THE LAW, SCIENCE, AND POLICY OF GENOME EDITING

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INTRODUCTION

Genome editing is the most significant breakthrough of our generation. *Rewriting Nature*[1] explores the intersection of science, law, and policy as it relates to this powerful technology. Since the manuscript went to press, genome-editing developments have continued apace. Researchers have reported encouraging results from the first clinical trials to treat β-thalassemia and Sickle-Cell Disease,[2] the first wheat-crop variety that is resistant to a crippling fungal disease and features no growth or yield deficits,[3] and proof-of-concept data establishing the therapeutic effects of the first clinical trial involving the injection of a therapy directly into the bloodstream of patients suffering from a genetic, neurological disease.[4] Chinese regulators promulgated rules to approve

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[1] PAUL ENRÍQUEZ, REWRITING NATURE: THE FUTURE OF GENOME EDITING AND HOW TO BRIDGE THE GAP BETWEEN LAW AND SCIENCE (2021).

[2] Haydar Frangoul, David Altshuler, M. Domenica Cappellini, Yi-Shan Chen, Jennifer Domm, Brenda K. Eustace, Juergen Foell, Josu de la Fuente, Stephan Grupp, Rupert Handgretinger, Tony W. Ho & Antonis Kattamis, Andrew Kernytsky, Julie Lekstrom-Himes, Amanda M. Li, Franco Locatelli, Markus Y. Mapara, Mariane de Montalembert, Damiano Rondelli, Akshay Sharma, Sujit Sheth, Sandeep Soni, Martin H. Steinberg, Donna Wall, Angela Yen, Selim Corbacioglu, *CRISPR-Cas9 Gene Editing for Sickle Cell Disease and* β*-Thalassemia*, 384 N. ENG. J. MED. 252, 258-59 (2021).

[3] Shengnan Li, Dexing Lin, Yunwei Zhang, Min Deng, Yongxing Chen, Bin Lv, Boshu Li, Yuan Lei, Yanpeng Wang, Long Zhao, Yueting Liang, Jinxing Liu, Kunling Chen, Zhiyong Liu, Jun Xiao, Jin-Long Qiu & Caixia Gao, *Genome-Edited Powdery Mildew Resistance in Wheat Without Growth Penalties*, 602 NATURE 455, 460 (2022).

[4] Julian D. Gillmore, Ed Gane, Jorg Taubel, Justin Kao, Marianna Fontana, Michael L. Maitland, Jessica Seitzer, Daniel O'Connell, Kathryn R. Walsh, Kristy Wood, Jonathan

gene-edited crops.[5] These and other developments are testament to the expansive reach and promise of genome editing. *Rewriting Nature* showcases the technology's power to transform what we eat, how we provide healthcare, how we confront the challenges of global climate change, who we are as human beings, and more.

One of my goals in writing the book was to help spur robust dialogue and debate about the future of genome editing and the synergistic roles that law, science and public policy can play in promoting or hindering specific uses of the technology. I am grateful to the *Boston University Law Review* for organizing this symposium on *Rewriting Nature* and bringing together an extraordinary group of gifted scholars, academics, entrepreneurs, and thinkers, including several members of the National Academy of Sciences, as well as scientists and lawyers to engage in diverse discussions of my book. I am indebted to Professors Rodolphe Barrangou, Naomi Cahn, Dana Carroll, Glenn Cohen, John Conley, Katherine Drabiak, Michele Bratcher Goodwin, Fred Gould, Henry Greely, Gary Marchant, Kevin Outterson, Christopher Robertson, Jacob Sherkow, Sonia Suter, and Allison Whelan for reading the book and contributing their thoughtful insights—during the live event, in print, or both. I am truly honored and humbled by the generous praise they bestow on my work and the collective caliber of insight they bring to the discussion. It is my honor and privilege to share this platform with so many accomplished people who have inspired and taught me a great deal through their work. I am encouraged by the consonance on a vast range of ideas among participants but even more so by the disagreement, as it presents opportunities for engagement and progress. My Essay, thus, focuses on the hard questions and challenges that spring from our disagreements, which allowed me to clarify, refine, and expand on ideas presented in *Rewriting Nature* and to articulate new ones that point towards future work.

I. ON DEFINING GENOME EDITING

Professor Sherkow's thoughtful contribution focuses on Chapter 3 of *Rewriting Nature*, which lays the interpretive and normative groundwork for a working definition of the term "genome editing."[6] He is skeptical that such a

Phillips, Yuanxin Xu, Adam Amaral, Adam P. Boyd, Jeffrey E. Cehelsky, Mark D. McKee, Andrew Schiermeier, Olivier Harari, Andrew Murphy, Christos A. Kyrasous, Brian Zambrowicz, Randy Soltys, David E. Gustein, John Leonard, Laura Sepp-Lorenzino & David Lebwohl, *CRISPR-Cas9 In Vivo Gene Editing for Transthyretin Amyloidosis*, 385 N. ENG. J. MED. 493, 499-501 (2021).

[5] Dominique Patton, *China to Allow Gene-Edited Crops in Push for Food Security*, REUTERS (Jan. 25, 2022, 3:41 PM), https://www.reuters.com/world/china/china-drafts-new-rules-allow-gene-edited-crops-2022-01-25/.

[6] *See* Jacob S. Sherkow, *Writing Definitions in* Rewriting Nature*: Lessons from FDA Law*, 102 B.U. L. REV. ONLINE 22, 22-23 (2022).

definition is necessary and observes that "the law is quite able to muddle along without a clear definition of a particular thing."[7]

I concur with the sentiment that definitions can sometimes engender more problems than solutions in some legal contexts, particularly when they are "riddled with vagueness, ambiguity, and incompleteness."[8] *Rewriting Nature* explores several of the inherent limitations concerning the use of specific terminology, which may (1) render the meaning of words "malleable" and capable of "evolv[ing] over time and cultures"; (2) be overbroad, so as to make the meaning of words "inherently ambiguous" and difficult to apply uniformly; and (3) trigger the collapse of a definition's relevance and application to unforeseen circumstances under the weight of undue "stringency" and "rigidity."[9] I caution at the outset that "no definition is perfect" and recognize that "[n]o one-size-fits-all definition" will ever apply perfectly in every situation.[10]

To support his thesis, Sherkow analogizes the term "genome editing" to the words "family" and "sale."[11] He notes that "no one seems to be particularly confused" about the meaning of those words in different legal contexts and, therefore, argues that the law is able to "muddle along" without definitions.[12] But Sherkow's proposition brings to light a fundamental distinction that attenuates the analogy's scope and application in the legal realm. The terms "family" and "sale" are precisely the type of words that courts are well equipped to construe and interpret based on ordinary meaning and other canons of statutory construction, as well as principles of legislative intent. While judges are unlikely to be fazed by the meaning of the word "sale" in the context of tax, real estate, and commercial laws,[13] there is an inherent challenge for judges, who may fairly be presumed to lack scientific training and to be unfamiliar with a given complex, emerging technology, to construe or infer plain meaning from a scientific term such as genome editing.

The likelihood of confusion over the meaning of such a technical concept is substantial. Without the guiding light of a clear and robust definition grounded in science, judges may follow whatever rules of construction they deem fit or turn to less reliable sources such as general-use dictionaries—which often lack accuracy, specificity, and clarity—in search of an "ordinary" meaning for a specialized concept.[14] This is highly problematic for the reasons I outline in

[7] *Id.* at 23.

[8] ENRÍQUEZ, *supra* note 1, at 83.

[9] *Id.* at 74-75.

[10] *Id.* at 74, 89.

[11] Sherkow, *supra* note 6, at 23.

[12] *See id.* at 23.

[13] *Id.*

[14] *See* ENRÍQUEZ, *supra* note 1, at 83-91 (describing the problems associated with overreliance on dictionaries as sources of ordinary meaning while noting the ambiguity and lack of clarity of dictionary definitions of genome editing).

Rewriting Nature. Furthermore, if legal disputes ensue, litigants may introduce evidence of the meaning of genome editing that serves their specific purposes. This opens the door for select "stakeholders to inject self-serving, arbitrary, and subjective interpretations" about the meaning of genome editing.[15]

Courts, of course, are not obligated to follow reference sources, such as dictionaries, and may wholly ignore expert testimony that they deem irrelevant to the inquiry presented. Judicial discretion in these domains contributes to the phenomenon in which courts render interpretations and meanings that eschew scientific evidence. Such occurrences are neither speculative nor hypothetical.

In *Nix v. Hedden*,[16] the U.S. Supreme Court acknowledged that from the perspective of botany—the scientific discipline that concerns the study of plants—a tomato falls within the definition of "fruit," a term that refers to the "ripened ovary of a plant and its contents," including the seeds.[17] Notwithstanding its botanical classification as a fruit, the Court held that a tomato is a vegetable, as a matter of law, because people (1) grow them in gardens among other vegetables and (2) serve them cooked or raw during dinner but not alongside dessert—the way they generally serve fruits.[18] The Court afforded no deference to the scientific meaning of a disputed term and instead relied on the so-called common knowledge of the people at the time to dictate the meaning of fruit. It is not hard to fathom, in light of *Nix* and similar cases, why scientists and advocates of science-based law and policy are often dismayed when courts ignore relevant scientific evidence and offer jejune legal reasoning as the basis to decide cases with vast repercussions in many areas of society.[19] Absent guidance about the meaning of a scientific concept such as genome editing, courts may churn out a litany of arbitrary decisions featuring broad interpretations and meanings that cannot be reconciled with the particular subtleties and technical context of a given case.

Next, I wish to address Sherkow's—and, to some extent, Professor Greely's—comments regarding "universal definitions"[20] that may "fit[ ] all situations."[21] Sherkow, for instance, grafts a "universality" sine qua non onto my proposed definition of genome editing. But my sense is that he misreads my normative claims. *Rewriting Nature* features no such universality requirement.

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[15] *Id.* at 91.

[16] 149 U.S. 304 (1893).

[17] *Id.* at 307; *see also* ENRÍQUEZ, *supra* note 1, at 87-89 (discussing *Nix*).

[18] *Nix*, 149 U.S. at 307.

[19] Despite *Nix*'s holding, the botanical definition of a fruit remains unchanged nearly one hundred and thirty years later. But so too does the legal treatment of tomatoes as vegetables under U.S. trade law remain unchanged. *See* Harmonized Tarif Schedule of the United States Revision 2 (2022), USITC Pub. 5293, § 2, ch. 7 (Feb. 2022), https://hts.usitc.gov/current [https://perma.cc/UXJ3-FR7Y].

[20] *See* Sherkow, *supra* note 6, at 24, 25, 28.

[21] Henry T. Greely, *Rewriting (Non-Human) Nature*, 102 B.U. L. REV. ONLINE 16, 18 (2022).

The thrust of my argument is that, due to the increasing reach of the technology across a wide range of disciplines, "[c]ongruity and uniformity on genome-editing terminology [are] sorely needed at this point in time."[22] *Congruity* (contextual harmony)[23] and *uniformity* (consistent treatment)[24] under the law—namely, the harmonious and consistent application of the term—are thus the principal focus of my definitional prescription. *Rewriting Nature* says nothing about a need for *universality* (an all-inclusive concept without limit or exception existing under all conditions)[25] in defining genome editing.

Congruity and uniformity breed *predictability*, which is a quality that the law ought to promote even if outcomes lead to some degree of variation in a given context of a legal dispute. A court may construe or interpret the word "family" liberally to encompass parents, children, siblings, grandparents, cousins, and in-laws and their relatives for purposes of one law regulating family gatherings, but narrowly to refer only to the parent-child relationship for purposes of determining an individual's qualification as a dependent under a tax law. Such context-dependent degrees of variation, however, would not vitiate the benefits of a robust definition that, for example, anchors "family" to a common denominator that excludes, say, friends and co-workers from the family unit, regardless of the express contextual statutory intent of a specific law or regulation.[26] The definition of "family" may not be universal, but the term can still be *uniformly* applied to encompass individuals related by blood or marriage in different contexts.

In any event, it is worth reiterating that the book "advocates for the adoption of a (more) uniform definition of genome editing primarily aimed at building a science-based, legal and policy framework to address current and future predicaments within the ambit of genome-editing technologies" and rejects the

[22] ENRÍQUEZ, *supra* note 1, at 73.

[23] *See Congruous*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/congruous [https://perma.cc/48PL-GFJE] (last visited Mar. 9, 2022) (defining the term as "being in agreement, harmony, or correspondence"; "conforming to the circumstances or requirements of a situation; appropriate"; and "marked or enhanced by harmonious agreement among constituent elements").

[24] *See Uniform*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/uniform [https://perma.cc/K3XN-H86T] (last visited Mar. 9, 2022) (defining the term, in relevant part, as being "consistent in conduct or opinion," such as in the "*uniform* interpretation of laws").

[25] *See Universal*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/universal [https://perma.cc/P3D4-3ZGD] (last visited Mar. 9, 2022) (defining the term as "including or covering all or a whole collectively or distributively without limit or exception"; "present or occurring everywhere"; and "existent or operative everywhere or under all conditions").

[26] For purposes of this Essay, we need not engage in an exercise of defining the term family. Suffice it to note that, unlike "family," the term genome editing lacks an "ordinary" meaning.

universal adoption of a rigid, one-size-fits-all definition of genome editing.[27] The definitional prescription concerns efforts to disseminate accurate, science-based information, so as to (1) promote efficient and effective channels of interdisciplinary communication, (2) engage in fruitful discussions grounded on a common *understanding* of genome editing, and (3) prevent the spread of vagueness, ambiguity, indefiniteness, and confusion in future discussions about genome-editing technologies.

Despite the inherent limitations on specific terminology enumerated in *Rewriting Nature*, I conclude that such limitations may be largely allayed and overcome by subjecting the proposed definition to rigorous scrutiny and debate. It is true that no one definition may apply perfectly in every situation, but we cannot let the perfect be the enemy of the good. There is value in formulating a robust, science-based definition of genome editing at this early juncture of technological development. Just so, there is no principled reason to avoid subjecting the definition to additional scrutiny as time goes by and the technology continues to develop.

It may be that one option is for the law to "muddle along" without a genome-editing definition for some time. But is it prudent to merely muddle along aimlessly without strategy as courts, policymakers, and society navigate the intersection of law, science, and policy of genome editing? Or would the preferable choice be to confront a complex, foreseeable problem with the benefit of time and widespread input from scientists, interdisciplinary experts, stakeholders, and the public? My sense is that we ought to collectively strive, as a society, to undertake important and difficult dialogues that will promote civic engagement and respectful conversations about science and technology. Sherkow's and Greely's thoughtful critiques allowed me an opportunity to clarify some of the things I said and did not say in *Rewriting Nature*, for which I am grateful.

II. GERMLINE GENOME EDITING AND THE CONSTITUTION

Turning the page on the discussion pertaining to definitions, a number of contributors offered unique perspectives about *Rewriting Nature*'s take on germline genome editing ("GGE") and the Constitution. Professors Suter and Cahn, for example, are skeptical that a subcategory of GGE may potentially give rise to a fundamental right protected by the Constitution.[28] They argue that the "Rehnquist conception of fundamental liberty interests," which encompasses "[a] rigid and literalist conception of our history and tradition," excludes forms of assisted reproductive technology ("ART") such as GGE.[29]

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[27] *E.g.*, ENRÍQUEZ, *supra* note 1, at 73, 75, 89.

[28] *See* Sonia M. Suter & Naomi R. Cahn, *Regulating Technology as We Rewrite Nature*, 102 B.U. L. REV. ONLINE 29, 30 (2022).

[29] *Id.* at 31.

Suter and Cahn refer to the Supreme Court's two-prong approach articulated in *Washington v. Glucksberg*,[30] in which the Court concocted a standard to determine whether a fundamental right exists in the Constitution.[31] Under *Glucksberg*, the asserted right must (1) be "objectively, 'deeply rooted in this Nation's history and tradition'" and (2) include a "'careful description' of the asserted fundamental liberty interest."[32] To the extent that the Court may apply a narrow interpretation of *Glucksberg* as controlling the inquiry of whether a select use of GGE constitutes a cognizable fundamental right under the Constitution *today*,[33] I am inclined to concur with Suter and Cahn's analysis because modern GGE constitutes "a nascent biotechnology" not yet proven safe and effective, for which "no deeply rooted history exists."[34] *Rewriting Nature* recognizes that contingency.

My analysis and conclusion on this topic, however, ultimately diverge from Suter and Cahn's perspective because of the structural constitutional jurisprudence erected after *Glucksberg*. Most notably, my thesis recognizes that *Lawrence v. Texas*[35] and *Obergefell v. Hodges*[36] jointly abrogate *Glucksberg*'s approach to determining fundamental rights and indeed abandoned the type of rigid application that Suter and Cahn invoke in their analysis. *Lawrence*, for example, clarified that "[h]istory and tradition are the starting point but not in all cases the ending point of the substantive due process inquiry."[37] *Obergefell* subsequently qualified *Glucksberg*'s specific breed of substantive due process. *Obergefell* noted that the definition of rights "in a most circumscribed manner, with central reference to specific historical practices, . . . may have been appropriate for the asserted right" of physician-assisted suicide in *Glucksberg* but is not the approach the Court has "used in discussing other fundamental rights, including marriage and intimacy."[38] The Court explained that certain fundamental rights protected by the Constitution "come not from ancient sources alone. They rise, too, from a better informed understanding of how constitutional imperatives define a liberty that remains urgent in our own era."[39]

Obergefell's reasoning thus expressly distinguished the nature of the right under review. On one hand, the Court endorsed *Glucksberg*'s narrow holding, which ascribed more weight to historical practices and tradition when striking a

[30] 521 U.S. 702 (1997).

[31] *Id.* at 720-21.

[32] *Id.*

[33] It is, however, quite unlikely that the Court would grant certiorari to address that question today.

[34] ENRÍQUEZ, *supra* note 1, at 337.

[35] 539 U.S. 558 (2003).

[36] 576 U.S. 644 (2015).

[37] *Lawrence*, 539 U.S. at 572 (quoting Sacramento v. Lewis, 523 U.S. 833, 857 (1998) (Kennedy, J., concurring)).

[38] *Obergefell*, 576 U.S. at 671.

[39] *Id.* at 671-72.

purported right of physician-assisted suicide—a right involving, at its core, the *termination of life*. Conversely, the Court went out of its way to explain that a narrow reading of *Glucksberg*—one centered exclusively on such reference to historical practices—was *not* the appropriate analytical framework with which to examine other rights involving marriage and intimacy, which stem from broad protected liberties that are associated with the *family-unit sphere and procreation* rights.

This nuanced distinction involving fundamental rights—namely, whether the judiciary has implicitly been distinguishing rights associated with the termination of life versus advancement of liberty and autonomy in the procreation and family-unit contexts—is significant for purposes of discussing whether a cognizable right to select uses of GGE may exist under the Constitution. A fundamental right involving parental autonomy to make healthcare decisions and use GGE to rescue one's child from death and suffering at the hands of congenital disease would be the polar opposite of the asserted right to terminate one's life that *Glucksberg* rejected.

The post-*Glucksberg* line of precedents informs the distinctions that *Rewriting Nature* draws between a putative right related to specific uses of GGE and the breed of substantive due process articulated in the privacy realm, which includes *Roe v. Wade*[40] and its progeny. For instance, *Roe* protects a woman's constitutional right to terminate her pregnancy.[41] The Court has restricted such a right in recent decades by incorporating an "undue burden" standard into its jurisprudence.[42] My collective reading of these precedents suggests that at least some members of the Court in recent decades have tacitly applied a heightened version of legal scrutiny—perhaps something akin to the strict-scrutiny standard that exclusively applies to *government* action impinging fundamental rights—in private substantive-due-process cases involving the termination of life, regardless of whether the circumstances arise at an embryonic stage or the point of imminent death. This would explain why cases like *United States v. Rutherford*[43] and *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*[44] have failed to crystallize certain rights for terminally ill patients. *Rewriting Nature* hints at this distinction, but I am indebted to Suter and Cahn's thoughtful essay for prompting me to more clearly articulate this point here.

[40] 410 U.S. 113 (1973).

[41] *Id.* at 154 ("[T]he right of personal privacy includes the abortion decision.").

[42] *See, e.g.*, Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 876 (1992) (plurality opinion) ("[T]he undue burden standard is the appropriate means of reconciling the State's interest with the woman's constitutionally protected liberty.").

[43] 442 U.S. 544, 559 (1979) (holding that the FDA can preclude terminally ill cancer patients from obtaining a drug not recognized as "safe and effective").

[44] 495 F.3d 695, 713 (D.C. Cir. 2007) (holding that there is no such right of access to experimental drugs that have not been proven safe and effective).

Elucidation of the heightened standard applicable in termination-of-life cases, as well as the legal treatment afforded to them under the current substantive-due-process framework, further buttress my proposition that *Roe* and its progeny are largely inapplicable to the GGE context discussed herein. After all, "clinical interventions to cure or ameliorate disease in an embryo—with the intent to *save* a child from premature death—are at the opposite end of what abortion achieves."[45] The parents who seek GGE want to rescue their offspring from imminent death caused by harmful genetic mutations, whereas the parents who seek an abortion do not wish to bring the embryo to term. Framing the issue in this context may determine what breed of substantive due process presumably applies to the facts of a given case.

Suter and Cahn's resistance to my proposed theory discerning among discrete subtypes of substantive due process may explain why they argue that substantive-due-process rights are "on shaky ground" and worry that "[i]f *Roe* falls," so too might "other fundamental rights, such as same-sex marriage."[46] Perhaps Suter and Cahn are right. But I am less convinced than they may be in this regard.

The GGE fundamental-right arguments I advance in *Rewriting Nature* are largely independent of *Roe*'s specific brand of privacy-based substantive due process. Several sections of the book note, for example, that a cognizable right that protects select uses of GGE may encompass a right "in its comprehensive sense"[47] and flow from jurisprudence related to "procreative, parental autonomy, and—*to some extent*—privacy rights."[48] The analytical thrust of my proposed framework could, therefore, outlast a potential demise of *Roe*'s viability as a constitutional precedent.

On this point, like Suter and Cahn, I too point to comments by Justices of the Supreme Court, who have previously expressed a willingness to overrule certain substantive-due-process precedents.[49] But I would go a step further and discern the specific "species" or subtype of substantive due process inherent in each commentary. To my knowledge, even the most "conservative" jurists have not expressed an appetite for outright overruling procreation-based and parental-autonomy substantive-due-process holdings directly predicated upon *Meyer v. Nebraska*,[50] *Pierce v. Society of Sisters*,[51] and *Skinner v. Oklahoma*[52]—all

[45] ENRÍQUEZ, *supra* note 1, at 346 (emphasis added).

[46] Suter & Cahn, *supra* note 28, at 32.

[47] Obergefell v. Hodges, 576 U.S. 644, 671 (2015).

[48] *See, e.g.*, ENRÍQUEZ, *supra* note 1, at 331, 337, 338 (emphasis added).

[49] *See, e.g.*, *id.* at 353 n.76; Suter & Cahn, *supra* note 28, at 32 n.24.

[50] 262 U.S. 390 (1923).

[51] 268 U.S. 510 (1925).

[52] 316 U.S. 535 (1942). *Skinner* held that the right to procreate was both a fundamental *right* and *liberty* protected under the Constitution. *See id.* at 541. Thus, while the Court's majority struck down the Oklahoma sterilization statute under equal-protection grounds, it also hinted at the application of substantive due process. The concurring opinions expressly

precedents that, at this point, are very long in the tooth. It is hard to fathom that most, if not nearly all, of the Justices appointed to the Court in recent decades would, for example, uphold a statute impinging on the parental autonomy to decide whether to send children to parochial schools. In a similar vein, when viewed through the termination-of-life prism—rather than the one-size-fits-all, substantive-due-process lens—it seems plausible but, overall, less probable that a panel of Justices would open the door to the States' annulling some subset of more than 500,000 same-sex marriages.[53]

My argument here stems from the observation that even some individuals who outright reject *Roe*, *Lawrence*, and *Obergefell* would effectively make a substantive distinction between the rights of gay and lesbian couples to marry under *Loving* and the rights of women to terminate a pregnancy under *Roe*. Because the former implicates a right within the family-unit sphere (in closer proximity to parental-autonomy precedents) and the latter involves what some may frame as the termination of life (in line with *Roe*), the two would presumably share different fates if a particular branch of the doctrine of substantive-due-process tree falls; one branch may fall while others hold up, so long as the tree still stands.

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Lastly, Suter and Cahn astutely comment on the evolving composition of the Supreme Court and surmise that "it is highly improbable, at a moment when substantive due process interests seem especially vulnerable, that the Court would recognize a fundamental procreative interest in [ART] and especially to genetically manipulate one's offspring in a manner that could be heritable to future generations."[54] I wish to counter this proposition by making two brief points.

First, Suter and Cahn frame the issue as one involving a fundamental right "to genetically manipulate one's offspring."[55] The ultimate framing of an issue presented for judicial review plays a pivotal role in the outcome of a given case. In *Rewriting Nature*, I draw parallels to the questions presented in *Glucksberg*,

invoked due process. *See id.* at 544-45 (Stone, C.J., concurring); *id.* at 546 (Jackson, J., concurring). In any event, Justices have recognized that the right to procreate under *Skinner* provides support to other rights protected under substantive due process. *See, e.g.*, *Obergefell*, 576 U.S. at 674-75 (linking the right to procreate to the later-recognized right to marry); *id.* at 691 (Roberts, C.J., dissenting) (same).

[53] A recent May 2020 study reported there were an estimated 513,000 married, same-sex couples in the United States. *See* Christy Mallory & Brad Sears, *The Economic Impact of Marriage Equality Five Years After* Obergefell v. Hodges, UCLA SCH. OF L. WILLIAMS INST. (May 2020), https://williamsinstitute.law.ucla.edu/publications/econ-impact-obergefell-5-years/ [https://perma.cc/JN7K-ZG9P].

[54] Suter & Cahn, *supra* note 28, at 32.

[55] *Id.*

Bowers v. Hardwick,[56] and *Lawrence* to posit that the answer to whether parents have a cognizable right to select uses of GGE under the Constitution would vary under a series of hypothetical statements.[57] Suter and Cahn's framing mirrors one of those statements, which presumably carries a negative connotation: Is there a right to "genetically modify offspring"?

Parents would better serve their interests by framing the question as one associated with a right to rescue offspring from, in some cases, an imminent death; or more broadly, to make child-healthcare decisions to prevent impending life-threatening disease or death. Again, these questions can evoke the sort of nuanced, substantive-due-process subtype distinctions I discuss in this Essay. More importantly, they play a role in elucidating whether the right in question involves an entirely novel fundamental right (genetic modification) or represents a mere *extension* of already-existing fundamental rights rooted in parental autonomy and procreation (making child-healthcare decisions).

Second, with regard to the argument that the proposed fundamental right associated with GGE is unlikely to materialize at this moment due to an "increasingly conservative" Supreme Court, admittedly I have no idea what the Court may do in a case that raises the GGE constitutional question under discussion. Nor have I the slightest idea as to the composition of the Court ten or twenty years from now. Above all, we must remember that the GGE constitutional questions raised in the book are on the distant horizon. *Rewriting Nature* is forward-looking and seeks to explore these issues early on so that we have ample time to contemplate the benefits and potential downsides associated with uses of the technology.

In the end, I think Suter and Cahn make an excellent point that ought not to be overlooked, which is that these issues do not arise in a vacuum of science, law, and policy. *Rewriting Nature* acknowledges that the composition of the Court at a particular point in time would be an important factor to consider.[58] Perhaps I am too sanguine, but part of me generally resists the urge to think of these issues along political lines. I will offer one last comment on this point.

The current COVID-19 pandemic has led to an increase in the political polarization of vaccine mandates. The Court has been called on to resolve disputes about such mandates.[59] Regardless of how each Justice has come down in favor or against a vaccine mandate in a given context, all Justices are nevertheless fully vaccinated.[60] They have availed themselves of a scientific

[56] 478 U.S. 186 (1986).

[57] *See* ENRÍQUEZ, *supra* note 1, at 347.

[58] *See id.* at 353 n.76.

[59] *See* Biden v. Missouri, 142 S. Ct. 647 (2022); Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin., 142 S. Ct. 661 (2022).

[60] Jessica Gresko & Mark Sherman, *High Court Confirms Justices Have Received COVID-19 Booster*, AP NEWS (Jan. 4, 2022), https://apnews.com/article/coronavirus-pandemic-joe-biden-us-supreme-court-health-centers-for-disease-control-and-prevention-85207706b48cc76147a17d7a476fd9c6.

breakthrough—a messenger ribonucleic acid ("mRNA")-based vaccine—to protect their lives. So too have most representatives in Congress, regardless of political affiliation. The point is that many of these issues, including vaccinations, can certainly be political and become politicized. But it does not have to be so. Judges are human, after all. They have surprised legal experts by voting in unexpected ways in myriad cases—Kennedy in *Lawrence*,[61] O'Connor in *Grutter v. Bollinger*,[62] Gorsuch in *Bostock v. Clayton County*,[63] Roberts in *NFIB v. Sebelius*,[64] to name a few—and will continue to do so.

Regardless of political association, I am confident that judges are unified in protecting the lives of children. My hope is that precedent, science, as well as tempered, science-based law and policy—not politics—will be the driving forces that shape the future of GGE. I have no principled reason to believe that, at some point in the future, judges would summarily dismiss the pleas of desperate parents and haphazardly oppose a safe and effective treatment that can spare the life of a child because they are bound to blindly follow a particular constitutional ideology. My sincere hope is that by the time that future comes, *Rewriting Nature* will have at least contributed to jumpstarting relevant science-based discussions about those future issues surrounding genome editing.

III. COUNTERING SKEPTICISM OF SCIENTIFIC PROGRESS

Professor Drabiak offers a different critique of my proposed approach to GGE. She is doubtful that GGE will ever be safe and effective. Based on a presumption of "unknown factors" associated with GGE, she argues that parents lack the authority to make decisions that can "substantially limit [a] child's life path."[65] She further argues for a "right to an open future," which would limit parental authority to consent to GGE medical interventions or, in the alternative, a "right to genomic integrity" that would forbid carrying out "intentional germline modifications."[66]

Drabiak's essay offers a provocative viewpoint that induced me—and probably other symposium participants—to think about GGE from another angle. It is clear, however, that we approach law and science differently.

From my perspective as a scientist, the most unexpected of her arguments is perhaps the assertion that GGE "will *never* be safe and effective."[67] The "never-

[61] 539 U.S. 558 (2003).

[62] 539 U.S. 306 (2003).

[63] 140 S. Ct. 1731 (2020).

[64] 567 U.S. 519 (2012).

[65] Katherine Drabiak, *Framing Germline Modifications of Human Embryos*, 102 B.U. L. REV. ONLINE 7, 15 (2022).

[66] *Id.*

[67] *Id.* at 12 (citing George J. Annas, Lori B. Andrews & Rosario M. Isasi, *Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations*, 28 AM. J.L. & MED. 151, 154-78 (2002) ("[M]any believe that . . . inheritable

will" proposition in this regard deals in absolutes and is laden with the type of "value judgment"[68] that she ascribes to the scientific community when it points to incremental advances in basic research as the basis for its optimism about a given technology. Optimism, however, is clearly distinguishable from hype. The former is grounded on promising results from empirical research, which spotlight areas of improvement and future research directions. The latter is unsupported by evidence, replete with deceptive simplicity,[69] and prone to manipulation by parties with ulterior motives.

The principle underlying the never-will assertion further concerns me because it implies an unwillingness to consider new evidence that may disprove a given hypothesis. That is antithetical to the scientific method and would all but foreclose an open dialogue about the potential benefits and harms of developing and using any nascent technology. As Professor Barrangou articulated, science and technology are here to help humanity solve big problems that call for big solutions.[70] Averring that GGE will never be "safe and effective" would be akin to claims that interoceanic aviation would never have been safe, or even possible, because the 1903 Wright Flyer covered a ground distance of 120 feet.[71] The same holds true about the once-nascent technology that brought us the mRNA vaccines against SARS-CoV-2, the virus that causes COVID-19. And let's not forget in vitro fertilization ("IVF"), which since 1978 has led to the birth of more than eight million babies.[72]

Safety and efficacy are relative terms. GGE is no different than other therapeutic contexts in that regard. The U.S. Food and Drug Administration's ("FDA") determination that a drug is safe, for example, does not indicate a complete absence of risk or potential harm. Safety means that the therapeutic "benefits of the drug outweigh the risks."[73]

Adherence to a "never-will" principle would have precluded virtually every modern-era, technological advance in telecommunications, space travel, human medicine, transportation, and more. We should not be skeptical of robust scientific evidence. Scientists, however, must ground their optimism about a given technology firmly in scientific facts to avoid misinterpretation of scientific progress. On that point, *Rewriting Nature* warns that GGE is "not yet ready for

genetic alternations at the embryo level will never be safe because they will always be inherently unpredictable in their effects on the children and their offspring.")).

[68] *Id.* at 7, 10, 14.

[69] *See* ENRÍQUEZ, *supra* note 1, at 386 n.72.

[70] Rodolphe Barrangou, *Boston University Law Review Online* Virtual Discussion on *Rewriting Nature* (Nov. 5, 2021).

[71] *1903 Wright Flyer*, SMITHSONIAN NAT'L AIR & SPACE MUSEUM, https://airandspace.si.edu/collection-objects/1903-wright-flyer/nasm_A19610048000 (last visited Mar. 11, 2022).

[72] Bart CJM Fauser, *Towards the Global Coverage of a Unified Registry of IVF Outcomes*, 38 REPRODUCTIVE BIOMEDICINE ONLINE 133, 133 (2019).

[73] 21 U.S.C. § 355-1(a)(1).

primetime"[74] and that any experiments in the human germline at this time would be "premature" and pose risks not outweighed by potential benefits.[75] Ultimately, we must not lose sight of the fact that GGE is a promising, nascent biotechnology that will continue to develop and improve in years to come.

Still, my most substantive disagreement with Drabiak concerns her discussion of the rights to "an open future" and "genomic integrity."[76] The rights are tentative and lack specificity; they appear to enshrine an ideal but are rife with obstacles that would preclude their application in the law. The rights also leave me wondering about their source of origin, presumptive limits, constituent elements, how they would be implemented, what mechanisms of enforcement would be available, and how they would interact with other related rights. The language associated with the framing of these rights leads me to assume, perhaps incorrectly, that they derive from human-rights treaties. Accordingly, I wonder about the kinds of obstacles Drabiak foresees in efforts to incorporate them into domestic law, and whether they would be self-executing.

I further question what it means to have an amorphous right that protects "genomic integrity." Drabiak explains that the right "preclude[s] intentional germline modifications."[77] But does this mean the right suggests that a purported sanctity (inviolability) of the human germline must be protected? If so, does it follow that we have a duty to maintain the integrity of genomic loci that trigger human disease and death? I am not persuaded that the integrity of a genome featuring a deleterious mutation that causes, for example, Tay-Sachs disease or Cystic Fibrosis is worthy of protection under a fundamental right.

If we equate this presumed germline-integrity argument with a right to *bodily* integrity, how should we reconcile said right against the constitutionally recognized principle of parental autonomy to make decisions on behalf of children, including granting or withholding consent for medical care? Suppose a toddler with a severe form of aortic stenosis, a congenital heart defect that may lead to congestive heart failure, needs a heart transplant. Assuming the parents opt in favor of the surgery, would that decision render them infringers of the child's right to bodily integrity? The likely answer under the law of parental autonomy to direct offspring medical-care decisions is no. It is therefore hard to reconcile this concept against a right to "germline integrity" solely because the treatment is molecular in nature and occurs at an embryonic stage. I admit I do not quite understand the logic dictating that at some point in the future, if and when the technology is safe and effective, preventing offspring death and

[74] ENRÍQUEZ, *supra* note 1, at 161, 337. *See also* Paul Enríquez, *Genome Editing and the Jurisprudence of Scientific Empiricism*, 19 VAND. J. ENT. & TECH. L. 603, 666 (2017).

[75] ENRÍQUEZ, *supra* note 1, at 276.

[76] Drabiak, *supra* note 65, at 15 & n.47 (referencing Dena S. Davis's theory of a right to an open future).

[77] *Id.* at 15.

suffering with the use of GGE constitutes an "infringe[ment] upon the dignity and rights of the future child."[78]

The right to an "open future" is similarly ambiguous. Revisiting the aortic-stenosis hypothetical above, under Drabiak's proposal, parents who choose the heart-transplant procedure would likely violate the child's rights because a heart transplant carries significant risks, including death, and is *not ever completely* safe and effective. The parents could not consent to the transplant because it constitutes an intervention that may "substantially limit their child's life path."[79] But would not parents also violate the "open-future" right if they do nothing and allow congestive heart failure itself to limit the child's life path?

Medical-care decisions of this sort are deeply personal. At a minimum, however, a safe and effective medical intervention performed at the molecular level, which cures or protects a child from serious illness or death, cannot ipso facto violate any children's rights. As *Rewriting Nature* notes, implied consent is logically embedded in the parental autonomy to make medical-care decisions regarding the use of therapeutic GGE intervention.[80] Surely, the child whose corrected germline once bore a deleterious mutation that causes Tay-Sachs disease would not grow up wishing her parents did nothing to spare her from a life-threatening disease, death, and suffering.

IV. ON THE NEXUS OF GENOME EDITING AND ADMINISTRATIVE LAW

Professor Greely's creative and forward-looking essay contributes a wealth of perspectives, ranging from human genome editing and art to law and regulation, and constitutes a resource for a myriad of future paper topics.[81] I wish to tackle two brief points warranting clarification—one about the regulation of crops in this Section and another about GGE in the concluding Section.

Greely, Professor Gould, and I agree that a regulatory system for crops should focus on the product at issue, rather than the process by which it was created.[82] I also agree that regulation should be commensurate with the degree of risk inherent in each product derived from genome editing. Greely's view that my "basic position is that if no meaningful differences exist between non-regulated and regulated crops, neither should be regulated,"[83] however, oversimplifies my stance about the future regulatory scheme for genome-edited crops.

A significant portion of my analysis and recommendations about the regulation of crops in *Rewriting Nature* are guided by the Chapter 7 hypothetical embodiment, which contemplates the making of a fungus-resistant banana crop using recombinant DNA-free genome editing that features a single-point

[78] *Id.*

[79] *Id.*

[80] ENRÍQUEZ, *supra* note 1, at 368.

[81] *See generally* Greely, *supra* note 21.

[82] *See, e.g.*, ENRÍQUEZ, *supra* note 1, at 256.

[83] Greely, *supra* note 21, at 20.

mutation in a receptor protein.[84] Based on the specific facts concerning that embodiment, a mutant crop that has zero foreign DNA and is—but for the single-residue substitution—genetically identical to its naturally occurring counterpart should not be subject to onerous regulations applicable to crops derived from older genetic-engineering techniques.[85] My regulatory prescription for the deregulation of such crops devoid of foreign DNA, therefore, extends exclusively to that fact pattern. The choice to cabin a regulatory analysis to that embodiment was deliberate, so as to allow substantive and nuanced discussion of regulation of that crop. I did not expand on the many other possible types of gene-edited crops due to space constraints and other factors. But *Rewriting Nature* alludes that a different regulatory scheme would be applicable to crops featuring other types of genetic modifications.[86] And I have further discussed some of these distinctions in greater detail in previous works.[87] To make clear, I neither advocate nor endorse a simplistic one-size-fits-all approach to the regulation of crops.

Suter and Cahn, for their part, embrace much of *Rewriting Nature*'s proposed GGE regulatory framework. They also strengthen my arguments by placing them "in the context of other potential regulatory structures."[88] I embrace their feedback in full as it provides additional support for a robust GGE regulatory framework based on science, ethics, and the free market. I only wish to focus briefly on their suggestion that, because the FDA does not specialize in reproductive technologies, it may be useful to look to other administrative agencies such as the UK Human Fertilisation and Embryology Authority, the UK regulatory agency for fertility treatment and research. Although many before us have proposed the creation of a new agency in the United States to oversee matters of reproductive technology, Suter and Cahn's essay persuades me to contemplate this matter further in future works. The idea is provocative and interests me because it calls for a "metanationalist"[89] approach to ART regulation. Certainly, it would be beneficial to inspect and study comparative international law to address the issue of future GGE regulation, which has become a "global problem" in the wake of the 2018 birth of the first gene-edited babies in China.[90]

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[84] *See* ENRÍQUEZ, *supra* note 1, at 252-53.

[85] *Id.*

[86] *See, e.g.*, *id.* at 254-56.

[87] *See, e.g.*, Paul Enríquez, *CRISPR GMOs*, 18 N.C. J.L. & TECH. 432, 538 n.536 (2017).

[88] Suter & Cahn, *supra* note 28, at 33.

[89] Paul Enríquez, *Deconstructing Transnationalism: Conceptualizing Metanationalism as a Putative Model of Evolving Jurisprudence*, 43 VAND. J. TRANSNAT'L L. 1265, 1269, 1303-10 (2010).

[90] *See* Paul Enríquez, *Editing Humanity: On the Precise Manipulation of DNA in Human Embryos*, 97 N.C. L. REV. 1147, 1152-53 (2019).

ADDITIONAL PERSPECTIVES AND FUTURE DIRECTIONS

This final Section addresses miscellaneous commentary, reflects on the progress made, and contemplates perspectives about the future of genome editing.

Although Greely endorses my approach to GGE, he contends I make an important error by "dismiss[ing] preimplantation genetic diagnosis" ("PGD") as an alternative to GGE intervention.[91] To be clear, I do not advance the proposition that PGD is an unsuitable alternative for GGE in some contexts. Nor do I mean to imply that *certain heterozygous* couples who might potentially carry a faulty allele cannot successfully avail themselves of PGD to conceive a healthy child.[92] To the contrary, both GGE and PGD are methods that could, and likely will, be used side-by-side. My comments about the limitations of PGD relate mostly to homozygous parents—namely, couples in which each parent carries an allele with deleterious genetic mutations that guarantee the onset of genetic disease in their offspring—and concern the practicability of using PGD to help such couples conceive healthy children.

For this category of homozygous parents carrying a faulty allele, GGE is virtually the only way to conceive an otherwise healthy, biologically related child.[93] That is because *every* fertilized embryo available for implantation features the faulty alleles (because each parent carries a copy of said allele). No amount of PGD in that scenario would allow the parents to screen among embryos for one without the faulty alleles. For them, PGD is *not* a viable alternative to conceive healthy offspring. This contrasts with the case of a heterozygous couple who could, in theory, screen for embryos without faulty alleles. The problem is that the heterozygous couple would potentially need to produce and screen many embryos, which can be expensive and lead to otherwise "good" embryos being discarded. In that sense, GGE would benefit even the heterozygous parents because they would potentially need to produce fewer embryos. After performing GGE, they could then screen a subset of embryos prior to implantation.

Professor Carroll participated in the 1975 Asilomar Conference on Recombinant DNA and the recent International Summits on Human Genome Editing in 2015 and 2018 and, thus, brings a wealth of experience to the discussion. His essay reflects a thoughtful and measured approach to human GGE. While he agrees with my general GGE approach, he notes that it is difficult for him to understand why I might leave a door open for potential GGE

[91] Greely, *supra* note 21, at 17.

[92] In this context, I use "faulty allele" to refer to an allele that features a genetic mutation associated with the onset of a genetic disorder or disease.

[93] *See* ENRÍQUEZ, *supra* note 1, at 364. I suppose one alternative would be to perform GGE on each of the parental gametes, rather than on the fertilized embryo. But that is beyond the scope of the subject of GGE in human *embryos* contemplated in that section.

cosmetic modifications but, at the same time, foreclose editing the human germline to modify some disabilities.[94]

Carroll refers to the proposed four-tiered, normative framework in Chapter 11, which distinguishes among permissible and impermissible uses of GGE technologies.[95] My response to Carroll's question embarks from the recognition of a special history of irrational discrimination against some minority groups on the basis of race, gender, sexual orientation, specific disabilities, and other protected categories under the law.[96] Such past discrimination strongly counsels against sanctioning GGE to modify traits associated with protected groups, regardless of whether the modifications are technologically feasible. Unlike certain therapeutic GGE interventions for which evidence exists to establish safety and efficacy in the near future, cosmetic uses of GGE are not technologically feasible at this time and raise fewer concerns about unlawful discrimination against protected classes.

Consider a set of parents seeking to perform GGE to edit an embryo's race and eye color. *Rewriting Nature* explains that there is no constitutional justification to modify an embryo's race because the law already prohibits racial discrimination.[97] Having green eyes, however, is not associated with a protected class under the law. GGE aimed at eye-color modifications may give rise to ethical, access, and other equitable considerations but, so long as the technology is safe and effective to use, such interventions may warrant a less restrictive approach because (1) they are distant in the future and (2) do not raise serious concerns of insidious discrimination. The *nature* of the GGE intervention sought should, therefore, dictate whether a specific GGE use ought to be banned or regulated. *Rewriting Nature* proposes a framework to assist in making those important distinctions among GGE subtypes. The framework is flexible. In the disability realm, for example, it counsels against modifying traits related to certain protected disabilities such as deafness, while recognizing that GGE associated with disabilities closely linked to therapeutic conditions (such as diabetes and congenital cardiovascular disease) may be permissible.[98]

This brings me to Professors Goodwin and Whelan's contribution, which fits neatly within a growing body of law and social-science literature focused on the intersection of genetics, clinical ethics, and social equality.[99] I welcome and embrace their essay in full and am delighted to see that it fills an important gap in the conversation. I devote some space in *Rewriting Nature* to issues of social inequality, inequity, and institutional discrimination, but I do not explore topics

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[94] Dana Carroll, *Rewriting Nature: The Case of Heritable Human Genome Editing*, 102 B.U. L. REV. ONLINE 1, 6 (2022).

[95] ENRÍQUEZ, *supra* note 1, at 360-78.

[96] *See id.* at 368.

[97] *Id.*

[98] *See id.* at 370-71.

[99] *See, e.g.*, Laura Hercher & Anya E.R. Prince, *Gene Therapy's Field of Dreams: If You Build It, Will We Pay?*, 97 N.C. L. REV. 1463 (2019).

of fairness, cost, and access to genome-editing technologies with any sufficient depth. The advent of genome editing and its application to myriad facets of society raise an alarming potential to exacerbate healthcare disparities between privileged and nonprivileged communities. Goodwin and Whelan forecast that the incidence of some diseases among "wealthy, largely White, populations will decrease, while those in historically marginalized or vulnerable populations will remain unchanged or even worsen."[100] Sadly, I agree. But I am encouraged by the work being done by scholars, community leaders, and regulators to build networks and support the institutional infrastructure that will ameliorate social inequality as healthcare-related technologies continue to develop.

Lastly, I want to acknowledge the significant contributions of Professors Barrangou, Cohen, Conley, Gould, and Marchant.[101] Gould and Barrangou—as did Greely—sagaciously noted the importance of focusing on nonhuman uses of genome editing, which can arguably exert a greater impact on society in the long run. Gould's discussion about "omics" technologies and the increased use of artificial intelligence and data science in crop breeding added context to *Rewriting Nature*'s push to adopt science-based regulatory frameworks that focus on products, rather than the processes through which they are derived. Barrangou provided compelling arguments for deploying genome-editing tools to modify trees and forests, which could help ameliorate the impacts of the global climate-change crisis. Conley and Marchant added a much-needed soft-law perspective to the conversation and put the spotlight on the development of new informal mechanisms of international governance for emerging technologies. Finally, Cohen focused his perspicacious remarks on the nexus of normativity and the theory of a jurisprudence of scientific empiricism, which *Rewriting Nature* introduces as a theoretical structural framework to address questions of science in law. There is much to share about that theory, its underlying mechanisms, and methodology in future work.

My deepest thanks to the *Boston University Law Review* for making this symposium possible and to all participants, whose superb insights elevated the quality of the discourse. Conversations such as these are precisely what is needed to close the gap between law and science and pave the road ahead for genome-editing technologies. I look forward to many engaging and lively discussions in years to come.

[100] Allison M. Whelan & Michele Goodwin, *Will the Past Be Prologue? Race, Equality, and Human Genetics*, 102 B.U. L. REV. ONLINE 37, 39 (2022).

[101] *Boston University Law Review Online* Virtual Discussion on *Rewriting Nature* (Nov. 5, 2021).