017 Petition at 17.

For all vaccines, FDA reviews pre-approval studies that are designed to demonstrate the safety and effectiveness of the product (see Appendix I). FDA also reviews and conducts post-approval surveillance to monitor and continue to ensure the safety of vaccines once they are marketed (see Appendix II).

Based on your inclusion in the 2017 Petition of the bar chart "*Study Shows Vaccinated Children Are Sicker than Vaccine-Free Children*" (2017 Petition at 2), we assume that you are requesting that FDA conduct studies comparing vaccinated and unvaccinated children and the incidence in each group of various (non-vaccine-preventable) illnesses and conditions, such as those listed in the bar chart (allergies, asthma/chronic bronchitis, neuro-dermatitis, herpes, otitis media, hay fever, hyperactivity, scoliosis, epilepsy/seizures, migraine, thyroid disease, and diabetes mellitus). 2017 Petition at 2.

There exists an extensive body of published scientific literature testing the hypothesis that vaccinated children are in some way less healthy that unvaccinated ones. Numerous studies have looked for possible associations between vaccinations and a range of illnesses, conditions, and non-vaccine-targeted infectious diseases, but these studies do not support the 2017 Petition's

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[35] A decision about whether and how an individual should be compensated "may be appealed and petitioners who reject the decision of the court (or withdraw their petitions within certain timelines) may file a claim in civil court against the vaccine company and/or the health care provider who administered the vaccine." HRSA, "National Vaccine Injury Compensation Program." Available at https://www.hrsa.gov/vaccine-compensation/index.html (accessed Mar. 24, 2020).

[36] *Id.*

contention that vaccinated children are less healthy than unvaccinated ones. We list a few of these publications below:

- A 2018 study examined whether exposure to multiple vaccines through the first 23 months of life was associated with an increased risk for infections not targeted by vaccines. The authors found that, among children 24-47 months of age with emergency room and inpatient visits for non-targeted infections, compared with children without such infections, there was no significant difference in estimated cumulative vaccine antigen exposure through the first 23 months of life.[37]

- The data from the KiGGS study,[38] which you mention in the 2017 Petition (2017 Petition at 2, bar chart), have been examined for associations between vaccination and certain diseases or conditions. In 2017, researchers working with these data reported that they had found no correlation between vaccinations in the first year of life and the occurrence of atopic diseases (hay fever, atopic dermatitis, and asthma).[39] The authors concluded

  > our results provide no evidence that immunisations in the 1st year of life may increase the risk of atopic disease. If any association exists at all, our results may be interpreted as weakly supportive of the hypothesis that immunisations may slightly decrease the risk of atopy…Our results add to the current evidence and are in line with the majority of similar studies in this field.[40]

- The Institute of Medicine (IOM) of the National Academies[41] issued a report in 2013 on the safety of the U.S. childhood immunization schedule.[42] The IOM committee reviewed the scientific literature and solicited input from the public.[43] As stated in the Report Brief, [44]

  > [u]pon reviewing stakeholder concerns and scientific literature regarding the entire childhood immunization schedule, the IOM committee finds no evidence that the schedule is unsafe. The committee's review did not reveal an evidence base suggesting that the U.S. childhood immuniza-

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[37] Glanz, JM, Newcomer, SR, Daley, MF, et al. Association between estimated cumulative vaccine antigen exposure through the first 23 months of life and non-vaccine-targeted infections from 24 through 47 months of age. *JAMA*. 2018 Mar 6;319(9):906-913. Available at https://jamanetwork.com/journals/jama/fullarticle/2673970 (accessed Mar. 31, 2020).

[38] KiGGS is a long-term interview and examination study of the comprehensive health status of children and adolescents in Germany, commissioned by the German Federal Ministry of Health and conducted by the Robert Koch-Institute. *See* https://www.kiggs-studie.de/english/home.html (accessed Mar. 31, 2020).

[39] Schlaud M, Schmitz R, Poethko-Müller, C, et al. Vaccinations in the first year of life and risk of atopic disease – results from the KiGGS study. *Vaccine*. 2017 Aug 8;35(38):5156-5162. Available at https://www.sciencedirect.com/science/article/pii/S0264410X17310629?via%3Dihub (accessed Mar. 31, 2020).

[40] *Id.*, at 5161.

[41] Now the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine. The Health and Medicine Division provides independent, objective, evidence-based advice to policy makers, health professionals, the private sector, and the public.

[42] The National Academies Press, "The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies" (2013). Available at https://www.nap.edu/catalog/13563/the-childhood-immunization-schedule-and-safety-stakeholder-concerns-scientific-evidence (accessed Mar. 31, 2020).

[43] *Id*. at 3-4.

[44] The National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division, The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies, Report Brief, Jan. 16, 2013, at 2. Available at https://www.nap.edu/resource/13563/ChildhoodImmunizationScheduleandSafety_RB.pdf (accessed Mar. 31, 2020).

> tion schedule is linked to autoimmune diseases, asthma, hypersensitivity, seizures, child developmental disorders, learning or developmental disorders, or attention deficit or disruptive disorders.
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> The Report Brief concluded that, "[i]n this most comprehensive examination of the immunization schedule to date, the IOM committee uncovered no evidence of major safety concerns associated with adherence to the childhood immunization schedule."[45]

Because there already exists a significant body of scientific literature of high quality that has studied – and generally does not support – the contention that vaccinated children are less healthy that unvaccinated ones, FDA denies your request that FDA conduct additional studies in this area.

D. Your Request That FDA Ban Direct-To-Consumer Pharmaceutical Advertising

In the 2017 Petition, you request that FDA "[b]an direct pharmaceutical advertising to consumers and allow such advertising only to medical professionals." 2017 Petition at 17.

No statute exists that would authorize FDA to implement a complete ban on direct-to-consumer advertising (DTCA). Additionally, we note that the U.S. Supreme Court has found that speech in support of pharmaceutical firms' marketing activities is constitutionally protected under the First Amendment. *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011). Thus, it is unlikely that an outright ban on DTCA would pass constitutional muster.

Moreover, we do not believe it is appropriate to ban DTCA that complies with FDA regulations. Rather, DTCA should be closely regulated and monitored to ensure that it is truthful, balanced, and non-misleading. DTCA may have both positive and negative aspects relating to public health. Positive aspects include making patients more aware of possible medical conditions and treatments for those conditions, motivating patients to ask questions of their healthcare providers, and helping patients ask better questions. Negative aspects include potentially causing patients to think that a drug works better than it does, and patients' not getting a clear depiction of the risk profile of a drug from DTCA.

To address these concerns, FDA closely monitors DTCA for prescription medical products, including vaccines, and takes legal action as appropriate against misleading promotional materials. FDA also engages in many activities to promote and facilitate voluntary compliance by industry, including publication of guidance documents, advising companies on draft promotional materials, issuance of untitled and warning letters regarding misleading promotional materials, and outreach to our stakeholders.

For the above legal and public health reasons, FDA denies your request to ban direct-to-consumer pharmaceutical advertising.

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[45] *Id.* at 4.

E. Your Request That FDA Promulgate the Provided Regulation on an Expedited Basis

In the above sections of this letter, we have addressed the four substantive requests contained in the 2017 Petition's *Exhibit A: Vaccination Moratorium Regulation*. 2017 Petition at 17.

In the 2017 Petition, you also ask that FDA "[e]xercise…regulatory discretion to immediately promulgate the requested Regulation as an emergency ruling to protect the public health, and especially the health of children" and "[h]old hearing(s), permit public comments, issue permanent regulations, consistent with our expressive association rights and humanitarian law, implementing the emergency discretion and emergency Regulation on a regular basis." 2017 Petition at 1.

We interpret these two statements to be a procedural request for FDA to promulgate the referenced "Regulation" (2017 Petition at 17) as an interim final rule followed by notice-and-comment rulemaking.[46]

Because we have denied the substantive requests contained in the 2017 Petition, we also deny this procedural request for a rulemaking.

F. Your Request That the President Mandate FDA Action

In the 2017 Petition, you request "[i]ntervention by the President of the United States mandating Agency action." 2017 Petition at 2.

This request appears to be directed to the President of the United States rather than to FDA. If so, it is misdirected.

Because this request is not addressed to the FDA, we deny this request.

G. Your Claim About the Relative Health of Vaccinated and Unvaccinated Children

The 2017 Petition, in *Actions Requested*, makes the following claim: "The science is settled. Vaccinated children are less healthy than unvaccinated children." 2017 Petition at 2. Following this claim is a bar graph entitled "*Study Shows Vaccinated Children Are Sicker than Vaccine-Free Children*." 2017 Petition at 2. We assume that you include the bar graph in support of your claim.

Your statement does not present a request for FDA action. However, we refer you to section III.C of this letter, in which we discuss this claim and the bar graph.

[46] We note that a regulation would not be an appropriate legal vehicle for most of the actions you request.

IV. The 2019 Petition

In this response to the 2019 Petition, we begin with *Exhibit A: Vaccination Suspension Regulation*, addressing the requests you make there for substantive action by FDA. 2019 Petition at 18. We then address the first two items in *Actions Requested*, which we believe constitute a request for FDA to take certain procedural actions relating to the regulation you propose. 2019 Petition at 2. Finally, we address the last three items contained in *Actions Requested*. 2019 Petition at 2-3. We note that some of the requests in the 2019 Petition repeat those in the 2017 Petition.

A. Your Requests Relating to a Suspension

In the 2019 Petition, you request that FDA "[s]uspend the current approvals for all vaccine drugs, and/or prohibit all vaccines from birth to age eighteen, with 'Not for Childhood Vaccination' placed on all vaccine labels by suspending the existing vaccine approvals as to minors, and in the alternative, prohibit all vaccination. The Suspension is to continue unless and until the requirements of the NCVIA have been met for each and every vaccine and version of the vaccine." 2019 Petition at 18. This statement appears to contain requests for three separate substantive FDA actions. We address each of these in turn below.

1. Your Request That FDA Suspend Vaccine Approvals

In the 2017 Petition, you request that FDA "[i]mpose a five year moratorium on all childhood vaccines from birth to age eighteen…by suspending the existing vaccine approvals as to minors." 2017 Petition at 17. In the 2019 Petition, you request that FDA "[s]uspend the current approvals for all vaccine drugs, and/or prohibit all vaccines from birth to age eighteen…by suspending the existing vaccine approvals as to minors." 2019 Petition at 18.

Insofar as this request in the 2019 Petition repeats the one made in the 2017 Petition ("suspending the existing vaccine approvals as to minors"), we refer you to section III.A.3 of this letter for our response.

Insofar as your request in the 2019 Petition applies to a larger set of vaccines than does your request in the 2017 Petition ("all vaccine drugs" vs. "all childhood vaccines"), the reasoning in section III.A.3 of this letter applies to this broader request as well. In the 2019 Petition, you do not provide data or information that would constitute reasonable grounds to believe that any FDA-licensed, marketed vaccine "is not safe and effective for all of its intended uses" (or that any other grounds for license revocation exist under 21 CFR § 601.5(b)(1)). Therefore, we deny your request to suspend approvals for all vaccines.

Because we are denying your request to suspend vaccine approvals, the issue of how long such a suspension should last is moot.

2. Your Request That FDA Prohibit Vaccinations

In the 2017 Petition, you request that FDA "[i]mpose a five year moratorium on all childhood vaccines from birth to age eighteen" (2017 Petition at 17), which we interpret to be a request for a five-year moratorium on childhood vaccinations (i.e., the administration to children of vaccines approved for pediatric use); we address that request in section III.A.1 of this letter. In the 2019 Petition, you request that FDA "prohibit all vaccines from birth to age eighteen…and in the alternative, prohibit all vaccination." 2019 Petition at 18.

Your request in the 2019 Petition appears to apply to a larger set of vaccinations ("all vaccines from birth to age eighteen" and "all vaccination") than does your request in the 2017 Petition ("all childhood vaccines from birth to age eighteen"). We interpret this to be a request for either a prohibition on the administration of all vaccines to children or a prohibition on the administration of all vaccines to persons of all ages.

Although this request is broader than the request in the 2017 Petition, our description in section III.A.1 of this letter of FDA's role in vaccine recommendations and requirements applies to this broader request as well. FDA declines your request to prohibit the administration of vaccines because, as explained in section III. A.1 of this letter, it is outside the scope of FDA's authority to impose such a prohibition.

3. Your Request That FDA Require Changes to the Labeling of Licensed Vaccines

You request that the statement "'Not for Childhood Vaccination' [be] placed on all vaccine labels." 2019 Petition at 18. This repeats a request in the 2017 Petition (2017 Petition at 17); for our response, see section III.A.2 of this letter. For the reasons outlined in section III.A.2 of this letter, we deny your request for FDA to require changes to the labeling of licensed, marketed pediatric vaccines.

B. Your Request That FDA Notify Certain Parties

You request

> [i]mmediate notification of all public health agencies, physicians, pharmacies, hospitals, schools, universities and similar to the effect that vaccination programs, schedules and policies are immediate [sic] placed on hold until further notice since no vaccine has met the legal requirements for approval and are [sic] therefore unapproved drugs pending scientific determination.

2019 Petition at 18.

As described in sections III.A.1 and IV.A.2 of this letter, FDA does not provide vaccination recommendations and does not develop immunization schedules. As further described in section III.A.1 of this letter, FDA likewise does not impose any vaccination requirements. Because it is outside the scope of FDA's authority to "[place] on hold" "vaccination programs, schedules and policies," FDA declines your request to issue a related notification.

C. Your Request That FDA Suspend or Repeal the Vaccine Injury Compensation Program

In the 2017 Petition, you request that FDA "[s]uspend (pending repeal) the 1986 National Childhood Vaccine Injury Act and return vaccine injuries to the Constitutionally-mandated, traditional civil justice system" (2017 Petition at 17); we respond to that request in section III.B of this letter. In the 2019 Petition, you request that FDA "[s]uspend (pending repeal) the Vaccine Injury Compensation Program and return vaccine injuries to the Constitutionally-mandated, traditional civil justice system." 2019 Petition at 18.

As described in section III.B of this letter, Congress established the VICP[47] through the NCVIA.[48] As further described in section III.B, FDA does not have the authority to suspend or repeal statutes. Therefore, we deny this request because it is not within the scope of FDA's authority to suspend or repeal any part of the NCVIA, including that part establishing the VICP.

D. Your Request That FDA Set Up a Panel to Issue a Report

In the 2019 Petition, you request that FDA

> [s]et up and fund a Blue Ribbon Panel of experts not connected in any way to the pharmaceutical industry or government agencies, therefore free of any conflict of interest, to evaluate all aspects of vaccine approval, safety and science with a Report to be made public no later than two years [sic] the date of the Regulation to at least partially remediate the failure of the Agency or supervising Department to provide the Mandated Reports since 1989.

2019 Petition at 18.

1. Advisory Committees

Multiple expert panels already exist that examine vaccine safety. There are four relevant advisory committees, described below, that provide independent, expert advice to HHS and its components on matters relating to vaccines. Federal advisory committees are subject to transparency requirements,[49] and advisory committee members are subject to federal conflict of interest laws (18 U.S.C. § 208) and Government-wide standards of ethical conduct regulations (5 CFR Part 2635).

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[47] The National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743, 3758; codified at 42 U.S.C. § 300aa-10 *et seq*.

[48] The National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743, 3755; codified at 42 U.S.C. § 201 *et seq*.

[49] *See* the Federal Advisory Committee Act (at 5 U.S.C. App. 2); the Government in the Sunshine Act (at 5 U.S.C. § 552b).

- **The Vaccines and Related Biological Products Advisory Committee**

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) advises the Commissioner of Food and Drugs in helping to ensure safe and effective vaccines and related biological products for human use and, as required, any other product for which FDA has regulatory responsibility.[50] VRPAC's responsibilities include reviewing and evaluating data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases.[51]

VRBPAC includes members who are authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.[52] In addition, the core of VRBPAC voting members may include one technically-qualified consumer representative. The VRBPAC may also include one non-voting industry representative.[53]

VRBPAC meetings are held several times a year, and are open to the public except as determined otherwise by the Commissioner, in accordance with applicable federal laws.[54] Notice of all meetings is given to the public,[55] and meeting materials are available on the VRBPAC website.[56]

- **The Advisory Committee on Immunization Practices**

The Advisory Committee on Immunization Practices (ACIP), discussed in section III.A.1.a of this letter, advises the Director of the CDC regarding the use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the U.S.[57] For each vaccine, ACIP's responsibilities include providing advice on population groups and/or circumstances in which the vaccine is recommended, recommendations on contraindications and precautions for its use, information on recognized adverse events, and recommendations that

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[50] FDA, "Charter of the Vaccines and Related Biological Products Advisory Committee." Available at https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/charter-vaccines-and-related-biological-products-advisory-committee (accessed Mar. 24, 2020).

[51] FDA, "Vaccines and Related Biological Products Advisory Committee." Available at https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee (accessed Mar. 24, 2020).

[52] *Id*.

[53] FDA, "Charter of the Vaccines and Related Biological Products Advisory Committee." Available at https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/charter-vaccines-and-related-biological-products-advisory-committee (accessed Mar. 24, 2020).

[54] *Id*.

[55] *Id*.

[56] FDA, "Meeting Materials, Vaccines and Related Biological Products Advisory Committee." Available at https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/meeting-materials-vaccines-and-related-biological-products-advisory-committee (accessed Mar. 24, 2020).

[57] CDC, "Advisory Committee on Immunization Practices (ACIP): Charter." Available at https://www.cdc.gov/vaccines/acip/committee/charter.html (accessed Mar. 24, 2020).

address special situations or populations that may warrant modification of the routine recommendations.[58] ACIP may revise or withdraw its recommendations regarding a particular vaccine as new information on, among other things, disease epidemiology or vaccine effectiveness or safety, becomes available.[59]

ACIP includes members who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety.[60] ACIP includes one or more people who are knowledgeable about consumer perspectives and/or social and community aspects of immunization programs.[61] ACIP also includes members who represent other federal agencies with responsibility for immunization programs in the United States, and representatives of liaison organizations that bring related immunization expertise.[62]

ACIP meetings are held several times a year.[63] Meetings are open to the public, except as determined otherwise by the Director of CDC, in accordance with applicable federal laws,[64] and are available online via live webcast and telephone.[65] Notice of all meetings is given to the public,[66] and meeting materials are available on the ACIP website.[67]

- **The National Vaccine Advisory Committee**

The National Vaccine Advisory Committee (NVAC) advises the HHS Assistant Secretary for Health, who serves as the Director of the National Vaccine Program.[68] NVAC's responsibilities include studying and recommending ways to encourage the availability of an adequate supply of safe and effective vaccination products, recommending research priorities and other measures that the Director of the National Vaccine Program should take to enhance the safety and efficacy of vaccines, advising the Director in implementation of the National Vaccine Program, and identifying areas of government and non-government cooperation that should be considered.[69]

NVAC members include individuals who are engaged in vaccine research or the manufacture of vaccines, physicians, members of parent organizations concerned with immunizations, representatives of state or local health agencies, and representatives of public health

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[58] *Id*.
[59] *Id*.
[60] *Id*.
[61] *Id*.
[62] CDC, "Advisory Committee on Immunization Practices (ACIP): Committee Members." Available at https://www.cdc.gov/vaccines/acip/members/index.html (accessed Mar. 24, 2020).
[63] CDC, "Advisory Committee on Immunization Practices (ACIP): Charter." Available at https://www.cdc.gov/vaccines/acip/committee/charter.html (accessed Mar. 24, 2020).
[64] *Id*.
[65] CDC, "Advisory Committee on Immunization Practices (ACIP): Meeting Information." Available at https://www.cdc.gov/vaccines/acip/meetings/index.html (accessed Mar. 24, 2020).
[66] *Id*.
[67] *Id.*
[68] HHS, "Vaccines & Immunizations: National Vaccine Advisory Committee (NVAC)." Available at https://www.hhs.gov/vaccines/nvac/index.html (accessed Mar. 24, 2020).
[69] *Id*.

organizations.[70] NVAC also includes members who represent the perspectives of the vaccine manufacturing industry and groups engaged in vaccine research.[71]

NVAC meetings are held at least three times per year,[72] and are open to the public, except as determined otherwise by the Secretary of HHS, in accordance with law.[73] Notice of all meetings is given to the public,[74] and meeting materials are available online.[75] NVAC Reports and Recommendations are also available on the NVAC website.[76]

- **The Advisory Committee on Childhood Vaccines**

The Advisory Committee on Childhood Vaccines (ACCV) advises the Secretary of HHS on issues relating to the VICP,[77] including recommending changes to the Vaccine Injury Table; advising the Secretary in implementing the Secretary's responsibilities under section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including certain adverse reaction reporting requirements; advising the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; recommending to the Director of the National Vaccine Program research related to vaccine injuries that should be conducted; and consulting on the development and revision of vaccine information materials.[78]

The ACCV includes three members who are health professionals, at least two of whom are pediatricians, who are not employees of the U.S. government and who have expertise in the health care of children; the epidemiology, etiology, and prevention of childhood diseases; and the adverse reactions associated with vaccines.[79] The Committee also includes members of the general public, at least two of whom are legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death.[80] ACCV also includes attorneys, at least one of whom is an attorney whose specialty includes representation of people who have suffered

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[70] HHS, "Vaccines & Immunizations: NVAC: Members: Membership." Available at https://www.hhs.gov/vaccines/nvac/members/membership/index.html (accessed Mar. 24, 2020).
[71] *Id*.
[72] HHS, "Vaccines & Immunizations: NVAC Charter." Available at https://www.hhs.gov/vaccines/nvac/charter/index.html (accessed Mar. 16, 2020).
[73] *Id*.
[74] *Id*.
[75] HHS, "Vaccines & Immunizations: National Vaccine Advisory Committee (NVAC) Meetings." Available at https://www.hhs.gov/vaccines/nvac/meetings/index.html (accessed Mar. 16, 2020).
[76] HHS, "Vaccines & Immunizations: Reports & Recommendations." Available at https://www.hhs.gov/vaccines/nvac/reports-and-recommendations/index.html (accessed Mar. 16, 2020).
[77] HRSA, "Federal Advisory Committees: Advisory Committee on Childhood Vaccines." Available at https://www.hrsa.gov/advisory-committees/vaccines/index.html (accessed Mar. 31, 2020).
[78] HRSA, "Charter: Advisory Commission on Childhood Vaccines." Available at https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/accvcharter.pdf (accessed Mar. 24, 2020).
[79] HRSA, "National Vaccine Injury Compensation Program: Job and Advisory Committee Opportunities." Available at https://www.hrsa.gov/vaccine-compensation/job-opportunities.html (accessed Mar. 31, 2020).
[80] *Id*.

a vaccine-related injury or death, and one of whom is an attorney whose specialty includes representation of vaccine manufacturers.[81]

ACCV meetings are held at least four times a year, and are open to the public, except as determined otherwise by the Secretary, in accordance with applicable federal laws.[82] Notice of all meetings is given to the public,[83] and meeting materials are available on the ACCV website.[84] ACCV Reports and Recommendations are also available on the ACCV website.[85]

2. Reports

A number of independent reports on vaccine safety have been conducted by entities unaffiliated with government agencies or vaccine manufacturers.[86] The Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine (HMD)[87] is a private, nonprofit institution that provides independent, objective analysis and advice to help government and the private sector make informed health decisions.[88] HHS has commissioned HMD to prepare multiple publicly-available independent reports that examine all of the current medical and scientific evidence on vaccines and vaccine safety.[89, 90]

Additionally, HHS' Agency for Healthcare Research and Quality (AHRQ) also commissioned an independent, peer-reviewed evidence report on vaccine safety from the Southern California Evidence-based Practice Center, located at the RAND Corporation, a

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[81] *Id*.
[82] HRSA, "Charter: Advisory Commission on Childhood Vaccines." Available at https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/vaccines/accvcharter.pdf (accessed Mar 24, 2020).
[83] *Id*.
[84] HRSA, "Federal Advisory Committees: Advisory Commission on Childhood Vaccines: Meetings." Available at https://www.hrsa.gov/advisory-committees/vaccines/meetings.html (accessed Mar. 24, 2020).
[85] HRSA, "Federal Advisory Committees: Advisory Committee on Childhood Vaccines." Available at https://www.hrsa.gov/advisory-committees/vaccines/reports-recommendations.html (accessed Mar. 31, 2020).
[86] We address the reports required under the NCVIA, which you discuss in the 2019 Petition, in Section IV.I of this letter.
[87] Formerly the Institute of Medicine.
[88] NAS, "About the Health and Medicine Division." Available at http://www.nationalacademies.org/hmd/About-HMD.aspx (accessed Mar. 31, 2020).
[89] CDC, "Vaccine Safety: HDM Reports." Available at https://www.cdc.gov/vaccinesafety/research/iomreports/index.html (accessed Mar. 16, 2020).
[90] The National Academies makes available a searchable list of reports, including HMD reports relating to vaccines and vaccine safety; the reports themselves may also be downloaded. The National Academies, "National Academies Press." Available at https://www.nationalacademies.org/publications (accessed Mar. 31, 2020). *See*, for example, https://www.nap.edu/search/?topic=288&author=HMD&rpp=20&ft=1&term=immunization+safety and https://www.nap.edu/search/?author=HMD&rpp=20&ft=1&term=vaccine+safety&topic=288 (accessed Mar. 31, 2020).

nonprofit organization.[91] In addition, CDC provides access to detailed published information about vaccine safety.[92]

You do not present any data or information that would warrant the establishment and funding of a panel of experts "to evaluate all aspects of vaccine approval, safety and science" and publish a report on this subject. Therefore, and in light of the multiple expert advisory committees that consider vaccine safety on an ongoing basis, as well as the existing published independent reports on vaccine safety, FDA declines your request to set up a panel to conduct a study and publish a report on this topic.

E. Your Request That FDA Ban Direct-To-Consumer Vaccine Advertising

In the 2017 Petition, you request that FDA "[b]an direct pharmaceutical advertising to consumers and allow such advertising only to medical professionals" (2017 Petition at 17); we have addressed that request in section III.D of this letter. In the 2019 Petition, you request that FDA "[b]an direct vaccine drug advertising to consumers and allow such advertising only to medical professionals, under 21 CFR 202."

While the request in the 2017 Petition applies to a broad set of products ("pharmaceutical advertising"), the request in the 2019 Petition appears to apply to only a subset of these products ("vaccine drug advertising"). Because vaccines are biological products that also meet the definition of drugs under the FD&C Act, our response in section III.D of this letter applies to this narrower request as well. As explained in that section, no statute exists that would authorize FDA to implement a complete ban on DTCA of vaccines, and it is unlikely that an outright ban on DTCA of vaccines would pass constitutional muster. For the legal and public health reasons described in section III.D of this letter, FDA denies your request to ban direct-to-consumer vaccine advertising.

F. Your Request That FDA Promulgate the Provided Regulation on an Expedited Basis

In the 2017 Petition, you request that FDA "[e]xercise…regulatory discretion to immediately promulgate the requested Regulation as an emergency ruling to protect the public health, and especially the health of children" and "[h]old hearing(s), permit public comments, issue permanent regulations, consistent with our expressive association rights and humanitarian law, implementing the emergency discretion and emergency Regulation on a regular basis" (2017 Petition at 1); we address that request in section III.E of this letter. You make a similar request in the 2019 Petition: that FDA "[e]xercise…regulatory discretion to immediately promulgate the requested Regulation as an emergency ruling to protect the public health, and especially the health of children" and "[h]old hearing(s), permit public comments, issue permanent regulations, consistent with our expressive association rights, Federal, International Treaty and humanitarian law, implementing the emergency discretion and emergency Regulation." 2019 Petition at 2.

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[91] AHRQ, "Safety of Vaccines Used for Routine Immunization in the United States." Available at https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/vaccine-safety_research.pdf (accessed Mar. 31, 2020).

[92] CDC, "Vaccine Safety: Publications." Available at https://www.cdc.gov/vaccinesafety/research/publications/index.html (accessed Mar. 31, 2020).

We interpret these two requests in the 2019 Petition to constitute a procedural request for FDA to promulgate the referenced "Regulation" (2019 Petition at 18) as an interim final rule followed by notice-and-comment rulemaking.[93]

Above, we have addressed the five substantive requests contained in the 2019 Petition's *Exhibit A: Vaccination Suspension Regulation*. 2019 Petition at 18. Because we have denied these substantive requests contained in the 2019 Petition, we also deny this procedural request for a rulemaking.

G. Your Request That the President Mandate FDA Action

In the 2017 Petition, you request "[i]ntervention by the President of the United States mandating Agency action" (2017 Petition at 2); you repeat this request in the 2019 Petition (2019 Petition at 2). For our response to this request, see section III.F of this letter.

H. Your Claim About the Relative Health of Vaccinated and Unvaccinated Children

In the 2017 Petition, you make the claim that "[t]he science is settled. Vaccinated children are less healthy than unvaccinated children" (2017 Petition at 2); we address that claim in section III.G of this letter. In the 2019 Petition, you make the same claim, and further state:

> By recommending what should be considered illegal drugs and/or biologicals that harm the health of recipients the Agency is violating its stated and statutory mandates and bringing avoidable harm to the residents and citizens of the United States in enormous numbers, generating a costly and devastating health crisis that strict adherence to the law would have avoided.

2019 Petition at 2.

Like the statement in the 2017 Petition, these statements in the 2019 Petition do not present a request for FDA action. Insofar as your statement repeats that in your 2017 Petition ("The science is settled. Vaccinated children are less healthy than unvaccinated children"), we refer you to our response in section III.G of this letter. With regard to your statement about FDA's recommending products, we refer you to our discussion in section III.A.1.a of this letter, in which we explain that FDA does not provide vaccination recommendations.

[93] We note that a federal regulation would not be an appropriate legal vehicle for most of the actions you request in Exhibit A of your Petition.

I. Your Statements Relating to Reports Required under the National Childhood Vaccine Injury Act

In the 2019 Petition, you state that

> [t]he Agency and its supervising Federal Department have failed to implement the NCVIA in several important ways. The mandate from Congress that vaccines are to become safer has been flagrantly consistently and illegally ignored. The mandate from Congress that an Annual Vaccine Safety Report (hereinafter, Mandated Reports) shall be made to Congress has been flagrantly consistently and illegally ignored each and every year since the NCVIA required the Mandated Reports, starting in December, 1989.

2019 Petition at 2-3.

The NCVIA provides, in part, that the Secretary of HHS shall

> (a)…
> (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
> (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
> …
> (c) Report
> Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

42 U.S.C. § 300aa-27.

Your statement does not present a request for FDA action. However, insofar as you are requesting that FDA submit to Congress the reports required by 42 U.S.C. § 300aa-27(c), we point out that the authority to prepare and submit the reports required by 42 U.S.C. § 300aa-27(c) has not been delegated by the Secretary of HHS to FDA.[94] Therefore, to the extent you are requesting such action in your Petition, we deny this request because the action you request is not within the scope of FDA's authority.

V. Conclusion

For the factual, scientific, and legal reasons given above, FDA denies the requests in the Petitions. Licensed vaccines, including childhood vaccines, are subject to stringent standards, and are demonstrated by vaccine manufacturers and determined by FDA to be safe, pure, and potent before FDA authorizes the manufacturers to place them on the market. You have not

[94] Delegations of Authority and Organization; Reorganization and Republication; Final Rule, 66 Fed. Reg. 30991, 30996 (June 8, 2001).

presented data or information that might support a safety labeling change or the suspension of any indications, including pediatric indications, in the biologics license for any licensed, marketed vaccines, including childhood vaccines.

FDA declines your request to conduct studies on a possible association between childhood vaccinations and a variety of non-vaccine-preventable illnesses and conditions in light of the substantial body of scientific research that already exists. FDA has essentially found no evidence that supports your statement that vaccinated children are less healthy than unvaccinated ones. We also decline your request to establish a panel to evaluate vaccine safety in light of the multiple advisory committees with this mandate and the multiple independent reports on this topic that already exist.

We deny your procedural requests for rulemaking because we deny the substantive requests in the Petitions. Finally, we deny your remaining requests because the actions you request fall outside FDA's scope of authority.

For these reasons, we deny the Petitions in their entirety.

Sincerely,

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff

Appendix I: Aspects of the Vaccine Licensure Process

A. Vaccines are Biologics and Drugs

Vaccines are both biological products under the Public Health Service Act (PHS Act) (42 U.S.C. § 262) and drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321). The PHS Act defines a "biological product" as including a "vaccine…or analogous product…applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i)(1). The FD&C Act defines drug to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1)(B).

B. Clinical Investigations of Vaccines

Before a vaccine is licensed (approved) by FDA and can be used by the public, FDA requires that it undergo a rigorous and extensive development program that includes laboratory research, animal studies, and human clinical trials to determine the vaccine's safety and effectiveness.

The PHS Act and the FD&C Act provide FDA with the authority to promulgate regulations that provide a pathway for the study of unapproved new drugs and biologics. 42 U.S.C. § 262(a)(2)(A) and 21 U.S.C. § 355(i). The regulations on clinical investigations require the submission of an Investigational New Drug application (IND), which describes the protocol, and, among other things, assures the safety and rights of human subjects. These regulations are set out at 21 CFR Part 312. *See* 21 CFR § 312.2 (explaining that the IND regulations apply to clinical investigations of both drugs and biologics).

The regulations provide that, once an IND is in effect, the sponsor may conduct a clinical investigation of the product, with the investigation generally being divided into three phases. With respect to vaccines, *Phase 1* studies typically enroll fewer than 100 participants and are designed to look for very common side effects. *Phase 2* studies may include up to several hundred individuals and are designed to determine the common short-term side effects such as redness and swelling at the injection site and fever. If an investigational new drug or biologic progresses past *Phase 1* and *Phase 2* studies, it may progress to *Phase 3* studies. For *Phase 3* studies, the sample size is often determined by the number required to establish efficacy of the new vaccine, which may be in the thousands or tens of thousands of subjects. *Phase 3* studies are usually of sufficient size to detect less common adverse events.

If product development is successful and the clinical data are supportive of the proposed indication, the completion of all three phases of clinical development can be followed by submission of a Biologics License Application (BLA) pursuant to the PHS Act (42 U.S.C. § 262(a)), as specified in 21 CFR § 601.2.

C. Biologics License Applications

A BLA must include data demonstrating that the product is safe, pure, and potent and that the facility in which the product is manufactured "meets standards designed to assure that the biological product continues to be safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i). FDA does not consider an application to be filed until FDA determines that all pertinent information and data have been received. 21 CFR § 601.2. FDA's filing of an application indicates that the application is complete and ready for review but is not an approval of the application.

Under § 601.2(a), FDA may approve a manufacturer's application for a biologics license only after the manufacturer submits an application accompanied by, among other things, "data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency." The BLA must provide the multidisciplinary FDA reviewer team (medical officers, microbiologists, chemists, biostatisticians, etc.) with the Chemistry, Manufacturing, and Controls (CMC)[95] and clinical information necessary to make a benefit/risk assessment, and to determine whether "the establishment(s) and the product meet the applicable requirements established in [FDA's regulations]."[96]

FDA generally conducts a pre-license inspection of the proposed manufacturing facility, during which production of the vaccine is examined in detail. 42 U.S.C. § 262(c). In addition, FDA carefully reviews information on the manufacturing process of new vaccines, including the results of testing performed on individual vaccine lots.

FDA scientists and physicians evaluate all the information contained in a BLA, from safety and effectiveness data through manufacturing information, to determine whether the application meets the statutory and regulatory requirements. By holding an advisory committee meeting, FDA may also seek input from sources outside of FDA to determine whether a vaccine application should be approved.

As part of FDA's evaluation of a vaccine as a whole, FDA takes all of a vaccine's ingredients into account (including preservatives, adjuvants, and other ingredients used during manufacture).[97] FDA licenses a vaccine only after the Agency has determined that the vaccine is safe and effective for its intended use, in that its benefits outweigh its potential risks.

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[95] Also referred to as Pharmaceutical Quality/CMC.

[96] 21 CFR § 601.4(a).

[97] For further information about vaccine ingredients, see FDA, "Common Ingredients in U.S. Licensed Vaccines." Available at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/common-ingredients-us-licensed-vaccines (accessed Aug. 31, 2021).

Appendix II: Aspects of Vaccine Postmarketing Safety Monitoring

Post-marketing surveillance of vaccine safety is crucial to detect any rare, serious, or unexpected adverse events, as well as to monitor vaccine lots. Manufacturers often conduct post-marketing observational studies. However, FDA also uses multiple tools and databases to evaluate the safety of vaccines after they have been licensed and used in the general population.

The Vaccine Adverse Event Reporting System (VAERS) is a national passive surveillance vaccine safety database that receives unconfirmed reports of possible adverse events following the use of a vaccine licensed in the United States. VAERS is co-administered by the FDA and the Centers for Disease Control and Prevention (CDC). Anyone can make a report to VAERS, including vaccine manufacturers, private practitioners, state and local public health clinics, vaccine recipients, and their parents or caregivers. Surveillance programs like VAERS perform a critical function by generating signals of potential problems that may warrant further investigation.

It is often difficult to determine with certainty if a vaccine caused an adverse event reported to VAERS. Many events that occur after vaccination can happen by chance alone. Some adverse events are so rare that their association with a vaccine is difficult to evaluate. In addition, we often receive reports where there is no clear clinical diagnosis. FDA draws upon multiple sources of data and medical and scientific expertise to assess the potential strength of association between a vaccine and a possible adverse event.

Monitoring and analysis of VAERS reports typically includes daily in-depth medical review of all serious reports, statistical data mining techniques, and epidemiological analysis. We look for patterns and similarities in the onset timing and clinical description. We review published literature to understand possible biologic hypotheses that could plausibly link the reported adverse event to the vaccine. We review the pre-licensure data and any other post-marketing studies that have been conducted. We also consider "background rate," meaning the rate at which a type of adverse event occurs in the unvaccinated general population. When necessary, we discuss the potential adverse event with our federal and international safety surveillance partners. We also carefully evaluate unusual or unexpected reports, as well as reports of "positive re-challenges" (adverse events that occur in the same patient after each dose received). When there is sufficient evidence for a potential safety concern we may proceed to conduct large studies, and we may coordinate with our federal, academic and private partners to further assess the potential risk after vaccination. In addition, when potential safety issues arise, they are often presented to various U.S. government advisory committees, including the Vaccines and Related Biological Products Advisory Committee, the Advisory Committee on Immunization Practices, the Vaccines Advisory Committee, and the Advisory Committee on Childhood Vaccines, and are often discussed with experts from other countries and from the World Health Organization. Federal agencies that assist in population-based vaccines safety studies include the Centers for Medicaid and Medicare (CMS), the Department of Defense (DoD), and the Indian Health Services (IHS). In addition, we generally communicate and work with international regulatory authorities and international partners to conduct studies in vaccine safety.

The Vaccine Safety Datalink (VSD) project has actively monitored vaccine safety in more than 9.1 million people nationwide, over 3% of the US population. The VSD can monitor vaccine

safety with near real-time surveillance systems, which is particularly important for new vaccines. If there is a vaccine safety signal in the VSD, chart reviews and case series analyses are done when assessing the possible association between a vaccine and an adverse event. If needed, VSD is able to use its large health care database to further evaluate specific vaccine safety concerns.

The Clinical Immunization Safety Assessment (CISA) is a national network of six medical research centers with expertise conducting clinical research related to vaccine safety. The goals of CISA are: to study the pathophysiologic basis of adverse events following immunization using hypothesis-driven protocols; to study risk factors associated with developing an adverse event following immunization using hypothesis-driven protocols, including genetic host-risk factors; to provide clinicians with evidence-based guidelines when evaluating adverse events following immunization; to provide clinicians with evidence-based vaccination or revaccination guidelines; and to serve as a regional referral center to address complex vaccine safety inquiries. Advances in genetics and immunology continue to help us further assess the safety of vaccines, and FDA has established a genomics evaluation team for vaccine safety.

Finally, the Sentinel Initiative is a national electronic system that will continue to improve FDA's ability to track the safety of medical products, including vaccines. Launched in May 2008 by FDA, the Sentinel System will enable FDA to actively query diverse automated healthcare data holders—like electronic health record systems, administrative and insurance claims databases, and registries—to evaluate possible safety issues quickly and securely. The Sentinel Initiative will cover 100 million people in the US. It is also anticipated that Sentinel will facilitate the development of active surveillance methodologies related to signal detection, strengthening, and validation.