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## Vaccine Hesitancy: Experimentalism as Regulatory Opportunity

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Vaccine Hesitancy: Experimentalism as Regulatory Opportunity

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VACCINE HESITANCY:  
EXPERIMENTALISM AS REGULATORY OPPORTUNITY

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*This symposium on patient innovation has prompted us to explore problems related to departures from official vaccination schedules. At a time in which vaccine confidence has been plummeting across the world, we argue that a more granular understanding—and ultimately a more finely tuned regulatory framework—is needed to reflect the current behavioral heterogeneity among indicated patients who choose to forego or delay administration of recommended vaccines. In particular, we focus on a phenomenon we term “vaccine staggering:” a departure from vaccination schedules in the form of delays in receiving one or more vaccines, which is motivated by the desire to boost the efficacy of each vaccine received by a child or adult.<sup>1</sup>*

*Current regulatory approaches subsume staggering into vaccine hesitancy frameworks. The scientific literature, however, has begun to explore possible benefits of specific forms of staggering, as well as the need for the production of more information on different forms of vaccine staggering. The Essay thus argues in favor of separate treatment for vaccine staggering as opposed to vaccine refusal and further notes that the current conceptual and regulatory problems*

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<sup>1</sup> See *infra*, Part III.B.

*surrounding vaccine staggering point to broader systemic issues in vaccination policy and vaccine data infrastructure in the United States.*

*The Essay proceeds as follows. It begins with a brief background section on the evolution of vaccination schedules. Part II describes different types of behaviors that may result in departures from vaccination schedules, highlighting the disjunction between behavioral heterogeneity and the unified regulatory framework, which currently lumps together materially different behaviors under the “vaccine hesitancy” umbrella. Part III then focuses specifically on the case of vaccine staggering and advocates for a separate treatment of staggering behaviors as opposed to other types of departures from official vaccination schedules. The Essay further argues that the persistence of unitary treatments of vaccine-related behaviors increases uncertainty and promotes conflicting discourses outside scientific circles, an especially concerning phenomenon at a time in which outbreaks of vaccine-preventable disease are once again becoming more frequent. The Essay concludes by briefly pointing out that the specific problems surrounding current approaches to vaccine staggering also illustrate systemic limitations of the vaccine data infrastructure in the United States.*

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## I. VACCINATION SCHEDULES

The World Health Organization provides recommendations to program managers on vaccination schedules,<sup>2</sup> which are then adopted at the national level by the relevant regulatory bodies. In the United States, vaccination schedules are set by the Centers for Disease Control and Prevention<sup>3</sup> upon recommendations from the Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts focusing on vaccines and related

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<sup>2</sup> WORLD HEALTH ORG., WHO RECOMMENDATIONS FOR ROUTINE IMMUNIZATION - SUMMARY TABLES (2019), [https://www.who.int/immunization/policy/immunization\\_tables/en/](https://www.who.int/immunization/policy/immunization_tables/en/)

<sup>3</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, CHILDHOOD IMMUNIZATION SCHEDULE (2013), <https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-child-immun-bw-office.pdf>

biopharmaceutical products,<sup>4</sup> which works in consultation with entities like the American Academy of Pediatrics and the American Academy of Family Physicians.<sup>5</sup>

ACIP's recommendations include both the types of vaccines recommended for different populations and the timeline according to which they should be administered—the schedule. Currently, schedules are divided into three categories across the lifespan: children up to six years old,<sup>6</sup> seven to 18 years old<sup>7</sup> and ages 19 and older.<sup>8</sup>

Since 1994, a federal program—Vaccines for Children—was established to enable the CDC to purchase ACIP-recommended vaccines at discount prices and make them available to grantees at the state or local level.<sup>9</sup> The program covers Medicaid-eligible children, uninsured and underinsured children, as well as American Indian and Alaska Native children.<sup>10</sup> Some ACIP-recommended vaccines for adult populations are covered through state Medicaid programs, although there is great variation across the United States as to which vaccines are covered by

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<sup>4</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, *Advisory Committee on Immunization Practices Policies and Procedures* (2018), <https://www.cdc.gov/vaccines/acip/committee/downloads/Policies-Procedures-508.pdf>

<sup>5</sup> See e.g. Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, in *Law in PUBLIC HEALTH PRACTICE*, RICHARD A. GOODMAN ET AL. (EDS.) (2006), at 268.

<sup>6</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, 2020 RECOMMENDED VACCINATIONS FOR INFANTS AND CHILDREN, <https://www.cdc.gov/vaccines/schedules/easy-to-read/child-easyread-compliant.html>

<sup>7</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, 2020 RECOMMENDED VACCINATIONS FOR CHILDREN 7-18 YEARS OLD, <https://www.cdc.gov/vaccines/schedules/easy-to-read/adolescent-easyread-compliant.html>

<sup>8</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, RECOMMENDED ADULT IMMUNIZATION SCHEDULE FOR AGES 19 YEARS OR OLDER, UNITED STATES, 2020, <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-compliant.html>

<sup>9</sup> See e.g. U.S. MEDICAID, QUALITY OF CARE VACCINES, <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/quality-of-care-vaccines/index.html>

<sup>10</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, THE VFC PROGRAM: AT A GLANCE (2016), <https://www.cdc.gov/vaccines/programs/vfc/about/index.html>

specific programs.<sup>11</sup> In addition to vaccination schedules, the CDC provides additional vaccination recommendations for specific populations,<sup>12</sup> including travelers,<sup>13</sup> racial and ethnic populations,<sup>14</sup> or vaccines recommended for immigrants and refugees coming to the United States.<sup>15</sup>

While the federal government operates in an advisory capacity—through ACIP’s recommendations promoted by the CDC—it cannot impose vaccination requirements. The ability to mandate vaccination has long been understood as an emanation of the police power of the states,<sup>16</sup> which in turn have consistently relied on ACIP’s recommendations.<sup>17</sup>

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<sup>11</sup> See generally Sara Rosenbaum et al., *The Epidemiology of U.S. Immunization Law: Medicaid Coverage of Immunizations for Non-institutionalized Adults*, NAT’L IMMUNIZATIONS PROGRAM REPORT (2003), [https://publichealth.gwu.edu/departments/healthpolicy/DHP\\_Publications/pub\\_uploads/dhpPublication\\_5F6FC614-5056-9D20-3D48DB884F5C18C8.pdf](https://publichealth.gwu.edu/departments/healthpolicy/DHP_Publications/pub_uploads/dhpPublication_5F6FC614-5056-9D20-3D48DB884F5C18C8.pdf)

<sup>12</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, VACCINES AND IMMUNIZATIONS FOR SPECIFIC GROUPS OF PEOPLE (2016), <https://www.cdc.gov/vaccines/spec-grps.html#conditions>

<sup>13</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, NEED TRAVEL VACCINES? PLAN AHEAD (2018), <https://wwwnc.cdc.gov/travel/page/travel-vaccines>

<sup>14</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, VACCINES AND IMMUNIZATIONS FOR SPECIFIC GROUPS OF PEOPLE, *supra* note 12.

<sup>15</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, VACCINES FOR IMMIGRANTS AND REFUGEES (2019), <https://www.cdc.gov/vaccines/adults/rec-vac/immigrants-refugees.html>

<sup>16</sup> *Jacobson v Massachusetts*, 197 US 11 (1905) (recognizing the power of the states to compel vaccination). It should be noted that, even prior to the Supreme Court’s decision in 1905, most states were already imposing mandatory vaccination to some extent. See e.g. *Viemester v. White*, 72 N.E. 97 (N.Y. 1904) (finding that a law excluding unvaccinated children from admittance to, and attendance of, public schools did not violate articles. 9, § 1 and 1 §§ 1 and 6 of the Constitution).

<sup>17</sup> Malone & Hinman at 268. We address the issue of exemptions to state vaccine mandates *infra*; see notes 22-XX and accompanying text.

Mandatory vaccination has also long been tied to school attendance. The first law to impose mandatory school vaccination was passed as early as 1850 in Massachusetts,<sup>18</sup> with another ten states following suit by the early twentieth century<sup>19</sup>. In 1922, the Supreme Court upheld the constitutionality of city ordinances excluding unvaccinated children from attending public schools.<sup>20</sup> Recurring measles outbreaks in the mid-twentieth century eventually led all 50 states to mandate school vaccination, starting in 1980-81.<sup>21</sup>

The progressive expansion of vaccination mandates throughout the twentieth century, however, has not translated into homogenous approaches to vaccination policy at state level. Mandates vary considerably across the country, with an overwhelming majority of states allowing some form of non-medical exemption to vaccination mandates.<sup>22</sup>

Non-medical exemptions are sets of justifications defined by state regulators as grounds for the refusal of mandatory vaccination, which are not linked to any temporary or permanent health conditions. The CDC publishes a list of health conditions that may render certain vaccines unsuitable for specific individuals.<sup>23</sup> For example, in the case of the MMR vaccine (measles,

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<sup>18</sup> See Jessica Bylander, *The United States' Piecemeal Approach to Vaccine Policy*, 35 HEALTH AFF. 195 (2016), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1599>

<sup>19</sup> Daniel E. Salmon et al., *Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present, And Future*, 367 LANCET 439 (2006).

<sup>20</sup> *Zucht v. King*, 260 U.S. 174 (1922) (examining mandatory vaccination in connection with attendance of public schools as well as “other place[s] of education”). See also *Viemester v. White*, *supra* note 16.

<sup>21</sup> Salmon et al., *supra* note 19, at 439.

<sup>22</sup> See generally Eileen Wang et al., *Nonmedical Exemptions from School Immunization Requirements: A Systematic Review*, 104 AM. J. PUB. HEALTH (2014).

<sup>23</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, WHO SHOULD NOT GET VACCINATED WITH THESE VACCINES? (2020), <https://www.cdc.gov/vaccines/vpd/should-not-vacc.html>

mumps, rubella)—a vaccine that is part of the vaccine schedule for children, typically administered in three doses between one and 6 years of age<sup>24</sup>—the CDC recommends that healthcare providers evaluate administration of the vaccine to patients suffering from certain blood, respiratory and immune system disorders, on a case by case basis, an evaluation that may result in the decision not to give the MMR vaccine to a patient.<sup>25</sup> Temporary conditions such as pregnancy can also result in departures from the standard adult vaccination schedule that are endorsed by the CDC.<sup>26</sup> These health-related justifications for not receiving a vaccine, or for delaying vaccination, constitute carve-outs to the overall regime. Both standard vaccination schedules and exemptions to the schedule based on medical reasons are endorsed by federal public health-oriented agencies (like the CDC) and professional organizations such as the American Academy of Pediatrics, the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists.<sup>27</sup> All states and the District of Columbia recognize medical exemptions.<sup>28</sup>

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<sup>24</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, MEASLES, MUMPS, AND RUBELLA (MMR) VACCINATION: WHAT EVERYONE SHOULD KNOW (2019), <https://www.cdc.gov/vaccines/vpd/mmr/public/index.html>

<sup>25</sup> *Id.*, WHO SHOULD NOT GET VACCINATED WITH THESE VACCINES?, *supra* note 23.

<sup>26</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, GUIDELINES FOR VACCINATING PREGNANT WOMEN (2016), <https://www.cdc.gov/vaccines/pregnancy/hcp-toolkit/guidelines.html> (listing, among others, the human papillomavirus as “not recommended” and the MMR vaccine as “contraindicated” during pregnancy, whereas inactivated influenza vaccines are “recommended” during pregnancy).

<sup>27</sup> See AM. ACAD. PEDIATRICS, IMMUNIZATION SCHEDULES (2020), <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Pages/Immunization-Schedule.aspx>

<sup>28</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, WHAT IS AN EXEMPTION AND WHAT DOES IT MEAN? (2017), <https://www.cdc.gov/vaccines/imz-managers/coverage/schoolvaxview/requirements/exemption.html>. See also Tiffany L. Wang et al., *Mandatory Influenza Vaccination for All Healthcare Personnel: A Review on Justification, Implementation and Effectiveness*, 29 CURR. OPIN. PEDIATR. 606 (2017), [https://pubmed.ncbi.nlm.nih.gov/28700416/?from\\_term=mandatory+influenza+vaccination&from\\_pos=1](https://pubmed.ncbi.nlm.nih.gov/28700416/?from_term=mandatory+influenza+vaccination&from_pos=1); Guglielmo Dini et al., *Influenza Vaccination in Healthcare Workers: A Comprehensive Critical Appraisal of the*

Until the mid-twentieth century, justifications based on health conditions were the only admissible grounds for vaccination exemptions. From 1960s onwards, however, states began allowing a different type of carve-out by recognizing non-medical exemptions based on either religious or philosophical beliefs, or both.<sup>29</sup> Religious exemptions initially emerged somewhat narrowly, linked to organized religions that object to vaccination—very few do, and none of the major organized religions—<sup>30</sup>but expanded conceptually and through case law to encompass situations in which an individual claims “sincerely held beliefs.”<sup>31</sup> In addition to religious exemptions, some states allow for exemptions based on personal beliefs, also known as

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*Literature*, 14 HUM. VACC. IMMUNOTHER. 772 (2018),  
[https://pubmed.ncbi.nlm.nih.gov/28787234/?from\\_term=mandatory+influenza+vaccination&from\\_pos=2](https://pubmed.ncbi.nlm.nih.gov/28787234/?from_term=mandatory+influenza+vaccination&from_pos=2); Samantha Pitts et al., *A Systematic Review of Mandatory Influenza Vaccination in Healthcare Personnel*, 47 AM. J. PREV. MED. 330 (2014),  
[https://pubmed.ncbi.nlm.nih.gov/25145618/?from\\_term=mandatory+influenza+vaccination&from\\_pos=8](https://pubmed.ncbi.nlm.nih.gov/25145618/?from_term=mandatory+influenza+vaccination&from_pos=8)

<sup>29</sup> See generally PAUL A. OFFITT, *DEADLY CHOICES: HOW THE ANTI-VACCINE MOVEMENT THREATENS US ALL* (2010)

<sup>30</sup> See e.g. Miriam Krule, *Why Is There a Religious Exemption for Vaccinations?*, Slate (Feb. 5, 2015), <https://slate.com/technology/2015/02/religious-exemption-for-vaccines-christian-scientists-catholics-and-dutch-reform-church.html>; Ginia Bellafante, *Why Are There Religious Exemptions for Vaccines?*, N.Y. TIMES (Apr. 12, 2019), <https://www.nytimes.com/2019/04/12/nyregion/measles-vaccines-religious-exemptions.html>. Christian Science is one of the very few religions that advocates for “praying for healing” as opposed to reliance on vaccination, but it characterizes its own approach to vaccination by stating that “our practice isn’t a dogmatic thing [in the area of vaccination].” See CHRISTIAN SCIENCE, *A CHRISTIAN SCIENCE PERSPECTIVE ON VACCINATION AND PUBLIC HEALTH*, <https://www.christianscience.com/press-room/a-christian-science-perspective-on-vaccination-and-public-health>

<sup>31</sup> *Dalli v. Board of Ed.*, 358 Mass. 753, 754 (1971).

philosophical exemptions.<sup>32</sup> By late 2019,<sup>33</sup> 45 states and the District of Columbia recognized some form of non-medical exemption.<sup>34</sup>

As we further detail in the following section, the relationship between non-medical exemptions and the proliferation of infectious diseases is well established: the CDC points out that “[s]tudies have shown that vaccine exemptions tend to cluster geographically, making some communities at greater risk for outbreaks.”<sup>35</sup>

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<sup>32</sup> NAT’L CONFERENCE ST. LEGIS., STATES WITH RELIGIOUS AND PHILOSOPHICAL EXEMPTIONS FROM SCHOOL IMMUNIZATION REQUIREMENTS, <https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>

<sup>33</sup> To be updated closer to publication date.

<sup>34</sup> STATES WITH RELIGIOUS AND PHILOSOPHICAL EXEMPTIONS FROM SCHOOL IMMUNIZATION REQUIREMENTS, *supra* note 32.

<sup>35</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, STATE VACCINATION REQUIREMENTS (2016), <https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html>. See also Saad B. Omer et al., *Geographic Clustering of Nonmedical Exemptions to School Immunization Requirements and Associations with Geographic Clustering of Pertussis*, 168 AM. J. EPIDEMIOLOGY 1389 (2008), <https://pubmed.ncbi.nlm.nih.gov/18922998/>; Y. Tony Yang et al., *Sociodemographic Predictors of Vaccination Exemptions on the Basis of Personal Belief in California*, 106 AM. J. PUB. HEALTH 172 (2016), <https://pubmed.ncbi.nlm.nih.gov/26562114/>

## II. DEPARTURES FROM VACCINATION SCHEDULES

### A. PUBLIC HEALTH PROBLEMS ASSOCIATED WITH DEPARTURE FROM VACCINATION SCHEDULES

Robust adherence to vaccination practices—including following vaccination schedules—has long been considered a key practice in contemporary public health.<sup>36</sup> Yet, in recent years, levels of vaccine confidence have been declining,<sup>37</sup> prompting the World Health Organization to add vaccine hesitancy in 2019 to the list of ten greatest threats to global public health.<sup>38</sup>

As explained in the following section, the concept of vaccine hesitancy encompasses a broad array of materially distinguishable behaviors, which may result in either delays or the non-administration of recommended vaccines to indicated populations.<sup>39</sup> Both delays in vaccine administration and—especially—vaccine refusal can trigger significant individual and public health consequences. A study looking at nationwide surveillance data collected between 1985 and 1992 showed that the risk of contracting measles faced by children exempted from vaccination to was 35 times higher than the risk faced by non-exempted children.<sup>40</sup>

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<sup>36</sup> See Sandra W. Roush et al., *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 J. AM. MED. ASS'N 2155 (2007), <https://www.ncbi.nlm.nih.gov/pubmed/18000199>

<sup>37</sup> See Heidi J. Larson, *The State of Vaccine Confidence*, 392 LANCET 2244, (2018), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)32608-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32608-4/fulltext)

<sup>38</sup> WORLD HEALTH ORG., TEN THREATS TO GLOBAL HEALTH IN 2019 (2019), <https://www.who.int/news-room/feature-stories/ten-threats-to-global-health-in-2019>

<sup>39</sup> *Infra*, Part II.B.

<sup>40</sup> See D. A. Salmon et al., *Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risk of Measles*, 282 J. AM. MED. ASS'N. 47 (1999).

B. REGULATORY PROBLEMS ASSOCIATED POSED BY DEPARTURES FROM VACCINATION  
SCHEDULES

*1. A Conceptual Blur*

Setting aside the case of non-vaccination attributable to medical conditions, other forms of departure from vaccination schedules are highly heterogenous, often resting on motivations that are yet not fully understood.<sup>41</sup> As seen above, from a legal perspective, these departures fall (somewhat too neatly) into two categories: religious or philosophical.<sup>42</sup> In practice, the motives leading to refusal of, or delays in, vaccination, as well as the forms through which departure from vaccination schedules occur, are manifold and not properly captured in our regulatory and policy approaches to vaccination.

One of the recurring expressions used to describe departures from vaccination schedules that are not linked to medical conditions is “vaccine hesitancy.”<sup>43</sup> While in widespread currency in different milieus, from the scientific community<sup>44</sup> to the popular press,<sup>45</sup> the expression is employed with some degree of variation, leading to a lack of uniformity in shared understandings

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<sup>41</sup> See Omer et al., *infra* note 82.

<sup>42</sup> *Supra*, Part I.

<sup>43</sup> See generally N. MacDonald et al., *Vaccine Hesitancy: Definition, Scope and Determinants*, 33 VACCINE 4161 (2015). See also C. McClure, *Vaccine Hesitancy: Where We Are and Where We Are Going*, 39 CLIN. THER. 1550 (2017); E. Dubé et al., *Vaccine Hesitancy: An Overview*, 9 HUM. VACCINE IMMUNOTHER. 1763 (2013); R. Jacobson, *Vaccine Hesitancy*, 90 MAYO CLIN. PROC. 1562 (2015); Tara C. Smith, *supra* note XX.

<sup>44</sup> *Id. ib.*

<sup>45</sup> See e.g. Amelia Harnish, *Fighting Vaccine Hesitancy, One Parent at a Time*, N.Y. TIMES (Apr. 19, 2020), <https://www.nytimes.com/2020/04/19/parenting/measles-vaccine-hesitancy.html>

of which behaviors follow under the umbrella of hesitancy. In the following sections, we map out the most common usages of the concept of hesitancy, and proceed to argue that current applications of the concept lack granularity.

## 2. *Vaccine Refusal*

Vaccine refusal refers to the intentional rejection of a recommended vaccine, absent any health conditions that render vaccination contraindicated.<sup>46</sup> In the context of childhood vaccination, refusal consists in parental rejection of vaccinations included on the infant and childhood schedules applicable to a particular child, absent any health conditions that render vaccination contraindicated.<sup>47</sup>

Vaccine rejectors intentionally forego (or have their children forego) the opportunity to receive a vaccine for which they are indicated.<sup>48</sup> Several outbreaks of infectious diseases across the United States in the early twenty-first century have been linked to growing levels of vaccine refusal. For example, in a 2014 measles outbreak traced back to Disneyland in California, almost half of the 111 people for which measles infection was reported were had deliberately refused

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<sup>46</sup> See e.g. Andrzej Grzybowski et al., *Vaccination Refusal. Autonomy and Permitted Coercion*, 11 PATHOG. GLOBAL HEALTH 200 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5498765/>

<sup>47</sup> See *supra* Part I. See also generally Tara C. Smith, *Vaccine Rejection and Hesitancy: A Review and Call to Action*, OPEN FORUM INFECT. DIS. (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5597904/>; Varun K. Phadke et al., *Association Between Vaccine Refusal and Vaccine-Preventable Diseases in the United States: A Review of Measles and Pertussis*, 315 J. AM. MED. ASS'N. 1149 (2016); Omer et al., *supra* note **Error! Bookmark not defined.**

<sup>48</sup> Phadke et al., *supra* note 47.

vaccination.<sup>49</sup> Similarly, in 2019, large measles outbreaks in New York and New Jersey were linked to significant levels of vaccine refusal among indicated members of a community.<sup>50</sup>

As noted above, growing pockets of unvaccinated populations are increasing the risk of outbreaks of several infectious disease pathogens, and pose intractable challenges to public health policy. So far, 47 states still allow for some form of non-medical exemption—as of mid-2020, the states that only admit medical exemptions are Mississippi, West Virginia<sup>51</sup> and, more recently, California.<sup>52</sup> Following the 2019 measles outbreaks, New York has eliminated religious exemptions.<sup>53</sup>

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<sup>49</sup> *Id., ib.* See also U.S. CTRS. DISEASE CONTROL & PREVENTION, *Measles Outbreak — California, December 2014–February 2015*, 64 Morbidity and Mortality Weekly Report (MMWR) 153 (Feb. 20, 2015), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a5.htm>; Karen Kaplan, *Vaccine Refusal Helped Fuel Disneyland Measles Outbreak, Study Says*, L.A. TIMES (Mar. 16, 2015), <https://www.latimes.com/science/sciencenow/la-sci-sn-disneyland-measles-under-vaccination-20150316-story.html>

<sup>50</sup> Robert McDonald et al., *Notes from the Field: Measles Outbreaks from Imported Cases in Orthodox Jewish Communities — New York and New Jersey, 2018–2019*, U.S. CTRS. DISEASE CONTROL & PREVENTION (May 17, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a4.htm>; Michelle Andrews, *Why Measles Hits So Hard Within N.Y. Orthodox Jewish Community*, KAISER HEALTH NEWS (Mar. 11, 2019), <https://khn.org/news/why-measles-hits-so-hard-within-n-y-orthodox-jewish-community/>; Sharron Otterman & Sean Piccoli, *Measles Outbreak: Opposition to Vaccine Extends Well Beyond Ultra-Orthodox Jews in N.Y.*, N.Y. TIMES (May 9, 2019), <https://www.nytimes.com/2019/05/09/nyregion/measles-outbreak-ny-schools.html>

<sup>51</sup> See generally J. Colgrove & A. Lowin, *A Tale of Two States: Mississippi, West Virginia, And Exemptions To Compulsory School Vaccination Laws*, 25 HEALTH AFF. 348 (2016), <https://www.ncbi.nlm.nih.gov/pubmed/26858391>

<sup>52</sup> See also Paul L. Delamater et al., *Change in Medical Exemptions From Immunization in California After Elimination of Personal Belief Exemptions*, 318 J. AM. MED. ASS'N 863 (2017), <https://jamanetwork.com/journals/jama/fullarticle/2652640>; Michelle M. Mello et al., *Shifting Vaccination Politics — The End of Personal-Belief Exemptions in California*, 373 N. ENGL. J. Med. 785 (2015), <https://www.nejm.org/doi/full/10.1056/NEJMp1508701>

<sup>53</sup> See e.g. David Keppler, *New York Ends Religious Exemption to Vaccine Mandates*, ASSOCIATED PRESS (Jun. 14, 2019), <https://apnews.com/cdab615894c24163a7947d67c6874f2f>

### 3. Vaccine Hesitancy

In their study of parental concerns leading to departure from vaccination schedules, Hagood and Herlihy propose breaking down the concept of vaccine hesitancy into three categories: “vaccine rejectors,” “vaccine resistant” and “vaccine hesitant” parents.<sup>54</sup> Vaccine rejectors are defined as parents who are “unyieldingly entrenched in their refusal to consider vaccine information.”<sup>55</sup> Vaccine resistant parents are those who reject vaccination at a given point in time but are nonetheless “willing to consider information regarding the safety and efficacy of vaccines.”<sup>56</sup> And vaccine hesitant parents are those expressing “generalized anxiety about vaccines” but who are not “are not as committed to misinformation about vaccinations” as parents in the other two categories.<sup>57</sup>

As noted above, we believe that it is important to distinguish between outright rejection of vaccination in general (or a specific vaccine) and hesitancy regarding the safety and efficacy of vaccines (or of a specific vaccine). While we cannot emphasize enough that neither vaccine refusal nor vaccine hesitancy are desirable behaviors from a societal and public health perspectives, we argue that the search for solutions to curb the rising detrimental public health effects of both refusal and hesitancy must recognize de facto patterns at the root of departures from vaccination schedules. In Part III, when discussing the phenomenon of vaccine staggering, we illustrate how

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<sup>54</sup> E. Allison Hagood & Stacy Mintzer Herlihy, *Addressing Heterogeneous Parental Concerns About Vaccination with a Multiple-Source Model: A Parent and Educator Perspective*, 9 HUMAN VACCINES & IMMUNOTHERAPEUTICS 1790 (2013).

<sup>55</sup> *Id.*, at 1791.

<sup>56</sup> *Id.*, at 1792.

<sup>57</sup> *Id. ib.*

current public policies fail to take into account these material distinctions,<sup>58</sup> and connect that failure to systemic lacunas in the vaccine ecosystem, which stretch into the field of vaccine R&D and vaccine data collection.<sup>59</sup>

We also note that Hagood and Herlihy’s proposed categorizations—which we argue require further refinement—were developed as a response to the lack of granularity in current explanatory models for vaccine hesitancy. As the Authors put it when discussing vaccine education:

Previous models of vaccine education have not addressed differences in levels and motives of vaccine concerns in parents. These differences may require changes in education approaches based on type of parental concern. Addressing vaccine concerns will require a multi-modal approach involving more than just a pediatrician or primary health care provider, as well as more than one educational approach.<sup>60</sup>

Hagood and Herlihy’s characterization of vaccine hesitancy is not the only possible treatment of the concept. In 2016, Paterson and co-authors in the United States and the United Kingdom examined vaccine hesitancy, defining it as comprising “individuals and groups who delay or refuse vaccines.”<sup>61</sup> Siddiqui and others, writing about hesitancy in the United States in 2013, distinguished between “vaccine refusal” and “vaccine hesitancy” as they emphasize that

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<sup>58</sup> *Infra*, Part III.A.

<sup>59</sup> *Infra*, Part III.B.

<sup>60</sup> Hagood & Herlihy, *Addressing Heterogeneous Parental Concerns About Vaccination with a Multiple-Source Model*, *supra* note 54, at 1790.

<sup>61</sup> P. Paterson et al., *Vaccine Hesitancy and Healthcare Providers*, 34 *VACCINE* 6700 (2016), <https://www.ncbi.nlm.nih.gov/pubmed/27810314>

both types of behavior are closely linked to “fear of vaccines.”<sup>62</sup> At the international level, the World Health Organization combines the concepts of delaying vaccination and refusing vaccination under the umbrella of “vaccine hesitancy:” “delay in acceptance or refusal of vaccines despite availability of vaccination services.”<sup>63</sup>

#### *4. Problems with Current Definitional Heterogeneity*

Conceptual heterogeneity within vaccine hesitancy is problematic for two reasons. First, given the magnitude of the problems posed by under-vaccination of indicated populations in the twenty-first century, definitional clarity is necessary to guide present and future policies. As such, the current definitional variability stands in the ways of coherent and holistic approaches to in a world where outbreaks of vaccine-preventable diseases take place more frequently than in previous decades.<sup>64</sup>

Second, definitions that lump together the concepts of vaccine refusal and delays in vaccine administration are particularly problematic in that, in their lack of granularity, they risk being potentially misleading, especially in the context of childhood vaccinations. Sound policy, as well

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<sup>62</sup> Mariam Siddiqui et al., *Epidemiology of vaccine hesitancy in the United States*, 9 HUMAN VACCINE IMMUNOTHER. 2643 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4162046/>

<sup>63</sup> WORLD HEALTH ORG., IMPROVING VACCINATION DEMAND AND ADDRESSING HESITANCY (2019), [https://www.who.int/immunization/programmes\\_systems/vaccine\\_hesitancy/en/](https://www.who.int/immunization/programmes_systems/vaccine_hesitancy/en/). See also *id.*, REPORT OF THE SAGE WORKING GROUP ON VACCINE HESITANCY (2014), [https://www.who.int/immunization/sage/meetings/2014/october/1\\_Report\\_WORKING\\_GROUP\\_vaccine\\_hesitancy\\_final.pdf](https://www.who.int/immunization/sage/meetings/2014/october/1_Report_WORKING_GROUP_vaccine_hesitancy_final.pdf)

<sup>64</sup> See e.g. U.S. CTRS. DISEASE CONTROL & PREVENTION, CDC MEDIA STATEMENT: MEASLES CASES IN THE U.S. ARE HIGHEST SINCE MEASLES WAS ELIMINATED IN 2000 (Apr. 25, 2019), CDC Media Statement: Measles cases in the U.S. are highest since measles was eliminated in 2000

as any prescriptive approaches to address under-vaccination problems, should be based on operational definitions that accurately reflect the gamut of behavioral heterogeneity in refusal of vaccines and departures from vaccination schedules. Moreover, as Shen and Dubey have reminded us, “[v]accine-hesitant parents who are on the fence far outnumber vaccine refusers.”<sup>65</sup> With discourse surrounding vaccination topics being such a polarized area,<sup>66</sup> by conflating a delay with outright refusal of a vaccine, regulators and policymakers—as well as practitioners relying on international, federal and state guidelines—risk alienating large swaths of under-vaccinated populations who have concerns about the administration of vaccines (or a certain vaccine) but do not identify as outright refusers.

We propose that, at a minimum, regulators and policymakers should recognize the difference between vaccine refusal and delays in the administration of vaccines. If nothing else, the concept of “vaccine hesitancy” should be reserved for behaviors that do not constitute an intentional and outright refusal of vaccines, or of a particular vaccine. Furthermore, as we will show in Part III, the concept of hesitancy needs further refinement, particularly when used for vaccine policy and regulatory purposes.

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<sup>65</sup> Shixin (Cindy) Shen & Vinita Dubey, *Addressing Vaccine Hesitancy: Clinical Guidance for Primary Care Physicians Working with Parents*, 65 CAN. FAM. PHYSICIAN 175 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6515949/>

<sup>66</sup> See e.g. Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J. L. REFORM 353 (2004); A. Schmidt et al., *Polarization of the Vaccination Debate on Facebook*, 36 VACCINE 3606 (2018), <https://www.ncbi.nlm.nih.gov/pubmed/29773322>; Brendan Nyhan, *Spreading Along with Measles: Polarization on a Hot-Button Issue*, N.Y. TIMES (Feb. 2, 2015), <https://www.nytimes.com/2015/02/03/upshot/spreading-along-with-measles-polarization-on-a-hot-button-issue.html>

### III. REGULATORY OPPORTUNITY

#### A. ADDRESSING VACCINE HESITANCY

As seen in Part II.A, departures from vaccination schedules, both in the form of vaccine refusal and delays in the administration of vaccines, pose growing public health problems. In 2019, then-FDA Commissioner Scott Gottlieb suggested that, given the broad array of non-medical exemptions granted at state level, the federal government might have to play a greater role in the regulation of vaccination schedules.<sup>67</sup> This idea, which has been echoed by commentators in the public health field,<sup>68</sup> has also been met with criticism, both as a matter of legal feasibility,<sup>69</sup> and as public policy.<sup>70</sup>

In this section, we take on a sub-set of the problems associated with vaccine hesitancy (defined as not to include vaccine refusal). Specifically, we examine a particular form of delay in the administration of recommended vaccines as a way to illustrate the need for greater granularity in approaches to hesitancy—the staggering of vaccination due to immunogenicity concerns. This

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<sup>67</sup> Elizabeth Cohen & John Bonifield, *FDA Chief: Federal Government Might Step in If States Don't Change Lax Vaccine Laws*, CNN (Feb. 20, 2019), <https://www.cnn.com/2019/02/20/health/vaccine-exemptions-fda-gottlieb/index.html> (quoting Commissioner Gottlieb as stating that “[s]ome states are engaging in such wide exemptions that they're creating the opportunity for outbreaks on a scale that is going to have national implications” and that if “certain states continue down the path that they're on, I think they're going to force the hand of the federal health agencies”).

<sup>68</sup> See e.g. Scott C. Ratzan et al., *States Are Failing on Vaccinations. The Federal Government Must Lead*, WASH. POST (Mar. 7, 2019), [https://www.washingtonpost.com/opinions/states-are-failing-on-vaccinations-the-federal-government-must-lead/2019/03/07/1e90ece8-40f5-11e9-922c-64d6b7840b82\\_story.html](https://www.washingtonpost.com/opinions/states-are-failing-on-vaccinations-the-federal-government-must-lead/2019/03/07/1e90ece8-40f5-11e9-922c-64d6b7840b82_story.html)

<sup>69</sup> Per the current legal architecture, the states have the power to tailor vaccine mandates, not the federal government. See *supra* notes XX and accompanying text.

<sup>70</sup> See Wendy Parmet, *Gottlieb's Threat of Federal Vaccine Mandates: Questionable Legality, Poor Policy*, (Feb. 28, 2019), <https://www.statnews.com/2019/02/28/gottlieb-federal-action-vaccine-mandates/>

phenomenon, we argue, is materially different from other types of delay: for instance, delays attributable to a parent indecision as to whether to have a child vaccinated due to concerns with vaccine safety; delays attributable to political, legal or other worldviews; or delays attributable to parental neglect.

To be sure, this Essay does not call into question the current scientific consensus; rather, it points to widely acknowledged gaps in current scientific knowledge—a phenomenon inherent to the scientific process<sup>71</sup>—and explains that these gaps are not recognized in current regulatory approaches.

In Part II.B., we describe the concept of vaccine staggering by contrasting it with the concepts of simultaneous administration of vaccines and combination vaccines. We argue that vaccine staggering should be treated separately from other forms of vaccine hesitancy—and, preferably, without the hesitancy label attached to it—both from a regulatory and a policy perspective. Finally, in Part III.C we argue that the conceptual and information shortcomings we identify in connection with vaccine staggering point to larger problems in United States vaccine ecosystem.

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<sup>71</sup> See generally THOMAS KUHN, *THE STRUCTURE OF SCIENTIFIC REVOLUTIONS* (1962) (UNIVERSITY OF CHICAGO PRESS); KARL POPPER, *THE LOGIC OF SCIENTIFIC DISCOVERY*, (1968) (HUTCHINSON, LONDON); ISAAC NEWTON, *PHILOSOPHIAE NATURALIS PRINCIPIA MATHEMATICA*, BOOK II (1687) (ROYAL SOCIETY, LONDON); ARISTOTLE, *POSTERIOR ANALYTICS* (1960) (HUGH TREDENNICK ET AL. EDS.)

## B. VACCINE STAGGERING

### 1. *The Emergence of Combination Vaccines and Simultaneous Administration of Vaccines*

The CDC defines combination vaccines as “tak[ing] two or more vaccines that could be given individually and put them into one shot.”<sup>72</sup> Simultaneous administration of vaccines refers to giving or receiving more than one vaccine dose at the same time, which can occur either through the administration of a combination vaccine or the administration of multiple non-combination vaccines at the same time.<sup>73</sup>

As of mid-2020, scientific and regulatory guidelines endorse the simultaneous administration of some vaccines,<sup>74</sup> as well as the administration of combination vaccines.<sup>75</sup> The Institute for Vaccine Safety at the Johns Hopkins Bloomberg School of Public Health summarizes the current guidelines as follows: “Combination vaccines and simultaneous administration of vaccines currently routinely recommended to the general population in the U.S. have not been shown to cause any other adverse events at a greater rate than their individual vaccine components.”<sup>76</sup>

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<sup>72</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, COMBINATION VACCINES (2019), <https://www.cdc.gov/vaccines/parents/why-vaccinate/combo-vaccines.html>

<sup>73</sup> U.S. CTRS. DISEASE CONTROL & PREVENTION, MULTIPLE VACCINES AND THE IMMUNE SYSTEM (2018), [HTTPS://WWW.CDC.GOV/VACCINESAFETY/CONCERNS/MULTIPLE-VACCINES-IMMUNITY.HTML](https://www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html)

<sup>74</sup> See *supra* note 71 and accompanying text.

<sup>75</sup> INST. VACCINE SAFETY, DO COMBINATION VACCINES OR SIMULTANEOUS VACCINATION INCREASE THE RISK OF ADVERSE EVENTS? (2018), [http://www.vaccinesafety.edu/vs-combo.htm#\\*\\_](http://www.vaccinesafety.edu/vs-combo.htm#*_)

<sup>76</sup> *Id., ib.* An example of a combination vaccine is the MMRV (measles, mumps, rubella and varicella vaccine). See U.S. CTRS. DISEASE CONTROL & PREVENTION, MMRV (MEASLES, MUMPS, RUBELLA & VARICELLA) VIS (2019), <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.html>. The guidelines further caution that

Concerns with simultaneous administration of vaccines (as well administration of combination vaccines) arose from the mid-1980s onwards, as the roster of recommended childhood immunizations grew.<sup>77</sup> Many of these concerns were linked adverse events associated with the administration of vaccines that may induce fever,<sup>78</sup> and in particular to the (rare) possibility of febrile seizures associated with the administration of MMRV vaccines.<sup>79</sup> Scientific studies, however, have shown that concerns with adverse events resulting from the simultaneous administration of vaccines to be “unfounded.”<sup>80</sup> “The immune systems of infants and children encounter millions of antigens in their environment every day; vaccines only contain a tiny fraction of a typical child's daily exposure to antigens.”<sup>81</sup>

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[t]These conclusions do not necessarily consider vaccines recommended only for special populations in the United States such as Yellow Fever vaccine (international travelers) or Smallpox vaccine (military personnel).” *Id., ib.*

<sup>77</sup> See *supra* note **Error! Bookmark not defined.** and accompanying text.

<sup>78</sup> See DO COMBINATION VACCINES OR SIMULTANEOUS VACCINATION INCREASE THE RISK OF ADVERSE EVENTS? (2018), *supra* note 75. Katrin S. Kohl et al., *Fever after Immunization: Current Concepts and Improved Future Scientific Understanding*, 39 *CLINICAL INFECTIOUS DISEASES*, 389 (2004). See also generally U.S. CTRS. DISEASE CONTROL & PREVENTION, POSSIBLE SIDE EFFECTS FROM VACCINES (2020), <https://www.cdc.gov/vaccines/vac-gen/side-effects.htm>

<sup>79</sup> See U.S. CTRS. DISEASE CONTROL & PREVENTION, MMRV (MEASLES, MUMPS, RUBELLA & VARICELLA) VIS, *supra* note 76.

<sup>80</sup> See INST. VACCINE SAFETY, DO COMBINATION VACCINES OR SIMULTANEOUS VACCINATION INCREASE THE RISK OF ADVERSE EVENTS?, *supra* note 75.

<sup>81</sup> See INST. VACCINE SAFETY, DO COMBINATION VACCINES OR SIMULTANEOUS VACCINATION INCREASE THE RISK OF ADVERSE EVENTS?, *supra* note 75.

## 2. *The Case of Vaccine Staggering*

As indicated above, in this Essay we introduce the expression “vaccine staggering” to refer to departures from vaccination schedules (delays in receiving one or more vaccines) motivated by the desire to boost the efficacy of each vaccine received by a child or adult. Omer and others have described this phenomenon in the following way:

Instead of refusing vaccines, some parents delay vaccination of their children. Many parents follow novel vaccine schedules proposed by individual physicians (rather than those developed by expert committees with members representing multiple disciplines). Most novel schedules involve administering vaccines over a longer period than that recommended by the Advisory Committee on Immunization Practices and the American Academy of Pediatrics or skipping the administration of some vaccines.”<sup>82</sup>

The “novel vaccine schedules” described by Omer and others are also known as “alternative” vaccination schedules, both in the United States and abroad. Before explaining why we think the proliferation of these alternative timelines for vaccination warrant greater study and institutional attention, we would like to reiterate that the practice of vaccine staggering, currently subsumed into hesitancy frameworks, is at odds with existing guidance from scientific and regulatory bodies alike. As such, the arguments we make here are not in favor of vaccine staggering as a practice, but rather in favor of 1) building a better and more granular vaccine data infrastructure that will help scientific and regulatory bodies deal with this particular form of vaccine hesitancy in more comprehensive ways; and 2) recognizing that, given the current polarization of debates on vaccine-related themes, it is poor policy to address the behavior of adults who wish receive recommended vaccines according but stagger their administration (or wish their

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<sup>82</sup> Omer et al., *Vaccine Refusal, Mandatory Immunization, and the Risks of Vaccine-Preventable Diseases*, 360 N. ENGL. J. MED. 1981 (2009), <https://www.nejm.org/doi/full/10.1056/NEJMsa0806477>

children to receive all recommended childhood vaccines according to a staggered timeline) in the same way that vaccine rejection and vaccine delays motivated by other reasons are addressed.

Moreover, we submit here that the term “alternative schedules” should not be used in connection with the practice of vaccine staggering. Vaccination schedules are regulatory and public health tools. Departures from the schedule—even if based on concerns with the efficacy of vaccines—do not amount to either. In fact, our argument is that these departures illustrate scientific and regulatory holes in our vaccination infrastructure,<sup>83</sup> and as such the emphasis should be on addressing the underlying problems leading to departures from schedules, rather than elevating ongoing vaccination practices—with relevance, but in circumvention of medical consensus and regulatory mandates—to schedule-like status.

We propose that the practices that currently are often described as adherence to an “alternative schedule” be regarded as vaccine staggering. This expression speaks to the deliberate intention of having vaccines administered over a longer period of time when compared to the ones established by vaccination schedules issued by scientific and regulatory bodies. Vaccine staggering is distinguishable from other types of delays in the administration of a recommended vaccine. For instance, a delay may be prompted by temporary, health-related circumstances, such as the indicated patient for a specific vaccine having a moderate or severe illness<sup>84</sup> or being pregnant.<sup>85</sup> This situation is materially different from the decision of a parent or physician to

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<sup>83</sup> *Infra*, Part III.C.

<sup>84</sup> See U.S. CTRS. DISEASE CONTROL & PREVENTION, CONTRAINDICATIONS AND PRECAUTIONS (2020), <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html> (“Vaccination should be deferred for persons with a moderate or severe acute illness.”)

<sup>85</sup> *Id.*, *ib.* (“[W]omen known to be pregnant generally should not receive live, attenuated virus vaccines”).

stagger vaccination across a period of time because of concerns with reduced immunogenicity<sup>86</sup>—the practice we label staggering. Moreover, as noted above, staggering vaccination is fundamentally different from delaying vaccination, due to reliance on vaccine misinformation such as the belief that vaccines are generally unsafe,<sup>87</sup> or that vaccination campaigns are political, governmental or ideological tools.

Vaccine staggering gained popularity in the second decade of the 21<sup>st</sup> century. One of the most influential proponents of “alternative schedules” is Dr. Robert Sears—commonly known as Dr. Bob—whose book, *The Vaccine Book: Making the Right Decision for Your Child*, was published by one of the largest literary publishers, Hachette.<sup>88</sup> The book quickly became extremely popular. At the time of writing, the book had over 3,600 ratings and over 490 reviews on Goodreads, with an average score of 4.17 out of 5.<sup>89</sup>

Among several arguments, Dr. Sear’s book advocated for the practice of vaccine staggering and offered specific “alternative vaccine schedules” to be used in lieu of the schedules developed and endorsed by advisory scientific bodies and regulators. It is worth underscoring the fact that these specific recommendations—as well as the bulk of Dr. Sears’ arguments—are directed at

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<sup>86</sup> Immunogenicity has been defined as “the ability of a molecule or substance to provoke an immune response” and “the strength or magnitude of an immune response.” JANEWAY’S IMMUNOBIOLOGY (2012) (KENNETH MURPHY, ED.), cited in Siddhartha Mahanty et al., *Immunogenicity of Infectious Pathogens and Vaccine Antigens*, 16 BMC IMMUNOL. 31 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4446803/#CR1>

<sup>87</sup> See e.g. S. Geoghegan et al., *Vaccine Safety: Myths and Misinformation*, 11 FRONT. MICROBIOL. 372 (2020), <https://www.ncbi.nlm.nih.gov/pubmed/32256465>

<sup>88</sup> HACHETTE, MEET OUR AUTHORS, <https://www.hachettebookgroup.com/landing-page/contributor/>

<sup>89</sup> GOODREADS, THE VACCINE BOOK: MAKING THE RIGHT DECISION FOR YOUR CHILD, [https://www.goodreads.com/book/show/779230.The\\_Vaccine\\_Book](https://www.goodreads.com/book/show/779230.The_Vaccine_Book)

parents, not to audiences in the scientific and peer-review worlds. And the book has been successful in reaching its intended audience, with many parents now asking pediatricians to “that their children receive vaccines according to Sears' schedule, rather than that recommended by the American Academy of Pediatrics, the Centers for Disease Control and Prevention, and the American Academy of Family Physicians.”<sup>90</sup> As leading commentators like Offit and Moser have noted, there are many problematic features in Dr. Sears’ book,<sup>91</sup> one of which being the suggestion that parents may make better decisions for their children if they become familiar with non-scientific literature challenging recommendations concerning vaccination issued by scientific bodies and public health-oriented agencies.<sup>92</sup>

While Dr. Sears remains the most influential proponent of a specific temporal departure from official vaccination schedules—even after being put on a 35-month probation by the Medical Board of California for writing a vaccine exemption without obtaining the child’s vaccine

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<sup>90</sup> Paul A. Offit & Charlotte A. Moser, *The Problem With Dr Bob's Alternative Vaccine Schedule*, 123 PEDIATRICS e164 (2009), <https://pediatrics.aappublications.org/content/123/1/e164>

<sup>91</sup> Offit and Moser’s criticism of the arguments in the book include Dr. Sear’s argument that “doctors do not know much about vaccines and that if parents educate themselves they will know more than their doctors,” “cast[ing] doubt on the reliability and motives of the CDC and pharmaceutical companies,” minimizing the importance of vaccine-preventable diseases, implying links between vaccination and the proliferation of chronic diseases, and casting doubts over the sufficiency of vaccine safety testing . *Id. ib.*

<sup>92</sup> *Id., ib.*

records<sup>93</sup>—multiple are easily located online and offline. By 2013, a study reported that more than one in ten parents communicated to their pediatrician the intention “to follow an alternative immunization schedule for their child.”<sup>94</sup>

Currently, the best available scientific evidence indicates that no form of non-medical departure from official vaccine schedules should occur, as both lack of vaccination and delayed vaccination increase the risk of the occurrence of an infectious disease.<sup>95</sup> In line with our previous arguments about the overall need for greater granularity in addressing problems in this field, we note here that that there is a need for more data on the different rationales behind current parental preferences for vaccine staggering,<sup>96</sup> as well as more scientific data on the effects of staggering.

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<sup>93</sup> See Soumya Karlamangla, *California Doctor Critical of Vaccines is Punished For Exempting 2-Year-Old Boy from All Childhood Immunizations*, L.A. TIMES (Jun. 29, 2018), <https://www.latimes.com/local/california/la-me-ln-sears-license-20180629-story.html>

<sup>94</sup> See Marissa Wheeler & Alison M. Bittenheim, *Parental Vaccine Concerns, Information Source, and Choice of Alternative Immunization Schedules*, 9 HUM. VACCINE IMMUNOTHER. 1782 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3906282/>. See also A. Saada et al., *Parents' Choices and Rationales for Alternative Vaccination Schedules: A Qualitative Study*, 54 CLIN. PEDIATR. 236 (2015), <https://www.ncbi.nlm.nih.gov/pubmed/25200366>

<sup>95</sup> See Daniel A. Salmon et al, *Vaccine Hesitancy: Causes, Consequences, and a Call to Action*, 33 VACCINE D66 (2015), [https://pubmed.ncbi.nlm.nih.gov/26615171/?from\\_term=%22vaccine+refusal%22+and+incidence&from\\_pos=3](https://pubmed.ncbi.nlm.nih.gov/26615171/?from_term=%22vaccine+refusal%22+and+incidence&from_pos=3)

<sup>96</sup> E. Allison Hagood & Stacy Mintzer Herlihy, *Addressing Heterogeneous Parental Concerns About Vaccination with a Multiple-Source Model: A Parent and Educator Perspective*, 9 HUMAN VACCINES & IMMUNOTHERAPEUTICS 1790 (2013).

With regard to the latter point, commentators have often noted that “[t]he consequences of delayed vaccination, as compared with vaccine refusal, have not been studied in detail.”<sup>97</sup>

There is scientific literature focusing on the impacts of concomitant versus staggered vaccine provision on immune responses in humans. These data are generally limited by small sample sizes and extraneous biases such as confounding due to differential vaccine makeup. Critically, this literature on live and inactivated vaccine provision is highly discordant, suggesting that the scientific community still has an extremely limited understanding of the impacts of the immune response after vaccine provision. Several studies suggest an immune negative interference with some concomitant vaccines,<sup>98</sup> while others indicate no difference in immune response with concomitant vaccine provision.<sup>99</sup> Therefore, arguments for or against staggering cannot be validated or disputed at this time.

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<sup>97</sup> See Omer et al., *supra* note 82.

<sup>98</sup> See e.g. J. Labadie et al., *DPT-IPV Hib Vaccine Study Group, Multi-center Study on the Simultaneous Administration of DPT-IPV and HIB PRP-T vaccines. Part 1. Immunogenicity*, NAT’L INST. PUBLIC HEALTH & ENVIRONMENT (1996); Daniel E. Park et al., *The Differential Impact of Coadministered Vaccines, Geographic Region, Vaccine Product and Other Covariates on Pneumococcal Conjugate Vaccine Immunogenicity*, 33 *PED. INFECT. DIS. J.* S130 (2014), <https://pubmed.ncbi.nlm.nih.gov/24336055/>; D. M. Emperador et al., *Interference of Monovalent, Bivalent, and Trivalent Oral Poliovirus Vaccines on Monovalent Rotavirus Vaccine Immunogenicity in Rural Bangladesh*, 62 *CLIN. INFECT. DIS.* 150 (2016), <https://doi.org/10.1093/cid/civ807>;

<sup>99</sup> Particularly for non-live vaccines. See e.g. J. H. Leung et al., *Immunogenicity and Reactogenicity of Tetravalent Vaccine for Measles, Mumps, Rubella And Varicella (MMRV) In Healthy Children: A Meta-Analysis Of Randomized Controlled Trials*, 14 *EXPERT REV. VACCINES* 1149 (2015), <https://doi.org/10.1586/14760584.2015.1057572>; T. Nolan et al., *Safety and Immunogenicity of Concurrent Administration of Live*

In other words, we have reliable data on vaccination practices as they related to official schedules, as well as data indicating that departures from the schedule increase the risk of infectious disease—by contrast, there is very limited data on staggered vaccination, almost exclusively centered on pediatric populations (thus disregarding adult ones).

To be clear, our point is two-fold: first, no other schedules should at this point be considered other than the ones issued by the CDC and state regulatory authorities, and adults (including parents deciding on behalf of their children) should comply with vaccination schedules if there are no medical reasons to skip or delay the administration of a vaccine. And second: at the same time, we advocate for the production of more data around the phenomenon of staggering, even if those data lead to complete disproof of any claims of staggering. Given the prominence of so-called “alternative vaccination schedules” and consequent parental deviation from official schedules, we submit that regulators and advisory bodies should prioritize the acquisition of deeper knowledge on the reasons behind staggering, as well as scientific data on departures from official vaccination schedules—and we submit that a strategic approach to vaccine staggering on the part of regulators and policymakers is long overdue. Ignoring the specificities of vaccine staggering from a regulatory perspective—the current status quo—fuels uncertainty and conflicting discourses outside the scientific arena at a time in which outbreaks of vaccine-preventable disease are on the rise.<sup>100</sup>

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*Attenuated Influenza Vaccine with Measles-Mumps-Rubella and Varicella Vaccines to Infants 12 to 15 Months of Age*, 121 PEDIATRICS 508 (2008), <https://doi.org/10.1542/peds.2007-1064>.

<sup>100</sup> *Supra*, XX.

While accruing more data on the scientific aspects of staggering should constitute an immediate priority, we also point out that recommendations and other treatments of vaccination themes by regulators and advisory bodies should start acknowledging the material differences between staggering and vaccine refusal, as well as between staggering and other forms of delays in vaccination. Parental concerns with immunogenicity associated with the administration of a vaccine have health-related dimension, rooted in the belief that staggering will maximize the immune response triggered by a vaccine. Yet, this type of departure from vaccination schedules is not contemplated, with staggering being lumped together with actual instances of hesitancy, and occasionally with vaccine refusal. This is something that both our regulatory system and the vaccine-related vocabulary fail to acknowledge.

To sum up, the now entrenched phenomenon of parents actively seeking temporal departures from official vaccination schedules is one the reasons we need concerted policy and regulatory interventions in the area of vaccine staggering. A second reason is the current lack of conceptual clarity at the regulatory and policy levels, which either lumps or conflates this very specific behavior with behaviors that have nothing to do with the desire to increase the immunological response triggered by the administration of a vaccine. A third reason is the current lack of information surrounding the manifold motivations behind vaccine staggering, which is needed to enable more persuasive policy and regulatory interventions targeting individuals and communities who engage in vaccine staggering in a data-starved environment. And, relatedly, a fourth reason is the current lack of these data—granular scientific information on the effects of vaccine staggering—which is critical for the calibration of current approaches.

## C. VACCINE STAGGERING AS AN EMBODIMENT OF LARGER DATA INFRASTRUCTURE

### PROBLEMS

The phenomenon of vaccine staggering illustrates problems that occur at a more systemic level in the vaccine ecosystem in the United States. We briefly discuss these connections here, incorporating some of the arguments we have made in the specific context of staggering into larger considerations about shortcomings of the vaccine data infrastructure in the United States.

First, the conceptual problem identified with regard to vaccine staggering affects other areas in vaccine policy and regulation. As seen above, the concept(s) of vaccine hesitancy commonly used are overly heterogenous and imprecise. From a regulatory perspective, our system does not distinguish—as it should—between delays in the provision of vaccines and vaccine refusal. At a time of growing lack of confidence in vaccination as a crucial public health tool, this irresponsiveness of the regulatory system is particularly troubling.

Second, the current (and continued) lack of scientific and socio-behavioral information surrounding vaccine staggering feeds into a larger patchwork problem in our vaccine data infrastructure. Most ongoing research on issues related to vaccine hesitancy is predominantly focused on parental behavior. By narrowing the production of data primarily to these situations, we are neglecting the adult population in general, which constitutes the majority of the United States population. Adults have many recommended and/or required vaccines and with the dearth of scientific study of hesitancy in this population, interventions cannot be effectively developed and implemented.

Third, and relatedly, vaccine data in the United States is not collected in any national repository and are solely maintained in the providing healthcare systems electronic health record. Therefore, it is impossible to track, evaluate, or improve vaccination rates in the overall population.

To impact this area, a robust—possibly mandatory—preferably national immunization data system is necessary.

While these larger problems exceed the scope of this Essay, taking the necessary steps to address sectoral problems within the vaccine ecosystem in the United States is overdue. We have made the case that action on vaccine staggering at both the scientific and regulatory levels is important to reduce confusing and conflicting discourses, as well as to more accurately reflect the current heterogeneity in vaccine-related behaviors.