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## Science, Public Bioethics, and the Problem of Integration

#### O. Carter Snead\*

Public bioethics — the governance of science, medicine, and biotechnology in the name of ethical goods — is an emerging area of American law. The field uniquely combines scientific knowledge, moral reasoning, and prudential judgments about democratic decisionmaking. It has captured the attention of officials in every branch of government, as well as the American public itself. Public questions (such as those relating to the law of abortion, the federal funding of embryonic stem cell research, and the regulation of end-of-life decisionmaking) continue to roil the public square.

This Article examines the question of how scientific methods and principles can and should be integrated into the making and enforcement of laws in this domain without compromising the integrity of science, the

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democratic legitimacy of government, or both. It identifies, analyzes and critiques one prominent model of integration, namely, the proposal to delegate virtually all public bioethical questions to scientific experts for resolution solely using the tools of their respective disciplines. The Article argues that this model of integration raises serious prudential concerns relating to democratic accountability (and thus legitimacy). More deeply, it argues that the proposal is unsustainable in principle because of the fundamental conceptual incompatibility between the premises and methods of modern science and the ethical principles that comprise the currency of public bioethical deliberation. It concludes by offering a provisional way forward, arguing that integration should be a function of defining and policing the boundaries of scientific methods and ethical reasoning, according to their respective competencies for the particular public bioethical question at issue. The Article provides an analytic tool to facilitate this line drawing, and illustrates its application with reference to several contemporary debates within public bioethics (i.e., the recent FDA approval of Plan B emergency contraception, the federal funding of embryonic stem cell research, and the impact of cognitive neuroscience on theories of criminal punishment).

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[T]he contradiction between the policy role of scientific knowledge and the principles of democratic decisionmaking has emerged as a central structural problem in western democracies.

--- Dorothy Nelkin<sup>1</sup>

Science can only ascertain what is, but not what should be, and outside of its domain[,] value judgments of all kinds remain necessary.

— Albert Einstein<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Dorothy Nelkin, Scientific Knowledge, Public Policy and Democracy: A Review Essay, 1 Sci. COMM. 106, 107 (1979).

<sup>&</sup>lt;sup>2</sup> YUVAL LEVIN, IMAGINING THE FUTURE: SCIENCE AND AMERICAN DEMOCRACY 6

[S] cience sans conscience n'est que ruyne de l'ame.

— Francois Rabelais<sup>3</sup>

#### INTRODUCTION

Public bioethics — the governance of the practice of medicine, biotechnology, and biomedical research in the name of ethical goods — is a relatively young species of law.<sup>4</sup> Nevertheless, over its brief lifespan, it has had a broad and deep impact in the public square. In the past decade alone, the American polity has been roiled by political and legal questions involving: the law of abortion;<sup>5</sup> federal funding of embryonic stem cell research;<sup>6</sup> termination of life-sustaining measures;<sup>7</sup> state, federal, and intergovernmental efforts to ban human

<sup>3</sup> FRANCOIS RABELAIS, PANTAGRUEL ch. 8 (1532) (". . . science without conscience is but the ruin of the soul.").

<sup>4</sup> Bioethicists William F. May, James Childress, and the late John C. Fletcher of the Center for Humanism in Medicine at the University of Virginia have offered a similar (though somewhat narrower) definition of "public bioethics," namely, "the activity of official public bodies established by federal or state governments to address — in public, with public participation — bioethical issues arising in public policy or public culture." William F. May et al., *Public Bioethics*, UNIV. VA. HEALTH SYS. (Oct. 6, 2004), http://www.healthsystem.virginia.edu/internet/him/publicbioethics.cfm. For a discussion of the emergence of public bioethics as a form of governance, see *infra* Part I (drawing heavily on O. Carter Snead, *Public Bioethics and the Bush Presidency*, 32 HARV. J.L. & PUB. POL'Y 867 (2009) [hereinafter Snead, *Public Bioethics*]). This Article uses the terms "law" and "governance" interchangeably to refer both to the deliberative processes of the Executive and Legislative branches of the federal government, as well as the products that issue therefrom in the form of executive orders and memoranda, administrative rules, regulations, and statutes.

<sup>5</sup> See, e.g., Robert J. Pushaw, Jr., Partial-Birth Abortion and the Perils of Constitutional Common Law, 31 HARV. J.L. & PUB. POL'Y 519 (2008) (challenging politicized nature of Supreme Court abortion jurisprudence); Charlie Savage, On Sotomayor, Some Abortion Rights Backers Are Uneasy, N.Y. TIMES, May 28, 2009, at A1 (discussing now-Justice Sotomayor's possible jurisprudential leanings with regard to abortion); Katherine Q. Seelye et al., On the Issues: Social Issues, N.Y. TIMES, http://elections.nytimes.com/2008/president/issues/abortion.html (last visited Mar. 17, 2010) (contrasting abortion views of 2008 presidential candidates).

<sup>6</sup> See, e.g., THE PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 2-5 (2004) [hereinafter MONITORING STEM CELL RESEARCH]; see also Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009) (repealing President Bush's limitations on federal funding for embryonic stem cell research).

<sup>7</sup> See, e.g., O. Carter Snead, The (Surprising) Truth About Schiavo: A Defeat for the Cause of Autonomy, 22 CONST. COMMENT. 383 (2006) (discussing legal and ethical issues involved in termination of life-sustaining measures); O. Carter Snead, Dynamic Complementarity: Terri's Law and Separation of Powers Principles in the End-of-Life Context, 57 FLA. L. REV. 53 (2005) (same).

<sup>(2008) (</sup>quoting Albert Einstein).

cloning (in some or all its forms);8 Oregon's legal regime for physician assisted suicide (and Attorney General John Ashcroft's efforts to nullify it by interpretive rule);9 and federal regulations regarding conscience protections for healthcare providers.<sup>10</sup> It should not be all that surprising that public bioethics has captured the attention of lawmakers and citizens alike. Few domains of governance feature the relationship between law and morality as starkly. In the public bioethics context, the government deploys its coercive powers in service of vigorously, often bitterly, contested moral claims about fundamental human concerns. To what class of individuals should the law extend its protection? When does the life of such an individual begin or end? What are the contours of the right to bodily autonomy? How do judgments about these matters stand in relation to obligations to alleviate suffering, the freedom to conduct scientific research, or to practice medicine as one sees fit? These are only a handful of the vexing moral questions at the heart of public bioethics.

Advances in biomedical science and biotechnology are, in an obviously causal sense, the reason that public bioethics emerged as a branch of governance in the first instance. But how should (or can) those charged with making or enforcing the law integrate the premises, methods, and findings of science itself into public bioethical deliberations? More pointedly, how can such officials fruitfully integrate science into public bioethics without compromising the integrity of science, the democratic legitimacy of government, or both?

The aim of this Article is to explore this "problem of integration," to articulate its complexities, and to offer a provisional way forward. It will examine one particularly prominent model of integration (termed here the "Maximal Deference" approach). Under this proposed approach, public officials delegate virtually all public bioethical questions to scientific experts, who will ostensibly appeal only to the tools of their respective disciplines to adjudicate the contested public

<sup>&</sup>lt;sup>8</sup> See, e.g., PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY 19-33 (2002) [hereinafter HUMAN CLONING] (discussing efforts in United States to ban cloning); Nigel M. de S. Cameron & Anna V. Henderson, Brave New World at the General Assembly: The United Nations Declaration on Human Cloning, 9(1) MINN. J.L. SCI. & TECH. 145, 148 (2008) (discussing history and content of 2005 United Nations Declaration on Human Cloning).

<sup>&</sup>lt;sup>9</sup> See Gonzales v. Oregon, 546 U.S. 243, 258-60 (2006) (invalidating interpretive rule as beyond Attorney General's statutory authority).

<sup>&</sup>lt;sup>10</sup> See, e.g., Rescission of the Regulation Entitled "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law," 74 Fed. Reg. 10207-01, 10208 (proposed Mar. 10, 2009) (to be codified at 45 C.F.R. pt. 88).

questions at issue.<sup>11</sup> The Article argues that the Maximal Deference model of integration raises serious prudential concerns relating to democratic accountability (and thus legitimacy). More deeply, it argues that this model is unsustainable in principle because certain key premises and methods of modern science are incompatible with the ethical principles that comprise the currency of public bioethical deliberation. The Article concludes by offering a provisional way forward. This proposal holds that integration should be a function of defining and policing the boundaries of scientific methods and ethical reasoning according to their respective competencies for the particular public bioethical question at issue.

To this end, the Article will proceed in the following manner. Part I explores the evolution of public bioethics as a form of governance in the United States. Part II identifies and explains the Maximal Deference model and discusses its historical origins. As a first step in critiquing the Maximal Deference model, Part III will provide a necessarily compressed and abstracted account of modern science as a mechanism for the active production of a narrowly circumscribed yet extremely powerful and useful kind of knowledge.<sup>12</sup> Specifically, it will discuss certain key premises and methods of modern scientific reasoning that render it unfit to supply answers to normative questions, namely, the commitments to physicalism, reductive mechanism, and strict adherence to clear epistemic rules.

Drawing on the foregoing discussion, Part IV argues that the Maximal Deference model is unsound. Procedurally, delegating bioethical questions to scientists creates serious problems for democratic accountability, and thus legitimacy. More importantly, this model fails *in principle* because key premises and methods of scientific reasoning are incommensurable with the humanistic principles that comprise the currency of public bioethical deliberation. The costs of ignoring this problem of incommensurability are grave. They include, for example, the risks of smuggling unstated humanistic principles into the governing process. Worse still, deferring to science alone to settle bioethical disputes could flatten or jettison essential humanistic

<sup>&</sup>lt;sup>11</sup> Whether the Maximal Deference model of integration is put forth in the public square as a serious proposal or as a mere rhetorical tactic is not entirely clear. As will be discussed in Part II, *infra*, this model is one that is routinely invoked by public figures, and it is rooted in a vision of governance that has been present since before this nation's inception. Accordingly, this Article aims to take the arguments for this model of integration seriously on their own merits, and seeks to provide a serious and sustained analysis and critique in response.

<sup>&</sup>lt;sup>12</sup> This discussion will be limited to the physical and life sciences. It does not address social sciences.

principles on the grounds that they are unintelligible in scientific terms. Such principles include foundational concepts such as freedom, equality, justice, and even "personhood" itself.

Part V offers a provisional way forward. Under the proposed approach, integration is a function of defining and policing the boundaries of scientific methods and ethical reasoning, according to their respective competencies for the particular public bioethical question at issue. This approach provides an analytic tool to facilitate this line drawing, and illustrates its application with reference to three contemporary debates within public bioethics: the recent FDA approval of Plan B emergency contraception, the federal funding of embryonic stem cell research, and the impact of cognitive neuroscience on theories of criminal punishment.

#### I. WHAT IS PUBLIC BIOETHICS?

#### A. Public Bioethics: Marrying Moral Principles with State Action

Bioethics emerged in America as a field of scholarly inquiry during the 1960s.<sup>13</sup> Extraordinary advances in biomedicine and biotechnology had transformed the practice of medicine by extending life (though often in diminished condition, raising ethical questions about termination of treatment and end-of-life care); driving up costs (leading to distributive justice issues); and creating an increased need for human subjects for biomedical research (prompting ethical questions about the relationship between the right to personal autonomy and interests of the broader society in pursuing research

<sup>&</sup>lt;sup>13</sup> See Gilbert C. Meilaender, Body, Soul, and Bioethics 1 (1995) ("Albert Jonsen dates 'the birth of bioethics' from the year 1962, when Shana Alexander's article describing the Seattle dialysis selection committee appeared in Life magazine. Elsewhere Jonsen describes 1965-75 as the 'formative decade' for bioethics in this country. David Rothman, in what is the first history of the bioethics movement, dates its beginning with the 1966 publication of Henry Beecher's articles exposing abuses in human experimentation."). The origin of the term "bioethics" is contested, though its first usage appeared in 1970. It has been attributed both to Sargent Shriver (original funder of the Georgetown Kennedy Institute of Ethics) and Van Renesslear Potter (research oncologist from University of Wisconsin). Whereas Shriver used the term to denote the ethical analysis of the development and application of biomedical science, Potter seemingly meant something more capacious, encompassing the relationship between man, his environment, and the civilized world (an "open ended biocybernetic study of self-assessment toward evolutionary, physiological, and cultural adaptation"). Shriver's definition more closely approximates the meaning of the term as it is used in America. For a discussion of the history of the term, see generally ALBERT JONSEN, THE BIRTH OF BIOETHICS 27 (1998).

aimed at developing treatments for dread diseases and injuries).<sup>14</sup> The revolution in molecular biology began in 1953 with the discovery of the structure of DNA by James Watson and Francis Crick.<sup>15</sup> This discovery prompted questions about human identity and man's new capacities to understand and perhaps even modify it.<sup>16</sup> The invention and development of in vitro fertilization — allowing human conception and manipulation of the human embryo outside of the body — similarly prompted vexing humanistic questions about the meaning of procreation, the moral status of the embryo, and the ethics of screening, selecting, discarding, or otherwise experimenting on such embryos.<sup>17</sup> More recently, the development of techniques and

<sup>16</sup> Recombinant DNA technology was developed in 1973 by Stanley Cohen and Herbert Boyer. See Cohen et al., Construction of Biologically Functional Bacterial Plasmids In Vitro, 70 PROC. NAT'L ACAD. SCI. 3240, 3240 (1973). Later, this technology was advanced by the discovery of restriction endonucleases by Werner Arber, Daniel Nathans, and Hamilton Smith, which led to their winning the Nobel Prize for Medicine in 1978. See The Nobel Prize in Physiology or Medicine 1978, http://nobelprize.org/nobel\_prizes/medicine/laureates/1978/ (last visited July 29, 2009). Techniques for artificially combining the genetic or cellular material of different mammalian species (such as by fusing their respective embryos) to create interspecies hybrids or chimeras have existed since the 1980s, and in 1997, two American researchers filed a patent application for chimeras made from combinations of humans and animals. Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 443 (1999). For a good overview of the science behind these techniques, see generally *id.* at 445-47; Tara Seyfer, *The Science of Chimeras and Hybrids*, 29 ETHICS & MEDICS 7 (2004).

<sup>17</sup> See R.G. Edwards et al., Early Stages of Fertilization In Vitro of Human Oocytes Matured In Vitro, 221 NATURE 632, 635 (1969); see also AH Handyside et al., Birth of a Normal Girl After In Vitro Fertilization and Preimplantation Diagnostic Testing for Cystic Fibrosis, 327 NEW ENG. J. MED. 905, 908 (1992) (describing successful preimplantation diagnosis for genetic disorder that causes cystic fibrosis). For a discussion of these issues see The President's Council on Bioethics, Reproduction AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES pt. I, chs. 3-5 (Mar. 2004) [hereinafter REPRODUCTION AND RESPONSIBILITY]. Subsequent developments raising similarly vexing ethical concerns include: the cloning of Dolly the sheep by somatic cell nuclear transfer (by Ian Wilmut in 1996), the derivation of stem cells from human embryos (by a team led by James Thomson in 1998), and the "completed" sequencing of the genome for all human chromosomes (by the Human Genome Project in 2006). See James A. Thomson et al., Embryonic Stem Cell Lines Derived from Human Blastocysts, 282 SCIENCE 1145 (1998); Ian Wilmut et al., Viable Offspring Derived from Fetal and Adult Mammalian Cells, 385 NATURE 810 (1997); U.S. Department of Energy Office of Science Human Genome Project Information Site, http://www.ornl.gov/sci/techresources/Human\_Genome/home.shtml (last visited July 30, 2008); see also S.G. Gregory et al., The DNA Sequence and Biological Annotation of Human Chromosome, 441 NATURE 315 (2006) (detailing sequence of final chromosome

<sup>&</sup>lt;sup>14</sup> See JONSEN, supra note 13, at 12.

<sup>&</sup>lt;sup>15</sup> J.D. Watson & F.H.C. Crick, A Structure for Deoxyribose Nucleic Acid, 171 NATURE 737, 737 (1953).

practices to enhance human performance or extend lifespan "beyond the normal" leads to questions about the meaning of human flourishing and its relationship (if any) to human finitude.<sup>18</sup> New research on the relationship of brain, mind, and behavior, made possible by recent advances in powerful (though non-invasive) techniques for imaging the structure and function of the brain gives rise to questions about free will, moral responsibility, and all of the social institutions and principles that rest on these concepts.<sup>19</sup> The continued development of medical interventions and techniques that sustain basic biological functioning long after cognitive capacities have irretrievably passed away raises profound questions about autonomy and dignity at the end of life, our collective obligations to provide humane care for the aged and dying, and even the definitions of "life" and "death" themselves.<sup>20</sup>

This explosion of biomedical innovation reoriented the physician's role towards technical and scientific mastery, emphasizing competence above all else. This had salutary effects on patient outcomes, but raised concerns about the doctor-patient relationship, and gave rise to much disagreement about the proper ends of medicine.<sup>21</sup> As Albert Jonsen has noted, "the scientific training of which modern medicine was so proud seemed to transform the healer into the technician who was remote, difficult to see, and even more difficult to understand."<sup>22</sup>

<sup>20</sup> See Alan Meisel & Kathy L. Cerminara, The Right to Die (3d ed. 2004 & Supp. 2008); The President's Council on Bioethics, Controversies in the Determination of Death (2008); The President's Council on Bioethics, Taking Care: Ethical Caregiving in Our Aging Society (2005).

<sup>21</sup> See JONSEN, supra note 13, at 12 (noting that Harper's Supplement in 1960 featured an article on "The Crisis in American Medicine" describing such worries).

<sup>22</sup> Id.

in project).

<sup>&</sup>lt;sup>18</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, BEYOND THERAPY 14 (2003), available at http://www.bioethics.gov/reports/beyondtherapy/.

<sup>&</sup>lt;sup>19</sup> See Henry T. Greely, Prediction, Litigation, Privacy, and Property: Some Possible Legal and Social Implications of Advances in Neuroscience, in NEUROSCIENCE AND THE LAW: BRAIN, MIND, AND THE SCALES OF JUSTICE 114, 114 (Brent Garland ed., The Dana Press 2004); Joshua D. Greene & Jonathan D. Cohen, For the Law, Neuroscience Changes Nothing and Everything, 359 PHIL. TRANSACTIONS ROYAL SOC'Y LONDON BIOLOGICAL SCI. 1775, 1775-76 (2004); Judy Illes & Stephanie J. Bird, Neuroethics: A Modern Context for Ethics in Neuroscience, 29 TRENDS NEUROSCIENCE 511, 515 (2006); Stephen Morse, Determinism and the Death of Folk Psychology: Two Challenges to Responsibility from Neuroscience, 9 MINN. J.L. SCI. & TECH. 1, 20-35 (2008); Robert Sapolsky, The Frontal Cortex and the Criminal Justice System, PHIL. TRANSACTIONS ROYAL SOC'Y LONDON BIOLOGICAL SCI. 1787, 1787-88 (2004); O. Carter Snead, Neuroimaging and the "Complexity" of Capital Punishment, 82 N.Y.U. L. REV. 1265, 1290-93 (2007) [hereinafter Snead, Neuroimaging].

A series of conferences were convened to reflect on these tensions between the humanistic and scientific dimensions of medical practice.<sup>23</sup> As Doctor S. Marsh Tenney (then Dean of the Dartmouth Medical School) noted at one of the very first such events:

Although [medicine's] foundations have become more rational, its practice — the welding of science and humanism — is said to have become more remote and indifferent to human values, and once again medicine has been forced to remind itself that it is often the human factors that are determinant.<sup>24</sup>

Shortly thereafter, several centers were founded to explore bioethical questions in a sustained and rigorous way.<sup>25</sup>

At roughly the same time as these physicians, scientists, theologians, legal scholars, and social scientists were considering such questions at academic conferences and in newly founded centers, Congressmen on Capitol Hill turned their attention to the *public* dimension of bioethics, and took up the issue of governance in this domain. Senator Walter Mondale convened hearings in 1968 in connection with his proposal to create a "President's Commission on Health Science and Society." would policies Commission recommend on organ This transplantation, genetic engineering, behavior control, human subjects protections, and the financing of research.<sup>26</sup> Mondale's initial efforts foundered, but in 1973 Senator Edward Kennedy convened hearings to discuss proposed research on living fetuses slated for abortion, as well as the discriminatory and abusive treatment of human subjects in scientific research (such as those that had occurred in Tuskegee,

<sup>&</sup>lt;sup>23</sup> Id. at 13-14. Such conferences included the "Great Issues in Modern Medicine" held at Dartmouth College in 1960; "Man and His Future," held by the Ciba Foundation in London in 1962; and the Nobel Laureate Series at Gustavus Adolphus College, which included "Genetics and the Future of Man" (held in 1965, featuring a presentation by William Shockley on eugenics, and a rebuttal by Paul Ramsey) and "The Human Mind" (in 1967, featuring a presentation by James Gustafson). *Id.* 

<sup>24</sup> Id. at 13.

<sup>&</sup>lt;sup>25</sup> See id. at 25-27. Such institutions included: the Hastings Center (founded in 1969 to study ethical issues relating to death and dying, behavioral control, genetic engineering and counseling, and population control); the Society for Health and Human Values (founded in 1969 in response to concerns about an undue emphasis on mechanistic explanations in medical education); and the Kennedy Institute of Ethics at Georgetown University (opened in 1971 to study issues in reproduction and ethics). *Id.* 

<sup>&</sup>lt;sup>26</sup> See id. at 90 (citing Hearings on S.J. Res. 145 Before the Subcomm. on Gov't Research of the Senate Comm. on Gov't Operations, 90th Cong., 2d Sess. 1 (1968) (statement of Sen. Walter Mondale)).

Alabama).<sup>27</sup> After much debate, these hearings culminated in the passage of the National Research Act.<sup>28</sup> Among other things, this Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged "to identify basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and develop guidelines that should be followed in such research," and to conduct a "comprehensive study of the ethical, legal, and social implications of advances in biomedical research." The Act directed the Secretary of Health, Education and Welfare<sup>29</sup> to implement the National Commission's advice within a stated period of time, or to show cause why such action was not taken.<sup>30</sup>

With the passage of this statutory mandate directing the National Commission to "do bioethics" in an enforceable way, public bioethics in America was born. Since then, public bioethics has been a permanent and active feature of the work of the political branches of government. At the federal level alone, the Executive and Legislative branches have taken numerous actions in response to ethical issues raised by advances in biomedical science and biotechnology.<sup>31</sup> Numerous federal commissions<sup>32</sup> on bioethics have been convened to

<sup>31</sup> For an extended reflection on public bioethics at the federal level from 2001–2009, see Snead, *Public Bioethics*, *supra* note 4.

<sup>&</sup>lt;sup>27</sup> See V.N. Gamble, Under the Shadow of Tuskegee: African Americans and Health Care, 87 AM. J. PUB. HEALTH 1773, 1773 (1997) (discussing Tuskegee Syphilis Study, forty year government study in which hundreds of black men were "deliberately denied effective treatment for syphilis in order to document the natural history of the disease").

<sup>&</sup>lt;sup>28</sup> National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974).

<sup>&</sup>lt;sup>29</sup> Today, the Department of Health, Education and Welfare is known as the Department of Health and Human Services. *See* U.S. Department of Health and Human Services, Historical Highlights, http://www.hhs.gov/about/hhshist.html (last visited Mar. 17, 2010).

<sup>&</sup>lt;sup>30</sup> For a detailed discussion of the Mondale and Kennedy hearings, see JONSEN, *supra* note 13, at 92-100.

<sup>&</sup>lt;sup>32</sup> See, e.g., Former Bioethics Commissions, http://bioethics.gov/reports/past\_ commissions/index.html (last visited July 29, 2009). The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research was created in 1974, the President's Commission for Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was created in 1978, the Ethics Advisory Board was created in 1978, the Human Embryo Research Panel was created in 1994, the Biomedical Ethical Advisory Committee was created in 1988, the National Bioethics Advisory Commission was created in 1996, the President's Council on Bioethics was created in 2001, the Advisory Commission on Human Radiation Experiments was created in 1994, and the NIH-DOE Joint Working Group on Ethical, Legal and Social Implications of Human Genome Research was formed in 1989. *Id.* 

offer advice.<sup>33</sup> Administrative agencies such as the Department of Health and Human Services ("HHS"), the National Institutes of Health ("NIH"), and even the Justice Department have propounded regulations that touch and concern bioethical matters. Such issues have included human subjects protections,<sup>34</sup> the federal funding of embryo and fetal research,<sup>35</sup> gene therapy research,<sup>36</sup> conscience protections for health care providers,<sup>37</sup> and physician assisted suicide.<sup>38</sup>

Similarly, Congress has enacted several laws concerning abortion and fetal personhood,<sup>39</sup> research involving embryos and fetuses,<sup>40</sup> conscience protections for health care providers,<sup>41</sup> the patenting of human embryos,<sup>42</sup> organ transplantation,<sup>43</sup> and end-of-life

<sup>37</sup> See 45 C.F.R. § 88.1 (2009); Recission of the Regulation Entitled "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Polocies or Practices in Violation of Federal Law," 74 Fed. Reg. 10,207-01 (proposed Mar. 10, 2009) (to be codified at 45 C.F.R. pt. 88).

<sup>38</sup> See, e.g., Gonzales v. Oregon, 546 U.S. 243, 275-76 (2006) (invalidating Attorney General's efforts to ban physician assisted suicide by administrative rule).

<sup>39</sup> See, e.g., Born Alive Infant's Protection Act, 1 U.S.C. § 8 (2006); Unborn Victims of Violence Act of 2004 (Laci and Conner's Act), 18 U.S.C. § 1841, 10 U.S.C. § 919a (2006) (recognizing child in utero as legal victim if he or she is injured during commission of crime); Partial Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531 (2006) (banning form of late term abortion); Hyde Amendment, Pub. L. No. 94-439 § 209, 90 Stat. 1434 (1976) (restricting federal funding of abortion).

<sup>40</sup> See, e.g., Fetus Farming Prohibition Act of 2006, Pub. L. No. 109-242, § 2, 120 Stat. 570, 570-71 (2006) (criminalizing acceptance of human tissue when pregnancy was deliberately started to provide such tissue or if human embryo was gestated in nonhuman animal); Dickey Amendment, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996) (prohibiting Department of Health and Human Services from using appropriated funds for creation of human embryos for research purposes or for research in which human embryos are destroyed).

<sup>41</sup> See, e.g., Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, § 508(d)(1)-(2), 118 Stat. 2809, 3163 (2004) (forbidding use of federal funds to programs that subject any health care entity to discrimination on basis that that entity does not provide for abortions).

<sup>42</sup> See, e.g., Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101 (2004) (forbidding use of federal funds to programs that issue patents on claims directed to or encompassing a human organism).

<sup>&</sup>lt;sup>33</sup> For an extended reflection on public bioethics at the federal level from 2001–2009, see generally O. Carter Snead, *The George W. Bush Administration: Public Bioethics and the Bush Presidency*, 32 HARV. L. J. & PUB. POL'Y 867 (2009).

<sup>&</sup>lt;sup>34</sup> See, e.g., 45 C.F.R. § 46 (2008) (known as "The Common Rule").

<sup>&</sup>lt;sup>35</sup> National Institute of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170-02 (July 7, 2009). *See generally* MONITORING STEM CELL RESEARCH, *supra* note 6 (discussing ethical, legal, and scientific dimensions of this issue).

<sup>&</sup>lt;sup>36</sup> For a comprehensive discussion of the law, ethics, and science of this matter, see REPRODUCTION AND RESPONSIBILITY, *supra* note 17.

decisionmaking.<sup>44</sup> Congress has debated (though not enacted) many more bills in this domain, relating to issues such as abortion,<sup>45</sup> human cloning,<sup>46</sup> and funding for non-embryonic sources of pluripotent cells (stem cells).<sup>47</sup>

Even the federal judiciary has contributed to the development of public bioethics. The U.S. Supreme Court has reserved the bulk of the abortion question to itself in the seminal case of *Roe v*. *Wade* and its progeny.<sup>48</sup> It has also issued opinions in landmark cases relating to end of life decisionmaking,<sup>49</sup> physician assisted suicide,<sup>50</sup> and the patenting of living organisms.<sup>51</sup>

Governors, state legislatures, and state courts have been similarly active in public bioethics. Given their nearly plenary authority to act

<sup>45</sup> See, e.g., Child Interstate Abortion Notification Act, H.R. 1063, 110th Cong. (2007) (preventing transportation of minors in circumvention of certain laws relating to abortion).

<sup>46</sup> See, e.g., Human Cloning Prohibition Act of 2007, S. 1036, 110th Cong. (2007) (proposing to prohibit human cloning); A Bill to Prohibit Human Cloning and Protect Stem Cell Research, S. 812, 110th Cong. (2007) (same).

<sup>47</sup> See, e.g., The HOPE Act, S. 30, 110th Cong. (2007) (promoting stem cell research from non-embryonic sources, such as amniotic fluid).

<sup>48</sup> See, e.g., Gonzales v. Carhart, 550 U.S. 124 (2007) (upholding Partial Birth Abortion Ban Act of 2003); Stenberg v. Carhart, 530 U.S. 914 (2000) (striking down Nebraska law and invalidating all state laws criminalizing partial birth abortion); Planned Parenthood of Se. Pa.v. Casey, 505 U.S. 833 (1992) (purporting to reaffirm core holding of *Roe v. Wade* but changing constitutional status of right to abortion from fundamental right to protected liberty interest and abandoning *Roe*'s trimester framework in favor of pre- versus post-viability dichotomy of regulation; before fetal viability, state may not "unduly burden" woman's right to choose abortion, whereas post-viability, state may restrict abortion provided it includes exceptions for the woman's life and "health" as defined in *Doe v. Bolton*); Doe v. Bolton, 410 U.S. 179 (1973) (holding that "health" includes physical, emotional, psychological, and familial factors, as determined by abortion provider); Roe v. Wade, 410 U.S. 113 (1973) (declaring abortion to be fundamental right, and purporting to provide framework establishing contours of state regulation of abortion).

<sup>49</sup> See Cruzan v. Missouri, 497 U.S. 261, 281-82 (1990).

<sup>50</sup> See Vacco v. Quill, 521 U.S. 793, 807-08 (1997); Washington v. Glucksberg, 521 U.S. 702, 735 (1997).

<sup>51</sup> See Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980).

<sup>&</sup>lt;sup>43</sup> See, e.g., National Organ Transplant Act, Pub. L. No. 98-507, 98 Stat. 2339 (1984) (outlawing sale of human organs).

<sup>&</sup>lt;sup>41</sup> See, e.g., An Act for the Parents of Theresa Marie Schiavo, Pub. L. No. 109-3, 119 Stat. 15 (2005) (authorizing suit by parents of Theresa Schaivo that could provide injunctive relief for vindication of her rights relating to medical treatment necessary to sustain her life); Patient Self-Determination Act, Pub. L. No. 101-508, §§ 4206, 4571, 104 Stat. 1388-115, 1388-204 (1990) (requiring health care providers to provide written information to adults regarding their rights under state law to make decisions regarding medical care and right to formulate advance directives).

in the name of the health, safety, welfare, and morals of citizens, it should not be surprising that the states have been fertile soil for this type of governance.<sup>52</sup> To take only a few examples, states have been involved in the regulation of abortion (to the extent permitted by Supreme Court precedent),<sup>53</sup> the use of assisted reproductive technologies,<sup>54</sup> embryo research,<sup>55</sup> human cloning,<sup>56</sup> research involving human subjects,<sup>57</sup> physician assisted suicide,<sup>58</sup> end-of-life decisionmaking,<sup>59</sup> and the definition of death.<sup>60</sup>

<sup>53</sup> FLA. STAT. ANN. § 390.01114 (West 2009) (Parental Notice of Abortion Act) (requiring parental notification for women under age of 18 prior to abortion); KAN. STAT. ANN. § 65-6709 (2009) (requiring informed consent of woman); N.D. CENT. CODE § 14-02.1-01 (2008) (North Dakota Abortion Control Act) (requiring "informed consent" and mandatory waiting period).

<sup>54</sup> See, e.g., CAL. HEALTH & SAFETY CODE § 125325 (West 2010) (governing procedures for solicitation and donation of oocytes for assisted reproductive technology); FLA. STAT. ANN. § 742.11 (West 2009) (creating presumption that any child conceived by artificial insemination is child of husband and wife); LA. REV. STAT. ANN. 9:126 (2009) (stating that any fertilized human ovum is not property of physicians or donors); VA. CODE ANN. § 20-156 (2009) (regarding legal status of children of assisted conception); WASH. REV. CODE ANN. §§ 26.26.700–26.26.740 (West 2009) (defining rights of donors and children created through assisted reproduction under Uniform Parentage Act).

<sup>55</sup> See, e.g., MICH. COMP. LAWS ANN. § 333.2685 (West 2009) (restricting nontherapeutic research on live human embryos, fetuses, or neonates); N.J. STAT. ANN. § 26:2Z-2 (West 2009) (stating that it is policy of state to permit research on human embryonic stem cells); 18 PA. CONS. STAT. ANN. § 3216 (West 2009) (criminalizing experimentation on unborn child).

<sup>56</sup> See, e.g., ARK. CODE ANN. § 20-16-1002 (West 2009) (making human cloning Class C Felony); CAL. HEALTH & SAFETY CODE § 24185 (2006) (prohibiting human cloning to produce children); MICH. COMP. LAWS ANN. §§ 333.16274, 333.16275, 750.430a (West 2009) (prohibiting human cloning); N.J. STAT. ANN. § 26:2Z-2 (prescribing administrative and civil penalties to those who engage in "human cloning," as defined by statute); N.D. CENT. CODE § 12.1-39-02 (2008) (making human cloning Class C Felony); R.I. GEN. LAWS § 23-16.4-2 (2008) (prohibiting somatic cell nuclear transfer); VA. CODE ANN. §§ 32.1-162.21, 32.1-162.22 (West 2009) (imposing civil penalties to those who engage in cloning).

<sup>57</sup> See, e.g., Grimes v. Kennedy Krieger Inst., 782 A.2d 807 (Md. 2001) (holding that parent cannot consent to participation of child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to health of subject).

<sup>58</sup> See, e.g., FLA. STAT. ANN. § 765.309 (West 2009) (pointing out that nothing in code should construe to authorize "mercy killing or euthanasia"); N.Y. PENAL LAW

<sup>&</sup>lt;sup>52</sup> See, e.g., Poe v. Ullman, 367 U.S. 497, 539 (1961) ("In reviewing state legislation, whether considered to be in the exercise of the State's police powers, or in provision for the health, safety, morals or welfare of its people, it is clear that what is concerned are 'the powers of government inherent in every sovereignty.' Only to the extent that the Constitution so requires may this Court interfere with the exercise of this plenary power of government." (citation omitted)).

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Public bioethics is distinctive as a species of governance because it merges state action with strong and contested moral claims. The currency of public bioethical discourse includes concepts such as autonomy, justice, equality, dignity, and personhood. These and other similar ethical principles are indispensable to the political deliberations in this domain. An extended reflection on a most vexed public bioethical issue — federal funding for embryonic stem cell research — confirms that this is so.<sup>61</sup>

#### B. A Modern Illustration of Public Bioethics: Federal Funding of Stem Cell Research

The moral, legal, and public policy dispute over embryonic stem cell research (and related matters, such as human cloning) is the most prominent issue in public bioethics of the past decade. Since the derivation of human embryonic stem cells in 1998 at the University of Wisconsin,<sup>62</sup> the issue has been debated and discussed by scholars, politicians, members of the popular media, and the public at large. It has been a key element of political campaigns, as well as of the

<sup>60</sup> See, e.g., Uniform Determination of Death Act, 12 U.L.A. 271 (1985); Uniform Law Commissioners, Uniform Determination of Death Act, July 21, 2004, http://www.nccusl.org/Update/uniformact\_factsheets/uniformacts-fs-udda.asp (noting forty-three states have adopted Uniform Determination of Death Act, or substantially similar legislation).

<sup>61</sup> The extended reflection that follows is also a necessary precursor for the discussion, in Part V.B.2, of my proposed model of integration for the public bioethical issue of embryonic stem cell research.

<sup>62</sup> See Thomson et al., supra note 17, at 1145.

<sup>§ 120.30 (</sup>McKinney 2009) (making promotion of suicide attempt felony); Oregon Death with Dignity Act, OR. REV. STAT. ANN. §§ 127.800–127.897 (West 2009) (allowing terminally-ill people to end their lives through voluntary self-administration of lethal medications, expressly prescribed by physician for that purpose); Washington Death with Dignity Act, WASH. REV. CODE ANN. §§ 70.245.010–70.245.904 (West 2009) (allowing terminally ill adults seeking to end their life to request lethal doses of medication from physicians).

<sup>&</sup>lt;sup>59</sup> See, e.g., 2003 Fla. Laws 418 (giving governor authority to issue stay to prevent withholding of nutrition and hydration from patient under circumstances like that of Theresa Marie Schaivo); Bush v. Schiavo, 885 So. 2d 321 (Fla. 2004) (overturning stay issued by legislature to prevent continued withholding of nutrition and hydration from Theresa Marie Schaivo); *In re* Conroy, 486 A.2d 1209 (N.J. 1985) (setting forth guidelines with respect to life sustaining treatment); *In re* Quinlan, 355 A.2d 647 (N.J. 1976) (holding that decision by daughter to permit noncognitive, vegetative existence to terminate by natural forces was valuable incident of her right to privacy which could be asserted on her behalf by her guardian); Florida Governor's Office, Exec. Order No. 03-201 (Oct. 21, 2003) (staying continued withholding of nutrition and hydration from Theresa Schaivo).

activities of the political branches of government at the state and federal level.

The primary question raised by the practice of embryonic stem cell research is whether it is morally defensible to disaggregate (and thus destroy) living human embryos in order to derive pluripotent cells (stem cells) for purposes of basic research that may someday yield regenerative therapies.<sup>63</sup> The public question at issue over the past decade is whether and to what extent to fund such research with taxpayer dollars. This issue raises additional contested normative questions about moral complicity, respect for conscience in a pluralistic society, the moral and political significance of government endorsement (e.g., through federal funding), and the obligations of citizenship.

The embryos used in this kind of research are typically donated by individuals or couples who conceived them by in vitro fertilization ("IVF") in the context of receiving assisted reproduction treatment, but who no longer need or want them for such a purpose. There are reports of some researchers creating embryos by IVF solely for use (and destruction) in research.<sup>64</sup> Theoretically, embryos for use in stem cell research could also be created by somatic cell nuclear transfer (that is, human cloning for biomedical research, or so-called "therapeutic cloning"), though efforts to derive pluripotent cells from cloned human embryos have not yet succeeded.<sup>65</sup>

The scientific aspirations for embryonic stem cell research are manifold, including the goals of understanding the mechanisms of

<sup>&</sup>lt;sup>63</sup> Pluripotent cells are unique and valuable because they are undifferentiated (meaning that they have the capacity to become any kind of tissue in the body) and, in principle, self-renewing (that is, they can reproduce themselves indefinitely without losing their pluripotency). They can be derived from the inner-cell mass of the early embryo (embryonic stem cells), the gonadal ridge of the early fetus (embryonic germ cells), and perhaps from a variety of other sources, including amniotic fluid, bone marrow, adipose cells, etc. Recent developments suggest that adult cells can be reprogrammed to pluripotency through the introduction of certain genetic factors. *See, e.g.*, Kazutoshi Takahashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861 (2007) (demonstrating generation of induced pluripotent human dermal fibroblasts with four transcription factors).

<sup>&</sup>lt;sup>64</sup> See Sheryl Gay Stolberg, Scientists Create Scores of Embryos to Harvest Cells, N.Y. TIMES, July 11, 2001, at A1.

<sup>&</sup>lt;sup>65</sup> For extended discussion of the science, ethics, and public policy of embryonic stem cell research and human cloning, see MONITORING STEM CELL RESEARCH, supra note 6; HUMAN CLONING, supra note 8; see also O. Carter Snead, The Pedagogical Significance of the Bush Stem Cell Policy, 5 YALE J. HEALTH POL'Y L. & ETHICS 491, 496-503 (2005); O. Carter Snead, Preparing the Groundwork for a Responsible Debate on Stem Cell Research and Human Cloning, 39 NEW ENG. L. REV. 479, 481-87 (2005) (keynote address for symposium).

early human development, to test and develop pharmaceuticals, and ultimately, to devise new regenerative therapies. According to prominent researchers in this field, realizing these aspirations will require the creation of a bank of embryonic stem cell lines large enough to be sufficiently diverse both for the creation of models to study all relevant diseases or injuries that might admit of regenerative cell-based therapy, and for purposes of immunocompatibility (i.e., to avoid tissue rejection by transplant recipients) should such therapies be developed.<sup>66</sup> This program will thus require the use and destruction of millions of human embryos. Given the scarcity of donated IVF embryos for this purpose,<sup>67</sup> creating embryos solely for the sake of research (by IVF or cloning) seems to be a necessity for realizing the aspirations of advocates of embryonic stem cell research.<sup>68</sup>

American Presidents, through their directives to the NIH (responsible for a large portion of federal research funding), have taken divergent normative views on this question. For present purposes it is worth examining how such ethical judgments have driven the policies of recent administrations.

For the past thirty years the political branches have been locked in a stalemate on the issue. The National Commission recommended that Congress charter a permanent body known as the Ethics Advisory Board ("EAB") to review and approve any federally funded research involving in vitro embryos. Thereafter, this requirement was adopted as a federal regulation.<sup>69</sup> While the EAB issued a report in 1979 approving, as an abstract ethical matter, the funding of research involving the use and destruction of in vitro embryos, its charter expired before it had the opportunity to review and approve any concrete proposals. Its membership was never reconstituted, but the legal requirement for EAB approval remained in place. Thus a de facto moratorium on the funding of embryo research was sustained until 1993, when Congress (at the urging of the newly elected President Clinton) removed the EAB approval requirement from the law.<sup>70</sup>

<sup>&</sup>lt;sup>66</sup> See Robert Lanza & Nadia Rosenthal, The Stem Cell Challenge, SCI. AM. 92 (2004).

<sup>&</sup>lt;sup>67</sup> The most comprehensive study, conducted by RAND in 2003, estimated that as of that date, there were 400,000 or so embryos in cryopreservation, only 2.8 percent of which have been formally designated for donation. See David I. Hoffman et al., *Cryptopreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063, 1068 (2003).

<sup>68</sup> See Lanza & Rosenthal, supra note 66, at 92.

<sup>&</sup>lt;sup>69</sup> Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research, 45 C.F.R. § 46.204(d) (1982) (nullified 2003).

<sup>&</sup>lt;sup>70</sup> See National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43,

President Clinton thereafter directed the NIH to formulate recommendations governing the federal funding of embryo research. The NIH Human Embryo Panel convened and issued a report in 1994 recommending federal funding for research involving the use and destruction of in vitro embryos — including research protocols in which embryos were created solely for this purpose (subject to certain limitations).<sup>71</sup> President Clinton accepted most of these recommendations (though he rejected the panel's approval for funding projects using embryos created solely for the sake of research),<sup>72</sup> and made preparations to authorize such funding. Before he could act, however, control of Congress shifted from democrat to republican, and the new majority attached an appropriations rider to the 1996 Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act. The amendment forbade the federal funding of:

[T]he creation of a human embryo or embryos for research purposes; or [for] research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero [under the relevant human subjects protection regulations].<sup>73</sup>

This amendment (known as the "Dickey Amendment," after its chief sponsor), which has been reauthorized every year since, appeared to short-circuit the Clinton administration's efforts to fund embryo research. That is, until 1998, in the wake of the derivation of human embryonic stem cells,<sup>74</sup> the General Counsel of President Clinton's Department of Health and Human Services issued an opinion declaring that the Dickey Amendment permitted the funding of research involving stem cells that had been derived from the disaggregation (and thus destruction) of human embryos, so long as the researchers did not use federal funds to destroy the embryos in the first instance. In other words, so long as researchers used private resources to destroy the embryos in question, subsequent research

<sup>§ 121(</sup>c), 107 Stat. 122, 133 (1993) (repealing 45 C.F.R. § 46.204(d)).

<sup>&</sup>lt;sup>71</sup> See NAT'L INSTS. OF HEALTH REPORT OF THE HUMAN EMBRYO RESEARCH PANEL 44-45 (Sept. 1994).

<sup>&</sup>lt;sup>72</sup> President Clinton's position was supported by the Washington Post editorial board as well. See Editorial, Embryos: Drawing the Line, WASH. POST, Oct. 2, 1994, at C6.

<sup>&</sup>lt;sup>73</sup> Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

<sup>&</sup>lt;sup>74</sup> Thomson et al., supra note 17, at 1145.

involving the resultant cellular products derived from the embryodestructive act was not, literally, research "in which" embryos are destroyed, as contemplated by the Dickey Amendment.<sup>75</sup>

Before any funds could be authorized under this new interpretation, President George W. Bush was elected, and as is typical of newly elected presidents, he ordered suspension of all pending administrative agency initiatives for review (including those relating to funding embryo research). In resolving the moral and political question presented, President Bush appealed to both a robust conception of human equality and the findings of modern embryology. The relevant science confirmed that the five-to-six day old human embryo used and destroyed in stem cell research is a complete, living, self-directing, integrated, whole individual.<sup>76</sup> An embryo is a member

<sup>&</sup>lt;sup>75</sup> Memorandum from Harriet S. Rabb, General Counsel of the Department of Health and Human Services, to Harold Varmus, Director of the National Institutes of Health, Federal Funding for Research Involving Human Pluripotent Stem Cells (Jan. 15, 1999) (on file with National Archives).

<sup>&</sup>lt;sup>76</sup> President Bush implicitly rejected the argument that because the embryos used in stem cell research may be capable of "twinning," they are not yet stable individuals, and thus not entitled to substantial moral respect. Twinning is the process by which cells that become disarticulated from the embryo sometimes, through a process of restitution and regulation, resolve themselves into a new, whole organism. It is believed that twinning occurs in very few cases - monozygotic twins are rare, accounting for only 1 in 240 births. President Bush may have been moved by the argument that, as a biological matter, "indivisibility" is not regarded as a necessary criterion for individuation in an organism. Other species are clearly classified as individual organisms, despite their capacity for the biological equivalent of twinning (for example, flatworms). Rather, organisms are defined according to the level of integration and organization of their constituent parts. Human embryos show highly integrated organization, specialization, and differentiation well before the blastocyst phase of development (that is, when they are used in stem cell research). Accordingly, there is strong support for the proposition that a blastocyst is clearly an individuated organism, that is, a whole, individual member of the human species. See George W. Bush, Stem Cell Science and the Preservation of Life, N.Y. TIMES, Aug. 12, 2001, at WK13; see, e.g., Louis Guenin, The Nonindividuation Argument Against Zvgotic Personhood, 81 Philosophy 463, 485 (2006) (arguing in favor of embryo research on other grounds). Moreover, opponents of the twinning argument cite recent research (showing a dramatic increase in incidence of monzygotic twinning after blastocyst transfer) to support the notion that monozygotic twinning is caused by an extrinsic disruption (for example, blastomere biopsy, as performed in preimplantation genetic diagnosis), and is not an intrinsic quality of the early embryo. See, e.g., MONITORING STEM CELL RESEARCH, supra note 6, at 80 ("Evidence for this, they suggest, may be seen in the increased incidence of monozygotic twinning (up to tenfold in blastocyst transfer) associated with IVF. This suggests, in their view, that twinning is neither a proof of the absence of an integrated individual organism with a drive in the direction of development nor a demonstration ex post facto of the absence of moral worth of the embryo before twinning."); HUMAN CLONING, supra note 8, at 271 (personal statement of Doctor William B. Hurlbut) ("Monozygotic twinning (a mere 0.4 % of births) does

of the human species, who, given the proper environment will (if all goes well) move itself along the trajectory of human biological development from embryo, to fetus, to neonate, to child, to adolescent, to adult.77 The biological status of embryos as human organisms did not, however, settle the question of their moral status. For this judgment, President Bush invoked human equality as a principle of classical liberalism underlying the nation's founding. In his judgment, the only coherent (non self-destroying) understanding of human equality is one that encompasses all human beings without discrimination on the basis of accidental characteristics such as age, size, condition of dependency or vulnerability, circumstances, or the esteem of others. Accordingly, President Bush concluded that the intentional use and destruction of embryos in stem cell research is gravely immoral and unjust. Furthermore, he took the position that the intentional creation of embryos (by IVF or cloning) for use and destruction in research is, a fortiori, morally unacceptable.<sup>78</sup>

<sup>77</sup> It is a basic premise of modern embryology that the zygote (one-cell embryo) is an organism and is totipotent (that is, moves itself along the developmental trajectory through the various developmental stages). For a general overview of the developmental trajectory of zygotes, see MONITORING STEM CELL RESEARCH, *supra* note 6, at Appendix A, Notes on Early Human Development.

<sup>78</sup> President Bush has also expressed several other ethical concerns about human cloning for biomedical research, including the following worries: that its practice makes reproductive cloning inevitable (as the only remaining step for that procedure is transfer of the cloned embryo to a woman's uterus); it represents an unprecedented step towards more refined techniques of engineering human organisms with a preselected genetic constitution; and the massive number of ova required to conduct cloning research creates dangerous incentives to exploit women, particularly poor women as sources. See, e.g., Address Before a Joint Session of the Congress on the State of the Union, 44 WEEKLY COMP. PRES. DOC. 117 (Jan. 28, 2008) (calling on Congress to "pass legislation that bans unethical practices, such as the buying, selling, patenting, or cloning of human life"); Address Before a Joint Session of the Congress on the State of the Union, 42 WEEKLY COMP. PRES. DOC. 145 (Jan. 31, 2006) (asking Congress to prohibit human cloning in all its forms); Address Before a Joint Session of the Congress on the State of the Union, 41 WEEKLY COMP. PRES. DOC. 126 (Feb. 2, 2005) (calling for scientific advances to always serve human dignity rather than taking advantage of some lives for benefit of others).

not appear to be either an intrinsic drive or a random process within embryogenesis. Rather, it is a disruption of normal development by a mechanical or biochemical disturbance of fragile cell relationships that provokes a compensatory repair, but with the restitution of integrity within two distinct trajectories of embryological development."). For evidence that embryos are integrated at the earliest stages of development, see *id.* at 263-64 (personal statement of Professors George and Gomez-Lobo) (explaining, with extensive reference to findings of modern embryology, manifold ways in which embryo, from its earliest stages of development is unitary, integrated, differentiated, self-directing organism).

In making this judgment, President Bush implicitly rejected the notion that an individual's moral status (and the attendant protections that it entails) waxes and wanes according to the judgment of others. in light of physical, mental, or circumstantial criteria that such others might establish.<sup>79</sup> He argued that this competing approach stands the equality principle on its head — privileging the claims of the strong over those of the weak. In such a regime, the rights (including the basic right to life) of the weak are determined entirely according to the needs and desires of the strong. Nothing, he concluded, could be more anathema to the American principle of intrinsic, inalienable rights. Moreover, he believed that this principle of contingent personhood would produce monstrous practical results (including, for example, a sliding scale of moral and legal standing for people based on their cognitive ability, usefulness, strength, and so on). By extension, he rejected the arguments of those who assert that the human embryo is not entitled to a high degree of moral respect because it lacks certain preferred (actively exercisable) capacities or characteristics.<sup>80</sup> This, in President Bush's mind, was tantamount to the most unjust and invidious kind of discrimination. He likewise rejected the more

<sup>&</sup>lt;sup>79</sup> President Bush's conception of human equality stands in stark contrast to those frameworks that define "persons" (that is, rights-bearing individuals who merit moral concern and forbearance) in a more exclusive fashion — according to more exacting criteria such as the presence or absence of certain active capacities (such as sentience, the ability to feel pain, and so on). This competing approach is reflected in H. Tristram Englehardt's argument that persons are those who have the ability to be "concerned about moral arguments and ... convinced by them. They must be selfconscious, rational, free to choose, and must possess moral concern." MEILAENDER, supra note 13, at 109-10 (quoting H. TRISTRAM ENGELHARDT, JR., THE FOUNDATIONS OF BIOETHICS (1986)). In a similar vein, bioethicist Ronald Green has argued that the criteria for personhood needs to be determined by those who are indisputably persons (that is, members of the able-minded community of reasoners), according to their judgments about how granting or withholding moral personhood might affect the liberty interests of the decisionmakers. See Ronald Green, Toward a Copernican Revolution in Our Thinking About Life's Beginning and Life's End, 66 SOUNDINGS 152, 152-57 (1983). Under these and related approaches, "personhood" or moral worth is something that is earned or accrued. It is not an intrinsic quality, co-extensive with merely being a living human being.

<sup>&</sup>lt;sup>80</sup> A prominent proposed characteristic for this purpose is the "primitive streak" — a biological structure that marks the location of the vertebral column and indicates the anterior-posterior axis of the organism (though recent evidence suggests that polarity may be established much earlier, perhaps by the locus of penetration of the egg by the sperm). The primitive streak also marks the moment after which twinning is no longer possible. Other suggested capacities marking personhood include the nervous system, the brain, and more mature human somatic form. For a review of these arguments and rejoinders to them, see MONITORING STEM CELL RESEARCH, *supra* note 6.

limited argument in favor of using and destroying donated embryos from fertility clinics because they are destined to be discarded and destroyed in any event. President Bush's understanding of equality dictated that living human beings should not be treated as raw materials to be exploited and destroyed for biomedical research purposes simply because someone else has made the decision that their lives were no longer useful and thus should be terminated.<sup>81</sup> And his devotion to the principle of radical equality and, in his words, respect for the "matchless worth" of every individual, led him to reject a straightforward utilitarian argument that assumed the personhood of the embryo, but nevertheless justified its use in research simply by virtue of the hoped-for lifesaving promise of the therapies that might emerge from it.<sup>82</sup>

As a legal matter, President Bush agreed with his predecessor that the Dickey Amendment, read literally, did not preclude funding for research where embryos had been destroyed using private resources. But he adopted a policy, announced on August 9, 2001, whereby federal funding would only flow to those species of stem cell research that did not create future incentives for destruction of human life in the embryonic stage of development. Concretely, this entailed funding for nonembryonic stem cell research (for example, stem cells derived from differentiated tissue — so-called "adult" stem cell research), and research on embryonic stem cell lines that had been derived before the announcement of the policy (i.e., where the embryos had already been destroyed).<sup>83</sup>

When he announced the policy, he said that there were more than sixty genetically diverse lines that met the funding criteria.<sup>84</sup> In the days that followed, more such lines were identified, bringing the number to seventy-eight. Though seventy-eight lines were eligible for funding, only twenty-one lines were available for research, for reasons relating both to scientific and intellectual property related issues.<sup>85</sup> As

<sup>&</sup>lt;sup>81</sup> For an extended exploration of this argument, see Gilbert Meilaender, Spare Embryos, WEEKLY STANDARD, Aug.–Sept. 2002, at 25.

<sup>&</sup>lt;sup>82</sup> See, e.g., Julian Savulescu, The Embryonic Stem Cell Lottery and the Cannibalization of Human Beings, 16 BIOETHICS 508, 529 (2002) ("ES cell technology stands to benefit everyone . . . . It is this property that may make it reasonable to kill some embryos to conduct ES cell research even if the embryo is a person.").

<sup>&</sup>lt;sup>83</sup> For general information regarding Bush stem cell policy, see The Bush Record: Fact Sheet: Advancing Stem Cell Research in Ethical, Responsible Ways, http://georgewbushwhitehouse.archives.gov/infocus/bushrecord/factsheets/stemcells.html (last visited Mar. 13, 2010).

<sup>&</sup>lt;sup>84</sup> Bush, supra note 76, at WK13.

<sup>&</sup>lt;sup>85</sup> The President's Council on Bioethics explained the process by which an eligible

of July 2007, the administration had made more than \$3.7 billion available for all eligible forms of research, including more than 170 million dollars for embryonic stem cell research.<sup>86</sup> By that time, nearly one thousand shipments of cell preparations from these lines had been shipped to researchers.<sup>87</sup>

Later in his administration, partly in response to the development of a revolutionary technique to produce pluripotent cells by reprogramming (or de-differentiating) adult cells (i.e., "induced pluripotent state cells" or iPS cells), without need for embryos or ova, President Bush directed the NIH to broaden the focus of its funding efforts to include any and all promising avenues of pluripotent cell research, regardless of origin.<sup>86</sup> In this way, President Bush's policy was designed to promote biomedical research to the maximal extent possible, consistent with his robust principle of equality regarding human embryos.<sup>89</sup>

Congress tried twice to override President Bush's stem cell funding policy and authorize federal taxpayer support of embryonic stem cell research by statute. President Bush vetoed both bills. Relatedly, a bill was introduced to formally authorize support for research on

cell line becomes available for use:

The process of establishing a human embryonic stem cell line, turning the originally extracted cells into stable cultured populations suitable for distribution to researchers, involves an often lengthy process of growth, characterization, quality control and assurance, development, and distribution. In addition, the process of making lines available to federally funded researchers involves negotiating a contractual agreement (a "materials transfer agreement") with the companies or institutions owning the cell lines, establishing guidelines for payment, intellectual property rights over resulting techniques or treatments, and other essential legal assurances between the provider and the recipient.

MONITORING STEM CELL RESEARCH, supra note 6, at 43.

<sup>86</sup> See generally Expanding Approved Stem Cell Lines in Ethically Responsible Ways, Exec. Order No. 13435, 72 Fed. Reg. 34591 (June 20, 2007); Message to the Senate Returning Without Approval the "Stem Cell Research Enhancement Act of 2007," 43 WEEKLY COMP. PRES. DOC. 833 (June 20, 2007). For funding figures, see The Bush Record, Advancing Stem Cell Research in Ethical, Responsible Ways, http://georgewbushwhitehouse.archives.gov/infocus/bushrecord/factsheets/stemcells.html (last visited Mar. 17, 2010).

<sup>87</sup> The recently announced Phase I clinical trials for embryonic stem cell-based therapies sponsored by Geron use Bush-approved cell lines. See Susan Jeffrey, First Embryonic Stem Cell Based Therapy Trial in Spinal Cord Injury Gets FDA Nod, Jan. 27, 2009, http://www.medscape.com/viewarticle/587411.

<sup>88</sup> See Expanding Approved Stem Cell Lines in Ethically Responsible Ways, 72 Fed. Reg. at 34,591.

<sup>&</sup>lt;sup>89</sup> Id.

alternative (i.e., non-embryonic) sources of pluripotent cells.<sup>90</sup> It passed in the Senate with seventy votes, but was killed procedurally in the House of Representatives.<sup>91</sup>

Apart from the White House and NIH, official bodies within the Executive branch promoted the administration's policy regarding stem cell research funding. The President's Council on Bioethics produced a report exploring the arguments for and against the policy (as well as three reports on related issues, including cloning, assisted reproductive technologies, and alternative sources of pluripotent cells).<sup>92</sup> The FDA issued guidance documents and sent letters to interested parties, including government officials, giving assurances that the agency foresaw no difficulties and was well prepared to administer the approval process of any therapeutic products that might emerge from research using the approved embryonic stem cell lines.<sup>93</sup>

On March 9, 2009, President Obama rescinded all of President Bush's previous executive actions regarding funding for stem cell research, and affirmatively directed the NIH to fund all embryonic stem cell research that was "responsible, scientifically worthy... to the extent permitted by law."<sup>94</sup> He gave the NIH 120 days to provide more concrete guidelines.<sup>95</sup> In July of that year, the NIH adopted a policy of federal funding for research involving cell lines derived from embryos originally conceived by IVF patients for reproductive purposes but now no longer wanted for such purposes. The NIH guidelines restrict funding to these kinds of cell lines on the grounds

<sup>95</sup> Id.

<sup>&</sup>lt;sup>90</sup> The Hope Offered through Principled and Ethical Stem Cell Research Act (the HOPE Act), S. 30, 110th Cong. (2007).

<sup>&</sup>lt;sup>91</sup> The Act was received in the House of Representatives on April 16, 2007, but never left the House Committee on Energy and Commerce. *See* Snead, *supra* note 4, at 886–87.

<sup>&</sup>lt;sup>92</sup> See HUMAN CLONING, supra note 8; MONITORING STEM CELL RESEARCH, supra note 6; REPRODUCTION AND RESPONSIBILITY, supra note 17; PRESIDENT'S COUNCIL ON BIOETHICS: ALTERNATIVE SOURCES OF PLURIPOTENT CELLS: A WHITE PAPER 1-62 (2005), available at http://bioethics.georgetown.edu/pcbe/reports/white\_paper/.

<sup>&</sup>lt;sup>93</sup> See, e.g., Letter from Bernard A. Schwetz, Acting Principal Deputy Commissioner of Food and Drug Administration, to Senator Edward Kennedy (Sept. 5, 2001) (concluding that "[t]hus, as intended and practiced, the FDA regulation of xenotransplantation products, while aimed first and foremost at safeguarding the public health, should not impose a substantial impediment to xenotransplantation product development, including HEPSC that are produced by culture in vitro with mouse cells").

<sup>&</sup>lt;sup>94</sup> Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Exec. Order No. 13,505, 74 Fed. Reg. 10,667, 10,677 (Mar. 9, 2009).

that there is, as yet, no social consensus on the morality of creating embryos solely for the sake of research (either by IVF or somatic cell nuclear transfer, also known as human cloning).<sup>96</sup> Additionally, the NIH guidelines forbid federal funding of research in which human embryonic stem cells are combined with non-human primate blastocysts, and research protocols in which human embryonic stem cells might contribute to the germline of non-human animals.<sup>97</sup> The final version of the NIH guidelines explicitly articulate the animating principles for the policy: belief in the potential of the research to reveal knowledge about human development and perhaps regenerative therapies, and the embryo donor's right to informed consent.<sup>98</sup> Neither President Obama nor the NIH guidelines have discussed the moral status of the human embryo.

The foregoing discussion illustrates the extraordinary extent to which rich ethical concepts such as personhood, equality, justice, beneficence, and autonomy, drive the law concerning embryonic stem cell research. This illustration fairly represents the larger field of public bioethics more generally. Few species of governance blend law and morality to the same extent. This feature of public bioethics will prove crucial to the question of how science should and can be integrated into the governing process and the law that it produces. And this example of the public question of funding for embryonic stem cell research will prove crucial to the below discussion of the problem of (and perhaps the beginnings of a solution to) integration of science into this domain.

#### II. THE PROBLEM OF INTEGRATION FOR SCIENCE AND PUBLIC BIOETHICS: ONE PROMINENT PROPOSAL EXPLORED

#### A. The "Maximal Deference" Model

From the foregoing it is clear that public bioethics offers a unique synthesis of scientific evidence, ethical principles, and prudential judgments about governance. How, then, should these disparate elements be integrated? Over the past decade — principally in the context of the debate over federal funding for embryonic stem cell research — one model of integration for science and public bioethics has garnered substantial traction among a wide array of very

<sup>&</sup>lt;sup>96</sup> See National Institute of Health on Human Stem Cell Research, 74 Fed. Reg. 32170-02 (July 7, 2009).

<sup>97</sup> Id.

<sup>&</sup>lt;sup>98</sup> Id.

influential public figures. Simply stated, the proposal is that the adjudication of vexing public bioethical questions should be delegated<sup>99</sup> to scientific experts who are to apply the neutral and objective tools of their respective disciplines. Moreover, proponents of this model of integration condemn public bioethical decisionmaking based on personal judgments about moral goods to be pursued or harms to be avoided as the illegitimate "politicization" of "scientific" matters. Thus, the proposal contemplates strong, seemingly categorical deference to experts solely deploying the premises and methods of science. Accordingly, this approach to integration will be termed the "Maximal Deference" model.

An impressive assembly of public figures has come forward to defend Maximal Deference as a model of integration. Chief among them is Professor Irving Weissman, Director of Stanford University's Institute for Stem Cell Biology and Regenerative Medicine. Doctor Weissman is an esteemed researcher. He is the recipient of numerous awards, including the Linus Pauling Medal for Outstanding Contributions to Science (given by Stanford University) and the Jessie Stevenson Kovalenko Medal (given by the National Academy of Sciences Council).<sup>100</sup> He has been also been a high profile participant in the public square — arguing forcefully in favor of federal and state funding for embryonic stem cell research (including the adjunct technique of cloning for biomedical research). In 2004 he was one of the leading proponents of Proposition 71, a successful state referendum that created a right (under the California constitution) to engage in embryonic stem cell research, and developed a mechanism for state funding of such research to the tune of \$3.7 billion. Weissman even appeared in campaign ads supporting the referendum.101

Weissman has been an outspoken proponent of the Maximal Deference model of integration. In fact, he advised President Obama to adopt this approach to federal funding of embryonic stem cell research:

I reported ... to the Obama transition team, June 2nd .... If you decide to lift the ban ... don't replace one ideology with another, you should only go on the basis of what is

<sup>&</sup>lt;sup>99</sup> Here, "delegation" refers both to formal delegation of authority by legal means, · or informal delegation, in the form of categorical deference to the opinion of experts.

<sup>&</sup>lt;sup>100</sup> Community Academic Profile of Irving L. Weissman, M.D., http://med.stanford.edu/ profiles/stemcell/researcher/Irving\_Weissman/ (last visited Mar. 8, 2010).

<sup>&</sup>lt;sup>101</sup> Michael Fumento, *The Great Stem-Cell-Research Scam*, N.Y. POST, July 15, 2009, http://www.fumento.com/biotech/greatstemcell.html.

*scientifically possible*.... And Obama in his speech, and I was there, said just that. He said we're going to remove politics and ideology from scientific decision making.<sup>102</sup>

Weissman expressed strong disagreement and even disgust with the NIH guidelines implementing President Obama's executive order. The guidelines limited funding eligibility to embryonic stem cell lines derived from donated IVF embryos originally conceived for reproductive purposes and prohibited funding for research involving cell lines derived from embryos created solely for the sake of research (by IVF or somatic cell nuclear transfer (i.e., human cloning)). Weissman lamented that the NIH based its guidelines in part on ethical considerations rather than entirely on the projected capacities of scientific researchers. He construed President Obama's executive order as including no such limits.<sup>103</sup> Weissman thought that the NIH guidelines departed from the strictly science-driven rationale of the executive order that they were meant to elaborate.<sup>104</sup>

Weissman is not alone in his support for the Maximal Deference model of integration. The starkest statement in this vein by a public official was made by then-Congressman, now Ohio Governor Ted

<sup>104</sup> See Brownell, supra note 102, at 3 (" 1 was very surprised that when the NIH interpreted [President Obama's] speech to write guidelines, they said they would only fund research on embryonic stem cells derived from IVF clinic embryos, or blastocysts,' Weissman said."). On March 29, 2009, President Obama confirmed that he regarded ethical considerations as legitimate side constraints on scientific research, though he did not elaborate how this might work:

QUESTION (from John Ward, Washington Times): [D]o you think that scientific consensus is enough to tell us what we can and cannot do?

OBAMA: No. I think there's — there's always an ethical and a moral element that has to be — be a part of this.

President Barack Obama, Press Conference (Mar. 24, 2009), available at http://www.washingtonpost.com/wp-dyn/content/article/2009/03/24/AR2009032403036.html.

<sup>&</sup>lt;sup>102</sup> Julia Brownell, Director Chides NIH Policy, STANFORD DAILY, Apr. 24, 2009, at 3 (emphasis added).

<sup>&</sup>lt;sup>103</sup> To be fair to Weissman, President Obama's executive order explicitly noted the "broad agreement in the scientific community that the research should be supported by Federal funds," and appeared on its face to authorize funding for all species of embryonic stem cell research (including projects involving cell lines derived from embryos created solely for the sake of research by IVF or human cloning). The only restriction imposed by the executive order was that the research be "conduct[ed] responsibl[y]," "scientifically worthy," and "permitted by law." Exec. Order No. 13,505, 74 Fed. Reg. 10,667 §§ 1, 2 (Mar. 9, 2009). Accordingly, Weissman is correct that President Obama's executive order is far broader and more permissive than the NIH guidelines that implement it.

Strickland (also in the context of the embryonic stem cell debate): "We should be guided strictly by the best available science, and we should not allow theology, philosophy, or politics to interfere with the decision we make on this issue."<sup>105</sup>

Support for the Maximal Deference model can also be inferred from the condemnation of reliance on ethical principles as impermissibly importing politics into scientific decisionmaking. In reacting to President Bush's funding policy, certain critics did not take issue with the ethical principle animating it, namely, respect for equality of each member of the human species, irrespective of her age, size, location, race, sex, usefulness (or burdensomeness) to others, possession or lack of certain favored physical or mental capacities, or the worth assigned to her by others. Instead, they seemed to argue that any moral constraint on embryonic stem cell research constituted the impermissible politicization of science. Nobel Laureate Harold Varmus, who serves as co-chair of President Obama's Council of Advisors on Science and Technology ("PCAST"), wrote in an op-ed entitled The Enlightenment Returns, that President Bush's funding policy was an example of "dogma [taking] precedence over evidence, and opinion over facts."<sup>106</sup> In a press conference, Varmus recapitulated this criticism, promising that the new administration would "use sound, scientific practice and evidence, instead of dogma."107

Others echoed the same sentiment. Doctor John Kessler, Director of Northwestern University's Stem Cell Institute, referred to the Bush policy not as rooted in a misguided ethical principle, but rather as a "really, really unwelcome intrusion of politics into science."<sup>108</sup> United States House Speaker Nancy Pelosi also denounced the Bush funding policy in the same terms: "We've had a situation where it's faith or

<sup>&</sup>lt;sup>105</sup> FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE 185 (2003); Yuval Levin, The Moral Challenge of Modern Science, 14 NEW ATLANTIS 32 (2006) [hereinafter Levin, Moral Challenge], available at http://www.thenewatlantis.com/publications/the-moralchallenge-of-modern-science.

<sup>&</sup>lt;sup>106</sup> Kurt Gottfriedl & Harold Varmus, Editorial, The Enlightenment Returns, 5921(323) SCIENCE 1538, 1538 (Mar. 2009).

<sup>&</sup>lt;sup>107</sup> Rob Waters & Roger Runningen, *Obama to Restore 'Scientific Integrity' as Part of Stem-Cell Shift*, BLOOMBERG, Mar. 8, 2009, http://www.bloomberg.com/apps/news?pid=20601087&sid=aRLJP31E75FU ("We view what happened with stem-cell research in the last administration as one manifestation of the failure to think carefully about how government use of scientific advice occurs . . . . Public policy must be guided by sound, scientific advice.").

<sup>&</sup>lt;sup>108</sup> Brandon Keim, Bush Stem Cell Ban Wrong, but Not Anti-Science, WIRED, Mar. 11, 2009, http://www.wired.com/wiredscience/2009/03/obamastemcells2/.

science — take your pick . . . We're saying science is an answer to our prayers . . . . We need science, science, science, science, science."<sup>109</sup>

U.S. Representative Diana DeGette, a key sponsor of a bill (twice vetoed) to liberalize President Bush's funding policy for embryonic stem cell research,<sup>110</sup> decried that "[t]he President's policy was based on politics rather than science, and as we've seen the research develop in the ensuing three years, we can really see what the problem with that is."<sup>111</sup> Similarly, a spokesman from the Juvenile Diabetes Research Foundation (which strongly and actively supports funding for embryonic stem cell research) noted that reversing the Bush policy signaled the return of "scientists making scientific decisions."<sup>112</sup> Patient advocate Michael J. Fox also celebrated the reversal of the Bush policy as "get[ting] politics out of science."<sup>113</sup>

At a congressional hearing in 2006, U.S. Representative Eleanor Holmes Norton went farther than perhaps any elected official, condemning the appeal to non-scientific considerations in a host of public issues. She offered a withering critique of what she termed "the unmitigated politicization of the one area that Americans always held off from politics, and that is science itself."<sup>114</sup> Holmes Norton applied her critique to some key bioethical matters: "Whether Schiavo or creationism, renamed Intelligent Design, or stem cell research or, God help us, global warming itself, there are views floating around this Congress that essentially reach conclusions on these matters of huge scientific moment, based on their own personal beliefs."<sup>115</sup>

Taken together, the foregoing quotations from scientists, physicians, public advocates, and elected officials, on their face argue for delegating the moral, political, and legal dispute over federal funding

<sup>113</sup> Press Release, The Michael J. Fox Found. for Parkinson's Research, Michael J. Fox Foundation Statements on President Obama's Executive Order Overturning Ban on Federal Funding for Stem Cell Research (Mar. 9, 2009), available at http://www.michaeljfox.org/newsEvents\_mjfflnTheNews\_article.cfm?lD=300.

<sup>114</sup> U.S. Representative Mark Souder (R-IN) Holds a Hearing on RU-486, "Abortion Pill," POLITICAL TRANSCRIPT WIRE, May 19, 2006, http://www.accessmylibrary.com/ coms2/summary\_0286-16826420\_ITM. The author testified at this hearing.

<sup>&</sup>lt;sup>109</sup> Carla Marinucci, Pelosi Rebuts Critics, Defends Funding Plans; Stem Cell Research, S.F. CHRON., Apr. 18, 2009, at A4.

<sup>&</sup>lt;sup>110</sup> Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. (2005).

<sup>&</sup>lt;sup>111</sup> Interview by Susan Dentzer with Diana Degette, PBS NewsHour (Aug. 9, 2004), *available at* http://www.pbs.org/newshour/bb/health/july-dec04/degette.html.

<sup>&</sup>lt;sup>112</sup> Daniel Callahan, Stem Cells: Science, Ethics, and Ideology, HASTINGS CENTER BIOETHICS F., Mar. 9, 2009, http://www.thehastingscenter.org/Bioethicsforum/Post. aspx?id=3234.

<sup>&</sup>lt;sup>115</sup> Yuval Levin, Science Warrior: Hillary Clinton Leaves the Facts Behind, 18 NEW ATLANTIS 115, 118 (2007).

for embryonic stem cell research to scientists, who will resolve it by "scientific" means. To be clear, resolution of this question entails the adjudication of the contested *normative* claims discussed above, including the moral and legal status of the living human embryo, the role of government in supporting morally controversial scientific research with taxpayer dollars, allocation of scarce governmental resources, moral complicity, the duties of citizenship, and the common good.

At this point, one might object that the foregoing statements should not be taken literally — the speakers cited above are not *really* advocating a near-categorical deference to scientific experts in public bioethics. Perhaps they are speaking figuratively. Perhaps what they really mean is that one should not distort or conceal scientific data for political purposes. Perhaps they are simply skipping a step in the argument — they have implicitly ruled out the possibility of a meaningful ethical dispute, and thus the only remaining questions are empirical. Or perhaps, less charitably, they are trying to cloak their ethical and political judgments in scientific terms in order to associate their positions with the enormous social capital of science as an ostensibly neutral and objective mechanism for producing knowledge.

But even granting for the sake of argument the above claims about the true intentions of its apparent advocates, there are very good reasons to proceed with a critique of the Maximal Deference model nonetheless. First, it is an argument that is regularly made by prominent public figures and, at the very least, deserves a response because it might be taken seriously, sowing confusion or error in the public square. Further, debunking the Maximal Deference model will prompt its apparent advocates to think more clearly about the nature and provenance of their judgments and to style their public arguments accordingly, thus contributing to a more sound and transparent democratic process of deliberation. Finally, as the following subparts will show, the Maximal Deference model of integration for public bioethics is not new or unserious; rather, it is a recent iteration of a very old aspiration for "scientific governance" that has been advanced since before the American founding by an array of esteemed thinkers. Accordingly, it merits a serious and sustained scholarly response.

The balance of the Article thus aims to critique the Maximal Deference model of integration for public bioethics and to demonstrate that it is problematic for reasons relating to democratic accountability (and thus legitimacy) and, more deeply, that it is unsustainable in principle because of the conceptual incommensurability in the tools of modern science and those of public bioethics. As a first step in this critique, it is necessary to locate the above proposal in its historical and theoretical context.

#### B. The Genealogy of the Maximal Deference Model of Integration

American political culture derives its distinctive flavor as much from faith in scientific and technological progress as from a commitment — some might even say an addiction to resolving social conflicts through law.

— Sheila Jasanoff<sup>116</sup>

Modern science and the American project have been deeply intertwined since the founding era. Both were signature achievements of the Age of Reason, when "science was ... esteemed as the highest expression of human rationality."<sup>117</sup> Like other Enlightenment thinkers, the framers held the view that "no system of government or of society could be sound and stable if it contravened any of the fundamental principles of nature revealed by science."118 Since the nation's birth, there has been tremendous optimism that America would prove to be fertile soil for maximal scientific progress. In return, the fruits of science would be harnessed for both the promotion of the nation's domestic flourishing, and the projection of its interests abroad. Some founders believed that modern science itself could demonstrate the humanistic truths of classical liberalism in which American democracy was ostensibly grounded. Still other thinkers from the founding to the present day have pressed an even more ambitious view, arguing for a political regime that is organized and governed entirely by scientific principles.

The Maximal Deference model of integration for public bioethics seems to emerge from this confluence of esteem for science as a rigorous, objective, and powerful engine of producing useful knowledge, skepticism about the governance of science by nonscientists, and optimism about the possibility of "scientific" governance. Each foundational component will be briefly treated in turn.

<sup>&</sup>lt;sup>116</sup> Sheila Jasanoff, Science at the Bar: Law, Science, and Technology in America 1 (Harvard Univ. Press 1997) (1995).

<sup>&</sup>lt;sup>117</sup> I. BERNARD COHEN, SCIENCE AND THE FOUNDING FATHERS 20 (1995). According to political scientist David Guston, "[b]oth science and equality were born of Enlightenment rationality." See David Guston, The Essential Tension in Science and Democracy, 7 Soc. EPISTEMOLOGY 3 (1993).

<sup>&</sup>lt;sup>118</sup> COHEN, supra note 117, at 280.

#### 1. Science and the Founding Generation

Awe and optimism for the power and promise of modern science a key component underlying the Maximal Deference model — have been quintessentially American traits since the nation's inception. Many of the Founding Fathers themselves were men of science. Benjamin Franklin was a fellow of the two most prestigious scientific academies in the world (the Paris Academie Rovale des Sciences and the Royal Society of London),<sup>119</sup> and was regarded as one of the most important scientists of that era.<sup>120</sup> Thomas Jefferson had a lifelong passion for science. He was President of the American Philosophical Society (the first American scientific society, founded by Franklin).<sup>121</sup> Indeed, Jefferson delivered a lecture on paleontology before this body shortly after his inauguration as the nation's second Vice President. While Secretary of State, Jefferson commissioned and hung portraits of science icons Sir Isaac Newton and Francis Bacon in the State Department.<sup>122</sup> Though not a practitioner himself, John Adams shared an abiding respect and interest in science. In one of his writings on European politics he included "without explanation or transition" a seemingly disconnected meditation on the chemistry of combustion (weighing in on a debate between Joseph Priestly and Antoine Laurent Lavoisier on the nature of heat) and the physics of magnetism.<sup>123</sup> James Madison had studied Newton at Princeton where he wrote an essay on the "parallelism between the world of nature and the world of human affairs."124

Thomas Jefferson (along with other Enlightenment thinkers) was optimistic that the methods of modern science (first articulated by Bacon and powerfully demonstrated by the success of Newton) would particularly flourish in the newly founded nation, to the great benefit of its people:

124 Id. at 20.

<sup>&</sup>lt;sup>119</sup> Id. at 14.

<sup>&</sup>lt;sup>120</sup> See id. at 23.

<sup>&</sup>lt;sup>121</sup> Id. at 22.

<sup>&</sup>lt;sup>122</sup> See id. at 57. Francis Bacon, Isaac Newton, and John Locke were Jefferson's "trio of immortals." Locke's portrait also hung in the state department (and later at Monticello).

<sup>&</sup>lt;sup>123</sup> See id. at 304-05 ("Juxtaposed to a long set of reflections about European politics he interposed . . . a query concerning certain new discoveries in the chemistry of combustion, a topic then being elucidated by the studies of Joseph Priestly and Antoine-Laurent Lavoisier, both good friends of Franklin's . . . Adams suddenly shifts his intellectual gears, turning abruptly from the chemistry of respiration to the physics of magnetism. 'The loadstone [or natural magnet] is,' he wrote 'in possession of the most remarkable, wonderful and mysterious property in nature.' ").

Could the genius of Bacon place itself on the high ground of all the sciences in their present state of advancement, and marshal them before him in so great a country as this, and under a government like ours, he would point out their objects, foretell their successes, and move them on their march  $\ldots$  125

This was a view held also by Philadelphia physician, signer of the Declaration, and delegate to the Constitutional Convention, Doctor Benjamin Rush.<sup>126</sup> The experience of Joseph Priestly (one of the fathers of modern chemistry) in America, confirmed that the fledgling liberal democracy was well suited to the thriving of science (both in practice and application).<sup>127</sup> In his travels in nineteenth century America, Alexis de Tocqueville also found the new democracy a fertile place for science. He observed that American democracy was compatible with a robust commitment to science, owing to the fact that in a liberal democracy a wider array of people are free (in principle) to pursue their interests (including scientific interests), irrespective of where they fall in the class system.<sup>128</sup>

The founding generation (and its intellectual forebears) regularly invoked scientific metaphors in service of their political arguments. James Harrington, whose *Oceana* is regarded as singularly influential in the drafting of the U.S. Constitution, drew upon the work of William Harvey (discoverer of the circulation of the blood) in arguing for a bicameral legislature. Harrington went so far as to compare the two houses with the ventricles of the heart — both in terms of size differential and distinctive functions.<sup>129</sup> In arguing against Franklin's proposal for a unicameral legislature (and in favor of bicameralism), John Adams invoked Newton's Third Law of Motion:<sup>130</sup> "The president of Pennsylvania might, upon such an occasion . . . to have recollected

<sup>&</sup>lt;sup>125</sup> GEORGE H. DANIELS, SCIENCE IN AMERICAN SOCIETY 127 (1971).

<sup>&</sup>lt;sup>126</sup> See Roy MacLeod, Science and Democracy: Historical Reflections on Present Discontents, 35 MINERVA 369, 371 (1997) (noting that Rush "expected much improvement to flow 'naturally' from the 'harmony between the sciences and government,' in a land which Providence had appointed men to explore and settle").

<sup>&</sup>lt;sup>127</sup> See id. ("Joseph Priestly, fleeing a mob in England, found in America in 1794 an attitude 'far more favourable toward the sciences and the arts than any monarchical government has ever been. A free people will in due time produce anything useful for mankind.' ").

<sup>&</sup>lt;sup>128</sup> See Guston, supra note 117, at 3, 6.

<sup>&</sup>lt;sup>129</sup> See id. at 21.

<sup>&</sup>lt;sup>130</sup> Newton's Third Law (or Axiom) of Motion is: "To any action there is always an opposite and equal reaction." ISAAC NEWTON, THE PRINCIPIA 417 (I. Bernard Cohen & Anne Whitman eds. & trans., Univ. of Cal. Press 1999) (1687).

one of Sir Isaac Newton's laws of motion, namely, — 'the reaction must always be equal and contrary to reaction,' or there can never be any *rest*."<sup>131</sup>

Many such metaphors were introduced into the deliberations at the Constitutional Convention itself. In one instance, Madison's notes indicate that one delegate compared the power of the federal government to preempt state laws to the "attractive principle which would retain . . . the centrifugal force [without which] planets will fly from their orbits."<sup>132</sup> Some commentators have gone so far as to declare the Constitution to be designed according to Newtonian principles.<sup>133</sup> The *Federalist Papers* contain additional scientific metaphors.<sup>134</sup> According to historian of science, I. Bernard Cohen, "The Founding Fathers used science as a source of metaphors because they believed science to be a supreme expression of human reason."<sup>135</sup>

In addition to providing a plethora of metaphors, the founders directly invoked modern science for substantive propositions. Jefferson argued that modern science confirmed the truth of human equality asserted by the Declaration of Independence: "The general spread of the light of science has already laid open to every view the

<sup>133</sup> See id. at 283-84. This view, however, seems to derive from a misreading of Newton's Principia. As Cohen observes:

The fundamental working principle in Newtonian rational mechanics, as developed in the *Principia*, is that orbital motion is the result of an *unbalanced* force and is in no sense a case of equilibrium or balanced forces. The Newtonian natural philosophy is concerned almost entirely with problems of dynamics, with the science of unbalanced forces and motions or — more exactly — forces (that is, unbalanced forces) and the motions they generate, the changes in motions they produce. Only in one very small section, a sort of appendix to the 'Laws of Motion,' does Newton even introduce the subject of statics or balanced forces, that is, forces acting on bodies that are and remain at rest. It is thus simply wrong to claim, as Woodrow Wilson and other scholars have done, that the science of the *Principia* is centered on the notion of an equipoise or balance of forces.

<sup>134</sup> See id. at 269 (noting that in *Federalist No. 10*, Madison writes, "Liberty is to faction what air is to fire, an aliment, without which it instantly expires").

135 Id. at 229.

<sup>&</sup>lt;sup>131</sup> COHEN, *supra* note 117, at 229. Cohen notes here, however, that Adams misremembers the import of Newton's Third Law — Newton is referring here to the dynamic between two forces acting on two separate bodies, not, as Adams's metaphor implies, two forces acting on the same body with the result of equilibrium. *Id.* 

 $<sup>^{132}</sup>$  *Id.* at 258. Montesquieu made a similar metaphor in *Spirit of the Laws*, writing that in monarchies, "there is a power that constantly repels all bodies from the center, and a power of gravitation that attracts them to it." *Id.* at 35.

Id.

palpable truth that the mass of mankind has not been born with saddles on their backs, nor a favored few booted and spurred, ready to ride them legitimately, by the grace of God."<sup>136</sup>

As envisioned by Bacon, the founders meant for the powers of science to be deployed in the new republic for the relief of man's estate. The Constitution itself signals the view of its founders that science was to play an integral role in the life of the new republic. Among the limited powers enumerated by the Constitution, Congress is explicitly charged with the power "[t]o promote the Progress of Science."<sup>137</sup> Leon Kass has written that "[t]he American Republic is, to my knowledge, the first regime explicitly to embrace scientific and technical progress and to claim its importance for the public good."<sup>138</sup>

#### 2. Science and Self-Governance

Skepticism about the desirability (and even possibility) of governance of science by lay government officials — another key grounding for the Maximal Deference model — emerged as American science became a profession during the nineteenth century.

Historian George H. Daniels examined the transformation in the relationship between science, government, and the larger society from the founding to the present.<sup>139</sup> In doing so, Daniels discovered the emergence of what he has termed the "Pure Science Ideal."<sup>140</sup>

Daniels observed (along with Tocqueville) that in the first half of the nineteenth century, in order to generate public support for their work, scientists argued that their efforts were principally oriented towards providing practical benefits to society.<sup>141</sup> Moreover, they claimed that "science would demonstrate God's works and a scientific education would be conducive to a good moral education."<sup>142</sup>

<sup>139</sup> See Guston, supra note 117, at 13.

<sup>&</sup>lt;sup>136</sup> Diana Schaub, Montesquieu's Popular Science, 20 NEW ATLANTIS 37, 40-41 (2008).

 $<sup>^{137}\,</sup>$  U.S. CONST. art. I, § 8, cl. 8 (Congress actualizes this power through issuance of patents).

<sup>&</sup>lt;sup>138</sup> Leon R. Kass, *The Problem of Technology*, in TECHNOLOGY IN THE WESTERN POLITICAL TRADITION 1, 21 (Arthur M. Melzer et al. eds., 1993).

<sup>140</sup> Id.

<sup>141</sup> Id.

<sup>&</sup>lt;sup>142</sup> Daniels further argues that "[s]cientists needed to make this argument because it was not obviously true, they had to camouflage their activities in the colors of American values to protect their freedom to pursue their own scientific agenda." *Id.* at 13-14. This public strategy had been suggested in the seventeenth century by Rene Descartes. *See* RENE DESCARTES, THE DISCOURSE ON METHOD 159 (John Veitch trans., 1930) (1637).
However, from the latter half of that century forward as American science advanced, its practitioners found that the pursuit of excellence demanded increased specialization and professionalization. The notion of science for the sake of itself — separate and apart from the practical needs of the public — began to take hold. The concept of scientist-as-teacher gave way to scientist-as-researcher. According to Daniels, "for the first time, great numbers of scientific spokesmen began to vocally resent [sic] this dependence upon values extraneous to science."<sup>143</sup>

This Pure Science Ideal created tensions with the public and its government representatives. This tension between the practical demands of the public and the research agenda of scientists is apparent in the work of the Allison Commission — a joint, bipartisan congressional committee that investigated the activities of four federal scientific agencies from 1884 to 1886, including claims that such agencies were pursuing abstract research unconnected to practical concerns.<sup>144</sup> During the hearings, Congressman Hilary A. Herbert (an Alabama democrat) insisted that the political branches exercise direct democratic control over government science agencies, whereas several scientists argued that the laymen (including government officials) were in no position to judge the scientific legitimacy of research.<sup>145</sup>

Thus, the professionalization of American science and its development into an elitist meritocracy led to arguments in favor of self-governance by scientists and insulation from democratic influence. This theme of elitism ran through Vannevar Bush's 1945 government report, *Science: The Endless Frontier*, commissioned by President Roosevelt to explore how scientific research might contribute to the "improvement of national health, the creation of new enterprises bringing new jobs, and the betterment of the national standard of living."<sup>146</sup> Bush argued in the report that scientists should be given wide latitude to oversee and direct their own research in

<sup>&</sup>lt;sup>143</sup> Guston, supra note 117, at 13.

<sup>&</sup>lt;sup>144</sup> REXMOND C. COCHRANE, THE NATIONAL ACADEMY OF SCIENCES: THE FIRST HUNDRED YEARS 1863–1963, 144 (1978). Senator William B. Allison of Iowa chaired the committee.

<sup>&</sup>lt;sup>145</sup> Testimony Before the Joint Commission to Consider the Present Organizations of the Signal Service, Geological Survey, Coast and Geodetic Survey, and the Hydrographic Office, 48th Cong. 693-94 (1884) (statement of Rep. Hilary A. Herbert), available at http://books.google.com/books?id=Hocj26LFyPwC&printsec=frontcover&client=firefox -a#v=onepage&q=&xf=false.

<sup>&</sup>lt;sup>146</sup> OFFICE OF SCIENTIFIC RESEARCH AND DEV., SCIENCE THE ENDLESS FRONTIER, 1945 (quoting letter from President Roosevelt to Doctor Bush, contained within report); see also PHILIP KITCHER, SCIENCE, TRUTH, AND DEMOCRACY 138 (2001) (arguing that Bush report was most "important document about the place of scientific research in a twentieth-century democracy").

order to build the "scientific capital" that would ultimately ensure progress.<sup>147</sup> Bush's argument for unfettered free inquiry as the engine of scientific progress was resisted by other public figures, including Senator Harvey Kilgore (a West Virginia democrat), who argued to the contrary that scientific research (particularly the federally funded variety) should be oriented towards solving social problems on a broad scale.<sup>148</sup>

The argument for maximal scientific freedom and reliance on selfgovernance was perhaps most powerfully articulated in 1962 by philosopher Michael Polanyi in The Republic of Science.<sup>149</sup> Polanyi famously argued that "the soil of academic science must be extraterritorial in order to secure its control by scientific opinion."<sup>150</sup> According to this view, autonomy from external governmental oversight creates the space necessary for scientific creativity to flourish, which, in turn, yields socially useful developments. The scientific community should thus govern itself, according to its own internal meritocratic structures. According to Polanyi, "self coordination of independent initiatives by the most competent assures the most efficient possible organization of scientific progress."<sup>151</sup> Moreover, the governance of science through the usual democratic mechanisms is doomed to fail. In Polanyi's view scientific progress cannot be directed; rather, it emerges organically from the creative collaboration of the scientific community. The methods of science cannot be articulated; they can only be transmitted by masters to apprentices within the community itself.<sup>152</sup>

<sup>151</sup> JARVIE, *supra* note 150, at 214.

We have consultations, which of the [i]nventions and [e]xperiences, which we have discovered shall be [p]ublished: and which not: and take all an oath of secrecy, for the concealing of those which we think fit to keep [s]ecret:

<sup>&</sup>lt;sup>147</sup> KITCHER, supra note 146, at 139. Bush was an American engineer involved in the development of the atomic bomb and key science advisor to President Roosevelt.

<sup>&</sup>lt;sup>148</sup> See id., at 139-40.

<sup>&</sup>lt;sup>149</sup> Michael Polanyi, The Republic of Science: Its Political and Economic Theory, I(1) MINERVA 54 (1962), available at http://www.springerlink.com/content/x52241166w445660/ fulltext.pdf.

<sup>&</sup>lt;sup>150</sup> See id. at 67; IAN C. JARVIE, THE REPUBLIC OF SCIENCE: THE EMERGENCE OF POPPER'S SOCIAL VIEW OF SCIENCE 1935–1945, 220 (Rodopi 2001).

<sup>&</sup>lt;sup>152</sup> See id. at 219; see also Guston, supra note 117, at 15-17. The elitist model for the governance of science dates back much further in time — to the seventeenth century writings of one of the founders of modern science, Francis Bacon. Philosopher of Science, Philip Kitcher called Bacon's allegorical work, *The New Atlantis*, "the first report on science policy." See KITCHER, supra note 146, at 137. In *The New Atlantis*, Bacon describes a utopian society in which the elite scientists of Salomon's House direct their own work, free from the intervention of the government:

Proponents of this vision of scientific self-governance strongly oppose extrinsic oversight of science by non-expert government officials. This opposition is reflected in the remarks of George Ball to the American Political Science Association in 1977:

Scientifically trained men and women are far better equipped to decide whether and how certain types of research should be conducted so as to safeguard [the] public interest than legislatures or administrative tribunals or courts . . .

[They] should be permitted maximum freedom to decide what research to undertake and how to undertake it, subject only to such safeguards as they might individually or collectively impose to prevent experiments being conducted in such a matter as to threaten the public health or welfare.<sup>153</sup>

Nobel Laureate and former President of the California Institute of Technology, David Baltimore expressed similar concerns about the extrinsic governmental oversight of scientific research by non-experts:

The traditional pact between society and its scientists in which the scientists is [sic] given the responsibility for determining the direction of his work is a necessary relationship if basic science is to be an effective endeavor. This does not mean that society is at the mercy of science, but rather that society, while it must determine the pace of basic scientific innovation, should not attempt to prescribe its directions.

... First, the criteria determining what areas [of biological research] to restrain inevitably express certain sociopolitical attitudes that reflect a dominant ideology. Such criteria cannot be allowed to guide scientific choices. Second, attempts to restrain directions of scientific inquiry are more likely to be generally disruptive of science than to provide the desired specific restraints.<sup>154</sup>

Though some of those we do reveal sometime to the State, and some not.

FRANCIS BACON, THE NEW ATLANTIS 44 (1627).

<sup>&</sup>lt;sup>153</sup> Sissela Bok, *Freedom and Risk*, 107 DAEDALUS 115, 117-118 (1997) (quoting George Ball, Biology and Politics, Address Given to the American Political Science Association). George Ball served as Secretary of State during Johnson and Kennedy administrations.

<sup>&</sup>lt;sup>154</sup> David Baltimore, Limiting Science: A Biologist's Perspective, 134 DAEDALUS 7, 7-8, 11 (Fall 2005).

Bruce Jennings locates the foregoing arguments as rooted in the proposition that "democratic citizens and their political representatives cannot rationally manage the development of science and technology, nor can they understand modern science and technology sufficiently to use science effectively in other policy areas."<sup>155</sup> Thus, citizens and their representatives should "largely defer" to the judgments of the scientific elite, and implement their recommendations in the political process.<sup>156</sup>

In the context of public bioethics, the threads of this new elitism were evident in the congressional testimony of scientists and physicians in response to Senator Mondale's proposal to create the "President's Commission on Health Science and Society" in 1968. South African transplant surgeon Christiaan Barnard testified that there was no good that could come from the public meddling into the practice of medicine and that such a committee "would be an insult to your doctors."157 Owen Wangensteen, Professor Emeritus of Surgery at University of Minnesota similarly worried about public ethical judgments about medical practice, and argued that physicians should police themselves in this regard — "the fellow who holds the apple can peel it best."158 Another surgeon, Doctor C. Walton Lillehei likewise expressed his wish not to be ethically accountable to the public, composed of "people frustrated with their own inability to create."159 Doctor Jesse Edwards, representing the American Heart Association stated that "we do not believe that the time is ripe for a full dress government inquiry into these complicated technical questions."160

As the above comments confirm, it is a short step from this new elitism in science policy to the Maximal Deference model for public bioethics.

Id. at 94.

<sup>&</sup>lt;sup>155</sup> Bruce Jennings, Representation and Participation in the Democratic Governance of Science and Technology, Monograph 85-14, at 8, *available at http://www.law.uh.edu/* ihelg/monograph/85-14.pdf.

<sup>&</sup>lt;sup>156</sup> See id.

<sup>&</sup>lt;sup>157</sup> JONSEN, supra note 13, at 92.

<sup>&</sup>lt;sup>158</sup> Id. at 93.

<sup>&</sup>lt;sup>159</sup> Id.

<sup>&</sup>lt;sup>160</sup> Id. These statements prompted Mondale to exclaim in exasperation:

<sup>[</sup>A]ll we are proposing here is to create a measly little study commission to look at some very profound issues . . . I sense an almost psychopathic objection to the public process, a fear that if the public gets involved, it is going to be anti-science, hostile and unsupportive.

#### 3. Optimism for "Scientific" Governance

The foregoing argument that, all things considered, science is best governed by scientists, has and continues to be invoked in the American public square. But from the American founding to the present day there have been thinkers who have advocated an even more ambitious proposal, namely, the importation of the premises and methods of science directly into the process of governance itself.<sup>161</sup> Put in its strongest and most idealistic form, the claim was that "if politics were run by scientists, all issues of moment would eventually be depoliticized; and once reduced to science, all political questions could be solved."<sup>162</sup> The Maximal Deference model of integration for public bioethics appears to be a weaker and more limited species of this proposal.

The view that "there can be a science of government which is an image of the physical or biological sciences, was widely shared in the later eighteenth century and appears prominently in many works of the nineteenth."<sup>163</sup> Those who shared this view wanted to bring the rigor and certainty that they perceived in the fields of science and mathematics to the political sphere. According to David Guston, Enlightenment philosophers who heavily influenced the American founding embraced this aspiration:

In the seventeenth century, the unity of scientific and political investigation was forged by method. Galileo had introduced the resolutive-compositive method and Hobbes had imported it to England. Descartes' analytic-synthetic method was identical, as was Locke's. This particular method comprises the large part of the difference between the medieval mind and the modern mind: instead of using a particular method thought suited for a particular subject, the modern scientist applies a universal method across subjects.<sup>164</sup>

Prominent figures in American history have advocated such integration of scientific methods into the political process to greater or lesser extents. One such group, called the "Scientific Democrats," included philosopher John Dewey, President Herbert Hoover,

<sup>&</sup>lt;sup>161</sup> For a concise overview of the various permutations of this project, see Frank Laird, *Participating in the Tension: A Response to Guston*, 7(1) SOC. EPISTEMOLOGY 35 (Jan. 1993).

<sup>&</sup>lt;sup>162</sup> Roy MacLeod, Science and Democracy: Historical Reflections on Present Discontents, 35 MINERVA 369, 375 (1997).

<sup>&</sup>lt;sup>163</sup> COHEN, *supra* note 117, at 255.

<sup>&</sup>lt;sup>164</sup> Guston, supra note 117, at 10.

physicist Robert A. Milikan, the anthropologist Franz Boas, and the aforementioned Vannevar Bush.<sup>165</sup> These thinkers argued that the premises and methods of science should be deployed in the political sphere to alleviate human suffering:

In their optimistic view, modern science had proved its power in practice, by harnessing natural resources and creating new inventions such as the steam engine and the railroad, creating an industrial society with the potential to overcome scarcity. The task now was to apply the methods of modern science to the improvement of social organization itself.<sup>166</sup>

Dewey argued that the scientific method — "a shorthand designation for great and ever-growing methods of observation, experiment, and reflective reasoning"<sup>167</sup> — should be applied to social and political matters. In 1946, he wrote:

Science bears exactly the same relation to the progress of culture as to the affairs acknowledged to be technological (like the state of invention in the case, say, of tools and machinery, or the progress reached in the arts, say, the medical) .... A considerable part of the remediable evils of present life are due to the state of imbalance of scientific method with respect to its application to physical facts on one side and to specifically human facts on the other side ... the most direct and effective way out of these evils is steady and systematic effort to develop that effective intelligence named scientific method in the case of human transactions.<sup>168</sup>

This was a widely shared view in the Progressive Era. Progressives thought governance was "a science, and it could be carried out as dispassionately as any of the physical sciences by well educated, well trained administrators."<sup>169</sup> James M. Landis, one of the key architects of the New Deal went even further, arguing that such scientific experts should be left alone not only to determine the means by which social progress could be achieved, but also to decide *which social ends* should

<sup>&</sup>lt;sup>165</sup> Andrew Jewett, Science and the Promise of Democracy in America, 132(4) ON SCIENCE 64, 67 (2003).

<sup>&</sup>lt;sup>166</sup> Id. at 66.

<sup>&</sup>lt;sup>167</sup> LEVIN, supra note 2, at 88-89 (quoting DEWEY, RECONSTRUCTION IN PHILOSOPHY viii-ix (1920)).

<sup>&</sup>lt;sup>168</sup> Id. at 88.

<sup>&</sup>lt;sup>169</sup> GARY LAWSON, TEACHER'S MANUAL TO FEDERAL ADMINISTRATIVE LAW 40 (3d ed. 2004).

be pursued.<sup>170</sup> In this way, he was advocating a program very much akin to the Maximal Deference model of integration.

Throughout the twentieth century, various thinkers proposed a variety of ways to incorporate science into governance in the name of rationality and efficiency. In 1932, the Milikan Scientific Jury System was proposed to solve the problems of the depression.<sup>171</sup> Under this system, experts in the relevant fields would design and implement such policies. Milikan later elaborated on how to execute such a scientific approach to governance:

Those in control must either themselves be thoroughly trained in the method of the modern correct attack on the problem of economics, finance and government, or must at least be willing to choose as their advisors... the ablest, most high minded, most competent men in those fields. That alone constitutes the scientific approach to the problem of government.<sup>172</sup>

Relatedly, President John F. Kennedy espoused the view that most social problems are, at bottom, technological problems beyond the expertise of most people and "which do not lend themselves to the great sort of 'passionate movements' which have stirred this country so often in the past."<sup>173</sup> Instead, they are more appropriately resolved by those with technical expertise. In a similar vein, the Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology (chaired by Arthur Kantrowitz), drafted a model "Science Court" that would evaluate contested social matters and issues judgments concerning the relevant "scientific facts" involved.<sup>174</sup> Other such proposals have included the creation of "technical review boards," a "technological magistrature," and the office of "Certified Public Scientist."<sup>175</sup>

In short, throughout American history those impressed by the extraordinary humanitarian achievements made possible by modern science have looked to the premises and methods of science to make

<sup>&</sup>lt;sup>170</sup> See id.

<sup>&</sup>lt;sup>171</sup> See Nelkin, supra note 1, at 107.

<sup>&</sup>lt;sup>172</sup> Id. at 107-08 (quoting R. Millikan, Science and Social Justice, in R. TOBEY, THE NEW SCIENCES AND DEMOCRATIC SOCIETY, Ph.D. Diss., Cornell University (1969)).

<sup>&</sup>lt;sup>173</sup> Yuval Levin, Science over All? The Temptation in Obama's Stem Cell Policy, WASH. POST, Mar. 10, 2009, at A13 (quoting President Kennedy).

<sup>&</sup>lt;sup>174</sup> Leonard A. Cole, Resolving Science Controversies: From Science Court to Science Hearings Panel, in GOVERNING SCIENCE AND TECHNOLOGY IN A DEMOCRACY 244, 250 (Malcolm L. Goggin ed., 1986); see also Nelkin, supra note 1, at 108.

<sup>&</sup>lt;sup>175</sup> See Nelkin, supra note 1, at 108.

the political sphere more efficient, rational, and productive. This same optimism for scientific governance (reflected in the statements of Landis, among others) undergirds the Maximal Deference model of integration for public bioethics.

# III. SOME KEY PREMISES AND METHODS OF MODERN SCIENCE

One of the central claims of this Article is that given certain of its key premises and methods, modern science, by design, is indifferent to and thus incapable of supplying final answers for the normative questions at the heart of public bioethics. As a preliminary matter, it is necessary to provide some account of what these premises and methods are. It must be acknowledged at the outset, however, that given its manifold and diverse subject matter disciplines and subdisciplines it is difficult (if not impossible) to discuss responsibly "modern science" in a monolithic sense. For example, the methodologies of the biosciences differ in material respects from those of the physical sciences. Also, distinctions are regularly drawn between "applied" and "pure" science, though for present purposes these will be discussed together. Moreover, since its inception, modern science has undergone a series of developments, changes, and vexed philosophical challenges, far too complicated and extensive to responsibly discuss here.<sup>176</sup> Nevertheless, the following Part seeks to abstract and synthesize a set of common premises and methods that run throughout the various disciplines of modern science that render it unfit to resolve the normative disagreements at the heart of public bioethics. What follows is not meant to be a comprehensive exegesis of modern science.

Modern science, as founded by Rene Descartes and Francis Bacon in the seventeenth century, was meant to provide a powerful new mechanism for the production of clear, demonstrable, and (above all) useful knowledge. In his *Discourse on Method*, Descartes elaborated the

<sup>&</sup>lt;sup>176</sup> Since the seventeenth century, philosophers of science have debated and discussed the explanatory limits and normative neutrality of science. *See, e.g.,* DEL RATZSCH, SCIENCE AND ITS LIMITS, 73-99 (2000); THOMAS F. GIERYN, CULTURAL BOUNDARIES OF SCIENCE: CREDIBILITY ON THE LINE (1999) (exploring why science seems trustworthy); MARY B. HESSE, MODELS AND ANALOGIES IN SCIENCE (1963) (using models and analogies to explore philosophy of science); JASANOFF, *supra* note 116, at 94-96 (discussing how Western science draws limits for its own evaluation at its boundaries and noting that only insiders are capable of judging worth of science); KITCHER, *supra* note 146, at 12-28 (discussing limitations of scientific realism throughout its history); Dorothy Nelkin, *Science Wars: Responses to a Marriage Failed*, SOC. TEXT, Spring-Summer 1996, at 93-100 (exploring what role science and scientists should take in solving problems in science and society).

new empirical project and distinguished it from the more abstract and theoretical philosophical endeavors of past millennia:

So soon as I had acquired some general notions concerning Physics . . . they caused me to see that it is possible to attain knowledge which is very useful in life, and that, instead of that speculative philosophy which is thought in the Schools, we may find a *practical philosophy* by means of which, knowing the *force* and the *action* of fire, water, air, the stars, heavens, and all other bodies that environ us, as distinctly as we know the different crafts of our artisans, we can in the same way *employ them* in all those uses to which they are adapted, and thus render ourselves the masters and possessors of nature.<sup>177</sup>

Descartes's great innovation for science was to set aside the vexed "speculative" questions such as those regarding "the being or nature or goodness of things, questions also about first or ultimate causes."<sup>178</sup> The new approach self-consciously abandoned the teleology of the ancient natural philosophers who aspired to understand what things are in themselves.<sup>179</sup> Thus liberated from the seemingly paralyzing deeper questions about their purpose and meaning, science was free to single-mindedly pursue knowledge about the composition and function of natural things. Paradoxically, by narrowing its focus to these more "practical" questions, Descartes amplified the power of science to a level never before seen.

Accordingly, Descartes and Bacon set about to design a new method of scientific inquiry aimed at *how nature works*. The ultimate aim of this method was harnessing nature for humanitarian ends — to *put nature to work for humankind*.<sup>180</sup> The new method aspired to combine exacting rational analysis with active experimentation and the unbiased collection of empirical data.<sup>181</sup> Bacon placed new emphasis

<sup>&</sup>lt;sup>177</sup> RENE DESCARTES, DISCOURSE ON THE METHOD, *in* THE PHILOSOPHICAL WORKS OF DESCARTES 81, 119 (Elizabeth S. Haldane & G.R.T. Ross eds., 1981) (emphasis added).

<sup>&</sup>lt;sup>178</sup> LEON R. KASS, LIFE, LIBERTY, AND THE DEFENSE OF DIGNITY 279 (1985).

<sup>&</sup>lt;sup>179</sup> See, e.g., JOSEPH VINING, THE SONG SPARROW AND THE CHILD: CLAIMS OF SCIENCE AND HUMANITY 53-54 (2004) (quoting Jean Pierre Changeux, Director of Molecular Neurobiology Laboratory of Institute Pasteur: "No one . . . takes teleological arguments seriously anymore, at least not in biology.").

<sup>&</sup>lt;sup>180</sup> In Bacon's words, the ultimate purpose of science was to discern how to subdue nature for the "relief of man's estate." FRANCIS BACON, ADVANCEMENT OF LEARNING 42 (Albert S. Cook ed., 1904) (1605).

<sup>&</sup>lt;sup>181</sup> See KITCHER, supra note 146, at 109 ("Descartes emphasized the virtues of rational analysis, both to direct the mind in discovering solutions to problems and to frame the options experiments might discriminate. By contrast, Bacon stressed the

on subjecting natural phenomena to rigorous experimentation, believing that "the nature of things betrays itself more readily under the vexations of art than in its natural freedom."<sup>182</sup> This active method stood in stark contrast with the ancient approach to science, which operated by more passive observation and contemplation of phenomena in order to discern their natural ends.<sup>183</sup> American philosopher John Dewey later underscored the virtues of the new approach in contrast with the old by observing that:

Scientific principles and laws do not lie on the surface of nature. They are hidden, and must be wrested from nature by an active and elaborate technique of inquiry. [Thus, scientists] must force the apparent facts of nature into forms different to those in which they familiarly present themselves; and thus make them tell the truth about themselves, as torture may compel an unwilling witness to reveal what he is often concealing.<sup>184</sup>

Untethered from theoretical concerns about ultimate meaning and purposes in nature, and focused instead on the active empirical pursuit of knowledge about *how things work*, the powers of modern science grew exponentially. Three additional related features of modern science have contributed substantially to its flourishing, namely, its commitment to physicalism, reductive mechanism, and strict adherence to epistemic rules and limits. Because these elements bear on the fitness of modern science to adjudicate contested matters in public bioethics, each will be discussed briefly.

importance of unprejudiced observation and patient accumulation of empirical data.").

<sup>&</sup>lt;sup>182</sup> Francis Bacon, *The New Organon*, *in* THE WORKS OF FRANCIS BACON 19, 48 (James Spedding et al. eds., 1879).

<sup>&</sup>lt;sup>183</sup> See Leon R. Kass, Forbidding Science: Some Beginning Reflections, 15 SCI. & ENGINEERING ETHICS 271, 278 (2009) [hereinafter Kass, Forbidding Science] ("Ancient science had sought knowledge of what things are, to be contemplated as an end in itself satisfying to the knower. In contrast, modern science seeks knowledge of how things work, to be used as a means for the relief and comfort of all humanity, knowers and non-knowers alike."); see also HISTORY OF POLITICAL PHILOSOPHY 854 (Leo Strauss & Joseph Cropsey eds., 3d ed. 1987) ("[The modern scientific method] [was] distinguished in part from non-Baconian science by its resort to active experimentation, in contrast to passive contemplation of nature.").

<sup>&</sup>lt;sup>184</sup> JOHN DEWEY, RECONSTRUCTION IN PHILOSOPHY 32 (1920).

## A. Physicalism

Modern science is committed to the axiomatic premise of *physicalism*. Philosopher of science, Alex Rosenberg has noted that physicalism is "the assumption that there is only one kind of stuff, substance, or thing in the universe, from matter, material substance, and physical objects, all the way down to quarks."<sup>185</sup> All events are thus physical events — all phenomena are physical phenomena. Put another way, there is *nothing but* physical matter in the universe. This premise is widely shared and enforced as orthodoxy by scientists across biological disciplines.<sup>186</sup> According to Rosenberg, for example, "[t]he only biologists who deny physicalism are an assortment of cranks and creationists to whom serious science pays no heed. We're all physicalists now."<sup>187</sup> This commitment to physicalism underlies and points toward a key methodology of modern science: reductive mechanism.

## B. Reductive Mechanism

Stated generally, modern scientific explanation operates by way of *reduction*. That is, its chief explanatory aspiration is to explicate complex matters in the most simple and elemental terms. A reduction is thus an effort to explain a macrophenomenon in terms of the structure and function of its constitutive microphenomena.<sup>188</sup> Combining the axiom of physicalism with reductionism compels a methodological commitment to *mechanism*, namely, the evaluation and explanation of natural phenomena in terms of the structure, actions, and interactions of their most basic physical parts.<sup>189</sup> For the

<sup>&</sup>lt;sup>185</sup> Alex Rosenberg, Darwinian Reductionism or How To Stop Worrying and Love Molecular Biology 2 (2006).

<sup>&</sup>lt;sup>186</sup> Rosenberg notes that the "metaphysical thesis" of physicalism is accepted by reductionists and antireductionists alike. *See* Alex Rosenberg, *Reductionism* (and *Antireductionism*) in *Biology*, in THE CAMBRIDGE COMPANION TO THE PHILOSOPHY OF BIOLOGY 120, 120 (2007); see also David L. Hull, *What Philosophy of Biology Is Not*, 20 SYNTHESIS 157, 164 (1969) ("The views expressed by early materialists and mechanists were certainly overly crude, but to the extent that contemporary knowledge is applicable to the various stages of these controversies, the mechanist-materialists were right.").

<sup>&</sup>lt;sup>187</sup> ROSENBERG, supra note 185, at 4.

<sup>&</sup>lt;sup>188</sup> See, e.g., PATRICIA SMITH CHURCHLAND, BRAIN-WISE: STUDIES IN NEUROPHILOSOPHY 20-21 (2002) ("[A] reduction has been achieved when the causal powers of the macrophenomenon are explained as a function of the physical structure and causal powers of the microphenomenon.").

<sup>&</sup>lt;sup>189</sup> See Hull, supra note 186, at 164 ("Living creatures do what they do because of their organization and can be understood only in terms of their organization.").

life sciences, this approach dictates that "biological theories and the explanations that employ them . . . need to be grounded in molecular biology and ultimately physical science, for it is only by doing so that they can be improved, corrected, strengthened, made more accurate and more adequate, and completed."<sup>190</sup>

The process of inquiry prescribed by reductive mechanism requires breaking down, pulling apart, and dissolving natural phenomena into their discrete components so that they may be analyzed piece by piece. Leon Kass has described the method in the following way: "For greater precision, one works with cells or cell-free systems or, ideally, with isolated and purified molecules. Organisms are explained in terms of genes; vital functions are 'explained' by the motions and interactions of nonliving molecules."<sup>191</sup>

What do such reduced mechanistic explanations look like in the life sciences? Nobel Laureate Francois Jacob's<sup>192</sup> comments regarding the

<sup>191</sup> Kass, Forbidding Science, supra note 183, at 283.

<sup>192</sup> The Nobel Prize in Physiology or Medicine 1965, http://nobelprize.org/nobel\_ prizes/medicine/laureates/1965/ (last visited Aug. 6, 2009). Jacob shared the 1965 Nobel Prize for Physiology or Medicine with Jacques Monod and Andre Lwoff for

<sup>&</sup>lt;sup>190</sup> ROSENBERG, supra note 185, at 4. One of the most hotly contested questions in the philosophy of science is whether a completed reduction is possible — that is, whether it will ever be possible to explain all natural phenomena in terms of their structure and function at the quantum level. Such an aspiration was articulated at various times by scientific icons such as physicist Erwin Schroedinger and biologist Francis Crick. See, e.g., FRANCIS CRICK, OF MOLECULES AND MEN 10-14 (1966) ("The ultimate aim of the modern movement in biology is in fact to explain all biology in terms of physics and chemistry."); ERWIN SCHRODINGER, WHAT IS LIFE? WITH MIND AND MATTER AND AUTOBIOGRAPHICAL SKETCHES 3-4 (Cambridge Univ. Press 1967) (1944) (theorizing that living organisms can be most richly understood and explained in terms of physics and chemistry). This rich and complex debate is far beyond the scope of the present inquiry, but for a good introduction, see KITCHER, supra note 146, at 69-77 (arguing against possibility of such "Unity of Science" account, and arguing, for example, that "both biology and psychology seem to employ concepts that are not definable in the terms of the sciences proposed as reducing them"); ROSENBERG, supra note 185, at 153 (noting that chief obstacle to reducing biology to physics is principle of natural selection); id. ("Any subdiscipline of biology — from paleontology to developmental biology to population biology to physiology to molecular biology can uncover at best historical patterns, owing to the fact that (1) its kind vocabulary picks out items generated by a historical process, and (2) its generalizations are always open to being overtaken by evolutionary events."); id. ("[T]o complete the reduction, you need to be able to reduce the theory of natural selection to physical science.") Rosenberg argues that this is possible, and to this end argues that principle of natural selection is basic law of physical science. See Phillip Kitcher, The Hegemony of Molecular Biology, 14 BIOLOGY & PHIL. 195, 196-206 (1999) (articulating antireductionist view that sees molecular studies as important part of, but not whole of, contemporary biology); Philip Sloan, The Biophysics of Life, Lecture Series at Notre Dame Law School (Nov. 9, 2006).

definition of "life" offer some insight: "Biologists no longer study life today. They no longer attempt to define it. Instead, they investigate the structure of living systems, their function, their history.... The qualities, function and development of a living organism thus simply express interactions between its components."<sup>193</sup>

American philosopher John Searle echoed this conclusion when he declared that "[the world] consists entirely of physical particles in fields of force, and some of these particles are organized into systems that are conscious biological beasts such as ourselves."<sup>194</sup> Similarly, Australian philosopher of science, J.J.C. Smart has written that "[1]iving creatures are just very complicated physio-chemical mechanisms."<sup>195</sup>

Reductive mechanism has been an enormously successful program for modern science. Indeed, as Alex Rosenberg has observed, "the history of science, or at least, physical science since the seventeenth century, is the history of successive successful reductions."<sup>196</sup> Moreover, reductive mechanism is widely viewed as "the most powerful way to correct, deepen and broaden scientific theory. And, by and large, it is the only way to make technology based on it reliable enough to employ."<sup>197</sup>

## C. Strict Adherence to Epistemic Rules

The final feature of modern science relevant to the present inquiry is its commitment to strictly adhere to the epistemic rules prescribed by its own framework. That is, it single-mindedly focuses on only that

<sup>197</sup> Id. at 7.

their work on the genetic control of enzyme and virus synthesis.

<sup>&</sup>lt;sup>193</sup> VINING, supra note 179, at 9. Searle continued: "[S]ystems are collections of particles where the spatio-temporal boundaries of the system are set by causal relations . . . Babies, elephants, and mountain ranges are . . . . examples of systems." *Id.* at 8.

<sup>&</sup>lt;sup>194</sup> Stephen D. Smith, Science, Humanity, and Atrocity: A Lawyerly Examination, 104 MICH. L. REV. 1305, 1308 (2006).

<sup>&</sup>lt;sup>195</sup> Id. at 1306.

<sup>&</sup>lt;sup>196</sup> ROSENBERG, *supra* note 185, at 4-7 (mentioning, for example, Newton's reduction of the astronomical discoveries of both Kepler and Galileo to his Laws of Motion; reduction of Newtonian physics to a special cases of quantum physics and relativity theory; the twentieth century effort "to show . . . gravitational force and the forces between subatomic particles are all variations on a single underlying process that manifests itself in a variety of ways"; and the work of twentieth century physicists and chemists, who "show[ed] that the regularities of chemical synthesis could increasingly be explained and predicted by reducing them to regularities of atomic and subatomic bonding, which in turn were reduced to regularities of quantum mechanics").

species of knowledge that it produces by its narrow (yet extremely powerful) methodology. Modern science (which is not, of course to say, modern scientists) is deliberately indifferent to and does not recognize arguments or conclusions falling outside its framework. As Frank Laird has observed: "That science is epistemologically exclusionary seems beyond dispute, if one understands these terms to mean that certain theories, modes of discourse, and methods garner no respect in scientific debates."<sup>198</sup>

The "speculative" questions that Descartes originally tabled about the goodness (or badness), purposes, or ultimate meaning of natural things remain tabled. As David Hull, an iconic figure within the philosophy of science declared in his seminal essay of 1969, What the Philosophy of Biology Is Not, "from the point of view of contemporary biology, both vitalism and teleology are stone-cold dead."<sup>199</sup> Problems that cannot be reconceived and solved by the tools of science are not explored. Thus, modern science is "not the representation and demonstration of truth, but an art: the art of finding the truth - or, rather, that portion of truth that lends itself to be artfully found."200 Moreover, the knowledge produced by modern science is meant to be value-neutral.<sup>201</sup> As Stephen Jay Gould famously said, "the magisterium of science covers the empirical realm: what the Universe is made of (fact) and why does it work in this way (theory)," and is silent on "questions of ultimate meaning and moral value."202

This disciplined commitment to the epistemic framework of modern science has been a key to its flourishing. As Leon Kass has observed, "science of nature that has made enormous progress precisely by its metaphysical neutrality and its indifference to questions of being, cause, purpose, inwardness, hierarchy, and the goodness or badness of things, scientific knowledge included."<sup>203</sup> As will be shown below,

<sup>&</sup>lt;sup>198</sup> Laird, *supra* note 161, at 36; *see also* Guston, *supra* note 117, at 50 ("Science is a plural array of disciplines, but it is exclusionary in its refusal to accept some 'marginal' or 'boundary' enterprises.").

<sup>&</sup>lt;sup>199</sup> See Hull, supra note 186, at 163.

<sup>&</sup>lt;sup>200</sup> Leon R. Kass, Science, Religion, and the Human Future, COMMENT., Apr. 2007, at 147 [hereinafter Kass, Science].

<sup>&</sup>lt;sup>201</sup> See id. (noting how its ostensible neutrality makes modern science "perfectly adapted for, technical application" and confirms Hans Jonas's observation that "modern science contains manipulability at its theoretical core"). The premise that modern science is normatively neutral has been powerfully challenged by a diverse array of scholars. See generally JASANOFF, supra note 116; KITCHER, supra note 146; Laird, supra note 161; Levin, Moral Challenge, supra note 105.

 $<sup>^{\</sup>rm 202}\,$  Stephen Jay Gould, Rocks of Ages: Science and Religion in the Fullness of Life 3 (1999).

<sup>&</sup>lt;sup>203</sup> Kass, *Science*, *supra* note 200, at 38-39.

however, these self-imposed epistemic limitations which have fueled science's power as a producer of useful knowledge render the Maximal Deference approach an unsustainable model of integration for public bioethics.

## D. A Brief Word on the Non-Scientific Virtues of Scientists

Before proceeding to a critique of the Maximal Deference model in light of the above discussion of the premises and methods of science, it is necessary to say a brief word in defense of science and its practitioners. The foregoing account shows that modern science is, by design, indifferent to questions of value, purposes, ends, and meaning. The same, manifestly, *cannot* be fairly said of scientists or the scientific community. As noted above, the roots of modern science are clearly embedded in the humanitarian aspiration to relieve human suffering and advance knowledge. Moreover, the scientific community is a great exemplar of human virtues. Leon Kass has enumerated several such virtues including:

[E]nterprise (in imagining new possibilities), self-discipline and perseverance (in doggedly pursuing a line of experimentation), courage (in risking failure), measure and judiciousness (in weighing evidence), and intellectual probity and integrity (in reporting data, crediting others, and giving an honest account to one's sources of financial support)... [as well as] openness, trust, and (within the limits of scientific competition) generous sharing of materials and data.<sup>204</sup>

While these virtues are unintelligible in the language of science itself, they are amply exhibited in the work of good scientists. Moreover, these virtues make scientists invaluable participants in the public square, especially on matters relating to bioethics. Nothing in this Article should therefore be construed as denigrating the virtues or morality of scientists or the scientific community, or as suggesting that scientists should be *excluded* from deliberations on matters of public bioethical import. Quite the contrary — they are indispensible to a healthy polity.

<sup>204</sup> Id. at 43.

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# IV. THE UNSUSTAINABILITY OF MAXIMAL DEFERENCE AS A MODEL OF INTEGRATION FOR PUBLIC BIOETHICS

## A. A Brief Word on Maximal Deference and Democratic Legitimacy

There are prudential reasons to be cautious about the Maximal Deference model of integration, given its strong (indeed, seemingly categorical) default rule of delegation of public bioethical matters to scientists. Just as in other contexts, the broad delegation of important questions by public officials to a small community of experts raises important questions about democratic accountability, and by extension, legitimacy. Such concerns are complex and worthy of study in themselves. But they are outside the scope of the present critique, which focuses instead on the model's essential, insuperable defects (i.e., the problem of incommensurability, discussed below). Nevertheless, these prudential issues bear mentioning briefly, if only to flag for future consideration.

Leon Trachtman has observed that it is a first principle of liberal democratic theory that:

[A]ll power in a democracy flows from the people to and through their elected representatives. The people of a democratic society reserve to themselves the power, both directly and through their representatives, to influence public policy decisions and ultimately to govern the conduct of all social institutions which impinge on their lives.<sup>205</sup>

For the exercise of power to be legitimate, it must respect this principle. Thus, if public questions are delegated to a community of experts, political accountability and oversight are indispensible to preserving legitimacy. As Dorothy Nelkin has written, "[d]emocratic principles require that individuals be involved in the formulation and determination of policies affecting them."<sup>206</sup>

This is a fortiori true of public bioethics. First, the questions presented in public bioethics are matters of concern for all people in a democracy, lay and expert alike. Individuals rightly have strong opinions about the moral meaning of human life (and death), how science should be limited (or promoted) in the name of ethics, and what the proper ends of medicine are. Moreover, lay citizens provide much of the funding (directly or indirectly) for research in the

<sup>&</sup>lt;sup>205</sup> Leon E. Trachtman, *Science and Technology: Who Governs?*, in GOVERNING SCIENCE AND TECHNOLOGY IN A DEMOCRACY 141 (Malcolm L. Goggin ed., 1986).

<sup>&</sup>lt;sup>206</sup> See Nelkin, supra note 1, at 108.

biosciences that gives rise to public bioethical questions.<sup>207</sup> Also, such developments have concrete consequences for the whole society. Those consequences might include actual physical changes to the human gene pool (as in germline genetic modification), or the social disruptions wrought by new knowledge — "truth, like death, is no respecter of person, status or hierarchy."<sup>208</sup> Taking these matters out of the public's hands and reposing them in an elite community risks eroding democratic principles and raising the specter of what Karl Bracher has called the "frightful image of a mere technocracy, a rule by the managers and functionaries, which would evade control and the entire realm of democratic-parliamentary decision-making."<sup>209</sup>

Also, modern theories of administrative agency behavior provide good reason to be cautious about the Maximal Deference model of integration for public bioethics. As noted above, some progressives in first half of the twentieth century took the view that "agencies could be staffed with professional, dispassionate technocrats who could govern intelligently and scientifically."210 By the second half of the twentieth century, however, the reality of the administrative state called into question Landis's judgment that the rigor and neutrality of science could be translated into governance. It became clear that "agencies did not in fact (or at least did not always in fact) scientifically identify an uncontroversial conception of the public interest and then seek to attain it in disinterested technocratic fashion."<sup>211</sup> Indeed, theorists came to realize that "agency capture" by the regulated industry was a recurrent feature of agency behavior, notwithstanding the staffing of such agencies with scientific experts.<sup>212</sup> According to Gary Lawson:

<sup>&</sup>lt;sup>207</sup> See, e.g., Trachtman, supra note 205, at 141 (discussing how lay citizens elect representatives, who make funding decisions).

<sup>&</sup>lt;sup>208</sup> JARVIE, supra note 150, at 225.

<sup>&</sup>lt;sup>209</sup> See Nelkin, supra note 1, at 108-09.

<sup>&</sup>lt;sup>210</sup> LAWSON, supra note 169, at 40.

<sup>&</sup>lt;sup>211</sup> Id. at 45. Additionally, arguments about the explanatory limits of science discussed in KITCHER, *supra* note 146, at 85-91 (e.g., Kitcher's arguments about the subjectivity of scientific "significance," the realist-antirealist debate, etc.) counsel skepticism about "scientific governance."

<sup>&</sup>lt;sup>212</sup> See LAWSON, supra note 169; see also Thomas W. Merrill, Capture Theory and the Courts: 1967–1983, 72 CHI.-KENT L. REV. 1039, 1060-67 (1997). Another lesson to be drawn from the experience of administrative agencies is that scientists often disagree about empirical conclusions, and even more frequently on matters relating to normative questions. See, e.g., George J. Graham, Jr., The Necessity of the Tension, 7 SOC. EPISTEMOLOGY 25, 30 (1993).

By the early 1960s, [agency capture by the regulated industry] was almost universally regarded as the norm for agency behavior. The expectation, from almost everyone on every part of the political spectrum was that agencies would engage in narrowly industry-serving behavior, and that the regulatory process would, if left to its own devices, serve the interests of powerful economic groups at the expense of the broader public by providing an engine for legal cartelization.<sup>213</sup>

This insight counsels extreme caution for the context of public bioethics, where the pharmaceutical and biotechnology industries have enormous financial stakes riding on the resolution of contested issues of governance.

The foregoing represents only some of the prudential concerns for the Maximal Deference model of integration for public bioethics — or indeed any approach to governance in which crucial normative questions are delegated to an elite enclave of experts. These problems regarding political accountability and democratic legitimacy may or may not be insuperable. But the Maximal Deference model of integration fails for a more fundamental and decisive reason — the problem of incommensurability between the premises and methods of science outlined above and the ethical concepts that comprise the currency of public bioethics.

# B. The Problem of Incommensurability

The typical imperative from biology is not "Thou . . . shalt," but "If . . . then . . . else"

— Steven Pinker<sup>214</sup>

[S]o much in law . . . quietly mixes the "is" and the "ought."

- Steven D. Smith<sup>215</sup>

<sup>&</sup>lt;sup>213</sup> See LAWSON, supra note 169, at 40.

<sup>&</sup>lt;sup>214</sup> STEVEN PINKER, HOW THE MIND WORKS 27 (2004).

<sup>&</sup>lt;sup>215</sup> Steven D. Smith, Legal Scholarship as Resistance to "Science" 2 (Univ. of San Diego Sch. of Law, Public Law and Legal Theory Research Paper Series, Paper No. 32), available at http://law.bepress.com/cgi/viewcontent.cgi?article=1042&context=sandiegolwps. ("[T]he question [of why one should engage in legal scholarship] quietly mixes the 'is' and the 'ought'.").

'Once the rockets are up, who cares where they come down? That's not my department,' says Wernher von Braun.

— Tom Lehrer<sup>216</sup>

Why is the Maximal Deference model of integration for public bioethics unsustainable in principle? Simply stated, its one-size-fits-all default rule of delegation fails because modern science is designed to be indifferent to many (perhaps all) of the vexed public questions at the heart of this domain. For the reasons discussed above, the analytic power of modern science depends on this indifference to questions of ultimate meaning, purpose, and value. But public bioethics is, at bottom, the adjudication of precisely these kinds of questions. By way of review, modern science is axiomatically committed to physicalism and operates by means of reductive mechanism. Most important for public bioethics, modern science operates by strict adherence to welldefined epistemic rules - ignoring concepts and arguments that fall outside of its framework for the production of knowledge. By contrast, the currency of public bioethics are ethical concepts such as personhood, autonomy, beneficence, justice, and equality. These terms cannot be found the lexicon of the modern physical and life sciences. They are scientifically unintelligible.

For illustration of this point, it is useful to turn back to the previous example of the debate over federal funding for embryonic stem cell research. As discussed above, this debate - the defining issue for public bioethics of the last decade - involves a normative disagreement on many fronts. First, there is the question of the moral status of the human embryo that is intentionally disaggregated and destroyed in embryonic stem cell research. Is the embryo, simply by virtue of the fact that it is a living member of the human species (i.e., a human organism) entitled to moral respect and legal protection? Or must a given embryo satisfy additional criteria for "personhood" (e.g., developmental benchmarks, being "wanted" by a potential gestational parent, etc.) in order to merit moral regard and legal protection? Is it consistent with the norms of equality and justice to conscript a member of the human species into experimentation that necessarily entails his or her demise? What about scientific freedom? What about the humanitarian aspiration to pursue cures for diseases and injuries? What about the desire for knowledge for the sake of itself? What about respect for pluralism and coerced complicity of taxpayers? What about

<sup>&</sup>lt;sup>216</sup> TOM LEHRER, WERNHER VON BRAUN [Reprise/Warner Bros. Records 1965], in KITCHER, supra note 146, at 89.

the duties of citizenship and living with the consequences of elections? Thus, at the very least, the federal funding of embryonic stem cell research issues involves contested normative claims involving concepts including personhood, equality, autonomy, justice, and beneficence.<sup>217</sup> Of what help is modern science in this context?

On the surface, it would seem that modern science might offer a great deal of assistance. It can clarify the biological properties of the embryo. For example, modern embryology confirms that the embryo is a living, self-directing, integrated, whole member of the species *homo sapiens* — a human organism.<sup>218</sup> Modern science can also inform speculation about the promise of embryonic stem cell research to yield highly useful knowledge relevant to human development and perhaps regenerative therapies. Modern science thus adds value by filling in some of the terms of the normative debate.

But what about the decisive questions — Who counts as a person? Who gets to do the counting? How to understand the relationship between our obligations (if any) to human embryos and to those future patients who might be helped by embryonic stem cell research? What about the consciences of taxpayers? What does modern science have to say about these matters? It is useful to consider such questions individually.

What does science have to say about "persons"? As Steven D. Smith has written: "The premises and methods of science appear to dissolve 'persons' as a discrete ontological category. A person is now conceived to be, basically, an exquisitely complex system of particles."<sup>219</sup> This reduction does not help to draw moral distinctions among embryonic, fetal, and post-natal human beings. If anything, it muddies the ethical picture further. A completed reduction (if such a thing is possible) might even blur the distinction between "living" and "non-living" beings.

<sup>&</sup>lt;sup>217</sup> These ethical principles should be familiar to any student of bioethics — they overlap with those announced by the National Commission in its seminal Belmont Report — respect for persons, beneficence, and justice, and incorporated into the Common Rule at 45 C.F.R. pt. 46 (1991). See OFFICE OF HUMAN SUBJECTS RESEARCH, THE BELMONT REPORT (1979) [hereinafter BELMONT REPORT]. These principles were refined and extended by Jim Childress and Tom Beauchamp into what have become known as the "Georgetown Principles." See generally TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (2001).

<sup>&</sup>lt;sup>218</sup> Though, as Philip Kitcher points out, biological classification (along with the definition of scientific significance) is largely a function of scientific capacities and subjective interests. Nature does not divide itself into categories; such categories are imposed by scientists according to the abilities and needs. The taxonomies of the biosciences thus differ from those of the physical sciences. *See* KITCHER, *supra* note 146, at 78-81.

<sup>&</sup>lt;sup>219</sup> STEVEN D. SMITH, LAW'S QUANDARY 28 (2004).

How about "equality"? Yuval Levin has concisely captured the explanatory limits of modern science vis-à-vis human equality:

Science, simply put, cannot account for human equality, and does not offer reasons to believe we are all equal. Science measures our material and animal qualities, and it finds them to be patently unequal. We are, after all, obviously not all equally large or small, tall or short, strong or weak, healthy or ill. We are born physically and mentally unequal, and always remain so. To examine only our animal qualities is surely to conclude that we are far from one another's equals. And so to assume that there is nothing more to us than our animal qualities (as the modern scientific outlook does) is to assume inequality is the human condition.<sup>220</sup>

It would seem, therefore, that modern science does not shed light on the normative entailments of human equality as applied to embryonic stem cell research — or any other context for that matter.

What about the ethical principles of "beneficence" (the injunction to do no harm, and to maximize benefits while minimizing harms)<sup>221</sup> and "justice" (the normative framework for allocating the burdens and benefits of embryonic stem cell research)?<sup>222</sup> To evaluate what beneficence or justice requires in this context, one must have an exante conception of what constitutes "the good" or perhaps, less ambitiously, which goods should be pursued. And, moreover, one must have a prior conception of what constitutes a harm (or harms) to be avoided. But these are not questions about physical objects that admit of resolution through the method of reductive mechanism. As Leon Kass has written:

On the scientific view of the world, there can be no knowledge, properly so-called, of these matters, no knowledge, strictly speaking, about the purpose or meaning of human life, about human flourishing, or even about ethics: opinions about good and bad, justice and injustice, virtue and vice have no cognitive status and are not subject to rational

LEVIN, supra note 2, at 97.

<sup>&</sup>lt;sup>221</sup> See BELMONT REPORT, supra note 217, Part C.2.

<sup>&</sup>lt;sup>222</sup> See id. The debate over the scope and substance of "justice" may be the most vexed question in political theory. The Belmont Report offered a very brief summary of the perennial competing approaches to these questions: "These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit." *Id.* Part C.3.

inquiry — they are, as we are fond of saying, values, merely subjective. As scientists we can, of course, determine more or less accurately what it is different people *believe* to be good, but we are, as scientists, impotent to judge between them. Even political science, once the inquiry into how men *ought* to live communally, now studies only how they *do* live and the circumstances that move them to change their ways. Man's political and moral life is studied not the way it is lived, but abstractly and amorally, like a mere physical phenomenon.<sup>223</sup>

Not only does modern science not provide a definitive answer as to the question of "who" (if anyone) is harmed in embryonic stem cell research, but it remains silent on the question of what constitutes "benefit" and "harm" in the first instance.

The ultimate problem is that public bioethics involves normative disputes about ends, moral meaning, and value. But as George Graham has noted, "science cannot deduce or produce scientific conclusions concerning the appropriate goals or purposes of public policy. It can at best produce better understanding of causes and effects that surround those things that government policy will affect."<sup>224</sup> Frank Fukuyama points to an alternative array of disciplines as more fitting to supply ends, and offer tools to judge among competing purposes: "It is only 'theology, philosophy, or politics' that can establish the ends of science and the technology science produces, and pronounce on whether those ends are good or bad."<sup>225</sup>

Thus, it would seem that modern science is most suited to answering the empirical questions that attend public bioethical issues.

<sup>224</sup> George J. Graham, Jr., The Necessity of the Tension, 7 Soc. EPISTEMOLOGY 25, 30 (1993).

<sup>&</sup>lt;sup>223</sup> KASS, supra note 178, at 44. One might be able to provide a backwards-looking etiological, evolutionary account of how these concepts arose in human behavior and speculate as to their past value as adaptations, but as Brian Leiter and Michael Weisberg have persuasively argued, it does not yet seem that such insights will have value for debates about the ends to which human behavior should be directed in a forward-looking sense. At the most, this discipline might shed light on what mechanisms of social control are most efficacious. See Brian Leiter & Michael Weisberg, Why Evolutionary Biology Is (So Far) Irrelevant to Law (Univ. Texas Sch. Law Pub. Law & Legal Theory Research Paper No. 89, Oct. 2007). Similarly, one might be able to give a descriptive neurological account of the brain's pattern of activation when people act justly (or unjustly) or reflect on questions of justice, but this seems of limited use to the humanistic question of what kinds of actions justice prescribes or prohibits.

<sup>&</sup>lt;sup>225</sup> FUKUYAMA, supra note 105, at 185. John D. Kraemer and Lawrence O. Gostin make a similar argument in their article, *Science*, *Politics*, and *Values: The Politicization of Professional Practice Guidelines*, JAMA Mar. 2009, at 665-67, 666.

Conversely, modern science does not seem to be well designed to adjudicate those issues in public bioethics that involve ethical deliberations about matters such as meaning, purpose, value, the requirements of justice, the demands of equality, and respect for persons. This insight points towards a provisional way forward for integrating science and public bioethics, which will be discussed in Part V below. But first it is useful to discuss briefly the perils of ignoring the problem of incommensurability outlined above. That is, there are grave risks associated with trying to wield science to adjudicate matters of public bioethics, as the Maximal Deference model prescribes.

# C. Ignoring the Problem of Incommensurability: The Human Costs of Maximal Deference

The preceding subpart concludes that the premises and methods of science preclude its use as a tool to adjudicate public bioethical disputes that are ultimately grounded in normative disagreements involving moral, humanistic concepts (such as equality, justice, beneficence, and personhood.). Thus, the Maximal Deference model of public bioethics is unsound in principle, because it tries to harness science in this misguided way. This conclusion is strengthened when one considers the consequences of ignoring the conceptual incommensurability and pressing forward with the Maximal Deference model.

Modern science is, by design, indifferent to normative claims about purposes, moral meaning, and value. What happens when science nevertheless tries to grapple with these questions using only its own internal resources (as the Maximal Deference model prescribes)? There appear to be two possibilities. One possibility is that decisionmakers might smuggle in unstated normative principles to adjudicate public bioethical questions while purporting to apply scientific judgment alone. A recent report by the Bipartisan Policy Center's Science for Policy Project pejoratively terms this the "science made me do it" approach to policymaking.<sup>226</sup> Alternatively, given the unintelligibility of the humanistic concepts and principles of public bioethics in the scientific framework, one might be tempted to flatten or abandon such concepts altogether. Both alternatives pose serious risks for public bioethics.

<sup>&</sup>lt;sup>226</sup> BIPARTISAN POLICY CENTER, SCIENCE FOR POLICY PROJECT: IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 4 (2009).

## 1. Smuggling Unstated Norms

What normative goods might slip into scientific reasoning in the context of public bioethics? The most obvious candidate is the goodness of health and its preservation. This, indeed, was the humanitarian aspiration that fueled the development of modern science from its inception. Descartes was explicit in his judgment that the most compelling aspiration for human beings is "the conservation of health, which is without doubt the primary good and foundation of all other goods of this life."<sup>227</sup> Since the seventeenth century, health has been a principle good animating discussions and debates on ethical issues connected to the biosciences. This is *a fortiori* true of public bioethics. The goodness of health, for example, has grounded the arguments in favor of federally funding embryonic stem cell research.<sup>228</sup>

There is, of course, nothing intrinsically wrong about invocation of health as an animating good in public bioethics discourse. Indeed, among all the goods that populate debates over public bioethics, health might very well command the greatest consensus as a worthy aspiration. But the good of health does not emerge from scientific reasoning. It cannot, for reasons discussed above.<sup>229</sup> To claim that its status as a primary ethical good is derivable by scientific means is to engage in a kind of public deception (perhaps also a kind of selfdeception). To frame the ethical judgment that health should occupy a place of privilege in our debates over bioethics as a scientific claim is gravely misleading. It is understandable why someone would do this - science enjoys enormous social capital as a rigorous and more importantly, objective form of reasoning. Scientific conclusions therefore enjoy a standing in American society that other claims lack. But to make an ethical claim under the auspices of scientific reasoning corrupts and degrades the public square, which, at a minimum, requires participants to be honest and forthright about the sources of their claims.

Worse still, the invocation of health as a morally neutral, scientifically-derived good may have corrupting effects for the process of governance itself. It could degrade the notion of self-government, and creates the illusion that democracy can be replaced by science. Yuval Levin captures this peril in the following passage:

<sup>&</sup>lt;sup>227</sup> RENÉ DESCARTES, DISCOURSE ON METHOD 49 (Richard Kennington trans., Focus Publ'g 2007) (1637).

<sup>&</sup>lt;sup>228</sup> See supra note 177 and accompanying text.

<sup>&</sup>lt;sup>229</sup> See supra notes 184-202 and accompanying text.

If health and power over nature are the highest human goods, then surely science (as opposed to politics) must be the primary instrument of our fulfillment. Science, far more than politics, directs itself squarely to advancing these goods, and to the extent that politicians try to govern science, they may interfere with that great purpose. For this reason, there has long been an inclination to see science as beyond the reach of politics — an inclination encouraged by the fathers of modern science, and one that has established itself firmly in the political mindset. This inclination is perhaps the most fundamental threat to self-government in our time, and among the most profound moral challenges posed by the modern scientific project.<sup>230</sup>

Thus, smuggling of unstated norms into public bioethical discourse dressed up as scientific judgments is corrosive to self-governance. The Maximal Deference model of integration for public bioethics opens the door to this grave risk.

## 2. Flattening and Abandoning Ethical Principles

Instead of smuggling ethical norms into public bioethical discourse under the guise of scientific conclusions, those wielding science alone to "do bioethics" might be tempted simply to exclude as unintelligible any ethical principle that falls outside of the scientific framework (which is to say all of them). This happens when the strict adherence to the epistemic rules of modern science is generalized to public bioethics. Because it is impossible for modern science to give a *normative*<sup>231</sup> account of good, evil, equality, justice, beneficence, and even "persons," such principles are either flattened into mere artifacts produced by the brain (as shaped by evolution) or stripped of their

<sup>&</sup>lt;sup>230</sup> LEVIN, *supra* note 2, at 13-14.

<sup>&</sup>lt;sup>231</sup> By a "normative account," I mean one that supplies insight into the ends to which such concepts are oriented. This is to be distinguished from a *descriptive* account, including for example, an evolutionary biological explanation as to *how* a particular conception emerged in the past, or a neurobiological account of how the brain produces or judges behavior to be good, bad, just, unjust, etc. These descriptive accounts of *how* such concepts came to be as a historical matter or *how* they emerge from the structure and function of the brain do not supply moral prescriptions for conduct and its regulation. At the most, they might be useful in identifying the best means to pursue a normative end. But an account of "how something works" in a mechanistic sense — or even "why was this characteristic successful to the survival and reproduction of this organism in the past" — is not the same as "what is it for" in a moral sense.

rich normative meaning. The jump is thus made from the "methodological[] indifferen[ce] to questions of better and worse" to the conclusion that such "indifference [is] substantively reflected in the nature of things."<sup>232</sup> Stephen Jay Gould reflects this inclination in his statement that "[n]ature was not constructed as our eventual abode, didn't know we were coming (we are, after all, interlopers of the latest geological microsecond), and doesn't give a damn about us (speaking metaphorically)."<sup>233</sup>

Preeminent scientists (and sympathetic philosophers) have illustrated what the landscape looks like once stripped of its moral meaning. Nobel laureate Steven Weisberg noted that "the more the universe seems comprehensible, the more it also seems pointless."<sup>234</sup> To which astronomer Margaret Geller replied, "Why should it have a point? . . . It's just a physical system, what point is there?"<sup>235</sup> Citing Baruch Spinoza, Jean Pierre Changeux, director of the Molecular Neurobiology Laboratory of the Institute Pasteur agrees "Nature proposes no end to its operations . . . all final causes are only pure fictions imagined by men."<sup>236</sup> Another Nobel Laureate Francis Crick concurs: "[Y]our joys and your sorrows, your memories and your ambitions, your sense of personal identity and free will, are in fact no more than the behavior of a vast assembly of nerve cells and their associated molecules."<sup>237</sup>

Moreover, Nobel Laureate Francois Jacob has asserted that

[T]he way of viewing life and the human being has gradually changed. We can see how both have become subjects of research instead of revelation .... The intention of a psyche has been replaced by the translation of a message .... An organism is merely a transition, a stage between what was and what will be. Reproduction represents both the beginning and the end, the cause and the aim .... [B]iology has demonstrated that there is no metaphysical entity hidden behind the word "life."<sup>238</sup>

<sup>&</sup>lt;sup>232</sup> KASS, *supra* note 178, at 44.

<sup>&</sup>lt;sup>233</sup> Stephen Jay Gould, Nonoverlapping Magisteria, 106 NAT. HIST. 16, 25 (1997).

<sup>&</sup>lt;sup>234</sup> Steven WEINBERG, THE FIRST THREE MINUTES 154 (1977) (quoted in VINING, supra note 179, at 11).

<sup>&</sup>lt;sup>235</sup> Steven WEINBERG, DREAMS OF A FINAL THEORY 255 (1992) (quoted in VINING, supra note 179, at 11).

<sup>&</sup>lt;sup>236</sup> VINING, supra note 179, at 52.

<sup>&</sup>lt;sup>237</sup> Francis Crick, The Astonishing Hypothesis: The Scientific Search for the Soul 3 (1994).

<sup>&</sup>lt;sup>238</sup> VINING, supra note 179, at 51 (quoting FRANCOIS JACOB, THE LOGIC OF LIFE ix, 2,

This reduced and flattened understanding of longstanding humanistic principles is reflected in an argument made by members of the International Academy of Humanism (composed of renowned scientists including Francis Crick, Richard Dawkins, and E.O. Wilson) in favor of human cloning (another key contemporary debate in public bioethics):

What moral issues would human cloning raise? Some world religions teach that human beings are fundamentally different from other mammals — that humans have been imbued by a deity with immortal souls, giving them a value that cannot be compared to that of other living things. Human nature is held to be unique and sacred . . . . As far as the scientific enterprise can determine, . . . [h]umanity's rich repertoire of thoughts, feelings, aspirations, and hopes seems to arise from electrochemical brain processes, not from an immaterial soul that operates in ways no instrument can discover . . . . Views of human nature rooted in humanity's tribal past ought not to be our primary criterion for making moral decisions about cloning. . . . [I]t would be a tragedy if ancient theological scruples should lead to a Luddite rejection of cloning.<sup>239</sup>

What is wrong with abandoning ethical concepts as invalid because they cannot be demonstrated or illuminated by the tools of science (beyond a merely descriptive account)? First, such abandonment seems to result from confusing the self-consciously designed epistemic limits and normative neutrality of modern science with the limits of knowledge or understanding more generally. Descartes placed moral questions outside the ambit of modern science in order to free its massive analytic powers to explore the composition and function of natural things. Finding such moral questions outside the reach of the tools of modern science, some scientists and philosophers have thus concluded that these questions (and the concepts on which they depend) are meaningless. This seems to be a species of confusing the familiar with the necessary — confusing postulates with proofs. It appears to be a kind of epistemic provincialism.

But the nullification or radical reduction of ethical concepts in public bioethical discourse is worse than just an error in reasoning there are serious consequences for humankind. What does the

<sup>306 (</sup>Betty E. Spillman trans., Princeton Univ. Press 1973)).

<sup>&</sup>lt;sup>239</sup> Leon R. Kass, A More Perfect Human: The Promise and Perils of Modern Science, Lecture Delivered at U.S. Holocaust Museum (June 19, 2006), available at http://www.humanlife.net/view\_reports.htm?rpid=13.

governance of science and medicine in the name of ethics look like in a system without a rich conception of equality, justice, beneficence, autonomy, or even persons? How might the weakest and most vulnerable among us fare in such a regime? How could one defend even those humanitarian aspirations that modern science was developed to serve? Under such an approach, what is science for? What is medicine for? For that matter, what are government and law for? Modern science provides no way to answer these questions. And thus some are tempted to regard these questions as meaningless. This conclusion is perhaps the gravest risk of the Maximal Deference model of integration for public bioethics.

## V. A PROVISIONAL WAY FORWARD: POLICING THE BOUNDARIES OF SCIENTIFIC AND ETHICAL REASONING IN PUBLIC BIOETHICS

The foregoing has argued that the Maximal Deference model of integration for public bioethics is, in principle, unsustainable. What role, then, should science play in public bioethics? Obviously, wise governance in any context must rely on the most rigorously gathered and tested empirical data that modern science can provide. And such empirical findings must never be distorted or mischaracterized for political ends. But beyond these obvious commonsense observations, how can science enter public bioethics in a constructive way without corrupting the process of governance or becoming corrupted itself? Given the widely divergent and indeed incommensurable relationship between the premises and methods of modern science and the humanistic concepts at the heart of public bioethics, a working relationship between the two depends on restricting their application to their respective competencies. Thus, sound public bioethics depends on establishing and then policing the boundaries between science and ethics for this domain of governance.<sup>240</sup>

How can this be done? A good point of departure is the recent report of the Bipartisan Policy Center's Science for Policy Project, which recommends that government officials "explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy."<sup>241</sup> How can such lines be drawn?

<sup>&</sup>lt;sup>240</sup> I am indebted to Scott Brewer for the metaphor of "policing the boundaries." Kraemer and Gostin use a similar metaphor (borrowed from Establishment Clause jurisprudence) when they argue for a "wall of separation . . . between science, norms, and politics." *See* Kraemer & Gostin, *supra* note 225, at 667.

<sup>&</sup>lt;sup>241</sup> BIPARTISAN POLICY CENTER, supra note 226, at 4 (referring to administrative agencies).

The foregoing sections discussing the distinctive features of modern science and public bioethics illuminate a way forward.

## A. Defining Boundaries of Competency

Modern science is most useful in clarifying the factual predicates that underlie a normative debate. The powers of modern science reach their acme in matters of measurement, prediction, and to a somewhat lesser extent, control of natural phenomena. This is precisely what the methods of modern science were designed to do — disaggregate, reduce, analyze, model, and draw conclusions about *how things work* in terms of their physical structure and function.

Ethical reflection and argument is most useful in negotiating among and applying the humanistic principles that comprise the currency of public bioethics, such as equality, justice, autonomy, beneficence, and persons. Public bioethical reasoning seeks to discern when, how, and most importantly, *why* the government *should* regulate the behavior of people and institutions, in light of the moral meaning of advances in biomedical science and biotechnology, how such advances stand in relation to what (and who) *human beings are* in a normative sense (and, by extension, how they should be treated), and what the common good requires.<sup>242</sup>

The choice of whether and how to deploy modern science or ethical argument therefore depends on the *kind of public bioethical question that is under consideration*. One size manifestly does not fit all, contrary to the prescriptions of the Maximal Deference model. If the public question ultimately pertains to a normative matter, the problem of incommensurability precludes science from offering a decisive answer. If the public question, by contrast, is reducible to an empirical matter, then modern science should be deployed to offer the best possible answer.

Integration for public bioethics is thus an exercise in identifying and understanding the kind of public question being asked and discerning whether or not it admits of being answered by means of science. To facilitate clarity of thought in this regard, it is useful to formalize the array of possible relationships between the types of questions that arise in public bioethics and science's capacity to provide answers. To this end, the next section offers a Taxonomy of Relationships (with illustrative examples) to help identify and police the boundaries of competencies of science and moral reasoning for public bioethics.

<sup>&</sup>lt;sup>242</sup> For a review of competing approaches, see MEILAENDER, *supra* note 13, at ch. 1. Also, see TOM L. BEAUCHAMP & LEROY WALTERS, CONTEMPORARY ISSUES IN BIOETHICS 1-35 (2003), for a similar (if differently presented) discussion.

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## B. Policing the Boundaries: A Taxonomy of Relationships

Identifying and policing the boundaries of science and moral reasoning within public bioethics depends, for reasons discussed above, on understanding the relationship between the public question asked, and the kinds of answers that science is prepared to supply. To facilitate such understanding, these relationships can be expressed formally in a taxonomy divided into three parts, namely, the "relationship of identity" (where the public question is empirical, and thus asked in the same form as other matters of scientific inquiry); the "relationship of complementarity" (where the public question is ultimately normative, but its adjudication requires the mastery of certain scientific factual predicates); and the "relationship of preemption" (where a scientific claim is made *about* an ethical concept crucial to resolving the public question under consideration). Locating a public question within the taxonomy provides analytic clarity and may yield insight into how to structure (or critique) public decisionmaking. The taxonomy and its components are discussed more fully below, with examples provided for purposes of illustration.

## 1. The Relationship of Identity and the (Imperfect) Case of Plan B

It is imaginable that a public bioethical question could be posed in the same form to which modern science is accustomed. That is, it is possible that a public bioethical question could be, at bottom, narrowly empirical and thus answerable by the methods of science. Such a question would thus fall into the first category of the taxonomy - the relationship of identity. Examples of these kinds of questions are exceedingly difficult to find, given that most public bioethical matters involve some species of normative disagreement. There is, however, an example (albeit an imperfect one) that illustrates this relationship: the relatively recent dispute over the FDA's approval of В" levonorgetrel (sometimes called "Plan or "emergency contraception") for over-the-counter (OTC) sale to people older than eighteen years of age.

Levonorgestrel is a synthetic hormone (similar to progesterone) that has been approved as a *post-coital* means of preventing an unwanted pregnancy.<sup>243</sup> It is produced and marketed by Barr Pharmaceuticals under the brand name Plan B. It was approved for prescription use in

<sup>&</sup>lt;sup>243</sup> See Tummino v. Torti, 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009) (noting that approved dosage is "two pills taken 12 hours apart, each containing 0.75 mg of levonorgestrel" and "[1]t is commonly referred to as a 'morning after pill'").

the United States in 1999.<sup>244</sup> It is not entirely clear how Plan B prevents pregnancy. The approved labeling reflects this uncertainty:

Plan B<sup>®</sup> works . . . mainly by stopping the release of an egg from the ovary. It is possible that Plan B<sup>®</sup> may also work by preventing fertilization of an egg (the uniting of sperm with the egg) or by preventing attachment [of the newly conceived embryo] (implantation) to the uterus (womb), which usually occurs beginning 7 days after release of an egg from the ovary. Plan B<sup>®</sup> will not do anything to [an embryo] already attached to the uterus. The pregnancy will continue.<sup>245</sup>

There are no known serious or long-term side effects associated with Plan B (though it may cause nausea or abdominal pain in some cases).<sup>246</sup>

There has been a pitched moral disagreement over the use of Plan B.<sup>247</sup> Supporters of Plan B argue that it provides enormous social benefits by effectively preventing unwanted pregnancies (and thus abortions) following unprotected sexual intercourse. The principal objection to the use of Plan B is raised by those who regard the intentional (or negligent) destruction of human beings at the embryonic stage of development as a grave injustice (for the same reasons discussed above regarding objections to embryonic stem cell research). They argue that use of the drug is morally unacceptable because it might cause the death of a living human embryo by preventing its implantation in the uterus.<sup>248</sup> It is no answer, such

<sup>248</sup> That is, the drug might work as an "interceptive" (killing the newly conceived but as-yet-unimplanted embryo) rather than a "contraceptive" (preventing the union of gametes — egg and sperm — and thus preventing conception). See U.S. CONFERENCE OF CATHOLIC BISHOPS, DIGNITAS PERSONAE 5-6, available at http://www.usccb.org/comm/Dignitaspersonae/Dignitatis\_Vatican\_Summary.pdf for a discussion of this distinction and its moral implications; see also U.S. CONFERENCE OF CATHOLIC BISHOPS, Dec. 5, 2003, COMMENTS ON FDA PROPOSAL TO CHANGE EC FROM PRESCRIPTION TO OVER-THE-COUNTER, available at http://www.usccb.org/ogc/ecfda.shtml (raising additional concerns, including argument that widespread access to Plan B will promote unprotected sex, thus leading to spread of sexually transmitted diseases).

<sup>&</sup>lt;sup>244</sup> See id. at 522-23.

<sup>&</sup>lt;sup>245</sup> Barr Pharmaceuticals' Plan B Labeling, http://www.fda.gov/CDER/drug/infopage/planB/default.htm (last visited Apr. 2, 2010).

<sup>&</sup>lt;sup>246</sup> See Tummino, 603 F. Supp. 2d at 522.

<sup>&</sup>lt;sup>247</sup> See Russell Shorto, Contra Contraception, N.Y. TIMES MAG., May 7, 2006, http:// www.nytimes.com/2006/05/07/magazine/07contraception.html? (describing arguments for and against Plan B); ABC World News Tonight: Report on the "Morning After Pill" (ABC television broadcast May 8, 2006), available at http://mediamatters.org/ research/200605100014.

opponents argue, merely to observe that Plan B prevents pregnancy (medically defined as implantation of the embryo in the uterus) and prevents abortions because the drug might do so by causing the death of a living human organism (namely, the unimplanted embryo). Some supporters of Plan B take issue with the empirical claim that Plan B prevents implantation (and thus destroys newly conceived embryos).<sup>249</sup>

The public bioethical debate about Plan B, by contrast, is significantly narrower - relating to whether and to what extent the FDA should approve Plan B for over-the-counter (OTC) sale. In 2001, a large array of organizations filed a Citizen Petition seeking an FDA rulemaking to switch Plan B from prescription-only to over-thecounter status without restrictions.<sup>250</sup> Two years later, the original Plan B sponsor (Women's Capital Corporation) submitted a supplemental New Drug Application requesting the same (a procedural request that does not require a rulemaking<sup>251</sup>). In a long and controversial process, the FDA reviewed these requests, denied the Citizen Petition, but ultimately approved the drug for OTC distribution in 2006, subject to an age restriction (i.e., it was not made available OTC to anyone 18 years old or younger). The procedural twists and turns are not necessary to recite here.<sup>252</sup> Suffice it to say that as with any political or legal issue touching and concerning the beginnings of life and reproductive freedom, the matter was fraught with controversy. Abortion rights supporters and some reproductive health advocates have alleged that the FDA delayed approval because of improper political motives. Recently, a federal court agreed and vacated the FDA's denial of the Citizen Petition.253 The Obama Administration did not appeal the decision and announced that Plan B would be available OTC to people 17 years old or older.<sup>254</sup> Opponents of Plan B decried this decision as the improper politicization of public health. 255

<sup>&</sup>lt;sup>249</sup> William Saletan, *The Birds and the Plan B's*, WASH. POST, Apr. 2, 2006, http:// www.washingtonpost.com/wp-dyn/content/article/2006/04/01/AR2006040100005.html.

<sup>&</sup>lt;sup>250</sup> See Tummino, 603 F. Supp. 2d at 523; Initiation of Administrative Proceedings, 21 C.F.R. § 10.25(a) (2009) (describing process of citizen petitions).

<sup>&</sup>lt;sup>251</sup> See 21 U.S.C. §§ 355(c), (d) (West 2010); 21 C.F.R. § 314.71 (West 2010).

<sup>&</sup>lt;sup>252</sup> For an account of the approval process, see *Tummino*, 603 F. Supp. 2d at 524-38.
<sup>253</sup> See *id.* at 550.

<sup>&</sup>lt;sup>254</sup> See U.S. FOOD & DRUG ADMIN., UPDATED FDA ACTION ON PLAN B (LEVONORGESTREL) TABLETS (June 24, 2009), available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149568.htm.

<sup>&</sup>lt;sup>255</sup> See Gardiner Harris, F.D.A. Easing Access to 'Morning After' Pill, N.Y. TIMES, Apr. 23, 2009, at A14, available at http://www.nytimes.com/2009/04/23/health/23fda.html

Despite the wide array of rich moral arguments made for and against Plan B, the public bioethical question was quite narrow, and largely (if not entirely) empirical owing to the function of the Food, Drug, and Cosmetic Act. Under the statute, the FDA ultimately approves drugs for either prescription or over-the-counter (OTC) use. The decision on which branding to require is determined as a technical matter of the drug's safety and efficacy. The FDA must require prescription dispensing of a drug that "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for use except under the supervision of a practitioner licensed by law."256 Conversely, where an advisory panel of "qualified experts" has recognized that a certain category of drugs is "safe and effective for use" without medical supervision, those drugs may be sold without a prescription.<sup>257</sup> Here, "[s]afety means a low incidence of adverse reactions . . . under adequate directions for use . . . as well as low potential for harm which may result from abuse under conditions of widespread availability."<sup>258</sup> Safety must be proven by "adequate tests by methods reasonably applicable," including those showing "results of significant human experience during marketing."<sup>259</sup> Likewise, "[e]ffectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions ... will provide clinically significant relief of the type claimed."<sup>260</sup> Effectiveness must be shown by certain "controlled clinical investigations" described in regulations implementing the FDCA.<sup>261</sup>

Even if a specific drug has been originally approved for only prescription use, the commissioner of the FDA or an "interested party," such as a drug sponsor, may submit a supplemental application to "switch" the drug's status to allow for OTC dispensing.<sup>262</sup> Such a switch will be granted, and the drug "shall be exempted from

<sup>(</sup>quoting Wendy Wright's claim that "[p]arents should be furious at the F.D.A.'s complete disregard for parental rights and the safety of minors").

<sup>&</sup>lt;sup>256</sup> Exemptions and Considerations for Certain Drugs, Devices, and Biological Products, 21 U.S.C. § 353(b)(1)(A) (2006).

<sup>&</sup>lt;sup>257</sup> Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and Not Misbranded, and for Establishing Monographs, 21 C.F.R. § 330.10(a) (2009).

<sup>&</sup>lt;sup>258</sup> Id. § 330.10(a)(4)(i).

<sup>&</sup>lt;sup>259</sup> Id.

<sup>&</sup>lt;sup>260</sup> Id. § 330.10(a)(4)(ii).

<sup>&</sup>lt;sup>261</sup> Id.; see also 21 C.F.R. § 314.126(b) (2010) (describing clinical investigations).

<sup>&</sup>lt;sup>262</sup> See 21 C.F.R. § 353(b)(3) (2009); Tummino v. Torti, 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009).

prescription dispensing requirements when the Commissioner finds that such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is *safe* and *effective* for use in self-medication as directed in proposed labeling."<sup>263</sup> Thus, the driving consideration for whether to switch a drug from prescription to OTC status is essentially whether its use under the proposed labeling will meet the safety and effectiveness standards set forth in the regulations.

In evaluating these ad hoc branding switches, the FDA generally requires two types of studies: studies on the comprehensibility of the proposed labeling, and others with data from "actual use" of the medication.<sup>264</sup> Generally, if these studies (and any other available material) show the drug to (1) have an acceptable safety profile based on prescription use and experience; (2) have a low potential for abuse; (3) have an "appropriate safety and therapeutic index"; (4) have a positive benefit-to-risk assessment; and (5) be for a condition that is "self-recognizable, self-limiting, and requires minimal intervention by a health care practitioner," the requisite safety and effectiveness are met, and the switch is approved.<sup>265</sup> In short, once the scientific data appropriately shows that a drug is effective and physiologically safe in prescription-dispensing requirements self-administration, are removed.

Based on the taxonomy proposed in this Article, the controversy surrounding Plan B involves a "relationship of identity." By operation of the FDCA (and related regulations), the decision to switch Plan B from prescription to OTC is largely a question that is answerable by empirical means — namely, by undertaking the comprehensibility and actual use studies noted above. "Safety" and "efficacy" are certainly concepts with ethical content, but this content has been largely stipulated by the extant legal framework. What counts as a "harm" or a "benefit" has been clearly defined in advance of the debate.

Nevertheless, the case of Plan B is imperfect in important respects. First, the narrow empirical scope of the question is somewhat artificial insofar as it is imposed by the statute itself. Moreover, as Rebecca

<sup>&</sup>lt;sup>263</sup> 21 C.F.R. § 310.200(b) (2010) (emphasis added).

<sup>&</sup>lt;sup>264</sup> See Barbara Chevalier, The Constitutionality of the FDA's Age-Based Plan B Regulations, 22 WIS. WOMEN'S L.J. 235, 243 (2007).

<sup>&</sup>lt;sup>265</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, F.D.A.: DECISION PROCESS TO DENY INITIAL OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 7 (2005), *available at* http://www.gao.gov/new.items/d06109.pdf.

Dresser has noted, "value judgments are implicit in any FDA approval decision because determinations about a product's safety depend partly on judgments about the importance of the benefit it offers."<sup>266</sup> In the Plan B context, this ex ante moral judgment can even influence how one regards the empirical dimension of approval: "People who see unwanted pregnancy as a serious harm are more likely to consider Barr's study data adequate, while those worried about preserving traditional norms surrounding marriage and procreation are more likely to find the data deficient."<sup>267</sup>

Notwithstanding these imperfections, the recent case of Plan B's switch to OTC status serves as a rough illustration of relationship of identity. The import of this designation for the problem of integration will be discussed below.<sup>268</sup>

2. The Relationship of Complementarity and the Case of Federal Funding for Embryonic Stem Cell Research

The second division of the taxonomy — "the relationship of complementarity" — designates those questions in public bioethics that finally seek to resolve a contested normative dispute, but also require the mastery of certain background scientific matters. In this case, modern science can and indeed must be integrated in order to clarify the empirical dimensions of the dispute as a prerequisite to sound moral deliberations (about which the science is, by design, silent). Thus, this use of science facilitates clear and rigorous ethical deliberations, but it cannot offer a resolution. It would seem that the vast majority of questions in public bioethics present this relationship of complementarity.

The paradigm example of this relationship is the case of federal funding for embryonic stem cell research. For reasons discussed extensively above,<sup>269</sup> the ultimate questions presented by this public bioethical issue are normative. Who counts as a "person"? Whose good counts as part of the common good? Who decides and according to what criteria? How do these questions stand in relation to the humanitarian aspirations of scientists? How do they stand in relation to the freedom to conduct scientific inquiry for the sake of itself? What weight should be accorded to the consciences of taxpayers asked

<sup>&</sup>lt;sup>266</sup> Rebecca Dresser, Plan B Politics and Values at the FDA, Again, HASTINGS CENTER REPORT, Nov-Dec. 2004, at 9, 10.

<sup>&</sup>lt;sup>267</sup> Id.

<sup>&</sup>lt;sup>268</sup> See infra Part V.C.1.

<sup>269</sup> See supra Part III.

to fund embryonic stem cell research? What do the obligations of citizenship dictate? What about respect for pluralism?

At the same time, reasoning rigorously and clearly about the moral status of human embryos requires a sophisticated understanding of the biological properties of the embryo. The ethical debate also requires a scientifically sound understanding of the present and projected applications of embryonic stem cell research. But, it must be reiterated that none of these empirical details settle the ethical questions outlined above.<sup>270</sup>

The import of locating a public question within the relationship of complementarity for integration will be discussed below.<sup>271</sup>

3. The Relationship of Preemption and the Case of Cognitive Neuroscience and Capital Sentencing

The third and final division of the taxonomy is the "relationship of preemption," covering those instances in which a *scientific* claim is made about an established ethical principle (or set of principles) crucial to public bioethical deliberations. That is, this relationship presents itself when the claims of science and the claims of ethics seek to *occupy the same explanatory space*. Not surprisingly, this often presents a conflict in which a scientific account is offered that reduces, radically redefines, or nullifies altogether a longstanding ethical concept. Resolution of this conflict determines whether the public question is ultimately empirical or normative (and whether, by extension, it is rightly understood as featuring the relationship of identity or complementarity). This presents the most difficult and interesting array of problems for integrating science into public bioethics.

The paradigm example of the relationship of preemption in public bioethics is the question of how to integrate cognitive neuroscience into the criminal justice system — more specifically, in the context of capital sentencing. Cognitive neuroscience, put simply, seeks to understand how the brain enables the mind.<sup>272</sup> Like other modern scientific disciplines, it seeks and offers explanations in purely

<sup>&</sup>lt;sup>270</sup> There are some who have expressed the hope that science might someday render the ethical conflict moot by developing fully pluripotent cells in a way that does not require the use and destruction of human embryos (or even human ova). It may be possible that the newly developed IPS cells (discussed above) will provide such a scientific solution to this ethical problem.

<sup>&</sup>lt;sup>271</sup> See infra Part V.C.3.

<sup>&</sup>lt;sup>272</sup> For a full discussion of cognitive neuroscience as a field, including its premises and methods, see Snead, *Neuroimaging*, *supra* note 19, at 1273-96.
physicalist, reductive mechanistic terms that strictly observe welldefined epistemic rules.<sup>273</sup> Some prominent cognitive neuroscientists (and sympathetic philosophers) have argued for a "radical conceptual revision of criminal punishment itself" based on their work:

[M]ore specifically, they seek to use the premises and tools of neuroscience — and neuroimaging in particular — to embarrass, undermine, and ultimately overthrow retributive justice as a principle of punishment. Once retribution is discredited, they contend, criminal law will be animated solely by its proper end: namely, the purely forward-looking, consequentialist goal of avoiding socially harmful behavior. This new approach, it is hoped, will usher in a regime of "therapeutic justice," wherein criminal defendants will be treated more humanely.<sup>274</sup>

This call to change the law is driven by ostensibly scientific claims about ordinary conceptions of free will that undergird the ethical concept of moral responsibility on which capital sentencing (indeed all criminal punishment) is largely erected. Two of the most prominent defenders of this view are neuroscientist Jonathan Cohen and philosopher Joshua Greene:

Greene and Cohen argue that advances in cognitive neuroscience — enabled by neuroimaging — will ultimately demonstrate that "ordinary conceptions of human action and responsibility" are false. "[A]s a result, the legal principles we have devised to reflect these conceptions may be flawed" and must be radically overhauled and replaced with principles that are grounded in a neuroscientific view of the truth about free will and human agency. The primary focus of their critique is the principle of retributive justice — which, they assert, "depends on an intuitive, libertarian notion of free will that is undermined by science."<sup>275</sup>

It is beyond the scope of this Article to assess this argument and its implications for capital punishment.<sup>276</sup> For present purposes it is sufficient to notice that the argument illustrates the relationship of preemption insofar as it purports to answer a public bioethical question (about how to structure the capital punishment regime) by

<sup>&</sup>lt;sup>273</sup> See id. at 1277-80.

<sup>&</sup>lt;sup>274</sup> Id. at 1309.

<sup>&</sup>lt;sup>275</sup> Id. at 1309-10.

<sup>&</sup>lt;sup>276</sup> For such an analysis, see *id*.

displacing a longstanding ethical concept (moral responsibility and desert) with an ostensibly scientific one (hard determinism, grounded in physicalism, and reductive mechanism). The significance of locating this question within "the relationship of preemption" is discussed immediately below.<sup>277</sup>

## C. Applying the Taxonomy

The taxonomy of relationships discussed above is meant to provide some measure of analytic clarity in the process of identifying and policing the boundaries of scientific and moral reasoning within public bioethics. Applying the taxonomy forces public officials to think clearly about the kind of question under consideration. Is it normative? Is it empirical? This may yield beneficial results to varying degrees, depending on whether the question is a matter of first impression, or whether it arises in the context of an extant legal framework. For matters of first impression, the location of the question within the taxonomy might suggest a rule of decision (e.g., whether and to what extent the matter should be delegated to scientific experts for resolution). In those cases where the existing legal regime already forces the question into one category, the taxonomy allows a critical analytic distance necessary to assess the wisdom of such an arrangement. For the hardest cases, the taxonomy will allow a more focused and rigorous discussion of relevant dimensions of the problem at hand. In this way, the taxonomic approach is more flexible and responsive than the Maximal Deference model, which locates all public bioethical questions in the relationship of identity.

1. Generating a Rule of Decision for Public Matters of First Impression

In those instances where the public bioethics question is a matter of first impression, and there are no legal mechanisms in place for its resolution, the taxonomy points toward a rule of decision. For example, if the public question presents the relationship of identity (i.e., the question is, at bottom, an empirical matter), then delegation to scientific experts is fitting (provided that processes are in place to preserve political accountability). It would be unwise governance to allow those lacking the relevant disciplinary competence to resolve such questions. If, by contrast, the public question is finally normative

<sup>&</sup>lt;sup>277</sup> See infra Part V.C.3.

(as most seem to be in this domain), then its location within the relationship of complementarity would dictate that it should be resolved by political means by public officials accountable to the polity. Conversely, such questions manifestly should not be delegated to politically unaccountable experts for resolution merely by the premises and methods of modern science.

The case of federal funding for embryonic stem cell research here provides a useful illustration yet again. Applying the taxonomy requires public officials first to engage in sustained critical reflection on the kind of question presented in order to locate it properly within the taxonomy. For the reasons discussed extensively above,<sup>278</sup> such reflection reveals that the matter requires the mastery of scientific information (e.g., embryology, regenerative medicine, etc.), but, at bottom, the public question is finally normative, requiring the resolution of a wide array of contested moral issues. Having reached this conclusion and located the matter within the relationship of complementarity, public officials are on notice that the issue should be decided by politically accountable public officials, applying the humanistic concepts of moral reasoning. More importantly, this question should *not* be delegated to politically unaccountable scientific experts to resolve solely with the tools of their disciplines.

2. Providing a Critical Perspective on Extant Legal Frameworks

For public bioethical decisionmaking that is currently conducted within an extant framework by operation of law, the taxonomy provides a useful analytic perspective from which to assess the wisdom of such arrangements. Noticing where the existing legal mechanism locates the question taxonomically forces critical reflection on whether this prior judgment (and the rule of decision that it entails) is sensible.

Take, for example, the case of Plan B discussed above. Current legal arrangements, namely, the FDCA and related regulations, channeled this public bioethical decision into the relationship of identity. That is, the range of considerations was restricted to largely empirical questions of "safety" and "efficacy," to be determined by scientific studies regarding comprehensibility and actual use. Understanding the location of this question within the taxonomy provides insight into the virtues and limits of the present legal structure.

The current arrangement has the virtue of drawing upon scientific expertise to answer complicated empirical questions about how the drug might be used without the direct supervision of a physician (and

<sup>&</sup>lt;sup>278</sup> See supra Part V.A.

resulting public health consequences). These questions are, in fact, empirical and admit of resolution by scientific means. However, the approval regime does not make space for consideration of the full range of ethical concerns raised by switching the drug's branding status. Most obviously, the FDCA does not provide the opportunity to debate and resolve the question of the moral status of the embryo, and how to grapple with the uncertainty about Plan B's effect on the process of implantation. One might conclude that this is as it should be. Or one might come to the view that the statute should allow for a richer conversation about these moral questions that are currently off the table. In any event, applying the taxonomy promotes this kind of beneficial reflection on the regulatory status quo.

## 3. Providing Analytic Clarity for the Hardest Cases

For the hardest cases, namely, those involving the relationship of preemption, the taxonomy is meant to offer a measure of analytic clarity. Applying the taxonomy allows decisionmakers to identify these most vexed species of questions and puts them on notice that they must closely examine the competing claims of science and moral reasoning before settling on a process for resolving the public issue. They must, in effect, decide whether the question really is empirical or normative. Taking the example of cognitive neuroscience and capital sentencing, decisionmakers must inquire whether the claim that free will (and thus moral responsibility) is merely an illusion of the structure and function of the brain is indeed an empirically demonstrated scientific conclusion. Or, to the contrary, is this claim by cognitive neuroscientists simply a repackaging and extension of an undemonstrable axiom or metaphysical postulate of modern science (for example, physicalism and/or reductive mechanism)?<sup>279</sup> Answering this question will have important implications for how to structure decisionmaking about the capital sentencing framework. If Cohen and Greene are right, then this presents a relationship of identity, and thus delegation is in order. If not, then the question should be retained by politically accountable officials - as dictated by the relationship of complementarity. Thus, while taxonomy does not directly resolve these contested questions, it serves to provide focus and clarity to the deliberative process.

<sup>&</sup>lt;sup>279</sup> The resolution of this question is far beyond the scope of the present inquiry. For a good discussion of this question, see Michael S. Pardo & Dennis Patterson, *Philosophical Foundations of Law and Neuroscience*, 2010 U. ILL. L. REV. (forthcoming 2010) (on file with author).

## CONCLUSION

Public bioethics is still a relatively new area of law. More than virtually any other domain of governance it combines in dramatic fashion contested ethical claims with state action. For this reason, conflicts within public bioethics, such as those over abortion, embryonic stem cell research, end of life matters, and the relationship between mind, brain, and behavior have captured the imagination of the American public. Sound governance in this area depends on the proper integration of science into public deliberations and decisionmaking in this field. But identifying the appropriate model of integration is no easy task. The Maximal Deference model (which seemingly delegates all such matters to scientists to resolve solely by the tools of their disciplines) is unsustainable. Its strong default rule of delegation to elite enclaves of experts raises vexed prudential questions about democratic accountability and thus legitimacy. But it fails decisively in any event as a matter of principle because the premises and methods of modern science are conceptually incommensurable with the ethical principles that comprise the currency of public bioethical deliberations. The costs of ignoring this problem of incommensurability are grave in human terms. They include smuggling unstated norms into the political deliberations (a kind of deception), or worse still, flattening or abandoning humanistic principles (such as equality, justice, beneficence, and even personhood itself) that offer protection to the weak and vulnerable who are most at risk for exploitation and harm in this context.

What, then, is the proper approach to the problem of integration? Given the incommensurability of science and ethical reasoning, integration is thus a function of defining and policing the boundaries of their respective competencies. Line drawing here depends on clarity regarding the fit between the public question asked and the capacities of science to supply answers. Science should be deployed solely for empirical, descriptive inquiries. Ethical reasoning, by contrast, is fitting for normative disagreement. The tripartite taxonomy of relationships — identity, complementarity, and preemption — is meant to offer needed clarity, and in some cases may even point the way towards the soundest process of decisionmaking. In this way, the taxonomy is proposed as a tool for defending the integrity of science, the legitimacy of government, and the continuing vitality of key humanistic principles.