Updating Constitutional Doctrine: An Extended Response to the Critique of Compulsory Vaccination*

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* This Response addresses the concerns raised in Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y L. & ETHICS 39 (2012).

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I. INTRODUCTION

Science is not supposed to tout certainty for its findings.[1] It leaves absolute truth to other fields, such as mathematics, logic, and religion. There are, of course, well-confirmed theories and "laws" that do warrant the loose use of "certain." The bare theoretical possibility that the oxidation theory of combustion will fall and the phlogiston theory will be restored to its rightful place does not move the research establishment. And scientists (like many others) are certain that scientific methodology is a powerful tool for illuminating the world, if not everything about every aspect of existence.

So, within this very stance, scientists themselves should be skeptical of critiques of what is thought to be already established. Moderate conservatism of this sort is rational and often inevitable.[2] The burden of proof, at the start, is rightly on the critics of accepted scientific claims unless those claims are absurd (which is rarely the case). And, for their part, scientists like Semmelweis, Marshall, and Warren were also right not to take established matters as certain.

Calls for skepticism in the face of scientific claims generally, and vaccination claims in particular, are, thus, welcome among the rational. Professor Holland's article (the "Article") calls attention to important medical, scientific, and constitutional issues, but has flaws requiring attention. Skepticism of medical or scientific claims may be a rational necessity, but her Article is an uneven and incomplete expression of that skepticism, for the reasons that follow in this Response's Parts II-V. The Article relies, at various points, on flawed modes of inference and questionable sources of opinion and information; it fails to specify underlying value and policy assumptions; and its analysis of constitutional precedents and doctrine does not confirm her claims that compulsory vaccination programs are constitutionally suspect within current or preexisting doctrine.

One should ask what incites Professor Holland's complaints about current

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1. *See* PHILIP KITCHER, SCIENCE, TRUTH, AND DEMOCRACY 13 (2001) ("To claim the truth of a statement is not to declare the certainty of our knowledge. Whatever hopes our predecessors may have had, contemporary views about human knowledge are saturated by the conviction that our beliefs about nature are fallible, that absolute certainty is not an option for us. When someone maintains the truth of the thesis about the composition of the atmosphere, he can consistently acknowledge the possibility that further inquiry might reveal it to be false. Indeed, we spend our lives proclaiming true, and acting upon, beliefs we recognize as vulnerable to the course of future experience. There is no snapping shut of our minds, no insulation against critical scrutiny, when we move from saying what we believe to declaring its truth.").

2. Of course, critics should not have treated Marshall and Warren (bacteria cause many ulcers) and Semmelweis (germ theory of disease) as badly as they did, but much of the initial skepticism of received wisdom is sound. *See* Polyxeni Potter, *About the Cover: Ignaz Philipp Semmelweis (1818-65)*, 7 EMERGING INFECTIOUS DISEASES 368 (2001), *available at* http://wwwnc.cdc.gov/eid/article/7/2/ac-0702_article.htm; Kathryn Schulz, *Stress Doesn't Cause Ulcers! Or, How To Win a Nobel Prize in One Easy Lesson: Barry Marshall on Being... Right*, SLATE, Sept. 9, 2010, http://www.slate.com/blogs/thewrongstuff/2010/09/09/stress_doesn_t_cause_ulers_or_how_to_win_a_nobel_prize_in_one_easy_lesson_barry_marshall_on_being_right.html.

immunization practices and policies—at least as applied to hepatitis B vaccination, which is the Article's prime target. Here are some possibilities, starting with the least likely, but nonetheless important:

- It is in pursuit of loyal opposition to science in application—a way of keeping scientists honest and promoting due care in formulating, confirming, and disclosing hypotheses and findings. We are all from Missouri, after all.[3]And, no more than with any other institution, we probably should not rely on science to police its own domain.
- It is meant to vindicate autonomy and the rule of law, regularly scorned by overbearing governments and greedy pharmaceutical companies.
- Some think that there have been serious injuries from vaccinations, including those for hepatitis B; these pressing facts require ventilation and calls for reducing or terminating some programs.

I doubt that the Article is simply meant to keep science on its toes. It seems likelier to be a reaction to a sense of autonomy under assault by at least some vaccination projects, and a push toward deemphasizing them. True enough, autonomy is always under assault. Give the government or immense private interests an inch, and they will take a light year. (Sometimes little private interests do that too.)The Article does not claim there is a pattern (systematic or otherwise) of putting down individual liberty of certain sorts, but its critique of supposed conflicts of interest and "financial distortions" suggests a governmental and commercial indifference to claims against personal intrusions.

As for the view that there are facts showing that the risk of vaccine-related injury is unacceptable, I do not think that is made out here, although the author is right to reject arrogant dismissals about such injuries by persons who seem to *know* that nothing can go wrong. A central distinction to stress is that between *vaccine-caused* injury—whether it occurs and at what rate—and what constitutes "acceptable losses." Other critical distinctions concern the attribution of injuries to vaccines. Such distinctions include the differences between (1) associational links *simpliciter* and causation and (2) injuries caused by the active components of the vaccine and those caused by additives (e.g., thimerosal). I do not recall encountering any calls for halting hepatitis B vaccinations because of the one-in-1.1 million risk of anaphylactic shock concededly created by the vaccine.[4] The author does not insist on a zero incidence of vaccine-related injuries (never mind a zero incidence of adverse events correlated with vaccination), but her tolerance is not great. Not unexpectedly, her tolerance for "low benefit" is also limited.

3. Missouri is known as the "Show-Me" state. *See Missouri History: Why Is Missouri Called the "Show-Me" State?*, MO. SECRETARY ST. ROBIN CARNAHAN, http://www.sos.mo.gov/archives/history/slogan.asp (last visited Dec. 2, 2011).

4. *See, e.g.*, Eric E. Mast et al., Ctrs. for Disease Control & Prevention, *A Comprehensive Immunization Strategy To Eliminate Transmission of Hepatitis B Virus Infection in the United States; Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults*, 55 MORBIDITY & MORTALITY WKLY. REP., Dec. 8, 2006, at 1, 13.

"According to this information [from the U.S. Advisory Committee on Immunization Practices (ACIP)], the United States now vaccinates approximately 4 million infants per year to prevent approximately 525 cases of likely infection, or about 10,000 infants to prevent likely illness in one child."[5]

But this description does not constitute an argument for any legal or policy conclusion and, in this sense, cannot stand alone. Without applying the asserted facts and factual hypotheses to accepted value premises, this description imports no value conclusions whatever. In fact, privately, and as a matter of public policy, we often bear harms that seem, monetarily, to outweigh the benefits. Moreover, little is said about the seriousness of hepatitis B infections; only the number 525 is recorded. Still more, the very idea of "prevent[ing] 525 cases of likely infection" is sought to be trivialized by saying that the benefit is to one in 10,000. (On the figures presented, it's actually about one in 7600.) Something more is needed to explain the insistent call to arms.

What follows is not a point-by-point account and evaluation of the Article, and is not meant to be a comprehensive freestanding article either. I am addressing ideas that are worth further illumination. More specifically, I assess the Article's analysis of constitutional precedent and doctrine, criticize how it addresses the evidence of vaccination harm and benefit, and question its very framework for determining what constitutes harm and benefit on an individual and social scale. In the course of doing this, I try to probe the value premises underlying supposed collisions of personal autonomy with social claims and how these have been, and are likely to be, managed within a constitutional framework. In short, I try to address conceptual, doctrinal, and empirical flaws in the Article.[6]

II. THE OLDER CONSTITUTIONAL CONTEXT—*JACOBSON*: HANDLE WITH GREATER CARE

Much of Professor Holland's Article is about constitutional law. The threshold reason for this is obvious: If there are objections to compulsory vaccination, basic issues of the integrity of the person are openly contested, and rights will be invoked against government action. These are constitutional issues, and, if the constitution is to be obeyed, they are rule of law issues. Another

5. Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL'Y L. & ETHICS 39 (2012). For statutory sources and history, see *ACIP Charter: Authority, Objective, and Description, Authority*, CENTERS FOR DISEASE CONTROL & PREVENTION (Apr. 6, 2010), http://www.cdc.gov/vaccines/recs/acip/download/charter.pdf.

6. Because many issues derive from efforts to assess and compare advantages and disadvantages of vaccination programs, I note, for clarity, that references to "costs" should be broadly understood to include at least all direct adverse harms and disadvantages from vaccinations and their programs: the financial burden and physical and mental harms of adverse incidents attributable to the vaccine or the way in which the program is administered; attenuation of autonomy norms; even Heckler's Veto problems in objecting, rationally or not, to vaccination.

reason is that the constitutional matrix is a heuristic that drives us to probe the idea and practice of vaccination, or, indeed, any policy that finds itself embedded within a constitutional dispute. The constitutional framework, rightly used, illuminates the moral and policy issues and draws out analytical strands that might be overlooked within a looser framework for analysis. Rightly used, it skews nothing. (I do not address arguments against "over legalization," many of which are hugely flawed.)[7]

A third reason, amplifying the first two, is that adjudication involving technology generally, and vaccination in particular, may provide special challenges to constitutional interpretation and argumentation.[8] In this light, the constitution and vaccination need each other. The conceptual tools we use in constitutional theory and adjudication reflect the hierarchy of values embedded in the constitution; its text is not value free—a point quite independent of jurisprudential debates about meaning, interpretation, and authority. The rights, interests, and political structures embedded in the constitution are, to greater or lesser degree, aspects of American identity (a sprawling, but not meaningless, idea) and its vaunted exceptional status. What these rights, interests, and structures mean in theory and operation are tested constantly, but real-world developments—often technological innovations—push us to unpack and develop meanings that had been comfortably dormant. *Jacobson v. Massachusetts*[9]—that old, old case—represented a major medical innovation that had been introduced over a century earlier and pointedly required constitutional explication in a science-infused controversy.

Technological developments, from *Jacobson* through *Roe v. Wade* through future artificial gestation and cloning cases, require us to rethink our threshold values and, thus, necessarily how we implement them through tools for sorting and comparing constitutional claims. These tools are our standards of review. The competing views about and within science mentioned by Justice Harlan are with us now with increasing frequency and complexity.[10] *Jacobson* itself is, thus, a continuing presence. In a contemporary compulsory vaccination case applying today's doctrine,[11] the Court will be pressed to be more precise about its

7. *See* Michael H. Shapiro, *Is Bioethics Broke?: On the Idea of Ethics and Law "Catching Up" with Technology*, 33 IND. L. REV. 17, 87-103 (1999).

8. Michael H. Shapiro, *Constitutional Adjudication and Standards of Review Under Pressure from Biological Technologies*, 11HEALTH MATRIX: CASE W. RES. J.L. & MED. 351, 486 (2001) (referring to the goal of "learn[ing] more about constitutional adjudication by watching it when it is pressed by biomedical technology").

9. Jacobson v. Massachusetts, 197 U.S. 11 (1905).

10. "The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases." *Jacobson*, 197 U.S. at 35 (quoting Viemeister v. White, 72 N.Y. 97, 99 (1904)).

11. *See infra* text accompanying notes 50-81, 86-92, where I refer to such a case as *Jacobson 2.1* and differentiate it from a literal application of *Jacobson*'s original tenets today (*Jacobson 2.0*).

conceptual template than it was in saying, "According to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety."[12] This opaque formulation will not do today, although it seems as explicit as standards of review were at the time and was similar to the standard expressed in that exemplar of judicial aggressiveness, *Lochner v. New York*, which struck down the state's regulation of the working hours of bakers. Unless we view both courts and legislatures as black boxes, something more penetrable than "reasonableness" is required.[13]

Within *Jacobson*'s standard of review (which I construe as far from fully deferential to government), how does the Court address conflicting scientific claims (if at all), their legislative assessment and use, and the legislative valuations of means and ends? If a single study supports a given finding (confirming or disconfirming some hypothesis), does the strictest scrutiny entail deference to the accuracy of the raw data, or to the methodologies for generating and drawing inferences from them? With strict or other heightened scrutiny, flat references to the need to defer to the legislature simply do not work, as they do within minimal scrutiny.[14]Unlimited deference even to factual conclusions makes no sense under strict scrutiny, a point rightly mandated by the framework of the Article. But the idea of lay judges vetting the complexities of scientific claims does not inspire confidence either. So, there is much more to come beyond *Jacobson*.

A. The Claim that Jacobson *Has Been Expanded*

In *Jacobson v. Massachusetts*, the Supreme Court upheld the conviction and five-dollar fine[15] imposed on the defendant for refusing to be vaccinated against smallpox. The Rev. Jacobson was a Lutheran clergyman who had emigrated from Sweden, but the exact nature of his objection to vaccination was not made clear in the opinion. At least one historical commentary suggests he believed that vaccination was counter to God's preference that we follow nature. The same source says that he ultimately paid the fine, under threat of confinement.[16]The

12. *Jacobson*, 197 U.S. at 25.

13. Lochner v. New York, 198 U.S. 45 (1905).

14. *E.g.*, City of New Orleans v. Dukes, 427 U.S. 297, 303 (1976).

15. Five dollars was a much bigger deal at the time of *Jacobson*. The average factory worker in America in 1905 earned around thirteen dollars per week. MICHAEL WILLRICH, POX: AN AMERICAN HISTORY 285 (2011).

16. *Who Is Reverend Henning Jacobson?*, SUBURBAN EMERGENCY MGMT. PROJECT (Oct. 7, 2009), http://www.semp.us/publications/biot_reader.php?BiotID=653. Rev. Jacobson and his lawyers had vigorously pressed what we would now call the fundamental rights/liberty interest perspective. "Pickering and Ballard [Rev. Jacobson's counsel] claimed before the Supreme Judicial Court of Massachusetts that the Cambridge ordinance violated the 14th Amendment of the Constitution. Their briefs were filled with colorful language and religious allusions. They claimed that compulsory vaccination was a 'greater outrage than the scalping of a living victim by an Indian

case itself is rightly used to address autonomy issues and countervailing state interests, and it serves well within a tutorial on the nature and evolution of standards of review in constitutional theory and adjudication.

Justice Harlan's majority opinion is regularly invoked both to support and attack "compulsory" vaccination statutes. (As Professor Holland notes, there is little statutory or decisional law authorizing actual forced vaccination. Whether forced vaccination is worse than being fined—or worse than being imprisoned for refusal to pay up—is interesting, but not pertinent here.) Although law-trained persons regularly invoke the same cases to further opposing sides, *Jacobson* in particular has something for everyone. Professor Holland argues that *Jacobson*, as both the offspring of its time and as still-good (if uncertain) law, should be read as affording strong protection for individual claims against required vaccination, particularly when it is a condition for school attendance. She contends that the case has been "expanded" by including children-in-school within the scope of mandatory vaccination, and also by loosening the supposed constraints of "necessity," "emergency," and threats to an "entire population."[17]

Jacobson is an old case, and it is difficult to place ourselves within its historical and contextual framework. It is also opaque, not simply in the sense that it inevitably uses partially indeterminate concepts, but in the sense that its formulations differ from ours and require a kind of translation into contemporary terms. Even when we try to do this, it is hard to sort out whether the opinion "always meant *X*" or has been "expanded (or contracted)" to mean *X*.

It is, then, a challenge to answer sensibly the question, "How would *Jacobson* apply today?" It may be both that connotation and denotation of its key terms have shifted. The operational language has certainly changed. So what does this question mean? To note a simple real-world shift, the current and recent incidence of smallpox is zero. The smallpox virus is said to exist in laboratories only (unlike the polio virus); if not, it is now fully quiescent. The last U.S. smallpox case was in 1949, and the last anywhere was in Somalia in 1977.[18]There would be hardly any point in a compulsory vaccination program.[19]

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savage or the tattooing of a captive of a South Sea Islander.' They ended their brief by proclaiming that, 'here—in Massachusetts . . . a law complies a man to offer up his body to pollution and filth and disease; that compels him to submit to the barbarous ceremonial of blood-poisoning and virtually to say to the sick calf, 'Thou art my saviour: in thee do I trust,' and to bear ever after on his defiled body literally and truly the MARK OF THE BEAST.") (alteration in original; internal quotation mark omitted). Rev. Jacobson also said that he had experienced an adverse reaction to a prior smallpox vaccination, as did one of his sons.

17. *Holland, supra* note 5, at 46-48.

18. *See Smallpox Disease Overview*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp (last updated Dec. 30, 2004).

19. *Smallpox: Symptoms, Diagnosis and Treatment*, N.Y. TIMES HEALTH INFO., http://health.nytimes.com/health/guides/disease/smallpox/overview.html (last reviewed June 23, 2011). ("[T]he United States stopped giving the smallpox vaccine in 1972. In 1980, the World Health Organization (WHO) recommended that all countries stop vaccinating for smallpox. . . . Many people were

We, thus, need to ask a particular set of doctrinal questions, including: What is the proper interpretation of *Jacobson* concerning the nature and strength of the individual rights it recognized and—closely connected—concerning the burden of justification placed on the state? How does this interpretation compare to our current understanding of these rights and the burdens of justifying their impairment? How would this current understanding be expressed in contemporary articulations of standards of review? I address all of these questions.

I think that *Jacobson* should be understood to protect (as we would now put it) at least a "liberty interest." Although the Court's usage (and that of others) is not entirely consistent, that term generally designates a right that does not draw strict scrutiny (as do most "fundamental rights"),[20] but nevertheless receives far more protection than that afforded by the minimal rational basis test as used in substantive due process cases.[21]The operational standard of review for liberty interests has been, in many cases, a form of intermediate scrutiny. This view of *Jacobson* is not universal, and some accounts place the standard of review at or near minimal scrutiny, although the issue is not always clearly put.[22] One may complain about discontinuous tiers and the inappropriateness of giving names to standards of review (thus improperly reifying them, so the argument goes), but it is one effective way of recognizing hierarchies of constitutional interests and (perforce) of standards of review *in some form.* Some burdens of justification placed on the state are maximal, some are minimal, and some are "intermediate,"

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vaccinated against smallpox in the past. The vaccine is no longer given to the general public because the virus has been wiped out. The possible complications and costs of the vaccine outweigh the benefits of taking it. If the vaccine needs to be given to control an outbreak, it can have a small risk of complications. Some complications are mild, such as rashes. Others are more serious. Only military personnel, health care workers, and emergency responders may receive the vaccine today. Smallpox vaccination policies and practices are currently being reviewed.").

20. The right to bear arms may be an exception. *See infra* note 60. Note also that "liberty interests" are not always called "fundamental liberty interests," and it is unclear how the latter differ, if at all, from fundamental rights. As I said, usage is not consistent. As for designating what sort of individual interest the rational basis test "protects" in substantive due process, there seems to be no official terminology; it is simply a claim of liberty that does not rise to "liberty-interest" or fundamental rights status.

21. The rational basis test is sometimes used as a form of intermediate scrutiny in equal protection cases. *See infra* text accompanying note 57.

22. Kenneth Wing, for example, stresses the strong degree of deference accorded the legislature in *Jacobson*. KENNETH R. WING, THE LAW AND THE PUBLIC'S HEALTH 25 (2007). All-but-total deference is characteristic of minimal scrutiny, but even the strictest scrutiny requires (in theory) serious attention to government justifications, and this will include important strands of deference. (Courts are not going to rerun laboratory experiments.) Strict scrutiny is sometimes satisfied, which is what one would expect—indeed, demand—of a non-per se rule. *See, e.g.*, Burson v. Freeman, 504 U.S. 191 (1992) (plurality upholding electioneering restrictions). *See generally* Adam Winkler, *Fatal in Theory and Strict in Fact: An Empirical Analysis of Strict Scrutiny in the Federal Courts*, 59VAND. L. REV. 793 (2006). With intermediate scrutiny, one would expect intermediate degrees of deference.

reflecting the status of the right. We cannot do without such orderings to tell us the general direction of our analysis and where we are within it.

Jacobson's (operational) liberty interest was not watered down to cover children, in school or out. Nor were its references to "necessity" and "emergency" attenuated, further weakening the individual interests (somewhat inexplicitly) recognized in the case. Professor Holland thinks otherwise (bracketed remarks are mine):

> Initial interpretation of *Jacobson* was circumspect. From 1907 to 1914, state appellate and supreme courts construed *Jacobson* as permitting single vaccination mandates during smallpox outbreaks. The courts upheld mandates and exclusion of unvaccinated school children during emergencies. These decisions applied an "oppressive or arbitrary" standard and looked for evidence of public necessity, and, particularly, the threat of epidemic. These decisions held that statutes must incorporate medical exemptions. The decisions required that school boards act in good faith and exclude unvaccinated students only as long as the danger of smallpox endured.
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> Beginning in 1916, however, judicial interpretations of *Jacobson* broadened. The Alabama Supreme Court read *Jacobson* to contain the implied power to prevent epidemics, not simply to respond to existing ones. *[Is the author objecting to this, either as an interpretive or policy matter?]*A father sued the school board for excluding his unvaccinated daughter from school when there was no smallpox epidemic. *[Doesn't vaccination help to prevent epidemics? Do we always have to wait until the sword is loosed?]* The court upheld the state's delegation of authority to the school board and the state's right to prevent disease. The decision also argued that mandates for children, and not adults, were valid because a group of children "constitutes a condition different, with respect to hygienic circumstances, effects, and results, from that to be found in any other character of assemblage in a municipality."The court deferred to municipal authorities on public health.
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> . . . These decisions interpreted *Jacobson* expansively; in neither situation was there an imminent danger or necessity for the state to act in self-defense.[23]

Elsewhere, she argues:

> The regulation [in *Jacobson*] excluded all children from

23. *Holland, supra* note 5, at 49-50.

> compliance. The Court's paradigm [*This term is tendentious; it is not at all clear what the "paradigm" was; if it were clear, we would be much clearer on the holding, but that is part of what is at issue*] was clear: a mandate is permissible in "an emergency," when there was "imminent danger," when "an epidemic of disease . . . threatens the safety of [society's] members," when there was "the pressure of great dangers," and for an "epidemic that imperiled an entire population."[24]

Professor Holland also contends that "*Zucht* [*v. King*, another smallpox vaccination case] did shift *Jacobson*'s paradigm, though, by upholding a mandate exclusively for children, a subpopulation, and by affirming the validity of a preventive mandate for a disease not in circulation."[25]

But Justice Harlan used the term "emergency" only once, referring to what was "necessary for the public health or the public safety,"[26]—a not-very-illuminating phrase. As for the departure from "necessity," there is no clear explanation in the Article about what "necessity" or any "shift" from its use as a standard mean. In interpreting the opinion, one should not invoke the language referring to an "epidemic that imperiled an entire population" without also noting that *there was no such situation in Cambridge at the time*, at least by the Court's own description. The context of the quoted remark is this: "The state legislature proceeded upon the theory which recognized vaccination as at least an effective, if not the best-known, way in which to meet and suppress the evils of a smallpox epidemic that imperiled an entire population."[27]This is less a finding than a statement about the legislature's theory of vaccination in setting up a general program and did not address the specific situation in Cambridge.

As for conditions in Cambridge, Justice Harlan quoted Cambridge's board of health, which had adopted a regulation under the aegis of state law:

> Whereas, smallpox has been *prevalent to some extent* in the city of Cambridge, and still continues to increase; and whereas, it is necessary for the speedy extermination of the disease that all

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24. *Id.* at 8 (alternations in original) (footnotes omitted).

25. *Id.* at 12. The case reference is to *Zucht v. King*, 260 U.S. 174 (1922). There, a child was excluded from a public school because she had no certificate of vaccination and refused to be vaccinated. She argued that she had been deprived of liberty without due process and deprived of the equal protection of the laws, all under the Fourteenth Amendment. The Court, per Justice Brandeis, dismissed the writ of error because it found "in the record no question as to the validity of the ordinance sufficiently substantial to support the writ of error." *Id.* at 177. The Court, nevertheless, referred favorably to *Jacobson*, stating that it had "settled that it is within the police power of a state to provide for compulsory vaccination." *Id.* at 176. The opinion does not state what diseases were included within the vaccination program, but the lower court's opinion indicates that smallpox was the target. Zucht v. King, 225 S.W. 267 (Tex. Civ. App. 1920). Because of the procedural posture of the case, it is not clear what it held substantively, if anything.

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

27. *Id.* at 30-31.

> persons not protected by vaccination should be vaccinated; and whereas, in the opinion of the board, the public health and safety require the vaccination or revaccination of all the inhabitants of Cambridge; be it ordered, that all the inhabitants habitants of the city who have not been successfully vaccinated since March 1st, 1897, be vaccinated or revaccinated.[28]

There is nothing in *Jacobson* to indicate either that there was in fact an ongoing catastrophe or that the city or the Court thought there was. The italicized language simply recognizes the following: smallpox was present; it was contagious and harmful if contracted; *and a much worse situation could develop and could and should be prevented.* This is what "necessary" means here. It clearly includes the idea of reasonably believing that something *more serious may develop* out of current conditions. The idea that there has been some departure from a *sine qua non* of disaster, or complete failure of a means toward a goal, echoes the debate on the meaning of "necessity"—efficient or useful versus absolutely physically necessary—underlying *McCulloch v. Maryland.*[29]

Moreover, "necessity" is systematically equivocal. It might refer to those aspects of a situation that justify *some* liberty-impairing action. In *Jacobson*, Justice Harlan ruled that it was not necessary to exclude all other useful methods—a point doing double service for us by also telling us that a strict no-less-intrusive-alternative standard was not in use.[30] This softer "narrowing" requirement of his reasonableness standard of course is perfectly consistent with the functional status of Rev. Jacobson's claim as reflecting an important liberty interest, though not with its possible status as an A-1 fundamental right drawing the strictest scrutiny.

As for the claimed expansion to cover school children: first, children were presumptively included within the mandate, and, second, this was not facially limited to school attendance. "An exception is made in favor of 'children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination.'"[31]

When *Jacobson* was decided, the safety-benefit profile of smallpox vaccination was not as well understood as it is today, and relatively few children today would be considered unfit for vaccination—although it would not be recommended for children under twelve months, or for persons under eighteen under nonemergency circumstances, or for anyone with certain specified

28. *Id.* at 12-13 (emphasis added).

29. McCulloch v. Maryland, 17 U.S. 316, 408-09, 413-14 (1819).

30. *Jacobson*, 197 U.S. at 35 ("Since, then, vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that *particular method was—perhaps, or possibly—not the best* either for children or adults." (emphasis added)).

31. *Id.* at 12 (citation omitted).

conditions.[32] After all, we do not have smallpox anymore so there is nothing imminent or even possible (barring accidental release or, say, a monkey pox breakout into something like an old-style smallpox threat).[33] In any case, the issue of extensive coverage of children was not at issue in *Jacobson*, and there is nothing in the opinion to indicate that children—even children exclusively—cannot properly be the subjects of a vaccination program.[34]

In this light, it is too loose to describe *Jacobson*'s "paradigm" as involving "emergency," "imminent danger" (in any restricted sense), or epidemics threatening "entire populations." It is not entirely clear *what* the paradigm is.[35] It is, thus, uncertain what would constitute a "shift" of a paradigm. The *Zucht* children/school context does not clearly constitute an augmentation of a clear set of defining (necessary and sufficient) conditions or even of a specific cluster of criteria that might justify compulsory vaccination. In any case, as I suggested, to refer to shifts in paradigms requires specifying what the paradigm island there is a difference between applying the selfsame paradigm to a new situation as opposed to "shifting" it. This is the main difference between *Jacobson* and *Zucht*.

Thus, there is a major three-way distinction to be drawn between *correctly* applying a precedent to new situations; *incorrectly* applying it to those situations; and changing the rules, standards, or principles involved to cover something *unjustifiably* covered under that precedent because of the incorrect application. True, it is often difficult to distinguish between an incorrect application and an expanded application—in some cases, impossible. But the distinction remains, and lawyers are accustomed to distinguishing—sometimes successfully—between a mistaken use of a prior case and its alteration, whether by reasonable extension or by overruling. We will, however, never be rid of having to choose between saying "these earlier cases have always meant *X*" and "these earlier cases are being utterly misread by my colleagues." Still, it is precisely because *Jacobson* is unclear that we cannot definitively say that it has not swollen beyond

32. *Emergency Preparedness and Response—Vaccine Overview: The Smallpox Vaccine*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.bt.cdc.gov/agent/smallpox/vaccination/facts.asp (last reviewed Feb. 7, 2007).

33. Wendy Orent, *Will Monkeypox Be the Next Smallpox? The Thought of a New Human Poxvirus Evolving Under Our Noses Is Unsettling*, L.A. TIMES, Sept. 26, 2010, http://www.latimes.com/news/opinion/commentary/la-oe-orent-pox-20100926,0,6800911.story. According to the Centers for Disease Control and Prevention, monkeypox, also a serious infection, is preventable via the smallpox vaccine. *Smallpox Vaccine and Monkeypox, Monkeypox Fact Sheet*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/ncidod/monkeypox/smallpoxvaccine_mpox.htm (last updated Sept. 5, 2008).

34. It seems pretty well agreed today that some vaccination programs really do save lives and resources. I suppose smallpox is the gold standard. "The eradication of smallpox in the 1970s, by targeted use of smallpox vaccine, has not only prevented many thousands of deaths, but is estimated to have saved US $1.2 billion annually in the 25 years since the last case was reported." D. Isaacs et al., *Should Routine Childhood Immunizations Be Compulsory?*, 40 J. PAEDIATRICS & CHILD HEALTH 392 (2004).

35. *See infra* Part III.

its boundaries.

More generally, many, perhaps most, claims about the expansion, contraction, or distortion of a precedent are normatively ambiguous—that is, they might be interpreted as empirical claims, value claims, or both, and it may be difficult to untangle these strands. One would expect, for example, that those opposed to a particular new *application* of a concept or standard will view it as an *expansion* of what seems to have been in force. But here we have the familiar problem of distinguishing expansion of *denotation* by virtue of change of facts and expansion of *meaning*.[36]

To illustrate, consider Professor Wing's observation: "Today, we do not demand the threat of a pending epidemic to require childhood immunizations for school, suggesting perhaps that the standard for 'necessity' has relaxed considerably as the benefits and general safety of immunizations have become better established."[37]

But it is not clear that *Jacobson* ever required such a threat. In any case, we have to distinguish conceptual change from conceptual application-to-new-circumstances. It may be that precisely the same standards with the same conceptual meanings are in play in a new situation, pitting several variables against each other that may resolve differently from prior interplay in a different case. A high-risk vaccine requires a high-risk disease in order to justify even voluntary vaccination. But if newly developed vaccines for the same malady are far safer, the balance is different and compulsion may be more justifiable. Perhaps some malady has-been later found to be either more dangerous—or less so, or both, in different ways; this too would change the balance. Facts may change while meaning may not. There is *much* more commerce among the states these days, so there are *many* more situations covered by the commerce clause,[38] even if the conceptual meaning of the clause remained unchanged (which it probably did not). Of course, if the conceptual meaning becomes more expansive, coverage is even more amplified, as all constitutional lawyers know. Both augmentations have been at work in the commerce clause.[39]

So, it is no simple matter to sort out the meanings of *Jacobson*, given all the variations in facts, possible changes in public values, and the continuing reformulations of standards of review. But I think that the case is clear enough for us to say that Professor Holland's conclusion is overstated (italicized comments in brackets are mine):

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36. *See* Melvin Fitting, *Intensional Logic*, 2006; rev. 2011, STAN. ENCYCLOPEDIA OF PHIL., http://plato.stanford.edu/entries/logic-intensional (last updated Jan. 27, 2011).

37. WING, *supra* note 22, at 63.

38. U.S. CONST. art. I, § 8, cl. 3.

39. On shifts in denotation resulting from both empirical changes and changes of meaning, see Michael H. Shapiro, *Argument Selection in Constitutional Law: Choosing and Reconstructing Conceptual Systems*, 18 S. CAL. REV. L. & SOC. JUST. 209, 225 n.36, 256 (2009).

> Courts have used *Jacobson* to justify results that the original decision did not condone: vaccination mandates exclusively for children, with no imminent disease outbreaks, and with serious penalties for noncompliance. *[There is a big difference between saying* Jacobson *did not directly deal with some variable and saying that it would not have "justified" or could not have applied to the current result. Nothing in* Jacobson *foreclosed, for example, vaccinations exclusively for children. At most, it was simply beyond the issue presented at that time, but not excluded by anything said in the case. Indeed, the Court acknowledges the application to children, subject to exclusions.* Jacobson*'s language does not justify a conclusion that the results about which the author complains were* unjustifiable *under its terms.]* Punishments include loss of education, social isolation, parents' loss of custodial rights, child neglect sanctions against parents, and, even, forced vaccination. In *Jacobson* and *Zucht*, the Supreme Court upheld mandates for one vaccine during airborne epidemics. *[The Court did not uphold much on the merits in* Zucht *because it declined to rule on them and dismissed the writ of error. It nevertheless referred with favor to* Jacobson.*]*Courts have expanded the original *Jacobson* precedent dramatically. *[There are cases described by the author in which courts have indeed been too deferential. But this does not necessarily mean that* Jacobson *had been "expanded" rather than misapplied. Over deference is not justified by* Jacobson *and is arguably inconsistent with it.]*[40]

B. What did Jacobson *say?*

It is hard to understand *Jacobson*—but not *that* hard. It helps to check both what it said and what it did. Here are some major questions about *Jacobson*, and any reconstructions of it in contemporary language.

- What is the proper characterization of the right as recognized in *Jacobson*? How does it connect to plausible current characterizations?
- What is the *operational* standard of review? (There are *always* implicit or explicit standards of review in any valid constitutional argument that has to resolve competing constitutional claims.)
- What did the Court think the material facts and public values were?
- What caveats did the Court itself issue about its ruling? These could serve as interpretive guides.
- How would *Jacobson* be decided today?

40. Holland, *supra* note 5, at 53-54.

1. The Characterization of the Right

The best source on this is Justice Harlan himself:

> There is, of course, a sphere within which the individual may assert the supremacy of his own will, and rightfully dispute the authority of any human government,—especially of any free government existing under a written constitution, to interfere with the exercise of that will. But it is equally true that in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.[41]

This is not wholly unlike what we read today in major opinions of the Supreme Court. The second Justice Harlan said, dissenting in *Poe v. Ullman* and quoted in *Planned Parenthood v. Casey*:

> It [the liberty guaranteed by the Fourteenth Amendment's Due Process Clause] is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, . . . and which also recognizes, what a reasonable and sensitive judgment must, that certain interests require particularly careful scrutiny of the state needs asserted to justify their abridgment.[42]

But the first Justice Harlan's account does not tell us as much as we need to know, then or now. There is no precise description of the right. It is not couched as a matter of bodily integrity or personal security or "the right to define one's own concept of existence."[43] Moreover, there is no way to tell, however flowery the language, the "constitutional value" of the right until we see how it is pitted against the state's claim that its coercion is justified. We need to probe for the standard of review and how it is used.

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41. *Jacobson*, 197 U.S. at 29.

42. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 848 (1992) (quoting Poe v. Ullman, 367 U.S. 497, 543 (1961) (Harlan, J., dissenting from dismissal on jurisdictional grounds)); *see also* Lawrence v. Texas, 539 U.S. 558, 578 (2003) ("The Texas statute furthers no legitimate state interest which can justify its intrusion into the personal and private life of the individual."). Evidently somewhat out of control, the Court in *Casey* said: "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." *Casey*, 505 U.S. at 851. I suppose I would rather have liberty described too expansively than too narrowly, but without knowing more about the meaning of "liberty" at issue, this account is too boundless even for a constitutional standard. In any case, the quoted remark can't be taken as a rigorous expression of current doctrine.

43. *See* Casey, 505 U.S. 838.

2. *The* Jacobson *Standard of Review*

The loosely stated standard of review is contained within the same passage that extolled the claimant's liberty. One asks whether the regulation is "reasonable . . . as the safety of the general public may demand."[44] The language is not unlike that in *McCulloch v. Maryland* and, a bit later, in *Lochner v. New York*.[45] But this does not tell us much either. In *McCulloch*, Chief Justice Marshall inquired into the national bank's functions even less carefully than Justice Harlan examined Cambridge's findings and valuations. *McCulloch* was, in modern terms, closer to the nominal rational basis test than to strict scrutiny—despite the warnings about "pretextual" government action that evades constitutional limitations. In *Lochner*, it seems fairly clear that the "reasonableness" language served as a form of strict scrutiny for Justice Peckham. Under pressure from the majority, Justice Harlan's dissent was far more elaborate in its scrutiny of New York's law than was his examination of Cambridge's action, but in the end it seems his standard of review was similar to the one he used in *Jacobson* the year before.

I do not think that *Jacobson* is a case of minimal scrutiny and maximal or automatic deference. There is no reason not to take Justice Harlan's warnings about governmental abuse seriously. But there is not much of a case to be made for strict scrutiny. The proper level of scrutiny is somewhere in the middle.

3. *The Court's Caveats*

The Court's caveats about the limits of its ruling do not reveal anything different from the preceding account; they simply reinforce it. Against the claim of government power, the opinion insists, "[I]f a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge, and thereby give effect to the Constitution."[46] And, addressing the needs of vulnerable persons, the Court conceded that government "might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons."[47] The Court elaborated the last point a bit later:

> It is easy . . . to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body would be cruel and

44. *Jacobson*, 197 U.S. at 29.
45. Lochner v. New York, 198 U.S. 45 (1905).
46. *Jacobson*,197 U.S. at 31.
47. *Id.* at 28.

> inhuman in the last degree. We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned.[48]

But against more general claims of right, Justice Harlan said:

> It is not . . . true that the power of the public to guard itself against imminent danger depends in every case involving the control of one's body upon his willingness to submit to reasonable regulations established by the constituted authorities, under the sanction of the state, for the purpose of protecting the public collectively against such danger.[49]

Once again, I see neither strict scrutiny nor the nothingness of the substantive due process rational basis test.

III. TODAY'S CONSTITUTIONAL HIERARCHIES, STANDARDS OF REVIEW, AND THEIR APPLICATION TO OLD AND NEW BIOMEDICAL CONTEXTS

A. Jacobson 2.1*: Key Questions*

We should distinguish between *Jacobson 2.0* and *Jacobson 2.1*. The former would ask how the same Court at the same time would decide the case under present day epidemiological, vaccinological, and medical treatment conditions concerning smallpox.[50] (A literal *Jacobson 2.0* should not uphold compulsory vaccination, given the apparent demise of smallpox.) I think it more instructive, however, to ask a different set of questions. *Jacobson 2.1*, on the other hand, is a thoroughly modern case involving someone making the same claim (without any religious aspects, to keep things simpler) under current conditions and doctrines.

First, the broad question, "How would *Jacobson* be decided today by a contemporary Court?," is too unfocused for any clear answer. It could mean any of several things:

- How would the case be decided today *on the exact same epidemiological and medical facts* that existed in Cambridge in 1902?
- How would it be decided given the *current status of smallpox threats*?

48. *Id.* at 38-39.

49. *Id.* at 29-30.

50. Medical treatment of smallpox may benefit from modern antivirals, but evidently there is no specific medicine or other treatment accepted for smallpox treatment. *Smallpox | Description | Prevention | Causes and Symptoms | Treatment*, MODERN MED. GUIDE, http://www.modernmedicalguide.com/smallpox-description-prevention-causes-and-symptoms-treatment (last visited July 27, 2011).

- How would it be decided in any given case *involving a given disorder; a particular kind of vaccine indicated for it; manufactured and distributed in a particular way; and given specific local, regional, national, and international facts about the disorder and the surrounding situation*?
- In particular (given the Article's focus): How would it be decided when applied to hepatitis B vaccine programs as applied to children as a condition for entry into (pre)school?

The overarching question is, "What argument structure would the Court use?" This involves many constituent questions: What rights characterization would it use to identify the right and its constitutional value? What would be the standard of review, given the right's constitutional value and the nature of its impairment? How would that standard be used to vet matters of technical scientific dispute and the government's value judgments, implicit or explicit? An important linked question in the vaccination context, more pertinent now than in 1905 is whether there is a constitutional, moral, or policy problem with "piggybacking" vaccination and other public health programs onto society's educational missions?

There are parallel inquiries that suggest additional shades of important meaning:

- If we translate into modern terms *Jacobson*'s argument structure, which embraces constitutional values *as recognized in the 1905 decision*, what do we get? In the century-plus since then, we have not transmogrified into a world so different and bearing such a locked-in perspective that the comparison involves "incommensurable" values.[51]
- Would *Jacobson*'s argument structure be revised to explicitly recognize different constitutional valuations by characterizing a set of related but nonidentical rights? For example, might the Court recognize a top-level fundamental right of personal security, comprehending the integrities of body, mind, and identity, and generating strict scrutiny? (This may be what Professor Holland prefers.) Would it instead run away with maximal deference (retaining some special scrutiny for highly vulnerable persons—those who might die of an allergic reaction to a vaccine or its additives, for example)? This would treat the "right" as a liberty claim (i.e., invoking the liberty clause of the Fifth Amendment, Fourteenth Amendment, or both) with no special status, meriting only minimal scrutiny. Would it instead recognize a "liberty interest" in the current sense, drawing intermediate scrutiny? Would it borrow from equal protection jurisprudence and ramp up the rational basis test without acknowledging it to be intermediate scrutiny?

There is no reason to think that *Jacobson 2.1*, decided on the same medical or epidemiological facts acknowledged for Cambridge in 1905, would be decided

51. Nien-hêHsieh, *Incommensurable Values*, STAN. ENCYCLOPEDIA OF PHIL. (July 23, 2007), http://plato.stanford.edu/entries/value-incommensurable.

differently today. (I will not discuss the argument formulation, in current terms, if Rev. Jacobson 2.1 made an explicit claim under the free exercise clause, except to say that it would probably fail under *Employment Div., Dept. of Human Res. v. Smith*[52] and even under pre-*Smith* doctrine.)

However, there is ambiguity here. What does it mean to ask whether *Jacobson* would be decided "the same way" today? One could have in mind either the same facts prevailing in Cambridge when the case was brought or facts involving other health threats that are at least equally serious.[53] Moreover,

52. Employment Div. v. Smith, 494 U.S. 872 (1990) (ruling that with laws of general application—i.e., not targeting the protected interest in question, which in this case is free exercise of religion—there is no heightened scrutiny of claimed burdens on free exercise).

53. *See, e.g.*, Lawrence O. Gostin, Jacobson v. Massachusetts *at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576 (2005) ("If the Court today were to decide *Jacobson* once again, the analysis would likely differ—to account for developments in constitutional law—but the outcome would certainly reaffirm the basic power of government to safeguard the public's health . . . . Supreme Court jurisprudence has progressed markedly from the deferential tone of *Jacobson* and its progressive-era embrace of the social compact. The Warren Court, within the context of the civil rights movement, transformed constitutional law. The Court developed its "tiered" approach to due process and equal protection that placed a constitutional premium on the protection of liberty interests. Thus, the question arises: Would *Jacobson* be decided the same way if it were presented to the Court today? The answer is indisputably *yes*, even if the style and the reasoning would differ." *Id.* at 576, 580. I think that when mapped against the questions I unpacked in the text, this account is consistent with my own parallel answers. But the concept of "being decided the same way" is quite ambiguous. Separating the possibilities is important for the present analysis. It is possible that the Court would be somewhat less deferential in both tone and action, but there is a wide range of deferential stances between the strictest and the loosest scrutinies, and even strict scrutiny involves deference to legislative empirical findings and value preferences. The exact content of this deference will have to be specified through a variety of cases that test the operational meaning of all levels of scrutiny.) *See infra* Part III; *see also* Wendy K. Mariner et al., Jacobson v Massachusetts*: It's Not Your Great-Great-Grandfather's Public Health Law*, 95 AM. J. PUB. HEALTH 581, 586 (2005) ("A law that authorizes mandatory vaccination to prevent dangerous contagious diseases in the absence of an epidemic, such as the school immunization requirement summarily upheld in 1922, also would probably be upheld as long as (1) the disease still exists in the population where it can spread and cause serious injury to those infected, and (2) a safe and effective vaccine could prevent transmission to others."). *See generally* Arnold J. Rosoff *with* Shana Siegel, *Treatment Without Express Consent*, *in* TREATISE ON HEALTH CARE LAW § 17.05 (Matthew Bender/LexisNexis, 2010) ("In recent years, some courts have shown a greater skepticism toward claims of necessity for public health measures and an increasing sensitivity toward preservation of individual rights. Thus, if the Jacobson case were to arise today, probing questions might be asked about the seriousness of the health threat being addressed, the safety and efficacy of the inoculations, and the weight of the personal burdens and risks, if any, upon the citizens affected. While inoculations to combat smallpox would likely withstand such scrutiny—as have mandatory vaccination of school children, 56 mandatory blood tests for persons applying for a marriage license, mandatory examination, treatment, and/or quarantine of persons suspected of transmitting communicable diseases, 57 the fluoridation of public water supplies, etc.—other public health measures, particularly such controversial measures as mandatory testing for HIV infection, very well might not."). *See generally* Wendy E. Parmet, POPULATIONS, PUBLIC HEALTH, AND THE LAW 38-42 (2009) ("As the dreaded epidemics of previous centuries began to fade from memory, the necessity of public health interventions became less obvious and the limitation of individual liberty in the name of public health became less readily

deciding "the same way" does not necessarily mean that the same argument structure or underlying values would be applied. That is, "the same way" could refer to a similar (perhaps identical) adjudicatory outcome, or to the outcome as informed by the argument structure leading to it. The same adjudicatory outcome may result from differing argument structures and values.[54] This is a good time to make the transition to an explicit question: "How would the modern Court (or the Court of the moment, writing here in 2011) frame the substantive issues (assumed to be properly presented within the current limits of the judicial power) in cases of vaccination generally and vaccination of school children in particular?" The facts are, of course, highly variable, but not so ineffable that this question is meaningless. The question is not just about *Jacobson* or *Jacobson 2.0*, but about *Jacobson 2.1* (and beyond).

B. The Article's Attempted Reconstruction

There are reconstructions and reconstructions. The target here is *Jacobson 2.1*—a contemporary vaccination case using contemporary articulations of constitutional values. One can also try to reconstruct the case in the sense of simply clarifying it in its own terms. Although both Justice Harlans are noted for their lucidity, *Jacobson* could be easier to follow. Professor Holland seems to combine both tasks here: clarifying the case as it stands, and presenting an account of what would or should happen now in at least some public health and vaccination cases. She suggests that some latter-day Justices would have recognized a right against vaccination as fundamental, but the case for this is shaky.[55] In any case, in pursuing the reconstruction of *Jacobson*, she follows in

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accepted. At the same time, with less fear of contagious diseases, public health became less salient to both the culture and the law. Indeed, following *Jacobson*, the Supreme Court would not again face a question so starkly and directly related to a community's response to an imminent epidemic.") Question: Do these apparent attitude shifts reflect a value change or the application of constant values to changing facts? If the former, did the changing facts influence a rethinking of our values?

54. *See* Shapiro, *supra* note 39, at 216-21, 241-49.

55. Holland, *supra* note 5, at 83. Professor Holland also believes that some Justices would have recognized a right against vaccination as fundamental. "Some of the Justices who participated in the personal autonomy decisions, notably Justices Stevens, Brennan, Marshall, and Blackmun, would likely have found the right to refuse vaccination a 'fundamental' right and would have subjected the state's regulation to 'strict scrutiny.'" *Id.* I doubt this, but for some Justices, the claim is not outlandish. Still, it is not clear whether resisting vaccination involves one of "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, [which] are central to the liberty protected by the Fourteenth Amendment." Planned Parenthood Of Se. Pa. v. Casey, 505 U.S. 833 (1992). Indeed, broad as this formulation is, vaccination fits uncertainly within it. "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State." *Id.* at 851. Does fear of remote though serious adversities fall within this? Perhaps vaccination represents too trivial a threat to the sanctity of personhood to merit status within the

part the analysis of Professor Gostin. Neither seems to be suggesting that the matrix of variables presented should be understood simply as a reconstruction of *Jacobson* in modern terms. Rather, it is a preferred set of factors for any rational decision.

The proposed matrix contains the factors of "necessity," "reasonable means," "proportionality," and "harm avoidance" as a way to both illuminate *Jacobson* and inform current public policy. As Professor Gostin puts it:

> *Jacobson's* social-compact theory was in tension with its theory of limited government. Beyond its passive acceptance of state discretion in matters of public health was the Court's first systematic statement of the constitutional limitations imposed on government. *Jacobson* established a floor of constitutional protection that consists of 4 overlapping standards: necessity, reasonable means, proportionality, and harm avoidance. These standards, while permissive of public health intervention, nevertheless required a deliberative governmental process to safeguard liberty.[56]

As a reconstruction of *Jacobson*, this seems both useful and harmless; it does not take any liberties with the opinion.

Professor Holland, however, later invokes a significantly enlarged matrix as a clarification of *Jacobson*. She asks, in her hepatitis B hypothetical:

> How might the Supreme Court balance the interests of the state and the child? The Court would have to look to *Jacobson* and *Zucht* for a balancing test on vaccination for school attendance and to the Court's more recent precedents on personal autonomy to decide this case. The Court would have to review the following factors [public health necessity; reasonable means; proportionality; harm avoidance; non-discrimination; liberty interest in due process; and liberty interest in equal protection].[57]

This list of things the Court would consider in compelled vaccination cases certainly contains considerations that would be *relevant* in most cases. But the author asks, "How might the Court balance the interests of the state and child," without *first* characterizing the right(s) at stake and specifying the entailed

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mantle of a fundamental right or liberty interest.

56. Gostin, *supra* note 53, at 579.

57. Holland, *supra* note 5, at 67. I do not know to what "liberty interest in equal protection" refers. It is not an impossible or incoherent concept, but the term "liberty" is not, in constitutional law, ordinarily used to refer to our interest in being treated equally. However, it may refer to those fundamental rights (indeed construed as liberties), that are thought (by some) to be derived only or largely from the equal protection clause, e.g., the right to vote in state elections. *See* Harper v. Va. State Bd. of Elections, 383 U.S. 663, 665 (1966).

standard(s) of review. Instead, she jumps the threshold stage, and straightaway starts parsing the factors that specify the constitutional metric. This is backwards. I do not mention this as a point of literary criticism or esthetic preference or technical nitpicking. This is a matter of basic constitutional logic. Describing the "liberty interest" at stake is not something one simply throws into the "balance"; it is—in constitutional adjudication—an issue that is a starting point for substantive analysis. (The matter, to be sure, is complicated by the fact that there is bound to be some bounce-back between threshold valuation, analysis of government justifications, re-valuation of threshold matters, and so on.)

The elements of the matrix also include some anomalous and/or hard to understand entries. The references to a "liberty interest in equal protection" and to "proportionality" are especially problematic, as I will explain. There are also some technical problems with her account of current doctrine concerning the characterization of rights/liberty interests and the set of available standards of review. I discuss this in Section III.C, below.

C. A Note on Constitutional Values and Their Entailments: Standards of Review as Inherent in Adjudication and as Heuristics

I make a few points briefly.[58] I said in one article:

> The Constitution, at least as currently interpreted, embeds or encodes a hierarchy (or perhaps an ascending continuum) of values, and different standards of review are meant to track differences in constitutional value by placing very different burdens on government to justify its actions in different situations. In this sense, the constitution is both a repository and an engine for executing basic values.[59]

The Constitution embeds values, sorts them, and operationally *commits* us (if we take it as authoritatively calling for implementation) to things we now call "standards of review."To dwell on these standards is not a case of the tail wagging the dog; they are the dog. They are different aspects of the concept of

58. I have explained these points at greater length elsewhere. *See* Shapiro, *supra* note 39, at 269-71, 295-97; Shapiro, *supra* note 8, at 356-64.

59. *See* Shapiro, *supra* note 39, at 269-70; *see also* Shapiro, *supra* note 8 ("If constitutional hierarchies are recognized by converging interpretive theories and are taken seriously, they must be operationally reflected in standards of review of one sort or another. If they are not, then there are no hierarchies in the first place. To put it crisply, if constitutional hierarchy (among legal relations and their associated constitutional values) is accepted, to implement the hierarchy is to select and apply a standard of review. Doing so is embedded in realizing the hierarchy. Put otherwise, implementing a constitutional hierarchy amounts to the application of a standard of review.") (emphasis omitted). *Id.* at 366.As I noted in that article, some "hierarchies" are so simple one may be inclined to say that they are not hierarchies at all, as in "the President always wins.") But that is not how we operate, at least in theory, and probably not in fact. *Id.* at 359-60; *see also id.* at 354.

rights-as-authoritatively-implemented. They are not egregious artifacts that mask circularity, although they—along with many conceptual devices—can be used tendentiously to do so. But there is nothing in this account that dictates their exact formulation, or that they are to be ordered into tiers or step-functions separated by thresholds of constitutional value and of their impairments, as opposed to "spectra."

Still, standards of review, as the logical entailments of interpreting the constitution to find value hierarchies have taken certain crystallized forms. Both high theory and everyday adjudication have to take account of this, as the next few points about *Jacobson* show.

D. Technical Difficulties with the Article's Doctrinal Account

The Article to which I am responding presents itself as much more than a commentary on policy. It is a call for implementing constitutional values via adjudication and legislation. So, marking out the doctrine precisely is both a practical necessity and integral to theory.

Here is a passage from Professor Holland's article; again, the italicized, bracketed remarks are mine, as are footnotes.

> It is not certain what standard of review the Supreme Court would apply to a state compulsory vaccination mandate today.[*If constitutional valuations have changed since* Jacobson, *the question should be, "What standard of review is required, given the (new) rights valuation, for modern vaccination and various other public health/coercion cases?"*] The Supreme Court decided *Jacobson* before it had adopted explicit standards for review of government authority. In *Jacobson*, the Court required only that Massachusetts's statute be rationally related to the purpose of eradicating infectious disease. Since the 1940s, however, as Part II explores, the Court has held that a higher standard must apply if a state law impinges on a fundamental liberty interest. For a law to be constitutional under a strict scrutiny test, the highest standard, there must be a compelling governmental interest and the law must be narrowly tailored to achieve its end. [*Although the formal and informal terminologies are somewhat inconsistent, fundamental rights usually (not always)*[60] *draw stricter scrutiny than mere "liberty interests."*

60. *Cf.* Dist. of Columbia v. Heller, 554 U.S. 570, 593-94 (2008) (referring to the right to bear arms as having become fundamental to Englishmen). For Fourteenth Amendment purposes, the characterization is clearer in McDonald v. City of Chi., 561 U.S. 3025 (2010) (holding that under the Fourteenth Amendment the right to bear arms is fundamental and applies to the states). Neither case applied strict scrutiny, as far as I can tell—certainly not in express terms. Both cases may be counterexamples to the once-usual usual practice of assigning strict scrutiny to fundamental rights. But compare Troxel v. Granville, 530 U.S. 57, 65-66 (2000), where Justice O'Connor's plurality

(Justice Scalia seems to use "fundamental rights" and "fundamental liberty interests" synonymously.)[61] *The liberty interests recognized in* Casey *and* Cruzan[62] *did not draw strict scrutiny. Each case must be examined on its own, to some extent, and sweeping accounts of Court terminology are, even after all this time, still premature in this arena.*]In cases where strict scrutiny does not apply, the Supreme Court usually uses the lowest standard, the rational basis test. The rational basis test applies when the rights at stake are not considered fundamental. *[This is incomplete. It ignores, to this point at least, intermediate scrutiny—the middle tier. Note again* Casey, Cruzan, Romeo, *and* Harper—*all liberty interest cases, but no strict scrutiny.*[63] *The author's later comment on souped-up rational basis is only one form of intermediate scrutiny, and it seems, so far, to apply only in equal protection. Admittedly, the Court has been very loose about describing the standards of review attached to liberty interests, usually eschewing even the term "intermediate scrutiny." But whatever these standards are called, it remains that strict scrutiny is greater than intermediate-scrutiny-for-liberty-interests, which is greater than rational-basis-for-due-process.]*Under this standard of review, "if a law neither burdens a fundamental right nor targets a suspect class, we will uphold the [law] so long as it bears a rational relation to some legitimate end."*[The Court itself in* Romer v. Evans *was unfortunately speaking loosely here, and left out its middle tier. Whatever the Justices say in their looser moments, the doctrinal reality is more complex.]*

Between these two extremes of strict scrutiny and rational basis

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opinion used the terms "liberty interest," "fundamental liberty interest," and "fundamental right"—all on the same page—in describing a parent's right to control the care and upbringing of her child. The Court clearly acted with heightened scrutiny, but the standard of review was not specifically described.

61. "Our opinions applying the doctrine known as 'substantive due process' hold that the Due Process Clause prohibits States from infringing *fundamental* liberty interests, unless the infringement is narrowly tailored to serve a compelling state interest." Lawrence v. Texas, 539 U.S. 558, 558 (2003) (Scalia, J., dissenting) (citing Washington v. Glucksberg, 521 U.S. 702, 721 (1997)). To some extent, this compounds the confusion among these terms.

62. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990) (recognizing—*not* assuming *arguendo*—a liberty interest in refusing lifesaving medical treatment; the assumption *arguendo* was limited to viewing artificial nutrition and hydration as medical treatment); *see also* Youngberg v. Romeo, 457 U.S. 307 (1982) (holding that a mentally impaired inmate in civil institution had a liberty interest in personal security); Washington v. Harper, 494 U.S. 210 (1990) (ruling that a prisoner had a liberty interest in refusing antipsychotic drugs).

63. In *Harper*, the claimant was a convicted, incarcerated prisoner and thus his claim received intermediate scrutiny under *Turner v. Safley*; if the interest protected is less than a *fundamental* right, it would probably draw less-than-strict scrutiny whatever the setting. But recall that the fundamental rights found in *Heller* and *McDonald* apparently *didn't* generate strict scrutiny.

> review, the Supreme Court has required an intermediate level of scrutiny or a "pumped-up" rational basis test for liberty interests after *Jacobson. [In the first place, the only domain of pumped-up rationality seems to be equal protection, not substantive due process, although some claim* Lawrence v. Texas *to be an exception. In the second place, the equal protection rational basis test on steroids is not the only form of intermediate scrutiny.]*In these cases, the Supreme Court has struck down questionable state laws on the grounds that the state interest did not outweigh an individual's liberty interest. *[This is primarily, perhaps exclusively, a matter of equal protection. The account again leaves out intermediate scrutiny for liberty interests as framed within substantive due process. There may be a liberty interest branch, as well as a fundamental rights branch to equal protection, the former drawing intermediate scrutiny.]*[64]

E. An Outline of Jacobson 2.1: What Kind of Right, of What Value, and Bearing Which Standard of Review?

1. What Is the Right and What Do We Call It?

The difficulty in predicting general constitutional development (as opposed to outcomes in particular cases) is overestimated. It all depends on how one characterizes the asserted outcome or development. Accurate predictions—admittedly with low informational content—are easy to come by, and the information is not entirely empty. If the late columnist Drew Pearson could be eighty-four percent accurate, so can constitutional lawyers.[65] Prediction: the Court is not going to dismantle all fundamental rights all at once. We know this. Perhaps we can, then, predict a meaningful range of responses for *Jacobson 2.1.*

How would the right be described? And what considerations do we draw on when answering this? One characterization immediately comes to mind. The right not to be vaccinated could be called, "The right not to be vaccinated (whether with a stick, a pill, a scratch, etc.)." After all, it is all a form of battery (speaking loosely), even if administered with a Star Trekian hypospray.[66] This

64. Holland, *supra* note 5, at 48. (alteration in original) (footnotes omitted) (quoting Romer v. Evans, 517 U.S. 620, 631 (1996)) (citing City of Cleburne v. Cleburne Living Center, 473 U.S. 432 (1985)).

65. You have to have to been around a while to remember this; Pearson (the columnist, not the football player) died in 1969. Jim Heintze, *Books and Articles by and About Drew Pearson: A Selective Bibliography of Print Materials* (last visited Nov. 10, 2011), http://www.library.american.edu/pearson/bibliography.html.

66. For a general formulation (not specifically keyed to hyposprays), *see* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 269 (1990) ("At common law, even the touching of one person by another without consent and without legal justification was a battery. Before the turn of the century, this Court observed that '[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person,

designation, however, seems oddly particular and unilluminating. What happened to integrity of mind, body, identity, and personhood generally?[67] Still, the Court in *Harper* spoke of the prisoner's right to refuse antipsychotic drugs, holding that it is a liberty interest.[68] This, too, was oddly restricted. Does the liberty interest include antidepressant drugs also? Or did the Court think its description covered that and all medical-psychotropics? Why not "personal security," as in *Youngberg v. Romeo*,[69] or "bodily integrity," as mentioned in passing in *Washington v. Glucksberg*?[70] Are these descriptions curiously broad? Probably not. Personal security generally, and the integrity of body, mind and identity more particularly may be as good as we can get now, although technology (among other things) will press us to be more precise on what we mean operationally by our constitutional valuations and the standards of review they entail.[71]

The freestanding terms "autonomy" and "privacy" are too fat and too equivocal to rely on in precisely describing the right. If this is not already clear, it should become so as we move on.

2. What Is the Standard of Review and What Do We Call It?

The last time the Court newly characterized something as a fundamental right—the right to bear arms, in *McDonald v. City of Chicago*[72]—it declined to assign any *named* standard of review. But we know standards of review are not elective: the constitutional value of an interest and its standard of review are not

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free from all restraint or interference of others, unless by clear and unquestionable authority of law.' This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." (quoting Union Pac. Ry. Co. v. Botsford, 141 U.S. 250, 251 (1891))).

67. One who resists vaccination might object that the procedure does not cohere with "who she is"—her identity. Of course, vaccination in itself poses no direct threat to literal physical/mental identity.

68. Washington v. Harper, 494 U.S. 210, 222 (1990) (ruling that "respondent possesses a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment.").

69. Youngberg v. Romeo, 457 U.S. 307, 314, 315, 319 (1982) (grouping it among "fundamental liberties" and referring to it as a "liberty interest"; also holding that "Romeo retains liberty interests in safety and freedom from bodily restraint").

70. Washington v. Glucksberg, 521 U.S. 702, 720 (1997).

71. As we saw, the Court does speak of bodily integrity from time to time. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, at 896; *Cruzan*, 497 U.S. at 269, and of personal security, *Youngberg*, 457 U.S. 307 at 315. I do not try to explicate rigorously the overlapping ideas of the integrity of body, mind, and identity, and do not address issues of reducing any of these categories to any of the others.

72. McDonald v. City of Chi., 561 U.S. 3025 (2010). Its direct antecedent, Dist. of Columbia v. Heller, 554 U.S. 570 (2008) alluded to the fundamental rights of Englishmen but did not actually say the right to bear arms was a fundamental right under the American constitution. *McDonald*, however, said fairly clearly that both the pure Second Amendment right and the parallel Fourteenth Amendment right are fundamental.

simply entangled: they are interdefinable.[73] They derive from the same overarching and authoritative conceptual structure. Whatever standard of review is linked to the right to bear arms under the Fourteenth Amendment, it led to the remand in *McDonald*. Although this litigation did not survive the repeal of the Chicago and Oak Park ordinances,[74] the standard used would clearly have been some form of heightened scrutiny, even if not so described. Strict scrutiny itself has not been officially foreclosed.[75] After all, the value of a right is reflected largely through its standard of review. If one is confused about the correct standard of review, one is *necessarily* confused about the constitutional value of the interests in contention.

Jacobson 2.1, then, will be characterized ultimately by the standard of review used, implicitly or explicitly, however the opinion describes the right in question.[76] Perhaps neither the right nor the review standard will be clearly stated. To some degree, this is inevitable: the Court might formulate a right, but not be sure how to rank it. Moreover, there are tactical and political reasons for obscuring even the logical entailments of what one says. It may thus wish to be circumspect about how to describe the standard, given that it is supposed to implement a right of still-uncertain constitutional value.

But the doctrinal/logical fact remains: to characterize a right and decline—perhaps openly—to specify its standard of review suggests that *something* has provoked a departure from what might be considered basic judicial transparency.[77]The Court's grasp of what it was doing is askew, its confidence

73. *See* STEPHEN DARWALL, THE SECOND-PERSON STANDPOINT: MORALITY, RESPECT, AND ACCOUNTABILITY 12 (2006).

74. Afterwards, Chicago and Oak Park repealed their respective ordinances, rendering the case moot. National Rifle Ass'n v. City of Chi., 393 Fed.Appx. 390 (7th Cir. 2010).

75. Justice Breyer complained that Justice Scalia had not specified a standard of review. Justice Scalia complained about the complaint. Dist. of Columbia v. Heller, 554 U.S. 570, 634 (2008).

76. In *Youngberg*, 457 U.S. 307, the right to personal security was implemented, after a fashion, through the professional judgment standard, which involved very substantial deference to government. The relative absence of clear professional standards for treating severely mentally impaired persons was thought to require this, although one could argue that such impenetrability cuts the other way: the Court is simply deferring to a black box. *See generally* MICHAEL H. SHAPIRO ET AL., BIOETHICS AND LAW: CASES, MATERIALS AND PROBLEMS 408-412 (2003). One might well ask whether and when such deference vindicates the rule of law or weakens it.

77. It is not uncommon for courts to use standards of review (which they must) without identifying or explaining them, but in most cases it's clear enough what they are doing. Even in *Heller*, for example, the standard of review is clearly heightened, although one may well argue, as did Justice Breyer, that greater precision was called for. *See Heller*, 554 U.S. 570. Still, full disclosure was not jurisprudentially imperative. In Cohen v. California, 403 U.S. 15, 26 (1971), Justice Harlan did not use any words of art to signal his use of strict scrutiny until nearly the end of the opinion (state needed a "particularized and compelling reason" for criminalizing the use of an offensive word). There is no need to canvass the various reasons and explanations for circling around the designation of a standard of review, but confusion and rhetorical impact loom large, one would think.

that it is correct is weak, or some rhetorical maneuver is needed for value reinforcement or political accommodation. When matters become more sorted out, however, it will be quite irrational to characterize the right but to decline to specify the standard of review. It is like trying to withhold one side of a plane surface when delivering the other.

The chance that the Court will recognize a top-grade fundamental-right-with-strict-scrutiny is pretty low for the vaccination field,[78] simply based on past performance. Recall that although *Harper* involved a prisoner, subject to the middling *Turner v. Safley* standard of review, the Court nowhere hinted that the liberty interest in refusing antipsychotic drugs would generate strict scrutiny outside of a prison (or other confinement?) context.

On the other hand, however loose (in some eyes) the *Jacobson* decision was in allowing personal interests to be invaded by government, it did not apply minimal scrutiny, and the modern Court is also unlikely to do so. True, the *Jacobson* Court did seem to apply the "reasonableness" standard (not to be confused with the "rationality" standard) rather more loosely there than it did the following year in *Lochner v. New York*. (*Lochner's* majority opinion was written by Justice Peckham, who dissented without opinion in *Jacobson*.) There, the standard, whatever it was called, was pretty high on the strictness scale. Whatever we call the right at stake in compulsory vaccination cases, its value will almost certainly draw well-above-zero scrutiny. It will not be as if one is insisting on a right not to be prevented from storing nuclear waste on one's property.

So far, so easy. I excluded the very top niche and the very bottom niche of constitutional value sites. As I said, prediction can be easy. Just don't be too precise.

3. Penalties Versus Force: Which Government Action Does the Right Protect Us Against?

To ask, "What is the right *against*?," is another way of asking what the right

78. *Saenz v. Roe*, 526 U.S. 489 (1999), doesn't establish otherwise. There, the Court, per Justice Stevens, seemed to assign strict scrutiny to a claimed impairment of the right to travel. "Neither mere rationality nor some intermediate standard of review should be used to judge the constitutionality of a state rule that discriminates against some of its citizens because they have been domiciled in the State for less than a year. The appropriate standard may be more categorical than that articulated in *Shapiro* [v. Thompson, 394 U.S. 618 (1969)], but it is surely no less strict." *Id.* at 504. The source of law was the Fourteenth Amendment's Privileges and Immunities Clause. Some version of the right to travel had already been recognized as fundamental, deriving (I'm not clear how) from the equal protection clause. Shapiro v. Thompson, 394 U.S. 618, 638 (1969). The Court, however, did not clearly characterize the right as fundamental or as a liberty interest, though it assigned strict scrutiny, suggesting a fundamental right was at stake. (There was a passing reference to fundamental rights covered by Article IV's Privileges and Immunities clause, 526 U.S. at 502 n.14.) Operationally, it's a fundamental right because of the strict standard used.

is, and then one closes in on asking how much it is worth and what its associated standard of review is. Rights talk propels cascades. It is well known that neither *Jacobson* nor the law it applied authorizes vaccination by force. It authorizes fines and imprisonment, not holding someone in a headlock while assailing their bodies. This seems to be a pretty firm tradition, although I assume that some persons have been vaccinated by force.[79]

Suppose, however, we were inclined to endorse actual force in order to maximize public safety. Consider the question, "What could possibly be so wrong with forcing on you an only slightly painful needle stick that administers an effective vaccine bearing no risks?" Then, you raise the point, "It's not a matter of what you find right or wrong or even what some moral theory says is right or wrong. It's my body, my mind, my identity, my *person*, and you cannot mess with it directly at all; you can only provide incentives (comply or you pay or get locked up)."

The force of the distinction between penalty and force is clear here: We, in fact, do not force people to be stuck (or to swallow or be scratched). This is because of the value that we assign to the integrity of one's person. No one has to be vaccinated. To be sure, the penalties imposed may not be trivial, and one can well argue that suffering steep fines (perhaps any fine) and imprisonment is a serious breach of personhood, even if no one's physical person or mind is directly intruded upon. (Most people probably would prefer getting vaccinated to having to pay a thousand-dollar fine. Even the Rev. Jacobson seems to have complied.) One might make a parallel point about extended exclusion of children from school, given the critical importance of education.

It is not clear how much to make of the fact that we do not exercise force. The physical loss and risk attributable to the act of force are, by hypothesis, low to nonexistent. Yet we are inclined to admire those who refuse to sign loyalty oaths or to bow to the regent, even though the action required is, in itself, trivial. We do sanction arrests, shackles, and the death penalty. We have adopted a kind of clumsy compromise in upholding physical compulsion of certain sorts and not others, and physical compulsion in some but not all forms. But the fact that we simply do not by law force vaccination is a telling point going to the strength of the liberty interest, however described.

4. The Conceptual Interaction Between Threshold Rights and Countervailing Interests

Despite the abstract distinction between saying that X is a right, but that government can qualify it for reasons R, we often formulate the right (or no-right) by partially absorbing into it the countervailing reasons against describing

79. I have not canvassed vaccination law and practice through time and region to see to what extent force has been authorized.

or valuing it in certain ways. Indeed, we may deny that there is a right or liberty interest at all; we pack the government interest into the rights claim, and collapse it into a no-right (or at least a weak one). This is in many ways politically and even jurisprudentially efficient, if not entirely neat. We do not say that the right to gratuitously inflict pain on others is qualified by the harm it causes. We simply say there is no such right. We do the same with the right to injure ourselves in some ways. True, we could say there is a presumptive right to do what we want, qualified by harms imposed—the classic libertarian position.[80] But we simply do not talk this way in every case. We fragment human conduct into subsets, and, within these differing domains, there are arenas in which the overwhelming needs of society dictate a no-right (or even a who-would-ever-think-we-have-a-right-to-*X*?) stance. We inquire into "the point" of the right, of the harms done to others and to oneself, and say there is no right to mutilate oneself or others (beyond tattooing and affixing nose rings).Who demonstrates for recognizing such rights?

Let us apply this idea of interaction between rights and their countervails to vaccination and, for comparison, to the prisoner in *Washington v. Harper* who was administered Mellaril and other medicines over his objection.

5. What Exactly Is the Objection to Being Vaccinated?

The question here is not about the objection to being vaccinated over one's objection. It is about the vaccination itself, even if presented as a voluntary choice. Of course, one can question the moral propriety of forcing anyone to do anything over her objection, even if the thing done bears no risks at all. As I said, most exercises of fundamental rights do not have to be explained to others (not to oneself either). If there is a serious right against compulsory vaccination, "I just don't feel like it" is presumptively good enough. If your friends tell you they are trying to procreate and you press for rational reasons for doing so, the friendships may be impaired.

Still, one rightly wonders why a rational person would object to vaccination, either generally or in particular situations, or object to it more than to other medical procedures. Pressing this question makes a lot more sense than asking why someone or some couple living in reasonably normal circumstances would want children. Sometimes we need to ask what good are rights, right? We can speak grandly about the integrity of body, mind, and identity, but how are they even at stake with a (perhaps not-yet-existent) generation of drugs that are maximally effective and minimally intrusive?

Is pain avoidance the reason for objecting? The risk of adverse effects? *Which* adverse effects? If getting vaccinated makes the world look very purple for three seconds, and this is it—no further effects, no permanent damage, no

80. JOHN STUART MILL, ON LIBERTY 68 (1859).

porphyrophobia involved—are there any rational grounds for refusal? Perhaps, instead, the idea is that it is unnatural (not *necessarily* a religious objection) or interferes with God's will? (Recall that we are not at the moment concerned with the familiar idea that autonomous persons should not be forced to do anything, risky or benign, on behalf of anyone else at all, ever, except for duties we incur by having children or entering into contracts or statuses of certain sorts.)

The force of the question put to the vaccination objector is enhanced when we recall a basic observation about human behavior: not every unsought impingement on our persons is viewed as an incursion on our personal nature or identity or an interference with the order of things. Sometimes we decline to characterize something as an impingement on our integrity because it is just totally unimportant. For example, although we do not like crowding, most of us do not go to unusual lengths to arrange things so that no one ever brushes against anyone else.

Turn now to Justice Harlan's impassioned call for limiting government action where the right is explicitly invoked as sounding (at least in part) as *harm-avoidance*:

> It is easy, for instance, to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body would be cruel and inhuman in the last degree. We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned . . . . Until otherwise informed by the highest court of Massachusetts, we are not inclined to hold that the statute establishes the absolute rule that an adult must be vaccinated if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination, or that vaccination, by reason of his then condition, would seriously impair his health, or probably cause his death.[81]

What if the procedure is painless (a transdermal patch or small pill)? Suppose the risks of adverse effects, whether of vaccination, or of Mellaril and other medicines administered to Harper, were nil. To restate a familiar utilitarian "paradox," assume that administering the medicine by force will save the world. Surely a rational non-psychopath would accept the vaccination or medicine (religious authority aside). Would forced administration shock the conscience?[82] It is not as shattering as, say, torturing a child to death to preserve

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

82. *See* Rochin v. California, 342 U.S. 165, 172 (1952) (holding that use of swallowed morphine obtained by forcing an emetic into defendant's stomach through a tube violated the Due Process Clause of the Fourteenth Amendment, it being "conduct that shocks the conscience").

humanity. When there are no external risks, however, we can resist even modest interference with our persons for no reason at all. But when there are risks, we do say that some reasons for objecting are not good enough. In *Jacobson*, Justice Harlan made a point of quoting the Massachusetts Supreme Judicial Court in ruling on Rev. Jacobson's objection: "[W]hile they [the medical profession] have recognized the possibility of injury to an individual from carelessness in the performance of it [vaccination], or even, in a conceivable case, without carelessness, they generally have considered the risk of such an injury too small to be seriously weighed as against the benefits coming from the discreet and proper use of the preventive . . . ."[83]

6. The Article's Shaky Start on Jacobson 2.1

A word on the matrix of criteria suggested by Professor Holland in her account of what would have to be done in a *Jacobson 2.1* situation. As noted, they include "(1) public health necessity, (2) reasonable means, (3) proportionality, (4) harm avoidance, and (5) fairness."[84]

Here, the theoretical question and the practical adjudicative advocacy question coincide: What is this list supposed to do for us? Where do its elements *go* in the argument structure of a vaccination case? The concepts listed are her suggested criteria for assessing a rights claim against government assertions that serious interests are being promoted. "Necessity," in its clumsy way, is about both assessing the strength of the government interest in the situation at hand and appraising the means. Although it bears significant (if highly competitive) meanings, it is too opaque to be retained as a critical term in constitutional analysis unless it is carefully specified, as when used as a tool for evaluating mechanisms toward reaching a concededly significant objective. It reduces the scope of "necessity" to prefix it with "public health," but does not add much to its precision.

Moreover, it stands uneasily with "reasonable means." Is this concept meant to be a weaker standard than "necessary means"? A reasonable means criterion goes into every non-minimal standard of review. (Recall that the minimal rational basis test in substantive due process is not a true reasonableness requirement with any teeth.) An even harder question—and more important for our purposes—concerns the paired analytic operations a court should pursue in examining government choice of means. The court must examine the efficiency of mechanisms *with respect to the identified goals*, and it must also *evaluate* whether, in light of the value of the goals, the mechanisms are constitutionally adequate. Constitutional adequacy of means requires determining whether they "sufficiently" advance the goal, considering its value, and do so without undue

83. Commonwealth v. Pear, 66 N.E. 719, 721 (Mass. 1903).

84. Holland, *supra* note 5, at 46.

(disproportionate?) intrusion on protected interests. The intensity with which the courts perform these tasks varies with (among other things) the burden of justification defined by the standard of review. What is "reasonable" (in either the constitutional or everyday sense) may in some cases amount to a least restrictive alternative requirement, while in others a looser "narrowing" requirement may do for liberty interests not treated as major league fundamental rights. What is the difference? There are differences in how hard a court (and the legislature when it acts) looks for alternatives; in how the court addresses the data (if any) and the inferences drawn from them; and so on. This is exactly the sort of increasingly rigorous specification of review operations that courts will be pushed to perform under the pressure of technological innovation, although such pressures have always existed.[85]

Although it is hard to be certain about their meanings, the other elements of the proposed matrix—proportionality, harm avoidance, and fairness—seem to be miscategorized as independent aspects of analysis. Harm avoidance straddles both the goal-evaluation dimension ("necessity") and the efficiency of the mechanisms in moving toward the goal at relatively low cost (where "cost" refers primarily, but not exclusively, to burdened constitutional interests). Although "proportionality" is used (controversially) in Eighth Amendment jurisprudence,[86] the term is used differently here. This concept is often used in constitutional adjudication outside the United States, but is occasionally mentioned here also. I do not think that, as used so far, it significantly alters the content of what is already contained within our doctrines, expressly or impliedly. Importing the concept of proportionality is of questionable benefit, partly because it *seems* as if it is doing some work. Proportionality concerns the comparative analysis required identifying and evaluating goals, pitting them against interests impaired by moving toward the goals, and examining the relative efficiency of the means for so moving. Efficiency itself is value laden in any proportionality or balancing process. For example, whether a given means advances a goal efficiently in a constitutional sense depends in part on the value of the goal, which determines the value of moving any given distance toward it. So proportionality covers at least some forms of "balancing," as used in American constitutional jurisprudence. However, there might be some theoretical and functional differences between the two conceptual systems. For example, some proportionality formulations might suggest standards of review more akin to a continuous "sliding scale" than to a "step-function" with built-in tiers—i.e., thresholds that define where heightened scrutiny bursts onto the scene.[87] Yet it

85. For an account of the narrow tailoring requirement and its limits, see Grutter v. Bollinger, 539 U.S. 306, 339-40 (2003).

86. *E.g.*, Roper v. Simmons, 543 U.S. 551, 575 (2005) (ruling that execution of juveniles who were under eighteen when their crimes were committed is disproportionate and thus violates the Eighth Amendment).

87. I discuss this contrast in formulations of standards of review in Shapiro, *supra* note 39, at

does not seem that this is the reason for its inclusion within the Article's matrix. In any case, the claim that the "proportionality" argument structure is extensionally equivalent to what we already have—either adding some contained inference, or rhetorical flavor, or just cluttering things up—cannot be examined extensively here.[88] I simply note that Justice Breyer, rather obliquely, suggests this equivalence. (How this might affect outcomes is not clear.)He said, dissenting in *United States v. Playboy Entertainment Group, Inc.*,

> Consequently § 505's restriction [on access by juveniles to sexually oriented cable TV programming], viewed in light of the proposed alternative, is proportionate to need. *That is to say*, it restricts speech no more than necessary to further that compelling need. Taken together, these considerations lead to the conclusion that § 505 is lawful.[89]

So, I see little reason that the idea of proportionality adds to the constitutional and policy analysis of vaccination. I stress that I am not saying it has *no* incremental meaning—a point I turn to in Subsection III.E.6.The term helps to understand the meanings of "balancing" by directing attention to some aspects of use—and, in the other direction, the idea of balancing itself helps to illuminate that of proportionality: they are entangled concepts.

Much the same applies to the overlapping idea of "fairness," which concerns proportionality (among other things, such as justice, equality, and utility), which in turn concerns evaluating the burdens imposed by the government's means in light of the goals supposedly advanced. But this is what our standards of review already do. Rendering these already-contained aspects of judicial review explicit is not objectionable, but serious reconstruction of current doctrine is only

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269 n.136. The differing structures may yield different results, although this is far from inevitable, and often unlikely.

88. By "extensionally equivalent," I mean that the compared terms denote the same things but have a different meaning (or sense or intension). *Cf.* Ruth Barcan Marcus, *Extensionality*, OXFORD REFERENCE ONLINE THE OXFORD COMPANION TO PHILOSOPHY (2011), http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry=t116.e851> (last visited July 29, 2011).

89. U.S. v. Playboy Entm't Grp., Inc., 529 U.S. 803, 846 (2000) (emphasis added) (Breyer, J., dissenting). Justice Breyer evidently thought that proportionality language was fully translatable—at least in that context—into prevailing American terminology. The Court, however, ruled that a cable TV regulation meant to shield children from sexually oriented programming failed the least restrictive alternative standard. For more extensive comparative discussions of proportionality, see Dieter Grimm, *Proportionality in Canadian and German Constitutional Jurisprudence*, 57 U. TORONTO L.J. 383, 386 (2007) (noting that the test, in the jurisdictions analyzed, "requires a means–ends comparison"); Moshe Cohen-Eliya & Iddo Porat, *American Balancing And German Proportionality: The Historical Origins*, 8 INT'L J. CONST. L. 263, 265 (2010) ("One can, of course, deny that balancing and proportionality are similar and argue that, despite superficial similarities, they are analytically distinct. However, . . . we believe that the analytical differences between the two concepts are not substantial enough to account for the differences in attitudes toward them. Other, more promising explanations for the differences in attitudes between the U.S. and Europe may be found in aspects of legal and political culture.").

marginally advanced, if at all, by the Article's matrix. Although its elements bear significant meaning, what was needed was a mapping of the sort tried here, linking those terms to current constitutional doctrine, to see if they add anything. If they do, it does not seem to be much.

IV. VACCINATION ANALYTICS: WHAT DO WE PLACE INTO THE CONSTITUTIONAL ARGUMENT STRUCTURES?

Here, I apply the abstractions of the constitutional argument structures just discussed to some of the specific aspects of the hepatitis B vaccine issue, and vaccination issues generally.

A. Basic Questions About the Hepatitis B Vaccine Issue: Harms and Their Causes

1. Factual and Conceptual Background

No case has been made against any form of hepatitis B vaccine in general, nor as a condition of school attendance, nor as a routine accompaniment of birth. I think Professor Holland has made a case for asking vaccinologists, allied biomedical professionals, and public health experts to answer some specific questions (*e.g.*, whether the vaccine is thimerosal free), but her conclusion that the vaccine has caused widespread harm to children is not scientifically confirmed, and the anecdotes—in light of the research to date—are not persuasive as clues that the dangers of vaccination are significant. True, anyone is free to argue that science is not everything, and—here is an issue to pinpoint—one may believe that parents and individuals generally should be free to decide whether to allow personal invasions *even if their objections have no scientific warrant*. If the right not to be vaccinated is a liberty interest, then I suppose the claim is presumptively to be recognized—but it can be overcome under heightened scrutiny.

Professor Holland's Article also calls attention to the fact that there are varying degrees of need[90] in different regions of the world. "Need," here, is a

90. Indeed, in some places, the vaccine program arguably should be broader—given at birth, not just as a condition of school entry. *See* Koen Van Herck & Pierre Van Damme, *Benefits of Early Hepatitis B Immunization Programs for Newborns and Infants*, 27 PEDIATRIC INFECTIOUS DISEASE J. 861, 862 (2008) (stating that "In highly endemic countries, HBV is predominantly transmitted among young children through perinatal or child-to-child transmission. It makes sense, therefore, to vaccinate infants for early protection."). Even in the United States, infant vaccination might be justified across the board. *See id.* at 862-64 ("An effective vaccination strategy must focus on preventing HBV chronic carriage. Those infected at an early age are far more likely to become chronic carriers. For example, in the United States, children younger than 5 years of age represent only 1–3% of cases of acute HBV infections, but the risk of HBV infection to become chronic in children younger than age 5 is 30–90%. As a result, 30–36% of cases of chronic HBV infection in the United States contracted the infection during childhood. It is therefore important to have large-

function both of the incidence of infection and of the local health care system. For example, an effective voluntary system that generates high compliance may make compulsion unnecessary.

I do not see major issues about long-term efficacy. Most sources concur that booster shots are not necessary for at least fifteen years in most cases.[91] There is little support in the biomedical community for any claims of serious vaccine-caused complications, save for anaphylactic shock (about one-in-1.1 million).It does seem confirmed, however, that there is a nontrivial incidence of some minor adversities, all transient: fever, soreness, and a sense of discomfort or ill-being.

There is some support for the idea that *some* causal connection for *some* adverse events in *some* vaccination subjects cannot be entirely excluded, unless a causal link is simply inconsistent with well confirmed scientific findings about how things work (findings that of course are themselves corrigible).The Article should have highlighted this more clearly because it is at least consistent with its skeptical stance on vaccination. As things stand, however, existing evidence does not support a finding of any causal link between hepatitis B vaccine and any serious disorders (very rare anaphylactic shock aside), including neurological diseases such as multiple sclerosis. Science being what it is, one should assume a window of possibility for showing otherwise, but this "revision space" is not, in this case, a rational foundation for objecting to hepatitis B vaccination, compelled or otherwise.

> Recent attention has been given to the possibility that vaccination with a hepatitis B vaccine increases the risk for developing multiple sclerosis (MS). *While we cannot say with absolute certainly that the vaccine has never caused a case of MS*, some temporal associations are expected because hepatitis B vaccine is administered to the same age groups where symptoms of MS first occur. Since 1990, VAERS [Vaccine Adverse Event Reporting System] has received 76 U.S. reports of MS following vaccination with hepatitis B vaccine. These reports are spread fairly evenly over the years. CDC has undertaken a further prospective study of the possible association between demyelinating disease (neurological diseases) and the hepatitis B vaccine.[92]

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scale routine vaccination as early as in infancy to allow a maximum impact on reduction of HBV transmission."). Targeting only those at high risk because of their behavior (drug use, sex) is thought to allow too many victims to fall through the holes. "The main limitation of that selective [high risk targeting] strategy was the fact that no risk factor for HBV infection can be identified in over 30% of infected persons. Hence, a substantial proportion of HBV cases are missed by the 'at-risk' vaccination strategy." *Id.* at 861.

91. *See id.* at 684 (It may be, however, that several administrations are required at the outset.).

92. *See* Susan S. Ellenberg, *Vaccine Adverse Event Reporting System (VAERS)*, U.S. FOOD & DRUG ADMIN. (last visited July 15, 2011), http://www.fda.gov/NewsEvents/Testimony/ucm115058.

So, "no causal relationship has been found" *does not yield* "there is no causal relationship."[93] (Again, one would need to add premises about the inconsistency of a causal hypothesis with confirmed scientific accounts.)

There are several distinct questions about how to respond rationally to a scientific consensus-with-qualifications (no causal relationship established, but not-a-cause is not confirmed either). One is whether it is rational to *believe* that there is, in fact, a causal link between the vaccine and some serious adverse events, other than anaphylaxis, even in the face of existing data. (Adverse events caused in part because of certain contraindicating vulnerabilities are another matter.) It's hard to see how it can be rigorously rational, despite the impact of anecdotal reports, which certainly can have colossal impact, and indeed may provide *clues for further investigation.*[94] I am not sure that there is a consensus

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htm (emphasis added). ("With virtually universal childhood immunization, beginning at birth or shortly thereafter, any adverse medical event in a child will 'follow' vaccination, and some of these will coincidentally follow within a few days of a vaccination. Thus, even if a vaccine is not the cause of certain rare medical problems, it is a certainty that some number of these events will occur within a short interval following a vaccination. For this reason, the fact that an event—even a very serious event such as a death—occurs shortly after a vaccine has been administered cannot by itself lead to the conclusion that the event was caused by the vaccine. . . . A determination that the vaccine caused the post-vaccination event usually cannot be made on the basis of information acquired from individual VAERS reports."); *see also* Mast, *supra* note 4, at 15 ("A causal association has been established between receipt of hepatitis B vaccine and anaphylaxis. On the basis of VSD data, the estimated incidence of anaphylaxis among children and adolescents who received hepatitis B vaccine is one case per 1.1 million vaccine doses distributed (95% confidence interval = 0.1–3.9). Early post licensure surveillance of adverse events suggested a possible association between Guillain-Barré syndrome (GBS) and receipt of the first dose of plasma-derived hepatitis B vaccine among U.S. adults (181). However, in a subsequent analysis of GBS cases reported to CDC, FDA, and vaccine manufacturers, among an estimated 2.5 million adults who received >1 dose of recombinant hepatitis B vaccine during 1986–1990, the rate of GBS that occurred after hepatitis B vaccination did not exceed the background rate among unvaccinated persons. *An Institute of Medicine review concluded that evidence was insufficient to reject or accept a causal association between GBS and hepatitis B vaccination.*"(emphasis added) (citations omitted)).

93. Suppose the background incidence of some disorder is one per million persons (perhaps limited some way according to certain traits, such as age or gender). Suppose also the incidence of that disorder among every million persons given a particular vaccine is the same. No causal pathway between the vaccine and the disorder is known, but no scientific knowledge excludes it. No study finds a statistically significant result for a causal hypothesis—i.e., that the adverse event is not the result of chance. Of course, even if a finding of causality were statistically significant, this doesn't mean it couldn't have been the result of chance. Nor does failure of a result to be statistically significant mean, standing alone, that there is in reality no causal relationship. Does this entail that there can be no causal relationship between a given occurrence of the disorder and the vaccine? No, but this isn't saying much, and it's certainly not saying that there is a good reason to avoid the vaccine. What would it take to show causation? One would have to probe the possibility of predisposing individual conditions that set up the rare individual for the adverse event.

94. *See* Alison M. Stuebe, *Becoming a Physician: Level IV Evidence — Adverse Anecdote and Clinical Practice*, 365 NEW ENG. J. MED. 8, 8 (2011) (noting that adverse personal experience will create compelling memories and can transform clinical practice). But there has to be more involved than the occurrence of an event, *simpliciter.* Otherwise, the transformation in clinical practice may

that there is in fact no causal connection (rather than "none shown") between the hepatitis B vaccine and various adverse events cited by the vaccine's critics. Even if there is, it could be the result of loose conflation of "no cause shown" and "causation flatly excluded"; there are consensuses and consensuses.

Moreover, because of the *contested* nature of causation—cause-in-fact as well as proximate cause—some causal attributions may be value laden, or linked to one's personal preferences. Proximate cause is of course famous for its normative ambiguity, but the supposedly factual notion of cause-in-fact might also be, at least on occasion.[95]

Another question about rational causal belief concerns what one ought to do about these beliefs in various situations. Suppose everyone agrees that there is a causal link between the vaccine and an extremely rare, very serious disorder (how serious is of course critical). The obvious example is the accepted belief in anaphylaxis. Should one avoid vaccination, for oneself or one's child, because of this risk? Anaphylaxis can be fatal, especially if immediate medical help is unavailable. Hepatitis B is a serious disorder, but not necessarily life threatening.[96] One can ask the same thing concerning, say, multiple sclerosis and other serious neurological disorder: even conceding a causal link, is it rational to avoid vaccination, given the seriousness of the disorder and the probability and gravity of the described risk?

Here is another consideration. Suppose neither causation nor no-causation is established. If causation is not empirically excluded, then it must be considered at least possible. Assume that there are adverse event reports indicating a certain incidence of occurrence of a serious adverse effect. Since it is, by hypothesis, *possible* for there to be a causal link, is it rational to decline vaccination? (One can then proceed as above.)

One can understand being leery of any medical procedure, including vaccinations that are *generally known* to be safe, because of the expected disutility (roughly, the product of an event's probability and its gravity). If the risk of getting polio is one in a million and the risk of getting it from a vaccination is one in a million, what is the point—within the individual's decision framework—of taking it? From a collective standpoint, there may be an epidemiological reason to vaccinate on a large scale—to maintain the low level

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not be for the better.

95. *See* Taofikat Agbabiaka et al., *Methods for Causality Assessment of Adverse Drug Reactions: A Systematic Review*, 31 DRUG SAFETY 21, 22 (2008) (discussing the abundance of causal algorithms).

96. Hepatitis B is a liver disorder caused by viral infection. *Hepatitis B*, PUBMED HEALTH, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001324 (last reviewed Nov. 23, 2010) ("Early symptoms may include: Appetite loss; Fatigue; Fever, low-grade; Muscle and joint aches; Nausea and vomiting; Yellow skin and dark urine due to jaundice. People with chronic hepatitis may have no symptoms, even though gradual liver damage may be occurring. Over time, some people may develop symptoms of chronic liver damage and cirrhosis of the liver.").

of polio infection, depending on the risks of resurgence of the disease.

But it is difficult to understand why any of the data presented in the Article or its sources justifies a serious opposition to the hepatitis B vaccine. The author principally cites writings that support her position, and one can raise questions about the biomedical credentials of some of her principal sources.[97] The strongest material in her favor, presented by biomedical researchers, simply states that causation cannot be excluded, and there is not much of it cited in her Article.

We are, thus, left with a value/preference issue, but one with a constitutional dimension: Are we bound to leave such *decisions about small but nonzero degrees of risk* to individuals because of the importance of their liberty interests in the integrity of body, mind, and identity—of personal security in a comprehensive sense?

2. Adverse Events, Study Findings, and Causation

"Adverse event" reporting is, of course, critical to assessing the safety of medical mechanisms. Bare association of an adverse event with medical treatments *is* scientifically relevant. But there is relevance and *relevance*. Relying on such "anecdotal" information is a critical part of the scientific process and cannot rationally be dismissed out of hand. To do so reflects a basic misunderstanding of scientific research and advancement.

But such association generally cannot, at the start and standing alone, establish causation. Bare reports of adverse events, however awful, cannot justify opposition to a vaccination program, voluntary or otherwise, unless the scale of the events indicates the strong possibility of causation. If one person out of five hundred eating food from the same source suffers major digestive upset, there is no cause for general alarm (although it may happen anyway). If several dozen get sick, it is time to prosecute the food.

Moreover, the criteria for addressing whether linked events are causally related are not settled. "Currently, there is no universally accepted method for assessing causality of ADRs [(adverse drug reactions)]. No up-to-date review of the existing causality assessment methods is available."[98] Simply referring to adverse event reports does not provide sufficient warrant for avoiding or suspending vaccination, unless particular circumstances concerning scale and indicia of causation are satisfied. It, thus, will not do to state, without far more support than is offered, that "Since 2005, further scientific investigation has suggested severe deleterious health consequences for many young children from the hepatitis B vaccine. A 2008 study *associates* hepatitis B vaccination of male

97. *See infra* note 104.

98. *See* Agbabiaka et al., *supra* note 95, at 22 (2008). The article is an extensive literature review of the methods for assessing causation.

newborns with autism diagnoses from 1997-2002."[99]

But, as the Vaccine Adverse Event Reporting System (VAERS) states:

> VAERS data contains coincidental events and those truly caused by vaccines. More than 10 million vaccines per year are given to children less than 1 year old, usually between 2 and 6 months of age. At this age, infants are at greatest risk for certain medical adverse events, including high fevers, seizures, and sudden infant death syndrome. Some infants will experience these medical events shortly after a vaccination by coincidence. These coincidences make it difficult to know whether a particular adverse event resulted from a medical condition or from a vaccination. Therefore, vaccine providers are encouraged to report all adverse events following vaccination, whether or not they believe the vaccination was the cause.[100]

In any case, *even if a confirmed percentage of adverse events is considered caused by the vaccine*, this is not sufficient to withhold support for the vaccine program. It depends not only on incidence, but also on the seriousness of the events, the seriousness of the disorder being prevented, whether the disorder is in fact being prevented, and whether it is possible to stratify patients into high and low vulnerability groups. A one hundred percent probability of a mild fever with no adverse sequelae does not warrant suspending an otherwise justifiable preventive program.

As for causation itself, what is needed to support Professor Holland's reservations about hepatitis B vaccinations is an application of the various methods and algorithms of causation analysis. There is no cited reference in her Article that does this for hepatitis B, using any method of causation analysis. There is nothing referred to that provides a basis for accepting any causal hypotheses that adverse events—including multiple sclerosis—derive from the hepatitis B vaccine, except (most seriously) for fever and (very rarely) anaphylactic shock.[101]

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99. Holland, *supra* note 5, at 74 (emphasis added.).

100. *VAERS Data*, VACCINE ADVERSE EVENT REPORTING SYS., http://vaers.hhs.gov/data/index (last visited July 15, 2011).

101. *See, e.g.*, Annemarie L. Broderick & Maureen M. Jonas, *Hepatitis B In Children*,23 SEMINARS LIVER DISEASE 59, 66 (2003) ("Hepatitis B vaccines have been shown to be safe for both adults and children. Pain at the injection site (3 to 29 %) and a temperature greater than 37.7°C (1 to 6 %) have been the most frequently reported side effects, but these side effects were reported no more frequently among vaccinees than among persons receiving a placebo. Anaphylaxis is the only serious adverse event; this rare event occurs at a rate of approximately 1 per 600,000 vaccine doses. *[Editorial note: I cannot account for the variation in reported incidence.]* Reports of multiple sclerosis (MS) developing after HBV vaccination led to concern that the vaccine might cause MS in previously healthy subjects. This was refuted in a nested control study of two large cohorts of nurses in the United States. No association was found. In a case crossover study using the European MS database, recent vaccination against HBV, tetanus, or influenza did not appear to increase the

If so, both the individual patient's decision and the overarching moral and public policy issues concern the proper responses to conditions of uncertainty, given personal and societal risk preference patterns. However, given the risks of hepatitis B, the literature reports suggest that avoiding hepatitis B vaccinations given present knowledge may not be entirely a matter of risk aversion patterns. I note some possible alternative subtexts below.

The difficulties with marking out the nature of causation—whether we are speaking of cause-in-fact, proximate cause, or related ideas—are well known. Proximate cause, as suggested, is a standard example of normative ambiguity because it embraces both the empirical links among events and policy judgments. But even cause-in-fact has value components. We have to choose among competing notions of causality, and, in some fields at least, there is no overarching concept that unifies differing modes of analysis. The analysis of adverse drug reactions is a clear example:

> Numerous methods for causality assessment of adverse drug reactions . . . have been published. The aim of this review is to provide an overview of these methods and discuss their strengths and weaknesses. . . . We conducted electronic searches in MEDLINE (via PubMed), EMBASE and the Cochrane databases to find all assessment methods. Thirty-four different methods were found, falling into three broad categories: expert judgement/global [sic] introspection, algorithms and probabilistic methods (Bayesian approaches). . . . As a result of problems of reproducibility and validity, no single method is universally accepted. Different causality categories are adopted in each method, and the categories are assessed using different criteria. Because assessment methods are also not entirely devoid of individual judgements [sic], inter-rater reliability can be low. In conclusion, there is still no method universally accepted for causality assessment of ADRs.[102]

It is hard to see how American courts pursuing heightened scrutiny can do

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short-term risk of relapse in MS. Vaccines were commonly prepared with thimerosal, sodium ethylmercurichthiosalicylate, to prevent bacterial and fungal contamination. This preservative has aroused great public concern regarding mercury toxicity. Infants were considered at greater risk for mercury poisoning from thimerosal-containing vaccines. No adverse outcomes have been clearly associated with thimerosal use; nevertheless, in 1999, a joint statement was issued by the AAP, the American Academy of Family Physicians, the Advisory Committee on Immunization Practices, and the U.S. Public Health Service. These four bodies called for the national goal of removal of thimerosal from vaccines and the performance of studies to establish any relationship between thimerosal exposure and health effects. HBV vaccination in newborns was temporarily suspended in 1999 until thimerosal-free vaccines became available, unless the mother was infected with HBV. There are now two thimerosal-free HBV vaccines available in the United States for use in infants. Hence, parents can be reassured about the lack of exposure to mercury in HBV vaccines.").

102. Agbabiaka et al., *supra* note95, at 21.

more than inquire into the views of persons credentialed in empirical analysis (assuming credentials can even be agreed upon) and screen for conflicts of interest and other factors that may compromise adequate neutrality. This sort of inquiry would seem required by heightened scrutiny, but it obviously must operate within resource, knowledge, and ability constraints that limit judicial inquiry and decision.[103]

These difficulties are not extensively addressed in the Article, and there seems to be excessive reliance on the reporting of adverse events, *simpliciter*, as well as reliance on certain sources whose background and training are not directly in vaccine or epidemiological research, although they may have practiced medicine or acquired expertise in statistics.[104] There are no grounds for completely dismissing what they say, even though they have not yet made a case for "equal time." Credentials (training and experience, at the least) are hardly perfect proxies for sound opinions, never mind accurate results. But they are not nothing, and non-experts—including courts—have to pay serious attention to them. It is easy to say that one should avoid over-reliance on expert judgment, but it is hard to say just what counts as "over-reliance."Even if experts are often wrong, it is not clear what the threshold alternative is to according some authority to their views and to await better grounded informed opinion. The best that the laity can do is to inquire about rational foundations for judgment, including the investigation of conflicts of interest that are widely accessible outside of the experts' domain. This is especially important in light of the almost inevitable normative dimensions of expert conclusions. "These girders are strong enough" is not a simple factual judgment," any more than is "This vaccine is quite safe." Experts are wrong *often.* See Aristotle, Ptolemy, and the opponents of Semmelweis, Marshall, and Warren, and, more recently, Dan Shechtman, the winner of the 2011 Nobel Prize in Chemistry, who was expelled from his research group for "disgracing" it with his work on quasicrystals.[105] His results were considered "impossible." But the errors of experts are generally established by *other* experts running scientific studies and experiments, not simply reporting sequences of salient events!

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103. *See infra* notes 175, 193.

104. Michael Belkin describes himself as a statistician. Geoff Metcalf, *Vaccines That Kill Children? Geoff Metcalf Interviews Mandated-Immunization Opponent Michael Belkin*, WORLDNETDAILY.COM (Dec. 3, 2010), http://www.whale.to/m/belkin1.html. Dr. F. Edward Yazbak, M.D., is described as having practiced pediatrics for many decades. *Dr. F. Edward Yazbak*, MD, HEALTHGRADES, http://www.healthgrades.com/physician/dr-f-edward-yazbak-32ff3/ (last visited July 24, 2011).

105. Interview with Dan Shechtman, Distinguished Professor of Materials Science at Technion (Oct. 10, 2011), *available at* http://pubs.acs.org/cen/news/89/i41/8941notw1html?from_TRM_site=Ytterbium.

B. What If We Concede Causation?

I raised this possibility in the preceding section and add a few points. Completeness requires that we indulge such assumptions *arguendo.* The point of the question is this: Even where causality is conceded (or credibly posited), the risks, as understood so far, are extremely low. The risk of causing anaphylactic shock is about one-in-1.1 million, as noted.[106] Suppose one also accepts, as some do, that hepatitis B vaccine may cause serious autoimmune disorders in a group (fairly small) of susceptible subjects. What policy outcome? What constitutional rationale and outcome when someone refuses compelled vaccination and is fined or imprisoned?[107] Apply these questions to the points made by Geier and Geier:

> One would have to consider that there is [a] causal relationship between HBV and serious autoimmune disorders among certain susceptible vaccine recipients in a defined temporal period following immunization. In immunizing adults, the patient, with the help of their physician, should make an informed consent decision as to whether to be immunized or not, weighing the small risks of the adverse effects of HBV with the risk of exposure to deadly hepatitis B virus.[108]

But what exactly are they saying has been found? The "causal relationship" is not (necessarily) between *the vaccine* and the adverse event, but between *circumstances of administration of the vaccine* and the results. Part or all of the problem may be that the "inactive" substances included in the vaccination package are risky, e.g., thimerosal, a preservative (which has been significantly phased out).[109] Geier et al. state:

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106. *See supra* note 4.

107. See the discussion of possible constitutional argument structures for a latter-day *Jacobson*, *infra* Section III.E.

108. Mark R. Geier & David A. Geier, *A Case-Series of Adverse Events, Positive Re-Challenge of Symptoms, and Events in Identical Twins Following Hepatitis B Vaccination: Analysis of The Vaccine Adverse Event Reporting System (VAERS) Database and Literature Review*, 22 CLINICAL EXPERIMENTAL RHEUMATOLOGY 749 (2004); *see also* Arnon Dov Cohen & Yehuda Shoenfeld, *Vaccine-Induced Autoimmunity*, 9 J. AUTOIMMUNITY 699, 701 (1996) ("The data summarized here suggest that some vaccines may in rare cases induce autoimmune disorders. The subject of the vaccine-autoimmunity relationship is still obscure; reports have been rare, no laboratory experimentation on this topic has been undertaken, and there are few animal models. For the time being no conclusions can be drawn. Since vaccines are an important prophylactic intervention, the risk-benefit ratio clearly leans towards the advantages of infectious disease prevention. Vaccination routines should not be changed in the healthy population or for patients with known autoimmune disorders.").

109. *See* Broderick & Jonas, *supra* note 101. This does not mean there is no contaminant danger. *See* Katherine Hobson, *Charred Shrink Wrap in Merck Vaccines: Read the FDA Inspection Reports*, WALL ST. J.: HEALTH BLOG, July 29, 2011, http://blogs.wsj.com/health/2011/07/29/charred-shrink-wrap-in-merck-vaccines-read-the-fda-inspection-reports. Recall that some deny that the vaccine additive thimerosal causes adverse events.

> Hepatitis B is one of the most important infectious causes of acute and chronic liver disease both in the US and worldwide. In order to combat the life-threatening effects of hepatitis B infection, recombinant hepatitis B vaccines have been developed. The medical and scientific communities have generally accepted that recombinant hepatitis B vaccine—a highly purified, genetically engineered, single antigen vaccine—is a safe vaccine. *Information is presented showing that hepatitis B vaccine contains yeast, aluminium, thimerosal and hepatitis B surface antigen epitopes, which may result in hepatitis B vaccine being associated with autoimmune diseases among susceptible adult vaccine recipients. There is little doubt that the benefits of this vaccine overall far outweigh its risks.*[110]

Very young children are in no position to provide informed consent, to be sure, so their parents must make the choice. But I think that in the case of hepatitis B, this does not alter the conclusion that vaccination risks may be imposed within the legislature's discretion, even when heightened scrutiny is imposed. For other vaccination programs, the result may be different.

C. Efficacy, Safety, and Need

"I need this "ambiguously embeds matters of fact, value, and personal preference. There is a lot of information about hepatitis B carrier rates and the incidence of infection, but some disagreement about its significance. In the United States, we are rarely overwhelmed by epidemics, but we are far from home free: the smallpox-is-dead story is only about smallpox. Nevertheless, a pressing question concerns what levels of safety and prevention are morally and constitutionally "enough" to sustain compelled vaccination in various situations, *conceding* a certain set of facts. Here is a pinpoint illustration: Suppose one says (Professor Holland does not do so directly) "*onlyn* persons will be protected from X through this vaccination program."This formulation is significantly begging the question, and its circularity does not seem universally recognized. It is circular because the "only" presupposes an unstated value premise: it is just not *worth* other costs and risks to prevent ("merely") *n* persons from getting X. This is sometimes put in a remarkably blunt way: "[V]accinating over 100,000 children annually to ideally avoid 200 acute cases per year (mainly in drug addicts) is not considered logical from a public health standpoint [in Sweden]."[111]

This sort of buried premise on what is worth doing to save lives and preserve

110. Mark R. Geieret al., *A Review of Hepatitis B Vaccination*, 2 EXPERT OPINION ON DRUG SAFETY 113 (2003) (emphasis added).

111. Sten Iwarson, *Why the Scandinavian Countries Have Not Implemented Universal Vaccination Against Hepatitis B*, 16 VACCINE S56 (1998).

health requires ventilation—certainly far more than appears in some of the cited literature.[112] It is a plain moral and logical truth that, for all *n*, where *n* is any number, *n* lacks *independent moral* significance, whatever its import in number theory.)

How, then, should we characterize the degree of success or failure of the hepatitis B vaccine? To be sure, claims of "success" may be as normatively ambiguous and possibly question begging as claims of failure and uselessness, but the following account seems reasonably neutral. It suggests, among other things, some issues in causal attribution, noting that behavioral changes among adults—not children—may explain some of the decline in the incidence of the disease.

> In the United States of America, the impact of hepatitis Bimmunisation has been impressive. From 1990 to 2001, the overall incidence of acute hepatitis B declined by 66%, from8.1 to 2.8 cases per 100,000. The decline was most dramatic among children 0–11 years old, with an 89% decline, from1.1 to 0.12 per 100,000. Among adults, the reasons for the decline in incidence include vaccination, as well as safer sex and injection practices. However, among children the decline in incidence can be attributed to vaccination, which has been routinely recommended for all infants since1991.[113]

On the other hand, the hepatitis B situation is not such a big deal, right?

> In 1996, fifty-four cases were reported to the Center for Disease Control in the birth-to-1 age group. There were 3.9 million babies born that year so the incidence of hepatitis B is 0.001%. [0.00138%] *Does that sound like enough cases to warrant a vaccine?*90 to 95% of all hepatitis B cases recover completely after 3 to 4 weeks of nausea, fatigue, headache, arthritis, jaundice and tender liver. Approximately 50% of patients who contract Hepatitis B develop no symptoms after exposure. However, the exposure ensures that they will have life-time immunity.[114]

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112. *Id.* at S56-S57. No effort was made to unpack any material premises to demonstrate the conclusion.

113. David FitzSimons et al., *Long-Term Efficacy of Hepatitis B Vaccine, Booster Policy, and Impact of Hepatitis B Virus Mutants*, 23 VACCINE 4158, 4163 (2005). *See also* Broderick & Jonas, *supra* note 101, at 60 ("Although HBV infection is not highly endemic in the United States, similar effects have been noted. Due to both immunization strategies and changes in risk behaviors, the annual incidence of HBV infection has declined from about 200,000 cases to 79,000 over the last decade or so. From 1986 to 2000, the rate of acute hepatitis B among children 1 to 9 years of age declined more than 80%.").

114. *Hepatitis B*, VACCINE TRUTH, http://www.vaccinetruth.org/page_11.htm (last visited July 18, 2011) (emphasis added).

If numbers can be morally freighted and the moral weight of these particular numbers is known, then one can just *see* that the recommended vaccination program is unwarranted, right? Would the number would have to be, say, 762? Fifty-four babies with these symptoms is not worth it?[115]

The opposing side, which soft-pedals adversities rather than life-protection, is occasionally no better formulated. According to the Centers for Disease Control:

> Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses. A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people have gotten hepatitis B vaccine in the United States.[116]

On these figures, there were over ninety severe allergic reactions. This is not enough either. Is 762 the right number when adversities are played down?

It is sometimes denied that the vaccination program even serves to reduce the incidence of hepatitis B, although it is hard to distinguish these claims from "it doesn't reduce it (enough)" and "the program wasn't administered very well so it failed." The weight of authority, however, is that the programs have significantly reduced the incidence of hepatitis B—although there are no magic moral numbers here either—and some emphasize factors other than the vaccine to account for the low incidence of the infection.[117]

One might argue that the highest risk behaviors—drug use and sex—are simply not pursued by the younger school age children. There are some ready responses to this. First, even if few of the younger children pursue illicit conduct, those few should be protected, particularly since they are generally judged to be below the age of fully responsible behavior. In any case, getting hepatitis B is

115. Note that vaccinating babies is a way of reducing the risks of contracting hepatitis B in later childhood or in adulthood. *See* Mast, *supra* note 4. *See also* Ctrs. for Disease Control & Prevention, *Recommendations of the Immunization Practices Advisory Committee Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of all Pregnant Women for Hepatitis B Surface Antigen*, 37 MORBIDITY & MORTALITY WKLY. REP. 341 (1988) *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00000036.htm.

116. *Hepatitis B Vaccine: What You Need To Know*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-b.pdf (last visited July 18, 2011).

117. *See* F. Edward Yazbak, *The Hepatitis B Vaccine: What Went Wrong?*, VACCINATIONS NEWS, *available at* http://www.vaccinationnews.com/node/19957 (last visited July 15, 2011). *But see* R. S. Koff, *Review Article: Vaccination And Viral Hepatitis – Current Status And Future Prospects*, 26 ALIMENTARY PHARMACOLOGY & THERAPEUTICS, 1285, 1289 (2007)("By 2005, a 98% decline in HBV infection was reported for children 13 years of age of younger since 1990 and a 97% decline among adolescents aged 12–19 years, a result of the national programme of childhood immunization. The decline in hepatitis B among adults was less striking at 76%. Sexual transmission and injection drug use remained important risk factors in this group.").

disproportionate to whatever responsibility they bear. Second, there is a risk of horizontal transmission from students—including older students—who do contract hepatitis B, from whatever source. Third, once acute, a patient is at significant risk for developing chronic hepatitis B, which, though treatable, remains a serious condition.[118]

In pursuing her questions about whether the hepatitis B vaccine is, in fact and in value, needed, Professor Holland invokes the experience of some Scandinavian countries having a low incidence of hepatitis B.[119] In Denmark, for example:

> The report concluded that the effect of introducing hepatitis B vaccine into the childhood vaccination programme would begin to manifest itself in 15-20 years. After 40-50 years the immunisation programme would save an estimated 10 lives per year as a result of fewer cases of chronic liver disease. In the short term, a universal vaccination programme would mean that targeted vaccination children [sic] in daycare centres where there are children with chronic hepatitis B would be unnecessary, and children in the daycare centres with chronic hepatitis B would run a smaller risk of stigmatisation. The net costs would be substantial if hepatitis B was to be implemented as a stand alone vaccine. On the basis of the conclusions from the medical technology assessment report, the National Board of Health has recommended that hepatitis B is not introduced into the childhood vaccination programme, and has instead suggested optimising the current risk group vaccination strategy [....][120]

Some points to consider: First, the carrier rate of hepatitis B surface antigen A is higher in the United States than in Denmark. This may suggest a stronger need for a given vaccination program. The Danish experience may be instructive, but is not decisive for the United States. Second, why is saving ten lives over a half century not worth the effort—or is that not what was meant in the Danish report and in the Cowan article? What *is* the effort? Does the conclusion presuppose that we are to assess the program via a *simple* cost-benefit analysis, in

118. Broderick & Jonas, *supra* note 101, at 61 ("Children not infected at birth remain at risk from infected household and community contacts, especially in subpopulations in which HBV infection is prevalent. This is called horizontal transmission. The exact mechanisms are unknown, but transmission by shared toiletry items, such as toothbrushes, and even by activities such as sharing chewing gum has been postulated. Transmission by sexual contact and shared injection drug equipment represents risk factors for adolescents as well as adults.") Also, "Infants who acquire HBV perinatally have up to 90% risk of developing chronic HBV infection." *Id.* at 59.

119. Holland, *supra* note 5, at 72.

120. Susan A Cowan, *Denmark Decides Not To Introduce Hepatitis B into the Childhood Vaccination Programme*, 10 EUROSURVEILLANCE 2827 (2005).This article also stressed that much of the increased incidence was attributable to immigrants.

which harms and benefits are monetized? If so, this presupposition requires a fuller articulation and defense. To some extent, public policy operates within a cost-benefit framework, but often it does not, at least in the usual senses of that concept. Most parents do not cost out the expected value of a child when deciding to use all their resources to fund an organ transplant. Third, the Danish policy was not based on the probability and gravity of adverse effects, but on cost per life saved.[121] This is not a sufficiently complete way of assessing a policy's advantages and disadvantages. Fourth, hepatitis B vaccine policies do not pretend to be pitched on saving enormous numbers of lives that would be snuffed out by liver disease. It does save lives, but for each death, there are many more cases of illness and dysfunctionality; no one aspires to contract this disorder. Assessing the number of deaths prevented is focusing on a relevant variable, but far from the only one; *morbidity* is a central issue in formulating a rational hepatitis B policy.

Moving north in Scandinavia, Sweden's policy, as described in an article (somewhat dated) cited by Professor Holland, states:

> Northern and Western Europe are low-prevalence areas for hepatitis B, with HBsAg [hepatitis B surface antigen, indicating infection][122] carriage rates below 0.05%. [Some regions are at 20%.] Even among low-prevalence areas, however, great differences are seen. In Scandinavia, carrier rates are approximately 0.05% as compared with France, for instance, which has a carrier rate of approximately 0.5%.[The U.S. carrier rate is reported in at least one source to be 0.27%.][123] .... The limited spread of the hepatitis B virus in Scandinavia can be demonstrated by the low number of officially reported acute hepatitis B cases occurring annually in Sweden. Despite the low number of reported acute cases of hepatitis B, a substantial number of Sweden's immigrant population is HbsAg positive. These carriers, however, do not seem to have a major impact on the number of acute hepatitis B cases in Sweden. Over the past ten years increasing numbers of immigrants have entered the country, but acute cases of hepatitis B continue to be seen mainly among drug addicts and their contacts and to a certain extent, among male homosexuals with multiple partners.
>
> Countries in Scandinavia have chosen not to introduce universal infant immunization against hepatitis B because the problem is

121. *Id.*

122. *See* Mast, *supra* note 4.

123. Annemarie Wasley et al., *The Prevalence Of Hepatitis B Virus Infection in the United States in the Era of Vaccination*, 202 J. INFECTIOUS DISEASES 192 (2010). ("During the period 1999-2006, age-adjusted prevalences of anti-HBc (4.7%) and HBsAg (0.27%) were not statistically different from what they were during 1988-1994 (5.4% and 0.38%, respectively).").

> considered to be a very limited one. In the case of Sweden, *vaccinating over 100,000 children annually to avoid 200 acute cases per year (mainly in drug addicts) is not considered logical from a public health standpoint.*[124]

Without specifying other premises, including certain assumptions about what social preferences are in place, there is nothing "illogical" or irrational about vaccinating one hundred thousand children to prevent two hundred cases of a serious disorder—at least until we know what the criteria of "illogicality" are in this context. Which moral metric tells us that it is not worth it to do X to get Y? Comparison of the monetary valuation of bodily intrusions to lives and health? Which opportunity costs (the costs of foregone benefits) are at stake? If the Swedish approach to the logic (or illogic) of public health is part of the foundation for working out a rational American vaccination policy, this should be disclosed and explained more clearly. Cost-benefit analytics may be powerful tools of public policy, but, as they are usually pursued, such metrics are not always decisive—neither in fact or as a matter of value analysis.[125]Why, for example, do we have an orphan disease research policy in the United States? If a dollar spent on disease X would save one life and a dollar spend on disease Y would save one hundred lives . . . the drill here is obvious. Perhaps the policy is ill-considered, but we have it, and it is partly based on close assessments of the seriousness, as well as the incidence, of the disorder.[126]Consideration of opportunity costs looms large here.

To be sure, to say that in some cases we do not use cost-benefit analysis is not to deny that we consider advantages and disadvantages. The former process is often a more particularized and quantified version of the process of comparing advantages and disadvantages.[127]This cluster of issues concerning the moral aspects of harm and benefit analysis seem insufficiently addressed in any of the accounts about Scandinavian practice cited in Professor Holland's Article or this Reply. This is not made up for in other ways in the Article.

Moreover, there is a rather obvious subtext, although I make no claims about

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124. Iwarson, *supra* note 111, at S56-S57 (emphasis added).

125. *See generally* Steven Kelman, *Cost-Benefit Analysis: An Ethical Critique, in* FOUNDATIONS OF ENVIRONMENTAL LAW AND POLICY 93 (Richard L. Revesz ed., 1997).

126. Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 26 U.S.C., 35 U.S.C., & 42 U.S.C.).

127. Even this general remark may be controversial. Definitions of "cost benefit analysis" are varied. For example: "The quantification of the total social costs and benefits of a policy or a project, usually in money terms." John Black et al., *Cost–Benefit Analysis*, OXFORD REFERENCE ONLINE, http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry=t19.e611 (last visited Oct. 12, 2011). This formulation is consistent both with a quantification-only approach and a more general comparison of advantages and disadvantages. The latter formulation, however, may expand the meaning of the term beyond its more technical uses.

what motivates public policy in Scandinavia or anywhere else. The quoted article emphasizes the role of immigrants, gay persons, and addicts in maintaining the incidence hepatitis B. Its reference to "vaccinating over 100,000 children annually to avoid 200 acute cases per year *(mainly in drug addicts)*" (emphasis added) offers a rather pointed suggestion about values that affect vaccination policy. One might add that some children do grow up to be drug addicts, so why protect them from the inevitable? (I am not at all ascribing this view to Professor Holland.)

The hepatitis B literature does contain some indirect critiques of the Scandinavian policy.

> Although the proportion of young children infected by HBV in countries with low endemicity is small, this population largely contributes to HBV morbidity and transmission because of more frequent progression to chronic carriage when HBV is contracted early in childhood. Therefore, only newborn/infant universal vaccination could lead to efficient prevention of chronic carrier state and finally elimination of the disease. Of particular importance for countries with low endemicity is the element of HBV import through migration of HBV chronic carriers born in regions with high HBV endemicity, subsequently spreading HBV infection. As population movements increase, for example mobility into Europe, control of infectious diseases needs to be supported by appropriate strategies, such as infant immunization programs.[128]

Of course, the need for a particular vaccination program rests on the efficacy of the vaccination as well as the gravity and epidemiology of the disease. (It also rests on the adequacy of the administrative set up of the program.) The scientific sources indicate fairly clearly the substantial effectiveness and a long period during which boosters are not required; no one claims perfection.[129]

Finally, here is a note on thimerosal. This is vaccine preservative containing mercury, and it is being phased out of use. Whatever harms it causes are not intrinsic to hepatitis B vaccine. Whether it causes harms is contested, but I do not think that the studies suggesting risk can be ignored.[130] I note particularly the

128. Van Herck& Van Damme, *supra* note 90, at 865-866.

129. *See supra* note 91; *see also* Fitz Simons et al., *supra* note 113, at 4159 ("Each new study extends the known duration of efficacy of hepatitis B immunisation; several published reports document long-term efficacy lasting for 15 years and other studies will probably push this figure up to 20 years and longer."). The vaccine, however, is not one hundred percent effective. *See, e.g.*, Chuanfang Lee et al., *Research Effect of Hepatitis B Immunisation in Newborn Infants of Mothers Positive for Hepatitis B Surface Antigen: Systematic Review And Meta-Analysis*, 332 BRIT. MED. J. 328, 335 (2006) ("Repeated vaccination over months is required to mount an effective antibody response.").

130. Carolyn Gallagher & Melody Goodman, *Hepatitis B Triple Series Vaccine and*

quoted remarks by Geier, Geier & Zahalsky, attributing some autoimmune adversities to thimerosal additives in hepatitis B vaccines.

For future reference, here are other matters to consider: Suppose the law (federal or non-preempted state law, if any) prohibited the use of a vaccine, and that the enactment was based solely or primarily on adverse event reports and some rare but serious harms concededly caused by the vaccine itself. What then? Could the hepatitis B vaccine properly be banned? Although important, I will not discuss such issues here, except to say that for every right-against-X, one could (in theory) mount a right-to-X claim.

D. Education and Vaccination: A Note on the "Punishment" of Children and Piggybacking Public Health Measures onto Government Functions

Although the Article's title stresses vaccination of pre-school children, there is an implicit criticism of the use of compulsory schooling programs as a hook to latch onto children in order to vaccinate them. Professor Holland, for example, notes critically, that "[s]ome commentators reject the view that there must be a close nexus between school and vaccination to warrant a state mandate."[131] The result of this improper piggybacking is thought to work an injustice to the child excluded for lack of a required vaccination. Professor Holland states: "Punishments include loss of education, social isolation, parents' loss of custodial rights, child neglect sanctions against parents, and even forced vaccination."[132] Here, the term "punishment" is tendentiously pejorative—a weak

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Developmental Disability in US Children Aged 1-9 Years, 90 TOXICOLOGICAL & ENVTL. CHEMISTRY 997, 997 (2008) ("This study found statistically significant evidence to suggest that boys in United States who were vaccinated with the triple series Hepatitis B vaccine, during the time period in which vaccines were manufactured with thimerosal, were more susceptible to developmental disability than were unvaccinated boys."). Different forms of mercury compound may pose different risks. In any case, the Public Health Service in 1999 urged manufacturers to reduce or eliminate the preservative, and "[m]uch progress has been made to date in removing or reducing thimerosal in vaccines. New pediatric formulations of hepatitis B vaccines have been licensed by the FDA, Recombivax-HB (Merck, thimerosal free) in August 1999 and Engerix-B (Glaxo SmithKline, thimerosal free) in January 2007." *Thimerosal in Vaccines*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228#tox (last updated Mar. 31, 2010).But note that not all researchers concur on the thimerosal risk. *See* Osman David Mansoor & Peter Salama, *Should Hepatitis B Vaccine Be Used for Infants?*, 6 EXPERT REV. VACCINES 29 (2007) ("Concerns have been raised regarding the mercury preservative in vaccines leading to potential toxicity. But the evidence to date does not support any association of hepatitis B vaccine with serious adverse consequences. Protecting infants through immunization is the most effective control strategy. By 2005, over 80% of countries had implemented routine infant immunization. In countries with relatively low rates of hepatitis B virus infection, some have argued to defer immunization until later life. However, these arguments focus on the more visible acute infection. *The possible future cost from a single infant infection argues for universal infant hepatitis B immunization—given the very high costs of treating its consequences (e.g., liver transplant) and the very low price of the vaccine.*" (emphasis added)).

131. Holland, *supra* note 5, at 51.

132. *Id.* at 15.

rhetorical device complaining about school exclusion; the fact that it is a disadvantage not to be schooled does not render it a "punishment," and the exclusion, if adequately justified, is preferable under the circumstances to inclusion. The so-called punishment is a mechanism to protect the student's health and educational potential.

Although the argument is not explicit, the embedded view that schools should not be used as a device to implement vaccination requires some comment. One cannot assess the situation by focusing on any given student. The vaccination system is workable only in the large.[133] What is needed, then, is attention to the possible consequences of not having a vaccination program: there will be more students unable to study because of illness, however contracted. It is possible, of course, that a given school vaccination program is not justified. A smallpox vaccination program would not now be in order. But the lack of justification for any given program cannot rest on the considerations presented in this passage. The social isolation is not for nothing. As for more drastic measures, such as sanctions for neglect—there is not just one tray in the scale.

This view that compulsory school attendance programs can be used to further goals other than education is common, although one could not properly argue that schools are a kind of medium into which anything can be poured.(The goal—e.g., preventing sickness—is not always "other than education": it is hard to educate sick students.)But we have long used schools for more than standard educational purposes. (Don't ask me to list the purposes—many are sharply contested. For example, we also rely on schools to develop professional cadres of athletes and soldiers: think athletic teams, ROTC, and the armed services academies.) There is nothing illogical, contradictory, or otherwise irrational about this *in general*. Using the educational system as a device to insure at least one good meal a day for students is controversial and not well implemented, but it does not *necessarily* contradict educational goals, and may promote them. This is why education is (at least) a two-way deal: the supposedly peripheral objectives (promoting student health and well-being via vaccination, food

133. As to this last point, which contrasts the individual rationality and collective rationality frameworks, see James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 876-877 (2002). ("[P]erceptions differ sharply depending on whether the risk of vaccination is viewed from an individualistic or societal perspective. From the perspective of a single child, there may be greater risk if she is vaccinated than if she remains unvaccinated. For example, during the past two decades, the only cases of polio reported in the United States are caused by the vaccine; an unvaccinated child's risk of contracting wild polio virus is very small. State-imposed vaccination should be understood in this light. The state is explicitly asking parents to forego their right to decide the welfare of their children not necessarily for the child's benefit but for the wider public good. From a societal perspective, the choice not to immunize may be optimal to the individual if there is herd immunity, but in the aggregate, this choice could lead to failure of that herd immunity. Affording individuals the right of informed consent to vaccination, then, may not be for the greatest good of the community. Rather, informed consent can contribute to a 'tragedy of the commons' if too many people make the decision not to immunize.").

programs, etc.) not only enhance education, but may make it possible in the first place for some students. The Article's objections implicate serious disputes between competing political philosophies. From some of those moral and political vantage points, it is wrong for the state to displace parental or private responsibility generally.[134] Some of these objections are also informed by a more general opposition to paternalism in various forms, although the subject is not directly addressed in the Article. But these premises are not fully articulated or defended.

Piggybacking vaccination and other public health measures onto the educational system is meant to serve several overlapping (and usually nonconflicting) purposes: to further educational goals, to protect the children themselves (this includes both unvaccinated and vaccinated children—immunity is rarely complete),[135] and to promote public health *generally*. Using the school is simply one way to get at certain members of the public—children—who happen to be in particular places at particular times, thus ameliorating a serious logistical problem. There is no *inherent* policy or constitutional problem with this. Vaccinating the entire population outside any independent programs that gathers them together in groups would be hugely inefficient and possibly ineffective. As a byproduct rather than a primary goal, such programs may also reinforce notions of community responsibility by selective overriding of personal autonomy in certain matters. On the other hand, they may also erode the lofty normative status of autonomy. Impairing autonomy (in one way) in order to promote it (in another way) is a two-edged blade, bearing mixed social learning messages. Much depends on the conditions of public perception and debate. To be sure, public health is furthered by measures not linked to schools, and has improved significantly for reasons not limited to successful vaccination programs. But this does not damage the case for compulsory school vaccination.

Leaving aside the religious issues (which I do not cover here), does the combinatorial aspect of these functions—education and public health—raise federal constitutional issues? I denied this earlier. A standard form of individual rights claim is that the right is impaired and heightened scrutiny triggered when certain conditions are imposed on their exercise.

For example, suppose "The State of Anomie hereby establishes the Agency for Promoting Safety in Extreme Sports. No one who has ever had an abortion or performed, assisted, procured, aided, abetted, or encouraged an abortion need apply." I assume for the sake of argument that there is no fundamental right or liberty interest in a particular job, trade or profession (leave aside procedural due

134. For example, *Jesse Helms*, ANSWERS.COM, http://www.answers.com/topic/jesse-helms (last visited July 18, 2011) ("He believed it was the role of the private individual to help others, as he and his wife, Dorothy Helms, had done by adopting a nine-year-old orphan with cerebral palsy. In Congress he voted against federal aid to disabled people and against school lunch programs.").

135. *See infra* note 209.

process issues) or even in having a job. But canceling a job prospect as a sanction for having or performing an abortion is clearly an undue burden on a woman's rights under *Casey.* Similarly, if delivering a speech in a public forum is a fundamental right (subject to reasonable time, place and manner rules), it cannot be conditioned on paying prohibitive fees in advance.[136]

One might, then, argue that the interest in attending school is compromised by requiring vaccination. This will not work for various reasons. For better or worse, there is no fundamental right to education as such.[137] Moreover, if there is no independent constitutional infirmity in compelled vaccination, then conditioning school admittance on compliance is not itself unconstitutional.

E. Jacobson 2.1 Applied: the Pinpoint Issues

1. Some Assumptions

We are now in a position to work on some related reconstructions of *Jacobson.* I try to make the questions relatively precise, but the varying doctrinal possibilities and sharply different social situations make this difficult.

I start with a brief but instructive (if hard to penetrate) remark about comparing medical and epidemiological situations in different places: "Mandatory immunization may not be needed or appropriate for all societies, particularly those with health care systems that cover the entire population and stress prevention."[138]

There is of course some irony here. Many vaccination opponents are inspired by the same autonomy concerns that stir opposition to government-regulated health care systems, but it is precisely the latter systems in which there seems to be a lesser need for compulsory vaccination because most persons get vaccinated, more or less voluntarily, through the existing health care establishment.[139]

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136. Forsyth Cnty. v. Nationalist Movement, 505 U.S. 123 (1992).

137. San Antonio Sch. Dist. v. Rodriguez, 411 U.S. 1 (1973); *see also* Viemeister v. White, 72 N.E. 97 (N.Y. 1904) (decided under the New York constitution and cited in *Jacobson*).

138. Walter A. Orenstein & Alan R. Hinman, *The Immunization System in the United States-The Role Of School Immunization Laws*, 17 VACCINE S19, S23 (1999).

139. Gail Horlick et al., *Delivering New Vaccines to Adolescents: The Role of School-Entry Laws*, 121 PEDIATRICS S79, S81 (2008) ("Many countries around the world rely on other factors rather than law to increase vaccination coverage. For example, the United Kingdom relies on the individual's sense of responsibility to society to seek vaccination. However, comparisons between the United States and other countries have been complicated by differences in cultural context; what works in one society may not work in another. The United States has a historical tradition of individualism and freedom from government influence. Also, immunization programs in the United States and the United Kingdom differ in some key respects, which may impact implementation of new vaccines; for example, in the United Kingdom, vaccines are available at no charge." (footnotes omitted)); *see also* Cowan, *supra* note 120 ("In the Scandinavian countries, as well as in the Netherlands and the UK, Universal childhood vaccination has not been implemented because the incidence of the infection in the general population is very low."). It is not clear whether the low incidence is the result of the health care system, other factors, or some combination of these causes.

Most argument structures in constitutional law are not so rigid that major differences in situation cannot yield different outcomes. Suppose the hepatitis B situation in Scandinavian nations or the United Kingdom prevailed in the United States. This is, of course, a quite heroic supposition, because the "situation" in the United States might include sharp differences in social and legal values as well as in disease demographics. In any event, the American constitutional argument framework would still be applied to this limited Scandinavia-to-America social and medical transplant, but it might play out very differently. For example, the analysis of tradition might, on the one hand, reveal lesser concern for individuality across wide swaths of behavior, but greater concern in discrete fields such as vaccination. Europe, considered by many to be a lesser bastion of rigorous individuality than America, arguably has, in some locales, a greater tradition of voluntariness in vaccination. Traditions, depending on how described, differ from region to region.

But this is getting a bit ahead of the game. Assume that the U.S. Supreme Court says that a right to refuse vaccination is a serious liberty interest that instantiates an overarching right to personal security. Assume also that this right comprehends the integrity of body, mind and identity, but draws mid-level scrutiny.

There are many ways to pursue and describe the next series of analytic steps, and I avoid further comment on whether "balancing," "proportionality" and "fairness" are (in this context) extensionally equivalent. We would proceed *roughly* as the Supreme Court did in working out the logic of liberty interests in *Cruzan*, *Romeo*, *Casey*, *Harper*, and *Lawrence.* All these cases, rightly mentioned by Professor Holland, involved some form of "liberty of the person,"[140] so designated, and drew on nontrivial standards of review (not always designated), all derived from the due process clause of the Fourteenth Amendment. So we can discuss these cases as a doctrinal set and use them to analyze the constitutional properties of compulsory vaccination.

To overcome the presumption favoring a person's exercise of a given right against vaccination, the government can offer the justifications of promoting the health of children, adults, and society, and of reinforcing certain communitarian norms. In turn, such value reinforcement may feed back into promoting right actions and good results. (Normative systems are not simply dangling

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The author states: "During the past 10 years, the number of notified cases infected through injecting drug use (IDU) has declined. It is not known if this decline is due to vaccination among IDUs or to the success of needle exchange programmes. Although heterosexual transmission has remained low, it is now the leading route of infection. . . . Prevalence studies in Denmark over the past 20 years have shown a decline in the prevalence of HBsAg carriers from 0.15 % to 0.03 % in the indigenous population. During the same period there has been a considerable influx of people from high endemic countries. Studies of HBsAg prevalence in immigrants to Denmark in 1998 and 2002 have demonstrated a prevalence of 0.6% among children and 2.6% among pregnant women." *Id.*

140. *E.g.*, Lawrence v. Texas, 539 U.S. 558, 562 (2003) (protecting sexual practice liberties).

abstractions; they inform and often govern behavior in massive ways.)

This is not the place to write an entire hypothetical opinion, so I jump to the nub of the next stage of analysis. Here are the primary points that drive the constitutional argument in this not-so-imaginary *Jacobson 2.1*:

First, vaccinations work for hepatitis B and many other disorders, but they are not *perfectly* effective.

Second, vaccination is not a walk in the park: they all pose a risk of adverse effects, from trivial (quite common) to fatal (extremely rare).

Third, the scientific literature supports a causal connection between vaccination and adverse effects only for a small proportion of all the adverse effects that have occurred "within the curtilage" (or *res gestae*?) of vaccination. It takes far more than the bare occurrence of an adverse effect to establish causation.

Fourth, for most adverse events, the research can support a strong finding of "no causal link shown within accepted templates for causal analysis, therefore no rational reason to believe it for any given case."

Fifth, unless well-confirmed science forecloses a causal association, a "no cause shown" conclusion does not yield "causation is excluded; there is not and cannot be any causal link." If in fact some vaccination caused a single case of autism because of a one-in-billion vulnerability, no research study yet designed would be able to discern this (absent specific scientific causal path discoveries).[141] Although it would be an interesting exercise to imagine a clinical study capable of confirming such causation, I leave this to quantitative empiricists.

Sixth, many persons do not have a realistic understanding of the meaning of probability and assign greater danger or disvalue to highly improbable outcomes than is warranted. This seems to be consistent with general human predispositions toward certain forms of cognitive error (some of which may be "wired in" through evolutionary adaptation).[142]

Seventh, the impact of specific events (even when reported anecdotally)—especially when in one's face—can be enormous. This has advantages (it rationally spurs investigation) and disadvantages (we are prone to make causal attribution errors).[143]

Eighth, the pressing need for social protection for any given disorder varies

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141. There is apparently some evidence that *preexisting* autism is a predisposing factor for adverse vaccine reactions. Maria Dorota Majewska et al., *Age-Dependent Lower or Higher Levels of Hair Mercury in Autistic Children than in Healthy Controls*, 70 ACTANEUROBIOLLAE EXPERIMENTS (Pol.) 196 (2010). So far, the only example of serious caused adversity for hepatitis B vaccine seems to be anaphylactic shock, but here, biomedical specialists need to be consulted; I haven't run across anything else *shown*.

142. *See generally* 2 HANDBOOK OF SOCIAL PSYCHOLOGY 763 (Susan T. Fiske et al. eds., 5th ed., 2010).

143. *See supra* note 94 and accompanying text.

over time and place. The conditions that drive smallpox and polio are now totally different: there is no smallpox. Yet, although the incidence of polio is low (though variable), polio could re-emerge at any time if vaccination programs are not continued.[144]

2. The Vaccination-Resister's Claims

> So, here I stand, the resister: I'm risk averse, and *very* risk averse when it comes to my kids. I say where there's smoke, there's fire. I'm also more averse to what might be immediate (vaccination injury) rather than remote and unlikely (getting hepatitis B). You tell me that my reasoning is skewed, that I am overawed by mere salience, and I tell you that the exercise of important rights does not rest on the rationality of my decision, and anyway I don't think it's irrational. Rationality is normatively ambiguous. If I am unwilling to take a one in a million chance of anaphylactic shock (*scientifically confirmed*), it's my right to refuse, *either* for myself *or* my child. I think that "no cause shown between X and Y" doesn't mean "it has been shown that X *doesn't* cause Y," and that the bare possibility (*not refuted*) that the vaccine causes autism or MS is enough to justify refusing the vaccination. Still more, I don't care if there is some social benefit: I am not a mere means to an end and don't want to be injected with or forced to otherwise ingest something I don't want in my body, possibly impinging on my mind. In constitutional terms, here are my pinpoint claims ("pinpoint" compared to other formulations):
>
> I invoke my liberty interest (including parental liberty interest in child raising)[145] to follow my preference to avoid risk. I concede that I am overawed by anecdote, but hey, that's me, and I *know* that I'm right, and Kahneman & Tversky[146] and their ilk are rightly ignorable. Yes, I am aware that my personal security and dignity interests and those of my family can be compared with and weighed against social interests, but those interests don't outweigh my claim. Why should I take a chance of fatal

144. Horlick et al., *supra* note 139, at S79; *see supra* note 139.

145. *See* Troxel v. Granville, 530 U.S. 57, 65 (200) (recognizing a liberty interest in making decisions about the care, custody and control of one's children) (plurality opinion). As mentioned , the Court obviously used a form of heightened scrutiny, but did not say where it fell within the available range of standards. Somewhat confusingly, the Court spoke both of liberty interests and fundamental rights, referring to the "fundamental right to make decisions concerning the rearing of her two daughters."*Id.* at 68.

146. I'm referring here to the now vast literature on human proneness to cognitive error. *See,e.g.*, RICHARD NISBETT & LEE ROSS, HUMAN INFERENCE: STRATEGIES AND SHORTCOMINGS OF SOCIAL JUDGMENT (1980);Amos Tversky & Daniel Kahneman, *The Framing of Decisions and the Psychology of Choice*, 211 SCIENCE 453 (1981).

anaphylactic shock in order to prevent a disease that is generally nonfatal and treatable, and, in the United States, has an incidence far lower than what prevails in high endemic areas.

For that matter, why should I take a very high risk that I or my child will suffer even mild, transient fever and malaise under these non-urgent conditions?

And just in case you think, foolishly, that the risk of adverse effects is functionally zero (Who gets hit with the one-in-million catastrophe? Barely one in a million!), I say this: I invoke my liberty interest to maintain the integrity of my person whether there is danger or not. Even if the medical risk is zero, even if there is no psychological apprehension on anyone's part (and even if they experience positive pleasure from the needle stick), I don't want my body invaded by anything I don't want in me, whether this preference is idiotic or not. If I'm competent, I'm free to be irrational in that way, assuming it's irrational, which it isn't. (Don't ask me why it makes a difference whether I'm competent if I'm free to be as irrational as I want when competent.)

Yes, I understand that although the risk to me or mine may be zero, asserting my rights entails that certain risks are run by others (although I don't think those risk are that serious). Why are their preferences to be preferred to mine when mine are directly and immediately under threat? *Maybe* others will come down with something. But it's *certain* I'll get stuck or have to pay for it if I continue to refuse. Where rights are at stake, you can't just count up and compare utiles and declare that I don't have enough of them. As Nozick said, "Individuals have rights, and there are things no person or group may do to them (without violating their rights). So strong and far-reaching are these rights that they raise the question of what, if anything, the state and its officials may do."[147] So I don't owe nothin' to nobody—at least most of the time. I concede that if there is an overwhelming risk of really bad things going down—like one of those alien infections that perennially afflict The Enterprise and really mess everyone up—that forcing me to comply would be both morally and constitutionally justifiable. But that's not true with hepatitis B. Whether it's true for any disease going around, I don't have to say.

Finally, I don't even believe a lot of the claims about vaccine safety, efficacy, disease incidence, and disease treatment. The

147. ROBERT NOZICK, ANARCHY, STATE, AND UTOPIA IX (1974).

> people making these claims are operating under a conflict of interest: they want money. So, in many senses, I have a "divergent risk perception[]," and a "different [and nondelusional!] perception of reality"[148]compared to the mainstream.
>
> One more thing. You can't put a definitional stop on me by saying that my choices are stupid or insufficiently reflective and therefore violate some definitional rationality constraint on autonomy, and so I and my choices are not autonomous.[149] I don't see autonomy that way, but I'm not just claiming an autonomy right (bearing possible conceptual limitations)—I'm claiming a *liberty* right. I say I'm perfectly rational, but I don't have to make sense to you. Even if my decisions don't satisfy your (restricted) notions of "autonomous choice," they are within my constitutional liberty interests.

As a general matter, this set of claims is too broad to be sustained within current doctrine, although I would guess there is no shortage of persons who would support them. Buthow are courts to address this array of entangled empirical and value questions (including value questions associated with both risk and uncertainty)[150] under any given standard of review?

3. How Far To Go Within a Standard of Review

a. In General: Craig v. Boren

I start with an example that is far afield in subject matter, but not in constitutional relevance. In *Craig v. Boren*,[151] the Court invalidated a law that prohibited sales of 3.2% beer to males under age 21, but allowed sales to females 18 or over. Persons from 18 through 20 were thus treated differently because of their gender. *Craig* was the first case formally to apply intermediate scrutiny to gender-based classifications.[152] The standard was that "classifications by gender

148. Lotte Asveld, *Mass-Vaccination Programmes and the Value of Respect for Autonomy*, 22 BIOETHICS 245, 253 (2008).

149. *Id.* at 248("Internal autonomy or positive freedom as such involves reflection on one's actions, the outcome of which effectively determines those actions. When one acts on a whim, this is not an autonomous action."). There seems to be a normative/conceptual rationality plank to autonomy, but the point may go too far.

150. "Risk" refers to measurable probabilities of defined harms, and "uncertainty" applies when we cannot calculate the probabilities (and possibly when we cannot even tell if an outcome would be a harm or a benefit). *See generally* FRANK H. KNIGHT, RISK, UNCERTAINTY, AND PROFIT, at ix (Signalman Publishing 2009) (1921).

151. Craig v. Boren, 429 U.S. 190 (1976) (invalidating gender-based age requirements for purchasing 3.2% beer).

152. *Craig* was preceded by (for example), Reed v. Reed, 404 U.S. 71 (1971), which applied heightened, but non-strict, scrutiny to gender-based rules governing appointment of administrators

must serve important governmental objectives and must be substantially related to achievement of those objectives."[153]

What was the point of the government's gender classification? Was it to put down adolescent males and glorify the traditional image of female innocence? The main rationale—not well explained by Oklahoma—was to save lives and protect against injury to persons and property. The bare outline of the state's reasoning was simple—and clumsy: ingesting alcohol leads to driver impairment, which leads to more vehicle crashes, which in turn leads to more injuries and damages, which leads to more deaths. Preventing death and injury seem compelling, not just important, to invoke a freighted term from strict scrutiny.

In using its review standard, the Court did not second-guess the legislature's implicit view of the moral value of saving life or ask when life might properly be sacrificed for the greater good. As Justice Powell said in his concurrence, "No one questions the legitimacy or importance of the asserted governmental objective: the promotion of highway safety. The decision of the case turns on whether the state legislature, by the classification it has chosen, had adopted a means that bears a "fair and substantial relation" to this objective."[154]

Of course, the Court was not confronted by some clear and present risk of death, whether to specific persons or "statistical" ones. Still, death and injury were at stake. Yet the Court did not stress the prospect of death and injury despite the obvious accident risks. It glossed over the government's probable purpose, focusing instead on reviewing the "legislative facts":

> We accept for purposes of discussion the District Court's identification of the objective underlying [the law at issue] as the enhancement of traffic safety. Clearly, the protection of public health and safety represents an important function of state and local governments. However, appellees' statistics in our view cannot support the conclusion that the gender-based distinction closely serves to achieve that objective and therefore the distinction cannot under *Reed* withstand equal protection challenge.[155]

The Court attacked the means chosen to implement this goal—a gender classification based on taking arrests as gender-differentiated proxies for

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of decedents' estates. The Court described its task as determining whether a gender classification "bears a rational relationship to a state objective that is sought to be advanced." *Id.* at 76.

153. *Craig*, 429 U.S. at 197.

154. *Id.* at 211 (Powell, J., concurring).

155. *Id.* at 200 (majority opinion). The Court found the issue of actual purpose to be slippery, and such problems may arise more pointedly in other cases. By "legislative facts," I mean the general empirical findings that (supposedly) underlie a legislative action. *See* Kenneth L. Karst, *Legislative Facts in Constitutional Litigation*, 75 S. CT. REV.75 (1960) (defining and distinguishing the overlapping categories of legislative and adjudicative facts).

dangerousness. The Court attacked the very quality of the data presenting these comparative arrest records. It was that the arrest count itself was thought to be wrong (although it could have been); it was that biases might have affected the very decision to arrest one person as opposed to another, based on gender. The differing arrest rates of males and females might have been partly attributable to such biases. Thus, inferences about comparative dangerousness drawn from the differential arrest of boys and girls are likely to have been flawed. On this view, we cannot view the higher arrest rate for males as signaling that they are, as drivers, more dangerous than females. Of course, not everyone who drives under the influence is arrested, so the arrest rates may understate whatever danger there is, but this does not affect the overall analysis on either side. As Justice Brennan put it (in a footnote, oddly enough, considering the importance of the point): "The very social stereotypes that find reflection in age-differential laws... are likely substantially to distort the accuracy of these comparative statistics. Hence 'reckless' young men who drink and drive are transformed into arrest statistics, whereas their female counterparts are chivalrously escorted home."[156]

How did Justice Brennan know this? Of course, he did not. He, in effect, judicially noticed the omnipresence of male (and police) stereotyping of gender behaviors and implicitly argued: "This stereotype-induced distortion is so likely that we must consider its constitutional impact—and when we do, we see that the arrest data are tainted and unreliable. Without assurance that the arrest criteria in operation were sound, the data are an uncertain basis for inferences about much of anything." As a matter of constitutional analysis, one might well compare Justice Brennan's critique with the conflict-of-interest "financial distortion" attack on medical/vaccination claims made by pharmaceutical companies and allied health care practitioners.[157] (I am not necessarily endorsing either one as a winning constitutional argument or even as sound policy.)

The Court displaced not only the legislature's presentation of the *facts* of drunk driving arrest differentials, but its *valuation* of the significance of its "findings":

> Viewed in terms of the correlation between sex and the actual activity that Oklahoma seeks to regulate—driving while under the influence of alcohol—the statistics broadly establish that .18% of females and 2% of males in that age group were arrested for that offense. While such a disparity is not trivial in a statistical sense, it hardly can form the basis for employment of a gender line as a classifying device. Certainly if maleness is to serve as a proxy for drinking and driving, a correlation of 2% must be considered an unduly tenuous "fit." Indeed, prior cases have consistently rejected the use of sex as a decision-making

156. *Craig*,429 U.S. at 202 n.14.

157. *See infra* notes 191-194 and accompanying text.

> factor even though the statutes in question certainly rested on far more predictive empirical relationships than this.[158]

Justice Brennan grudgingly conceded that the "disparity is not trivial in a statistical sense." Indeed, it's an *order of magnitude* difference, as noted by then-Justice Rehnquist.[159] But that concession was of no moment: Justice Brennan's attitude was, in effect, 'order-of-magnitude, shmorder-of-magnitude: *both* figures are too low to justify impairing gender-equality interests.' The risks and losses are acceptable in light of the need to reinforce the gender equality norm. This "acceptable losses" stance is one major crux of the vaccination dispute: at several points, the Article suggests, by way of recounting Scandinavian practices, that compulsory hepatitis B vaccinations simply are not *worth* it as far as lives saved are concerned.[160]

For our purposes, Justice Brennan's key phrase is this: "Certainly if maleness is to serve as a proxy for drinking and driving, a correlation of 2% must be considered an unduly tenuous 'fit.'"[161]

Consider the premises embedded within Justice Brennan's dismissive statement. Note first what he is *not* saying. The claim that two percent of males are arrested over a given period is obviously not a claim that that specific group of males is, over a given period, involved in fatal or otherwise serious accidents. If that were the showing, and we could also show that females never caused accidents, the constitutional argument should play out quite differently. Moreover, the claim is not even that two percent represents an accident rate, with or without injury or damage. It is just arrests that are taken as an index for other rates: accidents, injuries, deaths, and property damage. What is the evidence for the link between drinking (of some sort, in some amount, with some measured

158. *Craig*, 429 U.S. at 201-02.

159. Id. at 226 (Rehnquist, J., dissenting).

160. *See supra* notes 111-112 and accompanying text.

161. *Craig*, 429 U.S. at 201-02 & n.14; Justice Powell offered a similar observation, particularly stressing the lack of a ban on possession. *Id.* at 211 (Powell, J., concurring)("It seems to me that the statistics offered by appellees and relied upon by the District Court do tend generally to support the view that young men drive more, possibly are inclined to drink more, and for various reasons are involved in more accidents than young women. Even so, I am not persuaded that these facts and the inferences fairly drawn from them justify this classification based on a three-year age differential between the sexes, and especially one that it so easily circumvented as to be virtually meaningless. Putting it differently, this gender-based classification does not bear a fair and substantial relation to the object of the legislation."). Justice Stevens also entered the fray, complaining of the "slight benefit" of Oklahoma's classification. *Id.* at 214 (Stevens, J., concurring)("The legislation imposes a restraint on 100% of the males in the class allegedly because about 2% of them have probably violated one or more laws relating to the consumption of alcoholic beverages. It is unlikely that this law will have a significant deterrent effect either on that 2% or on the law-abiding 98%. But even assuming some such slight benefit, it does not seem to me that an insult to all of the young men of the State can be justified by visiting the sins of the 2% on the 98%."). Why, exactly, isn't burdening ninety-eight percent for the sins of the two percent justified if (some of) those sins have fatal or other serious effects?

physiological impact) and road accidents? There are reams of material on the impairment worked by alcoholic intoxication and the consequences of driving under the influence. Let us assume that this scientific showing is sound: drunk driving increases the risk and actual incidence of road wrecks. (However, this is not to concede that drinking 3.2% beer in particular has any effect on accident rates. Justice Brennan, in fact, cast doubt on this.)[162]

But suppose the data show a very high probability that implementing the classification will prevent some deaths or severely disabling injuries, but no more than a few. Compare this to: "Administering one million doses of vaccine *V* will prevent *only* twenty deaths." How is this an "only"?[163] If we prevent just one death or crippling injury, isn't it worth it?—even if life is not a pearl beyond price? If that were what had been starkly presented in the record, and a striking gender differential had been soundly shown, what would we say—as citizens, legislators—and constitutional judges?

Of course, it was not starkly presented in the record, and, as we saw, the Court did not go out of its way to point out that averting death and injury was the dominating goal. Of course, it did indicate that even if it were the goal, the legislature picked a very poor way to promote it. Nevertheless, whatever one might say about the legislature's inept effort to reduce harm by restricting only one gender's activities instead of everyone's, *Craig* is still about the *death* of girls and boys and men and women as much as it is about gender discrimination. What costs and irritants are we willing to endure to save a life?

b. Judicial Review of Valuing Lives

We are attracted to questions like this in the way we are attracted to the sight—and site—of disasters. How many lives need to be saved to justify interfering with a basic right? How would we weigh art murder against people murder? ("I will destroy the Mona Lisa unless you kill a child as a sacrifice to me.") Isn't the ten-to-one ratio for how many criminals are to be let go to protect an innocent person seriously skewed? This is *way* too many innocents convicted. Even one in a 100 or one thousand is too many. (Or is it way too many guilty persons let go?) Why is it permissible (even for God) to save as few as ten good people, but not fewer? And why did Abraham stop at ten, in trying to save Sodom and Gomorrah?[164]Why not just one? Why does even a single innocent

162. *Id.* at 203 (majority opinion) ("None purports to measure the use and dangerousness of 3.2% beer as opposed to alcohol generally, a detail that is of particular importance since, in light of its low alcohol level, Oklahoma apparently considers the 3.2% beverage to be 'nonintoxicating.'") (citing OKLA. STAT., tit. 37, § 163.1 (1958)).

163. *Cf.* Mary F. McNaughton-Collins & Michael J. Barry, *Perspective: One Man at a Time — Resolving the PSA Controversy*, NEW ENG. J. MED. (2011) (asking "who is to decide what constitutes a "small" benefit and whether it outweighs the potential harms?").

164. *Genesis* 18:23-32.

resident have to die because of the evil of his neighbors? Remember the Trolley Problem (saving five by switching the tracks, thus targeting one victim) and the Fat Man problem (pushing the man onto the tracks to save five)? And the problem of deciding who gets the last kidney or dialysis machine? What about letting the violinist directly attached to your kidney die in order to vindicate a major, but temporary, intrusion on your personal integrity?[165] Suppose that we know that media presentations about suicide cause a small number of persons to kill themselves who otherwise would not, or causes them to do so earlier, thus reducing rescue opportunities. It is pretty clear that neither a statutory or administrative ban nor an injunction or damages are permissible under current constitutional doctrine. Why not? One death is not compelling enough? (Of course, it is "only" a statistical death.)[166]Are causal lines too thin—too many intervening causes—so that legal restrictions on speech cannot be considered necessary to promote the government's interests? Are less restrictive alternatives available so that necessity is again not satisfied?[167]

One of Justice Rehnquist's complaints about the majority opinion in *Craig* highlights the problem of judicial review of valuing life. He said:

> [T]he present equal protection challenge to this gender-based discrimination poses only the question whether the incidence of drunk driving among young men is sufficiently greater than among young women to justify differential treatment. Notwithstanding the Court's critique of the statistical evidence, that evidence suggests clear differences between the drinking and driving habits of young men and women. Those differences are grounds enough for the State reasonably to conclude that young males pose by far the greater drunk-driving hazard, both in terms of sheer numbers and in terms of hazard on a per-driver basis. The gender-based difference in treatment in this case is therefore not irrational.[168]

Again, there is no direct question of the form, "Is the interest in avoiding gender classification so strong that we cannot prevent the x deaths attributable to

165. WILLIAM STYRON, SOPHIE'S CHOICE (1979); Judith Jarvis Thomson, *A Defense of Abortion*, 1 PHIL. & PUBLIC AFF. 47 (1971); Judith Jarvis Thomson, *Turning the Trolley*, 36 PHIL. & PUBLIC AFF. 359 (2008).

166. *Cf.* GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 38-41, 137-41 (1978) (discussing the gains from saving known lives at the cost of losing a greater number of unknown lives).

167. *See* McCollum v. CBS, 249 Cal.Rptr. 187 (Cal.App. 3d. 1988), where parents sued rock musician Ozzy Osbourne and other parties because their son committed suicide after hearing music extolling it. The appellate court held that no cause of action had been made out for incitement or for intentional or negligent invasion of the parents' rights. The court did not discuss the use of a clear and present danger standard as an alternative to the incitement theory.

168. Craig v. Boren, 429 U.S. 190, 226 (1976) (Rehnquist, J., dissenting).

males being more dangerous than females"? But the suggestion is that, in this context at least, the Court should not displace the legislative judgment. (True, Justice Rehnquist applied a standard of review different from the majority's: the rational basis test, rather than intermediate scrutiny.)[169]

Justice Rehnquist's point might be reformulated this way. We ask why the interest in avoiding gender classification *in this case* is so monolithically important, and why so little attention is paid to lifesaving *where an order of magnitude difference in gender performance* is claimed?[170] Lifesaving is *really* important. Recall the claim that "[t]he possible future cost from a single infant infection argues for universal infant hepatitis B immunization—given the very high costs of treating its consequences (e.g., liver transplant) and the very low price of the vaccine."[171] Moreover, the more important the interest, the weaker should be the least-restrictive-alternative burden (a rigorous efficiency standard). There should be some functional relationship between degrees of importance and the search for better alternatives so that government is less burdened when it is trying to vindicate a massively important interest. Constitutional doctrine does not quite read in this finely calibrated way, but if there are degrees of compellingness and importance (there must be), there are degrees of weakening of the narrowing requirement for means-end connections, within standards of review and between them.

To be sure, Oklahoma cast doubt on the seriousness of its lifesaving rationale by banning sales only, not possession or consumption. One could well say that it offends important constitutional interests, whether about liberty or avoiding adverse classifications, to impair them with such ineffective mechanisms *when much more effective ones were available* (such as barring all drinking from eighteen through twenty years of age). But the showings were not *that* thin. Justice Powell, concurring, sided more with Justice Rehnquist than with the majority when he said that that state's data supported the claim that young men drive and drink and get into more accidents than young women. One wants to say, to the majority, "Well...?"[172]

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169. *Craig*,429 U.S. at 220. Intermediate scrutiny was put down as having "come[] out of thin air." *Id.*

170. The issue has to be carefully framed. Justice Rehnquist raised a basic issue of why the legislature couldn't conclude that certain risks *were* indeed sufficient to justify intruding on constitutional interests, but he did not describe the interest in the most accurate way: "The personal interest harmed here is very minor—the present legislation implicates only the right to purchase 3.2% beer . . . ." *Id.* at 226-27 (Rehnquist, J., dissenting). This is incomplete. The interest also concerns the *reasons* for rights limitation—for interfering with personal autonomy— and the reason in this case was gender and what was thought to be linked to it.

171. *See* Mansoor & Salama, *supra* note 130.

172. Justice Powell's concurring conclusion is thus unsettling, even if ultimately correct because the legislature didn't ban consumption, thus casting great doubt on both the very point and the effectiveness of its gender classification. But he made a lot of telling concessions, usefully applied to the vaccination context. *Craig*, 429 U.S. at 211 ("It seems to me that the statistics offered by appellees and relied upon by the District Court do tend generally to support the view that young

c. Narrowing

A final comment on "narrowing"—the search for lower-cost alternatives to the chosen legislative means. This is not some questionable doctrinal artifact: the requirement is a basic rationality constraint, although its form and rigor vary significantly across contexts. If there is another way to accomplish more or less the same thing at a lower cost in rights impairment, then the chosen maneuver is constitutionally questionable. To travel efficiently from San Francisco to Los Angeles, one does not normally take the Polar route. This constraint is, by definition, supposed to be weakened when applying less than strict scrutiny—the alternatives probably do not have to be *equally* effective, the costs imposed do not have to be the lowest possible, the legislature does not have to look as hard for them, and the courts do not have to second-guess the underlying empirical data as rigorously.

One could argue, for example, that with hepatitis B, the most efficient—least restrictive—alternative is simply to target those engaged in the highest risk behaviors: drug use and unsafe sexual practices. Of course, this would be less effective in reducing hepatitis B because not all cases are caused by these ill-famed risky behaviors. But some observers have also suggested that where such high-risk targeting has been attempted, it has not worked well.[173] I have not pursued this issue, but it seems of marginal relevance to the protection of children.

These, then, are the sorts of constitutional adjudication issues raised with increasing frequency by technological innovations, old and new, as well as by the increasing (or simply better noticed) complexity of things generally. Think again of *Craig* and how the Justices managed their bout with intermediate scrutiny. Justice Powell highlighted the issue of how the Court should delve into empirical data and inferences by referring to "the facts and the inferences fairly drawn from them."[174](He might also have asked how the Court was to approach legislative conclusions of value, but having accepted the legislative description and valuation of its goal, it was not at issue.)In the vaccination context, how should the Court apply Justice Powell's advice? For example, how is the Court to address the *data and evidence collection process*? Compare investigating the comparative incidence of arrests with determining the incidence of a

men drive more, possibly are inclined to drink more, and for various reasons are involved in more accidents than young women. Even so, I am not persuaded that these facts and the inferences fairly drawn from them justify this classification based on a three-year age differential between the sexes, and especially one that it so easily circumvented as to be virtually meaningless. Putting it differently, this gender-based classification does not bear a fair and substantial relation to the object of the legislation.").

173. "It has become evident that HBV transmission cannot be prevented with a strategy for vaccinating only the groups considered at highest risk." Broderick & Jonas, *supra* note 101, at 65.

174. *Craig*, 429 U.S. at 211 (Powell, J., concurring).

communicable disease.

Compare next the inferential processes in *Craig* with those in cases asserting a right against compelled vaccination. On promoting traffic safety: If males and females are arrested at different rates, does this reflect differing degrees of "gender-risk"? With respect to reducing disease, does the local epidemiological situation indicate that the infection rate is about to increase sharply?

Finally, examine the legislative valuations. Is the level of traffic risk enough to justify the gender classification? (Compare this question with that of separating race-based gangs in prisons to reduce violence.)Does saving the lives or promoting the health and functionality of fifty people justify a million vaccinations (compulsory? voluntary?) that bear risks Y and Z with probabilities P_Y and P_Z?Is there some constitutionally legitimate way for a Court to address stark legislative valuation problems without simply punting—deferring completely to the legislature?

This account, to be sure, barely scratches the surface in outlining material questions about how courts are to *use* a standard of review.[175] (And in pursuing this, one can push the comparison between *Craig* and vaccination cases too far.)Still, it is instructive to ask if we really know the incidence of hepatitis B carrier status (any more than we know the actual incidence of male and female drunk driving). How many cases would be avoided with a given vaccination program? How many lives would be saved? Can the vaccine-induced fever threaten long-term damage? How effective are the treatments for hepatitis B? Do the likeliest victims in fact have access to treatment? (Vaccination programs are likely to be less expensive than treatment.)[176] Can voluntary programs accomplish the same goals? (Compare the United States with the United Kingdom, Denmark and Sweden, as suggested earlier.)Suppose that they do so only a fraction as well? If we can only show "cause not shown" and not "causation is excluded," can we rightly punish persons for refusing to (in their view) risk autism or multiple sclerosis? Even if rare outcomes are assumed to be vaccine caused, should we still be able to compel?

Where specially protected interests are concerned, questions of this sort cannot be a matter of across-the-board judicial deference. This would be flatly inconsistent with acknowledging a fundamental right or a liberty interest (or, in

175. The difficulties in specifying plausible operational meanings for standards of review are vividly illustrated in a recent bout between the demands of First Amendment strict scrutiny and the need to defer to expertise even within that realm. *See* Holder v. Humanitarian Law Project, 130 S.Ct. 2705, 2727 (2010), upholding a statute banning "material support or resources" to foreign terrorist organizations. One infers that strict scrutiny was used because the Court stated that the intermediate standard in *United States v. O'Brien*, 391 U.S. 367 (1968), was insufficient; absent a spectrum approach to standards of review, the next threshold up is strict scrutiny. 130 S.Ct. at 2723.

176. *See, e.g.*, Peter A. Muennig & Kamran Khan, *Cost-Effectiveness of Vaccination Versus Treatment of Influenza in Healthy Adolescents and Adults*, 33 CLINICAL INFECTIOUS DISEASES 1879 (2001).

other contexts, a suspect or semi-suspect classification). It is likely that the Court will kick such questions to the legislative black box as often as it can it can, but every quantum of deference raises the question about whether we are taking our constitutional value rankings seriously.

4. Additional Moral Analytics, Some of Which Should be Absorbed Into Constitutional Adjudication.

There are some additional moral issues to discuss here, and they raise in turn the question of how courts are to address them within constitutional law. Would it be sound constitutional jurisprudence for the Court, say, to address Judith Jarvis Thompson's discussion of why a woman can dislodge the famous violinist stuck to her (for nine months) so her kidneys could help his own to recover?[177] Is "independent judicial moral analysis" the only way to address this thought experiment? For present purposes, however, I leave the issue aside and note only a few points.

■ *Reinforcing a culture of coercion.* I have suggested the need to analyze any cluster of rights dealing with the integrity of the self, a phrase I use to refer to the personal boundary problems of insulating body, mind, and identity from unwanted intrusion. (It may also extend to their (re)construction and the adjustment of their boundaries.) One analytic variable concerns the risk that any form of government compulsion will reinforce a culture of coercion. Of course, putting it this way risks a "this proves too much" response: all government is morally unsound within this framework. The point can be cabined (to a degree) by noting that the main risk occurs when we move beyond some standard, ineradicable baseline—e.g., we are all subject to tax and traffic law enforcement, even in a minimal state. Coercion by government (and in certain private interpersonal situations) is often essential, but it ought, in a liberal society, to be confined to furthering significant purposes. Vaccination does seem important in this sense, but the example of large-scale voluntary vaccination in places other than the United States is impressive.[178] So is the absence of physical force in U.S. vaccination programs. Why is coercion through the threat of penal or civil sanctions needed to achieve high vaccination compliance levels, and on what standard of need? The spectacle of unneeded coercion reinforces authoritarian behavior and our preferences for it. This is a human inclination that does not need to be beefed up; we are already overly inured to it.

This focus on norm and behavior change is not only a relevant moral approach (despite its gossamer nature), it also appears in judicial defenses of fundamental rights, sometimes in fairly simple form.[179] Consider these linked

177. *See supra* note 165and accompanying text.

178. *See,e.g., supra* note139.

179. N.Y. Times Co. v. Sullivan, 376 U.S. 254, 270 (1964) ("Thus we consider this case [defamation of a public official] against the background of a profound national commitment to the

claims:

> The state already applies coercion to many of our daily activities. Do we want to live in the sort of society that extends coercion to routine immunization? At present, many industrialized countries achieve high levels of immunization without the need for compulsion. If such high levels can be maintained through encouragement and incentives, this effectively achieves the aims of the moderate communitarian, without the need for legislation. Compulsory immunization would be certain to inflame those who already believe that their Government interferes too much with their freedom. What is more, coercion may alter perception of risk. People who are coerced into an action may be more likely to perceive the action as being risky than if they are persuaded into it. Recent examples, albeit adult rather than child, have been the mandatory immunization of military personnel against anthrax and smallpox, which led to many protests and loss of confidence. Most parents trust the assurances of health care professionals that the benefits of immunizing their child outweigh the risks. Making immunizations compulsory renders trust redundant. If State coercion can be avoided in the area of routine childhood immunization, so much the better. . . .[I]n order to respect autonomy, State coercion should be kept to a minimum. We believe that, in general, children should not be compulsorily immunized when similar results can be achieved by education and inducements. Australia is in the happy position of having achieved very high rates of routine childhood immunization, over 90%, without the need for compulsion.[180]

Perhaps this is an occasion for what is now sometimes called "empirical philosophy," which seems also to be a branch of psychology.[181] How would we test the risk that a given program of government coercion would adversely shift felt moral values and resulting behavior? If there is such a risk, how does it

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principle that debate on public issues should be uninhibited, robust, and wide-open, and that it may well include vehement, caustic, and sometimes unpleasantly sharp attacks on government and public officials."). The Court invalidated common law and statutory provisions allowing defamation recoveries against public officials without a showing of malice. *See also* Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue, 460 U.S. 575, 585, 592 (1983) (striking down a tax that appeared to the Court to "single out" the press, thus "undercutting the basic assumption of our political system that the press will often serve as an important restraint on government"). There had been no showing of any legislative motives impermissible under the First Amendment. *Id.*

180. Isaacs et al., *supra* note 34, at 395; *see also* P. Bradley, *Should Childhood Immunisation Be Compulsory?*, 25 J. MED. ETHICS 330 (1999) ("Compulsory vaccination cannot, with very few exceptions, be justified in the UK, in view of the high levels of population immunity which currently exist.").

181. *See generally* John Doris & Stephen Stich, *Moral Psychology: Empirical Approaches*, STAN. ENCYCLOPEDIA OF PHIL. (Apr. 19, 2006), http://plato.stanford.edu/entries/moral-psych-emp.

compare with the risk that in the United States, voluntary vaccination programs may not be adequate to the task of securing high compliance?[182] Does requiring parents to submit their children for vaccination erode our culture of familial autonomy—a culture that is of constitutional status? Many vaccination controversies concern the rights of parents to control the nurture and upbringing of their children.[183]

■ *The entanglement of individual rights assertion and community and government interests.*[184] I said earlier (Section III.E.4) that that rights-assertion stage and the government-societal interests stage flow into each other, but the point now is somewhat different. The "ping pong" I referred to concerns the continuing revaluation and possible recharacterization of something *as* an interest or right, or as one bearing a certain strength. The idea here, however, is that (on the one side) there are communitarian interests in preserving individual rights, as well as in preventing disease, and that (on the other) individual assertions of right are not asserted in a social vacuum: they are asserted against others, who have their own rights and interests, and their very description implicates concerns that may or may not be opposing.[185]

■ *Paternalism.* There is no call to review the mounds of commentary on paternalism generally and medical paternalism in particular. Claims of authority (government or private) to override individual choice are often based, not on harms likely to be inflicted on others, but solely on benefits to the person coerced or influenced (often through preventing harm to her). It is sometimes hard to disentangle such paternalism from coercion taken to avoid "externalities," but the motivations are in theory distinct.[186] Parallel difficulties are sometimes encountered in vaccination policy. Compelling adults to be vaccinated, for example, might be considered paternalistic because those who want to avoid infection can simply arrange for their own vaccination. This is not a fully

182. See the discussion of the limits of persuasion in James Colgrove & Ronald Bayer, *Manifold Restraints: Liberty, Public Health, and the Legacy of* Jacobson v Massachusetts, 95 AM. J. PUB. HEALTH 571, 573-74 (2005).

183. Bradley, *supra* note 180, at 331-32.

184. I do not mean to conflate society and government or their interests. However, in constitutional adjudication, the government is generally the voice of the community, despite the fact that individual rights claims *may be* communitarian claims of a sort within a liberal society. *See infra* note 186 and accompanying text.

185. *See generally* John Tomasi, *Individual Rights and Community Virtues*, 101 ETHICS 521 (1991) ("Rights are conflict notions.").

186. Crash helmet laws illustrate the point. Those who oppose these laws usually ignore the costs (monetary and otherwise) imposed on others who feel constrained by morality and social norms to rescue them, or deny that these costs can rightly be viewed as significant harms to others (especially if the cyclist is willing to die untreated). *Cf.* Ruth Faden & Sirine Shebaya, *Public Health Ethics*, STAN. ENCYCLOPEDIA OF PHIL. (Apr. 12, 2010), http://plato.stanford.edu/entries/public health-ethics ("Defenders of compulsory motorcycle helmet laws, for example, argued that the serious head injuries sustained by unprotected cyclists diverted emergency room personnel and resources, thus harming other patients.").

effective response because of incomplete vaccine effectiveness and uncertain access to vaccination services, and because of the need to protect children, most of whom cannot just hop in the car and go to the nearest vaccination site. In any case, "this is paternalism" is not necessarily a decisive objection in all contexts, even when understood to be confined to the competent and fully informed (or at least to those who had a fair opportunity to be fully informed).

Antipaternalism is not an explicit theme in Professor Holland's Article, but it surely is implicit in some of the accounts it refers to. No classical liberal is entirely comfortable with paternalism, but it seems quite clear that sometimes others *do* know better than you what is in your best interests, however competent you are. Friends do not let friends do really stupid things. And we are not supposed to let children run amok. (Protecting children is, etymologically, the archetype of "paternalistic" action.)But here we are talking about government or community paternalism, and even if government often is a force for good, it is not generally your close personal friend. A *practice* of government paternalism may easily do more harm than good, especially if there is a slippery slope nearby.

A plausible if not entirely convincing case of justifiable paternalistic compulsion rests on a rough distinction between short and long run autonomy. The imposition of coercion now, by avoiding future compromises of one's health and thus impairments of one range of opportunities, thus helps assure greater autonomy over a far more extended time. Compulsory vaccination is then defended on this ground, possibly padded by reference to familiar human frailties such as limited time horizons and "it can't happen to me" attitudes.

But whatever the merits of paternalistic approaches, we need to consider its application to vaccination. Not all aspects of compulsory vaccination reflect paternalistic reasons, but I do not try to untangle these strands here. I simply note that some unvaccinated persons *will* come down with avoidable sickness, and there *will* be costs not only to individual autonomy, but also to social interests. So paternalism and protection of society are conceptually and empirically intertwined.[187]

There is, however, a major benefit to antipaternalistic movements, even if they go too far. They act as a check on excessive power by government and by health care personnel.[188]Constraints on government that might seem foolish in particular instances might be justified as an institutionalized check on government—particularly its expansion in areas of important rights.[189]

187. One could maintain that they are intertwined even when each individual act contemplated is purely paternalistic because the practice and the scale of paternalism affect the nature of society and thus human interaction.

188. *See, e.g.*, Matthew McCoy, *Autonomy, Consent, and Medical Paternalism: Legal Issues in Medical Intervention*, 14 J. ALTERNATIVE & COMPLEMENTARY MED. 785, 786 (2008) (stating that there has been a shift from paternalism and that one effect has been the development of patient-centered informed consent doctrine).

189. *See generally* Vincent Blasi, *The Checking Value in First Amendment Theory*, 2 AM. B.

The relevance of analysis of paternalism to constitutional argumentation is clear enough, although the applicable doctrine may not be explicit. At the Supreme Court level, at least in modern times, the idea that paternalism is entirely illegitimate has not been vindicated. It does not work, as a *constitutional* argument, to say that some *weak* forms of paternalism motivations cannot properly underlie intrusions on specially protected rights.[190] As a matter of moral

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FOUND. RES. J. 521 (1977).

190. On "weak" paternalism (e.g., short-term interference to promote longer term goals), see Gerald Dworkin, *Paternalism*, STAN. ENCYCLOPEDIA OF PHIL., http://plato.stanford.edu/entries/paternalism (last updated June 1, 2010). There seems no straightforward rejection of all claims to all forms of paternalism as a legitimate interest under the rational basis test. Under heightened scrutiny, the situation is more complex: certain forms of weak paternalism may be permissible under such review, but strong paternalism is not a strong candidate for a compelling or important interest, even if it is legitimate. For example, in *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 846 (1992), the Court ruled that "[b]efore viability, the State's interests are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman's effective right to elect the procedure." The principal state interest identified by the Court was potential life—which clearly does not sound in paternalism: "On the other side of the equation is the interest of the State in the protection of potential life." *Id.* at 871. But some measures to protect the woman against her own decisions may be permissible as long as she retains the right to make "the ultimate decision." *Id.* at 877. Thus: "In attempting to ensure that a woman apprehend the full consequences of her decision, the State furthers the legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed." *Id.* at 882. It remains, as Justice Holmes suggested in his *Lochner* dissent, that the Fourteenth Amendment does not implement Herbert Spencer's Social Statics. *Lochner v. New York*, 198 U.S. 45, 75 (1905). *See generally* 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 507 (1996) (invalidating a ban on price advertising of liquor, and stating that "[s]uch speculation [on whether price advertising increases liquor consumption] certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends"). The standard of review was "the less than strict standard that generally applies in commercial speech cases." *Id.* at 507. Rigorous constitutional scrutiny does seem to embrace the antipaternalistic "shibboleth" Justice Holmes complained about in *Lochner*. But it is not excluded as a legitimate interest under minimal scrutiny, and some weak forms seem permissible under heightened review, as *Casey* indicates. In *Walters v. National Ass'n of Radiation Survivors*, 473 U.S. 305 (1985), a case upholding a limitation on the fee that veterans may pay to attorneys or agents representing them in trying to obtain certain benefits from the Veterans' Administration, the Court stated the following:

> It is not for the District Court or any other federal court to invalidate a federal statute by so cavalierly dismissing a long-asserted congressional purpose. If "paternalism" is an insignificant Government interest, then Congress first went astray in 1792, when by its Act of March 23 of that year it prohibited the "sale, transfer or mortgage . . . of the pension . . . [of a] soldier . . . before the same shall become due." Acts of Congress long on the books, such as the Fair Labor Standards Act, might similarly be described as "paternalistic" . . . .[*Lochner*'s] day is fortunately long gone, and with it the condemnation of rational paternalism as a legitimate legislative goal.

Id. at 323 (first four alterations in original) (citation omitted). This was not a heightened scrutiny case. Justice Stevens dissented (joined by Justices Brennan and Marshall, dissented, arguing that the Court had undervalued individual liberty and (operationally) implementing more rigorous scrutiny than did the Court, and criticizing the paternalistic justification as—in this case—irrational. *Id.* at 367.

analysis, one might conclude differently.

V. ADDITIONAL CRITICISMS.

A. Conflicts of Interest: the Vaccine Manufacturers (and Others) Want to Make Money.

I say people are no damn good. Human motivation is not always to do right by others, or (perhaps) even oneself. Some may even think it wrong to try to do right by others. I do not name names. But if we say all human action labors under a conflict of interest then we fail to mark out those special conflicts warranting legal (or other special) attention. Removing a judge or disbarring a lawyer on conflict-of-interest grounds requires more than claiming that they were (say) simply trying to advance their careers even when rendering the soundest decisions. Every judge is under an incentive to write praiseworthy opinions for personal advancement, not solely to serve society. There is a baseline of individual "aggrandizement" that is largely ineradicable and does not count as legally indictable, though it poses ongoing moral risks.

So, we should, *of course*, be skeptical about most vendor claims of perfection and safety. But how does this skepticism play out operationally? Physicians want business. They want you to consult them—we still have direct fee for service transactions, which reinforces this incentive. And if patients avoid Dr. K. at the local HMO, where there may be no direct pay for service, they might not last long there. Patients have to keep coming, so physicians will say what they need to say to keep and gain customers. Therefore, do not believe anything physicians say, right? As for pharmaceutical companies—do not take any analgesics, even over the counter: their developers and sellers just want to make money, whatever the risks to you.

Of course, this is hyper-hyperbolic. The Article was far from simply dismissing vaccines as lethal and ineffective. Their value and safety, however, are called into question, less pointedly, but nonetheless clearly. Professor Holland, for example, speaks of the "culture of conflicts of interest" and discusses at some length the "Financial Distortions in the Hepatitis B Mandates." She states, "The vaccination of four million infants per year yields a substantial annual income stream in the hundreds of millions of dollars," and she lists among the distorting factors "advisers' financial ties to vaccine manufacturers."[191]

Although I would not align vaccine manufacturers with those offering to sell the Brooklyn Bridge, the skeptical stance about vaccine quality is well taken as a *part* of a rational process of evaluating vaccination programs. This is no small task, since most of us cannot run biomedical research projects and there is a problem of evaluating qualified evaluators: they too would like to earn a good

191. Holland, *supra* note 5, at 77.

living. Nor is the conflict of interest problem confined to decentralized economic systems. But we are not about to dismantle capitalism, its markets, and government, so there will *always* be a basis for skepticism about many claims by many contracting parties. What do we do as consumers, then? We try to reduce any incremental, over-the-baseline risks to the public interest arising from incentives for individual or institutional aggrandizement, and we try to do it without unduly impairing the productive enterprise. It is pretty hard to do both, and the risks are largely non-eliminable. The list of standard public-protective measures is not that hard to formulate, but most of them bear internal tensions. We can say that vaccine evaluators should have minimal ties, if any, to vaccine manufacturers and distributors; but such evaluators were not trained in a vacuum: any competent researcher will know others in the field, and many of the best work for or with Pharma. Disallowing ties means losing able consultants, some of whom may in fact be sufficiently objective to render a reliable judgment, regardless of appearances.

How do we implant conflict of interest considerations into vaccine policy and constitutional analysis? The Article is not entirely clear on this. It does not call for shutting anything down. But, if we do not do so, how do we reduce risks and exercise due care? And what do we do about the hepatitis B vaccine in this light? If we cannot rely on need, efficacy, and safety claims, because of commercial (or other) incentives to lie, withhold, or distort information, why should we even permit voluntary vaccination?

The constitutional analysis is fairly straightforward, if imprecise. Conflicts of interest within the vaccination and other healthcare establishments pose risks to persons who are being compelled to accept treatment. If safety and efficacy conclusions are tainted by improper motivations and techniques, government justifications for coercion are correspondingly weakened or fail altogether. This is an analytic line one would expect (and sometimes demand) under heightened scrutiny. The parallel to Justice Brennan's attack on Oklahoma's methodology in *Craig* is clear. He raised the possibility of skewed motivations of the police in arresting more males than females: "[R]eckless young men who drink and drive are transformed into arrest statistics, whereas their female counterparts are chivalrously escorted home."[192] This did not establish that Oklahoma's conclusions were false and that the gender classification had no adequate foundation, but the asserted methodological flaws were taken to foreclose the government from confidently drawing its inferences about differential risks. Those inferences were not thought, in *Craig*, to warrant strong deference, if any. The surveys, as presented to the Court, did not, in Justice Brennan's view, *facially* exclude *nontrivial risks of impaired methodology.* Whether Justice Brennan's analysis was done well is arguable, but I think he was constitutionally obliged to pursue this general line of inquiry into the methodologies for gathering

192. Craig v. Boren, 429 U.S. 190, 203 n.14(1976).

data and drawing inferences from them, *given the elevated status of the individual constitutional interest involved.*

Still, skewed and conflicted motivations are intrinsic problems in every study *and every marketing effort.* This is why clinical trials generally require (where practicable) double-blind studies, and why pharmaceutical salespersons are not always taken at their word. And, this is why we are *always* at risk, whether we take a dose of ibuprofen or hepatitis B vaccine. Although they are obviously not the only source of risk, "baseline" conflicts of interest are inherent in human action and cannot be shut down. There is, then, no reason for automatic deference to the label or the package insert or to a physician's claim.

Nevertheless, in pursuing heightened scrutiny of empirical claims that inform risk assessment, courts should inquire into the presence of serious, ameliorable risks that exist *atop* the baseline incidence of mixed incentives that may compromise the public interest. When operating within such scrutiny, total reliance on legislative and administrative findings and inferences is inappropriate.[193] "The primary problem with legal conflict-of-interest doctrine is that it fails to recognize conflict of interest as a type of risk analysis aimed at setting *acceptable risk levels* regarding perverse incentives."[194] The point is as applicable in vaccinology as it is in regulation of the legal profession.

B. Impaired Informed Consent Processes

Professor Holland's central point here is that legislative and administrative law and practice has impaired the informed consent process in the administration of vaccines. If this process is compromised, then the government compulsion system is not effectively narrowed to reduce the costs to the assumed liberty interest at stake. Securing informed consent is at the core of protecting the integrity of the self, which is in turn the substance of the liberty interest.

Few claim that lack of perfect information means forecloses informed consent. Nor does confusion about one's preferences or the moral requirements of caring for oneself, one's family, and others render informed consent impossible. The few who say otherwise are using the concept of informed consent unsoundly. Such excess does not appear in the Article. But, the claim that informed consent—and, thus, autonomy and constitutional liberty—have been unduly burdened in the vaccine area is not clearly shown. The author argues:

193. *Cf. Holder v. Humanitarian Law Project*, *supra* note 176, 130 S. Ct. at 2727-28 (addressing the tension between heightened scrutiny and deference to government findings).

194. Kevin C. McMunigal, *Conflict of Interest as Risk Analysis*, *in* CONFLICT OF INTEREST IN THE PROFESSIONS 61, 62 (Michael Davis & Andrew Stark eds., 2001) (emphasis added); *see generally* CONFLICTS OF INTEREST IN CLINICAL PRACTICE AND RESEARCH (Roy G. Spece, Jr. et al., eds., 1996).

> The norm of informed consent in medicine requires doctors to provide extensive information about the known risks of interventions to patients and to allow the patients to make the ultimate decisions. Similarly, drug manufacturers are required by law to provide accurate and complete information about drug risks with their products. In vaccination law, however, these norms are substantially relaxed. The NCVIA does not require doctors or vaccine manufacturers to give complete warnings directly to the person or guardian of the child being vaccinated. It requires that doctors give government-produced information and requires that manufacturers provide proper warnings to doctors only, who are considered to be "learned intermediaries." Both industry and the medical community lobbied for this lowered standard.[195]

A legally imposed impairment of informed consent surely threatens our posited constitutional liberty interest in resisting vaccination. A law forbidding transmission of significant efficacy and safety information to prospective vaccinees would be unconstitutional under any version of heightened scrutiny, and possibly even under the rational basis test.[196] What about a law forbidding disclosures about claimed adverse events because they would be prejudicial and result in some persons losing needed vaccination protection? Same result. Suppose there was a law requiring that *all* adverse event reports be made available to vaccinees. Such a law would probably not be unconstitutional because of the marginal relevance of the undifferentiated mass of such reports.

But, the Article's claim that informed consent requirements have been seriously compromised by the law seems overstated. What does "complete" ("complete warnings" are not required) mean? No legal regime of informed consent requires disclosure of every conceivable risk. And, exactly why is the manufacturer required to directly inform the vaccinee? Could this be via package insert? Or manufacturers' representatives at the vaccination site? Does the law displace existing state doctrine concerning physicians' duties to disclose? Neither the National Childhood Vaccine Injury Act of 1986 nor the Court's opinion applying portions of it in *Bruesewitz v. Wyeth* seem to preempt state-imposed duties (whatever they are) on physicians; they only address the matter of design defects and duties to warn by manufacturers.[197]

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195. *Holland* at 79.

196. Some may think otherwise in special settings, e.g. the military or health professions. *See, e.g.*, George J. Annas, Opinion: *Don't Force Medical Pros to Get H1N1 Vaccine*, NEWSDAY, Oct. 3, 2009, http://www.newsday.com/opinion/opinion-don-t-force-medical-pros-to-get-h1n1-vaccine-1.1496620.

197. *Holland* states (*id.* at 59) (my remarks are in bracketed italics): "Complementing manufacturers' relief from disclosure requirements *[As argued, this seems quite overstated]* another provision exempts doctors from substantial federal disclosure requirements. *[Not clear what this means.]*It tasks the HHS Secretary to 'develop and disseminate vaccine information materials.' It

The federal law probably should have been more explicit, as the author suggests, but I do not think the Article shows that informed consent and therefore a constitutional liberty interest in personal security is compromised under the 1986 law. It is not clear exactly what the author wants done by manufacturers or physicians, although she refers to proposed state legislation requiring physicians to provide the package insert.

C. Unrepresentative Decision-making

This framework of criticism of vaccine policy is closely related to the concerns about conflicts of interest. Professor Holland states:

> Part of *Jacobson*'s rationale for deference to state legislatures was their representative nature; legislatures by their nature must take account of differing views in the population. If the legislature makes bad choices, the electorate can reverse those choices and unseat the legislators through popular elections. But ACIP [Advisory Committee on Immunization Practices][198] has become the driving force behind vaccination mandates, a federal advisory body with almost no public participation and no direct accountability to voters. Because of this change in the locus of true decision-making from legislators to ACIP, there are far greater risks of conflicts of interest. ACIP advisors have strong ties to industry, and financial and professional self-interest may outweigh public health in their decision-making.[199]

I do not know what theory of democratic representation is presupposed here. It seems to be assumed that if someone is not simply part of the lay citizenry, she

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states that these materials should outline the benefits and risks of vaccines and the availability of the VICP. Doctors are obliged to provide families with these information materials." I don't fully follow this. From which disclosure requirements are physicians exempted? If the idea is that the federal provisions preempt basic aspects of state informed consent laws, the point needs to be argued more clearly. *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011), doesn't seem to address this. It held that National Childhood Vaccine Injury Act preempted *design-defect* actions brought against vaccine manufacturers. The Court noted: "Manufacturers are generally immunized from liability for failure to warn if they have complied with all regulatory requirements (including but not limited to warning requirements) and have given the warning either to the claimant or the claimant's physician." *Id.* at 1074. True, this portion of the Act doesn't refer precisely to physicians, but it doesn't purport to relieve them of any liability either. The Act provides: "Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C.A. § 300aa-22(a)(West 2011). There is an expressly labeled preemption section: "No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part." *Id.* §300aa-22(e).

198. *See* 42 U.S.C.S. § 217a (West 2011), concerning the creation of advisory councils and committees for the Secretary of Health and Human Services.

199. Holland, at 77.

cannot "represent" it, despite the fact that members of government advisory committees are expected to act for the public interest, and not *just* some distinct constituency.[200] But, depending on their function, they can be aligned with particular groups. Indeed, why else would government seek to appoint members of *particular* groups in its quest for "representative" bodies? Members of government agencies and advisory groups are understood to be linked to a variety of frameworks, while at the same time operating under a public interest ideal. If this seems paradoxical, so do democracy and the very idea of objectivity. I do not think that Professor Holland would deny any of this, but, given her critique, one needs to recall that the duty to promote the public interest does not lie in having no definable perspective, but in being able to enter in some way into the perspective of others. As Thomas Nagel put it, "As in metaphysics, so in the realm of practical reason the truth is sometimes best understood from a detached standpoint; but sometimes it will be fully comprehensible only from a particular perspective within the world."[201]

It is thus not inconsistent with either democracy or the pursuit of sound public policy for persons exercising certain forms of government power to represent particular constituencies; it depends on the nature of the enterprise and what "representation" means in a given context. It is neither possible nor desirable for people to escape or elude all frameworks of interest, include some frameworks that are in tension with others. We do not and cannot function outside all value frameworks. To try to wrench ourselves from this reality *would* impair the public interest.[202]

To be sure, political representation, even if meant to provide a voice to certain interests, is supposed to be exercised with a degree of objectivity that avoids blind fanaticism. Certainly, not everyone can be trusted to work with appropriate objectivity or detachment all the time, but it seems unreasonable to impose, across the board, either some sort of proportional representation requirement (which presupposes *interest* representation) or a populist template

200. Although the law setting up the National Vaccine Advisory Committee doesn't use the term "public interest," the mandate of the Committee is inconsistent with simple representation of discrete partisan interests. *See* National Vaccine Program, 42 U.S.C.A. § 300aa-5 (West 2011). The Administrative Procedure Act is strewn with references to promoting the public interest. 5 U.S.C.A. § 551 (West 2011). In any case, as I argue in the text, an administrative committee member who acts (at least not blindly or reflexively) for a particular constituency or interest is not *necessarily* opposed to the public interest. In fact it is undemocratic and may damage the public interest systematically to *prevent* specialized or partisan representation across the board, in all forms. Context is critical.

201. *Cf.* THOMAS NAGEL, THE VIEW FROM NOWHERE 140 (1986). Nagel also urges that "the detachment that objectivity requires is bound to leave something behind." *Id.* at 87.

202. Suzanne Dovi, *Political Representation*, STAN. ENCYCLOPEDIA OF PHIL., http://plato.stanford.edu/entries/political-representation/#DelVsTru (last updated Oct. 17, 2011)(discussing, among other things, "interest-group pluralism, which [Melissa] Williams describes as the 'theory of the organization of shared social interests with the purpose of securing the equitable representation . . . of those groups in public policies'").

(undifferentiated peoplehood, no "elites")[203] onto all administrative advisory committees. In any case, "public members" are likely to have crystallized views on one side or another of many programs, whether concerning vaccine policy or sewer construction. Some administrators "representing the public" will be partisans or activists for some distinct position: there is no univocal mass public viewpoint.

Of course, I do not all claim that, for administrative representation, "It's all good."I concur with many seriously misanthropic views and assume that many agencies are often embarked on mischief. But much more is required than is shown in the Article before any case is made out that vaccine policy is so "distorted" that it needs to be upended in order to save it (if it is to be saved at all). Indeed, it is hard to state what the baseline for nondistortion might be. Members of the ACIP will, in the aggregate, hold many preexisting and competing points of view, and this does not automatically make that body "unrepresentative" or render their respective interests "conflicted," or keep them from trying in good faith to promote the public interest.

A particular complaint about unrepresentativeness is (quoting Belkin) that "the interests of newborn babies were not represented on the original panel that created this vaccination policy in 1991."[204] But the bare objection that newborns (and perhaps those unconceived when the vaccination policy was adopted) are not "represented" is a nonstarter in almost every argument.[205] What would it mean to "represent" them? Who could do so? Persons trained to imagine themselves in "the original position" behind "the veil of ignorance" made famous by John Rawls?[206] People who expect to be newborns once again? Whether one should be attentive to the interests of future persons, whatever their designation—contingent, certain, possible, potential—is one thing, but vaccine policy does not demonstrate a representational failure for failing to do the impossible. (True, someone can simply be designated as an official "representative" for the unconceived, but it is hard to see how this renders him or her a true representative in any plausible sense.)

Perhaps the argument from nonrepresentativeness is meant as the beginning of a critique of modern American administrative law generally, or at least in the health care area. If so, much more is required to make out a case.

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203. *Cf.* Margaret Canovan, *Trust the People! Populism and the Two Faces of Democracy*, 47 POL. STUDIES 2, 3 (1999) (explaining it as "an appeal to the 'people'").

204. *Holland* at 76.

205. Compare this to the issue of obligations to future or possible persons. *See generally* DAVID HEYD, GENETHICS: MORAL ISSUES IN THE CREATION OF PEOPLE 13, 24 (1992).

206. JOHN RAWLS, A THEORY OF JUSTICE 11 (Revised ed. 1999).

D. Communicable Versus Noncommunicable Disorders; Self-Protection Against the Unvaccinated

The prime target of vaccination policy is communicable disease (e.g., smallpox). But if one is really worried about getting such a disease, one need only get a vaccination, right? So, protect yourself; you do not need to try to compel others to do things that threaten you when you can easily blunt the threat. Moreover, for those disorders often caused by avoidable behaviors—drug use, sex—one can seriously reduce or eliminate the risk by in fact not pursuing the dangerous conduct.

If all this is so, what could justify the invasion of the liberty interest—even if the liberty interest were not *that* valuable? If coercion is either useless or unnecessary given the possibility of behavior change, invasions of even minor liberty interests are not justified.

Moreover, some diseases with corresponding vaccines are not communicable or contagious.[207] One rationale for compelled vaccination against such noncommunicable diseases is the protection of pregnant women whose children may become infected, as noted by Professor Holland.[208] But the simplest justification is just that it secures children against a genuine risk of physical harm and of interference with their education. This justification withstands a paternalism objection where children are concerned, although the parental autonomy objection has not withered away. For adults, however, the argument would be that, with no parents egging them on, they would simply delay, even though their rational selves would know that this is unduly risky.[209] This weakness-of-will framework is a standard criterion in efforts to justify forms of weak paternalism.[210]

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207. At least one source suggests that contagious diseases are simply highly communicable diseases. Communicable diseases are infectious diseases that can be transmitted from one person to another. Infectious diseases are those caused by microorganisms. *Controlling the Spread of Contagious Diseases: Quarantine and Isolation*, AM. RED CROSS, http://www.redcross.org/preparedness/cdc_english/IsoQuar.asp (last updated Feb. 23, 2006).

208. *See* Holland, *supra* note 5, at 51.

209. *See generally* Horlick et al., *supra* note 139, at S80("Laws are also used to require vaccinations against diseases for which herd immunity and free-riding do not play a role ([*e.g.*], tetanus, because there is no human-to-human transmission). The principal justification for a law in this setting is not to build herd immunity or prevent free-riding but simply to protect the child against an infection. Also, an argument can be made that these non–herd-immunity vaccines prevent harm to others by reducing the burden of health care costs caused by the diseases prevented. However, the principal rationale for the laws is simply the determination by society that the beneficence (avoidance of disease in the individual vaccine recipient) represented by a legal requirement outweighs the infringement on individual autonomy. Society has made the same determination for many other public health interventions, including, for example, motorcycle and bicycle helmet laws.").

210. *Cf.* Danny Scoccia, *In Defense of Hard Paternalism*, 27 L. & PHIL. 351 (2008); Gerald Dworkin, *Paternalism*, STAN. ENCYCLOPEDIA OF PHIL., http://plato.stanford.edu/ entries/paternalism (last updated June 1, 2010)(explaining that a weak paternalist holds it permissible to interfere with

The argument based on voluntary self-protection against communicable diseases implicates some connected points. Although it varies with age, children are generally far less capable of securing healthcare on their own than are adults. Moreover—a point that comprehends both adults and children—vaccination is not one hundred percent effective, so that one's risks of infection go up when the proportion of vaccinees in the population goes down. The greater the herd immunity, the safer one is.

Still, those who do not get vaccinated at all—saving some money and time—are free riding, relying on the immunity of others, and this is (as with most free-riding) often unfair, inegalitarian, and disutilitarian.[211] This framework for judgment is not much addressed in the Article. To be sure, free riding may seem more or less rational from the individual's perspective.

Finally, the avoidance of behaviors generally disdained—drug use and certain forms of risky sex—remains, at least in the background, as a reason for attacking the compulsory means chosen to further government interests.[212] But not all cases of hepatitis B come directly from such behaviors.

CONCLUSION

Professor Holland's Article provides an occasion for considering how far we should push our notion of rights within American traditions, constitutional and otherwise. True, many things provide such an occasion, but this is the only one that I have been asked to respond to on this occasion.

If Professor Holland wanted to add to the skeptical view of vaccination generally and hepatitis B vaccination in particular, then she has made a contribution. Responding to her arguments requires probing the complex ideas of integrity of body, mind, and identity, their place in constitutional and moral theory, and determining what government must show in order to override claims of right. And she has provided some indication that all is not what we would like it to be in the field of vaccinology and its practice. But her analysis is questionable in certain respects. Here are some points to consider. They reflect

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choice of means that may defeat one's goals).

211. In some regions, vaccinations are free of charge. *See* Horlick, *supra* note 139, at S81 (referring to the United Kingdom).

212. *See* Horlick, *supra* note 139, at S80 ("Some parents may see school-entry laws as displacing their traditional authority to decide what medical treatments their children should receive. These parents assert that they are in a better position to judge the medical needs of their children than the state. The hepatitis B vaccine is a case in point. Since the enactment of hepatitis B vaccine school-entry laws in the early 1990s, concerns have been raised that vaccination mandates are not justified if they are meant to prevent diseases that can be avoided primarily by behavior, such as abstinence from illegal drug use and certain sexual behaviors. The HPV vaccine may be considered by some to fall in the category of diseases that may be avoided by behavior. Concerns have also been raised that vaccination against sexually transmitted diseases in adolescents can increase premarital sexual activity.").

two dimensions of my response: a critique of her arguments as they were presented, and a description of frameworks and arguments that might have been invoked to further her analysis.

The nature of the right against vaccination, and the larger set of rights in which it resides, is not sufficiently made out. Sometimes it seems as if the analysis of risks is the only thing that counts; sometimes it seems as if personal preference, exercised as purely autonomous action, is the only thing that counts. Most of us want to do the right thing, but we do not want to be *made* to do it, even if the invasion of our interests seems minor from a detached perspective. But it is often right—even obligatory—for the community to make us do things over our objections.

The value premises that inform and drive the Article are not clear. These premises concern autonomy and personal integrity, the nature of harms to these interests and to individual and aggregate health, and *the terms in which we consider when it is* worth *it to inflict or allow certain kinds of harm on some persons in order to benefit them and others.* We need more transparency for the process of determining whether and when we should run the risks imposed by x thousand vaccinations in order to save the lives or protect against serious health threats of "only" n persons. Once again, how do we get to the conclusion that this is an "only," not worth the harms and injuries to personal integrity?

The operational meaning of standards of review—how they are applied and why—need greater specification, justification, and elaboration. This is necessary because the very logic of those standards implement our constitutional hierarchies. Because of this, I suggested ways of understanding their nature, structure, and use, and in particular the operational upshot of applying them in given cases.

The argument based on vaccination risk is not made out in the Article. Very few causal links between hepatitis B vaccination and adverse events are established. The Article does not sufficiently acknowledge the difficulties—far beyond recording adverse effects—in establishing causation. Even if causality of rare occurrences is conceded, the argument against compulsion is not made out. Nevertheless, in order to further the analysis, I observed that one can raise rights claims *even where causation of harm is not scientifically made out*, and suggested some arguments in defense of doing so (though I do not find them persuasive).

The Article's constitutional analysis suffers from a hyperextension of *Jacobson v. Massachusetts* and from various technical problems in articulating prior, existing, and projected doctrine. *Jacobson* is not sufficiently "translated" into contemporary doctrine. To that end, I offered an additional parsing of *Jacobson* and analyzed a hypothetical *Jacobson 2.1.*

The constitutional analysis is also burdened by an incomplete analysis of decision-making supposedly compromised by conflicts of interest and inadequate

public representation. Here, I tried to make the nature of the gaps in the Article more precise, but without offering any theories of representation or conflict of interest.

Still, the Article did enough to make us pause before automatically following our physicians' advice to vaccinate. Rarely, one suffers much more than a fever or redness or a sore behind, and most of the time we do not know why (anaphylaxis excepted), although in most cases research and theory strongly suggest no link between vaccination and serious adversities occurring within its *res gestae*. Vaccination advice comes from sources that may be burdened by more than everyday conflicted motivations, thus risking decisions that might work against the interest of some persons and against the public's interest generally. Perhaps the rational thing to do is to keep getting vaccinated (in most cases) and to keep complaining about it (in some cases)—a bit of a clumsy practice, but it is in order.