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Wendy E. Parmet

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## INFORMED CONSENT AND PUBLIC HEALTH: ARE THEY COMPATIBLE WHEN IT COMES TO VACCINES?

WENDY E. PARMET\*

In 1902, there were 284 deaths from smallpox in Massachusetts.<sup>1</sup> Responding to the outbreak, the Cambridge Department of Public Health enacted an ordinance requiring citizens to be vaccinated or show proof of vaccination.<sup>2</sup> Henning Jacobson refused to comply.<sup>3</sup> He was tried and convicted in state court.<sup>4</sup> Affirming his conviction in the seminal case of *Jacobson v. Massachusetts*, Justice John Marshall Harlan articulated in strong and eloquent words the right of a society not only to promote vaccination but to require citizens to be vaccinated: “[u]pon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members.”<sup>5</sup> Vaccination against smallpox, he concluded, was one protection that the state had the right to insist upon for the common good.

Less than ten years later, another great jurist and future Supreme Court Justice, Benjamin Cardozo, sitting on the New York Court of Appeals, heard *Schloendorff v. Society of New York Hospital*, a case concerning a woman who claimed that she was operated on without her consent.<sup>6</sup> In considering whether the charitable hospital could be liable for an alleged trespass, Judge Cardozo declared: “Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”<sup>7</sup> In issuing this powerful affirmation of self-determination that helped to give rise to the right of informed consent,<sup>8</sup> Judge Cardozo never cited *Jacobson*, nor did he consider how to apply the principle of self-determination when vaccinations are required to control a dangerous epidemic.

Today, as we contemplate the need for new vaccinations and new vaccination campaigns to meet the threat of emerging infectious diseases such as

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\* George J. and Kathleen Waters Matthews University Distinguished Professor of Law, Northeastern University. Many thanks to Kavita Bhandary, Ethan Eddy, Laurie Martindale, and Beeta Shapiro for their excellent research help and Jan McNew, as always, for her superlative secretarial assistance.

1. Massachusetts Dep’t of Health, Infectious Disease Deaths (unpublished data, on file with the *Journal of Health Care Law & Policy*).

2. *Jacobson v. Massachusetts*, 197 U.S. 11, 12-13 (1905).

3. *Id.* at 13.

4. *Id.* at 14.

5. *Id.* at 27.

6. 105 N.E. 92 (N.Y. 1914).

7. *Id.* at 93.

8. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 397 (3d ed. 1997).

SARS or bioterrorist attacks, it is more important than ever to examine the relationship between the principles enunciated in *Jacobson* and those expressed in *Schloendorff* and ask whether it is possible to be faithful to both. More particularly, as we try to develop new vaccines and plan for their mass administration in the event of a public health emergency (whether manmade or natural), we need to consider whether we can adhere to *Jacobson's* recognition of the importance of public health and *Schloendorff's* respect for what has become known as informed consent.

On their faces, the two principles would seem difficult if not impossible to reconcile, at least in the case of vaccinations used in emergencies.<sup>9</sup> Indeed, the very notion of informed consent seems somewhat inapt in the case of a medical intervention that the government may, according to *Jacobson*, constitutionally mandate.<sup>10</sup> After all, informed consent and self-determination seem, at first blush, to emphasize an individualism at odds with *Jacobson's* emphasis on the common good and the use of vaccinations as a *public* health measure. Moreover, legal requirements for informed consent may create practical hurdles to the development and administration of the new vaccines we may need to meet tomorrow's public health threats. Informed consent can, for example, add cumbersome steps to the administration of vaccinations in situations in which time is of the essence. It also creates risks of liability that may undermine efforts to attract research and investment in the development of new vaccines. For all of these reasons, public health advocates and policymakers may be tempted to say that we should not insist upon informed consent for vaccinations during public health emergencies.<sup>11</sup> Less drastically, federal legislation designed to promote the development of new vaccines would significantly curtail manufacturers' legal liability for failing to inform consumers of the potential risks of their vaccines.<sup>12</sup>

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9. For general discussions of the conflicts between individual rights and the public good in the face of public health threats, see George J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 *NEW ENG. J. MED.* 1337 (2002); Lawrence O. Gostin, *When Terrorism Threatens Health: How Far Are Limitations on Personal and Economic Liberties Justified?*, 55 *FLA. L. REV.* 1105 (2003); Wendy E. Parmet, *Liberalism, Communitarianism, and Public Health: Comments on Lawrence O. Gostin's Lecture*, 55 *FLA. L. REV.* 1221 (2003).

10. See generally *Jacobson v. Mass.*, 197 U.S. 1105 (1905). As one court noted, the choice given in such a situation seems to be a "Hobson's choice" that cannot readily be called free. Allison v. Merck, 878 P.2d 948, 954-55 n.9 (Nev. 1994).

11. Hence, the proposed Model State Emergency Health Powers Act ("MSEHPA"), while maintaining the form of informed consent, would have empowered state officials to require individuals to be vaccinated on pain of detention. The MSEHPA was drafted by the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities. See THE CENTER FOR LAW AND THE PUBLIC'S HEALTH AT GEORGETOWN AND JOHNS HOPKINS UNIVERSITIES, THE MODEL STATE EMERGENCY HEALTH POWERS ACT § 603(b)(3) (2001), <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf> (last visited Feb. 23, 2005). For a further discussion of the role of informed consent when choices are so curtailed, see *infra* Part III.

12. For a full discussion of this legislation, see *infra* notes 112-17, 135-39 and accompanying text.

But are informed consent and public health necessarily incompatible? In this Article, I will argue that they are not. To the contrary, informed consent actually serves public health. More specifically, I will contend that informed consent advances four major goals: compensation of injuries, prevention of injuries, promotion of trust, and recognition of choice. Each of these goals is important to the protection and promotion of public health. However, for informed consent to best advance these goals during a public health emergency, our vision of informed consent may need to change from a narrow, individually-based litigation right to a broader, public health principle.

I begin in Part I by discussing why vaccines are important to public health and how the law has been used to promote them. In Part II, I turn to informed consent, providing first an overview of the concept and its core components. I then examine more closely the four different goals promoted by informed consent and explain why in the case of vaccinations each of these goals helps to protect public health. Finally, in Part III, I discuss how informed consent can be reformulated to reflect and promote public health.

## PART I: VACCINATIONS AND THE PUBLIC HEALTH PERSPECTIVE

### *A. Vaccinations as Public Health Interventions*

There can be little doubt that vaccinations are among the most important and successful public health interventions. They have led to the eradication of smallpox as a natural disease<sup>13</sup> and the virtual disappearance of polio and the iron lung from the developed world.<sup>14</sup> Moreover, vaccinations have caused dramatic declines in the United States of many other once common killers, including diphtheria, tetanus, measles, and *Haemophilus influenzae* type B.<sup>15</sup> Vaccinations have also saved billions of dollars by dramatically reducing morbidity and mortality.<sup>16</sup>

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13. Holly Myers et al., *The Threat of Smallpox: Eradicated but not Erased*, J. HOMELAND SECURITY (Feb. 2004), at [http://www.homelandsecurity.org/journal/Articles/gursky\\_smallpox.html](http://www.homelandsecurity.org/journal/Articles/gursky_smallpox.html) (last visited Feb. 23, 2005). Of course, this eradication has brought its own risk. With the eradication of smallpox, humanity has lost its immunity to the disease, potentially making smallpox an extraordinarily lethal biological weapon. See *id.* (noting 119 million Americans are susceptible to the disease as of 2003).

14. Polio is now endemic in only seven nations. WORLD HEALTH ORG., POLIOMYELITIS, FACT SHEET NO. 114, <http://www.who.int/mediacentre/factsheets/fs114/en/> (last visited Feb. 26, 2005); see also GLAXOSMITHKLINE, DISEASES: POLIOMYELITIS, at <http://www.worldwidevaccines.com/polio/epidemiology2.asp> (last visited Feb. 23, 2005).

15. COMM. ON IMMUNIZATION FINANCE POLICIES AND PRACTICES, INST. OF MED., CALLING THE SHOTS: IMMUNIZATION FINANCE POLICIES AND PRACTICES 18 (2000).

16. Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J. L. REFORM 353, 369 (2004).

Importantly, many vaccines (but not all) are critical *public health* tools providing protection even to individuals who have not been vaccinated. By reducing the number of people capable of transmitting an infectious disease in a given population, vaccines help to interrupt the transmission of the targeted disease, resulting in a “herd immunity”<sup>17</sup> that can offer protection even to individuals who are not vaccinated or who do not become immune following vaccination.<sup>18</sup> As a result, vaccinations can lower the incidence of a disease in a community or population, benefiting the population as a whole.<sup>19</sup> For diseases such as smallpox, for which there is no known therapeutic intervention, this ability to protect the population is especially significant.

The ability of vaccines to reduce the risk for populations, however, raises a problem characteristic of many public health issues. Because it lowers the incidence of a disease in a population, vaccination-acquired immunity is a classic public good, susceptible to free-riders.<sup>20</sup> In a population in which a high percentage of people are vaccinated, individuals deciding whether they or their children should be vaccinated, face a relatively low risk of the natural disease. For these people, it may appear rational to be a free-rider and enjoy the benefits of living in a vaccinated population without incurring the risks of vaccination.<sup>21</sup> This

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17. COMM. ON THE EVALUATION OF VACCINE PURCHASE FINANCING IN THE U.S., BOARD ON HEALTH CARE SERVS., INST. OF MED. OF THE NAT'L ACADEMIES, FINANCING VACCINES IN THE 21ST CENTURY: ASSURING ACCESS AND AVAILABILITY 27 (2004) [hereinafter FINANCING VACCINES]. As the Institute of Medicine makes clear, vaccines vary with respect to their public health benefit. *Id.* Some vaccines, such as the human rabies vaccine, which is given rarely and only to exposed individuals, would appear to serve primarily as a clinical intervention to a threatened individual. *Id.* Other vaccines, such as the polio and smallpox vaccines which have freed whole populations of diseases that once were common and easily communicable, have significant public benefits. *See id.*

18. *Id.* Different diseases require different percentages of a population to be vaccinated in order for herd immunity to occur. *See* Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, in *LAW IN PUBLIC HEALTH PRACTICE* 262-80 (Richard Goodman et al. eds. 2003). Some vaccines can actually provide immunity for individuals who have not been vaccinated. Paul E. M. Fine & Ilona A. M. Carneiro, *Transmissibility and Persistence of Oral Polio Vaccine Viruses: Implications for the Global Poliomyelitis Eradication Initiative*, 150 *AM. J. EPIDEMIOLOGY* 1001 (1999). For example, the oral polio vaccine can protect unvaccinated persons by exposing them to a weakened virus that is shed from the intestines of a vaccinated person. *Id.*

19. FINANCING VACCINES, *supra* note 17.

20. A free-rider is an actor who does not bear his or her fair share of the cost of his or her use of a public good. The free-rider phenomenon only becomes a problem or an inefficiency when it leads to either excessive use of a public good or failure to participate in the collective action that produces the good in the first place. *See, e.g.,* RICHARD CORNES & TODD SANDLER, *THE THEORY OF EXTERNALITIES, PUBLIC GOODS AND CLUB GOODS* 541 (2d ed. 1996). The Institute of Medicine also notes that vaccine research is a public good because “it involves the identification of basic scientific knowledge that benefits everyone and is not diminished by someone’s use of that knowledge.” FINANCING VACCINES, *supra* note 17, at 43.

21. Doren D. Fredrickson et al., *Childhood Immunization Refusal: Provider and Parent Perceptions*, 36 *FAMILY MED.* 431, 436 (2004) (noting that “some non-immunizing parents are aware that their children may be at lower risk if most other children in the community are immunized”), <http://stfm.org/fmhub/fm2004/June/Doren431.pdf> (last visited Feb. 23, 2005). *See also* Bryan L.

problem may be exacerbated by the fact that as more people are vaccinated, more adverse events will occur (in aggregate), which may lead to a growing perception that vaccines are risky.<sup>22</sup> As Steve P. Calandrillo has noted: "Ironically, the success of immunization programs has led to proportionately greater concerns regarding vaccine safety today than worries about the illnesses that vaccines prevent."<sup>23</sup>

The public benefits that result from vaccinations, as well as the free-rider problem, provide strong rationales for legal interventions in support of vaccines.<sup>24</sup> Indeed, vaccinations may also be viewed as a *public* health intervention because they generally occur in the context of an organized collective undertaking to vaccinate a population.<sup>25</sup> From the beginning, vaccines have been administered not only as an individual clinical intervention, but as part of an organized public or social response to a disease that threatened a community's health.<sup>26</sup>

As a public health intervention, vaccines have long been regulated, promoted, and even, at times, compelled by law. In the United States, the roots of legal support for vaccination date to colonial times, when the city of Boston, faced with smallpox, provided free variolation (a forerunner of vaccination that inoculated an individual with smallpox pus to provide protection from the disease).<sup>27</sup> By the early eighteenth century, after the introduction of Edward Jenner's smallpox

Martin et al., *Adverse Reaction to Vaccines*, 24 CLINICAL REVIEWS IN ALLERGY & IMMUNOLOGY 263-76 (2003) (documenting parents' fear that vaccinations may hurt their children).

22. Perceptions of risk are also undoubtedly affected by the wide array of anti-vaccine information, much of it erroneous, available on the Internet. Robert M. Wolfe et al., *Content and Design Attributes of Antivaccination Web Sites*, 287 JAMA 3245 (2002) (reviewing web sites and speculating that they may influence parents).

23. Calandrillo, *supra* note 16, at 404. See also Fredrickson et al., *supra* note 21, at 431 (reporting perceptions that vaccines may be unsafe).

24. Hence, even theorists who oppose broad conceptions of public health and use of the police power have supported interventions on behalf of vaccinations, at least under some circumstances. See Richard A. Epstein, *Let the Shoemaker Stick to His Last: A Defense of the "Old" Public Health*, 46 PERSP. IN BIOLOGY & MED. 138 (Supp. Summer 2003).

25. The Institute of Medicine has defined public health as "what we, as a society, do collectively to assure the conditions for people to be healthy." COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, INST. OF MED., THE FUTURE OF PUB. HEALTH 19 (1988) [hereinafter FUTURE OF PUB. HEALTH]. Of course, vaccination will not always satisfy this definition. An individual who lives in Massachusetts and seeks to be vaccinated for yellow fever, which is not recommended for someone in the United States who is not traveling, cannot be said to participate in a collective public undertaking. But public support for vaccinations in the United States is widespread. Approximately half of all childhood vaccines, for example, are provided with public funds. See Ian Maclean Smith, *Vaccinations*, at <http://www.vh.org/adult/patient/internalmedicine/aba30/1997/vaccine1.html> (last visited Feb. 23, 2005).

26. See FUTURE OF PUB. HEALTH, *supra* note 25.

27. Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 HASTINGS CONST. L.Q. 267, 289 (1993).

vaccine (which relied upon the less dangerous cowpox virus),<sup>28</sup> Congress adopted a law empowering the President to “appoint an agent to preserve the genuine vaccine matter, and to furnish the same to any citizen of the United States.”<sup>29</sup>

In more recent decades, legal efforts to support vaccination have taken several different forms.<sup>30</sup> First, the federal government, through the National Institutes of Health (NIH), has supported basic research on vaccines.<sup>31</sup> Second, through the auspices of the Food and Drug Administration, the federal government has closely regulated the production of vaccines.<sup>32</sup> In addition, both state and federal governments have followed the example of seventeenth century Boston by providing financial support for vaccinations to individuals who cannot otherwise afford them. For example, the federal government is the single largest purchaser of vaccines.<sup>33</sup> Under the Vaccines for Children Program, the Centers for Disease Control and Prevention (CDC) negotiates large purchase contracts with manufacturers and makes vaccines available to uninsured and some under-insured children.<sup>34</sup> Medicare, Medicaid, and the State Children’s Health Insurance Program (SCHIP) also pay for vaccinations for their covered populations.<sup>35</sup> In

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28. Cynthia P. Schneider & Michael D. McDonald, “*The King of Terrors*” Revisited: *The Smallpox Vaccination Campaign and Its Lessons for Future Biopreparedness*, 31 J.L. MED. & ETHICS 580, 581 (2003).

29. James G. Hodge & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 844 (2001-2002).

30. Despite the efforts described below, supplies of recommended vaccines have frequently run short. Those studying the problem have cited numerous possible causes, including regulatory hurdles, market failures, and fears of liability. See, e.g., FINANCING VACCINES, *supra* note 17, at 73-79; National Vaccine Advisory Committee, *Strengthening the Supply of Routinely Recommended Vaccines in the United States: Recommendations from the National Vaccine Advisory Committee*, 290 JAMA 3122, 3124-25 (2003); U.S. GEN. ACCOUNTING OFFICE, CHILDHOOD VACCINES: ENSURING AN ADEQUATE SUPPLY POSES CONTINUING CHALLENGES (2002) [hereinafter GAO], <http://www.gao.gov/new.items/d02987.pdf> (last visited Feb. 23, 2005).

31. For example, in fiscal year 2003, the NIH spent \$978 million on vaccine development and another \$1.1 billion on “vaccine-related” research. NIH, ESTIMATES OF FUNDING FOR VARIOUS DISEASES, CONDITIONS, RESEARCH AREAS (Jan. 18, 2005), <http://www.nih.gov/news/fundingresearch/areas.htm> (last visited Feb. 23, 2005).

32. For a discussion of the regulation of vaccine production in the United States and in other nations, see generally Julie B. Milstien, *Regulation of Vaccines: Strengthening the Science Base*, 25 J. PUB. HEALTH POL’Y 173 (2004).

33. GAO, *supra* note 30, at 5.

34. *Id.*

35. See CENTER FOR MEDICARE & MEDICAID SERVICES (CMS), STAY HEALTHY, *at* <http://www.medicare.gov/Health/Overview.asp> (last visited Feb. 23, 2005); CMS, MEDICAID: A BRIEF SUMMARY, *at* <http://www.cms.hhs.gov/publications/overview-medicare-medicaid/default4.asp> (last visited Feb. 23, 2005); CMS, STATE CHILDREN’S HEALTH INSURANCE PROGRAM (SCHIP), *at* [http://www.cms.hhs.gov/schip/consumers\\_default.asp](http://www.cms.hhs.gov/schip/consumers_default.asp) (last visited Feb. 23, 2005).

addition, the federal government has purchased vaccines to stockpile in the event of a bioterrorist attack or other public health emergency.<sup>36</sup>

Two additional forms of legal support for vaccines deserve particular mention in anticipation of our discussion of vaccines and informed consent. First, to ensure a stable market for vaccines by reducing manufacturers' risk of liability, the federal government has enacted several compensation programs. For example, in 1976, fearful about a potential outbreak of "swine flu," Congress enacted the National Swine Flu Immunization Program, which enabled individuals who were injured by the swine flu vaccine to sue the government, rather than the manufacturer.<sup>37</sup> More broadly, in 1986 Congress enacted the National Childhood Vaccine Injury Act ("NCVIA"), which established a limited federal no-fault remedy for injuries resulting from listed childhood vaccines.<sup>38</sup> More recently, the Smallpox Emergency Personnel Protection Act ("SEPPA") provided a limited federal remedy for injuries arising from smallpox vaccinations given pursuant to a declared "smallpox emergency response plan."<sup>39</sup> Finally, and perhaps most importantly for a discussion of informed consent, state governments have mandated certain vaccinations, especially for schoolchildren.<sup>40</sup> This highly controversial use of the law to compel vaccinations is discussed in Section B.

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36. The Strategic National Stockpile, formerly known as the National Pharmaceutical Stockpile, is a national repository for antibiotics, chemical antidotes, and other medical equipment. See CDC, STRATEGIC NATIONAL STOCKPILE, at <http://www.bt.cdc.gov/stockpile/index.asp> (last visited Feb. 23, 2005). The Department of Homeland Security's fiscal year 2005 budget request includes \$400 million for the stockpile. See DEP'T OF HOMELAND SECURITY, FACT SHEET: PRESIDENT BUSH SIGNS BIODEFENSE FOR THE 21<sup>ST</sup> CENTURY, <http://www.dhs.gov/dhspublic/display?theme=43&content=3522&print=true> (last visited Feb. 23, 2005).

37. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (codified as amended at 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)). The Act amended § 317(k) of the Public Health Services Act. *Id.* For discussions of this program, see Thomas E. Baynes, Jr., *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 21 ST. LOUIS U. L.J. 44 (1977); Cyril H. Wecht, *The Swine Flu Immunization Program: Scientific Venture or Political Folly?*, 3 AM. J.L. & MED. 425 (1977/1978).

38. Pub. L. No. 99-660, 100 Stat. 3756 (1986) (codified at 42 U.S.C.A. § 300aa-1 to 34 (West 2003 & Supp. 2004)). The Act permits individuals to seek a civil remedy only after pursuing the statutory no-fault scheme. *Id.* at §300aa-11. For a discussion on the Act and its efficacy, see Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351 (2001).

39. Pub. L. No. 108-020, §2, 117 Stat. 638, 639 (2003) (codified at 42 U.S.C.A. §239 (West Supp. 2004)). For a fuller discussion of this act, see generally Edward P. Richards et al., *Smallpox Vaccine Injury and Law Guide* (June 7, 2004), <http://biotech.law.lsu.edu/blaw/bt/smallpox/svlaw.htm> (last visited Feb. 23, 2005); Myers et al., *supra* note 13.

40. See *infra* notes 62-69 and accompanying text.

### B. *The Police Powers and Vaccination*

Although it has always been controversial, legal requirements for vaccination date to the early days of vaccination. In 1827, Boston became the first city to require children to be vaccinated before entering school.<sup>41</sup> By the late 1800s, many states relied upon their police power to enact similar laws.<sup>42</sup> Frequently, these laws were challenged in court, the first recorded challenge occurring in 1830.<sup>43</sup> For the most part, lower courts upheld these laws, often on the rather dubious proposition that they did not actually require a child to be vaccinated; they simply made vaccination a prerequisite for obtaining the “privilege” of education.<sup>44</sup>

One of the most important challenges to vaccination laws occurred in 1900 when the plague came to San Francisco’s Chinatown.<sup>45</sup> The Board of Health responded to the threat by adopting a resolution requiring the inoculation of all Chinese residents of the city with a serum known as the Haffkine prophylactic.<sup>46</sup> The resolution was enforced by a quarantine forbidding Chinese residents to leave unless they were vaccinated.<sup>47</sup> The Board’s resolution was challenged in federal court.<sup>48</sup>

In its opinion in *Wong Wai v. Williamson*, the court noted that it was required to “review such legislation, and determine whether it in reality relates to, and is appropriate to secure, the object in view . . . .”<sup>49</sup> According to the court, the San Francisco resolution did not meet the test because the vaccination order was not based on any “established distinction in the conditions that are supposed to attend this plague, or the persons exposed to its contagion, but they are boldly directed against the Asiatic or Mongolian race as a class . . . .”<sup>50</sup> In addition, the court noted that requiring a vaccination only for individuals who leave the infected area made little sense, since the prophylactic was not recommended for people who had

41. Hodge & Gostin, *supra* note 29, at 851.

42. *See id.* (listing states such as New York, Connecticut, Pennsylvania, and others that enacted school vaccination laws between 1855 and 1889).

43. *Id.* at 853 (citing *Hazen v. Strong*, 2 Vt. 427 (1830)).

44. *Id.* at 862 (citing *Sadlock v. Bd. of Educ.*, 58 A.2d 218 (N.J. 1948)).

45. For a full discussion of the episode, see MARILYN CHASE, *THE BARBARY PLAGUE: THE BLACK DEATH IN VICTORIAN SAN FRANCISCO* (2003); NAYAN SHAH, *EPIDEMICS AND RACE IN SAN FRANCISCO’S CHINATOWN* (2001).

46. The vaccine had been developed a few years earlier by Swiss bacteriologist, Waldemar Haffkine. It had not been proven effective and was believed by many to cause numerous side effects, including possibly death. HOWARD MARKEL, *WHEN GERMS TRAVEL* 71 (2004).

47. *Id.* at 72.

48. *Wong Wai v. Williamson*, 103 F. 1, 2-3 (C.C.N.D. Cal. 1900).

49. *Id.* at 7 (quoting *Blue v. Beach*, 56 N.E. 89, 93 (Ind. 1900)).

50. *Id.*

already been exposed to the plague.<sup>51</sup> As a result, the court saw the ordinance as discriminatory and “not within the legitimate police power.”<sup>52</sup>

Five years later, the issue of compulsory vaccination appeared before the United States Supreme Court in *Jacobson v. Massachusetts*.<sup>53</sup> As in *Wong Wai*, the case concerned a vaccination order issued in response to an outbreak, this time smallpox. But in contrast to *Wong Wai*, *Jacobson v. Massachusetts* involved a well-known vaccine and an ordinance that was not facially discriminatory.

Justice Harlan’s opinion for the Court offered a powerful endorsement of the use of law to promote public health. He stated that liberty does not exist unto itself.<sup>54</sup> The only liberty an individual has is that “regulated by law.”<sup>55</sup> The law, he noted, includes the police power, which aims to support the “common good.”<sup>56</sup> Protection against an epidemic disease, he added, is clearly part of that good, indeed, it is “of paramount necessity.”<sup>57</sup>

Despite this strong endorsement of the police power and its application to vaccinations, it is important to note that the Court’s opinion did not conflict with the reasoning of the *Wong Wai* court. First, Justice Harlan’s discussion was carefully grounded in the Court’s acceptance of the importance and validity of vaccination as a method for combating smallpox.<sup>58</sup> The legislature’s determination was not subject to judicial invalidation, according to the Court, given that “strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was – perhaps or possibly – not the best either for children or adults.”<sup>59</sup> Of course, in framing its acceptance of mandatory vaccination in humanity’s experiences with smallpox, the Court did not rely upon and did not cite the type of scientific evidence that would be proffered and perhaps expected today. Instead, the Court was content to rely simply upon the common understanding, which had existed for decades, of the efficacy and importance of

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51. *Id.* Hence the vaccine should have been given to people within the quarantine area who were not yet exposed or people traveling to, rather than from, the city. *Id.*

52. *Id.* at 10. In a second case, the court invalidated again for reasons of discrimination the city’s subsequent quarantine order. *Jew Ho v. Williamson*, 103 F. 10 (C.C.N.D. Cal. 1900).

53. 197 U.S. 11 (1905). Many public health scholars have offered interpretations of *Jacobson*. See, e.g., Scott Burris, *Fear Itself: AIDS, Herpes, and Public Health Decisions*, 3 YALE L. & POL’Y REV. 479, 479-490 (1985); Elizabeth Cooper, *Social Risk and the Transformation of Public Health Law: Lessons from the Plague Years*, 86 IOWA L. REV. 869, 890 n.91 (2001); Lawrence O. Gostin, *The Model State Emergency Health Powers Act: Public Health and Civil Liberties in a Time of Terrorism*, 13 HEALTH MATRIX 3, 27-28 (2003).

54. *Jacobson*, 197 U.S. at 26-27.

55. *Id.* at 27 (quoting *Crowley v. Christensen*, 137 U.S. 86, 89 (1890)).

56. *Id.*

57. *Id.*

58. *Jacobson v. Massachusetts*, 197 U.S. 11, 34-35 (1905).

59. *Id.* at 35.

smallpox vaccination.<sup>60</sup> The opinion, however, did not address how the Court would have ruled had the city required an individual to be vaccinated with a relatively untried vaccine such as the Haffkine prophylactic, or for a disease less universally feared.

Second, while the Court was adamant that it would not second-guess the legislature's general assessment of the risk/benefit ratio of the smallpox vaccine (of course the Court did not use such contemporary jargon), it made clear that it was not deciding whether the state could require an individual who faced a higher, particularized risk to be vaccinated. The Court cautioned:

It is easy, for instance, to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body, would be cruel and inhuman in the last degree. We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned.<sup>61</sup>

In other words, the Court left open the possibility that the Constitution required individual exemptions, at least when failing to do so would be "cruel and inhumane" given the individual's own risk to a vaccine.

Since *Jacobson*, case law has focused on school vaccination laws.<sup>62</sup> In *Zucht v. King*,<sup>63</sup> the Supreme Court dismissed an appeal brought under the Equal Protection Clause to a school vaccination law, noting that *Jacobson* had settled the question of a state's power to compel vaccination.<sup>64</sup> Following *Zucht*, lower courts have affirmed that school vaccination laws do not deprive students of their rights of free exercise or due process.<sup>65</sup> Nevertheless, all state laws contain some exemptions. Most states grant religious exemptions,<sup>66</sup> and many states grant

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60. There was, to be sure, significant anti-vaccination sentiment at the time. Nevertheless, by 1905 the smallpox vaccine was well-established and well-accepted in medical and more broadly elite circles, as the laws promoting it attest. Hodge & Gostin, *supra* note 29, at 844-49.

61. *Jacobson*, 197 U.S. at 38-39.

62. There has also been a series of cases on the right of the military to require its personnel to be vaccinated. See *Mazares v. Dep't of the Navy*, 302 F.3d 1382 (Fed. Cir. 2002); *Bates v. Rumsfeld*, 271 F. Supp. 2d 54 (D. D.C. 2002); *O'Neil v. Sec'y of the Navy*, 76 F. Supp. 2d 641 (W.D. Pa. 1999). Because the liberties of service personnel are severely restricted under all circumstances, these cases are quite distinct from those pertaining to civilians. For a discussion of this issue, see Randall D. Katz, Note, *Friendly Fire: The Mandatory Military Anthrax Vaccination Program*, 50 DUKE L.J. 1835 (2001).

63. 260 U.S. 174 (1922).

64. *Id.* at 176.

65. See, e.g., *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002) (holding that a state statute's religious exemption provision based only on "recognized" religions violated the Free Exercise and Establishment Clauses); *Brown v. Stone*, 378 So.2d 218, 223 (Miss. 1979) (finding that the existence of religious exemptions violated the Fourteenth Amendment Equal Protection Clause).

66. Hodge & Gostin, *supra* note 29, at 873-74.

exemptions whenever the parents profess a philosophical objection to vaccination.<sup>67</sup> In addition, all states provide some exemption from the vaccination requirement when there is a medical contraindication.<sup>68</sup> Several courts have insisted that exemptions be granted liberally.<sup>69</sup> Thus, despite the firm legal bases for the general principle that states can require children to be vaccinated prior to school, existing law does not support a total abnegation of either individual choice or individualized decisionmaking.

## PART II: INFORMED CONSENT

### A. *The Many Incarnations and Purposes of Informed Consent*

There is little doubt that the principle of informed consent has taken on a fundamental, if not “sacramental” status, in contemporary thought.<sup>70</sup> In different forms and varied guises, the principle is pervasive in both health law and ethics. In bioethics,<sup>71</sup> it plays a central role in discussions of human subject experimentation.<sup>72</sup> Indeed, it was a, if not *the*, pivotal principle, articulated by the Nuremberg Declaration.<sup>73</sup> But the principle permeates more broadly, and appears in discussions of the physician-patient relationship,<sup>74</sup> medical privacy,<sup>75</sup> and even

67. *Id.*

68. *Id.*

69. See *LePage v. Wyo. Dep't of Health*, 18 P.3d 1177, 1181 (Wyo. 2001) (finding that Dept. of Health exceeded its statutory authority by requiring more than a written objection from a mother requesting religious exemption); *McCarthy v. Ozark Sch. Dist.*, 359 F.3d 1029, 1036 (8th Cir. 2004) (noting that the legislature acted properly to provide broad exemptions); *but see Farina v. Bd. of Educ. of N.Y.*, 116 F. Supp. 2d 503, 507-08 (S.D.N.Y. 2000) (holding that parents were not entitled to exemption where the court found that parents failed to show a sufficient nexus between their religious belief and their desire for exemption).

70. Gail H. Javitt, *Drugs and Vaccines for the Common Defense: Refining FDA Regulation to Promote the Availability of Products to Counter Biological Attacks*, 19 J. CONTEMP. HEALTH L. & POL'Y 37, 77 (2002) (quoting Richard W. Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455, 456 (1996)).

71. For a discussion of informed consent from a bioethical perspective, see Tom L. Beauchamp, *Informed Consent*, in *MEDICAL ETHICS* 185-208 (Robert M. Veatch ed., 1997).

72. Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 9 (1993).

73. 2 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181-82 (1997) [hereinafter TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS]; FADEN ET AL., *A HISTORY AND THEORY OF INFORMED CONSENT* 156-57 (1986).

74. See Jay Katz, *Informed Consent – Must it Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69, 77 (1994); Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 267-78 (1999).

75. Neil C. Abramson, *A Right to Privacy Tour de Force into Louisiana Medical Informed Consent*, 51 LA. L. REV. 755 (1991); Lawrence O. Gostin & James G. Hodge, Jr., *Personal Privacy and Common Goods: A Framework for Balancing Under the National Health Information Privacy Rule*, 86

the obligations of managed care organizations.<sup>76</sup> As has often been noted in bioethical discussions, informed consent plays a powerful role in supporting the values of individual autonomy and dignity.<sup>77</sup> However, as discussed below, informed consent can also be understood as critical to the development of a trusting relationship, especially between physicians and patients.<sup>78</sup>

Informed consent is also omnipresent in law. Although its spirit can be traced to the common law of battery, informed consent's origins are often assigned to Judge Cardozo's paean to self-determination in *Schloendorff*.<sup>79</sup> As a matter of doctrine, the principle is generally dated to 1957 when the court in *Salgo v. Leland Stanford Jr. University Board of Trustees*<sup>80</sup> recognized a tort action for a physician's failure to inform a patient about the known risks of a medical procedure prior to obtaining the patient's consent for the procedure.<sup>81</sup>

While informed consent is best known as an action in tort against a health care provider for failing to provide a patient with information considered material to obtaining a patient's consent,<sup>82</sup> variations of informed consent appear more broadly in modern American health law. For example, notions of informed consent are essential to federal regulations pertaining to the treatment of human

MINN. L. REV. 1439, 1466-69 (2002); Richard C. Turkington, *Confidentiality Policy for HIV-Related Information: An Analytical Framework for Sorting Out Hard and Easy Cases*, 34 VILL. L. REV. 871, 891-93 (1989).

76. Timothy S. Hall, *Third-Party Payor Conflicts of Interest in Managed Care: A Proposal for Regulation Based on the Model Rules of Professional Conduct*, 29 SETON HALL L. REV. 95, 136-37 (1998); Aaron D. Twerski & Neil B. Cohen, *The Second Revolution in Informed Consent: Comparing Physicians to Each Other*, 94 NW. U. L. REV. 1, 31-32 (1999); Susan M. Wolf, *Toward a Systemic Theory of Informed Consent in Managed Care*, 35 HOUS. L. REV. 1631, 1638-39 (1999).

77. E.g., Christine E. Gudorf, *Gender and Culture in the Globalization of Bioethics*, 15 ST. LOUIS U. PUB. L. REV. 331, 346-47 (1996); Elysa Gordon, Note, *Multiculturalism in Medical Decisionmaking: The Notion of Informed Waiver*, 23 FORDHAM URB. L.J. 1321, 1327-40 (1996).

78. See Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 216-18 (1998); Dana Ziker, *Reviving Informed Consent: Using Risk Perception in Clinical Trials*, 2003 DUKE L. & TECH. REV. 30, 32-37, at <http://www.law.duke.edu/journals/dltr/articles/2003dltr0015.html> (last visited Feb. 23, 2005); Dorothy Derrickson, Note, *Informed Consent to Human Subject Research: Improving the Process of Informed Consent from Mentally Ill Persons*, 25 FORDHAM URB. L.J. 143, 157-60 (1997).

79. See *supra* text accompanying notes 6-8.

80. 317 P.2d 170 (Cal. Dist. Ct. App. 1957).

81. *Id.* at 181.

82. Different jurisdictions impose different standards of care on the physician. Initially, and still in many jurisdictions, a physician was simply obligated to inform the patient of those risks that it was customary among physicians to disclose. See *Natanson v. Kline*, 350 P.2d 1093, 1106-7 (Kan. 1960) (setting forth this standard); see also Martin R. Studer, *The Doctrine of Informed Consent: Protecting the Patient's Right to Make Informed Health Care Decisions*, 48 MONT. L. REV. 85, 88-89 (1987). In the 1970s, several prominent cases adopted a "patient-centered" standard of care which required the physician to disclose those risks which a reasonable patient would find material. See *Canterbury v. Spence*, 464 F.2d 772, 786-87 (D.C. Cir. 1972); *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972).

subjects (“the Common Rule”)<sup>83</sup> and to the protection of private medical information (i.e., the “HIPAA regulations”).<sup>84</sup> Informed consent also plays a prominent role in the federal regulation of pharmaceutical marketing and advertising<sup>85</sup> and even in Oregon’s Death with Dignity Act.<sup>86</sup> In addition, conceptions of informed consent permeate duty to warn cases against the manufacturers of medical products.<sup>87</sup> As a result, in the discussion below, these product liability cases will be discussed in conjunction with the more traditional informed consent cases against medical providers. Finally, the principle of informed consent has influenced constitutional analysis, especially in cases concerning a patient’s right to decide whether to receive life-saving treatment.<sup>88</sup>

Given the myriad incarnations and permutations of informed consent in both law and ethics, it is overly simplistic and even misleading to assert that the concept has consistent core elements or clear purposes. Nevertheless, if there are any common elements to the concept of informed consent, they include the provision of information to an individual that is pertinent to that individual’s decision as to whether to undergo or forgo a particular medical intervention (including examinations, treatments, procedures, medication, and vaccinations) and the recognition that the individual has the right, after receiving the information, to choose whether to have that intervention.<sup>89</sup> Thus, while courts and ethicists debate about the standards that should determine what information should be given, and

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83. General Requirements for Informed Consent, 45 C.F.R. § 46.116 (2003).

84. Uses and Disclosures Requiring an Opportunity for the Individual to Agree or to Object, 45 C.F.R. §§ 164.510 - 164.522 (2003).

85. See William E. Holtz, *Consumer-Directed Prescription Drug Advertising: Effects on Public Health*, 13 J. L. & HEALTH 199, 214-15 (1999); Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141 (1997); Timothy McIntire, Note, *Legal and Quality of Patient Care Issues Arising from Direct-to-Consumer Pharmaceutical Sales*, 33 U. MEM. L. REV. 105, 127-29 (2002).

86. OR. REV. STAT. § 127.830 (2003).

87. Courts have used the terms “duty to warn” and “informed consent” almost interchangeably. See, e.g., *Mills v. United States*, 764 F.2d 373, 376-77 (5th Cir. 1985).

88. E.g., *Cruzan v. Dir. Mo. Dep’t of Health*, 497 U.S. 261, 278-79 (1990) (“[F]or purposes of this case, we assume that the United States Constitution would grant a competent person a constitutionally protected right to refuse lifesaving hydration and nutrition.”).

89. Informed consent is most generally applied to cases concerning whether a patient should have a particular surgical intervention. However, it has also been applied to cases discussing whether a patient should undergo a routine test or a highly sensitive blood test. See, e.g., *Doe v. Div. of Youth and Family Servs.*, 148 F. Supp. 2d 462 (D. N.J. 2001) (mother stated a claim under New Jersey Act when she claimed she withdrew her consent to have her blood tested for HIV); *Truman v. Thomas*, 611 P.2d 902, 907, 910 (Cal. 1980) (physician must inform patient about the risks of not having pap smear). Informed consent may also apply to whether a patient should see a particular physician. See, e.g., *Johnson v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996) (information concerning a physician’s past experience with a procedure is relevant to a patient’s decisionmaking and should have been admitted to help the patient decide whether to take a particular medication).

how it should be given,<sup>90</sup> all agree that informed consent requires the health care provider, or the manufacturer of a health care product, to convey information to a patient that a layperson might not otherwise be expected to know.<sup>91</sup> Moreover, it is clear that this information is not offered merely so that a patient will know what is happening to him or her. The concept is not known as “informed acquiescence.” Rather, the information is provided to empower the patient to make a decision whether to have or forgo the particular test or intervention at issue.<sup>92</sup> This, of course, assumes that a patient has a choice to make.<sup>93</sup> That is precisely why, in the case of vaccines mandated by law prior to entering school, the very notion of informed consent has struck some observers as rather paradoxical.<sup>94</sup>

Empowering and respecting a patient’s right to choose, however, is not the only purpose furthered by informed consent. Three others warrant consideration: compensating injured individuals, reducing injuries, and fostering trust. Although the association of each of these goals with informed consent may, at first glance, seem inimical to the protection of public health, each goal is actually not only compatible with public health, but supportive of it, at least in the case of vaccinations. In the next sections, I examine how informed consent promotes each of these goals and why they are conducive to protecting public health through vaccination. I then return to the key element of self-determination and examine its relationship to public health in the context of vaccines.

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90. Compare *Natanson v. Kline*, 350 P.2d 1093, 1106 (Kan. 1960) (articulating the reasonable physician standard), with *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972) (articulating the prudent patient standard). More than half the states follow the reasonable physician standard. *Ketchup v. Howard*, 543 S.E.2d 371, 378 (Ga. Ct. App. 2001).

91. See *Canterbury*, 464 F.2d at 780 (noting that “[t]he average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision”).

92. The question of whether the choices of incompetent patients, including minors and those rendered incompetent by disease or disability, is a complex one which has spawned a plethora of literature, especially in the context of life-saving treatments. See Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 423-26 (1974); Danuta Mendelson, *Historical Evolution and Modern Implications of Concepts of Consent to, and Refusal of, Medical Treatment in the Law of Trespass*, 17 J. LEGAL MED. 1, 39 (1996); Samantha Weyrauch, *Decision Making for Incompetent Patients: Who Decides and By What Standards?*, 35 TULSA L.J. 765 (2000). Due to space limitations, this article will assume that the patient is either competent or that a parent is the appropriate decision maker for a child. The issues that arise with respect to vaccinations for incompetent patients are difficult and complex but will not be explored here.

93. “Whatever the precise denomination, the duty to secure informed consent reflects a commitment to patient autonomy and self-determination.” Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. MED. 361, 364 (2002).

94. See, e.g., Allison v. Merck, 878 P.2d 948, 954-55 n.9 (Nev. 1994) (commenting that there is no real choice surrounding the issue of school vaccinations).

### B. *Informed Consent, Compensation, and Public Health*

Although informed consent is multi-faceted, it began as and remains a doctrine of tort law. More specifically, informed consent is a cause of action that patients can bring against health care providers for failing to give them information material to obtaining their consent to a medical procedure.<sup>95</sup> In most jurisdictions, this action is a species of negligence law.<sup>96</sup> In a small minority of jurisdictions, informed consent remains a form of battery.<sup>97</sup> In either case, an action of informed consent serves as a mechanism for compensating patients who are injured by medical encounters.<sup>98</sup> Or, to put it another way, the failure to obtain informed consent can create a liability on the part of a health care provider that can result in a judgment compensating a patient for a medically-induced injury.<sup>99</sup> As a result of this liability, providers in the last few decades have increasingly demanded written “consents” from their patients. These small-print forms may do little to empower patient decision-making, (or to prevent liability) but they do attest to the salient role of compensation and liability in popular conceptions of informed consent. Indeed, one poll found that seventy-nine percent of patients and fifty-four percent of physicians surveyed believed that consent forms given by health care providers are simply designed to prevent liability.<sup>100</sup> So viewed, informed consent seems to have little to do with improving public health; instead it would appear primarily as a vehicle for determining who pays whom.

Likewise, the cause of action commonly known as “duty to warn,” which is closely related to informed consent actions against health care providers, is also largely about compensation and liability.<sup>101</sup> Indeed, courts came to recognize duty to warn actions against vaccine manufacturers in large part because manufacturers were in many cases the only party available to provide compensation for an injured

95. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 398 (3rd ed. 1997).

96. *Id.*

97. *Id.* at 398-99.

98. *Id.* at 397.

99. *Id.*

100. Sheldon F. Kurtz, *The Law of Informed Consent: From “Doctor is Right” to “Patient has Rights,”* 50 SYRACUSE L. REV. 1243, 1253 (2000). Kurtz states:

Some studies of informed consent have also found that the use of consent forms may only aggravate patient understanding. On the other hand, in a Lou Harris poll, 65% of the general public and 64% of physicians agreed that consent forms are helpful . . . . But, in this same study 79% of patients and 54% of physicians believed that the primary purpose of consent forms was to protect physician’s [sic] from liability.

*Id.*

101. *See, e.g.,* Allison v. Merck, 878 P.2d 948, 955 (Nev. 1994) (noting that if a legislature were to protect vaccine makers from liability for failure to warn, the legislation, “to be just,” would have to include a means of compensation); *see also* Reyes v. Wyeth Lab., 498 F.2d 1264, 1294 (5th Cir. 1974) (noting that even if imposing liability undermined vaccination campaigns, it would still be important because courts need to consider the allocation of costs, and in the absence of social insurance, the loss should not lie with the victim).

plaintiff. Before the 1970s, under the so-called learned-intermediary doctrine, manufacturers of pharmaceuticals or other prescribed medical therapies or devices only had a duty to warn physicians, or other “learned intermediaries,” who were expected to use their expertise and determine the appropriateness of the therapy for the particular patient.<sup>102</sup> However, in several cases concerning the administration of polio in clinic settings, courts developed an exception to the learned intermediary doctrine for mass vaccinations. For example, in *Reyes v. Wyeth Laboratories* and *Davis v. Wyeth Laboratories*<sup>103</sup> the Fifth and Ninth Circuits respectively held that “where no individualized medical judgment intervenes between the manufacturer of a prescription drug and the ultimate consumer, ‘it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning.’”<sup>104</sup> In other words, manufacturers would have a duty to warn in situations in which there simply was no other party either to give a warning or to provide compensation.<sup>105</sup> Moreover, because some pharmaceuticals are considered necessary but “unavoidably unsafe” products, strict products liability actions are not generally available, except when there is a failure to warn or there is a defect in the manufacturing process.<sup>106</sup> The duty to warn action is, in effect, the only legal

102. *Reyes*, 498 F.2d at 1276.

103. 399 F. 2d 121 (9th Cir. 1968).

104. *Reyes*, 498 F.2d at 1276 (quoting *Davis*, 399 F.2d at 131).

105. See RESTATEMENT (THIRD) PRODUCTS LIABILITY § 6 cmt. e (1998) (stating that when a manufacturer supplies vaccines for use in mass clinics, the law requires a direct warning to patients, if feasible). The comment goes on to state that “[w]hen the content of the warnings is mandated or approved by a governmental agency regulation and a court finds that compliance with such regulation federally preempts tort liability, then no liability under this Section can attach.” *Id.*

106. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). This comment put the matter quite bluntly:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

*Id.* (emphasis added). The Third Restatement modifies this standard by clarifying that prescription drugs and medical devices are not governed by the general rules of product defectiveness, but rather, are defective only if the “foreseeable risks of harm . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.” RESTATEMENT (THIRD) PRODUCTS LIABILITY § 6 (c) (1998).

remedy left standing, and the only common law vehicle for compensation for injured patients.<sup>107</sup>

The compensatory function of these tort actions has often aroused great criticism. Both health care professionals and manufacturers have charged that large verdicts in tort actions are deleterious to the public health.<sup>108</sup> Critics of medical malpractice actions have claimed that high verdicts spur frivolous litigation and lead to unnecessary “defensive medicine.”<sup>109</sup> Informed consent litigation has also been castigated for imposing excessive costs on the health care system by requiring physicians and other providers to spend more time with patients than they otherwise would.<sup>110</sup> Not surprisingly, potential defendants have sought, sometimes successfully, a variety of so-called “tort reforms” to limit the availability or potency of informed consent actions.<sup>111</sup> With respect to vaccines, Congress has responded to these concerns by enacting several alternative compensation schemes that limit the liability of potential defendants.<sup>112</sup>

Manufacturers of pharmaceuticals and medical devices have also assailed the costs of duty to warn cases. They claim that large tort awards undermine the

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107. See RESTATEMENT (THIRD) PRODUCTS LIABILITY § 6 cmt. d (1998) (noting that “[f]ailure to instruct or warn is the major basis of liability for manufacturers of prescription drugs and medical devices”).

108. See, e.g., U.S. DEP’T OF HEALTH AND HUMAN SERVICES (DHHS), CONFRONTING THE NEW HEALTH CARE CRISIS: IMPROVING HEALTH CARE QUALITY AND LOWERING COSTS BY FIXING OUR MEDICAL LIABILITY SYSTEM 8-11 (July 25, 2002), <http://www.aspe.hhs.gov/daltcp/reports/litrefm.pdf> (last visited Feb. 23, 2005) (arguing that the litigation system offers little benefit for patients and fails to ensure quality care).

109. *Id.* at 1. From a somewhat different perspective, the Institute of Medicine has suggested that fear of tort litigation prevent physicians from being open about their errors and willing to undertake the type of reviews that would be necessary to improve system-wide safety. See COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, TO ERR IS HUMAN 5 (Kohn et al. eds., 2002). The Institute of Medicine argues:

The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system . . . . But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

*Id.*

110. The dissent in *Truman v. Thomas* illuminates this point, saying, “The consent instruction demanded by plaintiffs will impose upon doctors the intolerable burden of having to explain diagnostic tests to healthy patients.” 611 P.2d 902, 909 (Cal. 1980) (Clark, J., dissenting).

111. For a discussion of various so-called tort reforms, see FURROW ET AL., *supra* note 8, at 316-357.

112. A variety of federal laws exist that create total or limited liability for the manufacturers of certain vaccines. The broadest of these laws is the National Childhood Vaccine Injury Act (NCVIA), Pub. L. No. 99-660, 110 Stat. 3743 (1986) (codified as amended at 42 U.S.C.A. §§ 300aa-1 to 300aa-33 (West 2003 & Supp. 2004)). The Act provides a no-fault compensation scheme for claims (including duty to warn claims) against manufacturers that plaintiffs must follow prior to bringing tort litigation with respect to certain listed vaccines. For a discussion of the Act, see Scott, *supra* note 38; Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL., POL’Y & L. 59 (1999). Interestingly, this Act does not pertain to informed consent actions against health care workers.

profitability of the industry and lead to a supply shortage.<sup>113</sup> In the case of vaccines, this claim must be taken seriously. The market for vaccines is especially fragile for several reasons. Under FDA regulations, vaccines, as biologics, are subject to particularly intense oversight and regulatory monitoring, adding to the cost of manufacture.<sup>114</sup> In addition, in contrast to medications for chronic conditions that are taken repeatedly, sometimes daily for decades, the market for vaccines is limited.<sup>115</sup> In most cases, individuals are injected just a few times in their lifetime, making the demand for vaccines far smaller than the demand for medications taken repeatedly.<sup>116</sup> Moreover, without government intervention, there is no ready market for vaccines developed for rare pathogens that could be used by a bioterrorist, or that may reemerge either by accident or due to changing environmental circumstances.<sup>117</sup> Finally, because the federal government is the largest purchaser of some vaccines, it has enormous market power which it can use to reduce the price of vaccines.<sup>118</sup>

Given these market conditions and the high costs of informed consent and duty to warn cases, it is plausible that duty to warn litigation may threaten public health by reducing the supply of necessary pharmaceuticals or vaccines.<sup>119</sup> This does not mean, however, that the goal of informed consent to provide a mechanism

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113. Lynne Lederman, *Protection for Vaccine Makers-Product Liability Concerns Continue to Hinder Vaccine Development*, THE SCIENTIST, Oct. 27, 2003, at <http://www.biomedcentral.com/news/20031027/02> (last visited Feb. 23, 2005) (noting that “[l]awsuits are continuing to have a chilling effect on vaccine producers . . .”).

114. See Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 371, 380 (2002) (noting that manufacturers of vaccines “must satisfy not only new drug approval requirements but also a separate set of controls governing biologics, although recent amendments to the regulations have reduced some of these burdensome requirements”). The fragility of the market became especially apparent in fall 2004 when one of the only two manufacturers licensed to provide flu shots in the United States was unable to deliver due to manufacturing problems in a plant in England. Denise Grady, *Shortage Was Predicted*, N.Y. TIMES, Oct. 7, 2004, at A33.

115. Noah, *supra* note 114, at 382.

116. *Id.*

117. As a result, the government will fund the development of these vaccines and provide a market via the national pharmaceutical stockpile. Relevant laws include: Smallpox Emergency Personnel Protection Act of 2003, Pub. L. No. 108-020, 117 Stat. 638 (codified as amended at 42 U.S.C.A. §§ 233, 239 & 239a-h (West 2003 & Supp. 2004)), Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (codified as amended at 3 U.S.C.A.; 5 U.S.C.A.; 6 U.S.C.A.; 7 U.S.C.A.; 8 U.S.C.A.; 10 U.S.C.A.; 14 U.S.C.A.; 15 U.S.C.A.; 18 U.S.C.A.; 19 U.S.C.A.; 20 U.S.C.A.; 21 U.S.C.A.; 26 U.S.C.A.; 28 U.S.C.A.; 31 U.S.C.A.; 37 U.S.C.A.; 38 U.S.C.A.; 40 U.S.C.A.; 41 U.S.C.A.; 42 U.S.C.A.; 44 U.S.C.A.; 49 U.S.C.A.; 50 U.S.C.A.), and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (codified as amended in 42 U.S.C. and 21 U.S.C.).

118. GAO, *supra* note 30, at 5.

119. While I concede the plausibility of this claim, it is important to note that there has been little in the way of empirical evidence to support the assertion, and that numerous problems, other than the costs of litigation, affect the supply of vaccines. See Grady, *supra* note 114.

to compensate injured patients is inimical to public health. To the contrary, compensation is an especially necessary component of any public policy designed to protect public health by encouraging vaccinations.

There are several reasons why, from a public health perspective, compensation is particularly important for vaccination programs.<sup>120</sup> First, as was discussed earlier, when there is a low incidence of a disease in a population, either because of previously successful vaccination campaigns, or because the pathogen is only threatening or newly emerging, individuals may conclude that the risk of a vaccine does not warrant the benefits that accrue from being vaccinated.<sup>121</sup> Under these circumstances,<sup>122</sup> the availability of compensation may be an important way of reducing or offsetting individual costs, helping to ensure that a vaccination that is beneficial to the population is not economically unsound for the individual.<sup>123</sup> In effect, compensation serves as an insurance scheme, reducing an individual's risk and making it more likely that the individual will be willing to undertake the socially desirable action of being vaccinated. Compensation may therefore be a tool that can promote public health by realigning public and private costs and benefits.<sup>124</sup>

Compensation for vaccination-related injuries may support public health in another related and critical sense. Vaccination is a public health imperative in part because it benefits a population, not just the individuals who are vaccinated.<sup>125</sup> Laws that promote (or require) vaccination do so precisely because of this public

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120. By "public health perspective" I mean a viewpoint that places significant value on improving the health of a population qua population. For a more thorough discussion of the public health perspective, see Parmet, *supra* note 9, at 1233-37.

121. This may be why the issue of compensation has grown in salience as infectious diseases have waned in prominence. When people are dreadfully fearful of a disease, they clamor for vaccination and worry less about the availability of compensation. But when the risks of a disease are lower, an individual's willingness to be vaccinated appears to decrease. See Schneider & McDonald, *supra* note 28, at 583 (discussing why individuals were reluctant to be vaccinated against smallpox during the recent smallpox vaccination campaign).

122. Given the potential harm of a newly arriving infection, this may not always be the case. For example, if smallpox reappears, individuals would face a significant threat, since the disease, while not prevalent now, is rapidly contagious. *Id.* at 580-81. However, in such a scenario, the risks are inherently uncertain and individuals may well discount their own sense of risks by the uncertainty of the information. Another factor affecting individuals' perceptions of the risk/benefit ratio in the situation of a novel or reemerging pathogen is trust. *Id.* at 583-84. The more individuals trust public health authorities, the more likely they are to accept that a vaccine is also in their own interest. *Id.* For a further discussion of this factor, see *infra* notes 169-88 and accompanying text.

123. Of course, no compensation scheme can totally offset the costs associated with a vaccine-related injury. Monetary compensation is obviously an inadequate compensation for death or lifelong injuries. Nevertheless, in our legal system, monetary compensation is one of the ways we can reduce these costs.

124. Compensation schemes generally deal with only some of the economic barriers to vaccination. Studies have noted that underinsurance and significant co-pays reduce vaccination rates. See, e.g., FINANCING VACCINES, *supra* note 17, at 73-89.

125. See *supra* notes 17-19 and accompanying text.

benefit. Yet, without some mechanism for compensation, the individuals who are injured from vaccination, the very people who did precisely what was urged of them by public health officials, are the ones forced to bear all of the costs. Such a regime effectively says that a pathogen is a public concern, but the negative consequences arising from the effort to protect the public is just a matter of individual hard luck. This individualistic message clashes with and undermines the public health perspective that justifies public involvement with vaccines in the first place.<sup>126</sup>

The importance of compensation to the success of vaccination programs is evident from the difficulties faced by President Bush's campaign to vaccinate 500,000 first responders against smallpox. Despite the great fanfare with which the campaign was initiated, and the fears of terrorism that were pervasive in the wake of September 11th, only 39,353 civilian healthcare workers were vaccinated under the program.<sup>127</sup> Many reasons may be given for the low rate of compliance, including low perceptions of risk, but many scholars studying the program have also pointed to uncertainty concerning compensation and liability as a prime cause.<sup>128</sup> According to Schneider and McDonald, the uncertainty and gaps in the compensation system for smallpox violated a fundamental bond between individual and community.<sup>129</sup> They write:

As it was initially announced, the smallpox vaccination campaign asked citizens to put themselves and potentially their families at risk for the good of their country . . . . While citizens of a democracy are expected to contribute to the public good, and even to make sacrifices for the public good, the fundamental premise of a government responsible to its citizens supposes that the government will support those citizens equitably.<sup>130</sup>

The public health need for compensation, however, does not require that compensation be provided through informed consent litigation. Indeed, from a public health perspective there are sound reasons to rely primarily upon publicly-funded compensation programs. First, as noted above, given the special circumstances of the vaccine market, tort litigation may cause supply problems.<sup>131</sup> Second, tort litigation is both expensive and uncertain, meaning that many who

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126. This argument is closely related to those discussed below relating to trust. See *infra* text accompanying notes 169-88.

127. Myers et al., *supra* note 13.

128. See *id.*; Schneider & McDonald, *supra* note 28, at 583-84. For a thorough analysis of the liability issues surrounding the smallpox vaccination program, see Richards et al., *supra* note 39.

129. Schneider & McDonald, *supra* note 28, at 583-84.

130. *Id.*

131. See *supra* notes 113-19 and accompanying text.

deserve compensation will not receive it.<sup>132</sup> In addition, tort litigation usually fails to view vaccines and vaccine-related injuries as public problems. Private tort litigation effectively places the social cost of vaccines on private entities, health care workers or manufacturers.<sup>133</sup> Although this may be more preferable from a public health perspective than leaving the costs with injured individuals (since manufacturers and professionals can spread some of the cost), it still denies the full public health nature of the undertaking. Especially when there are laws that penalize individuals for not being vaccinated, the cost of injuries should in the first instance be borne by the public that benefits from the vaccination.<sup>134</sup>

Perhaps in recognition of these arguments, Congress has repeatedly loosened the bond between informed consent (or at least the manufacturer's duty to warn) and compensation, by creating alternative compensation schemes for vaccines believed to be important to public health.<sup>135</sup> This dissociation of informed consent from compensation began with the Swine Flu Act of 1976,<sup>136</sup> and continues today with the Project Bioshield Act, recently signed by President Bush.<sup>137</sup> Space here precludes a careful examination or assessment of the compensation provisions of these different statutory programs. Several points, however, warrant mention. First, these compensation programs demonstrate that private tort actions need not

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132. HARVARD MED. PRACTICE, PATIENTS, DOCTORS, AND LAWYERS: MED. INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION: REPORT OF THE HARV. MED. PRACTICE STUDY TO THE STATE OF NEW YORK 7-37 to 7-39 (1990).

133. See Noah, *supra* note 114, at 391 (quoting Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1154 (1987) (noting that "if the number of false positives attributed to a vaccine rises sufficiently, then the private costs imposed upon the manufacturer diverge from the social costs of the vaccine. Systematic underproduction results . . .").

134. See Lisa J. Steel, Note, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do For Our Children?*, 63 GEO. WASH. L. REV. 144, 144-45 (1994) (analogizing mandatory vaccinations to conscription for war).

135. See *supra* note 112.

136. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (codified as amended at 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)). This Act authorized the establishment and implementation of an emergency swine flu immunization program and provided an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program. *Id.* It also held the United States liable for personal injury or death arising out of the administration of the vaccine and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it. *Id.* § 2, 1115-16.

137. Project Bioshield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835 (codified at 42 U.S.C.S. §§ 247d-6a (Law. Co-op. 1994 & Supp 2004)). Like the Swine Flu Act, Project Bioshield immunizes manufacturers from liability for harm caused by certain vaccines and other agents, by deeming them federal employees for purposes of the Federal Tort Claims Act. *Id.* § 2, 839-40. Project Bioshield applies to research and development of qualified countermeasures against chemical, radiological, or nuclear agents that may be used in a terrorist attack. *Id.* Like the Swine Flu Act, Project Bioshield Act does not establish a no-fault compensation system, but allows personal injury claims to be brought directly against the federal government. *Id.*

serve as the primary mechanism for compensation.<sup>138</sup> However, while no-fault type programs may result in a fairer and more efficient compensation system that reduces the disincentives to produce vaccines, they may also lead to the ossification of the informed consent doctrine pertaining to vaccines. Without the possibility of damages, civil liability actions are seldom brought, and the law of informed consent, or of the duty to warn, pertaining to vaccines may develop slowly or not at all.<sup>139</sup> Eventually, this may impede the law's ability to fulfill the other objectives of informed consent. Moreover, even when civil actions for informed consent are obliterated and no-fault systems are put in place, informed consent remains critical as it supplies the "right," or ethical entitlement for compensation. In a legal system and culture based significantly on individualistic notions of right and justice, informed consent helps provide the ethical justification for why individuals who are unavoidably injured by vaccines ought to be compensated. Without informed consent's articulation of how such people are wronged, compensation schemes may lose some of their ethical grounding, and potentially their support, thereby jeopardizing their existence and ability to promote public acceptance of vaccinations.<sup>140</sup>

### C. Preventing Injuries

Another critical, but not always obvious, goal of informed consent is the reduction of medical injuries. This goal is not only compatible with public health, it is a public health goal. While vaccines have been enormously important to improving public health, injuries do occur. Although usually unavoidable, sometimes these injuries can be prevented. For example, in 1955, 260 cases of paralytic polio and eleven deaths were caused by a polio vaccine that was not properly inactivated.<sup>141</sup> Today, approximately 10,000 adverse vaccine-related events are reported each year.<sup>142</sup>

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138. However, other mechanisms are then required to ensure that the core elements of informed consent are maintained. See *supra* notes 89-94 and accompanying text.

139. Thus it is not surprising that the leading cases in the field derive from vaccinations prior to the act. See, e.g., *Reyes v. Wyeth Lab.*, 498 F.2d 1264 (5th Cir. 1974); *Davis v. Wyeth Lab.*, 399 F. 2d 121 (9th Cir. 1968); *Allison v. Merck*, 878 P.2d 948 (Nev. 1991).

140. As long as there is a legal right to informed consent, no-fault programs appear as statutory reforms that vindicate an individual's right to compensation. These no-fault programs operate in a relatively efficient manner rather than as welfare programs to aid the injured. Once the legal right to informed consent is abolished, compensation programs may appear as little more than welfare programs and may well end up losing support, as welfare programs often do in this society.

141. Milstien, *supra* note 32, at 176. Following this incident, regulatory changes were made to increase oversight of adverse events. *Id.*

142. NATIONAL IMMUNIZATION PROGRAM, CDC, OVERVIEW OF VACCINE SAFETY (2003) [hereinafter OVERVIEW OF VACCINE SAFETY], available at <http://www.cdc.gov/nip/vacsafe> (last visited Feb. 23, 2005).

Reducing vaccine-related injuries without reducing overall vaccination rates aids public health.<sup>143</sup> Informed consent does this in two distinct ways. First, as a tort action, informed consent is closely related to, and indeed often serves as a proxy for, a malpractice action against health care providers or a products liability action against manufacturers.<sup>144</sup> In informed consent cases, defendants are found liable only when plaintiffs can demonstrate that the defendant's failure to provide the required information caused a physical injury. The mere violation of the ethical imperative to disclose risks and to act as a fiduciary is insufficient to provide relief.<sup>145</sup> Hence, the informed consent cause of action provides defendants with a theoretical incentive to reduce physical injuries among patients.<sup>146</sup> Of course, whether tort actions actually serve to reduce injuries has been heavily

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143. This is for two reasons. First, vaccine-related injuries directly impair a population's health. Second, vaccine-related injuries lead people to resist vaccination. To the extent that injuries are reduced and that information is conveyed in a trustworthy manner, people may be more likely to accept vaccination. This does not imply that vaccine-related injuries for the currently licensed vaccine are significant from a population perspective, they are in fact quite rare. See CDC, SURVEILLANCE FOR SAFETY AFTER IMMUNIZATION: VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) – UNITED STATES, 1991-2001, 52 MORBIDITY AND MORTALITY WEEKLY REPORT 1-2 (Jan. 24, 2003). Between 1991 and 2001, Vaccine Adverse Event Reporting System received 128,717 reports of adverse events from over 1.9 billion net doses of human vaccines. *Id.* at 1. Of these, clinicians described 14.2% as serious, by which they meant as causing death, life-threatening illness, hospitalization or permanent disability. *Id.* at 2. In addition, there is a great deal of erroneous information available about vaccine-injuries. See Wolfe et al., *supra* note 22. This information may persist even if injuries become rarer. Nevertheless, it seems self-evident that public health supports improvements in vaccine safety.

144. Alan Meisel, *A "Dignitary Tort" as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 L. MED. & HEALTH CARE 210, 212 (1988); see also Kurtz, *supra* note 100, at 1244. In jurisdictions that rely upon the prudent patient standard of care, the tort of informed consent requires less of a reliance upon expert testimony than would an action for malpractice. *Korman v. Mallin*, 858 P.2d 1145, 1149 (Alaska 1993) (noting that "expert testimony concerning the professional standard of disclosure is not a necessary element of the plaintiff's case because the scope of disclosure is measured from the standpoint of the patient"); Laurent B. Frantz, Annotation, *Modern Status of Views as to General Measure of Physician's Duty to Inform Patient of Risks of Proposed Treatment*, 88 A.L.R. 3d 1008 (1978 & Supp. 2004) (citing *Roberson v. Christoferson*, 65 F.R.D. 615, 621 (D.N.D. 1975) (finding that while expert medical testimony is necessary to prove negligence, it is not necessary to prove failure to disclose under a theory of assault and battery)). Nevertheless, given the fact that providers need only disclose risks that a reasonable patient would find material, it is exceedingly difficult for a plaintiff to prevail in an informed consent case when the facts, at least theoretically, do not suggest negligent care. After all, if the physician's proposed treatment was within the standard of care and carried out non-negligently, a reasonable patient probably would not have found the risks material. Moreover, the patient will not generally be able to prove that he or she would have changed his mind if he or she had known of the risks. As a result, informed consent generally lies where there is a theoretical possibility of negligence, but the action may be easier for the patient to bring.

145. Meisel, *supra* note 144, at 211.

146. For a far more thorough description of the economic incentives of tort law itself, see WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF TORT LAW passim* (1987); GUIDO CALABRESI, *THE COST OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS passim* (1970).

debated.<sup>147</sup> As noted above, critics have claimed that malpractice actions lead to defensive medicine and interfere with more effective methods of reducing injuries.<sup>148</sup> Others contend that these actions do indeed have some positive deterrent effect.<sup>149</sup> For present purposes, it suffices to note that informed consent acts much in the manner of more traditional malpractice actions. In theory it reduces injuries, but whether it actually does so in practice is debatable.

Likewise, duty to warn actions parallel more traditional products liability actions and should offer whatever injury prevention benefits are associated with those actions.<sup>150</sup> Interestingly, duty to warn actions are the tort action of choice for plaintiffs injured by vaccines precisely because vaccines are believed to be “unavoidably” dangerous.<sup>151</sup> If this was really the case, duty to warn actions could not reduce overall injuries.<sup>152</sup> However, courts that have decided duty to warn cases have not always accepted the premise that a vaccine or a vaccination program may not be made safer. For example, in *Reyes v. Wyeth Laboratories*,<sup>153</sup> the court answered the claim that liability would undermine vaccination campaigns by noting that proper warnings would provide plaintiffs with the choice of using a safer vaccine.<sup>154</sup>

147. At best, the empirical evidence on malpractice litigation’s deterrent effect is mixed. See Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1597-98 (2002).

148. See *supra* notes 108-09 and accompanying text.

149. David A. Hyman & Charles Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Part of the Problem or Part of the Solution?* 7 (Mar. 28, 2004), Univ. of Md., Pub. Law Research Paper No. 2004-08, [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=526762](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=526762) (last visited Feb. 23, 2005); PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION 131 (1993) (suggesting that the rate of injuries due to medical negligence was roughly thirty percent less than it would have been if there were no malpractice litigation); Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?* 42 UCLA L. REV. 377, 401 (1994) (stating that the “general threat of liability clearly affects the behavior of doctors”). But *c.f.*, Don Dewees & Michael Trebilcock, *The Efficacy of the Tort System and Its Alternatives: A Review of Empirical Evidence*, 30 OSGOODE HALL L.J. 57, 82-83 (1992) (critiquing the data used by Weiler and colleagues).

150. Many scholars contend that products liability law, as embodied in the RESTATEMENT (SECOND) OF TORTS § 402 and RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2(a), has promoted safer products. See Larry S. Stewart, *A New Frontier: Design Defect Cases and the New Restatement*, 34 TRIAL 20, 23 (Nov. 1998); Ellen Wertheimer, *Calabresi’s Razor: A Short Cut to Responsibility*, 28 STETSON L. REV. 105, 127 (1998). For a competing view, see Albert A. Ehrenzweig, *A Psychoanalysis of Negligence*, 47 NW. U. L. REV. 855, 865 (1953).

151. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §6 cmt. d (1998).

152. The question of whether the vaccine was administered to a person who should receive the vaccine would remain. For a discussion of this issue, see *infra* text accompanying notes 158-64.

153. 498 F.2d 1264 (5th Cir. 1974).

154. *Id.* at 1293.

Of course, it is possible that whatever public health benefits might accrue from informed consent may be better realized by careful regulatory oversight.<sup>155</sup> Indeed, recent laws that have provided partial or complete immunity for vaccine manufacturers seem to rest on this assumption.<sup>156</sup> However, if, as under the recent federal acts, new vaccines to meet bioterrorist threats may be licensed for use without full Phase III testing, traditional systems of regulatory oversight may not be able to ensure adequate efficacy or safety.<sup>157</sup> In these circumstances, the duty to warn may serve as a useful and perhaps the only incentive to reduce vaccine-related injuries as much as possible.

So far, the discussion has treated informed consent and duty to warn tort actions as similar in their deterrent effect upon negligence or products liability claims. Informed consent, as either a tort action or as a more general legal principle, however, may also prevent injuries in its own unique way. Recall that informed consent requires a health care provider or manufacturer to give information about the risks and dangers associated with a medical procedure or treatment to a patient.<sup>158</sup> In situations in which the learned intermediary doctrine applies, and the obligation to obtain informed consent resides primarily with the health care professional, informed consent demands an interaction between patient

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155. That was the premise of the National Childhood Vaccine Injury Act, which established a no-fault compensation system by which vaccinees injured by certain listed vaccines can petition for a monetary award and required health care providers to report certain adverse events following vaccinations and led to the establishment of the Vaccine Adverse Events Reporting System housed within the FDA. Pub. L. No. 99-660, 110 Stat. 3743 (1986) (codified as amended at 42 U.S.C.S § 300aa-1 to 300aa-33 (Law. Co-op.2003 & Supp. 2004)); OVERVIEW OF VACCINE SAFETY, *supra* note 142.

156. For example, § 304(c) of the Homeland Security Act of 2002 deems smallpox vaccine manufacturers to be federal employees, thereby triggering the liability protections of the Federal Tort Claims Act. Pub. L. No. 107-296, 116 Stat. 2135 (codified at 42 U.S.C.A. § 233 (West 2003 & Supp. 2004)). Additionally, § 2 of the Smallpox Emergency Personnel Protection Act of 2003 establishes a no-fault compensation program for persons injured or killed by smallpox inoculation. Pub. L. No. 108-020, 117 Stat. 638 (codified at 42 U.S.C.A. § 239 (West Supp. 2004)). Finally, § 2(d)(2) of the Project Bioshield Act of 2004 deems manufacturers of all bioterror countermeasures, including vaccines, to be federal employees for the purposes of the Federal Tort Claims Act. Pub. L. No. 108-276, 118 Stat. 835 (to be codified at 42 U.S.C.A. § 247d-6a).

157. *See, e.g.*, 21 U.S.C.A. § 356 (West 1999 & Supp. 2004) (allowing fast-track approval of vaccines other “priority countermeasures” based solely on animal models without clinical validation). The approval of such vaccines is predicated on two assumptions: first, that it may not be ethical to conduct Phase III testing for diseases that are not now naturally occurring, and second, that an emergency may warrant the risk of administering a vaccine that may not be as effective or safe as one currently licensed. Even if we accept the first proposition, the second depends first on the assumption that officials are correct about the existence and nature of a risk and second that it might not be possible to make a novel vaccine any safer than it was originally made. Both propositions are questionable. Indeed, the lack of testing of new vaccines, the retrospective liability of tort law, and the duty to warn in particular, may provide useful incentives to make a novel vaccine as safe as possible. *See* Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163, 1303-04 (1998).

158. *See supra* notes 89-94 and accompanying text.

and provider that not only helps the patient exercise autonomy, but also gives the health care professional an opportunity to gain information about the patient's own health care status.<sup>159</sup> Of course, in an ideal world, physicians would have a long-standing, deep relationship with their patients, and would be aware of contraindications that may exist to a patient receiving a particular vaccine or other pharmaceutical. However, in the real world of managed care, high mobility, and medical specialization, physicians and other providers often lack all of the relevant information about their patients. In these circumstances, informed consent provides a way of informing the patient about what he or she should tell the physician.

For example, consider the facts underlying *Kemp v. New Jersey*.<sup>160</sup> The plaintiffs were a high school student, vaccinated for rubella while pregnant, and her infant, born with congenital rubella syndrome.<sup>161</sup> Because the rubella vaccine is contraindicated in early pregnancy,<sup>162</sup> and a health care worker, even a family physician, may not know that a teenage girl is pregnant, the process of obtaining the girl's informed consent and warning her about the risk to the fetus may provide the only incentive for the girl to reveal her condition or the possibility of her pregnancy.<sup>163</sup> Under these circumstances, informed consent may provide an opportunity for an appropriate individualized assessment of risk and prevent vaccine-related injuries.

The common law recognized the importance of informed consent and placed the obligation to have this dialogue on the professional. However, as courts now appreciate, vaccinations are often given in public health clinics or other mass settings in which there is no opportunity for a meaningful dialogue between a health care professional and patient. It is precisely for those situations that the courts created an exception to the learned intermediary doctrine and required another entity, generally a manufacturer, to provide a warning.<sup>164</sup> Under these circumstances, in which there is a chance that a physician will not have pre-existing medical information on the patient, the duty to warn would appear to be

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159. Jay Katz states that the physician-patient interactions that occur during the informed consent process can be "useful medical prescriptions" that also "respect patients' wishes to maintain and surrender autonomy." JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 84 (1984).

160. 687 A.2d 715 (N.J. 1997), 809 A.2d 77 (N.J. 2002). The issues before the court had to do with construction of the state immunity statute as well as the admissibility of expert testimony. *Kemp*, 687 A.2d at 716; *Kemp*, 809 A.2d at 78, respectively.

161. *Kemp*, 687 A.2d at 716-17.

162. NATIONAL IMMUNIZATION PROGRAM, CDC, GUIDE TO CONTRAINDICATIONS TO VACCINATIONS (2004) [hereinafter GUIDE TO CONTRAINDICATIONS], <http://www.cdc.gov/nip/recs/contraindications.htm#> (last visited Feb. 23, 2005).

163. In this scenario, a teenager may not answer truthfully if asked "might you be pregnant." But a warning, "you should know that this vaccine can lead to severe birth defects if you are pregnant," might provide enough of an incentive for a young woman to disclose the possibility.

164. See *supra* notes 101-07 and accompanying text.

even more crucial than a physician's warning to ensure that vaccinations are given only to those who should receive them.

The fact that informed consent, understood as warnings, promotes public health does not mean that such warnings need to be given by manufacturers or that they need to form the basis for tort liability. Instead, some courts have recognized that manufacturers can satisfy their duty to inform consumers by taking measures to ensure that the CDC issues warnings when vaccines are administered.<sup>165</sup> Moreover, the NCVIA removes the manufacturers' duty to warn the public directly and requires instead that vaccines be distributed with warnings provided by the CDC.<sup>166</sup> Likewise, the CDC's smallpox vaccination guidelines stress the role of public communication via the mass media and urge public health authorities to use videos to inform patients about the smallpox vaccine in the event of a smallpox emergency.<sup>167</sup> In the case of the smallpox vaccine in particular, which is not recommended for immuno-compromised individuals,<sup>168</sup> such warnings need to be given not simply to preclude the possibility of liability, or to satisfy some preference for individual autonomy, but because they can prevent a public health problem. In our desire to use vaccinations to protect public health, we need to take care not to create other public health problems. Informed consent helps to do that.

#### D. Promoting Trust

One goal of informed consent is to foster "mutual trust and education between doctor and patient."<sup>169</sup> By requiring that health care providers (or manufacturers) inform patients about the risks of particular medical procedures, informed consent seeks to promote a trust relationship between patient and provider, where the provider acts in the interest of the patient and shares with the

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165. See, e.g., *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1366 (3d Cir. 1992).

166. 42 U.S.C.A. § 300aa-26(a) (West 2003) requires the Secretary of Health and Human Services to develop "vaccine information materials for distribution by health care providers to the legal representatives of any child receiving a vaccine set forth in the Vaccine Injury Table." These materials are to be developed in consultation with the Advisory Committee on Childhood Vaccines, the Centers for Disease Control and Prevention, the Food and Drug Administration, health care providers, and parents' organizations. *Id.* § 300aa-26(b). The Act expressly relieves manufacturers of civil liability arising out of a failure to provide direct warnings to an injured party. *Id.* § 300aa-22(c).

167. CDC, ANNEX 3: GUIDELINES FOR LARGE SCALE SMALLPOX VACCINATION CLINICS 13, 18 (2002) [hereinafter CDC, ANNEX 3], <http://www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-3.pdf> (last visited Feb. 23, 2005).

168. GUIDE TO CONTRAINDICATIONS, *supra* note 162. See also CDC, RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP): USE OF VACCINES AND IMMUNE GLOBULINS IN PERSONS WITH ALTERED IMMUNOCOMPETENCE, 42 MORBIDITY AND MORTALITY WEEKLY RPT. 6-7 (Apr. 9, 1993).

169. Meisel, *supra* note 144, at 210. While noting the importance of this goal, Meisel argues that the judicial doctrine of informed consent has often failed to vindicate it. *Id.* See also MARC A. RODWIN, MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST 181-184 (1993) (discussing informed consent as among a physician's fiduciary obligations).

patient the information necessary for the patient to make informed choices and to feel respected in the course of treatment.<sup>170</sup> This trust is often critical to the success or failure of a therapeutic intervention.<sup>171</sup> While the efficacy of vaccines themselves almost certainly does not depend upon the existence of a trust relationship between physician and provider, trust may be critical to a patient's willingness to be vaccinated, or to have his or her child vaccinated.<sup>172</sup> In addition, trust won or lost in interactions concerning vaccinations likely can carry over to other interventions.<sup>173</sup> For example, a parent who loses faith in a pediatrician who fails to warn her about a possible side effect for a child from a routine vaccine may feel less confident in discussing with that same physician another issue affecting the child's health. Writ large, this erosion of trust can affect a population's health.<sup>174</sup>

In many situations, however, vaccines are administered outside of the physician-patient relationship. In an emergency, this is especially likely to be the case. As discussed above, in these circumstances, there is little possibility of a physician-patient dialogue, and the trust, or lack thereof, between the patient and physician is immaterial. That does not mean, however, that trust remains unimportant to public health or that informed consent plays no role in furthering it. Rather, it suggests that the trust that is at stake is that between the public and public health system. By providing informed consent, the public health system can help nurture that trust.

In the years since September 11th and the ensuing anthrax attacks, numerous scholars have considered the role of public trust in developing emergency responses. While the initial reaction to the terrorist events of 2001 may have been to assert the importance of aggressive and even coercive measures, many experts

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170. See *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972) ("The patient's reliance upon the physician is a trust of the kind which traditionally has exacted obligations beyond those associated with arms-length transactions"); Mark. A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 489-90 (2002) (remarking that informed consent is the most prominent example of fiduciary law); David Mechanic, *The Functions and Limitations of Trust in the Provision of Medical Care*, 23 J. HEALTH POL. POL'Y & L. 661, 672-73 (discussing the importance of disclosure and informed consent to patients' trust of physicians).

171. See Mechanic, *supra* note 170, at 662 (noting that the erosion of trust damages the effectiveness of medical interventions).

172. Studies confirm the importance of communication between physicians and parents in determining whether parents will consent to have their children vaccinated. See Fredrickson et al., *supra* note 21, at 436-437.

173. Hence a patient who feels a great deal of trust in a physician may feel less needful of receiving information about the possible adverse affects of a vaccine. If the patient has a great deal of trust in the physician, she may be more willing to take the physician's word that the vaccination should be given.

174. See Mechanic, *supra* note 170, at 662 (noting that "trust is an essential 'glue' that holds communities together and allows us to pursue our affairs without excessive suspicion, policing, and regulation. The erosion of trust, therefore, damages the effectiveness of medical interventions, and invites legislative and regulatory micromanagement of health affairs.").

have come to realize that any public health response to a bioterrorist event (or manmade health emergency) must necessarily rely primarily upon a population's willingness to comply.<sup>175</sup> This in turn requires trust, as nurtured by the information provided by informed consent.<sup>176</sup>

The world's experience in 2003 with SARS illustrates the point. While that experience highlighted the importance of surveillance and fastidious observation of infection control procedures in hospitals,<sup>177</sup> it also demonstrated the importance of trust in public health. Although quarantines and other isolation measures were used in Toronto, the city in this hemisphere most affected by the epidemic, authorities had to resort to obtaining a court order in only one instance.<sup>178</sup> Instead, the provincial government relied, mostly successfully, on the public's voluntary compliance with suggested public health measures.<sup>179</sup> In contrast, governments that emphasized more coercive measures may have instilled panic in their populations.<sup>180</sup> Certainly, in a wide-spread emergency, voluntary compliance will

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175. See Working Group on "Governance Dilemmas" in Bioterrorism Response, *Leading During Bioattacks and Epidemics with the Public's Trust & Help*, in 2 BIOSECURITY & BIOTERRORISM: BIODEFENSE, STRATEGY, PRACTICE, & SCIENCE 25, 31 (2004) [hereinafter Working Group on "Governance Dilemmas"]; Eric Aakko, *Risk Communication, Risk Perception and Public Health*, 103 WIS. MED. J. 25, 25-27 (2004); George J. Annas, *Puppy Love: Bioterrorism, Civil Rights, and Public Health*, 55 FLA. L. REV. 1171, 1179 (2003); James F. Childress & Ruth Gaare Bernheim, *Beyond the Liberal and Communitarian Impasse: A Framework and Vision for Public Health*, 55 FLA. L. REV. 1191, 1218-19 (2003). It is interesting to note that in all recent public health crises requiring the mass vaccination of civilians, public health officials have indeed relied upon voluntary vaccinations. For example, in 1947, smallpox reappeared in New York. Working Group on "Governance Dilemmas," *supra*, at 31. The public health department instituted a massive, voluntary immunization campaign that stopped the outbreak. *Id.* Likewise, in 1976, faced with what appeared to be the prospect of a massive swine flu epidemic, the government enacted a program that encouraged and promoted, but did not mandate, vaccination. See National Swine Flu Immunization Program of 1976, Pub. L No. 94-380, 90 Stat. 1113 (codified as amended at 42 U.S.C.A. § 247b (West 2003 & Supp. 2004)). Given the fact that the dreaded epidemic never arose, the one "silver lining" of the episode was the fact that the government did not use involuntary measures. Had it used such measures, the damage to public health would have been enormous.

176. Thomas A. Glass & Monica Schoch-Spana, *Bioterrorism and the People: How to Vaccinate a City Against Panic*, 34 CLINICAL INFECTIOUS DISEASES 217, 221 (2002).

177. C. David Naylor et al., *Learning from SARS in Hong Kong and Toronto*, 291 JAMA 2483, 2486 (2004); Robert A. Weinstein, *Planning for Epidemics - The Lessons of SARS*, 350 NEW ENG. J. MED. 2332, 2332-34 (2004). These reports also point out the need for a sufficient surge capacity, so that health care may be provided during an emergency.

178. NATIONAL ADVISORY COMM. ON SARS AND PUB. HEALTH, HEALTH CANADA, LEARNING FROM SARS: RENEWAL OF PUB. HEALTH IN CANADA 178 (2003).

179. *Id.* The report argues that there is a strong "duty to care" for those who were subject to isolation and quarantine orders. *Id.* This duty corresponds closely to the discussion above about the need to provide compensation to individuals for the costs they incur in following public health directives. See *supra* notes 120-30 and accompanying text.

180. MARK A. ROTHSTEIN ET AL., UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE, QUARANTINE AND ISOLATION: LESSONS LEARNED FROM SARS: A REPORT TO THE CENTERS FOR DISEASE CONTROL AND PREVENTION 9 (2003) (reporting that officials in Taiwan believe that

be essential if for no other reason than the fact that there will not be sufficient resources to compel people to follow public health directives.<sup>181</sup>

Informed consent is a necessary ingredient for public trust of public health.<sup>182</sup> Without clear information about the risks and benefits of a public immunization campaign, as well as a clear statement of what is not known, the public may be understandably skeptical and resistant to being vaccinated.<sup>183</sup> The public may also be more likely to panic and act in counterproductive ways if they are not given practical and credible information.<sup>184</sup> When SARS struck Toronto, public communication and information played a major role in stopping the epidemic. The Province of Ontario conducted a massive public education campaign, which included maintaining frequently updated websites, daily press conferences by public health leaders,<sup>185</sup> and a SARS telephone hotline, which received over 300,000 calls.<sup>186</sup> This type of public communications effort is not what we usually think of as informed consent, but it is, in effect, a public version of informed consent.<sup>187</sup> And it is one that not only abets public health, but is essential to it in an emergency.<sup>188</sup>

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aggressive use of quarantine in that country may have contributed to public panic, and thus proved counterproductive to containment efforts).

181. George Annas quotes Senator Sam Nunn, who played the president in the Direct Winter exercise, as saying, “[t]here is no force on earth strong enough to get 250 million Americans to do something that they do not believe is in their own best interests or that of their families.” Annas, *supra* note 175, at 1179.

182. See Weinstein, *supra* note 177, at 2334 (discussing public trust in relation to SARS).

183. See Glass & Schoch-Spana, *supra* note 176, at 221 (emphasizing the importance of communication to public trust). Here Rudolph Guiliani’s comments to New Yorkers on September 11th are probably the model of transparency. He told the public what was known and what was not known and by the clarity and transparency of his remarks, was able to maintain calm and order in the face of the greatest disaster ever to strike the nation. John Schwartz, *The Truth Hurts; Efforts to Calm the Nation’s Fears Spin Out of Control*, N.Y. TIMES, Oct. 28, 2001, § 4 at 1. In contrast, incomplete and ultimately misleading remarks from Secretary Tommy Thompson at the start of the anthrax attacks may have undermined the government’s credibility in that tragedy. *Id.* See also Glass & Schoch-Spana, *supra* note 176, at 221. Certainly the unwillingness of many postal workers to be vaccinated, when the CDC recommended it, and the willingness of many people to take Cipro, when they had no known exposure, suggests that the public lacked trust in their public health officials in the wake of the anthrax attacks. See, e.g., Sheryl Gay Stolberg, *A Nation Challenged: Steps Against Anthrax: Civilians are Reluctant to Join U.S. Test of Anthrax Vaccine*, N.Y. TIMES, Jan. 8, 2002, at A13 (postal workers exposed to anthrax are very unwilling to be vaccinated); Schwartz, *supra* (discussing how poor communication by the government regarding the anthrax attacks exacerbated panic); Jane Gross, *A Nation Challenged: The Doctors; Doctors Face Threat, and Fear, of Anthrax*, N.Y. TIMES, Oct. 17, 2001, at B1 (discussing public demand for Cipro as a result of panic over anthrax).

184. Glass & Schoch-Spana, *supra* note 176, at 218.

185. ROTHSTEIN ET AL., *supra* note 180, at 32.

186. Weinstein, *supra* note 177, at 2334.

187. See *infra* notes 229-32 for a further discussion of this model of informed consent.

188. Glass & Schoch-Spana, *supra* note 176, at 219-221 (emphasizing the importance of effective communication strategies in bioterrorism planning).

### *E. Dignity and Self-Determination*

Although the legal doctrine of informed consent has often been criticized for failing to be faithful to a patient's autonomy,<sup>189</sup> both courts and ethicists recognize that patient autonomy is a key goal of informed consent.<sup>190</sup> Informed consent furthers autonomy by providing patients with information necessary to making an informed choice that is properly reflective of their values and outcomes.<sup>191</sup>

In recent decades, the value given to autonomy in American law and bioethics has been the subject of criticism from numerous quarters. Some feminist bioethicists claim that the focus on autonomy has obscured the importance of relationships.<sup>192</sup> Communitarians have challenged the very notion that individuals have autonomous preferences and can be understood apart from and as more important than the communities in which individuals exist.<sup>193</sup> Public health advocates, invoking the spirit of *Jacobson*, have claimed that autonomy cannot be an absolute value and that it must give way at times to the greater good of public health.<sup>194</sup>

Space precludes a full discussion of the concept of autonomy or its relationship to public health. However, in considering the role of informed consent for vaccinations in the advent of a public health emergency, two separate issues require discussion: first, the role of informed consent in those situations in which vaccinations are not absolutely mandatory, and second, the extent to which self-determination and individual choice should be respected during public health emergencies.

In light of *Jacobson* and state laws that require children to be vaccinated prior to entering school, respecting informed consent for its furtherance of patient autonomy may seem either superfluous or disingenuous. Why, after all, should we demand an undertaking that exists to promote self-determination in situations in

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189. See, e.g., Marjorie Maguire Schultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 298-99 (1985).

190. *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972); Gerald Dworkin, *Autonomy and Informed Consent*, in MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP, VOL. III: APPENDICES STUDIES ON THE FOUNDATIONS OF INFORMED CONSENT, PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH 63, 66 (1982).

191. *Canterbury*, 464 F.2d at 780.

192. E.g., Susan M. Wolf, *Gender, Feminism, and Death: Physician-Assisted Suicide and Euthanasia*, in FEMINISM AND BIOETHICS: BEYOND REPRODUCTION 299 (Susan M. Wolf, ed. 1996).

193. JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 32-33 (2d ed. 2001); Elizabeth Cooper, *Social Risk and the Transformation of Public Health Law: Lessons From the Plague Years*, 86 IOWA L. REV. 869, 918-20 (2001); Joanna K. Weinberg, *Whose Right Is It Anyway? Individualism, Community, and the Right to Die: A Commentary on the New Jersey Experience*, 40 HASTINGS L.J. 119, 163-67 (1988).

194. LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 4 (2000).

which individuals may have no choice at all? Several answers can be given. One answer, as suggested by the analysis above, is that informed consent promotes many goals in addition to self-determination. Even when individuals have no choice, informed consent may be critical to ensuring that they give critical information to their health care provider or public health authority.<sup>195</sup> Likewise, informed consent may remain useful as a vehicle for determining liability and compensation or for promoting a better relationship between patient and physician.<sup>196</sup> Moreover, the absence of choice does not necessitate the complete elimination of respect for the individual. Even when people are required to submit to an undertaking, they are likely to feel better about it if they are given an explanation as to why that must be the case. “Because I told you so,” may or may not work with small children, but it certainly is not apt to foster trust with a population of adults.

More importantly, the fact that the state may require a vaccination in some circumstances does not mean that no choices exist. For example, even when the Court in *Jacobson* upheld the ability of the city to penalize an individual for refusing a vaccination, it suggested that exemptions might have to be given to individuals who can demonstrate that the vaccine would be especially dangerous to them.<sup>197</sup> Without the relevant material information, an individual might not be able to exercise this limited, but potentially critical choice. Likewise, all states that require schoolchildren to be vaccinated permit some medical exemptions.<sup>198</sup> Again, the exercise of these limited choices may well depend upon informed consent.

In addition, even in the vast majority of cases in which there is no medical reason to exempt an individual from a required vaccination, a choice, albeit a limited and difficult one, remains. In *Jacobson*, the plaintiff was left with the choice of being vaccinated or paying a five dollar fine.<sup>199</sup> Today, the choice available may be to home-school a child. In both a formal and a practical sense, this is not much of a choice. Many individuals are not able to educate their children at home.<sup>200</sup> Likewise, the choice suggested by a model emergency health powers act to be vaccinated or remain in isolation is not much of a choice.<sup>201</sup>

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195. Thus, even if the hypothetical teenager discussed above was required by law to take the vaccine if recommended by the school nurse, informed consent may be vital to enabling the nurse to learn of the teenager’s pregnancy, which might lead the nurse to exercise her authority to conclude that the teenager should not be vaccinated. See *supra* notes 160-63 and accompanying text.

196. See *supra* notes 160-64, 169-74 and accompanying text.

197. *Jacobson v. Massachusetts*, 197 U.S. 11, 38-39 (1905).

198. See *supra* notes 66-69 and accompanying text.

199. *Jacobson*, 197 U.S. at 14.

200. See Zenaida A. Gonzalez, *Students Learning at Home*, FLA. TODAY (Brevard County, Fla.), Sept. 24, 2000, at 1.

201. MSEHPA, art. VI; Gostin, *supra* note 53, at 18-20. The fact that informed consent may be necessary even when the choice is limited to vaccination or quarantine does not itself speak to the appropriateness of the limited set of options given. See Wendy E. Parmet, *Quarantine Redux*:

But, few choices (if any) are fully free. The difficulty of the choice, and the fact that the state may skew it by favoring one option over the other, does not negate the importance of being informed when making it. In other words, the fact that the state may use the law to make it costly to exercise a particular choice does not undermine the importance of allowing people to make that choice with as much information as a reasonable person would find relevant. Unless the state forcibly injects people against their will, which the state only has the power to do in limited circumstances when individuals are incompetent,<sup>202</sup> reasons remain to obtain informed consent.

There is, moreover, a deeper and more critical reason for providing informed consent, even in those situations in which the law limits an individual's action. As discussed above, public health relies significantly on public trust.<sup>203</sup> At times, the health of a population may warrant, from a public health perspective, the limitation of an individual's liberty of action.<sup>204</sup> However, in time such limitations will neither succeed nor remain in place unless the public broadly consents to them. Unpopular public health laws, even when they are effective in terms of population health, simply will not remain in place or be enforced unless they are broadly accepted, or at least tolerated.<sup>205</sup> In the long run, public health laws require public consent. And just as individual consent requires information, so does public consent. Unless a population understands why a vaccination is being required and what risks may follow from that vaccination, it is not likely to continue to submit to public health authorities or grant them the authority they seek to require vaccinations or deal with the next emergency. Hence, even when

*Bioterrorism, AIDS, and the Curtailment of Individual Liberty in the Name of Public Health*, 13 HEALTH MATRIX 85, 110-15 (2003).

202. See *Sell v. United States*, 539 U.S. 166, 179-80 (2003) (holding that the "Government [may] involuntarily . . . administer antipsychotic drugs to a mentally ill defendant . . . to render [him or her] competent to stand trial, but only if the treatment is medically appropriate [and] unlikely to have side effects that may undermine the fairness of the trial [and only if there are no] less intrusive alternatives"); *Washington v. Harper*, 494 U.S. 210, 221-227 (1990) (while recognizing that the individual has a "significant" constitutionally protected liberty interest in avoiding the unwanted administration of antipsychotic medication, a state may forcibly administer such medication to a mentally ill prisoner if the prisoner is dangerous to himself or others and the medication is in the inmate's medical interest); *Shine v. Vega*, 709 N.E.2d 58, 65 (Mass. 1999) (asserting right of competent patient not involved in the criminal justice system to refuse life-sustaining care).

203. See *supra* notes 174-88 and accompanying text.

204. Gostin, *supra* note 9, at 1159-69 (establishing a framework for determining when liberties should be limited for public health).

205. For example, while motorcycle helmet laws are apparently effective in reducing injuries, they remain widely unpopular and are increasingly being repealed throughout the nation. See Matthew L. Wald, *As Risks Make a Helmet More Vital, Fewer Motorcyclists Wear One*, N.Y. TIMES, June 14, 2004, at A13. In any political system in which public health laws remain accountable to officials, popular acceptance remains crucial. Unless a public understands and accepts the expert conclusion that a limitation on liberty will be efficacious and warranted, the limitation will not remain in place.

individuals are deprived of their choices, the public is not. The public still requires informed consent.<sup>206</sup>

So far, the discussion has focused on why informed consent remains crucial even when the state mandates vaccination. The question remains: should self-determination itself be vindicated? In response, it is important to recognize that absolute self-determination never exists. Individual choices are always influenced and constrained by the context in which they are made and the options that exist. Laws can alter those options. Indeed, they inevitably help to shape the social context in which options are exercised.<sup>207</sup> Public health laws act, in part, by influencing and shaping the context. Consider again the issues raised by childhood vaccine laws. These laws have helped us to obtain high rates of vaccination among schoolchildren. They do this not only by coercing individuals, but also by establishing norms and routines for childhood vaccinations. Most parents agree to their child being vaccinated when their health care providers discuss vaccination with them.<sup>208</sup> Childhood vaccination laws likely help to ensure that those discussions and vaccinations occur, by prompting parents to bring their child to a doctor or public health clinic, by highlighting for health providers their obligation to discuss vaccination, and by ethically obligating the state to ensure the accessibility of vaccinations. Without the legal requirement to vaccinate a child, it is debatable whether any of the above would occur with the regularity or frequency with which they occur. In other words, a law that appears on its face to be coercive or a violation of self-determination probably operates more by changing norms and providing the impetus and means for voluntary compliance than by actual compulsion. Indeed, given the fact that some means exist in all states for parents to seek exemptions, and that these laws have existed without repeal for over a hundred years, it does not seem inappropriate to suggest that the population consents to such laws.<sup>209</sup>

On the other hand, the success and acceptance of these laws may not justify the imposition of mandatory vaccinations in all situations in which a public health official might conclude that vaccinations would provide protections against a potential epidemic.<sup>210</sup> While public health officials in an emergency may be tempted to think that quick and decisive action is required, justifying the use of

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206. This point is closely associated with the discussion above relating to the importance of trust. See *supra* notes 169-88 and accompanying text.

207. Scott Burris et al., *Integrating Law and Social Epidemiology*, 30 J.L. MED. & ETHICS 510, 513-18 (2002) (discussing law's role in shaping determinants of health).

208. Fredrickson et al., *supra* note 21, at 437.

209. This does not mean that they have no opponents. It does suggest that few parents ultimately feel that they are being coerced and the community at large does not experience the laws as unduly authoritarian.

210. Obviously a mandatory vaccination could not be justified by any mode of ethical or legal reasoning unless this prerequisite was made. See *Jacobson v. Massachusetts*, 197 U.S. 11, 38-39 (1905) (cautioning that the police power should not be arbitrarily exercised).

compulsion and the abrogation of informed consent, it is possible that just the opposite is the case. In contrast to school vaccination laws, an emergency edict mandating a vaccination cannot work by shifting customs and creating an alternative environment in which vaccination becomes normalized. Nor can an emergency order gain its legitimacy by surviving decades of debate and judicial challenge. If public officials are to rely upon compulsion in an emergency, their use of force may well be perceived as truly coercive. As discussed above, this may erode trust in the public health system during an emergency at just the very moment in which trust is most urgently needed.<sup>211</sup> Of course, this may not happen. If the public is given sufficient information and there is a pre-existing deep well of trust, it may submit willingly to significant restrictions of liberty (“informed acquiescence”). Unfortunately, we cannot know whether this will occur until after the fact.

There is another issue that requires consideration in the emergency context. In light of the threat of bioterrorism and new infections, the federal government is supporting the development of new vaccines.<sup>212</sup> Because these vaccines are intended for diseases that are not currently threatening human populations, they may have to be approved without the standard human clinical trials.<sup>213</sup> As a result, public health officials will have far less information about the efficacy or risks associated with these vaccines than they do about the vaccines that have been mandatory for civilian populations in the past.<sup>214</sup> In effect, these vaccines will be

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211. See *supra* notes 175-88 and accompanying text.

212. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 allows for fast-track approval of vaccines and other anti-terrorism countermeasures for which clinical data is insufficient for traditional FDA approval. Pub. L. No. 107-188, 116 Stat. 595 (codified at 21 U.S.C.A. § 356-1 (West 2003)). In addition, the Project Bioshield Act of 2004 requires the appropriation of \$5.6 billion for vaccine and countermeasures research and development over the next ten years. Pub. L. No. 108-276, 118 Stat. 835 (to be codified in scattered sections of 42 U.S.C.).

213. Sections 122 and 123 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, for instance, authorize the Secretary of the U.S. Department of Health and Human Services to designate a potential vaccine or countermeasure for “priority review” by the FDA as a “fast-track product” under sections 515 and 506 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 356, (2000). 21 U.S.C.A. § 356-1 (West 2003). Products can be approved under this section without clinical trials, and subsequently administered to the public as enrollees in so-called “postmarketing studies.” See Approval Based on Evidence of Effectiveness from Studies in Animals, 21 C.F.R. § 314.610(b)(1) (2003); Approval Based on Evidence of Effectiveness from Studies in Animals, 21 C.F.R. § 601.91(b)(1) (2004). The FDA has promulgated a rule that requires notice to patients administered a product that was approved under section 123 without clinical studies. New Drug and Biological Drug Products, 67 Fed. Reg. 37,988, 37,990 (May 31, 2002) (to be codified at 21 C.F.R. §§ 314, 601). The rule provides that patients must be informed of the product’s risks and benefits, contraindications, and told that the drug was approved only on the basis of animal studies. See 21 C.F.R. §§ 314.610(b)(3) (for drugs); 601.91(b)(3) (for biologics).

214. The U.S. Department of Defense (DOD) dealt with a similar situation at the start of the Persian Gulf War by requesting and receiving a waiver of the Food and Drug Administration’s informed consent requirements to test pyridostigmine bromide and other unapproved countermeasures on soldiers without their permission. JONATHAN D. MORENO, *UNDUE RISK: SECRET STATE EXPERIMENTS ON*

akin to experimental interventions, even if they are fully approved by federal authorities.

Given an emergency, it may well be appropriate to approve and recommend vaccines for which we do not have complete information. It is difficult, however, to argue that it would ever be appropriate to use the law to coerce civilians to submit to such vaccinations.<sup>215</sup> Indeed, if self-determination and informed consent are ever critical, they are especially so in the case of uncertain treatments, as the court recognized over a hundred years ago in *Wong Wai*.<sup>216</sup> This is not only because both domestic and international law are clear about the importance of informed consent when humans are the subject of medical experiments,<sup>217</sup> but because in such a situation we cannot be confident that the medical intervention proposed will in fact benefit the patient (or even the population). In the face of uncertainty, neither traditional principles of medical beneficence nor arguments based upon expertise can support mandatory vaccination.<sup>218</sup> We cannot justify a limitation upon an individual's liberty on the theory that we are helping that individual or protecting her community because we really do not know whether we are doing either. Indeed, it is possible in some circumstances that the risks to both individuals and the community of taking a novel vaccine will end up being greater than the risk of the feared epidemic.<sup>219</sup> Under these difficult and fearsome circumstances, informed consent, of both the individual and the public, is more important than ever, not only to protect individuals, but to protect the public.

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HUMANS 270-71 (2000); Michael O'Connor, Note, *Bearing True Faith and Allegiance? Allowing Recovery for Soldiers Under Fire in Military Experiments that Violate the Nuremberg Code*, 25 SUFFOLK TRANSNAT'L L. REV. 649, 661-62 (2002).

215. The military, however, can require service personnel to be vaccinated. See, e.g., *Mazares v. Dep't of Navy*, 302 F.3d 1382, 1385 (Fed. Cir. 2002); *O'Neil v. Sec'y of Navy*, 76 F.Supp.2d 641, 645 (W.D. Pa. 1999). The military can require this even if there is no informed consent, see *Doe v. Sullivan*, 756 F.Supp. 12, 18 (D. D.C. 1991), *aff'd* 938 F. 2d 1370, 1381 (D.C. Cir. 1991). See also Robyn Pforr Ryan, *Should Combat Troops Be Given the Option of Refusing Investigational Drug Treatment?*, 52 FOOD & DRUG L.J. 377, 382 (1999).

216. See *supra* notes 45-52 and accompanying text.

217. See TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS, *supra* note 73, at 181-182, which commands an absolute prohibition on human experimentation without informed consent. Domestic law permits it in limited situations, such as when individuals are incompetent or when there is no risk of harm. Alan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 Wis. L. Rev. 413, 439 (1979). None of these exceptions would apply to a law requiring competent individuals to take an experimental vaccine. On the other hand, it is important to note that in the scenario discussed, the vaccine would be administered not for the purpose of research, but to provide protection for the individual and population.

218. Katz, *supra* note 72, at 81-82.

219. This is certainly true in the event that the pathogen itself is novel and its impact not well understood, or if the risk of an occurrence turns out to be less than predicted.

## PART III: INFORMED CONSENT FOR PUBLIC HEALTH

Informed consent is generally viewed as an individual right. But as the discussion above suggests, informed consent may be supportive of, if not vital to, public health. By providing information to individuals about recommended medical interventions such as vaccinations and by helping to compensate individuals when they are injured, informed consent helps to foster trust and a willingness to comply with public health recommendations. Likewise, by demanding that individuals be forewarned about specific risks associated with interventions such as vaccines, informed consent helps to prevent the inappropriate application of such interventions. And by respecting choices, however broad or limited they may be, informed consent provides individuals and communities with the respect and knowledge necessary for their acceptance and support of public health procedures.

The recognition that informed consent may serve public health goals does not mean, however, that traditional formulations of informed consent are those best suited to the promotion and protection of public health. As the courts recognized over thirty years ago when they limited the scope of the learned intermediary doctrine,<sup>220</sup> in the case of vaccinations for epidemics, the vision of informed consent as a private, clinical encounter between physician and patient is quite inappropriate. What is needed instead is a *public health* formulation of informed consent. Such a formulation should promote the core goals of informed consent – the provision of information necessary to making an informed choice, as well as the subsidiary goals of providing compensation, preventing unnecessary injuries, and promoting trust. However, a public health version of informed consent would move the locus of responsibility from a clinician or manufacturer to a public health authority, and the audience from individual to community. It would also ensure that the information provided would include not simply the risks and benefits applicable to individuals but also the risks and benefits that a given vaccination provides to a population.

To some degree, federal legislation has already moved us in this direction. For example, both the NCVIA<sup>221</sup> and the SEPPA<sup>222</sup> provide, although perhaps inadequately,<sup>223</sup> for public compensation of injured individuals. These compensatory schemes recognize, in different ways, both that compensation is critical to the success of vaccination programs and that the cost of vaccine-related

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220. See *supra* notes 101-07 and accompanying text.

221. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 110 Stat. 3743 (1986) (codified as amended at 42 U.S.C.A. § 300aa-1 to 300aa-33 (West 2003 & Supp. 2004)).

222. Smallpox Emergency Personnel Protection Act of 2003, Pub. L. No. 108-020, 117 Stat. 638 (codified as amended in scattered sections of 42 U.S.C.).

223. See Richards et al., *supra* note 39.

injuries is a social cost that should be borne by the public that is benefiting from a vaccination.<sup>224</sup> Likewise, both the NCVIA and the Project Bioshield Act recognize a public role for the provision of information about vaccine risks. Thus, the NCVIA delegates to the Secretary of the Department of Health and Human Services the development of vaccine warnings and relieves manufacturers of liability if they convey the government-issued warnings.<sup>225</sup> Likewise, the Project Bioshield Act requires the Secretary “to ensure to the extent practicable” that certain disclosures are made to recipients when the product is administered.<sup>226</sup> In addition, the CDC’s smallpox preparedness plan includes significant consideration of the information that needs to be conveyed by public health authorities.<sup>227</sup>

While important first steps, these laws do not fully embrace a public health conception of informed consent. In particular, three elements appear wanting. First, these laws do not provide for accountability from public health officials. While relieving private clinicians and manufacturers of their former legal obligations, the laws do not provide any mechanism to ensure that public health officials will play the role expected of them. Most critically, these laws do not hold public health agencies accountable for warnings that are inadequate or incomplete, or for warnings that are not publicized. While there are important reasons to provide public health officials with wide latitude and significant protection from liability, the “right” to informed consent is no longer a “right” if there is no means to enforce it. Moreover, given the strong incentives that public health officials have to encourage vaccination use, a real danger exists that important limiting information (including those relevant to the determination of contraindications) will be downplayed unless there are existing counterincentives. If public health professionals are to gain the public’s trust and replace clinicians and manufacturers as the informing agent, they must bear some responsibility for doing the job adequately.<sup>228</sup>

Second, more attention needs to be given to the public provision of information. Currently, the primary locus for information about vaccinations remains clinical encounters.<sup>229</sup> Public health authorities recognize that this will not be possible in an emergency. But, is the expectation that information will be conveyed in clinical encounters ever appropriate for vaccinations that are given to

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224. See *supra* notes 125-39 and accompanying text.

225. 42 U.S.C. §§ 300aa-1, 300aa-22 (2000).

226. 108 Pub. L. No. 276, 118 Stat. 825 (to be codified in scattered sections of 42 U.S.C.).

227. CDC, ANNEX 3, *supra* note 167, at 13, 18.

228. In suggesting that public health departments and agents should replace individual actors as the agents primarily responsible for informed consent, I am not suggesting that individuals should be relieved of all liability. As with existing law, manufacturers must be liable when they withhold information from public authorities or convey misleading information to either the public or individuals.

229. Fredrickson et al., *supra* note 21, at 437.

protect the public? If the benefits of routine vaccinations are to the public, and the provision of information about their risks and benefits can promote vaccination, then the assumption that information, even that which is prepared by public authorities, shall be given primarily when an individual is about to be vaccinated seems insufficient and inappropriate. It is insufficient because information given at that time will often only reach individuals who have already decided to be vaccinated.<sup>230</sup> It is also inappropriate because the dissemination of information from clinician to patient fails to display the responsibility of public health agencies and it fails to develop trust in those agencies. If in every situation short of a crisis, individuals receive information from their doctor, public health officials will not be able to build a level of trust that they will need to draw upon if and when an emergency arises and there is no time for individuals to turn to their clinicians. This suggests that it may be important for public health officials, at the federal level and especially at the state and local levels, to begin to provide their communities with more visible and prominent information about the risks and benefits of vaccinations now, well before any emergency exists.<sup>231</sup>

Finally, we need to reconsider the content of the information conveyed. Currently the information that public health authorities generally provide about vaccinations remains unduly influenced by individualist conceptions of informed consent. For example, the CDC's "Parent Guide to Vaccines" provides information about the risks an individual child faces if he or she is or is not vaccinated.<sup>232</sup> Oddly, the Guide says nothing to parents about the benefits that others obtain when a parent agrees to vaccinate a child. The information is all cast in an individualistic frame.

This is troubling for a number of reasons. First, it is misleading. It does not explain to parents the real reason why the government wants them (or requires them) to vaccinate their child. If a parent is not informed about the public benefit of vaccination, a parent may well respond thinking, "yes, but I know what is best for *my* child." Further, the parent may resent the state's intrusion in what appears to be a "private" decision. If, however, the government explains to the parent why the decision is not private, and how it affects other people, especially sick and

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230. This may not be the case with respect to infant vaccinations. Infants are far more likely than young and middle aged adults to see physicians regularly, thereby giving a physician the opportunity to discuss with a parent the pros and cons of vaccination, even if a parent had not previously decided to opt in favor of vaccination. An adult, however, may not see a physician for long periods of time and may not hear from the physician why he or she should be given a flu vaccine unless the adult makes an appointment to receive the vaccine.

231. In saying this, I recognize that public health authorities are already overstretched and underfunded. However, if informed consent is important to achieving high vaccination rates in an emergency, then the development of trust between public health authorities and the public with respect to vaccines needs to be understood as not separate from but a component of emergency planning.

232. NATIONAL IMMUNIZATION PROGRAM, CDC, PARENTS GUIDE TO CHILDHOOD IMMUNIZATION, <http://www.cdc.gov/nip/publications/Parents-Guide/default.htm> (last visited Feb. 23, 2005).

vulnerable children in the child's community, perhaps the parent will have a different attitude. Unless we provide parents with the full story, we should not assume their lack of interest in their neighbor.

More critically, if a public health emergency arises, it will be especially important for individuals to understand the public consequences of the decisions they make (e.g., to be vaccinated, to refrain from being vaccinated, to abide by a recommendation to wear a face mask, etc.).<sup>233</sup> Yet, it may be overly optimistic to assume that individuals will comprehend the public costs of their actions and develop the habit of taking the health of others into account at the moment at which an emergency arises. In a world in which we have come to think of our health care as our own business, and in a culture in which "good workers" don't stay home with influenza, people are apt not to appreciate the public health consequences of their actions. If we want them to do so during an emergency, we would be wise to provide them with the reasons to do so before an emergency occurs. Informed consent about routine vaccinations, including flu vaccines, may provide the golden opportunity. Properly framed and publicly disseminated, the information provided about vaccines can begin the process of reminding people of the public impact of their health care decisions and the public benefits of vaccines. So understood, informed consent can change from an individual right potentially in conflict with public health, to a public undertaking that strengthens it.

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233. The importance of educating people about the public health nature of vaccines became very apparent last fall when the United States faced a shortage of influenza vaccines. Suddenly the problem health officials confronted was not the refusal by some individuals to heed the call to be vaccinated, but the need to persuade individuals and clinicians to limit vaccinations to high risk individuals. The CDC responded by issuing recommendations to effectively ration the supply of vaccines. CDC, DHHS, INTERIM INFLUENZA VACCINATIONS RECOMMENDATIONS – 2004-05 INFLUENZA SEASON (Oct. 5, 2004), at <http://www.cdc.gov/flu/protect/whoshouldget.htm> (last visited Feb. 23, 2005). Some states issued orders limiting vaccinations to high risk individuals. *E.g.*, DEP'T OF PUB. HEALTH, COMMONWEALTH OF MASS., REVISED ORDER TO ESTABLISH RULES AND PRIORITIES FOR THE DISTRIBUTION AND USE OF INFLUENZA VACCINE, [http://www.mass.gov/dph/cdc/epii/flu/flu\\_order.htm](http://www.mass.gov/dph/cdc/epii/flu/flu_order.htm) (last visited Feb. 23, 2005). To be effective, both the non-binding recommendations and the binding state regulations require compliance and cooperation from clinicians and patients who understand and appreciate that vaccinations are not merely an individual medical intervention but a public good that in times of shortage should rightly be distributed in a way that is most protective of the public health.