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Restricting Scientific Legitimacy in the Age of Biotechnology?

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ABSTRACT

In the Age of Biotechnology, there is no more pressing question than whether a philosophy of science exists and translates into a notion that—with or without qualification—the sovereignty of science is central to the advancement of society and should be totally emancipated from concurrence or oversight by society at large. Far too many Americans choose neither to be "informed" nor to accept the responsibilities of citizenship to participate fully in a deliberative democracy—they have chosen instead to exercise their "right" to remain ignorant. Consequently, science reigns without restraint or even review. The scientific community has a coordinated responsibility to society, in general, to disclose to and educate the public about its research agendas in a transparent and understandable manner. In order to meet this responsibility, however, factual data—not "junk" science—is an absolute requirement for an "educated" partnership of interest between society and science in order to flourish.

Lawmakers and the courts must be in alignment with the march of science. For society to remain apathetic and for the legal system to fail to be responsive to advancement guarantees societal malaise or uneasiness and results in an absolute sovereignty of science. Both in dialogue and policy making, however, a principle of precaution has been introduced and accepted domestically and internationally as a means of mediation. This precautionary principle serves as a construct for evaluating scientific and biotechnological undertakings, which would create more potential risks rather than benefits before proceeding. In essence, this is a cost/benefit analysis.

This Article investigates the steps which need to be undertaken in order to ensure that scientific conduct is legitimized—and thereby recognized—as indispensable for global peace and progress. Contemporary philosophy of science embraces the positive value of scientific investigations that are not only useful and practical but also, at the same time, view biotechnology as a tool for viewing the whole of life in a positive, affirming way. Such a philosophy must seek to accommodate what may be seen as a shared partnership rather than codify an absolute sovereignty of science.

I
INTRODUCTION AND OVERVIEW: CONTAINING TECHNOLOGY

Inasmuch as technology can never be overcome, it is best to accept it as a part of a whole way of life and thus see it as a means to an end.[1] The manner and form of manipulation is, then, determinative of humankind's relationship to technology—as measured and forthcoming, or, as fractions and deceitful;[2] for within modern technology is a "possibility of a fuller relationship between man and being [i.e., that is, truth, "unconcealment" or what it means to be] and hence between man and all that is and has ever been."[3]

Presently, the terms science and technology are used interchangeably, but they are fundamentally different. Put succinctly, science is knowing, and technology is doing.[4] Science seeks the pursuit of knowledge for its own sake, while the goal of technology is to create products that solve problems and improve human life.[5] Biotechnology is, quite simply, technology based on biology. Its goal is to harness cellular and biomolecular processes, which endeavor to improve both the quality of life and the health of the world.[6] Additionally, biotechnology studies ways to reduce rates of infectious disease worldwide, create more precise tools for detecting disease and antiviral

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1 *See* MARTIN HEIDEGGER, THE QUESTION CONCERNING TECHNOLOGY AND OTHER ESSAYS 5 (William Lovitt trans., 1977).

2 *See* Richard Walton, *Heidegger in the Hands-On Science and Technology Center: Philosophical Reflections on Learning in Informal Settings*, 12 J. TECH. ED. 50 (2000). *See also* ASTC's Strategy 2022-2025, ASS'N SCI. & TECH. CTRS, https://www.astc.org/about/strategy/ [https://perma.cc/EQB9-4JKL].

3 HEIDEGGER, *supra* note 1, at 34, 37. *See* MARTIN HEIDEGGER, BASIC WRITINGS 3–35, 245, 349 (David Farrell Krell ed., 27th ed. 1977).

4 *See Science*, OXFORD ENGLISH DICTIONARY XIV 648 (2d ed. 1989) (Science seeks to "expand knowledge."); *1.4: The Science of Biology – Basic and Applied Science*, LIBRETEXTS (June 8, 2022), https://bio.libretexts.org/Bookshelves/Introductory_and_General_Biology/Book%3A_General_Biology_(Boundless)/01%3A_The_Study_of_Life/1.04%3A__The_Science_of_Biology_-_Basic_and_Applied_Science [https://perma.cc/48ZY-8732]; HEIDEGGER, *supra* note 1, at 3–35 (stating technology is a way to understand the world). *See generally* Kavita S. Jerath, SCIENCE, TECHNOLOGY AND MODERNITY (2021).

5 *See* HEIDEGGER, *supra* note 1; *Technology*, OXFORD ENGLISH DICTIONARY XVII 705–06 (2d ed. 1989). *See also How Does Technology Differ from Science*, ENOTES, https://www.enotes.com/homework-help/how-does-technology-differ-from-science-essay-469547 [https://perma.cc/9CKF-4TSJ]. *See generally* Liebe F. Cavalieri, *Science as Technology*, *in* 1 ETHICAL, LEGAL AND SOCIAL CHALLENGES TO THE BRAVE NEW WORLD 219 (George P. Smith, II, ed., 1982).

6 *See Biotechnology*, OXFORD ENGLISH DICTIONARY II 210 (2d ed. 1989). *See also* ROBERT CARLSON, BIOLOGY AS TECHNOLOGY: THE PROMISE, PERIL AND NEW BUSINESS OF ENGINEERING LIFE (2010).

therapeutics, and enhance agriculture productivity and genetically modified food.[7]

Regrettably, contemporary biological science and biotechnology have become political issues because of one principal fact: they put in focus the extent to which the government can restrict private medical research undertakings—in the name of safety, morality, or the public good.[8] Today, the complex ethical, philosophical, socio-legal, and medical issues of this Age of Biotechnology are often said to be "biopolitic" in that many of the issues have become "embryocentric"—simply because of limitations on federal funding for human embryonic stem cell research.[9]

In 2007, researchers in Wisconsin and Japan created human embryonic stem cells from human skin.[10] This scientific achievement broadened the pace of biotechnological progress, which seeks to perfect human cloning; create designer pathogens; explore new forms of assisted reproduction, organ transplantation, face and womb transplants, cryogenic preservation post mortem, and genetic enhancement; and strengthen efforts in expanding the use of genetically modified genes and food which would enrich and prolong a life resistant to disease.[11]

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7 *See* Doron Weber, *Reining in the Hubris of Science and Scientists*, WASH. POST (Feb. 8, 2019), https://www.washingtonpost.com/outlook/reining-in-the-hubris-of-science-and-scientists/2019/02/08/4276d61a-232f-11e9-90cd-dedb0c92dc17_story.html [https://perma.cc/ED58-A3QY]. *See generally* GEORGE P. SMITH, II, THE NEW BIOLOGY: LAW, ETHICS AND BIOTECHNOLOGY (1989).

8 SMITH, *supra* note 7 (federal research is, for example, regulated strictly); GEORGE P. SMITH, II, DISTRIBUTIVE JUSTICE AND THE NEW MEDICINE, 56 *passim* (2008). *See* George P. Smith, II, *Distributive Justice and Health Care*, 18 J. CONTEMP. HEALTH & POL'Y 421, 425–26 (2002). *See also* Rebecca Kunkel, *Rationing Justice in the 21st Century: Technocracy and Technology in the Access to Justice Movement*, 18 U. MD. L.J. RACE, RELIGION, GENDER & CLASS 366 (2018).

9 *See* George P. Smith, II, *Policy Making and the New Medicine: Managing a Magnificent Obsession*, 3 J. HEALTH & BIOMEDICAL L. 303, 306 (2008) (The American health care system has been described as "technologically driven."); GEORGE J. ANNAS, STANDARD OF CARE: THE LAW OF BIOETHICS 211 (1993). Embryonic emphasizes legal and political policy with specific regard to the scope of consequences arising from attempting to establish the moral statute of embryos and when embryonic life begins. *See* George J. Annas, *Politics, Morals and Embryos* 431 NATURE 19 (2004); GEORGE P. SMITH, II, LAW AND BIOETHICS: INTERSECTIONS ALONG THE MORTAL COIL 17 (2012).

10 SMITH, *supra* note 9, at 303.

11 George P. Smith, II, *Setting Limits: Medical Technology and the Law*, 23 SYDNEY L. REV. 283, 285–88 (2001). *See* George P. Smith, II, *Genetic Enhancement Technologies and the New Society*, 4 MEDICAL L. 85 (2000) (discussing assisted reproduction). *See also* George P. Smith, II, *Pathways to Immortality in the New Millennium: Human Responsibility, Theological Direction or Legal Mandate*, 15 ST. LOUIS U. PUB. L. REV. 447 (1996).

Today, the news media frequently reports the dynamic breadth of technological achievement. *The Economist* entitled its February 2020 cover story, "Big Tech's $2trn Bull Run."[12] On February 27, *China Daily* published an equally intriguing and hard-hitting lead story entitled, "Tech's Core Is Heart That Beats for Society."[13] Finally, *The Economist* revisited the topic of technology in an April 2020 article entitled, "Don't Waste a Good Crisis: Big Tech Firms Are Thriving. They Should Seize the Moment and Detoxify Their Relations With Society."[14] Showing national concern[15] over the phenomenal growth and power of Big Tech companies—particularly Amazon, Apple, and Google—Senator Amy Klobuchar wrote antitrust legislation in the U.S. Senate designed to limit preferential treatment that Big Tech companies give their own products.[16] Klobuchar's proposed legislation, the United States Innovation and Competition Act of 2021,[17] specifically revises the present antitrust laws applicable to mergers and anticompetitive conduct.[18]

As seen, Part I of this Article lays the predicate for the purpose of this discourse: specifically, to undertake a critical analysis of the extent to which science and technology should be contained or regulated by the law and society's social forces. Part II examines the efforts of the European Union to shape policies for developing the technology industry and proceeds to consider ethical concerns in domestic policymaking in this area. As this development occurs, the social responsibility of the polity to be informed and to participate in decision making is vital. This Part also confronts the use of fractionalizing science into whole science and junk science and then proceeds to study the consequence of this classification. Part III uses the science of the coronavirus pandemic as a paradigm to review the nature of the

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12 *Big Tech's $2trn Bull Run*, THE ECONOMIST, Feb. 22, 2020.

13 David Masi, *Tech's Core Is Heart That Beats for Society*, THE CHINA DAILY: GLOB. EDITION, Feb. 27, 2020, at 10.

14 *Don't Waste a Good Crisis: Big Tech Firms Are Thriving*, THE ECONOMIST, Apr. 4, 2020, at 9 ("They should seize the moment and detoxify their relations with society.").

15 *See* Scott Olster, *Big Tech Gets Bigger Amid Pandemic*, LINKEDIN, http://linkedin.com/feed/news/big-Tech-gets-bigger-amid-pandemic-4844500/ [https://perma.cc/DN6A-5LG8]. *See also* Shuman Bhattacharyya, *What a Waste! The Ways Companies Overspend when It Comes to Technology*, WALL ST. J., Mar. 10, 2021, at R1.

16 Alexander Bolton, *Democrats Pick Fight Against Big Tech Ahead of 2022 Election*, THE HILL (Apr. 27, 2022), https://thehill.com/homenews/senate/3467005-democrats-pick-fight-against-big-tech-ahead-of-2022-election/ [https://perma.cc/UWB5-DJKA].

17 United States Innovation and Competition Act of 2021, S. 1260, 117th Cong. (2021).

18 Bolton, *supra* note 16.

corruptive political intrusions into what should have been clear, evidence-based decision-making—or whole science. Part IV then illustrates the effort of the United States Environmental Protection Agency, through its rulemaking authority, to refrain from political "intrusions" into evidence-based scientific decision-making and thereby legitimize the scientific method.

Part V transitions to a consideration of the scope of the science of genetics and the associated consequences related to gene editing. Efforts at the national and international levels of government to codify an ethic of care in scientific experimentation are studied in Part VI. Continuing efforts to probe international practices in regulating risks arising from scientific experimentation through what is termed the Precaution Principle are probed in Part VII. As well, this Part studies how this Principle has become part of customary law and has been adopted in various pieces of environmental legislation in the United States. Part VIII examines the extent to which scientific testimony is admissible in federal litigation and the resulting state of judicial befuddlement, which has resulted from disagreement relative to the scope of decision-making authority by juries with no expertise in science. Finally, this Part studies the consequences of public lethargy in preventing any viable notion of participatory democracy to be fostered in scientific matters.

The conclusion of this Article is that if the administrative agencies charged with regulating the development and use of technology granted to them by a disinterested Congress in the United States, and if the judiciary remains in a state of befuddlement over its interpretative responsibilities to seek fairness and balance in their environmental decisions, science will have few societal restraints imposed. In other words, there will be no oversight of scientific work. When civic responsibilities to be "informed" are abnegated by the citizenry, and when there is little understandable effort made by the scientific community to "reach out" and seek to educate or explain their work and its limitations and costs as well as its benefits, an algorithm for preserving the *status quo* is created. Geopolitically, however, there is every reason to take pride in the certain, albeit incremental, steps being taken to "manage" the global scientific laboratory.

II
SHAPING POLICY

The European Union (EU) has ambitious plans to see that the technology industry is kept in check by seeking to fill the void, seen as

a "political paralysis," which the United States now finds itself in.[19] Even though the EU has been contending with serious issues of sluggish growth and political turmoil, seen dramatically with Brexit challenges, together with Asian influence, the Union is setting rules for the world economy.[20] EU rules are being transformed into global standards through market mechanisms.[21] Indeed, the direct consequence of what is termed "The Brussels Effect" is the Europeanization of many aspects of global commerce—not only through business practices but also public policies, especially data privacy, consumer health and safety,[22] environmental protection,[23] antitrust, and online hate speech.[24]

In 1996, the Nobelist Robert F. Curl of Rice University opined that while the twentieth century was "the century of physics and chemistry," the twenty-first century must be acknowledged as "the century of biology."[25] The success of scientific contributions to an understanding of the biology of life is undeniable. It is a statement of fact that support for basic scientific work is crucial to the continued advancement of social order. Yet, care must be taken to foreswear any effort to recognize science as an exclusive sovereign in determining "where we come from, who we are and where are we going."[26] Justifiable concern is properly given to the extent to which biologists are attempting to steer human progress and are being allowed to redefine the meaning

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19 *Trade Regulation: The Brussels Effect*, THE ECONOMIST, Feb. 22, 2020, at 63. *See generally* Anu Bradford, *The Brussels Effect*, 107 NW. U. L. REV. 1 (2012).

20 *Trade Regulation: The Brussels Effect*, *supra* note 19. *See* ANU BRADFORD, THE BRUSSELS EFFECT: HOW THE EUROPEAN UNION RULES THE WORLD (2019).

21 *Trade Regulation: The Brussels Effect*, *supra* note 19. *See Collusions and Collisions: The New Rules of Competition in the Technology Industry*, THE ECONOMIST, Feb. 22, 2021, at 49 [hereinafter *Collusions*].

22 *Collusions*, *supra* note 21. *See generally* Barbara Osimani, *The Precautionary Principle in the Pharmaceutical Domain: A Philosophical Enquiry into Probabilities Reasoning and Risk Aversion*, 15 HEALTH, RISK & SOC'Y 123, 129 (2013).

23 Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 PA. L. REV. 1002, 1007 (1997).

24 *Trade Regulation: The Brussels Effect*, *supra* note 19. *See also* BRADFORD, *supra* note 20.

25 John Casey, Naomi Frundlich & Julia Flynn, *The Biotech Century*, BLOOMBERG: U.S. EDITION (Mar. 9, 1997), https://www.bloomberg.com/news/articles/1997-03-09/the-biotech-century [https://perma.cc/S3ZQ-7B5V]. *But see* NAOMI ORESKES, M. SUSAN LINDEE & OTTMAR EDENHOFER, WHY TRUST SCIENCE? (2019). *See generally A Whole New World*, THE ECONOMIST, Apr. 6, 2019, at 3.

26 Weber, *supra* note 7. *See* SHELIA JASANOFF, CAN SCIENCE MAKE SENSE OF LIFE? (2018). *See generally A Whole New World*, *supra* note 25.

of life itself, and even go further to not only reconceive but to subsequently define, the very purpose of life.[27]

Establishing the scientific good to be derived from any potential scientific achievement that comes from experimentation invariably involves evaluating the risks versus benefits that will influence societal interests if achieved.[28] Inasmuch as "science is not a stand-alone enterprise," social involvement in this decision-making process is essential—for, it remains for society to approve or disapprove any given scientific advancement—to accept the achievement, restrict its operation or forbid its use.[29] As will be shown, a largely complacent, uninformed society refuses to accept shared decision-making responsibility with the scientific community.[30] Consequently, science is allowed to assert sovereignty over the ongoing scientific revolution.[31]

For ethicists, the foundational issue that confronts the application and use of synthetic biology is the extent to which this science may be misused and result in "biological terrorism or warfare."[32] Moreover, the means by which this new biological knowledge is processed must be assessed together with careful evaluation of the types of technology that will ultimately be developed and disseminated from this original basis of scientific knowledge.[33]

In other words, the basis of the ethical dilemma confronting science is whether it should be totally utilitarian—providing the greatest good to the greatest number—even if its result compromises the rights of some.[34] Perhaps the most equitable approach to resolving this dilemma would be to utilize a situation ethic—as opposed to an *a priori*

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27 *See* JEREMY RIFKIN, THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD (1998). *See generally* George P. Smith, II, *De Lege Lata, De Lege Ferenda*, 9 J. CONTEMP. HEALTH L. & POL'Y 233 (1993).

28 *See* sources cited *supra* notes 24–25.

29 *Id.*

30 WILLIAM J. LEDERER, A NATION OF SHEEP 8 (1961). *See* JASANOFF, *supra* note 26.

31 JASANOFF, *supra* note 26. *See* Gary E. Marchant & Lynda L. Pope, *The Problems with Forbidding Science*, 15 SCI. & ENG'G ETHICS 375 (2009).

32 27 INT'L SECURITY 89, 98 *passim* (2002–03). *See* ETHICS AND EMERGING TECHNOLOGIES 349–62; 535–36 (Ronald L. Sanders ed., 2014).

33 *See* Thomas Douglas & Julian Savulescu, *The Ethics of Knowledge*, 36 J. MED. ETHICS 687 (2010).

34 George P. Smith, II, *Manipulating the Genetic Code: Jurisprudential Conundrums*, 64 GEO. L.J. 697, 725 (1976); GEORGE P. SMITH, II, GENETICS, ETHICS AND THE LAW (1981). *See also* George P. Smith, II, *Pursuing a Right to Genetic Happiness*, 25 J.L. SOC'Y 1 (2022).

principle—in testing or measuring the scientific efficacy of each scientific experimentation before it is undertaken.[35]

A democratic society's needs and demands should, ideally, be reflected in national research programs and undertakings.[36] In the United States, the National Science Foundation (NSF) is—with a budget of some 7.1 billion federal dollars—unquestionably the dominant force in public research.[37] In 2019, the NSF anticipated funding approximately 8,000 grants to "contribute to human knowledge and [provide] the scientific understanding necessary to spur innovation across all fields."[38] The areas of research interest for the NSF run the gamut from biological sciences, geosciences, international science, and engineering to mathematical and physical sciences.[39] Commendable as the research programs sponsored by the NSF may be, government excesses invariably occur and detract from the efficacy of federal research grants.[40] Over recent years, taxpayer-funded research has supported "research into dog urine, guinea pig eardrums and the reproductive habits of parasitic flies, or screwworms."[41] More recently, scarce federal monies were expended for studying responses to "shrimp on miniature treadmills"[42] and the "sex life of urban tungaru frogs in comparison with the sex lives of forest frogs."[43] Freedom of thought and discussion must be permitted in order to ensure that scientific decisions truly reflect the will of the community—particularly with

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35 *See* George P. Smith, II, *Toward an International Standard of Inquiry*, 2 HEALTH MATRIX, J.L. MED. 167, 176, 191 (1992). *See also* George P. Smith, II, *Applying Bioethics in the 21st Century: Principlism or Situationism*, 30 J. CONTEMP. HEALTH L. & POL'Y 37, 50–51 (2014). Rather than have states or resolute principles guiding ethical decision-making, the situational ethic poses that only actions should be followed, which are humane and loving. JOSEPH FLETCHER, SITUATION ETHICS: THE NEW MORALITY (1966).

36 H. Fangerau, *Can Artificial Parthenogenesis Sidestep Ethical Pitfalls in Human Therapeutic Cloning? An Historical Perspective*, 31 J. MED. ETHICS 733, 735 (2005).

37 U.S. NAT'L SCI. FOUND., NSF FY 2020 BUDGET REQUEST TO CONGRESS (2019), https://nsf.gov/pubs/2019/nsf19005/nsf19005.pdf [https://perma.cc/9CXA-4J76].

38 *Id.*

39 *Id. See generally How to Make Sparks Fly: Lessons from the Pandemic on How to Promote Intervention*, THE ECONOMIST, Feb. 27, 2021, at 11 (noting the need to invest in more R & D in the technological boon in life sciences).

40 *See* Suzy Khimm, *Why 'The Sex Life of the Screwworm' Deserves Taxpayer Dollars*, WASH. POST (Apr. 26, 2012), https://www.washingtonpost.com/blogs/ezra-klein/post/why-the-sex-life-of-the-screwworm-deserves-taxpayer-dollars/2012/04/26/gIQAQvT1iT_blog.html [https://perma.cc/7QUL-JZY5].

41 *Id.*

42 *Id.*

43 *Frog Sex in the City*, SMITHSONIAN TROPICAL RSCH. INST. (Dec. 10, 2018), https://stri.si.edu/story/frog-sex-city [https://perma.cc/D3YD-R87G].

political decisions that, in turn, have wide ramifications. It is in the political sphere that the government has the greatest stake in repressing ideas, and it is here where major battles are fought. Yet, it is imperative that open discussion of new ideas be protected whenever they relate to "the building and maintenance of culture as a whole."[44]

A. Good or Evil Consequences?

Most scientists maintain that the positive or negative consequences of pure scientific research are of little or no relevance,[45] for it is only at the technological or applied level of scientific work where "good or evil consequence" are evaluated.[46] A stronger and preferred position acknowledges that "the whole of research whether pure or applied"[47] should be tied to an ethical and moral ethic of collective responsibility.[48] This duty of care, then, requires scientists to not only explain the focus and application of scientific discovery but also "the perils which they see may arise from use or abuse of new knowledge."[49] As new "word-menacing problems" arise, there should be an evolving scientific ethic to resolve these problems.[50] Yet, conduct that is likely to produce "limit-situations" for mankind as a whole—or, in other words, those activities "likely to produce dangers of cataclysmic physical or psychological proportions"[51]—should be subject to a duty of restraint.[52]

It has been suggested, quite simply, that the commitment to knowledge made by scientists expresses but a basic drive for the enlargement of human powers—a *libido dominandi*.[53] This will to power or desire to dominate is said to be a part of the cultural shift in modern society where this very drive supersedes the search for

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44 Richard Delgado & David R. Millen, *God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry*, 1 ETHICAL, LEGAL & SOC. CHALLENGES TO THE BRAVE NEW WORLD, 248, 249 (George P. Smith eds., 1983).

45 Julius Stone, *Knowledge, Survival and the Duties of Science*, 28 AM. U. L. REV. 231, 236 (1972).

46 *Id.*

47 *Id.*

48 *Id. See* Smith, *Manipulating the Genetic Code*, *supra* note 34.

49 Stone, *supra* note 45, at 236–38.

50 *Id.* at 241.

51 *Id.* at 240. *See generally* Neil B. Cohen, *Confidence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L. REV. 385 (1989).

52 Stone, *supra* note 45, at 244.

53 *Id.* at 235. *See generally* E. MICHAEL JONES, LIBIDO DOMINANDI: SEXUAL LIBERTIES AND POLITICAL CONTROL (2005).

meaning.[54] Scientists demand the total freedom to experiment and admit that they are guided "only by the very demands of science" and by their "own consciences."[55] Any restrictions placed on this freedom are honored if there are "pressing reasons of public policy."[56] This position is wholly consistent with the philosophy of André Gide, which holds that rather than conforming to external standards, personal internal standards are the only valid source of restraint.[57] Thus, one need only be true to her or his self.[58]

The discovery of fire initiated a progressive application of scientific knowledge.[59] Over the years, this discovery spurred one of the most significant transformations in human history for the past 500 years—namely, the beginning of the scientific revolution.[60] Today, the individual sense of self and society continues changing, just as it did when the early Renaissance spirit swept over medieval Europe.[61]

Both science and democracy not only encourage unconventional opinions and vigorous debate but also demand adequate reasoning, coherent argumentation, and vigorous standards for honesty and evidence.[62] Indeed, it has been posited that humanity's future is inextricably aligned with the future of science.[63] Put simply, science is correctly seen as the best force to satisfy the fundamental quest for

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54 JONES, *supra* note 53.

55 Stephen L. Carter, *The Bellman, the Snark, and the Biohazard Debate*, 3 YALE L. & PUB. POL'Y 358, 366 (1984).

56 *Id.*

57 JOEL FEINBERG & JULES COLEMAN, PHILOSOPHY OF LAW 479 (7th ed. 2004).

58 *Id.* One philosophical approach to resolving conflicts between external scientific standards of conduct and personal scientific "ethics" strives for a cultural revision or revolution where a "fresh" ethic for the life sciences would require all people to work for common ends, share binding visions, and agree on a set of shared values. Smith, *Manipulating the Genetic Code*, *supra* note 34, at 720.

59 *See* ISAAC ASIMOV, ASIMOV'S CHRONOLOGY OF SCIENCE AND DISCOVERY (1989). For the past 420 million years, fire has been a part of the story of Earth. The first stage of human intersection with fire was recorded 1.5 million years ago. Concrete evidence of utilizing flints to start fires occurred some 40,000 years ago. The use and control of fire occurred only 7,000 years ago. Andrew C. Scott, *When Did Humans Discover Fire? The Answer Depends on What You Mean by 'Discover*,*'* TIME (June 2018), https://time.com /5295907/discover-fire/ [https://perma.cc/C8GX-SN62].

60 *Id.*

61 RIFKIN, *supra* note 27. *See generally* Smith, *supra* note 34.

62 Carl Sagan, *Describing the World as It Is, Not as It Would Be*, *in* THE WRITING LIFE: WRITERS ON HOW THEY THINK AND WORK 309 (Marie Arana ed., 2003).

63 *See* MARTIN REES, ON THE FUTURE: PROSPECTS FOR HUMANITY (Princeton Univ. Press 2018).

knowledge.[64] The safe and ethical utilization of new technological advances in harnessing the vast potentialities that derive from it will determine the extent to which humanity is secured or is limited.[65] A central challenge to any effort taken is acceptance of the hard reality that whatever regulations are prudently set to constrain science will simply never be enforced worldwide—no effective, transnational supervision process exists.[66]

B. Whole Science

Today, "science claims a monopoly over the steering of human progress," a process secured and then implemented "through the kinds of engineered solutions that a biology armed with awesome" power[s] that can only be imagined.[67] Science "arrogates, to itself, the right to determine what life is for, along with the capacity to discover and redesign what life is."[68] The fundamental question of the twenty-first century, emerging from today's scientific dialogue with law, is how one lives and how "human needs, expectations and desires" are responsive to the hopes and promises of the New Biology and to the Era of Biotechnology.[69]

C. Junk Science

Given that few can clearly recognize what makes a scientific study good or bad, this uncertainty becomes the basis for questioning the validity of scientific evidence upon which federal-state regulatory programs are structured.[70] Scientific research has many built-in uncertainties existing because scientists must extrapolate specific

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64 *See, e.g.*, Dalvin Brown, *Big Tech Wants to Build the Metaverse. What on Earth Does That Mean?*, THE SEATTLE TIMES (Oct. 28, 2021), https://www.seattletimes.com/business/technology/big-tech-wants-to-build-the-metaverse-what-on-earth-does-that-mean/ [https://perma.cc/22B6-ZH6X]. *See generally* JOHN D. BERNARD, THE SOCIAL FUNCTIONING OF SCIENCE (1939).

65 *See* REES, *supra* note 63. *See* Catie Edmondson & Ava Swanson, *infra* note 77.

66 *Id.*

67 JASANOFF, *supra* note 26, at 168. *See* ISAAC ASIMOV, THE INTELLIGENT MAN'S GUIDE TO SCIENCE (1960).

68 *Id. See also* Brown, *supra* note 64.

69 JASANOFF, *supra* note 26, at 165. *See generally* GEORGE P. SMITH, II, FAMILY VALUES AND THE NEW SOCIETY: DILEMMAS OF THE 21ST CENTURY (1998); SMITH, *supra* note 7.

70 David Michaels & Celeste Monforton, *Manufacturing Uncertainty: Contested Science and the Protection of the Public's Health and Environment*, 95 AM. J. PUB. HEALTH S39 (2011). *See* Sound Science for Endangered Species, H.R. 4840, 107th Cong. at 1 (Sept. 2002).

evidence from studies, which allows scientists to recommend proactive measures.[71] "Absolute certainty is rarely an option."[72] Even using the best evidence available for scientific investigations does not protect the work product from being challenged by corporations on the grounds of insufficiency.[73] Major industries such as tobacco, chemical, asbestos, lead, and platinum routinely seek to "manufacture uncertainty" in scientific reports principally created for federal administrative agencies under congressional authority to set rules and regulations governing these industries and their products.[74] These manufactured uncertainties are termed "junk science," described as "faulty scientific data and analysis used to further a special agenda."[75] Aided by U.S. federal legislation in the Data Quality Act, formal challenges may be made to admit administrative agency findings on the grounds that they are of insufficient quality, objectivity, utility, or integrity.[76]

Compounding efforts to maintain research integrity is the underlying realization that much of the scientific information used to formulate regulation is sourced directly from groups and industries that the government is regulating.[77] Limited federal research funding and a lack of oversight is a major reason for this state of affairs.[78] Transparency

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71 *See* Michaels & Monforton, *supra* note 70.

72 *Id.* Many unreliable scientific studies—not verified by peer review before publication—add to misinformation, misunderstanding, and levels of confusion by the public. John P.A. Ioannidis, *Why Most Published Research Findings Are False*, PLOS MED. (Aug. 30, 2005).

73 Michaels & Monforton, *supra* note 70.

74 *Id.*

75 *Id. See* DON AGIN, JUNK SCIENCE (2006).

76 Consolidated Appropriations Act of 2001, Pub. L. No. 106-554, § 515 (2001).

77 David Michaels & Wendy Wagner, *Disclosures in Regulatory Science*, 302 SCIENCE 2073 (2003).

78 *Id. See also* M. Anthony Mills, *Fix Science, Don't Just Fund It,* INNOVATION FRONTIER PROJECT (Sept. 16, 2021), https://innovationfrontier.org/fix-science-dont-just-fund-it/ [https://perma.cc/B33Q-LPTT]. Two present Congressional proposals—the National Science Foundation for the Future (H.R. 2225) by the House of Representatives and the Senate's Innovation and Compensation Act (S.1260)—seek to resolve present federal issues of inadequate funding for research and development. While laudable, these proposals do not address four underlying issues in the competition for and awarding of federal funding for science and technology. These legislative proposals do not significantly alter the funding mechanisms in the two major science agencies—the National Science Foundation and the National Institutes of Health. Nor do they address the unequal distribution of federal science funding to prominent institutions of higher education in defined geographic clusters, ways to enhance "the integrity of scientific research," inequalities in scientific reward system, or the bureaucratization of science which has the effect of transforming "scientists into bureaucrats." *Id. But see* Catie Edmondson & Ava

within the scientific community might offer some hope that the very integrity of their research might be reserved to some degree.[79] Termed an epidemic of fraud, scientists often fail to report conflicting data in their investigations.[80] Indeed, researchers[81] have used misleading analytical methods of research.[82] Further, researchers may often succumb to self-deception and proceed to overemphasize only the portions of evidence that support a preferred conclusion,[83] which gives rise to falsification of experiments.[84] Although enforcement actions related to misconduct in research and development are primarily focused on the actions of individual researchers, the impact of falsified research extends to affected companies, industries, and the public at large.[85]

Swanson, *House Passes Bill Adding Billions for Scientific Research*, N.Y. TIMES (Feb. 15, 2022), https://www.nytimes.com/2022/02/04/us/politics/house-china-competitive-bill.html [https://perma.cc/KL99-8B8D] (reporting on legislative efforts in the House of Representatives to pour $300 billion into scientific research and development projects to strengthen the level of competition that America is encountering with the Chinese government).

79 *See* NICOLAS CHEVASSUS-AU-LOUIS, FRAUD IN THE LAB: THE HIGH STAKES OF SCIENTIFIC RESEARCH (Nicholas Elliott trans., 2019).

80 *Id.* at 10–15.

81 *Id.*

82 *Id. See* Sally Satel, *'Fraud in the Lab' Review: Experiments in Doubt*, WALL ST. J. (Aug. 14, 2019), https://www.wsj.com/articles/fraud-in-the-lab-review-experiments-in-doubt-11565823628 [https://perma.cc/VS7X-PDJS]. *See also* Chris Hamby & Sheryl Gay Stolberg, *Vaccine Mistakes and a Warning for the Future*, N.Y. TIMES, Dec. 24, 2021, at A1; Sheryl Gay Stolberg, Sharon LaFraniere & Chris Hamby, *Top Official Warned Vaccine Plant ad to Be 'Monitored Closely*,*'* N.Y. TIMES (Apr. 7, 2020), https://www.nytimes.com/2021/04/07/us/emergent-biosolutions-coronavirus-vaccine.html [https://perma.cc/QCB7-PSHD].

83 *See* George J. Annas, *Questing for Grails: Duplicity, Betrayal and Self-Deception Postmodern Medical Research*, 12 J. CONTEMP. HEALTH L. & POL'Y 297 (1996); RICHARD H. GIRGENTI, THE NEW ERA OF REGULATORY ENFORCEMENT: A COMPREHENSIVE GUIDE FOR RAISING THE BAR TO MANAGE RISK, 247 *passim* (2016).

84 CHEVASSUS-AU-LOUIS, *supra* note 79. *But see* Betsy McKay & Katie Camero, *Sharing Data Faster to Fight an Epidemic*, WALL ST. J. (Feb. 22, 2020), https://www.wsj.com/articles/sharing-data-faster-to-fight-an-epidemic-11582314253 [https://perma.cc/6EVH-Q357].

85 George P. Smith, II, *Judicial Decisionmaking in the Age of Biotechnology*, 13 NOTRE DAME J. ETHICS & PUB. POL'Y 93, 95 (1999). *See generally* B.C., *Liberation Theology: The Future*, THE ECONOMIST at 11, Apr. 6, 2019 (discussing the engineering of living organisms and the resulting changes).

III
THE SCIENCE OF THE CORONAVIRUS PANDEMIC: A CASE IN POINT

For a number of years, epidemiologists have been predicting and, at the same time, preparing for viral outbreaks such as COVID-19.[86] Even within an atmosphere of this character, the United States found itself ill-prepared to respond.[87] A major reason for this "surprise" can be attributed to the lack of strong budgetary appropriations to the National Institutes of Health and the National Science Foundation.[88] These two organizations are awarded only seven percent of the federal budget set aside for national defense.[89] This situation highlights "not only the serious lack of scientific knowledge among elected officials" but also what is seen as a "devaluation of scientific expertise."[90]

As a consequence of this situation, when the coronavirus pandemic took hold in the United States, it was predictable that "bad" (or junk) science would come into play.[91] Misrepresented personal "scientific" data was routinely presented to the public by pharmaceutical commercial interests[92] and by social media outlets such as Facebook, Instagram, Twitter, and Clubhouse.[93] The White House proceeded to create a "political atmosphere" by pushing the pace of clinical trials for a number of vaccines in order to establish their efficacy with the hope that a vaccine could be secured before the November election.[94]

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86 Marc Zimmer, *Opinion: Science in Time of Crisis*, THE SCIENTIST (Aug. 14, 2020), https://www.the-scientist.com/reading-frames/opinion-science-in-a-time-of-crisis-67761 [https://perma.cc/LJG4-YZWA].

87 *Id.*

88 *Id.*

89 *See generally* Joe Davidson, *U.S. Agencies Fail to Learn from Years Testing Pandemic Responses, GAO Finds*, WASH. POST (Nov. 17, 2021), https://www.washingtonpost.com/politics/2021/09/16/gao-report-covid-response-federal-agencies/ [https://perma.cc/YT9M-PE4V]. *See supra* note 38.

90 Zimmer, *supra* note 86. *But see* Edmondson & Swanson, *supra* note 78.

91 MARC ZIMMER, THE STATE OF SCIENCE: WHAT THE FUTURE HOLDS AND THE SCIENTISTS MAKING IT HAPPEN (2020). *See* Rammya Matthew, *We Must Not Be Guided by Bad Science on COVID-19*, BR. MED. J. (June 9, 2020).

92 *Id.*

93 Sheera Frenkel, *Misinformation Deepens Gap in Vaccinations*, N.Y. TIMES, Mar. 11, 2021, at A1.

94 Sharon LaFraniere et al., *Politics, Science and the Remarkable Race for a Coronavirus Vaccine*, N.Y. TIMES (Nov. 30, 2020), https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html [https://perma.cc/4YVR-PMK6]. *See* Paul D. Thacker, *The U.S. Politicization of the Pandemic: Raul Grijalva on Masks, BAME, and Covid-19*, BR. MED. J.

Moderna, a "Big Pharma" company, received nearly $2.5 billion to develop, manufacture, and sell an efficacious coronavirus vaccine[95] to the federal government. Interestingly, Pfizer, another major pharmaceutical, chose to keep an "arm's length" distance from government assistance and thus declined research and development monies.[96]

Evidence-based science was replaced by countless pseudoscientific assertions and claims made by people with questionable scientific qualifications, thereby complimenting "conspiracy theories"; this, in turn, gave rise to medical scams and promoted specious scientific work.[97] Literally, anything could be published as scientific fact in unaccredited "pay for play" journals as well as online journals without quality review or any verification of the provenance for sourced material.[98] Unvetted data was published "haphazardly," resulting in a flow of misinformation, which only led to public suspicion and confusion.[99]

Interestingly, even with the serious missteps seen in the rollout of an efficacious vaccine to combat the coronavirus, because of the pandemic, the whole field of science—and more specifically, pharmaceuticals—has a new burnished image.[100] "Big Science" is no longer seen by the average American as "money grubbing."[101] Rather, the notable success of Pfizer (with BioNTech of Germany), in the speedy development of a vaccine against COVID-19, has now placed

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(Sept. 8, 2020), https://www.bmj.com/content/370/bmj.m3430 [https://perma.cc/UBF3-WFS9].

95 LaFraniere et al., *supra* note 94. *But see* Nick Dearden, *Moderna Profits Show Why Big Pharma Can't Meet Our Health Needs*, AL JAZEERA (Mar. 16, 2022), https://www.aljazeera.com/opinions/2022/3/16/modernas-profits-show-why-big-pharma-cant-meet-our-health-needs [https://perma.cc/3VSW-UEZM].

96 LaFraniere, *supra* note 94.

97 Walter Scheirer, *A Pandemic of Bad Science*, 76 BULL. ATOMIC SCIENTISTS 175 (2020). *See* James M. DuBois et al., *Understanding Research Misconduct: A Comparative Analysis of 120 Cases of Professional Wrongdoing*, 20 ACCOUNTABILITY RSCH. 320 (2013).

98 Scheirer, *supra* note 97.

99 *Id. See* Kate Kelland et al., *Speed Science: The Risk of Swiftly Spreading Coronavirus Research*, THOMSON REUTERS (Feb. 19, 2020), https://www.reuters.com/article/us-china-health-research-analysis/speed-science-the-risks-of-swiftly-spreading-coronavirus-research-idUSKBN20D21S [https://perma.cc/84XC-AEDL]; George P. Smith, II, *Common Sense or Sensibility: Vaccine Hesitancy, Parens Patriae and the Common Good*, 19. J. HEALTH & BIOMEDICAL L. 1, 18–20 (2022).

100 *Reformulated: The Future of Drugmaking*, THE ECONOMIST, Apr. 10, 2021, at 62.

101 *Id.*

"Big Pharma" in "a seat firmly at the table" which allows them "a chance to be 'good' again."[102]

IV
A NEW EPA REGULATION: TOWARD AN ETHIC OF PROTECTION

The United States Environmental Protection Agency (EPA) in Washington, D.C. issued a final rule on January 6, 2021, entitled "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information."[103] This action establishes how the EPA will consider the availability of dose-response data underlying pivotal science used in its significant regulatory actions and influential scientific information.[104] When promulgating significant regulatory actions or developing influential scientific information for which the conclusions are driven by the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and effect, the EPA will give greater consideration to studies where the underlying dose-response data is available in a manner sufficient for independent validation.[105] This action also requires the EPA to identify and make publicly available the science that (1) serves as the basis for informing a significant regulatory action at the proposed or draft stage to the extent practicable, (2) reinforces the applicability of peer-review requirements for pivotal science, and (3) provides criteria for the Administrator to exempt certain studies from the requirements of this rulemaking.[106] Hopefully, this new regulation will go far in restraining political influences from dominating scientific decision-making.[107]

The need for scientific legitimacy—demonstrated through COVID-19 and EPA regulations—becomes more challenging when research

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102 *Id.*

103 86 Fed. Reg. 469 (Jan. 9, 2021) (to be codified at 40 C.F.R. pt. 304.4).

104 *Id.*

105 *Id.*

106 *Id.*

107 *Id. See* Dino Grandoni, *EPA Dismisses Dozens of Key Science Advisers Picked Under Trump*, WASH. POST (Mar. 31, 2021), https://www.washingtonpost.com/climate-environment/2021/03/31/epa-advisory-panels/ [https://perma.cc/QFP9-8K3V] (quoting Michael Regan, President Biden's new Administrator of the U.S. Environmental Protection Agency). Some forty outside experts appointed by President Trump to the EPA's Science Advisory Board and the Clean Air Scientific Advisory Committee were "purged" by Mr. Regan with the goal of restoring the role of science at the EPA and reducing the heavy influence of industry over promulgating environmental regulations. *Id.*

has the potential to alter genetic compositions of human beings permanently. With this possibility, gene therapy has become an important topic to consider the importance (and challenges) of legitimacy through regulation.

V
GENETIC MODIFICATIONS

Sir Isaac Newton's third law of physics applies as much to scientific development as it does to other aspects of life.[108] Accordingly, for every action, there is an equal and opposite reaction.[109] Thus, for every new and daring biotechnological advancement, a new medico-legal challenge is presented—a challenge rooted in complex sociopolitical, religious, moral, and ethical vectors of force.[110] Today, it is the issue of germline editing that attracts vast global interest and development.[111]

Although genetic research has expanded in recent years, the motivating force behind the New Biology has been basic to human society.[112] Since the time of Plato, people have attempted to improve humans through genetic research and experimentation, seeking to relieve or totally alleviate genetically determined human suffering.[113] These research efforts reflect the belief that society would prosper from methods making humans more fit because the world would be populated by the best physical specimens who, in turn, would beget superior offspring.[114] Some individuals, over the course of history, have been motivated to undertake genetic experiments by the power of possible scientific creation and manipulation.[115]

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108 *See* George P. Smith, II, *Genetics, Eugenics and Public Policy*, 10 S. ILL. L.J. 435 (1985). *See also* GEORGE P. SMITH, II, THE CHRISTIAN RELIGION: A SEARCH FOR PRINCIPLED DECISIONMAKING (2005).

109 *See* GEORGE P. SMITH, II, DISTRIBUTIVE JUSTICE AND THE NEW MEDICINE, Ch. 3 (2008).

110 *See* GEORGE P. SMITH, II, LAW AND BIOETHICS: INTERSECTIONS ALONG THE MORTAL COIL, chs. 2, 3 (2012). Adolf Hitler, through his program termed *Lebensborn*, or Fountain of Life, undertook genetic experimentation, which for him required the ruthless extermination of those seen as carrying inferior genes (e.g., Jews, homosexuals). *See* Smith, *Pursuing a Right to Genetic Happiness*, *supra* note 34, at 3, for a discussion of Hitler's Master Race Theory.

111 Smith, *Pursuing a Right to Genetic Happiness*, *supra* note 34, at 18.

112 *Id.* at 2–4.

113 *Id.* at 3.

114 *Id. See* George P. Smith, II & Thaddeus J. Burns, *Genetic Determinism or Genetic Discrimination?*, 11 J. CONTEMP. HEALTH L. & POL'Y 23 (1995).

115 Sheila Jasanoff, *Biology and the Bill of Rights: Can Science Reframe the Constitution?*, 13 AM. J.L. MED. 249, 275 (1990).

Essentially, gene therapy—by which alterations are made to genes—may be performed either in germ cells (e.g., sperm or egg cells) or in somatic cells (cells comprising other body tissues).[116] Use of germline therapy produces alterations to be inherited by future generations.[117] Contrariwise, somatic cell therapy affects only the treated individual.[118] Apprehension over gene therapy users are focused on the possibility that these interactions will permanently alter the genetic composition of human beings and thereby gradually erode the concept of humanity and personhood.[119] Indeed, intervention into the reproductive process creates deep concerns, if not fears, that "biological knowledge" will give rise to "biological reductivism" and be used to denigrate the rights of personhood—rights which all individuals enjoy to autonomy, dignity, personal integrity, and rights justified traditionally as protected civil liberties ensured by the United States Constitution.[120]

There are latent fears that the state could use gene therapy not only to modify human behavior but also to engineer new breeds of humans, possibly through cross-species transfer of genes, or even by cloning existing individuals.[121] The net effect of using these scientific techniques is compromising the very diversity of the whole gene pool.[122] Presently, the most rational line of defense against such "what-if" scenarios is gene therapy treatments; gene therapy treatments will most likely be feasible for treating a limited group of disorders caused by single genetic defects, not multifactorial conditions such as schizophrenic apprehension.[123]

As with medical treatments, which carry positive benefits as well as serious risks, should gene therapy become—over the course of time—a common technique, the technique will present a wide range of legal issues with constitutional significance.[124] For example, questions of religious freedom may well arise in connection with parental refusals

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116 *Id.*

117 *Id.*

118 *Id. See* Barbara Pfeffer Billauer, *Wrongful Life in the Age of CRISPR-CAS: Using the Legal Fiction of the Concepted Being to Redress Wrongful Gamete Manipulation*, 124 PENN. ST. L. REV. 435 (2020).

119 *Id. See* Douglas & Savulescu, *supra* note 33.

120 Jasanoff, *supra* note 115, at 275.

121 *Id.*

122 *Id.*

123 *See* Smith, *supra* note 34, *passim*.

124 Jasanoff, *supra* note 115, at 276–77.

to allow gene therapy treatment for minors.[125] Mandated treatment of genetic disorders, as a precondition to receiving a marriage license, would surely raise issues of due process and equal protection.[126] So long as the judiciary analyzes such policies within a traditional public health framework, state action could be validated. Efforts to control genetic disorders could be analogized to compulsory vaccination, upheld by the United States Supreme Court in *Jacobson v. Massachusetts* in 1905[127] as a legitimate state policy designed to prevent the spread of communicable diseases.[128] Accordingly, it could be argued that mandatory gene therapy would similarly prevent the vertical transmissions of disease from one generation to the next.[129]

In the spring of 2014, the White House Office of Science and Technology held firm to the policy that embryonic gene editing, at least for the present, should not be undertaken.[130] In other words, no alteration of the human germline for clinical purposes could be funded with federal research funds.[131] This was policy buttressed by reports from the National Academics of Science, Engineering, and Medicine in 2016–2017, and by a specific 1996 congressional prohibition in the Dickey-Wicker Amendment for federal research monies to be used on embryonic assisted reproduction.[132]

Human embryos were first edited in 2017, and then, in 2018, a Chinese scientist reported that he had gene-edited twin girls born in 2018.[133] Both of these scientific achievements were achieved "independent of governmental regulations or recommendations" and established clearly, once again, the sovereignty of science.[134]

In 2019, eighteen international scientists and ethicists urged an imposition and self-regulation of a voluntary global moratorium, of

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125 *Id.*

126 *Id.*

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

128 Jasanoff, *supra* note 115, at 276–77.

129 *See* Paige Winfield Cunningham, *'Designer Babies' Worry Both Parties*, WASH. EXAM'R (Nov. 30, 2015, 12:10 AM), https://www.washingtonexaminer.com/designer-babies-worry-both-parties [https://perma.cc/HKT2-4CTJ].

130 Raymond C. O'Brien, *The Immediacy of Genome Editing and Mitochondrial Replacement*, 9 WAKE FOREST J.L. & POL'Y 419, 442–44, 471, 479–80 (2019). *See generally* CARLSON, *supra* note 6. *See also* Smith, *supra* note 34.

131 O'Brien, *supra* note 130, at 442–44, 471, 479–80.

132 *Id.* at 426, 451.

133 *Id.* at 449.

134 *Id.*

indefinite length, on all clinical uses of human germline editing.[135] This moratorium would not apply to germline editing for research purposes.[136] One distinguished scientist at the University of California, Berkeley, faulted this proposal specifically because "no pathway toward possible responsible use" was set out in the moratorium itself.[137]

VI
CODIFYING AN ETHIC OF CARE: INTERNATIONAL AND DOMESTIC "GUIDELINES"

A. International Guidance

Several major international frameworks seek to guide, if not regulate, scientific experimentation.[138] Of the ten principles of the 1947 Nuremberg Code, which evolved as a response to the atrocities of World War II, three are pertinent to this analysis—namely, any scientific experimentation on humans must be for the advancement of the greatest good for society, the risks taken in experimentation must never exceed its benefits, and when injury, disability, or death is likely to occur, experiments should be terminated.[139] It is to be noted that this code imposes no radical principle on the researcher.[140] Rather, it merely restates a personal standard of conduct by imposing primary responsibility on the scientist for the safety of his subjects.[141]

The Declaration of Helsinki of 1964—presently in its seventh iteration, agreed to in 2013[142]—seeks to establish operative principles for guiding human research practice by imposing duties that an investigator must accept when undertaking research with a patient or a volunteer.[143] Article 16 and Article 17 affirm that research of this nature be done only when there is a careful assessment of risks and benefits, and it is shown that a reasonable benefit to the group of people studied

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135 Eli Adashi & I. Glenn Cohen, *JAMA Forum: Heritable Genome Editing: Is a Moratorium Needed?*, JAMA NETWORK (June 3, 2019), https://jamanetwork.com/channels/health-forum/fullarticle/2759655#237285293 [https://perma.cc/2ZAC-PJ6Y].

136 *Id.*

137 *Id.*

138 *Id.*

139 O'Brien, *supra* note 130, at 442–44, 471, 479–80.

140 *Id.*

141 *See* WORLD MED. ASS'N, *Declaration of Helsinki, 64th WMA Gen. Assembly* (Oct. 2013), https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [https://perma.cc/X9MR-HENX].

142 *Id.*

143 *Id.*

will result when the research is completed.[144] The research must follow protocols that are subject to independent ethical review and oversight,[145] and which further guarantee that the interests of the subject be part of this ethical assessment.[146] This is recognized as the first attempt of the medical community to self-regulate. It is also acknowledged that the "inducement" to accept the Declaration is the only form of regulatory "enforcement" provided for by the Declaration.[147] As O'Brien explains:

> Only one international document explicitly addresses heritable genetic modification, the 1997 Oviedo Convention. Not all member states of the Council of Europe have ratified the Oviedo Convention, including the United Kingdom, but the principles espoused in the Convention find resonance in foreign research reports on the subject of genome editing. The Convention and corresponding reports suggest, first, that any human genome editing should serve human health, not physical appearance or gender selection, and second, modification may not introduce changes that can be passed on to future generations.[148]

The 2015 Council of Europe's Convention on Human Rights and Biomedicine, together with UNESCO's Universal Declaration on the Human Genome and Human Rights, opposed germline modification and expressed fears that a new form of eugenics would arise from this work.[149]

B. Domestic Action

As early as 1966, the United States federal government, acting through the U.S. Public Health Service—a division of the Department of Health, Education, and Welfare—would not grant, renew, or continue to support research programs involving humans unless the institution at which the research is conducted reviewed the following: the risks and potential medical benefits of the research, the rights and

144 *Id.*

145 *Id.*

146 *Id.*

147 O'Brien, *supra* note 130, at 488.

148 *Id.* (internal citations omitted). *See generally* GEORGE P. SMITH, II, DIGNITY AS A HUMAN RIGHT? (2018).

149 Smith, *Manipulating the Genetic Code: Jurisprudential Conundrums*, *supra* note 34, at 729 (analyzing the scope of subsequent federal grant regulations for human research studies).

the personal welfare of the research subjects, and the need for their informed consent to participate.[150]

Furthermore, in 1974, the United States Congress established a National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (the Commission), whose purpose was to identify basic ethical principles for biomedical and behavioral research involving human subjects. The Commission issued a Report and Guidelines in 1975 on this topic, which broadly encouraged therapeutic research directed toward the fetus or its mother.[151]

The 1978 Belmont Report of the Commission concluded that scientific research involving human subjects should focus on three principles: avoidance of inflicting harm, acceptance of a duty of beneficence, and maintenance of a commitment to justice. These principles form the basis for judgment for evaluators seeking to ensure a reasonable balance between risk and desired benefits, to the individual and to society, and that both risks and benefits are equally shared.[152]

VII
THE PRECAUTIONARY PRINCIPLE: AN ETHIC OF RESTRAINT OR OF PRECAUTION?

Global efforts are made on a daily basis to regulate risk—even when risks of harm are remote.[153] Protecting health and the environment are of paramount importance for maintaining a good society.[154] The precautionary principle is one important example of such regulations and can be correctly seen as a principle that "imposes a burden of proof on those who create potential risks, and . . . requires regulation of activities even if it cannot be shown that those activities are likely to produce significant harms."[155]

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150 SMITH, *supra* note 148, at 66, 94. *See* Smith, *Manipulating the Genetic Code: Jurisprudential Conundrums*, supra note 34, at 729. *See also* O'Brien, *supra* note 130, at 447, 481.

151 *See The Belmont Report, Special Issue*, 63 PERSP. BIOLOGY & MED. 219 (Franklin G. Miller & Jonathan Kimmelman eds., 2020).

152 O'Brien, *supra* note 130, at 476–77.

153 Sunstein, *supra* note 23.

154 *Id.*

155 *Id.* at 1003.

It has been asserted that the precautionary principle is fast becoming, if not already established in fact, a binding part of customary law.[156] Whether it is "logically coherent, internally consistent and intellectually appealing" is an open question and largely dependent upon fact-sensitive applications.[157] Indeed, finding a Cartesian gloss of clarity, distinction, and objectivity within the principle of precaution is problematic.[158] Even though the principle is incorporated into the laws of the European Union, through the Treaty on the Functioning of the European Union (TFEU), it defies a uniform interpretation.[159] The European Commission adopted the principle and the implementation guidelines in 2000.[160] The principle applies to all EU actions in all areas of health and safety.[161] The United States Congress has brought into focus a notion of precaution and protection of the environment,[162]

156 *Id.* at 1005.

157 Patrick Jiang, *A Uniform Precautionary Principle Under EU Law*, 2 PEKING U. TRANSNAT'L L. REV 490, 492 (2014).

158 *See Descartes' Theory of Ideas*, STAN. ENCYCLOPEDIA OF PHIL. (Aug. 3, 2021), https://plato.stanford.edu/entries/descartes-ideas/ [https://perma.cc/76CJ-NYUD] (analyzing the major components of Descartes' epistemology as being clarity, distinctiveness, and objective society).

159 Sunstein, *supra* note 23, at 1007. *See* Jiang, *supra* note 157.

160 Sunstein, *supra* note 23, at 1007. *See* Jonathan B. Weiner & Michael Rogers, *Comparing Precaution in the United States and Europe*, 5 J. RISK RSCH. 317 (2002).

161 Jiang, *supra* note 157, at 495. *See also* ÉLYSÉE, *The Charter for the Environment*, https://www.elysee.fr/en/french-presidency/the-charter-for-the-environment [https://perma.cc/DT94-2XZZ]. France, for example, in the 2004 French Charter of the Environment, Article 5 states, "When the occurrence of any damage, albeit unpredictable in the current state of scientific knowledge, may seriously and irreversibly harm the environment, public authorities shall, with due respect for the principle of precaution and the areas within their jurisdiction, ensure the implementation of procedures for risk assessment and the adoption of temporary measures commensurate with the risk involved in order to preclude the occurrence of such damage." *Id.*

162 Sunstein, *supra* note 23, at 1006–07 n.17. In 1993, no doubt drawing upon the powerful mandate of NEPA to safeguard the environment, President William J. Clinton issued Ex. Order No. 12866, requiring all federal agencies to consider "the degree and nature of the risks posed by . . . [their] activities" and reduce all risks to public health, safety, and the environment. *See* Regulatory Planning and Review, 58 Fed. Reg. 190, 733–35 (Oct. 4, 1993). In 2007, the OMB updated the Risk Assessment Bulletin. National Research Council & National Academy of Sciences, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* (2007).

principally through the National Environmental Policy Act[163] and the Clean Air Act.[164]

The first international recognition of the precautionary principle was seen in the 1982 United Nations World Charter for Nature, where it was suggested that in circumstances where "potential adverse effects are not fully understood, the activities should not proceed."[165] The 1992 United Nations Conference on Environment and Development in Rio de Janeiro, acting under Principle 15, determined that in order to protect the environment the precautionary principle shall "be widely applied by States according to their capabilities" and that "lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[166] The Rio Declaration was framed in such a way to allow world governing organizations a "broad mandate to protect the environment without justifying their actions to a scientific certainty."[167] As a matter of policy, the Declaration suggests that preventative, cost-effective measures should be favored by the signatories to the Declaration "before environmental damage becomes permanent."[168]

"Discretion is integral to the precautionary principle" since only discretion can bridge the gap between scientific uncertainty and protective action.[169] Acknowledging that precaution is "an eminently

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163 National Environmental Policy Act of 1969, 42 USC § 4332. *See* Richard Lazarus, *The National Environmental Policy Act in the United States Supreme Court: A Re-Appraisal and a Peek Behind Curtains*, 100 GEO. L.J. 1507 (2012). Environmental impact statements are essentially cost-benefit models. A number of states have adopted state Environmental Protection Acts, which parallel the Federal Act and require state environmental impact statements of undertakings that could adversely affect state environments. *See State Environmental Policy Acts*, BALLOTPEDIA, https://ballotpedia.org/State_environmental_policy_acts [https://perma.cc/UX9N-KQLC]; Sarah Langberg, *A Full and Fair Discussion of Environmental Impacts in NEPA EISs: The Case for Addressing the Impact of Substantive Regulatory Regimes*, 124 YALE L.J. 576 (2014-2015).

164 The Clean Air Act, 42 U.S.C. 85 § 7409(b)(1) (2000). In setting national primary ambient air quality standards, the Act requires the Environmental Protection Agency to maintain "adequate margins of safety" to "protect the public health in the national standards." *Id.*

165 *World Charter for Nature*, U.N. GAOR, 37th Sess., 48th plen. mtg., Article 211(b), at 18 U.N. Doc. A/RES/37/7 (Oct. 28,1982).

166 U.N. Conference on Environment and Development, *Rio Declaration on Environment. and Development*, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I), annex I (Aug. 12, 1922).

167 Jiang, *supra* note 157, at 494.

168 *Id.*

169 *Id.* at 496.

political decision," the European Commission states that whatever suits the political situation—action or inaction—is proper.[170]

From a meeting of environmentalists to discuss the precautionary principle in Racine, Wisconsin, the 1998 Wingspread Declaration states unambiguously that "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically." In this context, the proponent of the activity, rather than the public, should bear the burden of proof.[171]

Today, there are several differing viewpoints on implementing the precautionary principle,[172] with one understanding being that "a lack of decisive evidence of harm should not be grounds for refusing to regulate."[173] The European Commission agreed that measures based on the principle "should not be blindly precautionary" but rather set within a "structured approach to the analysis of risk" and thorough assessments of the risk itself, and from "risk management [and] risk communication."[174] Others suggest that the principle requires that a "margin of safety" should be evident in all decision-making made under it.[175]

A. Judicial Recognition of the Precautionary Principle

Within the law of the European Community, the case law of the Court of First Instance, now the Court of General Jurisdiction, dealing with the precautionary principle, shows a judicial temperament that has found a point of balance in its decision-making, while respecting the European Community's legal order and conceding that the Community's institutions have "a certain margin of appreciation in this field," yet stating clearly that the judicial review of decisions made under the present system "is thorough enough to prevent abusive reliance on the precautionary principle."[176]

The Council of Europe represents the governments of individual member countries, while the European Commission represents the

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170 *Id.*

171 Sunstein, *supra* note 23, at 1006–07.

172 *Id.* at 1014.

173 *Id.* at 1012.

174 *Id.* at 1017.

175 *Id.* at 1013.

176 *See* Olivier Segnana, *The Precautionary Principle: New Development in the Case Law of the Court of First Instance*, 3 GER. L.J. E9 (2002); Jiang, *supra* note 157, at 515–16.

interests of the European Union as a whole.[177] The Commission has adopted working doctrines that govern the precautionary principle,[178] and the European Court of Justice has chosen to give wide deference to the Commission's decisions.[179] The Commission has determined that, in addition to following the general principles of EU law-making, the precautionary principle should "be informed, reasoned, and not arbitrary,"[180] as well as show respect for the common principles of "proportionality, non-discrimination, and legal certainty."[181] Further, "all of the available scientific evidence" should be considered in decision-making in order to attain full knowledge of known facts, and, further, that consideration should be "holistic," which in turn requires a cost-benefit analysis of economic and noneconomic factors in both the short and the long term.[182]

Interestingly, even with agreement upon ground rules for use of the precautionary principle by the courts, in practice, while policymakers "ostensibly pay due deference to scientific opinion, the final assessment of risk and application of the precautionary principle will be policy-driven rather than based on science."[183] When doubt arises, a preference may be to eliminate risk by imposing a ban, rather than a cost-benefit analysis that includes the damage caused by banning a potentially useful product.[184]

B. Geopolitics and the Precautionary Principle

Inasmuch as Germany's present climate strategy is said to be failing and thus giving it some of the highest electricity prices in Europe, the previous German Chancellor, Angela Merkel, announced in 2020 that, by the year 2030, Germany plans to generate sixty-five percent of its electricity from renewables—an increase from the present forty-two

177 *Do Not Get Confused*, COUNCIL OF EUR. (2022), https://www.coe.int/en/web/about-us/do-not-get-confused#:~:text=An%20international%20organisation%20in%20Strasbourg,rule%20of%20law%20in%20Europe [https://perma.cc/GQ5U-GS83].

178 *Id.*

179 *Id. See generally* Sunstein, *supra* note 23.

180 Jiang, *supra* note 157, at 491, 497.

181 *Id.*

182 *Id.* at 497.

183 I. Forrester & J.C. Hanekamp, *Precaution, Science and Jurisprudence: A Test Case*, 9 J. RISK RSCH. 297, 297 (2007). This conclusion is drawn from the decision of the Court of First Instance in the Pfizer judgment, T-13/99 with reference to the Alpharma judgment, T-7011. *See* Segnana, *supra* note 176.

184 *Id.*

percent levels.[185] Pressured by the European Union to tighten its emissions regulations of fossil fuels and to invest in green and nuclear energy—and more specifically in electric vehicle technology—Germany has pledged to wean its dependency on coal, and, by 2038, to retool its entire industrial base.[186] As a consequence of this action, thousands of jobs will be lost to workers in Germany's industrial coal regions.[187] In order to blunt the effect of these losses, the federal government is planning compensatory aid packages to assist those losing their jobs.[188] What is seen here is a geopolitical response—negotiated, in essence—by the European Union demanding Germany follow a high standard of long-term precaution in its generation of electricity and the goals of global climate change rather than to continue using coal burning for its own needs.[189]

VIII
THE OUTREACH OF DAUBERT AND SCIENTIFIC EVIDENCE: JUDICIAL BEFUDDLEMENT

In 1993, the United States Supreme Court determined the case of *Daubert v. Dow Pharma*[190] and the extent that expert scientific testimony is admissible in federal courts.[191] Rather than present a strong framework for principled decision-making for determining the admission of scientific evidence in federal litigation or a definitive checklist,[192] the Court presented five observations that serve as policy

185 Ruth Bender, *German Shift from Coal to Clean Energy Spurs New Pain*, WALL ST. J., Jan. 17, 2020, at A2.

186 *Id.*

187 *Id.*

188 *Id.*

189 *Id. See* Christian Starck, *Freedom of Scientific Research and Its Restrictions in German Constitutional Law*, 39 ISR. L. REV. 110 (2006). *See also Have Economists Led the World's Environmental Policies Astray*, THE ECONOMIST (Mar. 26, 2022), at 73, https://www.economist.com/finance-and-economics/2022/03/26/have-economists-led-the-worlds-environmental-policies-astray [https://perma.cc/FD54-2SG5] (examining the global effects of "decarbonizing" in order to achieve net zero emissions by 2050 will require a significant number of extreme positive incentives for change or EPICS). Germany has long been a bold and energetic leader in studying the effects of transboundary pollution and the causal effects of acidification. In fact, it was Germany that led thirty-four members of the Economic Commission of Europe to pass the Convention on Long Range Transboundary Air Pollution in 1979 (which went into effect in March, l985). George P. Smith, II, *Acid Rain: Transnational Perspectives*, 4 N.Y.L. SCH. J. INT'L & COMP. L. 457, 465, 474, 501 (1983).

190 Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

191 *Id.*

192 *Id.*

guidelines to assist judges in determining whether scientific expert testimony may be admitted as evidence in federal litigation.[193]

The central consideration suggests that courts should first determine whether a proffered scientific theory or technique has a scientific methodology that can be tested and then, secondly, ascertain whether that particular methodology has been subjected to peer review and publication.[194] The third policy consideration raises the issue of courts ascertaining the known or potential rate of error as well as the existence and maintenance of standards controlling a scientific operation.[195] It is then suggested that a court make a determination as to whether there is a general acceptance of a particular scientific theory or technique used in litigation.[196] The final consideration merely encourages trial court judges to review all other relevant Federal Rules of Evidence in deciding the propriety of admitting expert scientific testimony.[197]

One major, controlling consequence of *Daubert* is the high degree of certainty trial courts have demanded for admissibility of scientific evidence in federal cases.[198] Emboldened by the broad scope of *Daubert*, antiregulatory interests now urge that these guiding considerations for determining the relevance of scientific evidence be applied as principles for reviewing, when challenged, the very sufficiency of federal administrative regulations.[199] As trial judges have, in essence, become "gatekeepers" of all scientific testimony, the high level of scientific certainty required for admission of scientific evidence has led corporate defendants to become increasingly emboldened to accuse adversaries as practitioners of junk science.[200] Others, however, argue that the *Daubert* "standards" for determining scientific relevance and reliability be embraced as safeguards for protecting interests found in the *total* regulatory process.[201] A

193 *Id. See* George P. Smith, II & David M. Steenburg, *Environmental Hedonism or, Securing the Environment Through the Common Law*, 40 WM & MARY ENVTL. L. & POL'Y REV. 65, 78, 79 (2015) (much of the analysis of *Daubert* in the present Article is derived from this source). *See also* D.H. Kaye, *Is Proof of Statistical Significance Relevant*, 61 WASH. L. REV. 1333 (1986).

194 *See* Smith & Steenburg, *supra* note 193.

195 *Id.*

196 *Id.*

197 *Id.*

198 Michaels & Monforton, *supra* note 70.

199 *Contra id.*

200 David Michaels, *Scientific Evidence and Public Policy*, 95 AM. J. PUB. HEALTH 5 (2005).

201 *Id.*

scientific—rather than political—foundation should be maintained as the controlling vector of force in the oversight of the administrative regulatory process.[202]

The sentiments that Federal Judge David L. Bazelon expressed in 1977 regarding the extent to which the judiciary is challenged by the emerging new technologies of the day remain pertinent today.[203] Then, as now, judges were seen as "technically illiterate," with little knowledge or training to assess competing scientific arguments.[204] Today, the same scientific befuddlement arguably prevails.[205] The central role of judges is to "scrutinize and monitor the decision-making process to make sure that it is thorough, complete, and rational; that all relevant information has been considered; and that insofar as possible, those who will be affected by a decision have had an opportunity to participate in it."[206] When judges are required to consider highly technical and scientific evidence,[207] fulfilling this central role is exceedingly problematic to attain a level of "scientific consciousness."[208]

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202 *Id.*

203 David L. Bazelon, *Coping with Technology Through the Legal Process*, 62 CORNELL L. REV. 817 (1977). *See* Smith, *supra* note 85. *See generally* Reuel E. Schiller, *Rulemaking's Promise: Administrative Law and Legal Culture in the 1960s and 1970s*, 53 ADMIN. L. Rev. 1139 (2001) (challenging the judicial decision-making, administrative rulemaking, judicial review, and the philosophies of Judge Bogelani, Judge Skelly Wright, and Judge Harold Leventhal).

204 *See* Mark Grabowski, *Are Technical Difficulties at the Supreme Court Causing a "Disregard of Duty"?*, 3 CASE W. RES. J.L TECH & INTERNET 93 (2011).

205 *See* Smith, *supra* note 85; *see* JASANOFF, *supra* note 26. *See also* Donald E. Shelton, *Teaching Technology to Judges*, 40 JUDGES' J. 42 (Winter 2001).

206 Bazelon, *supra* note 203, at 823. *See* Leon R. Yankwich, *The Art of Being a Judge*, *in* HANDBOOK FOR JUDGES 12 (Glen R. Winters ed., 1975). A more succinct judicial philosophy is found in Justice Brett Kavanaugh's notion that the duty of judges is to be impartial and merely follow the law, not remake it. Brett Kavanaugh, *The Judge as Umpire: Ten Principles*, 65 CATH. U.L. REV. 681 (2016).

207 Bazelon, *supra* note 203, at 817.

208 *Id.* at 826, 828. *See* Smith, *supra* note 85. In addition to advancing a scientific base of knowledge for the judiciary, the relevance of complex social issues influences the whole judicial decision-making process is being advanced by Northeastern University's Institute for Health, Equity, and Social Research Justice under a grant from the Robert Wood Johnson Foundation. The specific purpose of this project is to train judges and their law clerks to be cognizant of the social determinants of health on those of low socioeconomic status and color which, over time, will improve health equity and population health. NORTHEASTERN LAW, Summer 2020 at 5, Vol. 19, No. 2. *See Northeastern Law Leaps to No. 5 for Health Care Law in 2022 U.S. News Ranking*, NORTHEASTERN LAW (Mar. 3, 2021). *See also About IHESJR*, NE. UNIV. INST. FOR HEALTH, EQUITY & SOC. JUST. RSCH., https://bouve.northeastern.edu/institute-for-health-equity-and-social-justice-research/about/ [https://perma.cc/88RH-J8S8]. *See Salus Populi: Educating the Judiciary About the*

A. Alternative Approaches to Judicial Decision-Making

Over time, a number of proposals have been made to resolve this situation; namely, by creating scientist judges and letting them operate in a specialized Science Court—much as is seen in present specialized areas of taxation, customs, and patents,[209] and veteran affairs. As well, courts could be "upgrade[d]" by providing "systematic instruction" to the judiciary, much as it is a part of the work of the Administrative Office of United States Courts,[210] in preexisting programs of continuing education in science and technology. This approach would be consistent with, and complement, the requirement that members of the practicing bar in all fifty states regularly participate in specialized programs to maintain their skill levels.[211]

Courts could appoint advisers to assist judges in understanding complex issues of scientific evidence in specific cases.[212] Perhaps the

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Social Determinants of Health, NE. UNIV. INST. FOR HEALTH, EQUITY & SOC. JUST. RSCH., https://bouve.northeastern.edu/institute-for-health-equity-and-social-justice-research/?ihesjr_projects=salus-populi-educating-the-judiciary-about-the-social-determinants-of-health [https://perma.cc/DD3P-MTSL].

209 *See* Bazelon, *supra* note 203, at 826, 828; Smith, *supra* note 85, at 107; George P. Smith, II, *The Environment and the Judiciary: A Need for Cooperation or Reform?*, 3 BOS. COLL. ENVT'L AFFAIRS J. 627 (1974); Allan Mazur, *The Science Court: Reminiscence and Retrospective*, 4 RISK: ISSUES IN HEALTH & SAFETY 161 (1993). *See also* George P. Smith, II, *Does the Environment Need a Court?*, 57 JUDICATURE 15 (1973).

210 Bazelon, *supra* note 203, at 828. The Federal Judicial Center in Washington, D.C. has a specific Education Division which conducts seminars, workshops, and symposia in specialized new legal areas such as neuroscience and technology together for the management of complex litigation for new federal judges. *See Education Programs*, FED. JUD. CTR., https://www.fjc.gov/education/education-programs [https://perma.cc/3748-7JM7]; *Judicial Seminars on Emerging Issues in Neuroscience*, AM. ASS'N FOR THE ADVANCEMENT OF SCI., https://www.aaas.org/programs/scientific-responsibility-human-rights-law/judicial-seminars-emerging-issues-neuroscience [https://perma.cc/T8W2-J4ED]; *Seminars for Newly Appointed United States District Judges, Held at Federal Judicial Center, Wash., D.C. l970 & 1971*, FED. JUD. CTR., https://www.ojp.gov/ncjrs/virtual-library/abstracts/seminars-newly-appointed-united-states-district-judges-held-federal [https://perma.cc/7VCM-ZDUM]. (Additionally, New York University and Vanderbilt Law Schools have seminar training programs for judges.); INST. OF JUD. ADMIN., *New Appellate Judges Seminar*, https://www.law.nyu.edu/centers/judicial/appellatejudgesseminar [https://perma.cc/YTG5-MZYH]; *New Federal Judicial Training Program to Debut at Vanderbilt Law School*, VAND. L. SCH. (Mar. 14, 2014), https://law.vanderbilt.edu/news/new-federal-judicial-training-program-to-debut-at-vanderbilt-law-school/ [https://perma.cc/FB7E-VVDA].

211 *See* AM. BAR ASS'N, *ABA MCLE Model Rule Implementation Resources*, https://www.americanbar.org/events-cle/mcle/modelrule/#:~:text=Requires%20lawyers%20to%20take%20the,one%20credit%20every%20three%20years) [https://perma.cc/MT65-AFCX].

212 *Contra* Bazelon, *supra* note 203, at 828; Arthur Kantrowitz, *Proposal for an Institution for Scientific Judgment*, 156 SCIENCE 763, 763 (1967).

simplest way to reach a level of "scientific consciousness" would be to appoint, when needed, Special Masters—essentially scientific case advisers—to assist the court in administering justice. The Federal Rules of Civil Procedure allow for the appointment of Special Masters to review and organize information and prepare reports for judges in managing their civil cases.[213] Masters also routinely supervise discovery in related conflicts and assist in moving litigation forward by conducting evidentiary hearings.[214]

B. Participatory Democracy: Educating the Public

At the core of this complex issue of scientific judicial review is the need for broader public participation in the administrative process.[215] Legislatures traditionally make value choices in reviewing legislative proposals and proceeding to enactment into legislation.[216] Today, this level of legislative scrutiny is delegated to administrative agencies.[217] In order to "manage" judicial review of regulatory actions by administrative agencies, citizens must be informed and "activated" at the basic or very first level of problematic issues. Ballot referenda and initiatives are, without doubt, the best way for the public to express their view and preferences to actual legislative proposals.[218] Absent voter participation and choice over problematic issues in legislative proposals, when real legal issues arise, these issues are ideally presented at the regulatory stage for proper hearings. It is at this stage that the judiciary is asked to referee the issues and resolve them.[219]

The "technical illiteracy" of the courts distinctly tracks with the passive ignorance and indifference shown by many young people in industrialized countries—an indifference shaken only when sociopolitical affairs have an impact on their individual and immediate

213 FED. R. CIV. P. 53(a)(1)–(3).

214 *See* Shira Scheindlin, *The Use of Special Masters in Complex Cases*, LAW360 (Aug. 15, 2017, 11:36 AM), https://www.law360.com/insurance-authority/articles/950395/the-use-of-special-masters-in-complex-cases [https://perma.cc/BS6V-JTXR].

215 Bazelon, *supra* note 203, at 829. *See* Smith, *Setting Limits: Medical Technology and the Law*, *supra* note 11, at 293–95.

216 Bazelon, *supra* note 203, at 829.

217 *Id.* at 829–30.

218 *See* Caroline J. Tolbert & David A. Smith, *The Educative Effects of Ballot Initiatives on Voter Turnout*, 33 AM. POL. RSCH. 283 (2005).

219 Bazelon, *supra* note 203, at 828–30. It is at this stage of inertia or abject failure, combined with a lack of legislative leadership at all levels, that the judiciary has no alternative but to "wade in" and endeavor to make "factual decisions more accurate and objective and our value choices more fair."

well-being.[220] Compounding this situation with young people is a realization that a considerable fraction of developed countries' populations have no science education.[221] A revealing public opinion survey, conducted by Eurobarometer in 2005, found disturbing data.[222] The survey revealed that, on average, only half of the Europeans surveyed knew that electrons are smaller than atoms, almost a third believed that the sun goes around the earth, and nearly a quarter affirmed that the earliest humans coexisted with dinosaurs.[223]

In 1968, Chief Justice Warren E. Burger of the United States Supreme Court observed that law reacts to social needs and demands and does not search out as do science and medicine.[224] The Chief Justice's sentiments apply—regrettably—in today's contemporary society. Because of this lethargic legal "vision," the notion that the law can rightly be seen as a "third culture," which acts as a synthesizer, translator, or catalyst for interpreting, "directing," and "calming" the intellectuals and the scientists (as the first and second cultures), is foolhardy.[225] The result of law's impotency is that science reigns as a sovereign with minimal constraint.[226]

"Law lag," as a term of art, nicely captures Chief Justice Burger's notion that law is reactionary to science and technology and not in a close partnership with it.[227] Indeed, encoded within this phrase is a tacit recognition of a hierarchical relationship which presently exists between science and law as it "regards the protection of life."[228]

Science promotes progress, while the law seeks to "extricate itself from outdated principles" and maintain its relevance by updating social values—all in order to keep pace with new scientific knowledge and maintain social order.[229] Throughout the 1980s, the courts

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220 *See* Bazelon, *supra* note 203, at 90, 817; Valenti Rull, *The Most Important Application of Science*, 15 EMBO REPS. 919 (2014).

221 *See* EUROPEAN COMMISSION, *Europeans, Science and Technology*, 224 EUROBAROMETER 3 (June 2005), https://europa.eu/eurobarometer/surveys/detail/447 [https://perma.cc/M44A-VFRU].

222 *Id.* at 40.

223 *Id.*

224 Warren E. Burger, *Reflections on Law and Experimental Medicine*, *in* 1 ETHICAL, LEGAL, AND SOC. CHALLENGES TO A BRAVE NEW WORLD at 211 (George P. Smith, II, ed., 1982).

225 *See generally* C.P. SNOW, THE TWO CULTURES: A SECOND LOOK (1963).

226 JASANOFF, *supra* note 26, at 68–69. *See* Smith, *supra* note 11.

227 JASANOFF, *supra* note 26, at 69.

228 *Id.*

229 *Id.*

largely accepted the often tantalizing "promises" made by scientific optimism.[230] This optimism, originating during the European Enlightenment, emphasized "reason and individuality rather than corporate tradition."[231] Man considered himself a part of nature, if not a member.[232] Fear of science was replaced by an attitude of positivism and participation.[233] The judicial attitude that evolved during the 1980s was to embrace science and not restrict its "claims of technological progress."[234] Today, although there are some small signs of a scientific confluence between law and science, the predominant mantra remains "scientific sovereignty" with the judiciary still in retreat.[235]

CONCLUSION

Fundamental to recognizing a philosophy of science is to understand and then accept, as Max Planck did, that science—in and of itself—is a positive value to society when its "products" are useful and practical and, as a matter of course, provide work opportunities.[236] Thus, science is a source for good. For Planck, in order to shape and utilize a philosophy of science, which serves as a frame for rational investigations of principles of being, knowledge, or conduct, it must be fully understood before discoveries should be pursued.[237] Martin Heidegger's philosophy of science, however, seeks to study and then utilize the technology of science as a tool for viewing the whole of life, and as a construct for pursuing a good healthy life. Put simply, science is a means to an end.[238]

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230 *Id.* at 79.

231 O'Brien, *supra* note 130, at 477.

232 *Id.*

233 *Id.*

234 JASANOFF, *supra* note 26, at 79.

235 *Id.* As Justice Michael D. Kirby of the High Court of Australia sees this situation, "No law can stop science and technology completely. There will always be a small corner of the world that will give sanctuary to the free spirit of the enquiring scientist and the technologist at work in the laboratory. Especially will this be so if profits dangle tantalizingly at the end of the endeavor." MICHAEL D. KIRBY, THROUGH THE WORLD'S EYE 50 (2000). *See generally* Bradley Schlaggar et al., *Bringing Science to Law and Policy: Panel Discussion*, 57 WASH. U. J.L. & POL'Y 147, 147–82 (2018).

236 MAX PLANCK, THE PHIL. OF PHYSICS 96, 103, 106–07 (W.H. Johnston trans., 1936).

237 *Id.*

238 Mark Blitz, *Understanding Heidegger on Technology*, 41 THE NEW ATLANTIS 63, 63–80 (2014), https://www.thenewatlantis.com/publications/understanding-heidegger-on-technology [https://perma.cc/W344-GNXJ]. *See* Michael Wheeler, *Martin Heidegger*, STAN. ENCYCLOPEDIA OF PHIL. (Oct. 12, 2011), https://plato.stanford.edu/entries/heidegger/ [https://perma.cc/PW9A-P2US].

In contemporary society, science advances applications of scientific knowledge, which are then used to satisfy basic human needs and maintain proper healthful living standards, which in turn secure social order.[239] Most of the tools of technology—specifically biotechnology—are by-products of scientific efforts.[240] Scientific research is said to satisfy the human thirst for knowledge and, thus, enhance human cultural heritage, which is knowledge-based. The vexing question in the Age of Modernity is whether scientific research should be dedicated to the service of human needs and social order or[241] whether scientific research should be unshackled and allowed to follow the paths that scientists wish to pursue for the advancement of knowledge. Accepting this second alternative assures the sovereignty of science.[242]

A real concern for singularitarians, or futurists, is that technological singularity will not be prudently guided to benefit and nurture human growth. Consequently, science will become uncontrollable and irreversible—resulting in unforeseeable changes to human civilization.[243] The creation of superintelligence, which will allow humans to transcend present biological limitations and, for example, confer cognitive powers to computers, will surely advance a sense of foreboding or apprehension.[244]

In order to maintain social order, laws need to coalesce with prevailing social values.[245] Today's contemporary values should be understood as being shaped not only by cultural norms but by science, medicine, and biotechnology, all of which in turn guide and, indeed,

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239 Blitz, *supra* note 238. *See* Kunkel, *supra* note 8.

240 Rull, *supra* note 220. *See generally* A COMPANION TO THE PHILOSOPHY OF TECHNOLOGY (Jan Kyrre Berg Olson et al. eds., 2009).

241 *See* JOHN D. BERNAL, THE SOCIAL FUNCTION OF SCIENCE (1939). *But see* Jay S. Kaufman, *Science Alone Can't Heal a Sick Society*, N.Y. TIMES, Sept. 12, 2021, at 2. *See generally* Kyrre Berg Olson et al., *supra* note 240.

242 *See* JASANOFF, *supra* note 26, at 67–70. The American poet, Walt Whitman, saw the "crowning" achievement of any Age as being one "of inquiry" and, consequently, as exploring everything—be it sound or "profane." HORACE TRAUBEL ET AL., WALT WHITMAN SPEAKS: HIS FINAL THOUGHTS ON LIFE, WRITING, SPIRITUALITY, AND THE PROMISE OF AMERICA, 163–64 (Brenda Wineapple ed., 2019).

243 RAY KURZWEIL, THE SINGULARITY IS NEAR: WHEN HUMANS TRANSCEND BIOLOGY (2005).

244 RAY KURZWEIL, THE AGE OF INTELLIGENT MACHINES (1990).

245 *Id. See* JASANOFF, *supra* note 26, *passim*. *See also* George P. Smith, II, *Social Justice and Health Care Management: An Elusive Quest*, 9 HOUS. J. HEALTH L. & POL'Y 1 (2008).

establish a new order of conduct.[246] In order to attain a point of equilibrium in the modern state, the law needs to not only oversee but direct and regulate the courses of scientific conduct which safeguard life, liberty, and the pursuit of happiness.[247] In popular government, the powers of common sense weigh heavily against "the powers of paradox" or, in other words, the "treasury of scientific knowledge."[248] But, if the standard of living and, indeed, survival is to have an enduring significance, a democratic society must use common sense in allowing scientific progress.[249]

No doubt, the central weakness to the quest for an ideal state of equilibrium is that the law's responsibilities are simply not being met.[250] Courts continue to struggle to understand complex scientific cases, regulatory agencies charged with executing legislative mandates are regularly entangled by uninformed and misdirected mandates for rule-making and scientific certainties, and society remains uninformed, lethargic, and unwilling to accept any responsibilities for participation in a deliberative democracy.[251]

Put simply, scientists need to explain to lawyers and general society the work of science in more fundamental and understandable terms.[252]

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246 JASANOFF, *supra* note 26, *passim*.

247 *Id. See* ANDREA BOGGIO ET AL., THE HUMAN RIGHT TO SCIENCE AND THE REGULATION OF HUMAN GERMLINE ENGINEERING (2018) (asserting that acknowledging a human right to science found in Article 15.1.b of the International Covenant on Economics, Social and Cultural Rights to participate and "to enjoy the benefits from scientific programs and its applications" should be used as a point of beginning for promoting responsible scientific and technological advancement by shaping principles and then developing frameworks that proceed to recognize the very international nature of "modern germline genomic engineering research.").

248 DANIEL J. BOORSTIN, CLEOPATRA'S NOSE: ESSAYS ON THE UNEXPECTED 177 (2011).

249 *Id. See* Andrea Boggio et al., *The Human Right to Science and the Regulations of Human Genetic Engineering*, 2 CRISPR J. 134 (2019) (observing that 141 world constitutions, out of a total of 202, contain one or more of four components of a "right" to benefit from programs in science and technology; namely, the "enjoyment of the benefits of scientific programs"; the "freedom" of science; the "protection" from adverse effects of science, and the "duty" to foster scientific and technological programs). *See also* BOGGIO ET AL., *supra* note 247.

250 *See* George P. Smith, II, *Biotechnology and the Law: Social Responsibility or Freedom of Scientific Inquiry?*, 39 MERCER L. REV. 437, 438 (1988).

251 *See* Smith, *supra* note 85. *See also* Bazelon, *supra* note 203; Shelton, *supra* note 205.

252 Lewis Thomas, *Overview: Regulating Biotechnology*, 3 YALE L. & POL'Y REV. 309, 314 (1985). *See* Tunku Varadarajan, *How Science Lost the Public's Trust*, WALL ST. J., July 24–25, 2021, at A11. *See also* Schlaggar et al., *supra* note 235; Ioannidis, *supra* note 72.

At the same time, lawyers need to listen more intently and participate in scientific dialogue.[253]

The public at large must seek factual data in order to at least attempt to understand and then engage in today's biotechnological debate as full participants rather than *witnesses* in the process of deliberative democracy.[254] Insofar as these disharmonies persist, the ultimate goal of law—namely, "to seek decisions that fall within the boundaries of scientifically sound social knowledge and approximately reflect the scientific state of the art"—will not be met.[255] The consequence of this public apathy is that the sovereignty of science will, of necessity, prevail as the fundamental ethic of experimentation.[256]

253 Thomas, *supra* note 252, at 314.

254 *Id.* (discussing Maxine Singer's worry over "the appalling lack of knowledge" about scientific issues). *See* CARLSON, *supra* note 6, at 210. *See also* Carter, *supra* note 55, at 386–94.

255 Stephen G. Breyer, *The Interdependence of Science and Law*, 280 SCIENCE 537 (1998).

256 *See* JASANOFF, *supra* note 26, *passim*.