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## Is State Power to Protect Health Compatible With Substantive Due Process Rights?

*Allan J. Jacobs, M.D., J.D.\**

### INTRODUCTION

Government action to further public health goals sometimes must be both rapid and drastic to be successful. Epidemics of disease can not only kill many people quickly, but can also have a ruinous impact on a society. For example, epidemics of communicable diseases have dealt serious blows, causing demographic and economic devastation to entire civilizations.<sup>1</sup> Injuries or exposure to toxic substances also can seriously damage the health of many people.<sup>2</sup>

The Supreme Court has asserted that the term “public health” means “[t]he health of the community.”<sup>3</sup> It rejected the use of the of an alternative definition: “[t]he ways and means of conserving the health of the *members of a community*, as by preventive medicine, organized care of the sick,

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1. See JARED DIAMOND, GUNS, GERMS, AND STEEL: THE FATES OF HUMAN SOCIETIES 195 (1997) (describing the disastrous effect on North American populations of epidemics introduced by Europeans); see also, generally, WILLIAM ROSEN, JUSTINIAN’S FLEA: PLAGUE, EMPIRE, AND THE BIRTH OF EUROPE (2007) (describing the plague epidemics in the Byzantine and Parthian Empires during the 6th Century and the depopulation and economic devastation to these civilizations as a result. Rosen speculates that these plague epidemics aborted the hitherto successful attempts of Byzantium to conquer the former Western Roman Empire. Rosen further speculates that the weakness of Byzantium and Parthia resulting from these epidemics may have been a necessary factor in the spread of Islam out of the Arabian Peninsula in the 7th Century.).

2. See, e.g., Margaret D. Sanborn et. al., *Identifying and Managing Adverse Environmental Health Effects: 3. Lead Exposure*, 166 CAN. MED. ASS’N J. 1287, 1287-89 (2002) (“[L]ead persists in lead paint, old plumbing and contaminated soil.”). In Ontario, over five percent of children living in urban areas have elevated blood lead levels. *Id.* at 1288. The effects of lead poisoning include anemia, kidney disease, and brain injury. *Id.* at 1288-89.

3. *Whitman v. Am. Trucking Ass’n, Inc.*, 531 U.S. 457, 465 (2001) (quoting WEBSTER’S NEW INTERNATIONAL DICTIONARY (2d ed. 1950)).

etc.,”<sup>4</sup> (*emphasis added*). This second definition is more rational, since it is people, not communities, who acquire disease and injury. Regardless, a public health law can be defined as a systematic governmental measure meant to prevent or ameliorate disease or injury.

Public health statutes, ordinances and regulations may interfere with personal liberties by restricting or imposing behavior or treatment. For example, states can quarantine people with infectious disease,<sup>5</sup> inject vaccines into the bodies of healthy persons,<sup>6</sup> and force patients with diseases to take medication.<sup>7</sup> Sick people are forbidden to procure and use certain substances they believe would help them but which the government deems ineffective or harmful.<sup>8</sup> Restrictions on smoking in public places<sup>9</sup> have been implemented to counter the known dangers of smoking.<sup>10</sup> Fluorides are added to drinking water<sup>11</sup> to prevent dental caries.<sup>12</sup>

Public health laws can pose difficult problems in adjudication. Prompt and extensive government action may be needed to prevent large-scale death or injury, however, the issues involved may be highly technical and

4. *Id.* at 465-66 (quoting WEBSTER’S NEW INTERNATIONAL DICTIONARY (2d ed. 1950)).

5. See generally Michelle A. Daubert, *Comment: Pandemic Fears and Contemporary Quarantine: Protecting Liberty Through a Continuum of Due Process Rights*, 54 BUFFALO L. REV. 1299 (2007).

6. See, e.g., *Zucht v. King*, 260 U.S. 174 (1922) (upholding a city ordinance requiring children attending public schools to be vaccinated); *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (upholding the power of a state to grant the board of health the ability to require and enforce vaccination of inhabitants).

7. See, e.g., *Washington v. Harper*, 494 U.S. 210 (1990) (holding the State has an interest in ensuring the safety of both prison staff and prisoners by providing a prisoner with medical treatment for his illness).

8. See, e.g., *United States v. Rutherford*, 442 U.S. 544 (1979) (holding no terminally ill exception exists to the denial of access to a drug not approved under the Food, Drug and Cosmetic Act); *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483 (2001) (finding no medical necessity exception existed to the prohibition under the Controlled Substances Act on manufacture and distribution of a drug); and *Gonzales v. Raich*, 545 U.S. 1 (2005) (holding that, under the Commerce Clause, Congress may criminalize intrastate manufacture, distribution, or possession of a substance even where states approve its use for medicinal purposes).

9. See, e.g., CAL. LAB. CODE § 6404.5(a)-(b) (West 2007) (“Smoking is prohibited in all enclosed spaces of places of employment. . . ‘Enclosed space’ includes lobbies, lounges, waiting areas, elevators, stairwells, and restrooms that are a structural part of the building.”).

10. See generally *Smoking and Tobacco Use: Health Effects*, CTR. FOR DISEASE CONTROL & PREVENTION, [http://www.cdc.gov/tobacco/basic\\_information/health\\_effects/](http://www.cdc.gov/tobacco/basic_information/health_effects/) (last visited Dec. 5, 2010).

11. See Ruth Roemer, *Water Fluoridation: Public Health Responsibility and the Democratic Process*, 55 AM. J. PUB. HEALTH 1337, 1337 (1965); see also Douglas A. Balog, *Fluoridation of Public Water Systems: Valid Exercise of State Police Power or Constitutional Violation*, 14 PACE ENVTL. L. REV. 645, 645 (1997) (for a more recent discussion).

12. See Roemer, *supra* note 11, at 1337; Balog, *supra* note 11, at 646.

difficult for non-scientists, including lawyers and judges, to understand. These issues may require comprehension of complex biological processes or understanding of mathematically sophisticated statistical inferences.<sup>13</sup> Judges may have to make decisions based on scientific data that they do not thoroughly understand, leading to far-reaching decisions with significant impact on individual liberty.

Finally, inaction motivated by respect for individual rights may result in externalities causing grave harm to third parties. For example, if a Typhoid Mary is not barred from her career in food preparation, then the bacteria she carries have the potential to cause illness or death to the numerous patrons at restaurants, diners, cafeterias, etc.<sup>14</sup> Thus, courts are asked to resolve conflicts involving either complex technical issues, measures which may be adopted or imposed in haste, or both simultaneously. They may have to choose between averting grave threats to the population and crimping important liberties.

The United States Supreme Court has, in some cases, upheld state claims of police power in the service of public health against individual claims of due process rights.<sup>15</sup> In other cases, however, the Court has upheld individual rights against state police power.<sup>16</sup> Some writers claim that these two lines of cases are incompatible.<sup>17</sup> This article will illustrate that the tension between individual rights and use of state police power in these Supreme Court cases can be rationally reconciled. It will frame a doctrinal approach involving two concepts, each of which is compatible with

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13. See, e.g., *Indust. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 611-12, 631 (1980) (This case fills 117 pages of United States Reports and decided which of two seemingly incompatible mandates in the Occupational Safety and Health Act (OSHA) was applicable to concentrations of benzene in the air. It chose to require OSHA to set a standard that "most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity," 29 U.S.C. § 655(b)(5) (2006), rather than allowing a standard that merely required regulations that assured conditions "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. § 652(8) (2006). The statute required OSHA to base standards on "research, demonstrations, experiments, and such other information as may be appropriate," and to consider "the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." 29 U.S.C. § 655(b)(5). The opinion notes that "the written explanation of the standard fills 184 pages of the printed appendix." *Indust. Union Dep't*, 448 U.S. at 631.).

14. Janet Brooks, *The Sad and Tragic Life of Typhoid Mary*, 154 CAN. MED. ASS'N J. 915, 915-16 (1996).

15. See, e.g., *Compagnie Francaise v. La. State Bd. of Health*, 186 U.S. 380, 393 (1902); *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905); *Zucht v. King*, 260 U.S. 174, 177 (1922).

16. See, e.g., *Roe v. Wade*, 410 U.S. 113, 163 (1973); *Planned Parenthood of S.E. Pa. v. Casey*, 505 U.S. 833, 879 (1992).

17. See, e.g., B. Jessie Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 279-80 (2007).

Supreme Court public health jurisprudence, if not implicit in it.

This article will first demonstrate that courts have used a unique standard of scrutiny in public health cases. Constraints imposed by dicta in *Jacobson v. Massachusetts*<sup>18</sup> can be generalized to articulate a common standard, termed here, “enhanced public health scrutiny.” This standard is less stringent than strict scrutiny in that it does not require adoption of the narrowest possible remedy. Second, it will characterize the beneficiaries of public health laws as those persons who would actually suffer injurious consequences from the government’s failure to act. The identity of these individuals, however, often cannot be determined in advance. Individuals who would sustain a specific illness or injury, but who are unidentifiable prior to such an event and whose harm would have been ameliorated by a public health law, termed here as “inchoate class.” This article will show that the Court has upheld public health laws that protect such inchoate classes. Conversely, decisions that favor individual liberty over police power do so in the absence of an inchoate class. Importantly, the doctrines described do not impact the right of a woman to terminate her pregnancy.<sup>19</sup>

Part I will summarize the constitutional basis for public health laws. Part II will discuss a recent decision,<sup>20</sup> which was subsequently reversed,<sup>21</sup> that ruled on a due process challenge to drug approvals provisions of the Food Drug and Cosmetics Act (FDCA).<sup>22</sup> This discussion will illuminate the issues involved in the conflict between government interests and individual liberties in this area, and will serve as a useful starting point for an elaboration of my thesis. Part III will argue that the Supreme Court has implicitly established enhanced public health scrutiny as a standard for judging the constitutionality of public health legislation that restricts individual liberty. Part IV will elaborate on the doctrine of inchoate classes, and will conclude that the protection of inchoate classes constitutes a compelling government interest. Part V will synthesize the doctrines elaborated in Parts III and IV, and will show that they generate a coherent

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

19. I use the term “termination of pregnancy” in preference to “abortion” throughout (except in quotations) because the medical meaning of “abortion” is loss of pregnancy for any reason prior to viability. See, F. GARY CUNNINGHAM ET AL., *WILLIAMS OBSTETRICS* 215 (23rd ed. 2010) (“[A]bortion is premature birth before a live birth is possible, and in this sense is synonymous with miscarriage. It also means an induced pregnancy termination to destroy the fetus.”). The definition of “abortion” is stable. See JACK A. PRITCHARD & PAUL C. MACDONALD, *WILLIAMS OBSTETRICS* 483 (15th ed. 1976).

20. *Abigail Alliance for Better Access to Developmental Drugs (Abigail 1) v. Von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006).

21. *Abigail Alliance for Better Access to Developmental Drugs (Abigail 2) v. Von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

22. The Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 301 (2006).

basis for analyzing challenges to public health laws. This analytical framework is compatible with existing Supreme Court jurisprudence.

### I. THE CONSTITUTIONAL BASIS OF PUBLIC HEALTH LEGISLATION

The Commerce Clause<sup>23</sup> is frequently invoked to provide the authority for Congress to enact statutes and regulations benefiting public health, such as the Food Drug and Cosmetics Act (FDCA)<sup>24</sup> and the Controlled Substances Act (CSA).<sup>25</sup> The Supreme Court has rejected due process challenges against these statutes without addressing the constitutional issues presented by lower courts. In *United States v. Rutherford*,<sup>26</sup> the Supreme Court upheld the FDCA drug approval process.<sup>27</sup> It declined to enjoin the federal government from “interfering with the interstate shipment and sale of Laetrile<sup>28</sup> [for the purpose of treating cancer], a drug not approved for distribution under the [FDCA].”<sup>29</sup> A lower court had enjoined the Food and Drug Administration (FDA) from interfering with interstate shipment and sale of commerce in Laetrile on the ground, *inter alia*, that such restriction violated the privacy rights of terminally ill cancer patients.<sup>30</sup> The unanimous reversal did not reach constitutional issues.<sup>31</sup>

The Court also rejected a challenge to the CSA in *United States v. Oakland Cannabis Buyers’ Cooperative*.<sup>32</sup> The Court held that a decision

23. U.S. CONST. art. I, § 8, cl. 3.

24. 21 U.S.C. § 355(a) (2006) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.” (emphasis added)).

25. Controlled Substances Act, 21 U.S.C. § 801 (2006) (“A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce. . .” (emphasis added)).

26. See *United States v. Rutherford*, 442 U.S. 544 (1979).

27. *Id.* at 558. The challenges to federal law discussed in this section are based on the 5th Amendment Due Process Clause, U.S. CONST. amend. V.

28. Laetrile is an extract of apricot pits that some have recommended as treatment for all types of cancer. C.G. Moertel et al., *A Clinical Trial of Amygdalin (Laetrile) in the Treatment of Human Cancer*, 306 NEW ENG. J. MED. 201, 201-06 (1982). There have been no clinical trials demonstrating any clinical efficacy for this substance. *Id.*; *Unproven Methods of Cancer Management: Laetrile*, 41 CA: CANCER J. FOR CLINICIANS 187, 188-90 (1991) [hereinafter CA]. Furthermore, Laetrile is broken down in the body, producing cyanide, and severe toxic reactions have been seen with its use. CA at 191.

29. *Rutherford*, 442 U.S. at 544.

30. *Id.*

31. *Id.* at 555-56 (“For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.”).

32. *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483 (2001).

by the FDA to classify marijuana as a drug with no medical indication was authorized by the CSA and overrode equitable claims of medical necessity.<sup>33</sup> The Court again declined to consider constitutional claims, including Fifth Amendment due process claims.<sup>34</sup> Most recently, in *Gonzales v. Raich*, the Supreme Court held that the Commerce Clause permitted federal regulation of private, non-commercial, state-sanctioned production of marijuana.<sup>35</sup>

The Taxing and Spending Clause<sup>36</sup> has also been used to support public health related measures. The Supreme Court allowed Congress to withhold highway construction funds from states that did not establish a drinking age of twenty-one.<sup>37</sup> The Court held that the general welfare provision of the Taxing and Spending Clause gave Congress the power to withhold funds to prevent youthful drinking,<sup>38</sup> which Congress found to be contrary to “safe interstate travel.”<sup>39</sup>

The Supreme Court has recognized that states have broader powers than those of Congress to enact public health legislation. In *Compagnie Francaise v. Louisiana State Board of Health*, the Supreme Court held that the Fourteenth Amendment Due Process Clause did not invalidate a state quarantine law.<sup>40</sup> The Court held that states had constitutionally protected powers (presumably under the Tenth Amendment) to “enact regulations protecting the health and safety of the people.”<sup>41</sup> The Court later held in *Jacobson v. Massachusetts* that the Fourteenth Amendment Due Process Clause did not prohibit states from using their police power to require vaccination during an epidemic.<sup>42</sup>

## II. SHOULD SUBSTANTIVE DUE PROCESS LIMIT GOVERNMENT REGULATION TO PROMOTE PUBLIC HEALTH?

Police power is first mentioned by the Supreme Court in *Gibbons v. Ogden*,<sup>43</sup> but was not applied by the Court to health regulations until 1902.<sup>44</sup>

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33. *Id.* at 491.

34. *Id.* at 494.

35. *Gonzales v. Raich*, 545 U.S. 1, 33 (2005) (the Court declined to rule on a challenge to enforcement of the Federal regulatory scheme based on substantive due process).

36. U.S. CONST. art. I, § 8, cl. 1.

37. *See S. Dakota v. Dole*, 483 U.S. 203, 212 (1987).

38. *Id.* at 208.

39. *Id.*

40. *Compagnie Francaise v. La. State Bd. of Health*, 186 U.S. 380, 393 (1902).

41. *Id.*

42. *See Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905).

43. *See Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824).

44. *See Compagnie Francaise*, 186 U.S. at 393 (quarantine laws were held, without further explanation, not to violate the Fourteenth Amendment).

Three years later, a dissent to the majority opinion in *Lochner v. New York* maintained that the Fourteenth Amendment “was [not] designed to interfere with the power of the State, sometimes termed its police power, to prescribe regulations to promote the health, peace, morals, education, and good order of the people.”<sup>45</sup> The majority, in dicta, was in partial agreement.<sup>46</sup>

On the other hand, state courts have upheld freedom from imposition of medical care as a common law right.<sup>47</sup> The United States Supreme Court established a fundamental privacy right limiting government interference with medical treatment (at least in the context of reproductive medicine) in a series of cases beginning with *Griswold v. Connecticut*<sup>48</sup> and *Roe v. Wade*.<sup>49</sup> *Roe* grounded this right on the Due Process Clause of the Fourteenth Amendment. *Roe* hints that the privacy right may encompass a right to access medical care beyond the context of reproduction.<sup>50</sup>

Eugene Volokh, a distinguished constitutional scholar at the University of California at Los Angeles, has argued that the Fourteenth Amendment may guarantee even more expansive rights. He suggested that a common law right of self-defense and constitutional guarantees of substantive due process should preclude government regulation of therapeutic modalities in some clinical circumstances.<sup>51</sup> One such circumstance is the presence of a

45. *Lochner v. New York*, 198 U.S. 45, 65 (1905) (Harlan, J., dissenting). Note that *Lochner* was decided less than two months after *Jacobson* and by the identical court. See *Jacobson*, 197 U.S. at 11.

46. The *Lochner* majority acknowledged the power of states to legislate on behalf of the safety of employees. See *Lochner*, 198 U.S. at 54-56. However, the Court believed that invocation of police powers was pretextual. See *id.* at 58-60. “There is, in our judgment, no reasonable foundation for holding this to be necessary or appropriate as a health law to safeguard the public health or the health of the individuals who are following the trade of a baker.” *Id.* at 58.

47. See *Mohr v. Williams*, 104 N.W. 12, 16 (Minn. 1905) (“If the operation was performed without plaintiff’s consent, and the circumstances were not such as to justify its performance without, it was wrongful; and, if it was wrongful, it was unlawful”); *Pratt v. Davis*, 79 N.E. 562, 565 (Ill. 1906) (choosing not to recognize an implied consent to a medical procedure when consent was not given by the patient, no unexpected conditions developed during the course of the operation, and no emergency arose); *Schloendorff v. Soc’y of the N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (“Every human being of adult years and of sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages.”).

48. See *Griswold v. Connecticut*, 381 U.S. 479 (1965). In overturning a state law prohibiting use, prescription and sale of contraceptives. *Id.* at 480. The Court discovered a right of reproductive privacy in the Constitution. *Id.* at 483-85.

49. See *Roe v. Wade*, 410 U.S. 113, 154 (1973).

50. *Id.* (“The detriment that the State would impose upon the pregnant woman by denying [the opportunity to obtain abortion] altogether is apparent. Specific and direct harm medically diagnosable even in early pregnancy may be involved.”).

51. Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1816 (2007).



fatal disease for which no effective treatment is available.<sup>52</sup> As a background to discussing this argument, I first shall describe the process of new drug approval.

Thalidomide, a drug used in Europe to treat nausea in pregnancy, caused limb deformities in thousands of children whose mothers took it in early pregnancy.<sup>53</sup> This experience led to the adoption of legislation requiring the FDA to certify both safety as well as efficacy of new drugs before they could be marketed to the public.<sup>54</sup> New drugs<sup>55</sup> are approved for marketing through a process stipulated by the FDCA.<sup>56</sup> The clinical evaluation process takes several years. Only 8.9 percent of new drugs first tested on humans in the United States are ever approved,<sup>57</sup> and cancer drugs are approved at an even lower rate.<sup>58</sup> Agents are selected for human trials on the basis of their activity against cancer cells grown in tissue culture.<sup>59</sup> They may be chemicals, antibodies or vaccines. Cancer drugs are tested in animals before they are given to humans; the starting dose in human trials usually is the dose that kills ten percent of mice.<sup>60</sup>

Three phases of testing are required before the FDA will consider approval for marketing for human use. Phase I trials utilize escalating drug doses in order to establish the dose which then will be used in effectiveness trials.<sup>61</sup> Typically, the dose is increased with each sequential group of three patients until unacceptable toxicity is reached.<sup>62</sup> The next lowest dose is used in Phase II trials. Few patients on Phase I trials have tumor shrinkage.<sup>63</sup> Prolonged responses are rare,<sup>64</sup> and I am unaware of a report

52. See *id.* at 1828-32.

53. See William A. Silverman, *The Schizophrenic Career of a "Monster Drug,"* 110 PEDIATRICS 404, 405-06 (2002).

54. See *Regulatory Information: Legislation*, FDA, <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last visited Dec. 5, 2010).

55. A "new drug" is "[any] drug . . . not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. . ." 21 U.S.C. § 321(p)(1) (2006).

56. See 21 U.S.C. § 355(a)-(j) (2006).

57. See Joseph A. DiMasi, *Risks in New Drug Development: Approval Success Rates for Investigational Drugs*, 69 CLINICAL PHARMACOLOGY & THERAPEUTICS 297, 298 (2001).

58. *Id.* at 301.

59. See Larry M. Weisenthal, *Antineoplastic Drug Screening Belongs in the Laboratory, Not in the Clinic*, 84 J. NAT'L CANCER INST. 466, 466 (1992).

60. E. A. Eisenhauer, P. J. O'Dwyer, M. Christian & J. S. Humphrey, *Phase I Clinical Trial Design in Cancer Drug Development*, 18 J. CLINICAL ONCOLOGY 684, 685 (2000).

61. See Barry E. Storer, *Design and Analysis of Phase I Clinical Trials*, 45 BIOMETRICS 925, 925 (1989).

62. *Id.* at 926.

63. Elizabeth Horstmann et al., *Risks and Benefits of Phase I Oncology Trials, 1991 Through 2002*, 352 NEW ENG. J. MED. 895, 899 (2005). This study reports a response rate of

of a patient on a Phase I trial who has ever been cured of cancer. On the other hand, severe toxicity is common.<sup>65</sup> Clinical improvement is not the goal of Phase I trials.

Phase II trials treat a small number of patients with a single kind of recurrent cancer.<sup>66</sup> The goals of a Phase II trial are to determine both whether the drug is effective against that kind of cancer and to further elucidate the drug's toxicity.<sup>67</sup>

Drugs effective against a specific type of cancer in Phase II trials are used in Phase III trials. These are randomized trials comparing the new drug against standard treatment of newly diagnosed cancer.<sup>68</sup> Phase III trials are performed after Phase II evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall risk-benefit relationship of the drug.<sup>69</sup> Such trials measure the therapeutic efficacy, the toxicity, and the impact on patient quality of life of the new regimen and compared these with standard treatment using sophisticated statistical techniques.<sup>70</sup> The new drug is marketed only with FDA approval after three phases of required government testing on humans.<sup>71</sup>

Volokh argued that this scheme for drug approval violates a fundamental right of medical self-defense, at least in patients with a fatal disease for which no effective treatment is known.<sup>72</sup> Analogizing the threat of deadly

4.4 percent for patients on Phase I trials of single new drugs. *Id.*

64. See A. Italiano et al., *Treatment Outcome and Survival in Participants of Phase I Oncology Trials Carried Out From 2003 to 2006 at Institut Gustave Roussy*, 19 ANN. ONCOLOGY 787, 789 (2008). The study reported a median of 2.3 months to cancer progression in patients on Phase I cancer trials, and a median 8.7 months until death. Since patients had to be quite stable to enter the trials, most would likely have done well for several months in any event. *Id.* Thus, these drugs generally have minimal effect, if any, on survival and time to progression. *Id.*

65. Horstmann, *supra* note 63, at 899 (reporting a death rate of 0.49 percent and a Grade 4 toxicity rate of 14.3 percent for patients in Phase I cancer trials).

66. John A. Blessing, *Design, Analysis, and Interpretation of Chemotherapy Trials in Gynecologic Cancer*, CHEMOTHERAPY OF GYNECOLOGIC CANCER 49, 55-56 (Gunter Deppe, ed., 1990).

67. *Id.*

68. See Investigational New Drug Application, 21 CFR 321.21(c) (2009).

69. Abigail 1, 445 F.3d 470, 473 (D.C. Cir. 2006) (reversed on *en banc* review in Abigail 2, 495 F.3d 695).

70. See example M. Tiseo, M. Bartolotti, F. Gelsomino, and P. Bordi, *Emerging Role of Fefitinib in the Treatment of Non-small-cell Lung Cancer*, 4 DRUG DES. DEVEL. THER. 2010 81 (May 25, 2010); available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2880339/>.

71. *Id.*

72. Volokh, *supra* note 51, at 1815.

disease to the threat of lethal force from humans or animals,<sup>73</sup> Volokh proposed that those with terminal illnesses be allowed to access post-Phase I drugs. He rooted this right in substantive due process.<sup>74</sup> Citing Supreme Court case law<sup>75</sup> that he believed embodied a right of self-defense in “this Nation’s history and tradition,”<sup>76</sup> Volokh tried to escape the problem that lethal self-defense is ordinarily allowed only in response to an imminent threat<sup>77</sup> by “construing imminence as simply requiring a present medical threat.”<sup>78</sup>

This doctrine was asserted judicially by Judge Rogers in *Abigail 1*, which reversed a dismissal for failure to state a claim of a suit to allow terminally ill cancer patients access to drugs that had completed Phase I testing.<sup>79</sup> The *Abigail 1* court held that regulations limiting access to these drugs impinged on a fundamental liberty interest based on Fifth Amendment substantive due process guarantees.<sup>80</sup> Applying strict scrutiny, the court remanded the case for determination of whether barring access by terminally ill patients to these drugs was “narrowly tailored to serve a compelling governmental interest.”<sup>81</sup>

The *Abigail 1* court’s analysis began with the *Glucksberg* two-prong test, which states that a fundamental right must be “objectively, deeply rooted in this Nation’s history and tradition,” (deep roots) “and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [it] were sacrificed” (ordered liberty).<sup>82</sup> Applying a third *Glucksberg* requirement that a fundamental right be carefully defined,<sup>83</sup> the *Abigail 1* court defined the putative fundamental right as a “[right] to privacy, liberty, and life [which includes] the right of terminally ill patients, acting on a doctor’s advice, to obtain potentially life-saving medication when no alternative treatment approved by the government is available.”<sup>84</sup>

The *Abigail 1* court found deep roots in the right to self-defense,<sup>85</sup> the

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73. *See id.* at 1817-18.

74. *See id.* at 1818-19.

75. *See id.* at 1819-21.

76. *Id.* at 1819 (quoting *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997)).

77. *Id.* at 1823.

78. *Id.* at 1824.

79. *See Abigail 1*, 445 F.3d 470, 486 (D.C. Cir. 2006).

80. *See id.* at 472 (citing *Glucksberg* 521 U.S. at 721; *Reno v. Flores*, 507 U.S. 292, 302 (1993)).

81. *Id.* (quoting *Glucksberg*, 521 U.S. at 721; *Reno*, 507 U.S. at 302).

82. *Id.* at 476-77 (quoting *Glucksberg*, 521 U.S. at 721) (internal citations and quotations omitted).

83. *See Glucksberg*, 521 U.S. at 721.

84. *Abigail 1*, 445 F.3d at 478.

85. *Id.* at 480.

doctrine of necessity,<sup>86</sup> and the common law liability in tort for interfering with efforts to rescue or to preserve a life.<sup>87</sup> It found that the “right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law”<sup>88</sup> was implicit in ordered liberty. The court analogized the right, whose recognition the plaintiffs sought, to a right recognized in *Cruzan v. Director, Missouri Department of Health*<sup>89</sup> to refuse life sustaining care.<sup>90</sup> The *Abigail 1* court mistakenly characterized the *Cruzan*-defined right as one demanding strict scrutiny.<sup>91</sup>

An *en banc* review (*Abigail 2*) reversed the *Abigail 1* decision.<sup>92</sup> In her dissent, Judge Rogers found an additional basis for access to post-Phase I drugs in the right to access life-saving procedures found in *Roe v. Wade*.<sup>93</sup> She characterized this right as distinct from, and more powerful than, the right of reproductive privacy that grounds a right to termination of pregnancy under most other circumstances.<sup>94</sup>

Although the *Abigail 2* court ultimately rejected the medical self-defense argument, the two decisions by Judge Rogers favoring the plaintiffs are a good starting point for discussion. First, these opinions present plausible arguments for the use of the substantive due process doctrine to overcome public health laws that restrict individual liberty.<sup>95</sup> Ultimately, they are not convincing for various reasons, some of which I shall elucidate. Second, the facts of this case are unusual in that both sides asserted similar interests—amelioration of the same kind of advanced cancer. This

86. *Id.*

87. *See id.* at 481.

88. *Id.* at 484, (citing *Cruzan v. Dir. Mo. Dep’t of Health*, 497 U.S. 261, 279 (1990) (quoting *Union Pac. R.R. Co. v. Botsford*, 141 U.S. 250, 251 (1891))).

89. *Cruzan*, 497 U.S. at 278.

90. *Abigail 1*, 445 F.3d 470, 484 (D.C. Cir. 2006) (“The logical corollary is that an individual must also be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life.”).

91. *Id.* (In fact, the *Cruzan* Court did not demand strict scrutiny; *see infra* pp. 19–20).

92. *See Abigail 2*, 495 F.3d 695, 697 (D.C. Cir. 2007).

93. *See id.* at 719 (Rogers, J., dissenting) (citing *Roe v. Wade*, 410 U.S. 113, 164–65 (1973)).

94. *See id.* at 721, (citing *Planned Parenthood of S.E. Pa. v. Casey*, 505 U.S. 833, 851 (1992)).

95. As does the prestige of the court and the eminence of the judges who supported the substantive due process argument. Both Judges Judith Rogers and Douglas Ginsburg have served as Chief Judge of the court, and Judge Ginsburg was nominated for the Supreme Court by President Ronald Reagan in 1987. *Biographical Directory of Federal Judges: Judith Ann Wilson Rogers*, FEDERAL JUDICIAL CENTER, <http://www.fjc.gov/public/home.nsf/hisj> (last visited Dec. 5, 2010); *Biographical Directory of Federal Judges: Douglas Howard Ginsburg*, FEDERAL JUDICIAL CENTER, <http://www.fjc.gov/public/home.nsf/hisj> (last visited Dec. 5, 2010).

fortuitous feature facilitates analysis of the competing claims of public necessity and individual rights. For this reason I ultimately shall assume, *arguendo*, that the law supports a right to medical self-defense, and will show that this is insufficient to overcome state power to enact public health legislation in the way that Volokh and Judge Rogers propose.

The *Abigail 1* court misconstrued the purpose of Phase I trials and the underlying science.<sup>96</sup> There is little reason to believe that a drug that has cleared Phase I will be more likely to prolong the life of a terminal cancer patient than will Laetrile or popcorn. Indeed, it is almost certain that making these agents available will do much more harm than good, since all are toxic and few are efficacious. Even when efficacious, the beneficial effect on terminal cancer patients is slight.<sup>97</sup> Nevertheless, the aura of science may persuade vulnerable patients to grasp at the straw of using such substances. It is not clear why a right of medical self-defense would require the government to allow availability setting of substances known to be harmful and which are not beneficial.

On the other hand, adoption of the doctrine of medical self-defense is likely to impede identification of effective drugs at the expense of the health of people who would benefit from the small minority of post-Phase I drugs that prove to be safe and effective. Daniel Meron, then General Counsel for the Department of Health and Human Services, emphasizes that allowing sale of post-Phase I drugs will discourage patients from enrolling in clinical trials,<sup>98</sup> which are needed to select effective substances from the large pool of candidate drugs. There also are legal problems with this doctrine. First, most courts that have ruled on the issue have held that the FDCA preempts

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96. VINCENT T. DEVITA JR. ET AL., *CANCER: PRINCIPLES AND PRACTICE OF ONCOLOGY* 513-14 (5th ed. 1997). Phase I trials do not establish safety or efficacy. Such trials only “determine a dose that is appropriate for Phase II trials.” Richard M. Simon, *Chapter 20: Clinical Trials in Cancer*, in 1 VINCENT T. DEVITA, JR. ET AL., *CANCER: PRINCIPLES AND PRACTICE OF ONCOLOGY*, 513 (5th ed. 1997). Only three to six patients in a Phase I trial receive the dose that will be used in Phase II trials and another three receive a higher dose, so the nature and extent of toxicity is not clearly understood except for the type of toxicity that characterizes an overdose. *Id.* at 514. When unacceptable toxicity is reached at a given dose level, requiring three to six patients, the previous dose is used for Phase II trials. *See id.* Furthermore, there generally is no reason to believe these drugs are efficacious. Effectiveness of a drug against one kind of cancer does not predict efficacy against other kind. *A fortiori*, a drug which kills animal cancers or cancer cells in the test tube is unlikely to affect any kind of human cancer. The vast majority of these drugs are never released, and it is almost unheard of for Phase I drugs to cure cancer or prolong life. *See id.* The success of cancer drug development, therefore, depends on screening large numbers of substances to find a few effective agents. *See id.*

97. Dean Gesme, *Should Terminally Ill Patients Have the Right to Take Drugs that Pass Phase I Testing?* No., 335 BR. MED. J. 479, 479 (2007).

98. Daniel Meron, *Balancing Government Regulation Against Access to Drugs*, 37 SETON HALL L. REV. 929, 931 (2007).

state tort remedies; and that removing this preemption and exposing pharmaceutical manufacturers to product liability suits might reduce the availability of investigational drugs.<sup>99</sup>

Second, to the extent that the government finances health care, and especially if it guarantees care for all, a right to medical self-defense could support a constitutional requirement that the government pay for *any* treatment for a serious illness that a patient wants and that some physician believes *may* conceivably benefit the patient. A Comment in the Tennessee Law Review argues, for example, that if the government both monopolizes health care and rations its availability, it thereby traduces patients' due process rights.<sup>100</sup> Furthermore, the self-defense and necessity analogies extend beyond seeking treatment for terminal illness. Deadly force can be used in self-defense against situations other than attempted murder, provided another person uses or threatens violence.<sup>101</sup> Volokh's self-defense analogy should be broad enough to apply to cover *any* treatment for *any* disease when (1) the disease can cause mortality or serious morbidity, and (2) some authority proposes that such treatment *might* be effective. There is no shortage of groups that have succeeded in acquiring statutory rights to be paid for their services of unproven merit.<sup>102</sup> The medical self-defense doctrine would allow advocates of unproven care to bypass the democratic process and obtain payment for the groups' practitioners through constitutional challenges in court. The medical self-defense doctrine might mandate payment for any treatment of serious illnesses, even if cost-ineffective or totally futile, as long as a patient and his practitioner, whether a physician, chiropractor, or other professed healer, believes it might be beneficial. Constitutionalizing this right could prevent government health benefit programs from taking measures to control the costs of medical care. Thus, the creation of a right of medical self-defense might make it impractical or impossible for the government to pay for individual medical care. Admittedly, libertarian proponents of the doctrine of medical self-defense might not be averse to such an outcome.

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99. *Id.* at 938-39.

100. See, J. Paul Singleton, *The Good, the Bad, and the Ugly: How the Due Process Clause May Limit Comprehensive Health Care Reform*, 77 TENN. L. REV. 413 (2010).

101. Volokh, *supra* note 51, at 1817, (citing N.Y. PENAL LAW § 35.15(2)(a)-(b) (McKinney 2006)); Model Penal Code § 3.04 cmt. 4(a), at 48 & note 35 (Official Draft and Revised Comments 1985) (as adopted in 1962).

102. See N.Y. INS. LAW § 3216 (g)(21) (McKinney 2006) (note that there are two paragraph 21's; the appropriate paragraph is the second of these), N.Y. INS. LAW § 3221 (k)(11) (McKinney 2006) (note that there are two paragraph 11's; the appropriate paragraph is the second of these), and N.Y. INS. LAW § 4303 (y) (McKinney 2007), which collectively require insurance coverage for chiropractors, and N.Y. WORKERS' COMP. § 305 (3) (McKinney 2006), which requires payment for "necessary" chiropractic care.

Finally, O. Carter Snead of the University of Notre Dame stated “self-defense is not a fruitful analogy.”<sup>103</sup> This is because “[t]he proposed right to medical self-defense does not involve the use of force against an aggressor, but rather the freedom to acquire certain instrumentalities of therapeutic self-help.”<sup>104</sup> Snead observed that disease is not an aggressor and the danger is not imminent.<sup>105</sup>

Although the medical self-defense doctrine did not prevail in *Abigail 2*, it could be successfully revived in the future. A court inclined to expansive interpretations of substantive due process could revive this doctrine, especially if the plaintiff were more likely than the *Abigail* plaintiffs to derive tangible benefit from nullification of a public health law. A differently constituted Supreme Court may develop a more expansive approach to the discovery of fundamental rights than *Glucksberg* provides. Consequently, this article will accept, *arguendo*, a right of medical self-defense that is putatively violated by various demonstrably effective public health laws. Using facts similar to the *Abigail* facts, as well as hypothetical situations that change the facts slightly, this article will demonstrate that substantive due process still does not provide a basis for nullifying effective public health laws.

It will first show that public health laws are not subject to strict scrutiny. The Supreme Court has not required that remedies under public health laws be narrowly tailored. For our purposes here, the applicable standard will be “enhanced public health scrutiny.” The classes of individuals will include: (1) who will definitely incur illness or injury under specific situations; but (2) who cannot be identified before the adverse event; and (3) whose health problems could be prevented or ameliorated if a public health law were in effect. Since these individuals cannot be identified in advance, this article characterizes them as an “inchoate class,” and will argue that protection of members of inchoate classes is a compelling government interest. The Constitution allows states to protect this interest by enacting public health laws that pass enhanced public health scrutiny.

### III. ENHANCED PUBLIC HEALTH SCRUTINY

The Supreme Court held early in the Twentieth Century that the Fourteenth Amendment did not preclude states from enacting laws that

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103. O. Carter Snead, *Unenumerated Rights and the Limits of Analogy: A Critique of the Right to Medical Self-Defense*, 121 HARV. L. REV. 1, 7 (2007).

104. *Id.*

105. *See id.* at 10 (observing that the doctrine of necessity does not support access to post-phase I drugs because, first, the actor must “believe in good faith that the unlawful act will remedy the greater evil” and, second, that the legislature must not have “already spoken to the proper disposition of the choice of evils in question”).

protect the public from epidemics using quarantine<sup>106</sup> and compulsory vaccination.<sup>107</sup> I have noted elsewhere<sup>108</sup> that *Jacobson v. Massachusetts* constrained the power of the government to compel vaccination in four ways, characterized by James G. Hodge and Lawrence O. Gosten<sup>109</sup> as follows:

(1) **public health necessity**. . . police powers must be based on the “necessit[y] of the case” and could not be exercised in “an arbitrary, unreasonable manner” or “go so far beyond what was reasonably required for the safety of the public;”<sup>110</sup>

(2) **reasonable means**. . . a reasonable relationship between the public health intervention and the achievement of a legitimate public health objective.<sup>111</sup> . . . [t]he methods adopted must have a “real or substantial relation” to protection of the public health, and cannot be “a plain, palpable invasion of rights;”<sup>112</sup>

(3) **proportionality**— “[T]he police power of a state . . . may be exerted in such circumstances, or by regulations so arbitrary and oppressive in particular cases, as to justify the interference of the courts to prevent wrong and oppression.”<sup>113</sup> Thus, a public health regulation may be unconstitutional if the intervention is gratuitously onerous or unfair; and

(4) **harm avoidance**— “[T]he measure itself should not pose a health risk to its subject. . . [R]equiring a person to be immunized despite knowing harm would be “cruel and inhuman in the last degree.”<sup>114</sup>

The first of these constraints, public health necessity, speaks to the required government interest in the health matter. Courts grant great deference in this area. Necessity could mean “necessary to achieve a legitimate or important health goal.” No known case law that invalidates a public health law as being unnecessary exists. Rather, courts in vaccination cases appear to construe public health necessity to mean “a highly desirable

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106. See *Compagnie Francaise v. La. State Bd. of Health*, 186 U.S. 380, 397 (1902).

107. See *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905).

108. See generally Allan J. Jacobs, *Needles and Notebooks: The Limits of Requiring Immunization for School Attendance* (2009) (unpublished) (on file with the Hamline Law Review).

109. See James G. Hodge, Jr. & Lawrence O. Gosten, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 856-57 (2001).

110. *Jacobson*, 197 U.S. at 28.

111. *Id.* at 26.

112. *Id.* at 31.

113. *Id.* at 38.

114. *Id.* at 38-39.



public health interest,” rather than applying the dictionary definition of necessary meaning “absolutely needed.”<sup>115</sup>

The subsequent three *Jacobson* principles addressed the constraints for achieving the public health necessity.<sup>116</sup> The requirement is not for a narrowly tailored remedy, but for one that is proportional in its impact and reasonable in its means.<sup>117</sup> The *Jacobson* Court’s only absolute requirement was that required measures should not knowingly impose “cruel and inhuman” harm on a burdened person.<sup>118</sup>

The Supreme Court has implicitly followed this approach in its subsequent jurisprudence. In *Cruzan*, the Court considered an appeal to terminate tube feeding to a woman in a persistent vegetative state.<sup>119</sup> The Court found a right to refuse treatment is a Fourteenth Amendment liberty interest.<sup>120</sup> However, it did not apply strict scrutiny in this context. It allowed states to require that decision-making surrogates demonstrate by “clear and convincing evidence” that their instructions represented the previously expressed wishes of the incompetent patient to discontinue care under these circumstances.<sup>121</sup> The state interest in “the protection and preservation of human life”<sup>122</sup> allows it to impose this standard “to guard against potential abuses in such situations.”<sup>123</sup>

Justice Brennan noted in his dissent that the Court did not define the level of scrutiny it applied to the right to refuse care.<sup>124</sup> Brennan wanted the Court to apply strict scrutiny,<sup>125</sup> and dissented in part because the Court failed to do so.<sup>126</sup> He criticized the failure of the majority to apply this

115. See *Whitman v. Am. Trucking Ass’n, Inc.*, 531 U.S. 457, 465 (2001) (quoting WEBSTER’S NEW INTERNATIONAL DICTIONARY (2d ed. 1950)).

116. *Jacobson*, 197 U.S. at 26-40.

117. *Id.* at 28.

118. *Id.* at 38-39.

119. The *Cruzan* Court defined persistent vegetative state. *Cruzan v. Dir. Mo. Dep’t of Health*, 497 U.S. 261, 266 (1990), note 1 (citing *In re Jobes*, 529 A.2d 434, 438 (N.J. 1987)) (“Vegetative state describes a body which is functioning entirely in terms of its internal controls. It maintains temperature. It maintains heart beat and pulmonary ventilation. It maintains digestive activity. It maintains reflex activity of muscles and nerves for low level conditioned responses. But there is no behavioral evidence of either self-awareness or awareness of the surroundings in a learned manner.”).

120. *Cruzan*, 497 U.S. at 279.

121. *Id.* at 284.

122. *Id.* at 280.

123. *Id.* at 281.

124. *Id.* at 304 (Brennan, J., dissenting) (“The Court, however, avoids discussing either the measure of that liberty interest or its application.”).

125. See *id.* at 304-07 (Brennan, J., dissenting).

126. See *Cruzan*, 497 U.S. at 303 (Brennan, J., dissenting) (“[I]f a requirement imposed by a State ‘significantly interferes with the exercise of a fundamental right, it cannot be upheld unless it is supported by sufficiently important state interests and is closely tailored to

standard.<sup>127</sup>

Instead, the *Cruzan* Court balanced the fundamental liberty interest against the state's interest in preserving health.<sup>128</sup> It cited the public health interest that trumped individual rights in *Jacobson*<sup>129</sup> and in *Breithaupt v. Abram*.<sup>130</sup> Even Justice Brennan, citing *Jacobson*, acknowledged that the right to refuse care is not absolute.<sup>131</sup> Justice Brennan also agreed with the majority<sup>132</sup> that Missouri had “a *parens patriae* interest in providing Nancy Cruzan, now incompetent, with as accurate as possible a determination of how she would exercise her rights under these circumstances.”<sup>133</sup>

Thus, the *Cruzan* Court found that an important right had to yield to state police power in a matter of public health interest. It did not define the nature of its scrutiny according to the paradigm of rational basis, intermediate,<sup>134</sup> or strict scrutiny. Granting maximum deference to patients' wishes would have required that states apply a substituted judgment standard<sup>135</sup> to a surrogate's decision to terminate treatment (expressed legally as allowing proof of the patient's desires by preponderance of

effectuate only those interests,” (quoting *Zablocki v. Redhail*, 434 U.S. 374, 388, (1978))).

127. See *id.* at 301-02 (Brennan, J., dissenting).

128. See *id.* at 279.

129. See *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905) (allowing compulsory vaccination at the time of a smallpox epidemic).

130. See *Breithaupt v. Abram*, 352 U.S. 432, 439 (1957) (holding that a state safety interest in compelling venipuncture of drivers for ethanol determinations overcame a constitutionally protected right of bodily integrity). *Cruzan* also cites three other cases in which substantial liberty interest were opposed to decisions made, at least partly, for protection or promotion of health. *Cruzan*, 497 U.S. at 278-79. *Harper* was not on point, in my opinion, because it used rational basis analysis to permit forced medication of a psychotic prisoner because of penologic concerns. *Washington v. Harper*, 494 U.S. 210, 224-26 (1990). *Vitek v. Jones*, dealt with involuntary transfer of a prisoner to a mental hospital, and was decided on procedural due process grounds in favor of the prisoner seeking to avoid transfer. *Vitek v. Jones*, 445 U.S. 480, 495-96 (1980). Because this paper discusses the extent of procedural due process rights, *Vitek* is not germane either. Finally, *Parham v. J.R.* is another Due Process case, this time finding in favor of the state with regard to procedures for admission of a child to a mental healthcare facility with the consent of the parents, in spite of “a substantial liberty interest in not being confined unnecessarily for medical treatment.” *Parham v. J.R.*, 442 U.S. 584, 600 (1979).

131. See *Cruzan*, 497 U.S. at 312 (Brennan, J., dissenting) (“the right to be free of unwanted medical intervention, like other constitutionally protected interests, may not be absolute.”).

132. *Id.* at 281. (“[T]here will, of course, be some unfortunate situations in which family members will not act to protect a patient. A State is entitled to guard against potential abuses in such situations.”) (internal quotes and citation omitted).

133. See *id.* at 315 (Brennan, J., dissenting).

134. See, e.g., *Craig v. Boren*, 429 U.S. 190 (1976).

135. See TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 99-100 (5th ed. 2001).

evidence).<sup>136</sup> Rather, states are allowed to impose a pure autonomy (or expressed wishes) standard<sup>137</sup> (requiring clear and convincing evidence as to what the patient would want done under the circumstances).<sup>138</sup>

*Planned Parenthood v. Casey* expresses the standard of scrutiny that currently applies to state regulation of pregnancy termination; a standard that falls outside the usual paradigm of rational basis, intermediate, or strict scrutiny.<sup>139</sup> *Casey* demands that regulations not place an undue burden on a woman's right to terminate her pregnancy before viability.<sup>140</sup> This represents a retreat from an older strict scrutiny standard set in *Roe v. Wade*.<sup>141</sup> The *Roe* Court had grounded a woman's decision to terminate her pregnancy in a substantive due process right of privacy,<sup>142</sup> which is not, however, an unqualified right.<sup>143</sup>

The *Casey* Court allowed states greater leeway to limit the rights *Roe* granted to women to terminate pregnancy. It held that "[o]nly where state regulation imposes an undue burden on a woman's ability to make this decision does the power of the State reach into the heart of [this right]," (*emphasis added*).<sup>144</sup> An "undue burden" is "a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable

136. See, e.g., *Superintendent of Belchertown State Sch. v. Saikewicz*, 370 N.E. 2d 417, 434 (1977).

137. See BEAUCHAMP, *supra* note 135, at 100-02.

138. See, e.g., *In re Storar*, 420 N.E.2d 64, 72 (N.Y. 1981). See also Helen L. Siegal, Notes and Comments, *In re Conroy: A Limited Right to Withhold or Withdraw Artificial Nourishment*, 6 PACE L. REV. 219 (1986) (for a dated, but clear, discussion of standards for surrogate decision-making).

139. See *Planned Parenthood of S.E. Pa. v. Casey*, 505 U.S. 833, 879 (1992).

140. *Id.* at 874.

141. See generally *Roe v. Wade*, 410 U.S. 113 (1973).

142. See *id.* at 153.

143. See *id.* at 154. See also, generally, *id.* at 153 (arguing that a right to privacy is a required that laws impinging on this Due Process right); *id.* at 155 ("[T]he court has held that regulation limiting these (Due Process) rights may be justified only by a 'compelling state interest.'"); *id.* (stating that limiting the right of privacy is subject to strict scrutiny, "justified only by a 'compelling state interest,'" and that "legislative enactments must be narrowly drawn to express only the legitimate state interests at stake."). However, the state develops an interest in the health of the mother sufficiently compelling to allow state regulation of termination of pregnancy at the end of the first trimester of pregnancy (approximately thirteen weeks after the last menstrual period. *Id.* "With respect to the State's important and legitimate interest in potential life, the "compelling" point is at viability. This is so because the fetus then presumably has the capability of meaningful life outside the mother's womb." See *id.* at 163. Furthermore, the state acquires a compelling interest in fetal life when a fetus "presumably has the capability of meaningful life outside the mother's womb." *Id.*

144. *Casey*, 505 U.S. at 874.

fetus,”<sup>145</sup> which remained unconstitutional.<sup>146</sup>

The *Cruzan* and *Casey* rulings are compatible with the *Jacobson* standard of scrutiny, which requires that: (1) the regulation must address a well-founded threat to public health, tantamount to a compelling government interest; (2) there is excellent empirical evidence that the proposed regulation will result in improved public health vis-à-vis failure to enact the proposed regulation; (3) the overall burden of the proposed regulation—relating both to health *and* non-health burdens—may not exceed the public health benefits; and (4) there must be exemption from the regulation for individuals who, for unusual reasons, would incur disproportionate adverse impact if they were subjected to the regulation.<sup>147</sup>

First, as discussed above, *Jacobson*’s public health necessity is equivalent to a well-founded threat to public health. Courts interpret public necessity broadly. For example, lower courts have upheld compulsory immunization even for certain childhood illnesses (such as rubella and measles) that only occasionally have grave consequences.<sup>148</sup>

Second, any public health law must be justified by a favorable risk-benefit calculus. Effectiveness of the measure in question (smallpox vaccination) was stressed in *Jacobson*<sup>149</sup> and was taken for granted in cases such as *Casey* (abortion procedures result in pregnancy termination), and *Cruzan* (termination of feeding results in death).<sup>150</sup> The *Jacobson* proportionality prong, as well as the harm avoidance prong, suggest that the benefits must exceed the risks.<sup>151</sup>

145. *Id.* at 877.

146. *See id.* The *Casey* Court deemed a spousal notification requirement to be an undue burden. *Id.* at 887-88; *see also id.* at 900-01 (the Court also found that a requirement of a woman reporting to the state detailed information in regards to the pregnancy and abortion, some of which would be made available to the public, was also unduly burdensome). *But see id.* at 882 (arguing that state requirements that did not constitute an undue burden include rules that physicians must inform patients of fetal consequences of the termination procedure); *id.* at 884 (arguing it is not an undue burden for a state to require that a patient’s informed consent must be personally elicited by a physician); *id.* at 885-87 (arguing that that a state’s mandate of a 24-hour waiting period between consent and the termination procedure, although a “particular burden” for some women, was not a substantial obstacle for the group as a whole, and therefore did not amount to an undue burden); *id.* at 899-900 (arguing that states have the right to require parental notification, provided there was an adequate judicial bypass procedure).

147. *See generally*, *Jacobson v. Massachusetts*, 197 U.S. 11 (1904).

148. *See, e.g.*, *Brown v. Stone*, 378 So. 2d. 218 (Miss. 1979); *Hanzel v. Arter*, 625 F. Supp. 1259 (S.D. Ohio 1985); *Farina v. Bd. of Ed.*, 116 F. Supp. 2d 503 (E.D.N.Y. 2000); *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002).

149. *See Jacobson*, 197 U.S. at 31.

150. *Casey*, 505 U.S. at 845; *Cruzan v. Dir. Mo. Dep’t of Health*, 497 U.S. 261, 267-68 (1990).

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

Third, everyone has interests other than health interests. The total burden of health interests and other interests cannot be greater than the benefit conferred by the public health law. Limitation on patients' scope of action imposed by *Casey* and on surrogates' power to make decisions imposed by *Cruzan* was justified in part by non-medical concerns. In *Cruzan*, the court relied on state interests in preserving life and avoiding error (possibly a euphemistic way of characterizing a state interest in preventing a surrogate from agreeing to a patient's death for the surrogate's own benefit, rather than out of respect for the patient's wishes).<sup>152</sup> In *Casey*, the state interest in "profound respect for the life of the unborn,"<sup>153</sup> allows regulation if there is no undue burden, even if the regulation has "no direct relation to [the woman's] health."<sup>154</sup>

Health-related laws may impose non-health burdens, including financial burdens not only on the laws' beneficiaries, but on burdened parties that do not benefit from the laws. For example, quarantines imposed to prevent epidemics may interfere with the ability of the quarantined person to earn a livelihood. Another example is the requirement, whose object is the safety of the flying public, that commercial pilots must have a current certificate verifying that they have passed specific medical examinations.<sup>155</sup> Because of such impact of public health laws beyond the scope of health, the reasonable means requirement demands that those subject to regulation cannot be subject to unreasonable deprivation unrelated to health issues.

It is important to note that the *Roe* Court cut the Gordian knot of possible fetal interests and rights by holding that a fetus is not a person.<sup>156</sup> The *Roe* Court acknowledged that "[i]f this suggestion of [fetal] personhood is established, the appellant's case, of course, collapses, for the fetus' right to life would then be guaranteed specifically by the [Fourteenth] Amendment."<sup>157</sup> This Court, therefore, held that "the word 'person,' as used in the Fourteenth Amendment, does not include the unborn."<sup>158</sup> Both

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152. There have been other cases addressing the doctor patient relationship in which the issues were not public health issues. See, for example, *Washington v. Glucksberg*, 521 U.S. 702, 705-06, 722-23 (1997) and *Gonzales v. Oregon*, 546 U.S. 243, 248-49 (2006), both of which deal with laws regulating physician-assisted suicide by competent patients. *Gonzales*, in any event, was not decided on constitutional issues.

153. *Casey*, 505 U.S. at 877.

154. *Id.* at 882.

155. For the requirements for each type of medical certificate see 14 C.F.R. § 61.23 (2009) (for the requirement that pilots hold a medical certificate) and 14 C.F.R. § 67.3 (2008) (establishing that a person who meets the medical standards prescribed in this part, based on medical examination and evaluation of the person's history and condition, is entitled to an appropriate medical certificate).

156. *Roe v. Wade*, 410 U.S. 113, 158.

157. *Id.* at 156-57.

158. *Id.* at 158.

enhanced public scrutiny and the concept of inchoate class discussed in the next section apply only to the interests of persons. By denying personhood to fetuses, *Roe* denies the protection of the Fourteenth Amendment to the unborn.

Finally, the *Jacobson* constraint of harm avoidance requires that individuals who possess atypical characteristics that subject them to specific and identifiable harm from a proposed regulation must be exempted from that regulation. This means, for example, that people with a known serious allergy to a vaccine must be exempted from compulsory vaccination requirements.

This completes discussion of the rights of those burdened by public health laws. The article will now discuss the beneficiaries of those laws. Many such beneficiaries of public health laws are individuals whose health would diminish in the future but for such a law, but who cannot be identified until their health is impaired. That is the subject of the next section.

#### IV. INCHOATE CLASSES

##### *A. Properties of Inchoate Classes*

Communities do not contract diseases or sustain injuries; individual people do. One usually cannot identify who will get sick or incur an injury until the adverse effect occurs. Such people may thus constitute an inchoate class of people that definitely exists, but whose members cannot be identified at the time measures are contemplated to protect their health. This section will demonstrate that rights-based claims against public health legislation may be overcome when satisfaction of such claims would violate fundamental health-related interests of members of an inchoate class. First, I must describe the characteristics of such inchoate classes.

An inchoate class with fundamental health interests (hereinafter “inchoate class”) is comprised of one or more individuals who possess three characteristics. First, members of the class will incur a well defined disease or injury in the absence of a specific public health law. Second, that injury will be averted as a proximate effect of that law.<sup>159</sup> Third, members of the

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159. The element of cause and effect is essential. For example, assume that college graduates have lower rates of heart disease than do non-graduates. Press Release, Am. Heart Ass'n, Higher Education Predicts Better Cardiovascular Health Outcomes in High-Income Countries, But Not In Low- and Middle-Income Countries, (Sept. 7, 2010), <http://www.newsroom.heart.org/index.php?s=43&item=1106>. College graduation may not be a cause of the lower rate. The finding may be a statistical artifact. It may also be the case that college graduation and low disease rates are proximate effects of a third phenomenon. Because there is not a well-established causal effect between less school and more disease,

class cannot be identified from among a broader class of individuals until they actually suffer the adverse event.

The adverse event that the inchoate class will experience must be empirically inevitable. The event may not be hypothetical. Rather, it must be certain that some unknown members of a larger class of people (which larger class may be either the entire population or a large segment of the population, such as all women, or all coal miners) will experience the event. It is not required that the event be logically necessary, but only that it can be empirically concluded that some people will experience it. An example of logical necessity of an adverse effect would be a situation in which a disease affects one hundred people, with sufficient medicine available to cure only ninety. The other ten inevitably will die. These unfortunate ten people form an inchoate class if we do not know which individuals will not be able to obtain the drug. We can enact a law to compel production of ten more doses of medicine, and by doing so we can so prevent those ten people from dying.

Empirical necessity sufficient to define an inchoate class exists when there is an extremely high probability of an adverse event occurring. For example, at least 150 men per 100,000 (about 225,000 men) have been diagnosed in the United States with prostate cancer every year since 1990.<sup>160</sup> It is so likely that some American men will be diagnosed with prostate cancer next year that reasonable people will assume this will happen. This is true even though the conclusion is based on high statistical probability rather than on logical necessity. If a public health law would prevent some cases of prostate cancer, then some of these unidentified 225,000 men who would otherwise get the disease next year would constitute an inchoate class.

Members of an inchoate class do not have to be found totally randomly among the total population. They can be members of a broad demographic group defined by factors such as age, occupation, residence, or gender. All members of inchoate classes involving prostate cancer will be men, for example. The larger group containing the inchoate class must be sufficiently larger than the inchoate class itself so that it is impossible to identify the specific individuals whose health will be impaired.

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those who did not graduate from college but who will experience an increase in heart disease do not constitute an inchoate class that would benefit from legislation to increase college graduation rates for the purpose of preventing heart disease. It follows that such legislation would not be public health legislation, as this also requires a well-established causal relationship to survive enhanced public health scrutiny.

160. See, e.g., NAT'L CANCER INST., *Surveillance Epidemiology End Results*, [http://seer.cancer.gov/csr/1975\\_2006/browse\\_csr.php?section=23&page=sect\\_23\\_table.04.html](http://seer.cancer.gov/csr/1975_2006/browse_csr.php?section=23&page=sect_23_table.04.html) (last visited Dec. 5, 2010).

To develop the concept of the inchoate class with fundamental health interests, I propose a hypothetical situation similar to the *Abigail* facts, though using a fictitious disease and assuming certain facts to remove complexity and ambiguity.

### Cardizap

The state of Randaynburg has an identical Pure Food, Drug and Cosmetics Law to the U.S. Federal statute that, for obscure reasons, preempts the Federal statute. Randaynberg is unique in having a high incidence of heart cancer, a disease virtually unknown anywhere else in the world. One in 200 residents of Randaynberg is diagnosed with heart cancer each year, and five percent eventually die of the disease. Removal of the heart is not feasible, so chemotherapy is the only treatment. No drug has ever been curative. The best drugs are only effective against thirty percent of people with heart cancer and prolong life an average of only nine months. The Amber Grail Foundation seeks an injunction to allow patients who have used all other drugs on the market to have access to a compound called Cardizap. The dose-limiting toxicity of Cardizap (i.e., the common side effect produced by an overdose) has been determined in Phase I testing, but the full toxicity spectrum is unknown. Furthermore, there has been no observed effect against heart cancer except for a two-month partial remission in one of thirty patients who received Cardizap for heart cancer. Prior experience has shown that allowing access to drugs that have only had Phase I testing diverts patients from clinical trials, thus retarding accurate evaluation of efficacy by six to twelve months. State regulators have reasonably estimated that this delay would result in an additional 1,000 QALY's<sup>161</sup> per year than would result from a policy of allowing the wider access to Cardizap sought by Amber Grail. The beneficial effect would be spread among 1,200 patients annually. It estimates that no more than ten QALY's would be achieved by allowing administration of Cardizap to patients with heart cancer for whom no other treatment is available. Some time in the future, Corazón Herzl will get heart cancer, but there is no way to know this until she actually gets the disease and is diagnosed. Her cancer will respond to Cardizap but we cannot know this either, unless and until she gets the drug. In the long run, however, Corazón Herzl or others like her will suffer from abandonment of the drug development program.

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161. UK Cochlear Implant Study Group, *Cochlear Implantation in Postlingually Deafened Adults II: Cost-Effectiveness Analysis*, 25 *EAR & HEARING* 336, 338 (2004) ("A QALY is a measure of duration of life weighted by quality of life. If a person lives for 10 yr in a state with a utility of 0.2 [i.e., with an eighty percent reduction of quality of life], the person has lived 2 QALYs. If an intervention improves the utility of the patient's state to 0.6 and sustains the improvement for 10 yr, then the patient has gained 4 QALYs (=  $10 \times [0.6 - 0.2]$ ).").



The inchoate class here consists of those who will get heart cancer during the six to twelve months between the date Cardizap would be approved if the approval process proceeds as the statute anticipates, and the date it would be approved if early availability of Cardizap to terminal patients retards the approval process. We do not know in advance exactly who will fall into this class. However, if the government allows unlimited use of Cardizap then people such as Corazón Herzl will suffer.

Not all scenarios in which possible members of an inchoate class seek benefit involve maintenance or suppression of government regulatory activity, as in the Cardizap scenario. In the following scenario the facts have changed so that benefit to the inchoate class requires that the government compel action by a private actor.

### Bristlecone Extract

Bristlecone pine extract was found to cure heart cancer. The drug is harmless enough to justify over-the-counter sales, but it is rare and hard to obtain. Paul Ronald Bach has purchased all of the bristlecone pine plantations in the world, as well as the patent on the extraction process. Bach is a mystic who is hostile to Western medicine. He sells his entire crop for use in cosmetics, though he would get a better price from pharmaceutical companies. As a result, there is no drug available to treat heart cancer patients. Bach's patent expires in ten years. It will take four years to synthesize bristlecone pine extract in the laboratory using a different process. Tin Woodsman recently was diagnosed with heart cancer. He has read about the concept of medical self-defense and would like to force Bach to supply the extract for medicinal use. Furthermore, his siblings, Lead Woodsman and Germanium Woodsman, believe they may be members of an inchoate class of persons who will develop heart cancer.

Conceptually, legal remedies to protect the interests of plaintiffs with a medical self-interest claim may require state action, state restraint, state compulsion of private action, or state prohibition or regulation of private action. Judicial intervention in the Bristlecone scenario may be less appealing to a libertarian than to a liberal; the reverse is true for the Cardizap scenario. Both challenges may rely on a concept of medical self-defense with equal plausibility.

### *B. The Inchoate Class and Public Health Legislation*

Can public health laws survive a robust substantive due process challenge, such as an argument based on the medical self-defense doctrine? There are cogent pragmatic reasons for such laws. Potential members of

inchoate groups may not proactively seek judicial remedies for their exposure to health hazards. Alternatively, a hazard such as an epidemic may be so pressing that severe damage will occur if the government does not promptly deal with the threat.

If achieving certain health outcomes is an interest sufficiently important to form the basis of a fundamental right such as medical self-defense, it should also be sufficiently important and fundamental to form the basis of a compelling government interest in enacting laws to protect that personal interest. How can courts resolve a challenge, based on a fundamental right, to a law upholding this fundamental interest in protecting susceptible individuals against an adverse health outcome?

Beginning with the proposition advanced in the previous section, that a law is facially constitutional if it meets the conditions of enhanced public health scrutiny. Analysis of the law and challenges to the law must be able to address both health-related and non-health related burdens of laws limiting rights for public health purposes. The right to protect oneself against a serious disease is fundamental, since critical life and liberty interests are at stake. But if a person's interest in combating a fatal illness is important enough to undergird a fundamental right, the same interest is important enough to ground a compelling government interest in aiding a person with a fatal illness in combating that illness.

A government that uses its police power to enact public health laws is, in effect, thereby acting on behalf of an inchoate class and its members against threats to their health. It is providing them with medical self-defense they cannot provide themselves because they do not know they will get sick. Protection from health threats is a fundamental interest of inchoate class members, because these threats inevitably will traduce their life and liberty interests. The government thus acts to defend fundamental life and liberty interests of those who otherwise would be harmed, but who cannot be identified until they incur the harm. Such action comprises a compelling government interest.

The Cardizap scenario fortuitously opposes two sides claiming the same health interest—relief of heart cancer. Accessing drugs immediately on the one hand, and orderly drug development on the other hand, are both advocated on the basis of an interest in helping patients with this disease. However, different individuals will experience relief depending on which policy is adopted. Each side can equally well base its claim on medical self-defense. Amber Grail claims that the right of self-defense guarantees its constituents' access to Cardizap. The government counters that it has a compelling interest in restriction of Cardizap to clinical trials in order to protect the fundamental interest held by an inchoate class, with members such as Herzl, in facilitating development of drugs against heart cancer.

Members of the inchoate class have the same interest in defending themselves against cancer as do those who already have the disease. But since they do not know who they are, someone else must represent their interests. The government is the only entity that plausibly can do this.

Since both sides in the Cardizap dispute have the same interests and the same right of medical self-defense, resolution of the dispute in the Cardizap scenario rests on a balance of equities. The issue is empirical: which of the two proposed solutions to the conflict will do more to alleviate the overall harm caused by heart cancer? Under the facts that are presented in the Cardizap scenario, the current rules for drug development will aid the inchoate class more than the immediate release of Cardizap will aid those who now have cancer. Therefore, Herzl and the government can justify the New Drug rules, as their interest is qualitatively similar but quantitatively greater than those for whom Amber Grail claims to speak.

Invocation of any putative right other than self-defense would lead to the same outcome. Everyone who has, or who will have, heart cancer has the same interest and the same right. Future victims require government protection because they do not know who they are. If both sides seek the same good, and have the same right, the conflict must be resolved by balancing equities of the two sides. Furthermore, the remedy need not be narrowly focused, but need only meet the tests prescribed by enhanced public health scrutiny.

Indeed, based on the same principle, a government body that possesses police power<sup>162</sup> also can compel Bach to make bristlecone pine extract available to the Woodsman family. In requiring Bach to make this drug available, the state is pursuing a compelling interest in protecting the life and health of the inchoate class of people that will develop heart cancer. Again, a medical self-defense argument can, but need not, be used to undergird a putative right to access the drug. And, again, the remedy need not be narrowly tailored.

Since the substantive interests of the opposing parties are the same, the only remaining considerations are the magnitude of the effect of alternative policies and the adequacy of the procedures used to determine these effects and to formulate rules. Determining the magnitude of the effect of alternative public health policies is a strictly empirical project that is likely to be highly technical and fact specific. Nevertheless, we have converted the need for subjective choices between two incommensurate doctrines into a factual question capable of objective and fair resolution.

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162. Or the federal government, to the extent that it can act under the aegis of the Commerce Clause, U.S. CONST. art. 1, § 8, cl.3, the Spending Clause, U.S. CONST. art. 1, § 8, cl.1, or the Necessary and Proper Clause, U.S. CONST, art. 1, § 8, cl.18.

Of course, most clashes of rights and interests do not involve identical health goals on both sides of the dispute. Indeed, public health laws can interfere with rights not related to health in order to advance health goals. For example, being subject to quarantine involves loss of liberty, and possibly of livelihood, but not loss of health. Nevertheless, opposition of a fundamental non-health right and a fundamental health interest invites courts to weigh the magnitude of the empirical effects of alternative solutions on both sides in the dispute. If competing interests are both fundamental, they cannot be prioritized using this doctrine. If one side loses something fundamental, then whatever the other side gains cannot, by definition,<sup>163</sup> be more than fundamental. One fundamental principle cannot be more elemental than another. What is left to distinguish between the parties' claims is the relative empirical benefit of their claims.

This solves the problem posed by B. Jessie Hill, a law professor at Case Western Reserve. She argues that cases such as *Jacobson* that rely on public health considerations, and cases such as *Stenberg v. Carhart*<sup>164</sup> (that rely on fundamental rights), use incommensurate arguments, speak past one another, and cannot be reconciled.<sup>165</sup> She appreciates that cases such as *Jacobson* often contain externalities that affect other individuals' health, while cases such as *Stenberg* do not.<sup>166</sup> Nevertheless, she believes that the incommensurateness of the demands of government power and the demands of individual rights cannot be reconciled by a means other than judicial balancing of doctrine.<sup>167</sup> This is incorrect; the concepts of enhanced public health scrutiny and inchoate classes allow courts to balance not doctrines, but equities. Such empirical decision-making may be better accomplished by agencies with expertise and by legislatures than by courts.<sup>168</sup>

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163. Merriam-Webster defines "fundamental" as serving as an origin, primary; basic, essential; of central importance." THE MERRIAM-WEBSTER DICTIONARY 201 (11th. ed. 2005). Black's Law Dictionary defines "fundamental law" as "the organic law that establishes the governing principles of a nation or state; esp. constitutional law." BLACK'S LAW DICTIONARY 697 (8th ed. 2004). Both of these definitions seem to imply that fundamental laws cannot be ranked according to importance.

164. *Stenberg v. Carhart*, 530 U.S. 914, 921 (2000).

165. Hill, *supra* note 17, at 279-83.

166. *Id.* at 326-28. Such externalities are avoided in termination of pregnancy cases by the expedient of defining a fetus as not being a person. See *Roe v. Wade*, 410 U.S. 113, 158.

167. Hill, *supra* note 17, at 327-28.

168. However, agencies may be influenced by political considerations. This is said to be true, for example, when agencies are asked to determine the efficacy of controversial treatments such as abortion, medical abortifacients and post-coital contraceptives. See, e.g., Gillian E. Metzger, *Abortion, Equality, and Administrative Regulation*, 56 EMORY L.J. 865, 877-78 (2007). There is no burdened inchoate class in this circumstance, the Supreme Court having decided that fetuses are not people with fundamental constitutional rights. See *Roe*, 410 U.S. at 158. However, if administrative actions single out reproductive procedures, courts can address these on the basis of the Equal Protection Clause and of *Roe* privacy

The next section will demonstrate that the application of enhanced public health scrutiny to laws that advance health-related interests of inchoate classes would lead to the same outcomes that the Supreme Court has achieved without explicit recourse to these doctrines. It will accomplish this by applying these doctrines retrospectively to some decided cases. Additionally, application of the doctrines to an undecided issue currently in litigation will show the doctrines' applicability to such laws. This will thus demonstrate that it is possible to elucidate a clear and consistent doctrine, compatible with the Court's prior decisions, that allows government to address threats to the health and safety of the public while preserving fundamental rights.

#### V. A COHERENT DOCTRINE FOR PUBLIC HEALTH JURISPRUDENCE

The conclusions derived from the previous two sections can be operationalized in the form of a four-step test to determine whether a public health law will survive a substantive due process challenge (see Figure 1).

The threshold question is whether a law is a public health law—meaning whether its purpose is to prevent or ameliorate disease or injury. The second step of the analysis is to determine whether the law's challenger has an interest emanating from a fundamental right protected by the Constitution that is burdened by the public health law. If so, the third step is to identify an inchoate class. An inchoate class is present when there are as-yet-unidentified individuals whose health will be impaired if a law is not implemented, but who will avoid the harm if the law is enforced. Finally, enhanced public health scrutiny is applied to determine whether the government may impose the regulation. This scrutiny requires that: (1) the law's purpose must be to ameliorate a well-founded threat to public health; (2) there is persuasive empirical evidence that the law will achieve this purpose; (3) the public health benefits of the law exceed the overall burden; and (4) the law exempts individuals who would incur disproportionate adverse impact from its application.

This analysis would uphold the Louisiana quarantine law that the Supreme Court upheld in *Compagnie Francaise*.<sup>169</sup> This case considered contending claims between police power and due process.<sup>170</sup> The Court

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rights and need not consider balancing with affirmative rights of persons other than the pregnant woman. *Id.* at 152-53.

169. See *Compagnie Francaise v. La. State Bd. of Health*, 186 U.S. 380, 393 (1902).

170. See *id.* at 387. Of interest is that an earlier quarantine case, *Morgan's Steamship Co. v. La. Bd. of Health*, 118 U.S. 455, 462 (1886), anticipates the concept of inchoate classes, though it sees them as burdened classes rather than as protected classes. "The danger comes from you [arriving ships], and though it may turn out that in your case there is no danger, yet, as you belong to a class from which all this kind of injury comes, you must

held that this statute did not violate the Fourteenth Amendment.<sup>171</sup> Applying the four-step analysis shows that the law in question was a public health law, and that it was effective. The beneficiary inchoate class consisted of those who would be exposed to serious infectious diseases without quarantine laws, but whom quarantine laws would save from disease.<sup>172</sup> The restriction was proportionate, and there was no individual who was disproportionately burdened. The positive impact of averting epidemics in the pre-antibiotic era was greater than the dual burden of ship owners' submission to inspection and passengers' detention when serious infectious disease was present on board.

In *Jacobson*, the balance was between the compulsory vaccination of healthy people versus the effect of smallpox on members of an inchoate class absent the vaccination program. Smallpox vaccination usually is merely annoying, but can sometimes carry unusual and serious complications.<sup>173</sup> The *Jacobson* Court permitted the compulsory vaccination.<sup>174</sup> In *Zucht v. King*, another smallpox vaccination case, the Court came to a similar conclusion.<sup>175</sup>

Similarly, the Court ruled in *Breithaupt v. Abram* that involuntary blood alcohol tests given to drivers did not violate the Fourteenth Amendment.<sup>176</sup> The *Breithaupt* Court balanced the violation of individual rights by forced venipuncture against prevention of highway mayhem. There was an inchoate class of future victims of accidents to which intoxication contributed, but which were preventable by blood alcohol tests.<sup>177</sup>

In *Addington v. Texas*, the Court rejected a claim that procedural due process required states to prove psychotic patients' danger to self or others beyond reasonable doubt to obtain civil commitment.<sup>178</sup> The Court rejected this argument, allowing the state to use the more lenient clear and

pay for the examination which distinguishes you from others of that class." *Id.*

171. See *Compagnie Francaise*, 186 U.S. at 393.

172. See *Morgan's Steamship Co.*, 118 U.S. at 459-60, upon which *Compagnie Francaise* relies. See *Compagnie Francaise*, 186 U.S. at 391-92.

173. See generally John D. Grabenstein & William Winkenwerder, *US Military Smallpox Vaccination Program Experience*, 289 JAMA 3278, 3280 (2003); Janie Parrino & Barney S. Graham, *Smallpox Vaccines: Past, Present, and Future*, 118 J. ALLERGY & CLINICAL IMMUNOLOGY 1320, 1323 (2006).

174. *Jacobson v. Massachusetts*, 197 U.S. 11, 37-39 (1905).

175. *Zucht v. King*, 260 U.S. 174, 176-77 (1922).

176. *Breithaupt v. Abram*, 352 U.S. 452, 439-40 (1957).

177. *Id.* at 449 (Warren, J., Black, J., and Douglas, J., dissenting) ("As against the right of an individual that his person be held inviolable, even against so slight an intrusion as is involved in applying a blood test of the kind to which millions of Americans submit as a matter of course nearly every day, must be set the interests of society in the scientific determination of intoxication, one of the great causes of the mortal hazards of the road.").

178. *Addington v. Texas*, 441 U.S. 418, 432-33 (1979).

convincing standard.<sup>179</sup> Its decision acknowledged the State's power to treat such patients without their consent under the *parens patriae* doctrine,<sup>180</sup> and to protect others against them under the police power doctrine.<sup>181</sup> There were two inchoate classes. The first was mentally ill people who would avert danger to themselves only if committed and treated. The second consisted of other people who would be injured by the mentally ill only if the latter were not committed.

If quarantine and civil commitment are permissible then, *a fortiori*, forced administration of medicine, which is less of a burden, also should be permissible. Indeed, the Court ruled in *Washington v. Harper* that forced medication was permissible, at least in a prison setting.<sup>182</sup> The Court rejected a psychotic prisoner's claim that procedural due process entitled him to a court hearing prior to being forcibly medicated. The Court held, though, that psychiatric determination by prison staff was sufficient, being "[it] is an accommodation between an inmate's liberty interest in avoiding the forced administration of antipsychotic drugs and the State's interests in providing appropriate medical treatment to reduce the danger that an inmate suffering from a serious mental disorder represents to himself or others."<sup>183</sup> As in *Addington*, there are two inchoate classes: those who would be harmed by untreated mentally ill prisoners, and the ill prisoners who would improve with treatment. Additionally, statutes exist which authorize civil detention to enforce medical treatment regimens in certain circumstances.<sup>184</sup> For example, courts have upheld statutes requiring confinement for the purpose of compulsory treatment of tuberculosis.<sup>185</sup>

As already noted, the *Rutherford* Court upheld FDA denial of approval to market Laetrile for treatment of cancer.<sup>186</sup> The proportionality of equity is one-sided in favor of banning Laetrile, which is both ineffective and unsafe.<sup>187</sup> The burdened liberty interests are the right of the purveyor to

179. *See id.* at 433.

180. *Id.* at 426.

181. *Id.*

182. *See Washington v. Harper*, 494 U.S. 210, 236 (1990).

183. *Id.*

184. *See* Cal. Health & Safety Code, §§ 121358-65 (2006), for an example of a statute authorizing involuntary detention of patients with tuberculosis under some circumstances.

185. *See, e.g., In re Mary Doe*, 205 A.D.2d 469, 469 (N.Y. App. Div. 1994); *Souvannarath v. Hadden*, 116 Cal. Rptr. 2d 7, 16 (Cal. Ct. App. 2002); *Levin v. Adalberto M.*, 67 Cal. Rptr. 3d 277, 302-03 (Cal. Ct. App. 2007); *In re Washington*, 735 N.W.2d 111, 131 (Wis. 2007). *See, also*, Calif. Health & Safety Code, §§ 121358 – 121365, an example of a statute authorizing involuntary detention of patients with tuberculosis under some circumstances.

186. *United States v. Rutherford*, 442 U.S. 544, 552-54 (1979).

187. *See Moertel, supra* note 28, at 204.

market an ineffective and unsafe preparation to desperate patients, and the right of these patients to use this material. The patients who would suffer from being duped into using Laetrile as an alternative to effective treatment comprise the inchoate class.

In *Cruzan*, the Court weighed the plaintiff's liberty interest in refusing medical care against the interest of a possible inchoate class of incompetent individuals whose death will be engineered against their prior wishes by their healthcare surrogates.<sup>188</sup> There was no inchoate class with health interests in the *Cruzan* dispute. It is difficult to ascribe any fundamental interest to someone who never will have cognitive or perceptual abilities. If there is an inchoate class with tangible interests, it consists of those who are now competent but who later will not be able to make medical decisions. Their interest in having their decision honored is not a health interest even though it involves medical care. This is because the patient's health will not improve from being allowed to die, and the interest proposed by the plaintiff is the timing of death. The State emphasized the risk of error and asserted that it was protecting patients without capacity from preventable death against their wishes. The State, in essence, was proposing an inchoate class of individuals who would die against their wishes. Assuming that some of these might recover cognition, the State was alleging that it was protecting a fundamental interest in life held by members of an inchoate class. With no plaintiff health interest, but an unrefuted claim of health interest by the defendant State, the four-step test predicts that courts will grant deference to states wishing to protect that interest in life. And that is exactly what the Court did.

In *Gonzales v. Raich*, the petitioners sought a preliminary injunction against the Drug Enforcement Administration from enforcing laws that prohibited their intrastate, non-commercial cultivation of marijuana.<sup>189</sup> The Court ruled, however, that the Commerce Clause gave the federal government authority over this practice.<sup>190</sup> The law clearly deals with public health. Proportionality is hard to determine, though, as the factual basis of this case rested on overblown claims propounded by both sides. Plaintiffs' claims that marijuana was "the only the only drug available that provides effective treatment,"<sup>191</sup> and that "discontinuation of marijuana

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188. See *Cruzan v. Dir. Mo. Dep't of Health*, 497 U.S. 261, 278 (1990) ("[A] competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment.").

189. *Gonzales v. Raich*, 545 U.S. 1, 7 (2005) (citing 21 U.S.C. § 810).

190. *Id.* at 26-33. "Because the [Controlled Substances Act] is a statute that directly regulates economic commercial activity, our opinion in [*United States v. Morrison*, 529 U.S. 598 (2000)] casts no doubt on its constitutionality." *Id.* at 26.

191. *Id.* at 7.



could very well prove fatal,<sup>192</sup> are inconsistent with what is known about the drug.<sup>193</sup> On the other hand, the congressional finding that marijuana was a hallucinogenic substance meriting classification under the CSA as a Class I substance is belied by widespread recreational experience with the drug.<sup>194</sup> Class I substances are characterized as having “no currently accepted medical use in treatment in the United States,” and as having “lack of accepted safety. . . under medical supervision.”<sup>195</sup> They may not be prescribed by physicians.<sup>196</sup> In short, there was little scientific reason to believe that an inchoate class existed whose members’ health would have benefitted from a court decision in either direction.

Finally, the sequence of pregnancy termination cases beginning with *Roe*, and extending through *Casey* and beyond, could have been adjudicated as a conflict between maternal interests such as reproductive privacy and protection of health, and the interest of fetuses in their own life. The Court could have found an inchoate class consisting of fetuses that would have survived but for termination of pregnancy and tried to balance equities. Instead, the Court held in *Roe* that a fetus does not have legal standing as a person,<sup>197</sup> thereby finessing the issue.<sup>198</sup> Subsequent to *Casey*, the Court decided that Congress had the power to define the end of the fetal state by allowing Congress to define birth. The Court in *Gonzales v. Carhart*<sup>199</sup> upheld Federal<sup>200</sup> criminal penalties<sup>201</sup> for a procedure called “dilatation and extraction,” where part of the fetus is delivered beyond the maternal cervix prior to killing the fetus.<sup>202</sup> Once fetal parts sufficiently exited the cervix, a conceptus was held to be close enough to having personal status to enjoy

192. See *id.* at 6.

193. See Stanley J. Watson et al., *Marijuana and Medicine: Assessing the Science Base: A Summary of the 1999 Institute of Medicine Report*, 57 ARCHIVES GEN. PSYCHIATRY 547, 552 (2000) (“[T]he data indicate a modest potential therapeutic value for cannabinoid drugs, particularly for indications, such as pain relief.”).

194. See 21 U.S.C. § 812(c)(10) (2006).

195. 21 U.S.C. § 812(b)(1)(B)–(C) (2006).

196. See 21 U.S.C. § 841(a)(1) (2006) (stating it is a crime “to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense” a Class I substance.).

197. *Roe v. Wade*, 410 U.S. 113, 158 (noting that “[T]he word “person,” as used in the *Fourteenth Amendment*, does not include the unborn”).

198. See *id.* at 164–65; see also *Planned Parenthood of S.E. Pa. v. Casey*, 505 U.S. 833, 846 (1992) (The Court has tacitly declined to embrace wholeheartedly its exclusion of fetuses from personhood. This is reflected in its reserving a state interest in fetal well-being after viability).

199. *Gonzales v. Carhart*, 550 U.S. 124 (2007).

200. See *id.* at 141–43 (quoting 18 U.S.C. § 131 (2000 Supp. IV)).

201. See *id.* at 132–33.

202. See *id.* at 136–40.

greater protection than a fetus *in utero*.<sup>203</sup> This nascent child presumably has sufficient personal status to belong to an inchoate class.

The pregnancy termination cases neither have an affect on, nor are affected by, the four-step test. If the *Roe* line of cases were reversed, fetuses would be brought under the public health umbrella by factors outside the ambit of public health law scrutiny. Fetuses might be brought under the protection of these laws if states could assign them personal status, which is not a public health measure. The four-step test can determine how courts should resolve conflicts among legally acknowledged persons in which public health is an issue, but it is neutral as to the definition of personal identity.

Finally, I will analyze *Flynn v. Holder*, a pending case brought by would-be bone marrow transplant recipients and an organization representing their cause.<sup>204</sup> The plaintiffs seek to overturn the National Organ Transplant Act (NOTA),<sup>205</sup> to the extent of allowing private parties to pay bone marrow donors. They claim violation of the Equal Protection Clause,<sup>206</sup> asserting that NOTA arbitrarily classifies bone marrow as an organ<sup>207</sup> for purposes of prohibiting valuable consideration, rather than as “renewable or inexhaustible loose-cell types” such as blood or sperm donations.<sup>208</sup> The complaint also alleges a substantive due process violation based on a right to pursue lifesaving medical treatment.<sup>209</sup> This article assumes, *arguendo*, the validity of the plaintiff’s constitutional claims.

Opponents of compensation for bone marrow donations argue that: (1) it is unpalatable to compensate for tissue donation; (2) the need to compensate donors will increase costs of transplantation; (3) poor people therefore will be excluded from having marrow transplantation; and (4) paying donors may jeopardize recipient safety because paid donors may not admit to germane medical conditions.<sup>210</sup>

Economics professors Gary S. Becker and Julio Jorge Elías have estimated that allowing a market in donation of kidneys and liver tissue would greatly

203. *See id.* at 158; *Washington v. Glucksberg*, 521 U.S. 702, 732-35 (1997).

204. *See* INST. FOR JUSTICE, *Flynn v. Holder: Challenge to the National Organ Transplant Act*, [http://www.ij.org/index.php?option=com\\_content&task=view&id=2900&Itemid=165](http://www.ij.org/index.php?option=com_content&task=view&id=2900&Itemid=165), (last visited Dec. 5, 2010).

205. *See* 42 U.S.C. § 274e (2006).

206. Compl. for Final J., *Flynn v. Holder*, No. 09-07772 (C.D.C.A., October 26, 2009), at 48-49 [hereinafter *Flynn Complaint*].

207. *See* 42 U.S.C. § 274e(c)(1) (2006).

208. *Flynn Complaint*, *supra* note 206, at 48-49.

209. *See id.* at 49-50.

210. *See* Kevin B. O’Reilly, *Ban on Paying Bone Marrow Donors Challenged in Court*, AMEDNEWS.COM, (Dec., 21, 2009), <http://www.ama-assn.org/amednews/2009/12/21/prsa1221.htm>.

increase the number of organs available for transplantation, while raising the cost of a procedure by no more than twelve percent.<sup>211</sup> Ted C. Bergstrom, also a professor Economics, modeled bone marrow transplantation and predicted that compensation of donors would markedly increase availability.<sup>212</sup>

We can analyze this case using the four-step test. First, NOTA is public health legislation, as it regulates treatment of disease. Next, a fundamental interest in seeking effective medical treatment for fatal illnesses such as leukemia by increasing the number of donors is pitted against possible endangerment of donors (not a major factor with bone marrow donation), endangerment of recipients, claims of commodification of donors, and exclusion of people without means from the bone marrow recipient pool. Assuming that each side is defending fundamental interests, we now look at the probable impact on identifiable and inchoate parties both in the status quo and in the situation that would obtain if plaintiff's injunction were granted.

There is an inchoate class that would benefit from a market in bone marrow donation. This class consists of those individuals with blood diseases who would obtain bone marrow donation only if donors could be compensated. This is weighed against the impact of the injury to donors and recipients of these extra donations, and perhaps against opportunity costs of using scarce resources to pay for the added bone marrow donations. It is possible to reasonably estimate the number of people who will feel coerced by having donated marrow for money, and to assign a qualitative or quantitative value to this. The four-step test predicts that the plaintiff will have a strong case, as saving lives is weighed against the burden on paid donors of possible coercion, discomfort, a small risk of danger, and possible loss of dignity. The NOTA provision fails the proportionality test of enhanced public health scrutiny, and whatever inchoate class would benefit from NOTA enforcement will derive less overall benefit than paid marrow transplantation would bring to the additional recipients.

As this analysis of *Flynn v. Holder* demonstrates, this model can be used to analyze any dispute in which there is a challenge to public health laws based on constitutionally guaranteed liberties.

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211. See Gary S. Becker & Julio Jorge Elías, *Introducing Incentives in the Market for Live and Cadaveric Organ Donations*, 21 J. ECON. PERSP. 3, 3 (2007).

212. Ted C. Bergstrom et al., *One Chance in a Million: Altruism and the Bone Marrow Registry* (UC Santa Barbara: Dep't of Econ. Working Paper) available at <http://escholarship.org/uc/item/2xt1p3gf> (last visited Dec. 5, 2010).

## CONCLUSION

This article has addressed, and resolved, the tension between substantive due process doctrine and the use of state power to safeguard public health against serious or systemic threats. It proposes doctrines that do not deny any existing or proposed constitutional rights, and that specifically do not require diminution of currently recognized reproductive rights. Rather, these doctrines elevate the health interests of members of the community to the same level of priority as the interest of those whose rights are burdened by laws that protect those health interests.

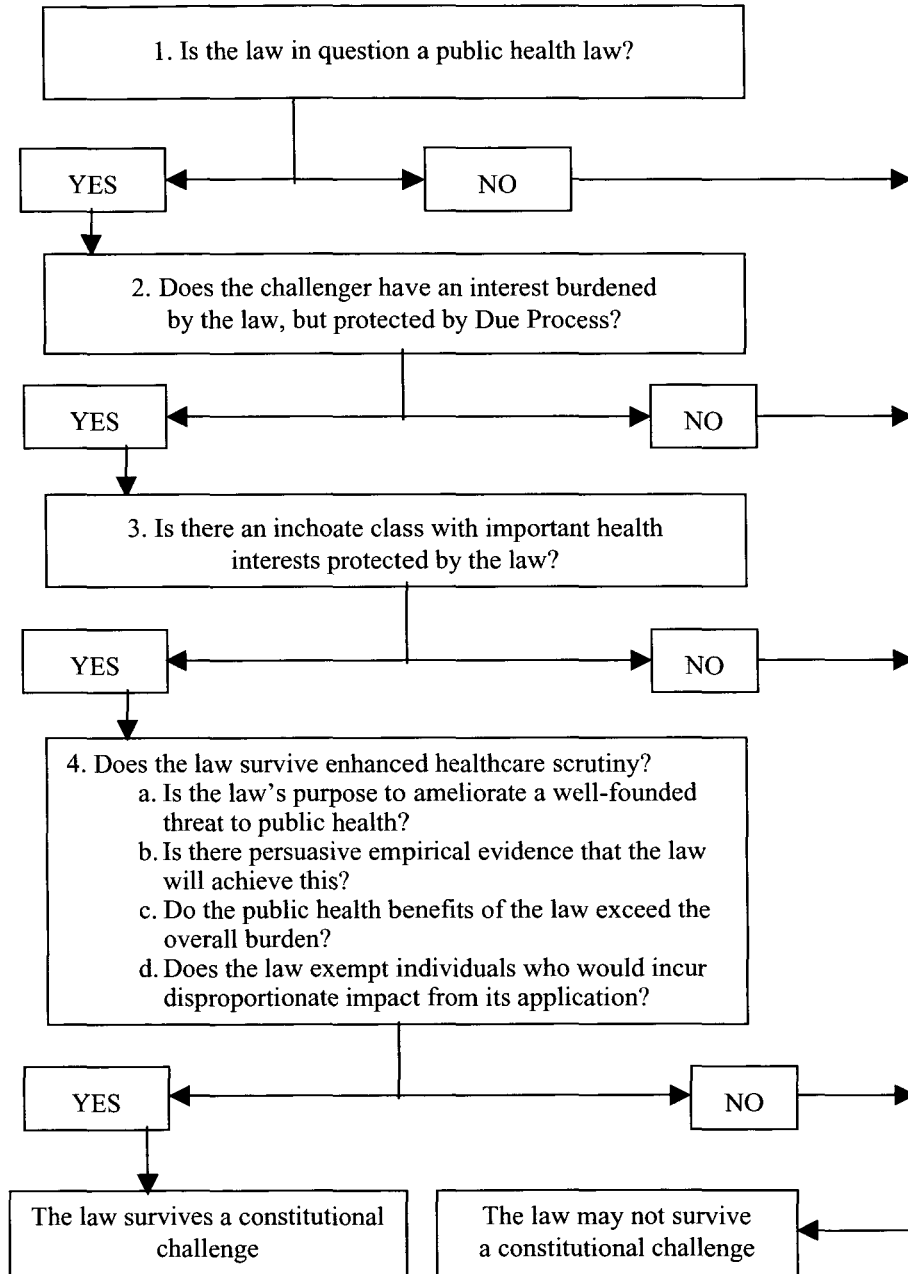
First, the proposed doctrine requires that a public health law comply with four elements (characterized as “enhanced public health scrutiny”): (1) the law’s purpose must be amelioration of a well-founded threat to public health; (2) there must be persuasive empirical evidence that the law will achieve this purpose; (3) the public health benefits must exceed the overall burden of the law; and (4) the law must exempt individuals who would incur disproportionate adverse impact if they were subjected to the law.

Second, the doctrine recognizes that the beneficiaries of public health laws comprise an inchoate class of individuals who: (1) will incur a specific disease or injury absent the proposed law; (2) cannot be identified before they incur this disease or injury; and (3) will not experience the disease or injury if the law is enforced. Prevention or amelioration of the threat to their health is a compelling government interest. Government protection of this interest can withstand challenges based on abrogation of fundamental rights of people outside the inchoate. The government, on behalf of the inchoate class, must only prove that the magnitude of protection offered by the public health law is greater than the magnitude of the harm caused by the law. This is an empirical inquiry.

Taken together, these two doctrines suggest a four-part test to determine whether a public health law should survive a rights-based challenge. The four steps are: (1) determine whether the law’s purpose is to improve public health; (2) determine whether the law burdens a fundamental right of a party opposing the law; (3) determine whether there is an inchoate class; and (4) determine whether the law survives enhanced public health scrutiny as defined above.

Applying this doctrine to cases that have been decided accurately mirrors the outcome of prior cases. Adoption of this doctrine would provide a clear and stable basis for addressing rights-based challenges to public health legislation without radically altering the law as it now stands.

**Figure 1. The four-step test for assessing the constitutionality of a public health law faced with a challenge based on fundamental rights.**



**Table 1: Summary of cases and analysis using paradigm of enhanced public health scrutiny and inchoate classes**

CASE	NOTE #	DUE PROCESS BURDEN	PUTATIVE HEALTH BURDEN	BALANCE OF EQUITY	SOURCE OF INCHOATE CLASS	DECISION
Compagnie Francaise (1902)	16	Quarantine; detention and exclusion	Grave infectious disease	State	Port residents who would contract illness	For state
Jacobson (1905)	7	Compelled vaccination	Contracting smallpox	State	Community residents	For state
Zucht (1922)	7	Same; exclusion from school	Contracting smallpox	State	Classmates	For state
Breithaupt (1957)	122	Involuntary venipuncture for forensic purpose	Highway injury and mortality	State	Drivers, passengers and pedestrians exposed to intoxicated drivers	For state
Addington (1979)	168	Involuntary commitment by clear and convincing evidence	Untreated mental illness; violence to others	State	Psychotic patients and their contacts	For state
Harper (1990)	8	Forced injection; no requirement for judicial hearing if prisoner	Untreated mental illness; violence to others	State	Psychotic prisoners and their contacts	For state
Rutherford (1979)	9	Right to sell and use ineffective and dangerous drug for cancer	Protection of public from quack remedy	State	Patients who would use Laetrile instead of effective treatment	For state
Cruzan (1990)	83	Autonomy in choosing to receive medical care	Protecting incompetent persons from unwanted death	State	Persons whom health care surrogates would allow to die against their will	For state
Raich (2005)	9	Putative pain relief and life preservation from marijuana	Protection of the public from marijuana	Indeterminate	Unclear if any	For state
Roe (1973) and other termination of pregnancy cases	17	Reproductive autonomy and protection of maternal health	Fetal life	Depends upon fetal status	None; fetuses have no personal status	Against state