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## *Articles*

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### Herd Immunity and Compulsory Childhood Vaccination: Does the Theory Justify the Law?

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#### ABSTRACT

Compulsory childhood vaccination is a cornerstone of U.S. public health policy. All fifty states compel children to vaccinate against many infectious diseases to achieve so-called herd immunity, a scientific theory that attempts to explain how societies protect themselves against infectious disease.

This Article explores both the theory and practice of herd immunity. The authors evaluate the scientific assumptions underlying the theory, how the theory applies in law, a game theory approach to herd immunity, and a possible framework for rational policymaking. The Article argues that *herd immunity* is unattainable for most diseases and is therefore an irrational goal. Instead, the authors conclude that *herd effect* is attainable and that a voluntary vaccination marketplace, not command-and-control compulsion, would most efficiently achieve that goal.

The Article takes on the bugaboo of the citizen “free rider” who is out to game the system, how a vaccination marketplace might work, and what factors policymakers must take into account in developing sound policies. The Article concludes that it is time for states to adopt more realistic and cost-efficient laws to achieve attainable herd effect, not illusory herd immunity.

#### INTRODUCTION

Many state and federal laws compel childhood vaccination based on the theory of herd immunity.<sup>1</sup> The theory describes a form of indirect protection in which non-immune individuals are protected from those that have acquired a disease and recovered.<sup>2</sup> Promoters of

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<sup>1</sup> See James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 833 (2002) (“Each state has school vaccination laws which require children of appropriate age to be vaccinated for several communicable diseases.” (citation omitted)); see also *State Information, IMMUNIZATION ACTION COALITION*, <http://www.immunize.org/laws> (last visited Mar. 6, 2014) (showing vaccination mandates by state, and while the Immunization Action Coalition is solely responsible for this website, its information is based on government sources, and the website is funded in part by the Centers for Disease Control and Prevention).

<sup>2</sup> See, e.g., Paul Fine et al., “*Herd Immunity*”: *A Rough Guide*, 52 CLINICAL INFECTIOUS DISEASES 911 (2011) [hereinafter Fine, *Rough Guide*]; Paul E.M. Fine, *Herd Immunity: History, Theory, Practice*, 15 EPIDEMIOLOGIC REVS. 265 (1993) [hereinafter Fine, *History*]; John P. Fox et al., *Herd Immunity: Basic Concept and Relevance to Public Health Immunization Practices*, 94 J. EPIDEMIOLOGY 179 (1971).

universal vaccination adopted this theory, suggesting that it applies to vaccine-induced immunity as well.<sup>3</sup> Today, herd immunity is the central rationale for compulsory vaccination, and the U.S. Supreme Court has long upheld the right of states to mandate vaccines under certain circumstances.<sup>4</sup> Vaccine proponents in the United States argue that the theory justifies vaccination of all children against vaccine-targeted diseases, except those few children with lawful exemptions.<sup>5</sup> Today, at or above ninety percent of all U.S. children have been vaccinated against routine childhood diseases, including measles, mumps, and pertussis.<sup>6</sup>

But the theory of herd immunity alone does not justify compulsion. The leap in logic from herd immunity theory to compulsory vaccination programs requires three fundamental assumptions: (1) that herd immunity is a valid and obtainable objective of vaccination policy; (2) that without compulsion, unvaccinated individuals, or their guardians, will seek to “free ride” on the immunity of the community; and (3) that individuals have an implied duty to society to be vaccinated to achieve herd immunity.<sup>7</sup> This Article looks at the underpinnings of the herd immunity theory and at the ties binding the theory to compulsory laws. Is herd immunity obtainable with modern vaccines? Are the assumptions of the theory relevant in the real world? Is there a free rider problem? Do members of society, and children in particular, have an obligation to accept vaccines “for the good of the herd”?

This Article concludes that herd immunity has only limited application in the world of policy. Given contemporary, imperfect vaccine technology and geographical and age-stratified vaccination mandates, herd immunity does not exist and is not attainable. Therefore, policy should seek to maximize attainable benefits, not unattainable ones, by relying on herd effect and the optimal use of scarce resources.

A game theory approach suggests that a market based on individual vaccination choices would best protect society. Game theory refutes

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<sup>3</sup> *Id.*

<sup>4</sup> See *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>5</sup> See Hodge, Jr. & Gostin, *supra* note 1.

<sup>6</sup> Ctrs. for Disease Control & Prevention, *National, State, and Local Area Vaccination Coverage Among Children Aged 19–35 Months—United States, 2009*, 59 MORBIDITY & MORTALITY WKLY. REP. 1171, 1171–73 (2010), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5936a2.htm>.

<sup>7</sup> See Douglas S. Diekema, *Choices Should Have Consequences: Failure to Vaccinate, Harm to Others, and Civil Liability*, 107 MICH. L. REV. FIRST IMPRESSIONS 90 (2009).

the free rider problem by showing that a unique equilibrium point exists that best balances vaccination benefits and disease harms. The Article finds that market-based, not regulatory, solutions better fit vaccination decision making.<sup>8</sup> This market approach suggests that in the long term, individuals will appropriately balance the relative costs of vaccination and infection, leading people to vaccinate voluntarily in light of the cost-benefit analysis. Although the equilibrium vaccination coverage is in almost all cases lower than the herd immunity threshold, “soft” regulation can achieve aggregate health benefits for society without imposing inefficient marginal costs on individuals and the healthcare system.<sup>9</sup> We therefore argue that personal choices in a market with adequate information would better allocate scarce healthcare resources, better protect the public health, and better respect individual autonomy. Our viewpoint may help explain why many developed countries, including those with political systems closest to our own, have only voluntary childhood vaccination programs. Vaccination uptake and disease levels in these countries, including Canada, the United Kingdom, Australia, and New Zealand, are comparable to those in the United States.<sup>10</sup>

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<sup>8</sup> Such market-based approaches have been well described in the literature of administrative and regulatory law. *See generally* OFFICE OF MGMT. & BUDGET, CIRCULAR A-4, at 7-9 (2003), available at [http://www.whitehouse.gov/omb/circulars\\_a004\\_a-4](http://www.whitehouse.gov/omb/circulars_a004_a-4) (outlining alternatives to federal regulation, including specification of performance as opposed to design standards, use of economic incentives, and informational measures); Bruce A. Ackerman & Richard B. Stewart, *Reforming Environmental Law*, 37 STAN. L. REV. 1333, 1336-37 (1985) (describing the “massive information-gathering burdens” on administrators attempting to impose command-and-control emissions regulations).

<sup>9</sup> *Cf.* Exec. Order No. 12,866 § 1(b)(3), 58 Fed. Reg. 190 (Oct. 4, 1993) (“Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as . . . providing information upon which choices can be made by the public.”); *id.* at § 1(b)(6) (“Each agency shall assess both the costs and the benefits of the intended regulation and . . . propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”); *see also* Exec. Order No. 13,563 § 1(b), 76 Fed. Reg. 14 (Jan. 21, 2011) (supplementing Exec. Order No. 12,866 and reaffirming general principles of regulatory policy).

<sup>10</sup> There is no mandatory vaccination in the United Kingdom. *Childhood Immunisation: A Guide for Healthcare Professionals*, BRIT. MED. ASS’N (June 2003), [http://www.worcslmc.co.uk/upload/Childhood\\_Immunisation\\_June\\_03.pdf](http://www.worcslmc.co.uk/upload/Childhood_Immunisation_June_03.pdf). Scandinavia and Germany also rely on voluntary vaccination rather than compulsion. *Id.* There are some vaccination requirements in Australia, but there is a broad right of conscientious objection. *Id.* Some provinces in Canada require vaccines but allow conscientious objection, and the country as a whole does not mandate vaccination. *Vaccine Safety Frequently Asked Questions*, PUB. HEALTH AGENCY OF CAN., <http://www.phac-aspc.gc.ca/im/vs-sv/vs-faq16-eng.php> (last modified Aug. 27, 2012). In 2012, the United Kingdom, with a

Every state in the United States currently mandates roughly twenty-five to thirty-five doses of vaccines to preschoolers and school-aged children, with limited rights of exemption.<sup>11</sup> While there are other vaccination mandates in the United States for military personnel, hospital workers, and university students, to name a few, this Article focuses exclusively on state mandates for preschoolers and schoolchildren. Today, if children do not comply with state vaccination mandates and do not have valid exemptions, they lose their ability to attend school, a fundamental right and obligation of citizenship.<sup>12</sup> Further, state agents may charge the parents with medical neglect and potentially remove children to foster care for failure to vaccinate.<sup>13</sup> Even if a state offers limited medical, religious, and philosophical exemptions, we consider its vaccination mandate to be compulsory for purposes of this Article. We do so because in the majority of states, exemptions are extremely limited,<sup>14</sup> and even in those states where they exist, there are strong legislative efforts to curtail them.<sup>15</sup> We note at the outset that many vaccine-related issues are beyond the scope of this Article. While further considerations of

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population of roughly 63 million, had 0 reported cases of diphtheria, 2092 reported cases of measles, and 3178 reported cases of mumps. *WHO Vaccine-Preventable Diseases: Monitoring System. 2014 Global Summary*, WORLD HEALTH ORG., [http://apps.who.int/immunization\\_monitoring/globalsummary/](http://apps.who.int/immunization_monitoring/globalsummary/) (select “United Kingdom of Great Britain and Northern Ireland (the)” from the dropdown menu) (last updated July 15, 2014). Similarly, Australia, with a population of roughly 23 million, had 0 reported cases of diphtheria, 199 reported cases of measles, and 195 reported cases of mumps in 2012. *Id.* (select “Australia” from the dropdown menu). In 2012, the United States, where choice is more limited, with a population of roughly 317 million, had 1 reported case of diphtheria, 55 reported cases of measles, and 229 reported cases of mumps. *Id.* (select “United States of America (the)” from the dropdown menu).

<sup>11</sup> See *States with Religious and Philosophical Exemptions from School Immunization Requirements*, NAT’L CONF. STATE LEGISLATURES (Dec. 2012), <http://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx> (showing that only Mississippi and West Virginia do not have religious exemptions).

<sup>12</sup> See, e.g., N.Y. PUB. HEALTH LAW § 2164 (Consol. 2011).

<sup>13</sup> See Kim Mack Rosenberg, *Forced Child Removal*, in *VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN* 238 (Louise Kuo Habakus & Mary Holland eds., 2012).

<sup>14</sup> See Y. Tony Yang & Vicky Debold, *A Longitudinal Analysis of the Effect of Nonmedical Exemption Law and Vaccine Uptake on Vaccine-Targeted Disease Rates*, 104 AM. J. PUB. HEALTH 371 (2014) (stating that fewer than ten percent of all children have exemptions).

<sup>15</sup> See, e.g., First Warning Letter from Jane R. Zucker, Assistant Comm’r, N.Y.C. Dep’t of Health & Mental Hygiene, to Principals (Nov. 8, 2012), available at <http://schools.nyc.gov/NR/rdonlyres/1B9F9BF4-34AE-49B9-8C45-B0176A0CA970/0/FirstWarningLetter.pdf> (threatening principals if they do not achieve 98.8% vaccination compliance).

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personal autonomy, vaccine safety, and vaccine injury are all critical and interrelated, we do not consider those issues in depth here.<sup>16</sup>

Part I defines and analyzes herd immunity and the closely related but distinct concept of herd effect. It contrasts disease eradication and elimination with control, highlighting the limits of what modern vaccination programs can achieve. It then explores the real world of disease outbreaks in vaccinated and unvaccinated populations. Part II introduces the Feudtner-Marcuse framework for “just” vaccination policy. This systematic approach highlights seven objectives of vaccination programs, including mandatory ones. Part III reviews game theory to understand the factors that drive people to choose or decline vaccination. We discuss a social equilibrium point that maximizes net public health gains. The Article ends by summarizing our conclusions and recommendations for U.S. vaccination policies.

## I

### HERD IMMUNITY AND ITS ASSUMPTIONS

Herd immunity depends on the time a disease persists within an infected host and the rate at which the disease spreads.<sup>17</sup> In a population of only susceptible individuals, the introduction of a single infected person will result in indiscriminate transmission to all others whom the infected person contacts until those infected people die or recover.<sup>18</sup> The average number of people in such a susceptible population who become infected is the so-called *basic reproduction number*  $R_0$ .<sup>19</sup> Each of those people who contracted the disease from the initial infected individual is able to transmit the disease to other susceptible contacts; this process repeats itself until the entire

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<sup>16</sup> Other sources provide more in-depth considerations of these issues. *See generally* VACCINE EPIDEMIC: HOW CORPORATE GREED, BIASED SCIENCE, AND COERCIVE GOVERNMENT THREATEN OUR HUMAN RIGHTS, OUR HEALTH, AND OUR CHILDREN, *supra* note 13; *see also* Mary Holland et al., *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 PACE ENVTL. L. REV. 480 (2011).

<sup>17</sup> *See* J.M. Heffernan et al., *Perspectives on the Basic Reproductive Ratio*, 2 J. ROYAL SOC'Y INTERFACE 281 (2005).

<sup>18</sup> *See* Fine, *History*, *supra* note 2, at 273 fig.5 (showing one hundred percent transmission from one individual to all other individuals with whom he or she has effective contact in an entirely susceptible population).

<sup>19</sup> Heffernan et al., *supra* note 17.

population is infected.<sup>20</sup> This model of disease transmission exhibits *epidemic* dynamics.<sup>21</sup>

#### A. Herd Immunity Threshold

By contrast, consider the case where a certain fraction  $\theta$  of the population has immunity to the disease. If a single infected individual comes into the population, the average number of secondary infections from transmission is then  $R_0(1-\theta)$ .<sup>22</sup> If  $R_0(1-\theta) < 1$ , then the disease on average will not spread to other susceptible people.<sup>23</sup> This means that the disease is likely to die out either through the host's death or recovery before further spread.<sup>24</sup> The threshold  $\theta_H$  of immune individuals to create these circumstances is  $\theta_H = 1-1/R_0$ , or the *herd immunity threshold*.<sup>25</sup> The underlying rationale for mass vaccination policies is to ensure that the fraction of immune individuals in society is above the herd immunity threshold, thus eliminating the disease from the population.<sup>26</sup> The moral of the herd immunity story, though, is that not every individual needs to be immune to provide protection to the society as a whole.<sup>27</sup>

#### B. Herd Effect

The concept of herd immunity refers to the complete removal of a disease from society; so long as *any* member of the population has immunity to the disease, however, the disease's ability to spread

<sup>20</sup> See Fine, *History*, *supra* note 2 (showing the complete spread of infection in an entirely susceptible society).

<sup>21</sup> See *id.* at 269 (defining the epidemic threshold for a simple mass-action model of infectious dynamics).

<sup>22</sup> To derive this relationship, note that within a susceptible population of size  $N$ , a single infectious individual will infect on average  $R_0$  persons. If  $N_I$  members of the population have immunity to the disease, however, then transmission is only possible within a subpopulation of size  $N-N_I$ . The resulting average number of secondary infections then decreases to  $(R_0/N)(N-N_I) = R_0(1-N_I/N) = R_0(1-\theta)$ .

<sup>23</sup> See Heffernan et al., *supra* note 17, at 281–87.

<sup>24</sup> *Id.*

<sup>25</sup> See generally Fine, *History*, *supra* note 2, at 269 (providing one example of use of the herd immunity threshold); Fine, *Rough Guide*, *supra* note 2, at 912 fig.1 (providing another example of use of the herd immunity threshold).

<sup>26</sup> See Fine, *Rough Guide*, *supra* note 2 (discussing the success of vaccination programs against measles, mumps, rubella, etc. in delaying or averting epidemics by keeping the amount of susceptible individuals below the threshold); see also Fine, *History*, *supra* note 2 (discussing the success of the global smallpox eradication program).

<sup>27</sup> See Fine, *History*, *supra* note 2.

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lessens.<sup>28</sup> This decrease in the rate of epidemic transmission is the *herd effect*.<sup>29</sup> Even if herd immunity itself is not achievable, society still benefits from a “buffer” of immune individuals in order to mitigate disease.<sup>30</sup> Although the concepts of herd immunity and herd effect are sometimes interchangeable, they describe different aspects of the immunity puzzle—whereas herd immunity aims to *eliminate* a disease from society, herd effect refers to infection *control*.<sup>31</sup> Since the 1960s, compulsory state vaccination programs have achieved herd effects for specific diseases, but none has achieved herd immunity. We maintain the analytic distinction between these terms in the discussion below.

### C. The Free Rider Problem

Why are universal mandatory vaccination policies necessary if we can achieve herd immunity by vaccinating only a fraction of the population? Proponents of compulsion argue that if vaccination is not mandatory, then herd immunity is generally unattainable due to a *free rider problem*.<sup>32</sup> From the perspective of an individual weighing the decision to vaccinate, it is in her best interest not to vaccinate because she is unlikely to become sick if all others are immune and are unlikely to transmit disease.<sup>33</sup> This decision-maker could then “free ride” on the immunity of others.<sup>34</sup>

If all individuals in a population attempt to free ride, then they all run the risk of illness. If the expected risks of vaccine injury outweigh those of illness, then no one will choose to vaccinate.<sup>35</sup> This situation

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<sup>28</sup> See T. Jacob John & Reuben Samuel, *Herd Immunity and Herd Effect: New Insights and Definitions*, 16 EUR. J. EPIDEMIOLOGY 601, 601 (2000) (defining herd effect).

<sup>29</sup> See *id.* (distinguishing herd effect and herd immunity).

<sup>30</sup> See Fine, *Rough Guide*, *supra* note 2, at 912 (discussing the importance of “selective vaccination”—specifically, vaccinating groups that play an important role in transmission, either in slowing transmission or reducing incidence among the entire population).

<sup>31</sup> See *infra* Part I.F. (discussing definitions of “control” and “elimination” in the context of vaccination policy).

<sup>32</sup> See Fine, *Rough Guide*, *supra* note 2, at 914.

<sup>33</sup> See *id.*

<sup>34</sup> See *id.*

<sup>35</sup> It is essential to distinguish between *perceived* and *absolute* costs of vaccination and infection. In general, individuals in society operate under limited information as to the probabilities of vaccine-related harm and infection and thus make individual estimations of expected costs consistent with such incomplete information. If all members of society had perfect information, absolute costs of vaccination and infection could be determined. In practice, such perfect information is never available. See *infra* Part III.

represents a *tragedy of the commons*, in which society loses an important benefit because of competing individual interests.<sup>36</sup> As the rate of infection decreases, individuals may perceive the risks of infection as declining, inducing some individuals to forego vaccination. This scenario has led some to decry that vaccines are the “victim[s] of their own success.”<sup>37</sup> Compulsory vaccination is then one solution to the potential free rider problem because it forces all children to assume part of the collective responsibility to prevent infectious disease.<sup>38</sup>

#### *D. Assumptions Underlying Herd Immunity Theory*

The potential social costs of the free rider problem are severe in the face of a highly infectious, life-threatening disease and the failure to reach the herd immunity threshold.<sup>39</sup> Under what conditions, however, is herd immunity actually possible? Many of the underlying assumptions of herd immunity may be irrelevant in the real world, as authoritative scientists have acknowledged.<sup>40</sup> We address the following core assumptions of the theory<sup>41</sup>:

1. Population homogeneity;
2. Well-mixing of the population;
3. Random vaccination of individuals;
4. Perfect vaccine efficacy; and
5. Age uniformity in the population.

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<sup>36</sup> See Chris T. Bauch et al., *Rapid Emergence of Free-Riding Behavior in New Pediatric Immunization Programs*, 5 PLOS ONE 1, 1 (2010).

<sup>37</sup> See Matthew Janko, *Vaccination: A Victim of Its Own Success*, 14 VIRTUAL MENTOR 3, 4 (2012).

<sup>38</sup> Dagobert L. Brito et al., *Externalities and Compulsory Vaccinations*, 45 J. PUB. ECON. 69, 69–70 (1991) (quoting J.E. STIGLITZ, *ECONOMICS OF THE PUBLIC SECTOR* 210 (2d ed. 1988)).

<sup>39</sup> See, e.g., V.A.A. Jansen et al., *Measles Outbreaks in a Population with Declining Vaccine Uptake*, 301 SCIENCE 804, 804 (2003) (relating the decline in measles vaccinations to “a number of large measles outbreaks”).

<sup>40</sup> See Fine, *History*, *supra* note 2, at 276.

<sup>41</sup> See *id.* (naming an incomplete list of assumptions); see also Fine, *Rough Guide*, *supra* note 2, at 912–14 (discussing probable complexities that would upset the core assumptions).

### 1. *The Assumption of Population Homogeneity*

Population homogeneity involves two related but distinct concepts: (1) compositional homogeneity and (2) spatial homogeneity.<sup>42</sup> Compositional homogeneity means that all individuals belong to a single identifiable group.<sup>43</sup> Persons within this group transmit the disease among themselves as if all group members are the same.<sup>44</sup> Compositional homogeneity ignores racial, sociological, economic, and genetic differences, all of which in the real world may affect resistance to an infectious disease.<sup>45</sup>

Spatial homogeneity, by contrast, refers to the degree of uniform spread over a geographic region.<sup>46</sup> Spatial homogeneity assumes that people behave identically in spreading disease.<sup>47</sup> But if a group of people lives in a particular area, and its members spread disease differently from the rest of society, then this violates the assumption of interchangeability.<sup>48</sup> For the simple analysis of herd immunity to hold true, both compositional and spatial homogeneity must exist.<sup>49</sup>

As a practical matter, however, compositional homogeneity *never* holds. Social stratification by age, ethnicity, class, gender, race, and sexual orientation, among other factors, results in differing individual risks.<sup>50</sup> For example, the Centers for Disease Control and Prevention (CDC) noted that more than fifty percent of all new cases of HIV infection between 2006 and 2009 were among men who have sex

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<sup>42</sup> See generally DIETRICH STOYAN ET AL., *STOCHASTIC GEOMETRY AND ITS APPLICATIONS* (2d ed. 1995) (discussing spatial homogeneity in the context of stochastic point processes); see also Fine, *Rough Guide*, *supra* note 2, at 913 (discussing models of heterogeneous populations).

<sup>43</sup> *Id.*

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

<sup>45</sup> *Id.*

<sup>46</sup> See generally STOYAN ET AL., *supra* note 42.

<sup>47</sup> Spatial homogeneity is mathematically defined by the property of translation-invariance for all probabilistic descriptors governing the spatial correlations among groups of individuals within a population, implying that the choice of origin for a Euclidean coordinate system adopted to describe the spatial region does not affect measured statistical properties.

<sup>48</sup> Fine, *Rough Guide*, *supra* note 2, at 913.

<sup>49</sup> *Id.* (listing heterogeneous populations as a complex problem disrupting herd immunity's core assumptions).

<sup>50</sup> See generally CDC *Fact Sheet: Estimates of New HIV Infections in the United States, 2006–2009*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 3 (Aug. 2011), <http://www.cdc.gov/nchstp/newsroom/docs/Hiv-infections-2006-2009.pdf> (providing statistics showing disparities in HIV outbreaks among differing populations).

with men.<sup>51</sup> Additionally, African Americans accounted for forty-four percent of new HIV infections in 2009.<sup>52</sup> These types of differences are compositional, relating to characteristics that distinguish population subgroups. Compositional heterogeneity increases the herd immunity threshold for the population, meaning that the minimum number of people vaccinated must be higher, because vaccination of low-risk individuals provides little marginal herd effect.

Spatial homogeneity, another bedrock assumption of herd immunity, similarly does not hold true in practice.<sup>53</sup> Scientists have studied the effects of clustering using network models, showing individuals as nodes on a graph with intersections indicating transmissible contacts.<sup>54</sup> Limiting the types and numbers of transmissible contacts can substantially change the rate at which a disease spreads through the population.<sup>55</sup> The existence of isolated, highly clustered groups of susceptible individuals can increase the required herd immunity threshold for the population as a whole because vaccinating people outside the clustered group provides little benefit.

Diseases spread more slowly when there is more distance between people.<sup>56</sup> This spatial effect can result in rapid disease spread within clustered areas, such as cities, even when disease spread is decreasing overall.<sup>57</sup> As travel technology continues to develop, diseases can spread quickly, both domestically and internationally. However, spatial dissemination coupled with transmission dynamics may lead to

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<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 4.

<sup>53</sup> See Martial L. Ndeffo Mbah et al., *The Impact of Imitation on Vaccination Behavior in Social Contact Networks*, 8 PLOS COMPUTATIONAL BIOLOGY 1, 7 (2012) (noting that spatial homogeneity fails to take into account the fact that “individuals frequently imitate others”).

<sup>54</sup> See generally Chris T. Bauch & Alison P. Galvani, *Using Network Models to Approximate Spatial Point-Process Models*, 184 MATHEMATICAL BIOSCIENCES 101 (2003) (using network models to evaluate spatial effects on ecological and epidemiological systems); Matt J. Keeling & Ken T.D. Eames, *Networks and Epidemic Models*, 2 J. ROYAL SOC'Y INTERFACE 295 (2005) (providing an overview of the process of approximating a network); Martial L. Ndeffo Mbah et al., *supra* note 53 (using network-based models to examine the correlation between the spread of disease and social contacts).

<sup>55</sup> Keeling & Eames, *supra* note 54, at 300–01 (contrasting networking models that account for clustering with random networks, which assume that connections are formed at random).

<sup>56</sup> See Bauch & Galvani, *supra* note 54, at 102.

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

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stationary patterns of infectious regions.<sup>58</sup> In sum, neither compositional nor spatial homogeneity assumptions hold true in the real world.

## 2. *The Assumption of a Well-Mixed Population*

The well-mixing assumption refers to the notion that all susceptible individuals are equally likely to become sick from an infectious individual.<sup>59</sup> Network models can test the well-mixing assumption and, in a well-mixed population, each node in a network model will have an intersection with every other node in that same model.<sup>60</sup> To understand how well-mixing affects the dynamics, consider the simple case of a population of nine individuals, three of whom are susceptible and six of whom are infected. If each infected individual contacts only one susceptible person, and if each susceptible person contacts two infected people, it follows that there are only six possible transmissible contacts in the population.

By contrast, the well-mixing assumption implies that there are eighteen transmissible contacts, overestimating the disease propagation rate by a factor of three. Isolated groups of highly connected, susceptible people may face particularly rapid disease transmission that might otherwise have spread relatively slowly through the population as a whole.<sup>61</sup> Clustering of susceptible individuals is again the key to understanding how to control disease dynamics. Indeed, all statewide mandates are for children and young adults, representing clusterings of susceptible individuals. No states mandate vaccination for the entire population today. The result of this

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<sup>58</sup> This pattern-forming phenomenon arises from an identical mechanism for the formation of so-called Turing patterns in reaction-diffusion chemical systems. Such patterns, which are stationary in time but heterogeneous in space, develop when an “inhibiting” species diffuses faster in space than a competing “growth” species, resulting in local activation of dynamic transmission that is inhibited on a global scale. See A.M. Turing, *The Chemical Basis of Morphogenesis*, 237 PHIL. TRANSACTIONS ROYAL SOC’Y LONDON 37, 57–58 (1952).

<sup>59</sup> James Holland Jones, *Notes on  $R_0$* , DEP’T ANTHROPOLOGICAL SCI. STANFORD U. 1, 2 (2007), <http://www.stanford.edu/~jhj1/teachingdocs/Jones-on-R0.pdf>.

<sup>60</sup> Alun L. Lloyd et al., *Infection Dynamics on Small-World Networks*, in MATHEMATICAL STUDIES ON HUMAN DISEASE DYNAMICS: EMERGING PARADIGMS AND CHALLENGES 209, 220–21 (Contemporary Mathematics Ser. Vol. 412, Abba B. Gumel et al. eds., 2006).

<sup>61</sup> See Fine, *Rough Guide*, *supra* note 2, at 913–14.

type of clustering is that the herd immunity threshold may be higher than estimated from the well-mixing assumption.<sup>62</sup>

U.S. policies for hepatitis B disease prevention provide a good example of how the well-mixing assumption applies in practice.<sup>63</sup> Although only a small portion of the U.S. population was at risk of contracting hepatitis B, namely intravenous drug users, those who had unprotected sex with multiple partners, and infants of hepatitis B positive mothers, it proved difficult for public health authorities to gain compliance among these target groups in the 1980s.<sup>64</sup> As a result, even though the herd immunity threshold would be much lower for the general population than the target group, U.S. public health authorities recommended universal vaccination of infants against hepatitis B to achieve herd immunity, and forty-seven states now mandate the vaccine.<sup>65</sup>

### 3. *The Assumption of Random Vaccination of Individuals*

In a heterogeneous population, different subgroups may face unique risks to certain infections and vaccine injuries.<sup>66</sup> A vaccination program that randomly immunizes people will generally require an especially high vaccination coverage ratio to achieve herd immunity because the disease will be able to propagate efficiently among high-risk individuals.<sup>67</sup> One solution is therefore to target the vaccination

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<sup>62</sup> See *id.* at 913.

<sup>63</sup> See Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y L. & ETHICS 39, 41 (2012); Rui Xu & Zhien Ma, *An HBV Model with Diffusion and Time Delay*, 257 J. THEORETICAL BIOLOGY 499, 499 (noting that "it is implicitly assumed that cells and viruses are well mixed").

<sup>64</sup> Holland, *supra* note 63, at 68–69 (citing Ctrs. for Disease Control & Prevention, *Recommendation of the Immunization Practices Advisory Committee (ACIP) Inactivated Hepatitis B Virus Vaccine*, 31 MORBIDITY & MORTALITY WKLY. REP. 317 (1982), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001116.htm>) (outlining recommendations of U.S. public health authorities that "higher-risk groups" receive hepatitis B vaccinations).

<sup>65</sup> See *Hepatitis B Prevention Mandates for Daycare and K-12*, IMMUNIZATION ACTION COALITION, <http://www.immunize.org/laws/hepb.asp> (last updated May 26, 2011).

<sup>66</sup> See *People at High Risk of Developing Flu-Related Complications*, CTRS. FOR DISEASE CONTROL & PREVENTION, [http://www.cdc.gov/flu/about/disease/high\\_risk.htm](http://www.cdc.gov/flu/about/disease/high_risk.htm) (last updated Nov. 7, 2013) (listing specific subgroups that are particularly susceptible to flu-related complications).

<sup>67</sup> See Fine, *Rough Guide*, *supra* note 2, at 914.

program only to those individuals who are at a highest risk of infection.<sup>68</sup>

Fine provides a simple example of this type of targeted vaccination program by considering a sample population composed of two equal-sized subgroups: high-risk and low-risk.<sup>69</sup> Following Fine's analysis, assume that each individual in the high-risk group, if infected, would infect five other high-risk members, and each low-risk individual, if infected, would infect one other low-risk member.<sup>70</sup> Under this idealized scheme, the high-risk and low-risk dynamics are separable because there are no transmissible contacts between groups.<sup>71</sup> The disease among the low-risk group is controllable without vaccination because the reproduction rate,  $R_0^{(LR)}$ , for the low-risk group is one, meaning that each person in this group would infect one other person on average.<sup>72</sup> This implies that the herd immunity threshold within the low-risk group is zero, and the disease will not spread, or  $\theta_H^{(LR)} = 0$ .<sup>73</sup>

By contrast, the disease will exhibit epidemic dynamics among the high-risk group because each high-risk individual will on average infect five others, so  $R_0^{(HR)} = 5$  and  $\theta_H^{(HR)} = 0.8$ .<sup>74</sup> If vaccination is only for the high-risk group, only 80% of that group needs to receive the vaccine to induce herd immunity in the population as a whole.<sup>75</sup> Surprisingly, such a program targeted only at high-risk individuals would require vaccinating only 40% of the total population, representing a substantial increase in the health of society at lower financial cost and risk of vaccine injury.<sup>76</sup> But a vaccination program that randomly vaccinated 80% of the total population from the high-risk and low-risk groups would *not* provide herd immunity at all

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<sup>68</sup> See Holland, *supra* note 63, at 68 (targeting hepatitis B vaccinations to high-risk groups).

<sup>69</sup> Fine, *Rough Guide*, *supra* note 2, at 914.

<sup>70</sup> *Id.*

<sup>71</sup> *See id.*

<sup>72</sup> *See id.*

<sup>73</sup> Some care is required here. If  $R_0 = 1$  exactly, then the disease will exist in an endemic steady state in which the number of infected individuals neither increases nor decreases on average. We therefore assume without loss of generality that the basic reproduction number is actually infinitesimally smaller than one to ensure that the disease is unable to sustain itself.

<sup>74</sup> Fine, *Rough Guide*, *supra* note 2, at 914.

<sup>75</sup> *Id.*

<sup>76</sup> *See id.*

because the fractional vaccination coverage for the high-risk population would be less than its required herd immunity threshold.<sup>77</sup>

Although society can achieve the greatest benefits by targeting high-risk groups, such a policy imposes the full costs of vaccination on one identifiable group while the benefits diffuse to the greater population.<sup>78</sup> One could characterize this program as imposing a tax on specific individuals based on inherent characteristics,<sup>79</sup> precluding an equitable distribution of the costs and benefits to society. This policy becomes particularly troubling when its targets are children, who are low-risk subjects, selected for convenience, as in the case with mandatory vaccination of schoolchildren against hepatitis B, a sexually transmitted disease.<sup>80</sup> Random vaccination fails to maximize herd immunity or herd effect; only targeted or universal vaccination can achieve that result.

#### 4. *The Assumption of Perfect Vaccine Efficacy*

Vaccines do not induce immunity perfectly; they usually fail in a certain fraction of people for a variety of reasons.<sup>81</sup> Furthermore, as a practical matter, vaccine “efficacy” is highly uncertain.<sup>82</sup> Scientists refer to efficacy as the relative fractional decrease in the rate of disease transmission between unvaccinated and vaccinated individuals in double-blind, randomized, clinically-controlled studies.<sup>83</sup> By contrast, the concept of vaccine “effectiveness” refers to the performance of the vaccine in the “real world,” outside of clinical trials.<sup>84</sup> This distinction is not necessarily clear because the goal of

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<sup>77</sup> See *id.*

<sup>78</sup> See *id.* (discussing potential equal rights violations in mandating that all young children receive the hepatitis B vaccine).

<sup>79</sup> Indeed, the Supreme Court’s recent extension of the taxation power in the Court’s ruling on the Affordable Care Act suggests that such a tax may be constitutional. See *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2599 (2012) (holding that the Constitution does not protect individuals from “taxation through inactivity”).

<sup>80</sup> See Holland, *supra* note 63, at 41.

<sup>81</sup> See *Flu Vaccine Effectiveness: Questions and Answers for Health Professionals*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/flu/professionals/vaccination/effectivenessqa.htm> (last updated Nov. 27, 2013) (finding, for example, that influenza vaccines are less effective in people with chronic, high-risk medical conditions).

<sup>82</sup> John Clemens et al., *Evaluating New Vaccines for Developing Countries: Efficacy or Effectiveness?*, 275 J. AM. MED. ASS’N 390, 392 (1996).

<sup>83</sup> See Geoffrey A. Weinberg & Peter G. Szilagyi, *Vaccine Epidemiology: Efficacy, Effectiveness, and the Translational Research Roadmap*, 201 J. INFECTIOUS DISEASES 1607 (2010); Fine, *Rough Guide*, *supra* note 2, at 913 tbl.1; *Flu Vaccine Effectiveness: Questions and Answers for Health Professionals*, *supra* note 81.

<sup>84</sup> Weinberg & Szilagyi, *supra* note 83, at 1608.

any vaccination policy is to control the rate of disease transmission. Nevertheless, either definition is sufficient for our discussion of herd immunity.

If a fraction,  $\phi$ , of the vaccinated population fails to develop immunity and thus remains susceptible to infection, then the fraction of the total population that must receive the vaccine to ensure herd immunity is  $\theta_H' = (1-1/R_0)/\phi = \theta_H/\phi$ .<sup>85</sup> If the fraction of the population that fails to develop immunity is greater than the herd immunity threshold, or  $\phi < \theta_H$ , then herd immunity is theoretically impossible, even if the entire population is vaccinated.<sup>86</sup> A herd immunity threshold,  $\theta_H$ , is generally high, ranging from 80%–99%.<sup>87</sup> For example, Fine estimates that the threshold for measles is 83%–94% and pertussis is 92%–94%.<sup>88</sup> As an illustration of the problem, measles vaccine has an estimated vaccine efficacy rate of 85%–95% for the first dose given to babies between 12–15 months.<sup>89</sup> This leaves unclear whether herd immunity is even theoretically achievable for measles. Thus, the assumption of perfect vaccine efficacy has limited bearing in real-world conditions.

### 5. *The Assumption of Age Uniformity*

Modern immunization programs target infants and young children for both scientific and practical reasons. Experience and science suggest that children are more vulnerable to infectious disease, but the practical reasons are also compelling.<sup>90</sup> Linking recommended and compulsory vaccination to “well-baby” and school check-ups provides a relatively low-cost method to oversee vaccination compliance. Adults, by contrast, lead more diverse lives and are more

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<sup>85</sup> See generally Fine, *History*, *supra* note 2.

<sup>86</sup> *Id.*

<sup>87</sup> See Fine, *History*, *supra* note 2, at 268 (providing estimates of the herd immunity thresholds for the following diseases: diphtheria (85%); malaria (80%–99%); measles (83%–94%); mumps (75%–86%); pertussis (92%–94%); polio (80%–86%); rubella (83%–85%); smallpox (80%–85%)); see also Fine, *Rough Guide*, *supra* note 2, at 913. It should be noted that there is scientific uncertainty regarding the precise values of the herd immunity thresholds for various diseases.

<sup>88</sup> Fine, *History*, *supra* note 2, at 268.

<sup>89</sup> *Canadian Immunization Guide: Measles Vaccine*, PUB. HEALTH AGENCY CAN., <http://www.phac-aspc.gc.ca/publicat/cig-gci/p04-meas-roug-eng.php> (last modified Oct. 9, 2013); Fine, *History*, *supra* note 2, at 268 tbl.1.

<sup>90</sup> See Gaston De Serres & Bernard Duval, *Pertussis Vaccination Beyond Childhood*, 365 LANCET 1015, 1015 (2005).

likely to assert autonomy rights in the courts and through political participation than young children or their parents.<sup>91</sup>

Children face particular problems from waning vaccine-induced immunity.<sup>92</sup> Immunity from vaccines generally requires several boosters to extend the period of protection. Adults, who may be less likely to receive boosters, have a greater fraction of susceptible individuals as a group than children.<sup>93</sup> Furthermore, unlike in prior decades, younger adults today do not have naturally acquired immunity because they never had infectious childhood diseases. Why then does the disease not produce an epidemic among adults? Are adults free riding on the vaccination programs of children?

We gain some insight into this question by comparing the differing vaccination policies for pertussis in European countries and the United States in the 1980s.<sup>94</sup> European countries had little or no pertussis immunization in childhood, resulting in widespread pertussis transmission among infants and children, but few adolescent or adult cases due to long-lasting natural immunity.<sup>95</sup> By contrast, the United States consistently administered pertussis vaccines to infants and children in the 1980s, causing an increase in pertussis cases among adults and adolescents because temporary vaccine-induced immunity had waned.<sup>96</sup> Therefore, while the adult population is not completely free riding on the vaccination of children, vaccinating children may have the unintended effect of increasing the average age when people become infected. For example, while chickenpox is a relatively mild disease among children, it can have extremely serious consequences in high-risk populations, including pregnant women, the elderly, and those who have compromised immunity.<sup>97</sup> Society may be disadvantaged by vaccinating children early, thus creating conditions

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<sup>91</sup> See generally Peter A. Briss et al., *Reviews of Evidence Regarding Interventions to Improve Vaccination Coverage in Children, Adolescents, and Adults*, 18 AM. J. PREVENTATIVE MED. 97 (2000).

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

<sup>93</sup> See generally Ctrs. for Disease Control & Prevention, *Noninfluenza Vaccination Coverage Among Adults—United States, 2011*, 62 MORBIDITY & MORTALITY WKLY. REP. 66 (2013), available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6204a2.htm?\\_cid=mm6204a2\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6204a2.htm?_cid=mm6204a2_w).

<sup>94</sup> De Serres & Duval, *supra* note 90, at 1015–16.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *Chickenpox (Varicella): People at High Risk for Complications*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/chickenpox/hcp/high-risk.html> (last updated Nov. 16, 2011).

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where older adults acquire the illness with greater risk of complications.<sup>98</sup>

While herd immunity assumes age uniformity, in practice this is virtually never present in real-world vaccination programs.<sup>99</sup> Overwhelmingly, children are the targets of mandatory vaccination programs, and this lack of age uniformity poses significant challenges given the temporary nature of vaccine protection.<sup>100</sup>

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In sum, the five underlying assumptions at the foundation of herd immunity—population homogeneity, well-mixing, random vaccination, perfect vaccine efficacy, and age uniformity—are of exceedingly limited practical relevance. The following cases highlight these limitations in practice.

#### *E. Herd Immunity Theory in Practice*

Recent experience shows infectious disease outbreaks in highly vaccinated populations. Such outbreaks seeming to violate the herd immunity theory have caused many researchers to reject the theory altogether. For instance, the International Medical Council on Vaccination states in its “Principles and Findings,” that “[w]e find the premise of herd immunity to be a faulty theory.”<sup>101</sup> Dr. Russell Blaylock argues that “[h]erd immunity is mostly a myth and applies only to natural immunity—that is, contracting the infection itself.”<sup>102</sup> Dr. Suzanne Humphries argues that “[s]ince the beginning of vaccination, there is little proof that vaccines are responsible for eradicating disease even when herd immunity vaccination levels have

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<sup>98</sup> See Timothy C. Reluga et al., *Optimal Timing of Disease Transmission in an Age-Structured Population*, 69 BULL. MATHEMATICAL BIOLOGY 2711, 2719 (2007) (suggesting that foregoing vaccination at a young age may provide greater aggregate social health benefits).

<sup>99</sup> See Briss et al., *supra* note 91.

<sup>100</sup> *Id.*

<sup>101</sup> *Principles and Findings*, INT’L MED. COUNCIL ON VACCINATION, <http://www.vaccinationcouncil.org/about/> (last visited Mar. 9, 2014).

<sup>102</sup> Russell Blaylock, *The Deadly Impossibility of Herd Immunity Through Vaccination*, INT’L MED. COUNCIL ON VACCINATION (Feb. 18, 2012), <http://www.vaccinationcouncil.org/2012/02/18/the-deadly-impossibility-of-herd-immunity-through-vaccination-by-dr-russell-blaylock/>.

been reached.”<sup>103</sup> Dr. Tetyana Obukhanych explains that “[t]he absence of viral epidemics in the [United States] is due to the absence of endemic viral exposure, not due to . . . herd immunity, and sporadic outbreaks . . . occur due to . . . viral exposure brought from abroad.”<sup>104</sup>

While these researchers acknowledge that vaccinations can create short-term immunity, and that vaccines can cause herd effect, they argue that vaccination’s long-term effects are often harmful to individuals and society. Despite nearly three hundred years of vaccination, scientists have not rigorously compared the long-term health outcomes of vaccinated versus unvaccinated subjects.<sup>105</sup> Without such critical information, some scientists are profoundly skeptical of current vaccine policies, including the goal of vaccine-induced herd immunity.<sup>106</sup>

Below, we consider empirical examples illustrating a range of problems with herd immunity in practice. They include: (1) primary vaccine failure—when a vaccine initially fails to induce immunity; (2) secondary vaccine failure—when the immunity the vaccine induced has waned over time and no longer offers protection; (3) mutation of the infectious virus—suggesting that the vaccine itself may have contributed to the viral shift; (4) importation of viral infections “just a plane ride away”; and (5) disease transmission, or “viral shedding,” by vaccinated people who show no symptoms of disease. In addition, there have been disease outbreaks in vaccinated populations that scientists simply cannot explain. While there are many examples, we will focus on the measles and varicella vaccination programs.

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<sup>103</sup> Suzanne Humphries, “Herd Immunity,” *The Flawed Science and Failures of Mass Vaccination*, INT’L MED. COUNCIL ON VACCINATION (July 5, 2012), <http://www.vaccinationcouncil.org/2012/07/05/herd-immunity-the-flawed-science-and-failures-of-mass-vaccination-suzanne-humphries-md-3/#sthash.aRBEJNVz.dpuf>.

<sup>104</sup> TETYANA OBUKHANYCH, *VACCINE ILLUSION: HOW VACCINATION COMPROMISES OUR NATURAL IMMUNITY AND WHAT WE CAN DO TO REGAIN OUR HEALTH* 90 (2012).

<sup>105</sup> However, a bipartisan bill introduced in the U.S. House of Representatives on April 25, 2013, cited as the “Vaccine Safety Study Act,” seeks to “conduct or support a comprehensive study comparing total health outcomes, including risk of autism, in vaccinated populations in the United States with such outcomes in unvaccinated populations in the United States.” H.R. 1757, 113th Cong. (2013), *available at* <https://www.govtrack.us/congress/bills/113/hr1757/text>. Although this bill only has a one percent chance of being enacted according to *GovTrack.us*, its purpose is to fund science that needs to be done to compare vaccinated versus unvaccinated health outcomes. *H.R. 1757: Vaccine Safety Study Act*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/113/hr1757> (last visited Mar. 14, 2014).

<sup>106</sup> See, e.g., *Principles and Findings*, *supra* note 101.

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### *1. The Case of Measles Vaccination and Immunity*

Before the United States embarked on state mandates for measles vaccination, one of the leading proponents of the vaccine, Alexander Langmuir, characterized the disease as a “self-limiting infection of short duration, moderate severity, and low fatality.”<sup>107</sup> In the same article, he noted that the disease had maintained a “remarkably stable biological balance over the centuries,” and that “[t]he decline in mortality demonstrates the degree to which we have adapted to this balance and have learned to live with this parasite.”<sup>108</sup> He explained that measles vaccination was by no means an urgent public health necessity, but rather he sought measles eradication because “it can be done.”<sup>109</sup> In the 1960s, Langmuir seemed to believe that vaccination policies could eradicate measles in the near term.

#### *a. Measles Outbreaks in Highly Vaccinated Populations*

At that time, scientists believed the herd immunity threshold to be 70% and that one dose of the vaccine would confer long-lasting immunity.<sup>110</sup> Over time, however, scientists pushed the herd immunity threshold up to 95%<sup>111</sup> and started requiring two doses of the vaccine.<sup>112</sup> Evidence suggests, however, that even these policies have not been enough to create herd immunity. During a 1985 measles outbreak in a Texas high school, more than 99% of the 1806 students in the school had been vaccinated against measles.<sup>113</sup> Upon testing, only 4.1% of the students, or 74 of them, lacked detectable antibodies due to either primary or secondary vaccine failure.<sup>114</sup> The authors concluded, “outbreaks of measles can occur in secondary

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<sup>107</sup> Alexander D. Langmuir et al., *The Importance of Measles as a Health Problem*, 52 AM. J. PUB. HEALTH 1, 1 (1962).

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 3 (citation omitted) (internal quotation marks omitted).

<sup>110</sup> Fine, *History*, *supra* note 2, at 285 (showing that as late as 1982, the World Health Organization estimated the herd immunity threshold for measles to be 70%).

<sup>111</sup> *Id.*

<sup>112</sup> See *Immunization Schedules: Recommended Immunization Schedule for Persons Aged 0 Through 18 Years*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html> (last updated Jan. 31, 2014) (stating that children should receive two doses of the measles-mumps-rubella vaccine by six years of age).

<sup>113</sup> Tracy L. Gustafson et al., *Measles Outbreak in a Fully Immunized Secondary-School Population*, 316 NEW ENGL. J. MED. 771, 771 (1987).

<sup>114</sup> *Id.* at 772.

schools, even when more than 99[%] of the students have been vaccinated and more than 95[%] are immune,” that is, they have measles antibodies.<sup>115</sup> They acknowledged that such an outbreak should have been virtually impossible but rationalized that the “[r]ates of primary vaccine failure in this range [*eds.*: 4.1%] are expected.”<sup>116</sup>

Another measles outbreak occurred in a 100% vaccinated school population in Illinois in 1984:

The affected high school had 276 students and was in the same building as a junior high school with 135 students. A review of health records in the high school showed that all 411 students had documentation of measles vaccination on or after their first birthday, in accordance with Illinois law.<sup>117</sup>

Not all students became ill, but scientists noted that those students who had received vaccines within the previous ten years were less likely to become sick than those who had been vaccinated more than ten years earlier.<sup>118</sup> Notably, officials could not explain how the seventeen-year-old index patient came down with the measles.<sup>119</sup>

The Centers for Disease Control and Prevention’s editors noted several possible reasons for the outbreak, including vaccine failure due to improper storage, vaccination of infants younger than one who might be less likely to acquire protection, and other factors.<sup>120</sup> Still, they concluded that “these risk factors did not adequately explain the occurrence of this outbreak.”<sup>121</sup> They further noted, “this outbreak suggests that measles transmission can occur within the 2%–10% of expected vaccine failures.”<sup>122</sup> In other words, they acknowledged that even with 100% vaccination, they could not ensure herd immunity with existing vaccine technology and stated explicitly that “[t]his outbreak demonstrates that transmission of measles can occur within

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<sup>115</sup> *Id.* at 771.

<sup>116</sup> *Id.* at 773.

<sup>117</sup> Ctrs. for Disease Control & Prevention, *Measles Outbreak Among Vaccinated High School Students—Illinois*, 33 MORBIDITY & MORTALITY WKLY. REP. 349 (1984), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000359.htm> [hereinafter *Measles Outbreak*]; see generally Benjamin M. Nkowane et al., *Measles Outbreak in a Vaccinated School Population: Epidemiology, Chains of Transmission and the Role of Vaccine Failures*, 77 AM. J. PUB. HEALTH 434 (1987) (describing a 1984 outbreak in a Massachusetts high school with a 98% immunization level, providing evidence that outbreaks may occur in highly immunized populations).

<sup>118</sup> *Measles Outbreak*, *supra* note 117, at 350.

<sup>119</sup> *Id.* at 349.

<sup>120</sup> *Id.* at 350.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.* (citations omitted).

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a school population with a documented immunization level of 100%.”<sup>123</sup>

*b. Actual and Perceived Outbreaks in Unvaccinated Populations*

Measles outbreaks have also occurred among the unvaccinated. A recent example happened in 2013 in a largely intentionally unvaccinated Hasidic community in Brooklyn, New York, when a teenager returned from abroad with subclinical measles.<sup>124</sup> Fifty-eight members of the Orthodox Jewish community became infected, the largest outbreak in the United States since 1996.<sup>125</sup> No one died, and no one outside the religious community became infected, but many of those who became ill had in fact been vaccinated.<sup>126</sup>

Sometimes, public health officials and others have blamed disease outbreaks on vaccine critics. Some have blamed Dr. Andrew Wakefield for measles outbreaks; in February 1998, he suggested that there might be a causal link between the MMR vaccine, gastrointestinal disease, and autism.<sup>127</sup> Having observed a new syndrome of gastrointestinal disease and autism in some children after vaccination with the MMR, he publicly recommended that parents consider using the single measles vaccine rather than the combination vaccine.<sup>128</sup> At the time he made the recommendation, a single measles vaccine was available. A few months later, the United Kingdom government took the single measles vaccine off the market.

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<sup>123</sup> *Id.*

<sup>124</sup> Ctrs. for Disease Control & Prevention, *Notes from the Field: Measles Outbreak Among Members of a Religious Community – Brooklyn, New York, March–June 2013*, 62 MORBIDITY & MORTALITY WKLY. REP. 752, 752 (2013) <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6236a5.htm>; see also Renee Ghert-Zand, *Measles Vaccine Developer Warns Jewish Anti-Vaxxers*, TIMES OF ISRAEL (Dec. 11, 2013), <http://www.timesofisrael.com/measles-vaccine-developer-warns-jewish-anti-vaxxers/>.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> A.J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637 (1998), retracted, Feb. 2, 2010, for reasons related to patient referrals and ethics committee approvals, not scientific fraud, available at [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(97\)11096-0/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/abstract) (last visited Mar. 9, 2014). For a discussion of the article and subsequent retraction, see Mary Holland, *Who is Dr. Andrew Wakefield*, in VACCINE EPIDEMIC, *supra* note 13, at 311–19; David Lewis, *The Exoneration of Professor Walker-Smith*, in VACCINE EPIDEMIC, *supra* note 13, at 320–38.

<sup>128</sup> F. Edward Yazbak, *Measles in the United Kingdom: The “Wakefield Factor”*, VACCINATION NEWS, <http://www.vaccinationnews.com/measles-united-kingdom-wakefield-factor> (last visited Mar. 9, 2014).

Many in the media have argued vociferously that Dr. Wakefield's public statement caused measles outbreaks in the United Kingdom.<sup>129</sup>

There is little data to support such assertions. In a careful review of United Kingdom data on measles in the ten years preceding Dr. Wakefield's statement and the ten years after, Dr. Yazbak notes that there were 188,483 reported measles cases in the ten years before 1998, compared to 28,289 cases in the ten years after, an 85% decrease.<sup>130</sup> Comparing the five years before and after 1998 also showed a 67% decline, suggesting that there was little or no "Wakefield Factor" for reported measles cases.<sup>131</sup>

Dr. Yazbak notes that measles outbreaks were occurring at about the same time in other countries. He points out that in Saudi Arabia, where vaccination rates were between 95% and 98%, there were 4648 cases of measles in 2007 compared to 373 in 2005.<sup>132</sup> The rate of infection was considerably higher in Saudi Arabia than the United Kingdom, and despite media sensationalism, rates of measles infection in the United Kingdom have declined steadily overall.<sup>133</sup>

*c. Potential Explanations for Outbreaks in Highly Vaccinated Populations*

Some argue that outbreaks in highly vaccinated populations are possible because mass vaccination creates "quasi-sterile environment[s]."<sup>134</sup> "[C]onstant re-infection cycles have an essential role in building a stable herd immunity. In a population that is not constantly exposed to the infection . . . a serious risk of re-emerging infections may arise."<sup>135</sup> In other words, young children's infections play a critical role in continually boosting the entire population's immunity. On measles, Dr. Humphries observes:

Susceptible age groups have essentially traded places since vaccinating. What used to happen with measles is that infants were protected by maternal antibodies, adults were protected by continued exposure, and infected children handled the disease normally and became immune for long periods of time. So, while

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<sup>129</sup> *Id.*; see also Holland, *supra* note 127; Lewis, *supra* note 127.

<sup>130</sup> Yazbak, *supra* note 128.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> Humphries, *supra* note 103.

<sup>135</sup> *Id.* (citing A.A. Navarini et al., *Long-Lasting Immunity by Early Infection of Maternal-Antibody-Protected Infants*, 40 EUR. J. IMMUNOLOGY 113 (2010)).

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measles vaccines have decreased the expression of measles infections, it has not necessarily improved the bigger picture.<sup>136</sup>

In sum, two doses of measles vaccine, even to one hundred percent of school populations, does not ensure societal protection from measles outbreaks. While there may be strong rationales for individuals to choose to vaccinate, there would appear to be a weak rationale to compel all children to take the vaccine if one hundred percent vaccination cannot reliably induce herd immunity.

## 2. *The Case of Varicella Vaccination and Immunity*

The U.S. varicella vaccination program provides perhaps an even more troubling example of imperfect vaccines and herd immunity. Drs. Goldman and King have surveyed this program since its inception in 1995.<sup>137</sup> They concluded, based on extensive data and analysis, that “rather than eliminating varicella in children as promised, routine vaccination against varicella has proven extremely costly and has created continual cycles of treatment and disease.”<sup>138</sup>

### a. *The Rollout of the U.S. Varicella Program*

The varicella-zoster virus (VZV) causes chickenpox or varicella as a primary infection.<sup>139</sup> A latency period follows the initial infection, after which the lifelong VZV can subsequently reactivate as herpes zoster (HZ), commonly known as shingles, a secondary infection. After only short-term safety and efficacy clinical trials, pharmaceutical company Merck licensed its varicella vaccine for children one year of age and older.<sup>140</sup> By 1996, the CDC’s Advisory Committee on Immunization Practices had recommended it for universal use in children twelve to eighteen months.<sup>141</sup> As of

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<sup>136</sup> *Id.*

<sup>137</sup> G.S. Goldman & P.G. King, *Review of the United States Universal Varicella Vaccination Program: Herpes Zoster Incidence Rates, Cost-Effectiveness, and Vaccine Efficacy Based Primarily on the Antelope Valley Varicella Active Surveillance Project Data*, 31 VACCINE 1680 (2013).

<sup>138</sup> *Id.* at 1691 (citations omitted).

<sup>139</sup> *Id.* at 1680.

<sup>140</sup> *Id.*

<sup>141</sup> Ctrs. for Disease Control & Prevention, *Prevention of Varicella: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 45 MORBIDITY & MORTALITY WKLY. REP. 1 (1996).

November 2012, all fifty states compelled varicella vaccination for preschool or schoolchildren.<sup>142</sup>

In cost-benefit analyses done before the start of the program, public health officials focused on chickenpox, largely disregarding possible effects on HZ epidemiology.<sup>143</sup> Lieu et al. modeled the cost-effectiveness of a routine varicella vaccination program, finding that vaccination was not cost effective.<sup>144</sup> Vaccine proponents could only justify the program by taking into account the cost of parents' absence from work due to sick children.<sup>145</sup>

Goldman worked as an analyst in one of the three CDC varicella surveillance sites from 1995 to 2005, so he closely observed the early rollout of the program.<sup>146</sup> He argues that the cost-effectiveness analysis from the beginning was based on four key but incorrect assumptions: (1) the vaccine's total cost of \$40 per dose; (2) a single dose confers lifelong immunity; (3) vaccine effectiveness is between 85%–95% with negligible adverse effects; and (4) a universal varicella program has no negative impact on the incidence of HZ.<sup>147</sup> There were many at the precensure phase who questioned these optimistic assumptions, but the licensure process moved forward nonetheless.<sup>148</sup> After licensure, the cost of the vaccine doubled, and one dose failed to protect against disease breakthroughs.<sup>149</sup> An accurate preliminary cost-benefit analysis would have scratched the program.

In addition, though, the assumptions about adverse events and the influence on HZ were way off the mark. People have reported a wide range of adverse events from the varicella vaccine, which proponents had characterized as negligible. These have included problems with vision, the central nervous system, rashes, strokes, secondary transmission to others, pneumonia, breakthrough varicella, Stevens-Johnson syndrome, autoimmune disorders, and death.<sup>150</sup> A 2005

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<sup>142</sup> *Varicella Prevention Mandates*, IMMUNIZATION ACTION COALITION, <http://www.immunize.org/laws/varicel.asp> (last updated Nov. 1, 2012).

<sup>143</sup> Goldman & King, *supra* note 137, at 1680.

<sup>144</sup> *Id.* at 1689.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.* at 1681.

<sup>147</sup> *Id.* at 1685.

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> *Id.* at 1690.

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study found adverse events in one-sixth of the subjects within forty-two days following vaccination.<sup>151</sup>

*b. Herpes Zoster and Varicella Zoster Virus*

Goldman observed herd effect when varicella case reports dropped precipitously after introduction of the vaccine, but saw that the surveillance sites were not capturing data on HZ prevalence. Starting in 2000, at Goldman's recommendation, his surveillance site started to track HZ incidences. After two years, HZ reports remained the same or increased in every adult category except those for adults older than seventy.<sup>152</sup> HZ had also increased among children who previously had chickenpox.<sup>153</sup> When Goldman sought to publish data about trends in HZ, his supervisor arranged for the Los Angeles County Legal Department to send him a "cease and desist" letter<sup>154</sup> to censor publication of the studies.<sup>155</sup> With a response from Goldman's lawyer, the Los Angeles Legal Department dropped its demand, and he published three articles on VZV and HZ.<sup>156</sup>

After widespread introduction of the vaccine in 2002, its effectiveness rate declined significantly, in large part because the boosting effects of naturally circulating varicella virus were gone.<sup>157</sup> Vaccine effectiveness declined rapidly and steeply, such that in several disease outbreaks, the reported vaccine effectiveness rates were between 44% and 56%.<sup>158</sup>

The costs and complications of varicella and HZ in adults are a different magnitude than those of chickenpox in children. Because the

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<sup>151</sup> Gary S. Goldman, *The Case Against Universal Varicella Vaccination*, 25 INT'L J. TOXICOLOGY 313, 315–16 (2006).

<sup>152</sup> Goldman & King, *supra* note 137, at 1681.

<sup>153</sup> *Id.* at 1682.

<sup>154</sup> See *Brief Summary of Chickenpox: A New Epidemic of Disease and Corruption*, DR. GOLDMAN ONLINE, <http://www.drgoldmanonline.com/SummaryofChickenpoxVaccine.pdf> (last visited Mar. 9, 2014) (discussing the "cease and desist" letter).

<sup>155</sup> Goldman & King, *supra* note 137, at 1682.

<sup>156</sup> G.S. Goldman, *Incidence of Herpes Zoster Among Children and Adolescents in a Community with Moderate Varicella Vaccination Coverage*, 21 VACCINE 4243 (2003); G.S. Goldman, *Using Capture-Recapture Methods to Assess Varicella Incidence in a Community Under Active Surveillance*, 21 VACCINE 4250 (2003); Gary S. Goldman, *Varicella Susceptibility and Incidence of Herpes Zoster Among Children and Adolescents in a Community Under Active Surveillance*, 21 VACCINE 4238 (2003).

<sup>157</sup> Goldman, *The Case Against Universal Varicella Vaccination*, *supra* note 151, at 314.

<sup>158</sup> Goldman & King, *supra* note 137, at 1689.

varicella vaccine's protection is short-lived, it shifted chickenpox to a more vulnerable adult population. Chickenpox in adults carries 20 times more risk of death and 10-15 times more risk of hospitalization compared to chickenpox in children.<sup>159</sup> A 2005 article reported that the universal varicella vaccination program caused an additional 14.6 million HZ cases, or a 42% increase among adults younger than fifty during a fifty-year period at a significant medical cost burden.<sup>160</sup>

The rationales for the varicella vaccination program were weak from the outset and weakened further with time. Rather than acknowledge problems and debate solutions when its weaknesses became clear, public health officials apparently made serious attempts to censor problematic information. Neither medical rationales (such as herd immunity) nor cost rationales (based on true cost-benefit analysis) seem to justify the vaccination program. Here, pursuing the objective of herd immunity created a far more costly public health problem than an elective program pursuing herd effect would have created. The varicella vaccine's apparent vaccine effectiveness rate was higher when the virus was in circulation. The marginal gains from the program have not outweighed their marginal costs. This recent example of a compulsory program to achieve herd immunity backfired; instead of herd immunity, the program created herd effect and a series of new, serious public health problems.

To be clear, vaccines have an important role in modern public health policy. Herd immunity as a theory, however, provides an irrational basis for guiding policy, leading to inefficiencies in the marketplace. Furthermore, policies based on herd immunity constrain the significant positive role that individual choice can play in furthering the public health.<sup>161</sup> Indeed, many of the failures noted above are a result of the modern insistence on compulsory vaccination as the only solution to the problem of infectious disease. Mandatory programs rely on unattainable herd immunity, which improperly balances the costs to individuals and the healthcare system with the marginal benefits from compulsory policies.

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<sup>159</sup> *Id.* at 1691.

<sup>160</sup> *Id.* at 1689.

<sup>161</sup> In the language of administrative law, reliance on the herd immunity theory as the basis for vaccination policy must not be "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A) (2012).

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*F. Eradication Versus Elimination: What Can Vaccination Policy Achieve?*

Herd immunity theory rationalizes elimination of infection within a specific population, driving transmission of a disease to zero.<sup>162</sup> Eradication requires global coordination of disease-control programs to ensure that a pathogen is not able to reintroduce itself anywhere in the world.<sup>163</sup> As a result, achieving disease eradication or extinction involves huge investments of healthcare resources toward the goals of developing safe and effective vaccines, ensuring sufficient vaccination coverage to ensure herd immunity in all geographic regions, and efficiently tracking and isolating infections as they arise.<sup>164</sup>

Hinman and others have developed specific terminology to describe the possible objectives of vaccination policy, reproduced below<sup>165</sup>:

1. *Control*: Reduction of disease incidence, prevalence, morbidity, or mortality to a locally acceptable level as a result of deliberate efforts; continued intervention measures are required to maintain the reduction;
2. *Elimination of disease*: Reduction to zero of the incidence of a specified disease in a defined geographic area as a result of deliberate efforts; continued intervention measures are required;
3. *Elimination of infection*: Reduction to zero of the incidence of infection caused by a specific agent in a defined geographic area as a result of deliberate efforts; continued measures to prevent reestablishment of transmission are required;
4. *Eradication*: Permanent reduction to zero of the worldwide incidence of infection caused by a specific agent as a result of deliberate efforts; intervention measures are no longer needed;
5. *Extinction*: The specific infectious agent no longer exists in nature or the laboratory.

This hierarchy highlights the inherent geographic limitations of vaccination policy. Extinction and eradication involve *global* removal

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<sup>162</sup> A. Hinman, *Eradication of Vaccine-Preventable Diseases*, 20 ANN. REV. PUB. HEALTH 211, 213 (1999).

<sup>163</sup> *Id.*

<sup>164</sup> See generally Fine, *History*, *supra* note 2 (detailing the efforts made throughout history toward global eradication of various diseases, including smallpox, influenza, polio, and pertussis).

<sup>165</sup> Hinman, *supra* note 162.

of a specific pathogen from nature, whereas control and elimination, both of disease and of infection, primarily concern *local* efforts to mitigate disease.<sup>166</sup> Few diseases have ever been eradicated; extinction has never been achieved for any modern pathogen.<sup>167</sup>

Hinman identified the following factors favoring eradicability<sup>168</sup>:

1. A highly effective, safe, cheap, and stable vaccine;
2. Lifelong immunity after natural infection or immunization;
3. A short period of communicability;
4. A highly characteristic clinical disease syndrome;
5. An easy and reliable means of diagnosis;
6. The absence of a nonhuman or environmental reservoir of disease;
7. A genetically stable causative agent; and
8. Seasonality of occurrence.

These factors for effective disease eradication raise several issues for a “just” vaccination policy that we address in Part II below.

### *I. Limitations on U.S. Vaccination Policy*

Can U.S. vaccination programs achieve control, elimination, or eradication of disease? Vaccine technology influences the theoretical capability to achieve any of these goals.<sup>169</sup> If the rate of vaccine failure exceeds the herd immunity threshold, society can *never* achieve elimination or eradication.<sup>170</sup> Therefore, disease control is likely the only feasible objective of vaccination programs when society possesses imperfect and potentially harmful vaccination tools.

If the harms of vaccination are high, increasing vaccination coverage imposes higher costs on society through adverse health effects.<sup>171</sup> When herd immunity is lacking, the marginal costs of mandates exceed their marginal benefits.<sup>172</sup> In the “just” vaccination framework, the results misallocate healthcare resources and fail to properly account for the individual’s autonomy interest.<sup>173</sup>

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<sup>166</sup> *Id.* at 213–14.

<sup>167</sup> David H. Molyneux et al., *Disease Eradication, Elimination and Control: The Need for Accurate and Consistent Usage*, 20 *TRENDS PARASITOLOGY* 347, 347 (2004).

<sup>168</sup> Hinman, *supra* note 162, at 214.

<sup>169</sup> See *infra* Part II.D.4.

<sup>170</sup> See *id.*

<sup>171</sup> Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 *U. MICH. J.L. REFORM* 353, 388–93 (2004).

<sup>172</sup> See *infra* Part II.

<sup>173</sup> See *supra* Part I.

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## 2. Communicability, Diagnosis, and the Problems of Contact Tracing

The capacity to control, eliminate, or eradicate a disease depends on the ability to identify cases of infection and proceed rapidly to isolate and treat them.<sup>174</sup> For a population lacking herd immunity, disease transmission among susceptible people is inevitable.<sup>175</sup> Control of infectious outbreaks then involves the process of contact tracing.<sup>176</sup> Contact tracing is the “backward” mapping of disease spread. Starting from any infected person or group of infected people, the problem is tracing the line of infectious contacts back to the first known “index” case, treating individuals along the chain to prevent further transmission.<sup>177</sup> Contact tracing is an iterative process that attempts to identify all contacts for each infected index case.<sup>178</sup>

If the rate of disease spread exceeds the rate at which scientists can trace cases, then the disease will spread faster than it is possible to control it, and contact tracing will fail.<sup>179</sup> The resulting “race to trace” involves a competition between infectious dynamics and the ability to identify and trace infectious individuals.<sup>180</sup> A short period of disease communicability facilitates elimination of a disease.<sup>181</sup> Conversely, a long period of communicability makes eradication or elimination virtually impossible.<sup>182</sup>

## 3. Disease Adaptability

To successfully eradicate infectious disease, the pathogen must be stable, and there must be no animal or other reservoir for the disease.<sup>183</sup> If a particular pathogen is not genetically stable, then

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<sup>174</sup> See Ken T.D. Eames & Matt J. Keeling, *Contact Tracing and Disease Control*, 270 PROC. ROYAL SOC’Y LONDON 2565, 2569 (2003) (describing contact tracing as efficient means of identifying cases of infection).

<sup>175</sup> See Fine, *Rough Guide*, *supra* note 2, at 913.

<sup>176</sup> See Ken T.D. Eames, *Contact Tracing Strategies in Heterogeneous Populations*, 135 EPIDEMIOLOGY & INFECTION 443, 443 (2006) (discussing models of contact tracing); Eames & Keeling, *supra* note 174, at 2565 (discussing how contact tracing can efficiently be used to identify individuals with sexually transmitted diseases).

<sup>177</sup> See Eames, *supra* note 176, at 444.

<sup>178</sup> See *id.* at 446.

<sup>179</sup> See *id.* at 448.

<sup>180</sup> See *id.* at 450.

<sup>181</sup> See *id.* at 448.

<sup>182</sup> See *id.*

<sup>183</sup> See David M. Morens & Anthony S. Fauci, *Emerging Infectious Diseases: Threats to Human Health and Global Stability*, 9 PLOS PATHOGENS 1, 2–3 (2013) (discussing

vaccines may not afford any protection against related strains.<sup>184</sup> A prime example is *Bordetella parapertussis*, which causes symptoms similar to *Bordetella pertussis*, the bacterium responsible for whooping cough.<sup>185</sup> Immunity to *B. pertussis* does not confer immunity against *B. parapertussis*, suggesting that the current *B. parapertussis* virus may have evolved in response to vaccination against *B. pertussis*.<sup>186</sup>

Diseases can also spread through animal and insect vectors.<sup>187</sup> For example, malaria infects humans through mosquitoes, so efforts to control malaria require insect-control programs.<sup>188</sup> More generally, when a pathogen can survive in nonhuman reservoirs, it can continue to infect the human population.<sup>189</sup> In many cases it may be impossible to identify which nonhuman repositories exist, making eradication unachievable.<sup>190</sup>

Disease eradication seems unattainable in the near future for all infectious childhood diseases, including measles and chickenpox.<sup>191</sup> Disease control seems to be the most viable goal. We consider next a framework within which to evaluate vaccination program objectives.

## II

### “JUST” VACCINATION POLICY AND PUBLIC HEALTH

Because herd immunity is not an appropriate objective of contemporary vaccination policy, the normative question arises as to what *should* be the correct goal. To address this issue, we adopt the Feudtner-Marcuse model of “just” vaccination policy, which identifies seven factors that must be appropriately weighted and balanced in designing vaccination programs.

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common reemergence of diseases with nonhuman reservoirs and pathogens that undergo rapid changes).

<sup>184</sup> See Daniel N. Wolfe et al., *The O Antigen Enables Bordetella Parapertussis to Avoid Bordetella Pertussis-Induced Immunity*, 75 *INFECTION & IMMUNITY* 4972, 4978 (2007).

<sup>185</sup> See *id.* at 4972.

<sup>186</sup> See SUZANNE HUMPHRIES & ROMAN BYSTRIANYK, *DISSOLVING ILLUSIONS: DISEASE, VACCINES, AND THE FORGOTTEN HISTORY* 324–30 (2013) (discussing “original antigenic sin committed by vaccination”); see also *id.*

<sup>187</sup> See Molyneux et al., *supra* note 167, at 351 (contemplating that insect vectors, such as mosquitoes, can infect humans with diseases).

<sup>188</sup> See *id.* at 350 tbl.2.

<sup>189</sup> See *id.* at 349.

<sup>190</sup> See *id.*

<sup>191</sup> See *infra* Part III.

Drs. Feudtner and Marcuse, who have worked extensively on U.S. vaccination programs, introduced the “just” vaccination policy framework more than a decade ago.<sup>192</sup> Overall, we agree with the elements of their framework; however, we draw substantially different conclusions concerning current U.S. vaccination policy.

#### *A. Framework for “Just” Vaccination Policy*

Feudtner and Marcuse’s framework provides seven objectives for modern vaccination policy<sup>193</sup>:

1. Minimization of the deleterious effects of disease;
2. Minimization of the deleterious effects of vaccination;
3. Optimization of personal liberty to choose or to refuse vaccination,<sup>194</sup>
4. Maximization of an equitable distribution of benefits and burdens across members of society;
5. Promotion of the duty of families to protect children;
6. Promotion of the duty of society to protect current and future children; and
7. Prudent utilization of healthcare resources.<sup>195</sup>

The framework provides a reasonably comprehensive approach, although the model entirely discounts the possible benefits of contracting and overcoming disease naturally, thereby achieving long-lasting immunity. Below, we explore open questions about how to weigh the factors in “just” vaccination policy.<sup>196</sup>

Feudtner and Marcuse propose three types of programs: elective, recommended, and mandatory. An elective program uses public education to inform individuals about the availability, benefits, and risks of vaccination, but leaves the choice to immunize at the sole

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<sup>192</sup> See Chris Feudtner & Edgar K. Marcuse, *Ethics and Immunization Policy: Promoting Dialogue to Sustain Consensus*, 107 PEDIATRICS 1158 (2001).

<sup>193</sup> *Id.* at 1163 tbl.2.

<sup>194</sup> Although Feudtner and Marcuse refer to the personal liberty objective in terms of “optimization,” it is somewhat ambiguous whether this term is equivalent to *maximization* in the same sense as used in the other objectives or whether Feudtner and Marcuse intend this factor to carry less weight in the balancing analysis. This distinction in turn depends on the questions of how and whether to weigh these factors.

<sup>195</sup> Feudtner & Marcuse, *supra* note 192, at 1163 tbl.2.

<sup>196</sup> Indeed, Feudtner and Marcuse analyze their model with what amounts essentially to a tabulation of the various factors. Such an approach avoids the difficult question of weighing the policy considerations, but we also disagree with many of their conclusions concerning whether mandatory vaccination programs best achieve certain objectives.

discretion of parents in the case of childhood vaccination.<sup>197</sup> A recommended program, by contrast, uses public education and expert advice to induce uptake.<sup>198</sup> Whereas the elective program provides information to the vaccine consumer but offers no opinion, recommended programs aim to raise immunization rates.<sup>199</sup> Finally, mandatory programs leave almost no discretion to individuals on whether to vaccinate, with significant penalties for non-compliance.<sup>200</sup>

Feudtner and Marcuse argue that mandatory programs best minimize disease harms, maximize the equitable distribution of benefits and burdens within society, promote the societal duty to protect children, and use healthcare resources most prudently.<sup>201</sup> They acknowledge, though, that elective programs best minimize vaccine harms and optimize personal liberty.<sup>202</sup> Furthermore, they assert that recommended programs best promote a familial duty to protect children.<sup>203</sup> In the model, a simple tabulation of the seven factors suggests that mandatory programs are the most “just.”<sup>204</sup> But to what extent does this conclusion follow? Agreeing with the model’s objectives in principle, we consider each of their factors in turn.

### *1. Minimization of Disease Harm*

A vaccination program in theory can reduce the risk of harm from infectious disease to zero if it completely eliminates the disease from circulation. The conclusion that a mandatory program best achieves this objective assumes that mandates ensure the highest level of uptake, thus reducing the rate at which disease can spread. Based on this theory, policymakers believe that minimizing individual choice necessarily reduces disease harms.<sup>205</sup> Imposing penalties for failure to vaccinate requires each individual to take on the burden of the collective, conceivably increasing the number of individuals willing to vaccinate.

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<sup>197</sup> Feudtner & Marcuse, *supra* note 192, at 1161.

<sup>198</sup> *Id.*

<sup>199</sup> *Id.*

<sup>200</sup> *Id.*

<sup>201</sup> *Id.* at 1163 tbl.2.

<sup>202</sup> *Id.* at 1163.

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*

<sup>205</sup> *Id.* at 1161.

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This analysis fails, however, when it is possible to eliminate or sufficiently mitigate the spread of infection without requiring all individuals to vaccinate. If herd immunity is possible, then society can obtain the same benefits without imposing *unnecessary* vaccination costs. The herd immunity theory applies precisely to this situation because it predicts a unique threshold beyond which a disease can no longer sustain infection throughout the population. If enough people in society have immunity, and if either a recommended or an elective program is sufficient to achieve the herd immunity threshold, then *mandatory programs impose excessive costs with no marginal gains*. These costs include manufacturing, healthcare providers, administration, and the costs of potential injury and treatment.

### 2. *Minimization of Vaccine Harm*

Vaccine harm is zero when people do not vaccinate, making this objective the opposite of factor one's minimization of disease harms. Some balance between disease prevention and protection against vaccine harms is necessary. Mandatory programs do not necessarily reconcile these competing objectives, given the temporary protection of vaccine-induced immunity and the uncertainty about potential vaccine harms. Conversely, choosing a purely elective program may or may not reach the herd immunity threshold and sufficiently prevent disease in the broader society. Nevertheless, as Feudtner and Marcuse acknowledge, an elective program best minimizes vaccine-related harms.<sup>206</sup>

### 3. *Maximization of an Equitable Distribution of Benefits and Harms*

In the absence of vaccines, all people share the expected risks of disease, but they do not share them equally.<sup>207</sup> People of different ages and health statuses have differing levels of natural immunity.<sup>208</sup> Natural immunity implies that, with age, more and more people have acquired the disease, recovered from it, and subsequently become immune.<sup>209</sup> This is because: (1) a longer lifetime implies a greater chance of having already encountered the disease, and (2) naturally-

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<sup>206</sup> *Id.* at 1163 tbl.2.

<sup>207</sup> *See, e.g.,* Reluga et al., *supra* note 98, at 2711–19.

<sup>208</sup> *Id.* at 2718.

<sup>209</sup> *See id.* at 2718–19.

acquired immunity among older individuals makes it more difficult for the disease to sustain itself among that group.<sup>210</sup> Thus, the result is that children are ordinarily at greater risk of infection than healthy adults.<sup>211</sup>

Vaccines create competing risks between infection and injury. On the one hand, requiring all children to vaccinate ensures that all children face the risks of both vaccination and disease. But such a program may not be preferable, however, if only a small portion of the population is particularly susceptible. Requiring vaccination of non-susceptible individuals forces them to accept risks without benefits, a scenario that raises the specter of constitutional equal protection violations under the Fourteenth Amendment.<sup>212</sup>

#### 4. Optimization of Personal Liberty

Elective vaccination programs maximize individual choice, protecting the autonomy interest in bodily integrity.<sup>213</sup> How much weight should we give to this? Feudtner and Marcuse give individual liberty little or no deference, nor do other proponents of mandatory vaccination.<sup>214</sup>

Several commentators have recently proposed tort-based negligence liability for individuals who choose not to vaccinate and transmit disease.<sup>215</sup> They argue that the tort system would then force unvaccinated individuals to accept responsibility for their choice.<sup>216</sup> Such a proposal is another form of a mandatory program with enforcement through civil liability. Individuals then would discount the possible risks of their actions by the “detection” probability of

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<sup>210</sup> See *id.* at 2712.

<sup>211</sup> However, this observation is not universally true. One prominent example is rubella, which can have severe health complications on unborn children when acquired by a pregnant mother. In this case, the most severe health costs may be associated with the older subpopulation of pregnant women, which may alter the choice of a vaccination program. See generally *id.* at 2711–21.

<sup>212</sup> See Holland, *supra* note 63, at 42–59, 85.

<sup>213</sup> Feudtner & Marcuse, *supra* note 192, at 1163 tbl.2.

<sup>214</sup> See generally Gregory A. Poland & Robert M. Jacobson, *The Clinician's Guide to the Anti-Vaccinationists' Galaxy*, 73 HUMAN IMMUNOLOGY 859 (2012); Susanne Sheehy & Joel Meyer, *Should Participation in Vaccine Clinical Trials be Mandated?*, 14 VIRTUAL MENTOR 35 (2012) (suggesting that the government should enforce a duty for all citizens to participate in clinical trials).

<sup>215</sup> See generally Rebecca Rodal & Kumanan Wilson, *Could Parents Be Held Liable for Not Immunizing Their Children?*, 4 MCGILL J.L. & HEALTH 39 (2010); Diekema, *supra* note 7.

<sup>216</sup> See Diekema, *supra* note 7, at 94.

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facing a lawsuit.<sup>217</sup> Despite valuation problems, Feudtner and Marcuse acknowledge that elective vaccination programs best maximize liberty for parents to choose on their children's behalf.<sup>218</sup>

##### *5. Promotion of a Familial Duty to Protect Children*

Feudtner and Marcuse identify the familial duty to protect children as the sole objective that a recommended program best fulfills, arguing that medical professionals can best help families protect children.<sup>219</sup> Parents concerned about the potential harms of vaccines are often in direct conflict with their physicians, some of whom refuse to accept and retain children in their practices who fail to comply with vaccination recommendations.<sup>220</sup> Unfortunately, physicians who refuse to see noncompliant families may leave them without healthcare.<sup>221</sup> A recommended program may serve the interests of protecting children while preserving the right to informed consent for the parent, but both physician and patient are on uncertain ground.<sup>222</sup>

By contrast, a mandatory program gives parents no discretion to act in their own children's best interests, a situation that drives a wedge between parents and physicians.<sup>223</sup> This could result in a "black market" of vaccination records, providing false information, and inhibiting the capacity of state, local, and federal agencies to track and contain the spread of disease in the event of an epidemic. Just as in the cases of abortion, medical use of marijuana, and other medical prohibitions, some families simply will not comply with state public health laws as a matter of conscience.

##### *6. Promotion of a Societal Duty to Protect Children*

Feudtner and Marcuse conclude that mandatory vaccination programs, rather than recommended ones, best promote society's duty to protect children.<sup>224</sup> Some view mandatory programs as the best

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<sup>217</sup> See Rodal & Wilson, *supra* note 215, at 63.

<sup>218</sup> Feudtner & Marcuse, *supra* note 192, at 1162.

<sup>219</sup> *Id.* at 1163.

<sup>220</sup> See Douglas S. Diekema, *Improving Childhood Vaccination Rates*, 366 NEW ENG. J. MED. 391, 393 (2012) (noting that asking patients to seek other healthcare options is counterproductive).

<sup>221</sup> *See id.*

<sup>222</sup> Feudtner & Marcuse, *supra* note 192, at 1163.

<sup>223</sup> *Id.* at 1161.

<sup>224</sup> Feudtner & Marcuse, *supra* note 192, at 1163.

way for the state to exercise appropriate paternalism and prevent children from contracting disease. The reason for the discrepancy between society's duty and the familial one is the recognition of an *implied duty of care* between all members of society and children, not just a recognition of the state's duty to the child.<sup>225</sup> The legal foundation for this implied duty is suspect, because there is no clear analog in common law criminal or tort systems for a duty to rescue, even when a person can do so at small or no cost to herself.<sup>226</sup> If the common law is unwilling to impose liability on individuals toward strangers, Feudtner and Marcuse may be wrong as a matter of law to suggest that a mandatory program may impose a duty on all members of society to protect children.

There is a distinction between a duty to rescue and an implied duty to vaccinate. Children have a higher risk of infection than healthy adults because of their age. If vaccine-induced harm carries a relatively small risk, then there may be a basis to impose such a duty on society as a whole. However, it still does not follow that mandatory vaccination is the optimal mechanism. Under the theory of herd immunity, society need not achieve complete vaccination coverage to mitigate the spread of infection.<sup>227</sup> If a recommended or elective program can contain disease, then it is likely superior to a mandatory one.

### 7. Prudent Utilization of Healthcare Resources

Thoughtful use of resources, unlike the six factors above, refers to *implementing* a particular program rather than to theoretical tensions between liberty and collective security.<sup>228</sup> At first, resource allocation may appear only incidental to a "just" vaccination program; on further examination, however, it is of primary importance in balancing society's healthcare interests.<sup>229</sup> This factor is foremost in the discussion of vaccination choice in Part III. Society should be willing to invest healthcare resources, including funding, infrastructure, and research, in those endeavors that are likely to achieve the greatest aggregate benefit at the lowest aggregate cost.<sup>230</sup> Although Feudtner

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<sup>225</sup> See *id.* at 1160.

<sup>226</sup> See generally Ernest J. Weinrib, *The Case for a Duty to Rescue*, 90 YALE L.J. 247 (1980) (evaluating the case for imposing a duty to rescue).

<sup>227</sup> See Poland & Jacobson, *supra* note 214, at 862.

<sup>228</sup> See Feudtner & Marcuse, *supra* note 192, at 1163.

<sup>229</sup> See *id.* at 1160–61.

<sup>230</sup> See *id.* at 1161.

and Marcuse suggest that a mandatory program best achieves the prudent use of resources,<sup>231</sup> this conclusion is doubtful. If the marginal benefit of a mandatory program does not exceed the marginal cost of implementation, then society can better invest its healthcare resources elsewhere.<sup>232</sup> This observation is particularly true for most childhood infectious diseases where herd immunity is per se unachievable because the vaccine failure rate exceeds the herd immunity threshold.<sup>233</sup> Undervaluing pragmatism risks exposing individuals to unnecessary harms for which there are no commensurate gains.<sup>234</sup> This factor is absolutely critical to ensuring efficiency in the vaccination market and therefore must play a central role in designing vaccination programs.

### *B. Weighing the Feudtner-Marcuse Factors*

Feudtner and Marcuse's attempt to analyze the justice of vaccination policies is insightful.<sup>235</sup> While we do not reach the same conclusions they do, we find their measurements relevant and worthy of further examination. We may agree that a *uniform* "just" vaccination policy is impossible.<sup>236</sup> "Just" policies depend upon the specifics of the individual, the population, the disease, and the potential vaccine efficacy, injuries, and costs. There is no "one-size-fits-all" solution, although that seems to be the goal of most mandatory programs.

We argue that the original model undervalues considerations of individual autonomy, misapplies the notion of a social duty to vaccinate, and critically fails to provide a pragmatic use of healthcare resources for infectious disease. We claim that the proper focus of programs cannot be eradication of disease "at all costs"; indeed, Feudtner and Marcuse acknowledge this limitation by advocating prudent allocation of healthcare resources.<sup>237</sup> Efficiency requires taking account not only of the costs of infection, but also of the costs

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<sup>231</sup> *Id.* at 1163.

<sup>232</sup> *See id.* at 1161.

<sup>233</sup> *See supra* Part I.E.1.i. (discussing measles as an example for which herd immunity is likely unattainable given the rapid rate at which the disease spreads through a population and the relatively low vaccine efficacy).

<sup>234</sup> *See Feudtner & Marcuse, supra* note 192, at 1161.

<sup>235</sup> *See id.* at 1160.

<sup>236</sup> *See id.* at 1162.

<sup>237</sup> *Id.* at 1160.

of the “cure.”<sup>238</sup> In striving for unattainable herd immunity, society pays a heavy price.<sup>239</sup>

We conclude that the appropriate and rational objective of modern vaccination programs should be to maximize herd effect to the extent that marginal gains in vaccination coverage are not outweighed by the marginal costs to the individual, the healthcare system, and society. This objective is fully consistent with contemporary regulatory policy<sup>240</sup> and properly balances individual choice, direct and indirect costs to healthcare, and the real benefit that vaccines provide in protecting individuals from infectious diseases.

### III

#### A GAME THEORY ANALYSIS OF VACCINATION DECISIONS

Proponents of mandatory policies argue that failure to vaccinate breaches an implied duty to other members of society to protect the herd.<sup>241</sup> Under free rider assumptions, herd immunity cannot exist without government compulsion.<sup>242</sup> Game theory, however, provides a useful alternative framework for examining the severity of the free rider problem. The aim of game theory is to identify optimal strategies for people in which their gains depend on others’ choices.<sup>243</sup> Using game theory, Chris Bauch and David Earn have attempted to quantify the effect of risk perception on a person’s willingness to vaccinate with perfectly efficacious vaccines.<sup>244</sup> Their analysis lays the foundation for market-based solutions to vaccination policy. In order to facilitate discussion, however, we will only generally review game theory and readers should refer to the original Bauch-Earn analysis for technical details.<sup>245</sup>

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<sup>238</sup> See *id.* at 1163.

<sup>239</sup> See *id.* at 1161.

<sup>240</sup> See Exec. Order No. 12,866 § 1(b)(6) (“Each agency shall . . . adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”); *id.* at § 1(b)(11) (“Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities . . . consistent with obtaining the regulatory objectives . . .”).

<sup>241</sup> See Diekema, *supra* note 7, at 93 (suggesting that parents who do not vaccinate their children should be subject to civil negligence liability).

<sup>242</sup> See *id.* at 91.

<sup>243</sup> See generally KEN BINMORE, GAME THEORY: A VERY SHORT INTRODUCTION (2007) (discussing game theory and the way humans interact in certain cooperative scenarios).

<sup>244</sup> See generally Chris T. Bauch & David J.D. Earn, *Vaccination and the Theory of Games*, 101 PROCS. NAT’L ACAD. SCI. 13391 (2004).

<sup>245</sup> See *id.*

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### *A. Game Theory of Vaccination Choice*

The following scenario provides the framework for the Bauch-Earn “vaccination game.”<sup>246</sup> Alice is a rational “player” in a large, homogeneous population trying to decide whether to vaccinate or to take her chances and get sick. To help her with the decision, she has in front of her a box of coins. Each coin is labeled according to the probability  $P$  that on any given toss it will come up heads; the coins are therefore biased, or rigged, to come up heads a specific fraction of the time. Alice can choose any coin in the box, and she will choose to vaccinate if, upon tossing the coin, it comes up heads; otherwise, she will not vaccinate. The “vaccination game” is therefore as follows: which coin should Alice choose in order to maximize her expected net health benefits, given that everyone else in the population is also playing this same game? In other words, how does Alice maximize her *individual* health benefits given the *collective* choices of others?

The “vaccination game” is a form of cost-benefit analysis, based on the information she gathers from others’ “successes” in the game. Furthermore, Alice is not an automaton; her goal is not merely to decide *whether* to vaccinate but, more importantly, to pick *the best* coin, that is, the coin that will minimize her risks of both vaccination and infection. Specifically, if her coin comes up heads, then Alice will face the risks of potential vaccine injury and future booster shots to preserve immunity.<sup>247</sup> Conversely, if the coin lands tails, then she faces the potential but uncertain risk of infection. Alice will discount the risks of infection by the probability that she may get sick, which decreases as a function of increasing vaccination coverage.<sup>248</sup> At the herd immunity threshold, Alice’s risks of not vaccinating are zero because she can “free ride” on herd immunity. With her biased coin

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<sup>246</sup> *Id.* at 13394 (describing how game theory can be used to develop schemes regarding disease eradication; the coin toss game set forth here serves as an illustration of the vaccination game described by Bauch and Earn).

<sup>247</sup> Note that this cost is an average cost over all possible “adverse” events of the vaccine, including the chance that nothing will happen. This average cost is always negative because the net benefit of the vaccine is prevention of the disease, which is not a *net* gain to the player if she does not have the disease when she starts the game.

<sup>248</sup> Beyond the herd immunity threshold, by definition the disease cannot support itself in the population, and no individual will attain the disease regardless of vaccination status. However, the rate at which a disease is transmitted through a population will increase as the fraction of people choosing to vaccinate falls below the herd immunity threshold, meaning that the probability of any individual acquiring the disease must also increase as the vaccine coverage level decreases.

and a perceived estimate of these risks, Alice can then figure out her best strategy.

To understand how other players will affect Alice's strategy in the "vaccination game," assume that Bob is also playing the game with a biased coin that comes up heads with probability  $Q$ . If Alice and Bob have equal information about the risks of vaccination and infection,<sup>249</sup> then they will both obtain gains. However, they will discount the risks differently because they are playing with different coins.<sup>250</sup> Who then is doing *better* in the game by drawing a greater payoff, where the payoff is maximization of all benefits and minimization of all harms? If Bob is obtaining a greater payoff with coin  $Q$ , then there is no reason for Alice to play with coin  $P$ ; the converse will be true if Alice obtains a better payoff. Furthermore, if Cindy can beat both Alice and Bob by using coin  $O$ , then both Alice and Bob will switch to Cindy's coin. It is through this type of information exchange based on the performance of other players that we can identify the *optimal strategy* for the vaccination game, a coin  $P^*$  with an expected payoff greater than with any other coin.<sup>251</sup>

### *B. Theoretical Optimum Vaccination Choice Strategy*

There are two possible variants to the "vaccination game": (1) the vaccine is perfectly efficacious, as in the scenario considered by Bauch and Earn,<sup>252</sup> and (2) the vaccine is imperfect, as in the "real-world" case. The analysis of this latter scenario is original to this Article.

#### *1. Using a Perfect Vaccine*

Bauch and Earn prove that there are two possible optimal strategies for the vaccination game with the perfectly efficacious vaccine.<sup>253</sup> If

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<sup>249</sup> Alice and Bob represent "average" members of the population in the sense that their estimates rely on the same information available to the public. The Bauch-Earn framework therefore faces several of the same limitations of the herd immunity theory discussed in Part II, but the results provide a useful systematic framework for evaluating the scope and direction of U.S. vaccination policy.

<sup>250</sup> Note that all players in the vaccination game will discount the costs of vaccination by the probability that the coin comes up heads and will similarly discount the costs of infection by the probability that the coin lands tails.

<sup>251</sup> See Bauch & Earn, *supra* note 244, at 13394 (Bauch and Earn prove that  $P^*$  is a stable Nash equilibrium for the vaccination game, meaning roughly that it is indeed better than any other coin that Alice could choose from her box.).

<sup>252</sup> *Id.*

<sup>253</sup> *Id.*

the perceived risks of vaccination are greater than the perceived risks of infection when *no one* is vaccinating,<sup>254</sup> then the optimal strategy is in fact never to vaccinate.<sup>255</sup> Indeed, this “tragedy of the commons” occurs *only* when the costs to the individual from vaccine uptake are extraordinarily high.

In the alternative case where the perceived vaccination risks are less than the worst-case infectious disease scenario, there is a *stable equilibrium point*  $P^*$  between zero and one that Bauch and Earn show is equal to the vaccination coverage  $\theta^*$  necessary to exactly balance the risks of vaccination and infection.<sup>256</sup> To understand why this result is true, note that when the perceived vaccination risks are less than the worst-case infectious disease scenario, then there must exist a vaccination coverage level  $\theta^*$  at which the expected risks of vaccination balance the risks of infection.<sup>257</sup> If society vaccinates below this level, then risks of infection will be greater than the risks of vaccination, and unvaccinated individuals will have an incentive to vaccinate.<sup>258</sup> Conversely, when society vaccinates above this level, the aggregate risks of vaccination exceed the aggregate harms of infection, and the incentive is to forego vaccination.<sup>259</sup> Therefore, deviations in either direction from the equilibrium coverage  $\theta^*$  should return over time to this equilibrium point.<sup>260</sup> The question is then whether  $\theta^*$  is at least equal to the herd immunity threshold  $\theta_H$ , the answer to which is no in practically all cases. Indeed, herd immunity is only obtainable as an equilibrium point when there are no further risks of vaccination or infection.<sup>261</sup> Bauch and Earn verify this

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<sup>254</sup> If no one in the population is vaccinating, then the vaccine coverage is zero, and the expected costs of infection are maximal for the individual.

<sup>255</sup> Bauch & Earn, *supra* note 244, at 13393.

<sup>256</sup> *Id.* at 13394.

<sup>257</sup> Recall that the probability of acquiring an infection decreases with increasing vaccine coverage from the “worst-case scenario” at zero coverage until it vanishes at the herd immunity threshold. Therefore, if the costs of vaccinating are below the “worst-case” level, these vaccination costs must meet with the expected infection costs at some vaccination level between zero and one.

<sup>258</sup> Bauch & Earn, *supra* note 244, at 13393–94.

<sup>259</sup> *Id.*

<sup>260</sup> *Id.* at 13394.

<sup>261</sup> The only point where the costs of infection are zero is at the herd immunity threshold, meaning that if the herd immunity threshold is an equilibrium point, the costs of vaccination must also vanish.

conclusion through simulations on model populations of susceptible, infectious, and recovered individuals.<sup>262</sup>

## 2. *Using an Imperfect Vaccine*

As in the real world, what if a vaccine provides imperfect immunity with an efficacy of probability  $\eta$ ? The new setup for the vaccination game then has several important changes:

- If Alice's biased coin comes up heads, she faces the expected risks of the vaccine itself *and also* the expected risks of infection if the vaccine fails.
- The expected risks of infection exist even at the herd immunity threshold because the vaccine is imperfect, meaning that society must invest additional resources to eliminate the disease. If the vaccine efficacy  $\eta$  is less than the herd immunity threshold, then herd immunity is impossible to achieve.

If the perceived risks of vaccination are greater than the “worst-case scenario” when no one vaccinates, then the optimal strategy is not to vaccinate.<sup>263</sup> However, the vaccination risks need not be this high. Alice would still choose not to vaccinate even if the expected vaccination risks are below the “worst-case” infection risks, because she also expects to face some infection risks when she vaccinates with an imperfect vaccine. In fact, this analysis predicts this “do not vaccinate” result in all cases where the expected vaccination risks exceed the “worst-case” infection risks *discounted* by the probability of vaccine efficacy  $\eta$ .

### C. *Vaccination Choice Strategy in the “Real World”*

How does the equilibrium vaccination coverage with the imperfect vaccine compare to the result for the game with the perfect vaccine? Intuitively, one might think that the equilibrium vaccination coverage with the imperfect vaccine should be less than the corresponding equilibrium coverage for the perfect vaccine. However, it turns out that this result is only true when the expected vaccination risks are high. When the expected vaccination risks are relatively low,<sup>264</sup> there

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<sup>262</sup> Bauch & Earn, *supra* note 244, at 13392.

<sup>263</sup> *Id.* at 13393.

<sup>264</sup> The notion of “relatively low” can be made quantitative by comparing the infectious cost curves for the perfect and imperfect vaccines and by noting that there exists a “cross-over” point at a certain level of vaccine coverage due to the longer tail on the cost distribution for the imperfect vaccine.

is a greater risk of infection than risk of vaccine harm.<sup>265</sup> When a vaccine provides even incomplete protection to infection, the marginal benefit of using it may be perceived to be relatively large.<sup>266</sup>

So what are the results of elective vaccination programs? A follow-up article by Perisic and Bauch in 2009 suggests that they work.<sup>267</sup> As with the herd immunity analysis in Part I, the game theory model assumes population homogeneity.<sup>268</sup> Utilizing a network population model, in which individuals in the population only interact with neighbors with whom they share a connection, Perisic and Bauch show that altruism develops within tightly connected “neighborhoods” of individuals, decreasing the total spread of disease.<sup>269</sup> Within small neighborhoods, people will voluntarily vaccinate with a relatively safe vaccine.<sup>270</sup> As the neighborhood size increases, however, the infection is more likely to escape to infect the larger population, thereby approaching the disease dynamics in a homogeneous population.<sup>271</sup>

Reluga, Medlock, Poolman, and Galvani have also shown that age stratification can affect optimal strategy.<sup>272</sup> They show that because vaccination at a young age increases the average age of initial infection, it may be better for people to acquire natural immunity through infection at a young age rather than to risk greater harm from waning vaccine-induced immunity at a later age.<sup>273</sup> Game theory suggests that a market will best balance vaccine and infection risks and benefits.

Although not the conventional wisdom, evidence suggests that individual choice is not at odds with public health benefits from vaccines. To the extent that individuals contribute to herd effect both through vaccine-induced and natural immunity, “soft” regulation of the market can create the same or higher levels of public health more efficiently than compulsion. Indeed, Drs. Yang and Debold have recently demonstrated that for several diseases, there is no statistically

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<sup>265</sup> Bauch & Earn, *supra* note 244, at 13393–94.

<sup>266</sup> *Id.*

<sup>267</sup> Ana Perisic & Chris T. Bauch, *Social Contact Networks and Disease Eradicability Under Voluntary Vaccination*, 5 PLOS COMPUTATIONAL BIOLOGY 1, 2 (2009).

<sup>268</sup> *Id.*

<sup>269</sup> *Id.*

<sup>270</sup> *Id.*

<sup>271</sup> *Id.*

<sup>272</sup> Reluga et al., *supra* note 98.

<sup>273</sup> *Id.* at 2718–19.

significant relationship, at the ninety-five percent confidence level, between measures of non-medical childhood disease exemptions and disease incidence rates in the fifty states.<sup>274</sup> Although several open issues of their study remain for the scientific literature to consider,<sup>275</sup> their empirically-based study results strongly reinforce the view that herd immunity should not be the *de facto* objective of vaccination policy.

A voluntary approach to maximizing herd effect ensures efficiency of the vaccination marketplace and preserves individual choice. Policymakers should reconsider the appropriate level of regulation of the vaccination market, explicitly balancing the costs of vaccination coverage with the expected benefits from a particular vaccination program.<sup>276</sup>

#### CONCLUSION AND RECOMMENDATIONS

Herd immunity is generally unattainable in the real world because key assumptions, like population homogeneity, do not exist and because current vaccine technology is imperfect. Vaccination programs should therefore aim to achieve herd effect, not herd immunity and concomitantly, disease control rather than eradication.

The free rider problem is a red herring. The Bauch-Earn game theory analysis and experience suggest that it does not drive individual decision making in the real world.<sup>277</sup> If safe and effective vaccines are available, most people will voluntarily accept the risks of vaccination rather than the potential risks of serious infectious disease.

Market forces will naturally lead to an equilibrium point for vaccination; mandates to increase coverage above the equilibrium point yield little or no marginal gains in the absence of obtainable herd immunity. Vaccination programs should therefore focus on “soft” regulation by investing in safer and more efficacious vaccine

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<sup>274</sup> Yang & Debold, *supra* note 14, at 374–76.

<sup>275</sup> *Id.* at 375.

<sup>276</sup> See OFFICE OF MGMT. & BUDGET, *supra* note 8, at 9–10 (noting that an agency “should also perform a [benefit-cost analysis] for major health and safety rulemakings to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes[.]” and that even “[i]f the non-quantified benefits and costs are likely to be important, [the agency] should recommend which of the non-quantified factors are of sufficient importance to justify consideration in the regulatory decision”).

<sup>277</sup> Bauch & Earn, *supra* note 244, at 13393–94.

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technology, ensuring informed consent and opening lines of communication between parents, physicians, and policymakers.

These conclusions lead to the following specific recommendations for U.S. federal and state vaccine policy makers. First, federal and state vaccination programs should acknowledge that the goal of vaccine policy is to control disease, not eradicate it. Effective programs should focus on creating herd effect, not herd immunity, and take into account all the economic costs and health risks of vaccination.

Second, states should experiment with market-based approaches to vaccination, freeing resources otherwise devoted to compliance to other healthcare needs. States can change mandates to recommended or elective programs with relative ease and observe what consequences follow. States can start by removing those vaccination mandates that have inadequate public health rationales, such as the mandate for tetanus, which is non-contagious, and for hepatitis B, which is primarily sexually transmitted and a disease for which children are at low risk.

Third, states should ensure that vaccine consumers receive complete information to make rational choices. States can impose higher informational requirements than current federal law. Under federal law, parents are required to receive only minimal information on vaccination benefits and risks.<sup>278</sup> States should require that parents or guardians receive all the information they would otherwise obtain with any prescription drug.

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Parents can and should be able to determine their own children's best interests and voluntarily choose vaccines based on complete and accurate information. Prior, free, and informed consent is the hallmark of modern ethical medicine.<sup>279</sup> The "choice" between fulfilling a child's vaccination mandates or foregoing her education is

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<sup>278</sup> 42 U.S.C. § 300aa—26 (2012) (describing the Vaccine Information Statements that the CDC now produces); see *Vaccine Information Statements*, CTRS. FOR DISEASE CONTROL & PREVENTION, [http://www.cdc.gov/vaccines/hcp/vis/index.html?s\\_cid=cs\\_000](http://www.cdc.gov/vaccines/hcp/vis/index.html?s_cid=cs_000) (last updated June 11, 2014).

<sup>279</sup> *Universal Declaration on Bioethics and Human Rights*, UNITED NATIONS EDUC., SCIENTIFIC, AND CULTURAL ORG. (UNESCO), at art. 6 (2005), [unesdoc.unesco.org/images/0014/001461/146180e.pdf](http://unesdoc.unesco.org/images/0014/001461/146180e.pdf) ("Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.").

scarcely a voluntary choice; it is a coerced choice at best. Because public health policies have not attained herd immunity for any childhood disease despite sixty years of compulsory policies and intensive effort, it seems both logical and wise to recalculate our policies. It is time to abandon the illusion of herd immunity through compulsion and to adopt realistic and respectful policies to achieve herd effect based on parents' informed choices.