

ARTICLE

ALL FOR ONE AND ONE FOR ALL: INFORMED CONSENT AND PUBLIC HEALTH

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ABSTRACT

The concept of informed consent is well established in the field of bioethics, but its application is unclear in the area of public health. The increasing prevalence of public health interventions creates a need to analyze the scope of government power as it relates to individual choice. This Article explores three different types of public health measures in which individual choice has been limited: (1) environmental interventions; (2) classic public health interventions to prevent contagious disease; and (3) public health information reporting or use. The reasons for limiting informed consent vary depending on the context, and the implications for the scope of an exception likewise vary. Careful consideration of the theoretical bases for exceptions indicates the importance of information disclosure in almost all situations, and may lead to novel solutions, such as a "fair use" model for health information. A singular "public health exception" concept is overly broad and superficial. Instead, there should be a fuller debate about the requirements of informed consent in the wide variety of public health settings.

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I. INTRODUCTION

Could you be vaccinated against H1N1 influenza without your consent? Do residents of a municipality need to consent to the chlorination of their drinking water? Should public health authorities have access to your personal medical information without your permission?

Informed consent is a bedrock principle of bioethics, but its application in the context of public health is unclear. In some descriptions of the doctrine, the category of “public health” is considered a standard exception to informed consent requirements. In others, only “public health emergencies” are exempted, similar to the general emergency exception.¹ Some reject the blanket exception altogether and insist that cases be evaluated individually, with public health needs balanced against individual autonomy.² Little theoretical work has been

1. RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 35–36 (1986).

2. See James F. Childress & Ruth Gaare Bernheim, *Beyond the Liberal and Communitarian Impasse: A Framework and Vision for Public Health*, 55 FLA. L. REV.

done in this area to understand the scope of state public health powers, and what has been done often applies concepts such as “social contract” in a relatively superficial manner.³ Given the vast expansion of public health interventions in recent decades, there is a growing call for an analysis of individual choice in this context.⁴

Part I of this Article begins with a brief overview of informed consent in health care and lays out the standard exceptions. This section examines why we have informed consent for treatment and the justifications for allowing exceptions. The standard exceptions to informed consent for treatment flow from the initial justification for the doctrine’s application. Informed consent is a means of acknowledging individual autonomy; in situations in which autonomy is impaired, or autonomy is not promoted by requiring individual consent, exceptions are appropriate. The focus is exclusively on adults throughout this Article, and I do not address either the application of informed consent doctrine to minors or the range of public health interventions that involve children.⁵ Additionally, discussion is limited to public health practice and treatment, not research.⁶

Parts II through IV explore three general categories of public health practices: environmental health interventions, classic public health interventions to combat contagious disease, and public health information reporting or use. These sections consider the scope of individual informed consent in various public health settings. In some cases individual consent is inapplicable for reasons similar to the standard

1191, 1197 (2003).

3. See, e.g., Michele Goodwin, *Deconstructing Legislative Consent Law: Organ Taking, Racial Profiling & Distributive Justice*, 6 VA. J.L. & TECH. 2, 88–90 (2001) (discussing the social contract in the context of presumed consent to public health measures).

4. See ROZ D. LASKER & THE COMM. ON MED. & PUB. HEALTH, MEDICINE & PUBLIC HEALTH 9, 20 (1997) (discussing the formation and expansion of government agencies geared toward addressing “categorical problems” in public health, such as “immunization, lead toxicity, sexually transmitted diseases, and tuberculosis”).

5. There is an extensive literature on consent and children. See, e.g., Yoram Unguru, *Pediatric Decision-Making: Informed Consent, Parental Permission, and Child Assent*, in CLINICAL ETHICS IN PEDIATRICS 1, 2 (Douglas S. Diekema et al. eds., 2011).

6. There is some debate about the line between public health treatment and public health research. See, e.g., CTRS. FOR DISEASE CONTROL & PREVENTION (CDC), DISTINGUISHING PUBLIC HEALTH RESEARCH AND PUBLIC HEALTH NONRESEARCH 1–2 (July 29, 2010) [hereinafter CDC Guidelines], <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf> (“Although some public health activities can unambiguously be classified as either research or non-research, for other activities the classification is more difficult.”). For my purposes, I will assume that the interventions discussed here are considered treatment.

exceptions—i.e., based on the analysis of autonomy. In other cases the original rationale for requiring informed consent (promoting autonomy) clearly applies, but there may be various justifications offered to limit its use in the specific public health situation. Drawing from political philosophy,⁷ I explore these justifications for limiting individual choice and identify the implications for the application of informed consent requirements. Different philosophical theories may explain why certain public health interventions are allowed without individual consent or explain why interventions are allowed in limited circumstances, but none justify a blanket exception to informed consent for all actions. The goal of this Article is not to resolve debates about the usefulness of various theoretical rationales, nor to identify one rationale that applies in all circumstances. Rather, it is to show that there are different reasons why individual informed consent may be avoided in different public health contexts; there is no single “public health exception.”

For each category of public health practice, I consider whether there needs to be a substitute for, or a modification of, legal consent requirements. Some important, perhaps even surprising, points come out of this analysis. First, each rationale for avoiding individual informed consent has different implications for the application of the scope of an exception. Nonetheless, all share one thing in common: while one aspect of informed consent may be deemed unnecessary (individual consent or authorization), the other part is still required (information disclosure). Second, the theoretical rationales for allowing an exception to informed consent may be different for different applications of the same public health intervention. For example, vaccination of health care workers without consent may be justified using a theory that does not justify nonconsensual vaccination of the general public.⁸ Furthermore, the rationale itself may provide crucial limitations on the extent of the exception. If the rationale for allowing the exception is utilitarian

7. Others have also drawn from political philosophy in evaluating public health, although not in the way I do here. *See, e.g.*, Childress & Bernheim, *supra* note 2, at 1192 (“Political philosophy . . . provides an important foundation for and sets limits on public health law. It identifies the normative values that should structure the relationship between the state and the individual, the legal powers that enable officials . . . to address public health threats, and the processes of reflection, deliberation, and justification that should direct the exercise of the legal powers.” (footnote omitted)); Onora O’Neill, *Informed Consent and Public Health*, 359 PHIL. TRANSACTIONS ROYAL SOC’Y LONDON 1133, 1133 (2004) (“The most basic philosophical difficulties with informed consent arise because consent is a propositional attitude.”).

8. *See infra* Part III.A.

(i.e., public health maximization), it may turn out that a better public health result is achieved by instituting a voluntary system, which includes consent, rather than by imposing mandatory requirements. For example, broader vaccination may be achieved through a consent-based intervention, even though an exception would appear to be permissible.

Finally, a shift away from focusing on individual authorization requirements in various public health contexts allows us to explore novel approaches to thorny problems. There is extensive current debate about the sharing and use of an individual's private medical information and the role of consent in this context. I suggest a type of "fair use" model of information sharing, drawing from intellectual property law.⁹ The end result of the work done here will be a better understanding of the scope of state public health powers and a fuller debate about the specific requirements for individual informed consent in public health settings.

II. THE DOCTRINE OF INFORMED CONSENT

A doctrine judicially created in the late 1960s and early 1970s, informed consent has become a standard part of medical practice.¹⁰ It is an interesting question whether the judicial doctrine drove the ethical one, or vice versa. Prior to development of the judicial doctrine, consent played little or no role in standard medical practice.¹¹ Unlike, for example, the doctrine of confidentiality that has a long history in medicine, informed consent did not show up in ethical codes until late in the twentieth century.¹² Informed consent for research developed separately from informed consent for medical practice, and its current structure is based on federal regulations.¹³ Regardless of its origins, informed consent now forms the bedrock of clinical bioethics. It is not, however, without its critics.¹⁴ While the principle of autonomy drives much bioethics discourse, many commentators have pointed out the need to balance autonomy against other interests and to incorporate other ethical approaches besides the principlist one upon which the doctrine of

9. See *infra* Part IV (discussing public health information reporting and use).

10. For more detail, see JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 15, 41, 44–46 (2d ed. 2001).

11. FADEN & BEAUCHAMP, *supra* note 1, at 86–87.

12. *Id.* at 84–86. A full analysis of this point is beyond the scope of this piece.

13. BERG ET AL., *supra* note 10, at 249.

14. See *generally id.* at 146–61 (focusing on three critiques: autonomy-oriented, health-oriented, and interactionist).

informed consent appears to be based.¹⁵ Autonomy is a Western (and distinctly American) value and may not fit well within other cultures and practices.¹⁶ Even under a principlist approach to bioethical issues in medicine,¹⁷ the principle of autonomy may sometimes be outweighed by the principle of justice, which can limit the distribution of scarce medical resources regardless of individual preferences, or by the principle of beneficence, which may weigh in favor of treatment even over the individual's objections.¹⁸ But even with these concerns, autonomy remains a strong concept within bioethics and medicine, and it is most often actualized through the doctrine of informed consent.¹⁹

Informed consent, while often referred to as a unitary concept, is really made up of two requirements—a duty to disclose information and a right to make decisions.²⁰ To meet the information requirement, physicians must disclose basic information about the patient's diagnosis and treatment options along with their risks, benefits, and alternatives.²¹ The patient is asked to either consent to or refuse the treatment. (In this sense, “informed choice” may be a better name for the doctrine than “informed consent” because refusals must also be informed.)²² The vast literature and extensive case law on informed consent will not be rehashed here.²³ More relevant for our purposes are the specific situations in which either or both requirements (disclosure and consent) are altered or avoided. The established exceptions include: incompetence,²⁴ waiver,²⁵ emergencies,²⁶

15. *Id.* at 32–34; *see, e.g.*, CARL E. SCHNEIDER, *THE PRACTICE OF AUTONOMY* 33 (1998) (recognizing the force of autonomy in bioethics, but arguing that it should be one of a “bouquet of concepts” that are considered with regards to medical decisions).

16. BERG ET AL., *supra* note 10, at 14.

17. A principlist approach identifies a series of core principles that should guide medical practice. *See, e.g.*, TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 12–13, 25 (6th ed. 2009). According to the version proposed by Beauchamp and Childress, the principles include: autonomy, nonmaleficence, beneficence, and justice. *Id.* at 12–13. In many applications of the principlist approach, the principle of autonomy seems paramount. Cara M. Cheyette, *Communitarianism and the Ethics of Communicable Disease: Some Preliminary Thoughts*, 39 J.L. MED. & ETHICS 678, 682 (2011).

18. FADEN & BEAUCHAMP, *supra* note 1, at 12–18.

19. *Id.* at 18–19.

20. BERG ET AL., *supra* note 10, at 41.

21. *Id.* at 54–60.

22. *Id.* at 54.

23. *See generally id.* at 41–52 (chronicling the development of consent requirements by the courts).

24. Jessica Wilen Berg, Paul S. Appelbaum & Thomas Grisso, *Constructing Competence: Formulating Standards of Legal Competence to Make Medical Decisions*, 48 RUTGERS L. REV. 345, 346–47 (1996).

25. Jessica Wilen Berg, *Understanding Waiver*, 40 HOUS. L. REV. 281, 326–29

therapeutic privilege,²⁷ and some public health interventions—the scope of which are the focus of this Article.

A. *Justification for the Doctrine of Informed Consent*

Why require individual informed consent? A number of reasons are offered by consent theorists.²⁸ First, individuals are most likely to know their interests and thus make better choices for their health and well-being.²⁹ Second, the information requirement may increase the likelihood that the intervention will be beneficial because the individual better understands what to expect, including being prepared to recognize problems that may arise.³⁰ Third, even if individuals err in their choices, we are better off as a society if we encourage individual decisionmaking and thus develop autonomous citizens.³¹ Fourth, individuals have a right to control what happens to their bodies.³²

The first three of these rationales are straightforwardly utilitarian—more utility overall comes from allowing individual choice, even if in a particular situation one could argue that the individual is making a poor decision. While overall we may be a better society if we encourage individual decisionmaking, this may not be true in all cases. Act-utilitarianism would allow variations of the rules to be determined on a case-by-case basis, and it is an unwieldy theory to apply.³³ Rule-utilitarianism seeks to identify the general rule that would increase utility and is a more common approach.³⁴ Here the general rule is thought to

(2003).

26. BERG ET AL., *supra* note 10, at 76.

27. *Id.* at 79.

28. *See id.* at 18–21 (“The primary goals of informed consent are the protection of patient or subject welfare and the promotion of autonomy.”); *see also* FADEN & BEAUCHAMP, *supra* note 1, at 7–16 (including also the principle of justice, but noting that “[t]he major moral and conceptual problems about informed consent are not justice-based and do not directly confront issues of social justice”).

29. BERG ET AL., *supra* note 10, at 20, 24.

30. *See id.* at 18 (discussing benefits that derive from informed consent, such as monitoring of symptoms).

31. *See* Berg, Appelbaum & Grisso, *supra* note 24, at 346 (opining that it is preferable to allow an individual to make his or her own choices even if another person is better able to make the decision); Charles W. Lidz & Robert Arnold, *Rethinking Autonomy in Long Term Care*, 47 U. MIAMI L. REV. 603, 605 (1993) (discussing the reasons that autonomous decisionmaking is superior to outsider decisionmaking in the health care context).

32. BERG ET AL., *supra* note 10, at 21.

33. BEAUCHAMP & CHILDRESS, *supra* note 17, at 339–40.

34. *Id.*; *see also* David O. Brink, *Mill’s Ambivalence About Rights*, 90 B.U. L. REV. 1669, 1671 (2010) (“[T]he most common indirect utilitarian theory of duty is rule utilitarianism.”).

favor individual choice. But even a general rule will have exceptions, and rule-utilitarianism allows for these when the rule with the exception would result in more overall utility than the rule applied without exception. (In essence, the rule is either defined more narrowly to exclude the exception, or the exception is built into the rule.)³⁵ Take the example of quarantine—a situation in which allowing individual choice may result in significant societal harms. An act-utilitarian would ask, for example, whether the quarantine of this particular person would increase overall utility. A rule-utilitarian would ask whether a rule permitting the quarantine of any person who finds herself in the particular situation would increase overall utility (regardless of the utility balance in a particular case). Both approaches would theoretically allow for quarantine without individual consent, provided the balance of utility worked in its favor.³⁶

The final rationale for requiring individual informed consent is rights based and closely linked to the development of the judicial doctrine.³⁷ But as with other rights-based justifications, it does not necessarily provide a sufficient rationale on its own.³⁸ Where does the right come from? Or to put it another way, why is there a right to control what happens to one's body? Appeal to a natural rights framework may solve the problem for some.³⁹ Individuals have inherent rights over their bodies, and informed consent simply recognizes those rights. But even if we accept a natural rights basis, individual rights of bodily integrity are not absolute, and there will be situations in which harm to the group may overcome individual authority to control what happens to oneself. From another perspective, individuals have rights, such as the right to control what happens to their bodies, because it increases overall utility (by, for example, encouraging autonomy, or because individuals are better suited to make decisions about themselves than others). Thus, rights theory may not stand on its own in this context; rather, the "rights" that arise are those that

35. J.J.C. Smart, *An Outline of a System of Utilitarian Ethics*, in J.J.C. SMART & BERNARD WILLIAMS, *UTILITARIANISM: FOR AND AGAINST* 10–11 (1973).

36. I'll return to this in more detail below when discussing quarantines. *See infra* Part III (discussing quarantine as a classic public health intervention).

37. *See* FADEN & BEAUCHAMP, *supra* note 1, at 40–41 (discussing how some decisions regarding medical treatment are protected by the constitutional right to privacy).

38. *See* BERG ET AL., *supra* note 10, at 21–22 (stating that the right to determine what happens to one's own body does not by itself justify informed consent).

39. The source of such natural rights raises other questions. For a full discussion of a rights-based right to informed consent (albeit in the research context), see generally CHARLES FRIED, *MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY* (1974).

serve a utilitarian basis. If the rights are based on utilitarian reasoning (e.g., according the rights results in a better society overall than when not doing so), there is always an argument that in certain contexts the overall utility favors overriding the right in question.

B. *Informed Consent Exceptions*

The commonly recognized exceptions to informed consent flow from the justifications. For the therapeutic exception, if the provision of information would so impair autonomy—by making it impossible for the individual to make a decision—then the detrimental information may be withheld.⁴⁰ Incompetent individuals lack autonomy, so providing them information or asking them for a decision would not promote autonomy.⁴¹ Waiver is itself an exercise of autonomy; it constitutes a choice either to limit disclosure of certain information or not to make a decision at all.⁴² In an emergency, limited time makes the full provision of information and sometimes decisionmaking impossible—autonomy is not promoted by allowing irreparable harm to occur due to strict enforcement of consent requirements.⁴³

What about the public health exception? First, it is worth spending a moment considering what is meant by “public health” in this context. There are many definitions of “public health.” According to the Institute of Medicine’s (IOM) report *The Future of Public Health*, “Public health is what we, as a society, do collectively to assure the conditions for people to be healthy[,]”⁴⁴ a definition that seems to include everything from homelessness prevention to vaccination to primary care to gun control. Others try to distinguish between individual medical care and

40. *Canterbury v. Spence*, 464 F.2d 772, 788–89 (D.C. Cir. 1972). The scope of this exception is extremely limited, and it is hard to conceive of a situation in which the information would be so damaging. *Id.*

41. There is a range of incapacities, and the determination of legal incompetence to make medical decisions may vary according to the situation. For additional discussion on this point, see Berg, Appelbaum & Grisso, *supra* note 24, at 345–51; and O’Neill, *supra* note 7, at 1133, noting that informed consent is not possible for “numerous patients with various types of incapacity.”

42. Berg, *supra* note 25, at 326–29, 332. I develop the idea of waiver in great detail elsewhere and will not repeat it here. *See generally id.* at 306–14, 319.

43. *See* BERG ET AL., *supra* note 10, at 76–77 (“If a patient’s condition is such that the time necessary for disclosure and consent would be so great that health or life would be seriously jeopardized . . . , none of the interests promoted by the informed consent doctrine are served.”).

44. COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, INST. OF MED., *THE FUTURE OF PUBLIC HEALTH* 19 (1988).

population health care.⁴⁵ Still others focus on the authority of the state to use legal coercion.⁴⁶ We need not resolve this debate. The limits of “public health” for purposes of a physician’s obligation to promote the health of the community may be different from our understanding of “public health” for purposes of an epidemiologist’s research agenda.⁴⁷ Because we are focused here on a public health rationale for limiting individual autonomous decisionmaking, at issue are those public health interventions which raise questions about the authority of the state to use legal coercion.

In the following sections, I consider some examples of such public health interventions in order to understand whether informed consent should play a role. I have divided the discussion of public health interventions into three general categories: environmental health activities, classic public health interventions used to combat contagious diseases, and use of an individual’s medical information for population health purposes (such as determining population disease burden). These provide a snapshot of the range of public health interventions that raise concerns about the use of state power without individual consent, and each highlights a different underlying rationale. Environmental health activities are examples of situations in which the initial justification for applying the doctrine of informed consent (autonomy) may not be pertinent. Contagious disease prevention activities provide examples in which the doctrine would likely apply but there are strong reasons to limit the requirement of individual

45. See, e.g., LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW* 16 (2d ed. 2008) (“Public health is organized to provide an aggregate benefit to . . . all the people in a given community. . . . Public health differs from medicine, which has the individual patient as its primary focus.”); Edmund D. Pellegrino, *Autonomy and Coercion in Disease and Health Promotion*, 5 *THEORETICAL MED. & BIOETHICS* 83, 85–86 (1984) (noting that personal autonomy is treated differently in curative medicine, which is for the benefit of individual patients, than in preventative medicine, which is for the good of the whole population).

46. For example, Professor Mark Rothstein explores a taxonomy of public health and divides the approaches into three categories: human rights, population health, and governmental intervention. Mark A. Rothstein, *Rethinking the Meaning of Public Health*, 30 *J.L. MED. & ETHICS* 144, 144–149 (2002), *reprinted in* *PUBLIC HEALTH ETHICS* 71–76 (Ronald Bayer et al. eds., 2007). Rothstein supports the narrow definition of public health as legal intervention. *Id.* at 76. Edmund Pellegrino focuses on the moral use of coercion to seek the community’s overall health, which is a socially desirable end. Pellegrino, *supra* note 45, at 86–89.

47. See Rothstein, *supra* note 46, at 72 (suggesting that “public health” for purposes of research questions is less complex than the social and political issues that need to be resolved for medical interventions); CDC Guidelines, *supra* note 6, at 2–3 (“The purpose of research is to generate or contribute to generalizable knowledge. The purpose of nonresearch in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service.”).

authorization. Finally, use of an individual's medical information is a mixed category in which the initial justifications for application of the doctrine and the range justifications for overriding it should lead to development of novel approaches. Not only may the discussion below clarify the scope of the public health exception, it may also be helpful in identifying what alternative protective measures should be applied to substitute for the lack of individual informed consent.

II. ENVIRONMENTAL PUBLIC HEALTH INTERVENTIONS

Environmental health activities have been around for as long as civilization and provide a good place to begin a discussion of the role (or lack thereof) of individual informed consent. "Sanitary measures and the protection of food and water supplies characterized virtually all of the early civilizations" and were used in ancient Egyptian, Greek, and Roman cities.⁴⁸ One of the most common environmental interventions, even today, is the regulation of water supplies. Few people suggest that individual informed consent should play a role here or in similar environmental health activities (such as regulation of air quality). Why not?

First, and most importantly, environmental interventions are not applied directly to a particular individual, but at the community level.⁴⁹ Public health interventions that are not applied at the individual level raise fewer autonomy concerns, weakening the initial rationales for requiring informed consent.⁵⁰ It is unclear whether the individual has special expertise for making community-level decisions, even with the provision of additional information. Thus, while we might think that each individual is best able to make the choice whether or not to undergo surgery, there is less reason to believe that each individual separately is best able to make the choice whether to

48. JOHN DUFFY, *THE SANITARIANS: A HISTORY OF AMERICAN PUBLIC HEALTH* 5–6 (1990).

49. When an environmental intervention moves to an individual application model, there is usually an effort to obtain consent. For example, while most communities fluoridate their water supply directly, some provide fluoride tablets to schoolchildren after obtaining parental permission. For an example of a parental permission form, see *Fluoride Tablet Permission Form*, SARANAC LAKE CENT. SCH., <http://saranalakecs.org/education/components/docmgr/default.php?sectiondetailid=3897&> (last visited Sept. 7, 2012).

50. See Spencer A. Hall, *Should Public Health Respect Autonomy?*, 18 J. MED. ETHICS 197, 197–99 (1992) (noting that "[t]here is no clear precedent for 'community autonomy'").

set certain clean air or water standards.⁵¹ The result may be that some corollary of informed consent is necessary at the group level.

Second, even though there may be individual *effects* from environmental public health interventions, there may be important reasons to limit individual choice. In fact, allowing such choice may fundamentally undermine the benefits for others in the society, perhaps resulting in less individual autonomy overall. The absence of basic environmental health standards can prevent individuals from exercising even their most fundamental rights of bodily integrity. For example, someone living in a community without basic environmental health protections, such as a clean water supply, may not be able to exercise much autonomy (or even survive until adulthood).⁵²

In thinking about these types of community-level decisions, consider the “tragedy of the commons” described by ecologist Garrett Hardin.⁵³ The concept of “the commons” refers to property or goods which are non-excludable (one individual cannot prevent the use by another individual) and rivalrous (the use by one person may prevent the use by others).⁵⁴ As a result, each individual may use up vast amounts of the resource, thus destroying its use for everyone. The so-called “tragedy of the commons” occurs when the economically rational (over)use by one

51. This is not to say that the individual might not vote, as part of a group, regarding the clean air standard. But it is less clear that we would have to accord each individual the right to consent to or refuse clean air in the same way we may do so for a surgery.

52. See, e.g., *The Need*, WATERAIDAMERICA, http://www.wateraidamerica.org/what_we_do/the_need/default.aspx (last visited Sept. 7, 2012) (noting that “[c]lean water is essential for life”). The theoretical rationale underlying such arguments is a communitarian one. In one basic form, communitarian theory posits that individuals are fundamentally social beings and that there is no liberty right to take any action that would undermine the bonds that hold society together because it would undermine society and thus wreak havoc with individual identity. See, e.g., Amy Gutmann, *Communitarian Critics of Liberalism*, 14 PHIL. & PUB. AFF. 308, 308–311 (1985) (remarking that communitarians disagree with the liberal idea that individual rights should be prioritized over societal rights). Similarly, other non-individualistic theories, such as feminist theories or theories of care, stress that obligations arise due to the bonds of care and affection between individuals and that the state should use its power to reinforce and support those bonds. Virginia Held, *The Ethics of Care*, in THE OXFORD HANDBOOK OF ETHICAL THEORY 537, 542, 549 (David Copp ed., 2006). Individual choices, which undermine those bonds (by causing harm to the group as a whole), may be limited. Liberty under this approach is a positive freedom—individuals may be restricted from certain actions that would make them less free. Communitarian theory can thus provide a basis for understanding limitations on individual autonomy, including limitations on individual informed consent for public health interventions.

53. Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1244 (1968).

54. Jose Apesteguia & Frank P. Maier-Rigaud, *The Role of Rivalry: Public Goods Versus Common-Pool Resources*, 50 J. CONFLICT RESOL. 646, 647 (2006).

person destroys the good for all.⁵⁵ Hardin's example was of overgrazing cattle on common lands.⁵⁶ If all people are allowed to act according to their own individual interests, the commons will not survive.⁵⁷ Public goods, by contrast, are those that are both non-excludable (there is no way effectively to prevent someone from using the good) and non-rivalrous (the use by one person does not limit the use by another).⁵⁸ For public goods, there are concerns about free riders who will not "pay" for the good in question.⁵⁹ If there are enough free riders, the good may be negated.⁶⁰ National defense is a paradigm example of a public good, and water and sanitation are paradigm examples of commons. In both public good and commons cases, society (via government) has an important role to play in setting parameters to address the flaws in individual decisionmaking and to accommodate for group interests. While a model of "community input and consultation" may be appropriate, assuming it could be applied in practice, it is less clear what role individual choice should play. Unlike the traditional medical context, requiring individual consent in the context of commons and public goods may result in less overall autonomy because the good will not continue to be available.⁶¹ As a result, most environmental health interventions do not use an individual informed consent model. But even if there is little role for individual consent here, the information disclosure aspect of the informed consent doctrine should be maintained. There is nothing in the analysis of commons or public goods that would support limiting information disclosure. In fact, the information disclosure remains crucial to protect autonomy.⁶² For example, municipalities routinely supply information about local water quality and the protective measures applied to their public water supplies.⁶³ To the extent

55. Hardin, *supra* note 53, at 1244.

56. *Id.*

57. *See id.* ("Freedom in a commons brings ruin to all.")

58. Peter P. Swire, *A Theory of Disclosure for Security and Competitive Reasons: Open Source, Proprietary Software, and Government Systems*, 42 HOUS. L. REV. 1333, 1373 (2006).

59. *Id.* at 1370.

60. *See* Hardin, *supra* note 53, at 1244–45 (explaining that everyone is "locked into a system of 'fouling our own nest,' so long as [they] behave only as independent, rational, free-enterprisers").

61. *See id.* at 1245 (remarking that "the oceans of the world continue to suffer from the survival of the philosophy of the commons" and warning that "we must soon cease to treat the parks as commons or they will be of no value to anyone").

62. *See* GOSTIN, *supra* note 45, at 411 (reasoning that information is traditionally a component of informed consent, which is based off of "personal autonomy and self-determination").

63. *See, e.g.*, CITY OF HOUS. DEPT OF PUB. WORKS & ENG'G, CITY OF HOUSTON,

individual choice is allowed, the individual has the burden to opt out by taking other measures (e.g., by seeking another water supply, such as a private well or bottled water), rather than by restricting the chlorination on a case-by-case basis. Information disclosure is necessary to exercise such individual choice.

Moreover, while there may be little role for individual consent, this is a good example of a context in which a group input may be appropriate. There are a variety of suggestions as to how to deal with group interests in decisionmaking. One idea, discussed extensively in the human subjects research literature, is to engage in a type of “community consultation” in order to gain community input into the decisionmaking process.⁶⁴ The community consultation process is not a substitute for individual informed consent; rather, it is a mechanism through which to involve the community in the development, review, and oversight of a research trial.⁶⁵ The consultation may be achieved through various means, and there is continuing debate about how best to achieve community involvement. Suggestions include identifying community spokespersons or leaders, holding special community meetings, surveying relevant groups, and implementing public notification mechanisms.⁶⁶ For example, UNAIDS, the United Nations Program on HIV/AIDS, publishes *Good Participatory Practice Guidelines* for HIV prevention trials. These guidelines lay out a detailed community engagement plan, which includes

DRINKING WATER QUALITY REPORT 2006 1–5,
http://documents.publicworks.houstontx.gov/documents/divisions/utilities/water_quality_report_2006.pdf (informing the public of the sources of drinking water and the quality of drinking water).

64. See, e.g., Jessica Berg, *Waiver of Informed Consent for Emergency Research*, 1 J. MED. & L. 1, 19, 26–27 (1997) (discussing the community consultation requirement for emergency research). There are also suggestions to use community consultation for international research and for U.S. research involving vulnerable populations (such as genetics research). See, e.g., Charles Weijer & Guy J. LeBlanc, *The Balm of Gilead: Is the Provision of Treatment to Those Who Seroconvert in HIV Prevention Trials a Matter of Moral Obligation or Moral Negotiation?*, 34 J.L. MED. & ETHICS 793, 805 (2006) (describing U.S. and international guidelines for community consultation in research).

65. See Patricia A. Marshall & Jessica W. Berg, *Protecting Communities in Biomedical Research*, 6 AM. J. BIOETHICS 28, 29 (2006) (noting that “community approval does not replace the need for individual consent[,]” and discussing various ways that communities can be consulted throughout the period community research projects are conducted).

66. Protection of Human Subjects; Informed Consent, 61 Fed. Reg. 51,498, 51,514–15 (Oct. 2, 1996); CLINICAL & TRANSLATIONAL SCI. AWARDS CONSORTIUM CMTY. ENGAGEMENT KEY FUNCTION COMM. TASK FORCE ON THE PRINCIPLES OF CMTY. ENGAGEMENT, DEP’T OF HEALTH & HUMAN SERVS., PRINCIPLES OF COMMUNITY ENGAGEMENT 115–16 (2d. ed. 2011) [hereinafter PRINCIPLES OF COMMUNITY ENGAGEMENT]; GENETICS & PUB. POLICY CTR., THE GENETIC TOWN HALL: MAKING EVERY VOICE COUNT 1–3 (2004); Marshall & Berg, *supra* note 65, at 29.

education, capacity building, and community empowerment.⁶⁷ In fact, the concept of community engagement is becoming more prevalent in public health practice generally.⁶⁸ The Centers for Disease Control and Prevention (CDC) stress the need to “broaden our understanding of the key principles that underlie successful community engagement in public health.”⁶⁹ The June 2011 second edition of *Principles of Community Engagement* provides a review of the concepts and principles, as well as a detailed plan for engaging communities in public health practice and research.⁷⁰ There are also frameworks for community input in the area of environmental law, requiring community referenda before allowing certain types of land development.⁷¹ Another example comes from the Convention of Biological Diversity, which requires “[p]rior informed consent” from indigenous communities for access to genetic resources.⁷²

All community consultation approaches have similar limitations, such as difficulties identifying the relevant “community” (there are often multiple, overlapping communities) and related problems identifying relevant spokespersons.⁷³ But despite these limitations, each approach provides an important recognition of the group interests at stake. While community input should not be thought of merely as an extension of individual informed consent, it can serve a similar role—providing a check against government intervention in situations

67. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS (UNAIDS), GOOD PARTICIPATORY PRACTICE GUIDELINES FOR BIOMEDICAL HIV PREVENTION TRIALS 31–32 (2007), available at http://whqlibdoc.who.int/un aids/2007/9789291736348_eng.pdf.

68. See, e.g., PRINCIPLES OF COMMUNITY ENGAGEMENT, *supra* note 66, at xv, 3; Mary Anne Morgan & Jennifer Lifshay, *Community Engagement in Public Health*, CONTRA COSTA HEALTH SERVS. 2 (2006), http://www.barhii.org/resources/downloads/community_engagement.pdf (describing Contra Costa Health Services’ community engagement efforts).

69. CDC/ATSDR COMM. ON CMTY. ENGAGEMENT, CTRS. FOR DISEASE CONTROL & PREVENTION, PRINCIPLES OF COMMUNITY ENGAGEMENT 1 (1997).

70. See generally PRINCIPLES OF COMMUNITY ENGAGEMENT, *supra* note 66 (outlining concepts, principles, and a detailed plan for community engagement).

71. Brant McGee, *The Community Referendum: Participatory Democracy and the Right to Free, Prior and Informed Consent to Development*, 27 BERKELEY J. INT’L L. 570, 568, 592 (2009); see also Melanie Nakagawa, Comment, *Overview of Prior Informed Consent from an International Perspective*, 4 SUSTAINABLE DEV. L. & POL’Y 4, 4, 6 (2004) (raising the issue of who should give consent in multilateral environmental agreements by explaining examples of land use conflicts in Chile and Alaska).

72. Joshua Rosenthal, *Politics, Culture, and Governance in the Development of Prior Informed Consent and Negotiated Agreements with Indigenous Communities*, in BIODIVERSITY AND THE LAW 373, 374 (Charles R. McManis ed., 2007); Laurel A. Firestone, Comment, *You Say Yes, I Say No: Defining Community Prior Informed Consent Under the Convention on Biological Diversity*, 16 GEO. INT’L ENVTL. L. REV. 171, 176 (2003).

73. Marshall & Berg, *supra* note 65, at 29.

where individual consent is absent.⁷⁴ Although many health departments already take steps to alert communities about environmental health efforts, more work should be done to develop mechanisms of gathering and incorporating community input with respect to the various environmental decisions that must be made before intervention. In the same way that the incompetence exception to traditional informed consent does not relieve physicians of their informed consent obligations, but simply shifts the disclosure and consent requirements to surrogate decisionmakers, in the environmental health context public health officials should be viewed as having corresponding obligations to inform and consult with affected communities. Individual informed consent may not play a significant role in environmental health interventions, but community consultation should.⁷⁵

III. CLASSIC PUBLIC HEALTH INTERVENTIONS TO COMBAT CONTAGIOUS DISEASES

Protection of the sanitary environment is one classic example of public health powers; protection against infectious disease (quarantine, isolation, and vaccination) is another.⁷⁶ I refer to these as “classic” examples because they (at least quarantine and isolation) have been around since the Middle Ages and are often thought of as fundamental public health powers.⁷⁷ Almost all states, foreign and national, have laws

74. OFFICE OF GOOD CLINICAL PRACTICE, FOOD & DRUG ADMIN., GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS, CLINICAL INVESTIGATORS, AND SPONSORS: EXCEPTION FROM INFORMED CONSENT REQUIREMENTS FOR EMERGENCY RESEARCH 25–26 (2011), <http://fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf> (providing the example of community consultation for emergency situations where individual informed consent is not available); Marshall & Berg, *supra* note 65, at 29–30 (distinguishing between individual informed consent and community involvement, and explaining the confusion that arises when the two forms of protection are aligned).

75. See McGee, *supra* note 71, at 571–73 (pointing out that community consultation can stop projects).

76. Quarantine is the separation of individuals who may have been exposed to the infectious agent. *Quarantine and Isolation*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/quarantine> (last visited Sept. 7, 2012). Isolation is the separation of individuals who are infected. *Id.* I’ll use the terms vaccination and immunization interchangeably below. Technically immunization is any process by which you achieve a sufficient immune response. DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 910 (30th ed. 2003). Immunization can occur after an initial, naturally occurring, infection. *How Vaccines Work*, NAT’L NETWORK FOR IMMUNIZATION INFO., <http://www.immunizationinfo.org/parents/why-immunize/how-vaccines-work> (last visited Sept. 7, 2012). Vaccination is one mechanism to achieve immunization by the direct introduction of a weakened or inert pathogen that triggers the body’s immune response, thus protecting against future infection. *Id.*

77. See *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905) (rejecting the defendant’s

granting explicit powers to public health authorities to quarantine individuals exposed to dangerous contagious diseases or isolate those who are infected to prevent further spread.⁷⁸ Mandatory vaccination is more controversial,⁷⁹ and in most cases is not imposed as an outright requirement, but rather posed as a condition for privileges such as public school entry⁸⁰ or employment.⁸¹ Even the best known of the U.S. vaccination cases, the Supreme Court's 1905 decision in *Jacobson v. Massachusetts*, involved a vaccination law that could be avoided if the individual paid a fine of \$5, moved from the jurisdiction (the requirement applied only to residents of Cambridge), or could show some health reason for exception.⁸²

The underlying focus of these public health interventions is on protection of public safety by preventing the spread of disease. The *Jacobson* court, for example, stressed that “[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.”⁸³ But while an argument can be made in favor of community self-defense against epidemics, unlike the environmental health interventions

assertion that by imprisoning him for refusing vaccination the state was invading his liberty because “[t]here are manifold restraints to which every person is necessarily subject for the common good”); DUFFY, *supra* note 48, at 7–8, 24 (explaining the history of isolation and quarantine). Vaccination came later, after the development of the smallpox vaccination by Dr. Edward Jenner in the late 18th century and the subsequent development of immunization by Louis Pasteur in the late 19th century. GOSTIN, *supra* note 45, at 372. Vaccination was preceded by variolation, or the process of direct introduction to the live pathogen. D.A. HENDERSON, SMALLPOX: THE DEATH OF A DISEASE 44 (2009). This was previously used in the smallpox context, most famously by Lady Mary Wortley Montagu, the wife of the British Ambassador to Constantinople, in the early 1700s. *Id.* at 45. She subsequently convinced the royal family to use it. *Id.* Cotton Mather advocated the technique around the same time in Boston. *Id.* Unlike vaccination, which uses a weakened or inert pathogen, variolation carries the risk that the patient will become ill with the disease in question and could spread it to others. *Id.* at 44–45. Even so, the illness and death rate from variolation was significantly below the rates for contracting the disease naturally. For example, for smallpox the death rate for variolation was approximately 2%, while the death rate for the disease in the population was 30%. *Id.* at 45.

78. GOSTIN, *supra* note 45, at 437.

79. *Id.* at 376–77.

80. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 868–73 (2002).

81. Healthcare workers are required to have a number of vaccinations. *See, e.g., Vaccines & Immunizations*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www2a.cdc.gov/nip/statevaccapp/statevacscapp/Administration.asp?statetmp=TX> (last visited Sept. 19, 2012).

82. *Jacobson*, 197 U.S. at 12, 38–39. The health exception was read into the statute by the Supreme Court, which assumed that any vaccination mandate would have such a limitation. *Id.*

83. *Id.* at 27.

described above, all three—vaccination, quarantine and isolation—are interventions that are applied at the individual level. The individual application of the intervention raises the same concerns about autonomy that justified application of the informed consent doctrine in the first place. Why not simply inform individuals and allow individual choice in these contexts? The problem is that the individual interests in these situations do not always line up with the community interests. While this may seem obvious in the case of quarantine and isolation, it is also true for vaccination, which may provide some benefit to the individual, but may also be harmful. Geoffrey Rose draws attention to this problem in his description of the “prevention paradox,” noting that “a [preventive] measure that brings large benefits to the community offers little to each participating individual.”⁸⁴ Herd immunity is achieved by vaccinating enough members of the population to prevent the spread of illnesses.⁸⁵ From the perspective of any one individual, the harms of vaccination may outweigh the benefits, especially if there is assurance that enough other members of society are vaccinated, thus achieving herd immunity for the group.⁸⁶ These so-called “free riders”—people who take advantage of the good in question (herd immunity) without “paying” for the good (by being immunized themselves)—may undermine the public good completely. If enough people assume that others will choose to be vaccinated and thus decide not to get vaccinated themselves, the end result may be a failure of herd immunity and an increased disease burden on the population in question. But while the free rider problem provides a good basis for justifying some government intervention, it may not be a strong enough argument for bypassing individual informed consent for vaccination. Unlike the environmental cases described above, here the individual is required to take on a direct burden, one which may have significant implications for individual health. There is great resistance in U.S. society to overriding individual autonomy when the issue is one of bodily integrity.⁸⁷

Assuming for our purposes that the doctrine of informed consent applies to the classic contagious disease interventions, are there rationales justifying an exception in these circumstances? There are some possibilities alluded to in the

84. Geoffrey Rose, *Strategy of Prevention: Lessons from Cardiovascular Disease*, 282 BRIT. MED. J. 1847, 1850 (1981) (emphasis omitted).

85. GOSTIN, *supra* note 45, at 378.

86. *Id.*

87. *Id.*

Supreme Court's opinion in *Jacobson*. The Court first appears to rely on a social contract rationale. Citing the “fundamental principle of the social compact[,]” the Court stressed that it was “not prepared to hold that a minority, residing or remaining in any city or town . . . , and enjoying the general protection afforded by an organized local government, may thus defy the will of its constituted authorities”⁸⁸ The “contract” here may be based on the notion of tacit consent—individuals who chose to remain in the jurisdiction requiring vaccination are thought to have agreed to the vaccination. In fact, the *Jacobson* case itself took pains to stress that the smallpox vaccination requirement applied only to residents of Cambridge, Massachusetts, and noted that the “safety of an entire population [cannot be] subordinated to the notions of a single individual who chooses to remain a part of that population.”⁸⁹ In addition to the tacit consent idea, the Court stated that the majority of the population understands vaccination to be an appropriate mechanism to prevent smallpox, indicating, perhaps, that hypothetical consent would function in this context.⁹⁰ An alternative basis for the contract appears to be fairness, as the Court refers to the possibility that a minority should not be allowed to put at risk the health of the majority.⁹¹ Should we understand these theoretical social contract arguments to provide a practical basis for intervening without individual informed consent, or even against the individual's express wishes?

A. *Social Contract*

In fact, the most commonly cited rationale for exercising state power even over individual objection in the public health context relies on social contract theory, although it is rarely examined in detail.⁹² The social contract idea rests on the notion that by choosing to live in a society we each agree to accept certain obligations.⁹³ Although an individual may not have

88. *Jacobson*, 197 U.S. at 27, 37.

89. *Id.* at 27–28, 38. The Court also noted that *Jacobson*, “while remaining in the community, refused to obey the statute” *Id.* at 39.

90. *Id.* at 34–35.

91. *Id.* at 37–38.

92. *See, e.g.*, Pellegrino, *supra* note 45, at 86–88 (discussing the use of the social contract theory in improving the health of the community).

93. *See id.* at 87–88 (“[A]n obligation of a good society [is] to provide some measure of health for its citizens, and a duty of a good citizen [is] to contribute to the health of society.”); *see also* JONATHAN WOLFF, AN INTRODUCTION TO POLITICAL PHILOSOPHY 42 (rev. 2006) (“[B]y quietly enjoying the protection of the state one is giving it one's tacit consent.”).

consented to a particular intervention at the time of its application, we can posit her prior consent as part of a social contract. John Locke noted that the concept of consent is extremely limited in this context.⁹⁴ Express consent is very rare, although it would most easily justify state power over individuals—few people expressly consent to live in a society and to the corresponding state power.⁹⁵

1. *Tacit Consent.* Instead of explicit consent, we might rely on tacit or implied consent based on the individual's acquiescence to governmental rule and his acceptance of the benefits of society. This poses problems. If consent is the basis for justifying the state's powers, it seems odd that mere tacit acceptance of the social arrangement could bind an individual.⁹⁶ Surely more is needed to justify state power, particularly where the individual in question, such as Jacobson, is objecting. Hume argues that mere residence in a jurisdiction is not enough for tacit consent, because the only way to "dissent" would be to leave the country.⁹⁷ Rousseau goes further to emphasize that absent true freedom to leave at will, which he argues rarely if ever exists, the concept of tacit consent cannot justify state power.⁹⁸ Consider the use of HIV asylums in Cuba to isolate infected individuals⁹⁹—one would be hard pressed to argue that those people who are confined "consented" to the confinement merely based on their continued residence in Cuba.

94. JOHN LOCKE, TWO TREATISES OF GOVERNMENT 291 (1821) (describing the "perfect member" of society as one who expressly consents, but noting that tacit consent is more common and complex); see also PETER JOSEPHSON, THE GREAT ART OF GOVERNMENT: LOCKE'S USE OF CONSENT 1–2 (2002) ("John Locke is known as the great modern proponent of the idea that a government must be established or founded on the consent of the governed if it is to make any claim to legitimacy.").

95. See JOSEPHSON, *supra* note 94, at 148–49 ("Many may be subject to the law; only a few are full, participatory members.").

96. There is an extensive debate about the role of express versus tacit consent, including the role it plays in Locke's philosophy. See *id.* at 149–56 (discussing critiques of Locke's tacit consent theory and Locke's deliberate concealment of the distinction between explicit and tacit consent). Resolving the issue is beyond the scope of this Article.

97. WOLFF, *supra* note 93, at 43.

98. JEAN-JACQUES ROUSSEAU, ON THE SOCIAL CONTRACT 110 (Roger D. Masters ed., Judith R. Masters trans., St. Martin's Press 1978) (1762) (asserting that the only context in which inhabiting a territory is sufficient "to submit oneself to sovereignty" is a "free State, because elsewhere an inhabitant can be kept in the country against his will by family, goods, the lack of a place of refuge, necessity, or violence; and then his sojourn alone no longer presupposes his consent to the contract or to the violation of the contract").

99. Helena Hansen & Nora Groce, *Human Immunodeficiency Virus and Quarantine in Cuba*, 290 J. AM. MED. ASS'N 2875, 2875 (2003).

While the tacit consent idea may not suffice to bind an individual resident, it may well suffice for the mandatory vaccination of certain groups, although even this is not without controversy. For example, one might argue that the choice to enter the medical profession, or perhaps a particular professional specialty, functions as tacit consent for public health interventions such as vaccination. The concept of a “social contract” between professionals and society is based on the idea that society accords professionals certain benefits, in exchange for certain obligations.¹⁰⁰ But even if tacit consent (by entering and remaining in the profession) functions in this context to create obligations, one must still establish that mandatory vaccination is one of those obligations.¹⁰¹ Recently there was great resistance to efforts to enforce mandatory H1N1 vaccinations of health care workers in New York state.¹⁰² In part, the resistance to the mandatory vaccination laws has been on utilitarian grounds; noncompulsory schemes coupled with education are better accepted and may result in greater rates of vaccination among the target population.¹⁰³ Mandatory vaccination is also used for military personnel¹⁰⁴—another context in which tacit consent may function through the decision to enlist in one of the armed services. But even if tacit consent justifies mandatory vaccination, there would be little basis for avoiding information disclosure, only for avoiding consent. Moreover, there are various safety and efficacy requirements that must be met before implementing a mandatory vaccination program in the military.¹⁰⁵

100. Allen E. Buchanan, *Is There a Medical Profession in the House?*, in CONFLICTS OF INTEREST IN CLINICAL PRACTICE AND RESEARCH, 105, 109, 113–14, (Roy G. Spece, Jr. et al. eds., 1996).

101. See Olga Anikeeva et al., *Requiring Influenza Vaccination for Health Care Workers*, 99 AM. J. PUB. HEALTH 24, 24–26 (2009) (discussing the implications of imposing a requirement of mandatory influenza vaccinations on health care workers).

102. Donald G. McNeil, Jr. & Karen Zraick, *New York Health Care Workers Resist Flu Vaccine Rule*, N.Y. TIMES, Sept. 21, 2009, at A18.

103. Anikeeva et al., *supra* note 101, at 27.

104. VACCINE HEALTHCARE CTRS. NETWORK, STRATEGIC PLAN 18 (2010), <http://vhcinfo.org/documents/VHCStratPlanWebResolution.pdf>.

105. John D. Grabenstein et al., *Immunization to Protect the US Armed Forces: Heritage, Current Practice, and Prospects*, 28 EPIDEMIOLOGIC REVS. 1, 16–17 (2006). There has been quite a bit of debate about the use of a mandatory anthrax vaccination in the military, based on concerns that its safety and efficacy have not been established (nor, possibly, the extent of the risk of exposure to anthrax). *Id.* at 14–15. Whether or not the mandatory anthrax vaccination is appropriate, the lack of information provided to members of the armed services during the vaccination effort raises additional concerns because there appears to be no basis for waiving the disclosure requirement, only the consent requirement.

2. *Hypothetical Consent.* If express and tacit consent are limited, hypothetical consent might be an alternative basis for grounding the social contract. Here, one would hypothesize that if an individual actually were given a choice, she would agree to be bound by the state in certain ways. The actualization of a hypothetical consent model is more complex than simply assuming the individual would agree to a particular law or state intervention. Such an assumption could not itself be binding.¹⁰⁶ Hobbes would argue that the hypothetical consent arises out of a determination that certain societal constraints are necessary for societal functioning and are mutually beneficial.¹⁰⁷ But the Hobbesian model would allow significant constraints on individuals, including the imposition of slavery, due to power differentials.¹⁰⁸ Hobbes's theory of moral justification does not seem to line up well with our current societal understanding of justice.

In contrast, Immanuel Kant develops the concept of a hypothetical social contract, drawing in large part from Rousseau, starting from a position of equality.¹⁰⁹ He identifies the fundamental "contract" upon which everyone would agree—the so-called "categorical imperative"—to always act so as to have that action be universal law.¹¹⁰ Developing this idea in more detail, John Rawls provides a way to implement the categorical imperative by positing a situation of equality where all individuals are in the "original position," behind a "veil of ignorance," which blinds them to their specific situations of religion, health, class, wealth, or talent.¹¹¹ Rawls offers three principles that everyone would agree to in the "original position": the Liberty Principle (everyone has an equal right to extensive individual liberty); the Fair Opportunity Principle (if inequalities exist via positions of power or authority, those positions should be open to all); and the Difference Principle

106. Will Kymlicka, *The Social Contract Tradition*, in *A COMPANION TO ETHICS* 186, 187–88 (Peter Singer ed., 1993) ("[A] hypothetical promise is no promise at all, for no-one has undertaken an obligation.").

107. *Id.* at 188–90. In some ways this starts to sound like communitarian approaches, which allow for limitations of individual autonomy based on the need for constraints that are necessary to keep the society functioning. See Gutmann, *supra* note 52, at 308.

108. Kymlicka, *supra* note 106, at 187–88.

109. IMMANUEL KANT, *GROUNDWORK FOR THE METAPHYSICS OF MORALS* 13–14 (Lara Denis ed., Broadview Press 2005) (1785); JOHN RAWLS, *A THEORY OF JUSTICE* 252–53 (photo. reprint 2005) (1971).

110. IMMANUEL KANT, *GROUNDING FOR THE METAPHYSICS OF MORALS* 29–30 (James W. Ellington trans., Hackett Publ'g 3d ed. 1993) (1785).

111. RAWLS, *supra* note 109, at 136–37.

(inequalities should only exist to the extent they are to the greatest benefit of the least advantaged).¹¹²

But while Rawls's theory provides a way to understand the distribution of property and resources within a society, he does not argue that anyone actually does consent to these principles—just that they would under his theoretical original position. While this is a useful thought experiment to identify principles of a just society, even Rawls acknowledges that it is not a tool to determine a priori rights.¹¹³ Rather, it functions as a standard against which we might determine the justness of current societal distributions.¹¹⁴ It is difficult to show that individuals would hypothetically consent to any and all exercises of state public health power that the authorities deem appropriate. We could do the same thought experiment with many medical interventions—showing that individuals would hypothetically consent to their application—and yet we still require individual consent at the point of actual intervention.¹¹⁵ Here too, we might argue that even if the general concept of vaccination would be agreed upon, the individual must agree to a specific vaccine (although there may be consequences for refusal). So although the social contract based upon prior consent idea is prevalent in discussions of public health authority, as a theoretical basis for limiting informed consent it has a number of flaws. It certainly does not alone justify the imposition of public health measures in the absence of individual informed consent in all situations of public health needs.

3. *Contract Based on Fairness.* A possible alternative to relying on consent as a basis for the social contract draws from H. L. A. Hart's theory of fairness.¹¹⁶ According to Hart, the issue is not whether each individual has tacitly or hypothetically consented to be governed; rather, the issue is whether it would be unfair to accept the benefits of society without also accepting its burdens.¹¹⁷ This, too, is a prevalent concept in public health literature. Individuals gain much from living in society, but

112. *Id.* at 60–62, 65, 75, 78.

113. *Id.* at 438.

114. *Id.* at 12–15.

115. See Catherine E. Blackburn, *The "Therapeutic Orgy" and the "Right to Rot" Collide: The Right to Refuse Antipsychotic Drugs Under State Law*, 27 HOUS. L. REV. 447, 452–53 (1990) (describing the informed consent requirement in medical procedures).

116. H. L. A. Hart, *Are There Any Natural Rights?*, 64 PHIL. REV. 175, 178, 190–91 (1955).

117. *Id.* at 185–86, 191.

society cannot function without limiting individual freedom.¹¹⁸ The social contract is based on the fairness of balancing the benefits to the individual from the state and the limits that are necessary to maintain those benefits.¹¹⁹ There are at least two problems, however, with the idea of fairness.¹²⁰ The first is that there may be some individuals who do not benefit from living in society, and they appear to not be bound under this theory.¹²¹ The second problem is identified by Nozick, who takes issue with the whole idea that any unsolicited benefits provided by society could ever create enforceable obligations for the individual, based on an idea of fairness.¹²² Although in some ways the fairness rationale is stronger than the consent rationale for a social contract, it is still hard to understand why fairness alone would justify the imposition of the full range of public health interventions against an individual's wishes. In some cases, such imposition may be patently unfair, no matter what societal benefits are available in exchange. Alternatively, one might posit a situation in which the individual in question has not yet obtained benefits but is still required to accept certain burdens—consider a potential émigré who has not yet been granted residency but is stopped at the border before entering a country and required to submit to various vaccinations before their case is even considered.¹²³ Despite these limitations, fairness may function as a useful basis for understanding social contract obligations for certain groups or certain individuals.

4. *Summary of Social Contract Justification.* While the social contract is most often cited for justifying state power, its philosophical roots are fairly complicated. Express consent

118. See George Klosko, *The Principle of Fairness and Political Obligation*, 97 ETHICS 353, 355, 358 (1987) (discussing individuals' obligations to society).

119. See *id.* at 354–55, 358 (explaining the balance between individuals' benefits and burdens).

120. WOLFF, *supra* note 93, at 60–65 (examining problems with the perceived innate fairness in a democratic system).

121. See Klosko, *supra* note 118, at 356 (“The fact that individuals widely believe that they are obligated to bear burdens . . . because of considerations rooted in the principle of fairness does not itself mean that they have these obligations.”); see also Charles H. Koch, Jr., *A Community of Interest in the Due Process Calculus*, 37 HOUS. L. REV. 635, 665 (2000) (explaining that some individuals do not benefit from living in society).

122. ROBERT NOZICK, ANARCHY, STATE AND UTOPIA 93–94 (1974).

123. The United States has certain immunization requirements for immigrants. See, e.g., *Notice of Revised Vaccination Criteria for U.S. Immigration*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/immigrantrefugeehealth/lawsregs/vaccination-immigration/revised-vaccination-criteria-immigration.html> (last visited Sept. 7, 2012) (listing vaccination criteria for U.S. immigration).

certainly justifies state power, but it is almost never present. Tacit and hypothetical consent pose certain problems, although each may provide a good justificatory basis in specific circumstances. Surely residence alone (tacit consent) cannot explain why an individual must comply with all public health restrictions, particularly those that entail individual risk. Hypothetical consent may provide a better explanation; many people may agree in the “original position” that appropriate public health restrictions should be put in place limiting individual choice. But in some sense this just begs the question: what constitutes appropriate restrictions? It is not clear that in the original position people would simply agree to be governed by whatever restrictions are thought to be appropriate by the relevant public health authorities; perhaps they would only agree to certain types of restrictions. Nor does fairness solve the problem, since for some the fairness of the benefits justifying the “contract” may be in question. Thus, Hart’s fairness theory may justify obligations for some people, but not others, and probably does not create a binding social contract justifying all public health interventions. As appealing as a social contract justification may be on the surface, it does not seem to function as a basis for overriding individual choice in the full range of public health interventions. A. John Simmons concludes that there must be grounds other than consent theory for justifying overall state power,¹²⁴ let alone for limiting informed consent. This does not mean that social contract theory does not have a role to play in understanding state public health power; it merely means that if the goal is to develop a framework to analyze the scope of state public health power in the absence of individual informed consent, we must seek guidance from other philosophical theories.

B. Utilitarianism

Perhaps the problem is with the idea of a “contract” in the first place; a stronger argument in favor of state public health intervention, even without individual informed consent, may be a utilitarian one. As the *Jacobson* court acknowledged, the Massachusetts “state legislature proceeded upon the theory which recognized vaccination as at least an effective if not the

124. See A. John Simmons, *Political Obligations and Consent*, in *THE ETHICS OF CONSENT* 305, 325 (Franklin G. Miller & Alan Wertheimer eds., 2010) (discussing objections to consent theory).

best known way in which to meet and suppress the evils of a smallpox epidemic that imperiled an entire population.”¹²⁵ In other words, despite its flaws, a system of vaccination provides better overall benefit to the community than a system risking a smallpox epidemic. The court also noted the very small risk to individuals (and the possibility that an individual with a real medical risk could opt out).¹²⁶

Utilitarianism offers an additional theory of state public health power. Moreover, it enables us to weigh the level of threat (or potential harm) to the community against the level of potential harm to the individual.¹²⁷ Jeremy Bentham argues that individuals have a duty to obey the state when it is in the group’s interest (or when it maximizes the common good—to put it in standard utilitarian terms).¹²⁸ Of course there are many difficulties with utilitarian theories. Not only is it often difficult to identify the specific course of action that maximizes overall utility,¹²⁹ but utilitarian reasoning naturally favors the will of the majority, even when it entails great detriment to a minority, as long as the overall utility is increased.¹³⁰ On its face, this approach seems to allow state persecution of minorities in favor of the common good. While potentially attractive in some public health contexts, a theory that potentially would allow, for example, the killing of small number of infected individuals to

125. *Jacobson v. Massachusetts*, 197 U.S. 11, 30–31 (1905).

126. *Id.* at 24, 39.

127. See JOHN STUART MILL, UTILITARIANISM 16–17 (George Sher ed., 1979) (defining utilitarianism principles, which require individuals to “sacrific[e] their own greatest good for the good of others”).

128. WOLFF, *supra* note 93, at 50–51. Consequentialist theories, such as utilitarianism, determine the ethical or correct course of action by looking at the consequences of different alternatives. The alternative that leads to the best result, however defined (e.g., most happiness, greatest good, etc.), is the correct one. See David O. Brink, *Some Forms & Limits of Consequentialism*, in THE OXFORD HANDBOOK OF ETHICAL THEORY, *supra* note 52, at 381–84. In contrast, natural rights theory—or Kantian theory—is not consequence driven, but deontological. Robert M. Veatch, *Revisiting A Theory of Medical Ethics: Main Themes and Anticipated Changes*, in THE STORY OF BIOETHICS 67, 81 (Jennifer K. Walter & Eran P. Klein eds., 2003) Deontological theories evaluate alternative courses of action based on the importance of particular values, without regard to the consequences of promoting those values. See David McNaughton & Piers Rawling, *Deontology*, in THE OXFORD HANDBOOK OF ETHICAL THEORY, *supra* note 52, at 424–26.

129. See Bernard Williams, *A Critique of Utilitarianism*, in SMART & WILLIAMS, *supra* note 35, at 86–87 (“[I]t is perfectly possible for an agent to be ignorant or mistaken . . . about what is the right action in the circumstances.”). One can apply utilitarian reasoning without adopting utilitarian theory—i.e., applying a consequentialist analysis focused on something other than maximal utility—which might avoid some of the pitfalls with utility calculations.

130. See *id.* at 105 (“[E]ven if the removal would be unpleasant for the minority, a utilitarian calculation might well end up favouring this step . . .”).

protect the community as a whole—as is done with animal herds to avoid the spread of disease¹³¹—should make us wary. On the other hand, utilitarian theory does not rely on express, tacit, or hypothetical consent and thus provides an independent basis for understanding the scope of state power and individual obligations.¹³² Furthermore, utilitarian theory is already a part of legal reasoning in public health cases, although it may not always be labeled as such.¹³³ Thus, the theory may seem comfortably familiar, even when applied to new cases. More importantly, because utilitarian theory is already used as a justification for limiting individual informed consent in a public health context, we should recognize this more clearly and be alert to its flaws (such as the difficulty making utility comparisons). In those cases where the flaws are prevalent, the justification for limiting informed consent is weakened.

We can draw from the work of John Stuart Mill in applying utilitarian theory to understand the appropriate scope of state public health interventions.¹³⁴ In *On Liberty*, Mill suggests a way to limit state powers under a utilitarian framework using the principle of liberty.¹³⁵ He states, famously, that “the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.”¹³⁶ This is commonly known as the “harm principle.”¹³⁷ Individuals should be left to their own devices within the private sphere because they are more likely to know what will increase their utility than others (even if they make mistakes) and because liberty is necessary for the full development of human

131. See 9 C.F.R § 71.14 (2012) (noting that compensation can be made “[w]hen, in order to prevent the spread of any contagious, infectious, or communicable disease, it becomes necessary to slaughter any diseased or exposed animals . . .”).

132. Cf. MILL, *supra* note 127, at 6–26 (defining utilitarianism and discussing utilitarian principles without mentioning consent principles).

133. See Robert I. Field & Arthur L. Caplan, *A Proposed Ethical Framework for Vaccine Mandates: Competing Values and the Case of HPV*, 18 KENNEDY INST. ETHICS J. 111, 114–15 (2008) (discussing utilitarianism in the public health context).

134. See generally MILL, *supra* note 127, at 7 (introducing utilitarian principles as those that promote happiness).

135. JOHN STUART MILL, *ON LIBERTY AND THE SUBJECTION OF WOMEN* 16–17 (Alan Ryan ed., Penguin Books 2006) (1859); see also ANDREW LEVINE, *ENGAGING POLITICAL PHILOSOPHY FROM HOBBS TO RAWLS* 143–48 (2002) (discussing Mill’s application of utilitarianism to the principle of liberty).

136. MILL, *supra* note 135, at 16. Of course we often debate the validity of state and federal laws which appear to be focused on protecting an individual from harming himself. Some of these may be justified via a social contract analysis, others may be invalid exercises of state power.

137. DAVID INGRAM, *LAW: KEY CONCEPTS IN PHILOSOPHY* 134 (2006).

beings (and thus the society is better off overall if people are left to make their own choices).¹³⁸ In fact, these two ideas mirror nicely the oft-cited reasons for requiring individual informed consent—that individuals are better able to determine which medical treatments are in their interests, and that promoting individual choice benefits society by encouraging individual autonomy.¹³⁹ State limits on individual liberty are warranted, then, on two grounds. First, intervention is permitted for those individuals who lack the capacity to determine their own good, such as children or incompetent adults.¹⁴⁰ Second, intervention is permitted in the public sphere on utilitarian grounds—i.e., to prevent harm to others. Correspondingly, individual informed consent may not be required in situations where the individual in question is incompetent, or the intervention is necessary to prevent harm to others. It is important to stress, however, that the assertion that state force is not warranted on paternalistic grounds does not mean that we must stand aside and let individuals make what are perceived as poor choices. To the contrary, society may take a variety of measures to encourage choices that it perceives to be in the interests of its members. Thus, we may have a third category in which intervention is permissible on paternalistic grounds, as long as it does not, in the end, remove the individual's ability to choose.¹⁴¹ That is, society may structure decisions in such a way as to encourage the preferred choice.¹⁴²

138. This is a form of rule-utilitarianism. Rule-utilitarianism seeks to effectuate rules that will generally result in the greatest good. Act-utilitarianism, on the other hand, focuses on individual acts and in each case evaluates what action will lead to the greatest good. These are also sometimes described as direct (act) and indirect (rule) utilitarianism. See David O. Brink, *Mill's Ambivalence About Rights*, 90 B.U. L. REV. 1669, 1671 (2010).

139. See *supra* Part I.A.

140. See Field & Caplan, *supra* note 133, at 111, 114, 118–19 (discussing the “categories of individuals,” including children and disabled adults, who have often been subject to interventions).

141. See RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS* 4–6 (2008) (discussing “libertarian paternalism,” which argues for “self-conscious efforts . . . to steer people’s choices in directions that will improve their lives,” while “maintain[ing] or increas[ing] freedom of choice.”).

142. One very interesting approach in this context is the idea of “nudges” described by Richard Thaler and Cass Sunstein in their book. *Id.* at 3–6. See also the articles and commentary discussing the ethics of nudges in volume 12, issue 2, of the *American Journal of Bioethics* (Special Issue) (February 2012). Creating incentives to influence choice may be permissible even with respect to fundamental interests of bodily integrity. See *Maher v. Roe*, 432 U.S. 464, 474 (1977) (finding that a state may, through differential funding, make “childbirth a more attractive alternative, thereby influencing the woman’s decision” to have an abortion).

To implement this theory, one needs a basis for distinguishing the public sphere (where intervention is allowed) from the private sphere (where it is not). This could be where a theory of natural rights comes into play—states may not interfere with the inherent rights of human beings.¹⁴³ If you accept that natural rights exist, this limitation may solve many problems. But the mere assertion of natural rights may not convince everyone of their existence, and it certainly does not suffice to determine what rights fall into this “natural” category.¹⁴⁴ In response, Jonathan Wolff argues we can draw from the concept of utility to delineate the public from the private sphere.¹⁴⁵ Those laws that promote general utility are within the public sphere and those that do not are within the private sphere.¹⁴⁶ Of course this may seem like circular reasoning. But the idea is that rather than try to distinguish public from private on other grounds (say by determining the inherent or natural rights of individuals), we should just ask whether the intervention in question promotes general utility. While debates remain about the integration of the liberty principle and utilitarian theory, these are beyond the scope of this Article. For our purposes, it is sufficient to acknowledge that this approach allows us to understand the scope of state powers in the public health context without relying on the limited notion of a social contract based either on fairness or consent.

C. *Application of Justifications to Contagious Disease Interventions*

In summary, for a utilitarian rationale to justify vaccination in the absence of informed consent, there must be some showing that the common good is indeed increased more than the aggregate of individual harms which may occur by allowing vaccination without consent. For this latter evaluation, there is both the harm of intervening without consent (a harm to autonomy, or a dignitary harm) and the potential physical harms from the vaccination.¹⁴⁷ Unless the disease in question is a

143. WOLFF, *supra* note 93, at 114–15.

144. *See id.* at 115–16 (discussing the difficulties of defending a “theory of natural rights” and the difficulties of determining “what natural rights we have”). Consider the ongoing debate in this country about whether the right to basic health care services is a “natural right” of human beings.

145. *Id.* at 116–20.

146. *See id.* (describing “the line between the private and public spheres”).

147. *See* Michelle M. Mello, *Rationalizing Vaccine Injury Compensation*, 22 *BIOETHICS* 32, 37 (2008) (“But, arguably, the burdens associated with vaccination requirements are special: they go beyond dignitary harms and economic losses to actual

serious threat to the community and unless the vaccine's safety and efficacy is well established, it may be difficult to justify jettisoning informed consent requirements. Moreover, even in those cases where this can be shown, allowing individual informed consent may still result in more overall utility than a mandatory system. This may be because the vast majority of people will accede to a voluntary system, and such a system will avoid the harm to individual autonomy. In fact, most vaccination efforts are voluntary, and almost all involve an opt-out for health (and sometimes other) reasons.¹⁴⁸ Even for those that are not voluntary, there is little basis for allowing an exception to the information disclosure requirement because the provision of information will allow individuals to determine the actual risks to themselves and may result in better overall compliance. Only the individual consent requirement may be excused, and that only in rare circumstances.¹⁴⁹

Quarantine and isolation raise similar issues. But unlike vaccination, there can be little direct therapeutic benefit to complying. (An individual who has been vaccinated, on the other hand, may well obtain additional immunity and thus direct therapeutic benefit.)¹⁵⁰ In fact, there may be considerable risk for those who are not infected but are quarantined with those who are. This is one reason why there is increasing interest in using techniques such as "quarantine in place," in which individuals observe distancing measures within their own homes.¹⁵¹ For any one individual, the choice to remain separated from others may not increase individual utility, but the separation of exposed or diseased individuals from the group benefits society as a whole.¹⁵²

physical injury . . .").

148. Even school vaccination requirements allow parental opt-outs based upon health, religious, or sometimes philosophical objections. See *School and Childcare Vaccination Surveys*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www2a.cdc.gov/nip/schoolsurv/schImmRqmt.asp> (last updated July 21, 2011) (providing a state-by-state list of permitted vaccination exemptions).

149. See, e.g., Gregory C. Keating, *Pressing Precaution Beyond the Point of Cost-Justification*, 56 VAND. L. REV. 653, 712–13 (2003) (In the context of the rabies vaccine, which has severe side effects, "[c]onsiderations of fairness and justice control only when individual consent is impossible to obtain").

150. There may be indirect benefits for the individual who avoids infecting friends or family members. Such benefits may encourage voluntary quarantines.

151. See Lawrence O. Gostin et al., *Quarantine: Voluntary or Not?*, 32 J.L. MED. & ETHICS (SPECIAL SUPPLEMENT) 83, 84 (2004) ("Reframing the stigmatizing term 'quarantine' along the lines of a 'snow day' or 'shelter in place' principles may aid in acceptance. A snow day is simply a request to limit interpersonal contacts . . . by asking citizens to stay home for a specified period of time.").

152. GOSTIN, *supra* note 45, at 12; see Mark P. Gergen, *Territoriality and the Perils of Formalism*, 86 MICH. L. REV. 1735, 1741 (1988) (noting that quarantine laws are tolerated

Perhaps individuals, not knowing exposure, would agree, hypothetically, to such constraints ahead of time. In other cases, the scope of the quarantined area may be large enough that the intervention is considered more akin to an environmental one than one of individual application. In still other cases, a utilitarian rationale justifies the quarantine, as the potential harm to the individual is outweighed by the benefits to the society as a whole. Under this rationale, quarantine and isolation should be used only rarely, when the benefits clearly outweigh the burdens. As with vaccination, utilitarian reasoning would require that if voluntary restrictions are more likely to achieve the sought-after results than mandatory restrictions, the former should be used.¹⁵³

The classic public-health-interventions-to-combat-infectious-disease category provides an example in which autonomy does play a role. But this is also a situation in which exceptions may function based on a variety of theoretical justifications. Each justification may apply differently to different groups, such as health care workers versus the general public, resulting in diverse applications of informed consent requirements. But no theory justifies the avoidance of information disclosure requirements. Even the extremely controversial mandatory anthrax vaccination of armed forces personnel during the Gulf War was supposed to include distribution of information pamphlets at the time of intervention. (Unfortunately, these were sometimes not available and other times not provided.)¹⁵⁴ It is worth recognizing that the traditional emergency exception to informed consent may also play a role in this context, possibly limiting expansive disclosure. But most situations calling for vaccination are not so time-sensitive as to prevent information disclosure.¹⁵⁵ Paradoxically, the “emergency” necessitating quarantine or isolation is not directed at the individual whose

because they are of positive utility, that is, “quarantines enhance the general welfare”).

153. See, e.g., George J. Annas, *Your Liberty or Your Life: Talking Point on Public Health Versus Civil Liberties*, 8 EMBO REP. 1093, 1096–97 (2007) (comparing the effectiveness of mandatory versus voluntary quarantine).

154. Bernard Rostker, *Information Paper: Vaccine Use During the Gulf War*, GULFLINK, <http://www.gulflink.osd.mil/va/> (updated Dec. 7, 2000); see also MILITARY VACCINE AGENCY, DEP’T OF DEF., ANTHRAX VACCINE IMMUNIZATION PROGRAM INFORMATION (Dec. 19, 2005), <http://www.vaccines.mil/documents/864Dec2005house-inhouse-out.pdf> (providing information on the Department of Defense’s Anthrax Vaccine Immunization Program as of 2005).

155. See *Recommended Immunizations for Adults*, CENTERS FOR DISEASE CONTROL & PREVENTION (last updated May 31, 2012), available at <http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read.pdf> (recommending immunizations windows that extend to four years or even longer).

liberty is restrained, but involves the risk of exposure of others. This is a fundamentally different situation than the typical emergency exception which justifies avoidance of requirements based on the promotion of the individual's own autonomy, which may be lost (through extensive harm to health or life) by insisting on fully informed consent in an emergency.¹⁵⁶

So although there is a public health exception to informed consent for classic contagious disease interventions, the exception only excuses the consent requirement (if even that), not the information disclosure obligations. The focus of those disclosures, however, may well be different than the traditional informed consent context. Professor Wendy Parmet suggests that we shift the scope of disclosure away from individual risks and benefits and towards the public health risks and benefits of any particular intervention.¹⁵⁷ For example, disclosure in the vaccine context would include the public benefit of vaccines and the harms of failing to achieve herd immunity.¹⁵⁸ Moreover, the obligation to disclose information would shift from the private clinical encounter to a public setting, and also from a professional liability model to a public accountability model for inadequate or unpublicized warnings.¹⁵⁹ Thus, informed consent for public health interventions may look substantially different than informed consent for individual medical treatment interventions.

IV. PUBLIC HEALTH INFORMATION REPORTING AND USE

Perhaps even more interesting than the traditional public health examples discussed thus far is the growing use of personal medical information for public health purposes.¹⁶⁰ The most

156. Douglas Andrew Grimm, *Informed Consent for All! No Exceptions*, 37 N.M. L. REV. 39, 70–71 (2007) (discussing “preservation of life or the prevention of serious bodily harm to the patient” as the primary justification for the traditional emergency exception to informed consent); John A. Gleason, *Quarantine: An Unreasonable Solution to the AIDS Dilemma*, 55 U. CIN. L. REV. 217, 234 (1986) (“It must be realized that quarantines are instituted in order to benefit the public, not the individual.”).

157. WENDY E. PARMET, POPULATIONS, PUBLIC HEALTH, AND THE LAW 198–203 (2009).

158. See Wendy E. Parmet, *Informed Consent and Public Health: Are They Compatible when it Comes to Vaccines?*, 8 J. HEALTH CARE L. & POL’Y 71, 107–10 (2005) (advocating for disclosing the public benefits and harms of vaccinations as opposed to just the individual benefits and harms).

159. *Id.*

160. There is also the use of personal health information for research purposes. While I acknowledge that the line between public health practice and research is not always clear, discussion of the limitations of informed consent for public health research is a topic for another article.

common use is contagious disease reporting.¹⁶¹ In addition to disease reporting, there are also efforts to gather information to determine population disease burden, or even to target interventions to persons at risk. Consider one New York City Health Department program that sends letters to diabetes patients who have glycemic control issues, like a high A1C test level, or who are overdue for a test.¹⁶² Although the actual testing is done with patient consent, the monitoring and notification letters are sent whether or not the patient has consented to the intervention.¹⁶³

Assuming, for purposes of argument, that the information in question should be within the control of the individual,¹⁶⁴ why and when is it permissible to use such information without consent? The usual justifications for requiring informed consent to treatment do not necessarily apply to sharing of information. That is not to say that consent may be avoided in all situations, just that the reasons for requiring consent here are not the same as the reasons for requiring consent to treatment. Confidentiality of medical information serves two primary purposes—it recognizes individuals' rights to control their identity and it encourages the free sharing of information with medical professionals.¹⁶⁵ The first rationale is rights-based and the second utilitarian: better health outcomes will be achieved if individuals share information with medical professionals, and the assumption is that they will not do that unless the information is kept confidential. But health outcomes may be better overall if some information (i.e., that related to contagious diseases) is shared in a limited way. Additionally, there is no evidence that mandated disclosure of some personal information (even identifiable information) results in patients being less willing to

161. See Terence L. Chorba et al., *Mandatory Reporting of Infectious Diseases by Clinicians*, 262 J. AM. MED. ASS'N 3018, 3018–19 (1989) (noting that all states have some form of mandatory communicable disease reporting).

162. N.Y.C. DEP'T HEALTH & MENTAL HYGIENE, THE NEW YORK CITY A1C REGISTRY: SUPPORTING PROVIDERS & PATIENTS IN DIABETES CARE, <http://www.nyc.gov/html/doh/downloads/pdf/diabetes/diabetes-a1c-reg-serv.pdf> (last visited Sept. 7, 2012).

163. See N.Y.C. DEP'T HEALTH & MENTAL HYGIENE, NEW YORK CITY A1C REGISTRY: IMPROVING DIABETES CARE IN NEW YORK CITY 25 (Sept. 30, 2011), <http://www.nyc.gov/html/doh/downloads/pdf/diabetes/diabetes-a1c-reg.pdf> (explaining that patients are automatically enrolled in the registry and must specifically opt-out of the A1C registry if they do not wish to be contacted).

164. In other words, assuming the information in question is, in fact, the individual's information as opposed to information regarding a family or group. See, e.g., Jessica Berg, *Grave Secrets: Legal and Ethical Analysis of Postmortem Confidentiality*, 34 CONN. L. REV. 81, 90–95 (2001) (discussing control over an individual's confidential information after his or her death).

165. PARMET, *supra* note 157, at 82–84, 97–98.

share information with health care professionals.¹⁶⁶ Debates about this lack of empirical evidence have come up in other contexts, such as the effect of mandatory reporting laws on individuals' willingness to seek medical care.¹⁶⁷

Even if the doctrine of informed consent applies to the use of individual medical information generally, various theoretical rationales may justify an exception for sharing some information. First, sharing information without individual identifiers raises few, if any, autonomy issues, bringing up questions about the justification for applying the doctrine in the first place.¹⁶⁸ The notion that individuals should have absolute rights to control information they generate is belied by the consistent narrowing of private space.¹⁶⁹ While control over identifiable information may have implications for individual identity (and thus for autonomy), control over de-identified information is less easily justified using an autonomy model.¹⁷⁰ At the very least, even if there are autonomy interests in controlling de-identified information, these interests should be balanced against other principles and other rights. Consider, for example, the use of information to determine population level disease burden, such as state-mandated cancer registries. In most cases the reporting is anonymous—the information is shared, but stripped of identifying characteristics. Here there is no rights-based justification for individual control over identity because the information is not linked to identity. Moreover, because the issue is anonymous information sharing, not individual intervention, the other autonomy-based rationales do not apply.¹⁷¹ Yet informing the individual about the disclosure remains

166. Berg, *supra* note 164, at 107.

167. See, e.g., Nichole Miras Mordini, *Mandatory State Interventions for Domestic Abuse Cases: An Examination of the Effects of Victim Safety and Autonomy*, 52 DRAKE L. REV. 295, 326 (2004) (describing the policy arguments used in support of and in opposition to mandatory reporting statutes). A large number of states have mandatory reporting for gunshot wounds. For a list of statutes, see *Family Violence Statutes*, AM. ACAD. ORTHOPAEDIC SURGEONS, <http://www.aaos.org/about/abuse/ststatut.asp> (last visited Sept. 7, 2012).

168. There is a vast amount of literature discussing identifiability of information, and I will not go into detail here.

169. See Jonathon W. Penney, *Privacy and the New Virtualism*, 10 YALE J.L. & TECH. 194, 205–10 (2008) (discussing the challenges to “informational privacy” in the digital age).

170. See Lawrence O. Gostin, *Health Information Privacy*, 80 CORNELL L. REV. 451, 519–21 (1995) (discussing a spectrum of the identifiability of information and the corresponding protections the information should receive, with anonymous information receiving the least protection).

171. *Id.* at 520 (recognizing that “patients have a weaker claim to control the use of nonidentifiable data because they are less likely to suffer personal harm by the disclosure”).

important. It allows individuals to prepare for a possible breach of confidentiality, and may enable them to take steps to minimize the harmful impact.

Second, even if identifiable information is shared, and thus autonomy clearly an issue, one of the rationales allowing an exception to informed consent requirements may apply. Sharing identifiable personal medical information raises autonomy issues, but not in exactly the same way as mandatory medical interventions because bodily integrity is not at issue. Consider contagious disease reporting. All states have mandatory reporting statutes for various diseases.¹⁷² Contagious disease reporting generally is not anonymous.¹⁷³ The practice of contact tracing requires individually identifiable information to be shared with public health authorities so other exposed individuals can be notified.¹⁷⁴ This does not mean that the initial infected individual has to be identified to the contacts, but the public health authority has access to identifiable information. As a practical matter, patients may be asked to provide informed consent before disclosure, but such authorization is not always required.¹⁷⁵ Social contract and fairness rationales may function to allow some information sharing. We currently live in a society that requires a great deal of information sharing to function well.¹⁷⁶ Moreover, a general rule allowing the sharing of such information may result in more overall utility than a rule allowing it to remain confidential; this is often the cited basis for confidentiality exceptions.¹⁷⁷

The information sharing context is one in which the initial autonomy rationale does not function in the same way as it might when bodily integrity is at issue, and also one in which various theoretical justifications may function to allow an

172. Chorba et al., *supra* note 161, at 3018.

173. See, e.g., Scott Burris et al., *The Role of State Law in Protecting Human Subjects of Public Health Research and Practice*, J.L. MED. & ETHICS 654 (2003) (noting that many states do not require informed consent “for the release of identifiable information for public health purposes”).

174. Nancy E. Kass & Andrea Carlson Gielen, *The Ethics of Contact Tracing Programs and Their Implications for Women*, 5 DUKE J. GENDER L. & POL’Y 89, 90–91 (1998).

175. Burris et al., *supra* note 173, at 656.

176. See Mary Jo Obee & William C. Plouffe, Jr., *Privacy in the Federal Bankruptcy Courts*, 14 NOTRE DAME J.L. ETHICS & PUB. POL’Y 1011, 1024–25 (2000) (“[S]ociety needs information to function; therefore, any action which chills the willingness of persons to provide information hurts society.”).

177. See, e.g., Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California’s Proposition 65*, 23 ECOLOGY L.Q. 303, 314–15 (1996) (discussing several utilitarian rationales for and benefits of information disclosure).

exception. Even if informed consent is applied in the traditional sense, it may not function to provide adequate protections from harm. Gathering public health information is crucial—what alternatives to the informed consent model might be used? One interesting approach may be to apply a framework analogous to the “fair use” exception in copyright law.¹⁷⁸ The doctrine allows third parties to use an individual’s intellectual property in a reasonable manner, even in the absence of consent.¹⁷⁹ Thus, even if individual medical information is viewed as the property of the individual (and this is still a point to be determined),¹⁸⁰ there could be various uses of the information allowed without individual informed consent. Some of the debates about the copyright fair use exception have taken issue with the idea that it can be “predicated on the implied or tacit consent of the author,” noting that such consent is fictional at best.¹⁸¹ Similar to the debates discussed earlier about tacit consent, an alternative rationale for justifying fair use, such as utilitarianism, may need to be explored.

Despite these barriers, developing a doctrine of information “fair use” may be a valuable mechanism that could be applied to allow the public health use of information without individual informed consent. The copyright fair use exception is delineated in § 107 of Title 17 of the U.S. Code.¹⁸² There are four factors to consider:

- (1) the purpose and character of the use, including whether such use is of commercial nature or is for nonprofit educational purposes;
- (2) the nature of the copyrighted work [purely factual versus creative work];
- (3) the amount and substantiality of the portion used in relation to the copyrighted work as a

178. See MARSHALL A. LEAFFER, UNDERSTANDING COPYRIGHT LAW §§ 10.01–.05, at 487–89 (5th ed. 2010) (describing the “fair use” doctrine). The application of the exception rests on four factors: noncommercial use, factual versus creative copyrighted work, amount and substantiality of the portion used, and the effect on the potential market for the protected work. *Id.* § 10.06, at 493–94; see also *Blanch v. Koons*, 467 F.3d 244, 256 (2d Cir. 2006) (discussing the distinctions between creative and factual work in the fair use context). These factors could be adapted to medical information use.

179. LEAFFER, *supra* note 178, § 10.02, at 487–88.

180. The well-known *Moore v. Regents of the University of California* case involved a question of a research use of information. 793 P.2d 479, 480–82 (Cal. 1990). Although the court rejected the idea of a property right in information, it did state that informed consent was required. *Id.* at 484–85, 487–89, 492–93.

181. 4 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.05, at 13-157 (2012).

182. 17 U.S.C. § 107 (2006).

whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work.¹⁸³

What would a public health fair use exception for individual health information look like? First, consider how the information is being used and by whom. Information used for public health purposes, particularly if gathered by government entities, such as public health departments (or upon direct authorization from a public health department), would be more likely to fall into the exception than, say, information gathered by health care institutions or pharmacies for marketing purposes.¹⁸⁴ Second, information “created” by the individual—for example, notes about patient feelings or patient statements—may be given more protection than more purely “factual” information about medical status, such as contagious disease diagnosis.¹⁸⁵ Third, the scope of use is relevant; information disclosed should not include the entirety of the individual’s medical record. Only that information necessary to achieve the public health goal in question should be shared. The fourth factor takes into account the potential market for the information. There is a growing interest in the potential value of personal data, and recent efforts (such as the Facebook IPO)¹⁸⁶ reflect the possibility that a clear market will emerge in this context. While there are already markets for third party aggregations of data, there is little financial gain to be had by individuals choosing to share their own information.¹⁸⁷ Changes in this area may result in limitations on fair use.

In addition to efforts to scope out the full contours of a fair use analog, future scholarly efforts should continue to scrutinize the role of autonomy, rather than just assume its application, and consider whether individual informed consent should (or even could) play a protective role in various settings. Work must also be done to develop better disclosure mechanisms and more secure information safeguards rather

183. *Id.*; see also *Fair Use*, U.S. COPYRIGHT OFFICE, <http://www.copyright.gov/fls/fl102.html> (last updated June 2012).

184. See *Harper & Roe Publishers v. Nation Enters.*, 471 U.S. 539, 540 (1985) (noting that commercial as opposed to nonprofit use is a “factor tending to weigh against a finding of fair use”).

185. Mental health information may be given more protection under this conception.

186. Somini Sengupta & Evelyn M. Rusli, *Personal Data’s Value? Facebook Set to Find Out*, N.Y. TIMES, Feb. 1, 2012, at A1.

187. See Joshua Brustein, *Start-Ups Seek to Help Users Put a Price on Their Personal Data*, N.Y. TIMES, Feb. 13, 2012, at B3 (discussing the value of personal data, and opining that “individually, [personal] bits of data are worth practically nothing”).

than relying on individual authorization as a means to protect individual interests. Moreover, while consent may not always be required for the sharing of public health information, as with the other exceptions, disclosure obligations still exist. Parmet's suggestions may be applicable here, too, indicating the need to shift the focus from the individual to the public setting.¹⁸⁸

Finally, the scope of permissible use of individual medical information in the research context must be examined. The growing trend in medical research is to use observational studies, drawing on existing data in medical records.¹⁸⁹ The line between such efforts and public health surveillance and monitoring is less clear than the line between traditional clinical trials and public health.¹⁹⁰ There is a type of fair use exception in patent law, allowing the use of patented inventions without prior licensing for experimental purposes.¹⁹¹ Like the scope of copyright fair use, the scope of the experimental use exception is subject to debate. Both, however, seem to be premised on the idea that even protected intellectual property can be used without permission or compensation, provided the use is not directly commercial.¹⁹² Although this Article does not directly address research uses of information, it may be that an experimental use exemption provides a valuable framework for understanding the limits of individual informed consent for research involving medical information.

188. Parmet, *supra* note 158, at 107–10.

189. See P. Jepsen et al., *Interpretation of Observational Studies*, 90 HEART 956, 956, 960 (2004) (noting that observational studies are frequently the only feasible way to research modern medical questions). There are other research studies for which requiring individual informed consent will also cause problems. See, e.g., Julius Sim & Angus Dawson, *Informed Consent and Cluster-Randomized Trials*, 102 AM. J. PUB. HEALTH 480, 481–82 (2012) (discussing incompatibility of informed consent with some cluster-randomized trials).

190. See, e.g., Sharona Hoffman & Andy Podgurski, *Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research*, 65 SMU L. REV. 85, 97–104, 109 (2012) (comparing clinical and observational research, discussing the benefits and risks of observational research, and discussing whether informed consent should be obtained in observational research).

191. WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 315–16 (2003). There is both a common-law experimental use exception and a statutory exception. 35 U.S.C. § 271(e)(1) (2011); *Madey v. Duke Univ.*, 307 F.3d 1351, 1360–61 (Fed. Cir. 2002).

192. See 17 U.S.C. § 107 (2006) (making commercial versus educational use a primary factor in evaluating fair use); *Madey*, 307 F.3d at 1362 (strictly defining patent experimental use defense to exclude any activity that has commercial implications).

V. CONCLUSION

There is no single theory that explains the scope (and limits) of state public health powers and the corresponding obligations of individuals to submit to state authority in a public health context. There are multiple bases for justifying state power to intervene without individual consent, and each has slightly different implications. As a result, there are varying degrees to which individual informed consent requirements apply in public health contexts. Some individuals may have expressly consented to certain limitations; others may be bound by fairness.¹⁹³ It is worth pointing out, however, that even if some people can claim that they are exempt from direct obligation to society to accept public health interventions, that does not mean they are free to do anything. The absence of political obligations (say to the state or community in general) does not presuppose the absence of moral obligations (such as the obligation not to harm others).¹⁹⁴ We may well have moral obligations to our communities to accept certain public health interventions such as quarantine, isolation, or vaccination. But this is further than we need go in delving into political theory. For purposes of this Article, we need only consider the role the justifications play in understanding the contours of a public health exception to informed consent.

While the prior discussion does not identify one single justification for allowing a public health exception to individual informed consent, it does provide some clear guidance in this area. First, no rationale examined appears to justify the avoidance of disclosure obligations, except when the traditional emergency or waiver exceptions apply. That is, while some public health interventions may be allowed without individual authorization, in all cases information should be shared either directly with the individual or through general public notification. Second, the framework governing information disclosure may need to shift from an individual model to a public health model. This may necessitate changes both in the content of the disclosures (e.g., inclusion of public health risks and benefits) and the location of the disclosures (e.g., moving from the individual clinical setting to the community level). Third, the use

193. See WOLFF, *supra* note 93, at 55–56 (discussing the principle of fairness in the context of consent).

194. *Id.* at 37–38 (discussing how political and moral obligations operate independently).

of a particular rationale to justify an intervention may only work in certain contexts, and it is worth taking the time to evaluate each fully. A social contract model may be applicable to certain groups (e.g., health care professionals), but not to others (e.g., the general public). Moreover, application of a rationale that initially appears to permit an exception, such as maximizing overall health, may, in fact, weigh in favor of individual consent when the use of a consent model will increase participation and thus overall health.¹⁹⁵ Fourth, where an exception to informed consent does come into play, effort should be made to consider what other protections may need to be implemented. Community consultation should play a larger role than it currently does in designing, implementing, and evaluating public health interventions. Finally, although autonomy remains a valued principle in our society and the doctrine of informed consent serves to protect and promote autonomy, development of alternative frameworks, such as “fair use” of personal health information, will be crucial to maintain an appropriate balance between public health needs and individual rights.

195. The U.S. Department of Health & Human Services recently convened a working group to study which policies, including mandatory requirements for influenza vaccination of health care workers, will best achieve target vaccination rates. *HHS Action Plan to Prevent Healthcare-Associated Infections: Influenza Vaccination of Healthcare Personnel*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, http://www.hhs.gov/ash/initiatives/hai/tier2_flu.html (last visited Sept. 7, 2012).