REGULATING TECHNOLOGY AS WE REWRITE NATURE[†]

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In *Rewriting Nature*,[1] Dr. Paul Enríquez hails the development of genome manipulation as akin to the development of the printing press, a revolutionary technology with transformative potential.[2] Regardless of the hyperbole, genome editing has the potential to treat or cure genomic diseases, such as diabetes and cystic fibrosis.

The problem is how to regulate this new technology "to restrict the rise of a premature industry aimed at engineering genetically modified humans."[3] This is, as Enríquez notes, not a new problem; science often advances before lawmakers can catch up, as has happened repeatedly over the past half-century in the reproductive technology space. In this brief comment, we agree with Enríquez on the need to regulate this area. We challenge, however, some aspects of his articulation of a constitutional right to use the technology, particularly with respect to germline gene editing ("GGE"). We also raise questions about the appropriate means of regulation, which requires looking not just at principles for regulation but also the correct source of that regulation.

I. CONSTITUTIONAL RIGHT

Enríquez examines the constitutional implications of bans on or regulations of GGE, arguing that the constitutional interests in GGE differ for four different potential applications of the technology: "(1) therapeutic uses to remedy disease; (2) prophylactic purposes, which may or may not be of therapeutic nature; (3) cosmetic or enhancement purposes; and (4) uses involving modification of

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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] *Id.* at 1.

[3] *Id.* at 310.

traits that raise concerns of unlawful discrimination."[4] He finds robust constitutional protection for Category One and none for Category Four, which he argues should be prohibited.[5] And he argues that Categories Two and Three concern polygenic traits, making their clinical applications a distant reality, at best. As a result, he argues it would be premature to regulate such uses.[6]

Although sympathetic to the distinctions Enríquez draws, we are skeptical about his conclusion that there is a fundamental right to GGE to "remedy disease" or for any other purpose. He bases his finding of this right on the long line of substantive due process cases[7] and the late John Robertson's expansive theory of procreative liberty.[8] In short, he argues that whether a future child would "suffer a debilitating, lifelong illness would certainly play a fundamental role" in deciding to pursue parenthood. In his view, the "right to have offspring" or "procreate" doesn't mean much "if that offspring is destined to suffer disease and premature death," especially because this right is "crucial to the survival of the species."[9]

Like Robertson, Enríquez finds greatest support for this position in *Skinner v. Oklahoma*,[10] which declared that there was a fundamental "right to have offspring" and "to perpetuat[e] . . . a [human] race."[11] He notes the *Skinner* Court's concern that state-imposed sterilization could "cause races or types which are inimical to the dominant group to *wither* and *disappear*."[12] Enríquez interprets these statements to suggest that the "constitutional structure erected by *Skinner*" protects not just biological procreation, but also the production of "offspring healthy enough to fulfill the biological role of perpetuating one's genotype."[13]

This line of reasoning, however, does not engage with several counterarguments. First, it is not clear whether the procreative liberty interest in

[4] *Id.* at 361.

[5] *See id.* (proposing prohibition of Category Four uses "because they create a likelihood of unlawful discrimination against specific groups and are not constitutionally justifiable.").

[6] *See id.*

[7] *See id.* at 337-38 (first citing Washington v. Glucksberg, 521 U.S. 702 (1997); then citing Lawrence v. Texas, 539 U.S. 558 (2003); and then citing Obergefell v. Hodges, 576 U.S. 644 (2015)) (Enríquez finds, under a broad reading of *Glucksberg* abrogated by *Lawrence* and *Obergefell*, that the right to perform select GGE interventions "might be articulated as the right to bear healthy offspring . . . which derive[s] from already-existing fundamental rights").

[8] *See id.* at 347 n.1 (citing John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 422 (1996) ("[P]rinciples of reproductive freedom and family autonomy appear to support a presumptive liberty right to obtain and use genetic information in making reproductive decisions.")).

[9] *Id.* at 361-62.

[10] 316 U.S. 535 (1942).

[11] *Id.*at 536.

[12] ENRÍQUEZ, *supra* note 1, at 362 (quoting *Skinner*, 316 U.S. at 541 (emphasis added)).

[13] *Id.*

Skinner is limited to "natural" procreation as opposed to procreation that depends on some form of assisted technology. Certainly, at the time the Court described the interest in procreation as fundamental, the Justices were not imagining procreation via in vitro fertilization ("IVF") or in combination with genetic manipulation of embryos or gametes. In addition, as scholars have noted, *Skinner* might best be understood to protect bodily integrity,[14] which would have no application to assisted reproductive technologies such as GGE that involve manipulation of gametes or embryos ex vivo. Moreover, the line of substantive due process cases related to procreation address the right *not to* procreate, through contraception or abortion,[15] not the right *to* procreate.[16]

Furthermore, the Supreme Court has expressed reluctance to apply substantive due process too broadly, even with respect to deeply personal decisions, such as medically assisted death. As then Chief Justice Rehnquist reasoned in *Washington v. Glucksberg*,[17] the key is whether the alleged liberty interest is part of our "Nation's history and tradition."[18] A rigid and literalist conception of our history and tradition clearly would not include any form of assisted reproductive technology, especially not germline genetic manipulation. Although IVF seems to deviate from our history and tradition, it mirrors in a petri dish the fertilization process that normally occurs in a fallopian tube. But there is no "natural" or *in vivo* version of procreation that involves intentional genetic manipulation of the embryo or gametes. The Rehnquist conception of fundamental liberty interests, therefore, would exclude any interest in GGE, whether to prevent "debilitating, lifelong illness" or to achieve some form of enhancement.

Finally, as the composition of the Supreme Court has become increasingly conservative, there is even more reason to be deeply dubious about a fundamental procreative liberty interest with respect to GGE. The appointment of Justices Kavanaugh and Barrett to fill, respectively, the seats of former Justice Kennedy and the late Justice Ginsburg has tipped the Court to a clear 6-3 conservative majority. One need only listen to the oral arguments in a case currently pending before the Court, *Dobbs v. Jackson Women's Health*

[14] *See, e.g.*, Radhika Rao, *Constitutional Misconceptions*, 93 MICH. L. REV. 1473, 1484-85 (1995) (reviewing JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES (1994)) ("The result in *Skinner* may simply rest upon the constitutional right to privacy of person, which prohibits state intrusions upon bodily integrity."); Sonia M. Suter, *The "Repugnance" Lens of* Gonzales v. Carhart *and Other Theories of Reproductive Rights*, 76 GEO. WASH. L. REV. 1514, 1526 (2008) ("In short, the Court itself is not fully sure whether it carved out a liberty interest grounded principally in bodily integrity, procreative rights, or relational interests.").

[15] Griswold v. Connecticut, 381 U.S. 479 (1965) (contraception); Roe v. Wade, 410 U.S. 113 (1973) (abortion).

[16] *See* Suter, *supra* note 14, at 1523-25.

[17] 521 U.S. 702 (1997).

[18] *Id.* at 721.

Organization,[19] to appreciate just how hostile the Court is to the jurisprudence underlying a procreative liberty interest.[20] *Dobbs* concerns the constitutionality of a Mississippi abortion ban at fifteen weeks, two months before viability, when the fetus can survive outside the woman.[21] That the Court took this case, which challenges a statute that so flagrantly violates nearly a half century of precedent following *Roe v. Wade*'s[22] prohibition of abortion bans before viability,[23] reveals how much the views of the Court have shifted. Moreover, the tenor of the questions on the part of the conservative Justices, except Chief Justice Roberts, suggests a willingness to undo the precedent of *Roe* explicitly or in effect.[24]

While one might distinguish abortion from other substantive due process rights, as some Justices and Mississippi's Solicitor General attempted to do, there is reason to believe that substantive due process rights are on shaky ground. If *Roe* falls, one might imagine a similar fall for other fundamental rights, such as same-sex marriage.[25] It is certainly no secret that several of the Justices are displeased by substantive due process jurisprudence generally, particularly when applied to interests that are not explicitly mentioned in the constitution.[26] Thus, 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 assisted reproductive technology and especially to genetically manipulate one's offspring in a manner that could be heritable to future generations. Although Enríquez distinguishes between "*Roe*'s brand of substantive due process" and that implicated by GGE,[27] the Court might not be

[19] 141 S. Ct. 2619 (2021) (granting petition for writ of certiorari).

[20] *See, e.g.*, Transcript of Oral Argument at 72-73, Dobbs v. Jackson Women's Health Org., 141 S. Ct. 2619 (2021) (No. 19-1392) [hereinafter *Dobbs*, Oral Argument].

[21] *See* Jackson Women's Health Org. v. Dobbs, 945 F.3d 265, 268-69 (5th Cir. 2019), *cert. granted*, 141 S. Ct. 2619 (2021); Mark Walsh, "*Feelings Run High": Two Hours of Tense Debate on an Issue that Divides the Court and the Country*, SCOTUSBLOG (Dec. 1, 2021, 7:22 PM), https://www.scotusblog.com/2021/12/feelings-run-high-two-hours-of-tense-debate-on-an-issue-that-divides-the-court-and-the-country/ [https://perma.cc/XW2B-FGLU].

[22] 410 U.S. 113 (1973).

[23] *Id.* at 163-64. This principle was reaffirmed in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992).

[24] *See* Sonia M. Suter, Opinion, *The Supreme Court Majority's Callous Disregard for Marginalized Women*, HILL (Dec. 11, 2021, 1:01 PM), https://thehill.com/opinion/judiciary/585295-the-supreme-court-majoritys-callous-disregard-for-marginalized-women [https://perma.cc/48QQ-D7TV].

[25] *See* Obergefell v. Hodges, 576 U.S. 644 (2015).

[26] Justice Thomas repeatedly asked the attorneys in the *Dobbs* oral arguments what the nature of the right was, noting that he understood "exactly" what the Second and Fourth Amendments are "talking about because [they're] written." *Dobbs*, Oral Argument, *supra* note 20, at 86.

[27] ENRÍQUEZ, *supra* note 1, at 345-46 (noting that clinical interventions to cure disease in an embryo "are at the opposite end of what abortion achieves").

persuaded. Moreover, he concedes that restrictions on government funding of GGE might be constitutional.[28]

II. REGULATION

Regardless of whether there is a constitutional right to access GGE, regulatory issues remain critical. The existence (or nonexistence) of a constitutional right does not determine how to regulate or the source of regulation, unless there is an outright ban. There are a range of possible responses to GGE, from a moratorium to a laissez-faire market, including potentially different sources of regulators.[29] As a baseline, in the United States, reproductive technologies, such as in vitro fertilization, the use of donor gametes, or preimplantation genetic testing, are subject to comparatively little mandatory regulation at the state and federal levels, with professional societies providing recommended standards about how and when to use the technologies. By contrast, GGE is subject to federal administrative regulation and Congressional funding oversight.[30] Enríquez proposes that the FDA regulate all forms of GGE, regardless of whether they are used therapeutically,[31] and he comprehensively explains why the limited federal court precedent suggests that this is a reasonable approach.[32] Yet it is important to place his proposal in the context of other potential regulatory structures to show just why it is so reasonable.[33]

A. *Free Market/Laissez-Faire*

At one end of the regulation continuum is a free market, or a "genetic supermarket," that would, on the buyer side, allow consumers free choice while, on the seller side, permit unconstrained production of new technologies.[34] This is comparable to Richard Posner and Elisabeth Landes's proposal for an

[28] *See id.*

[29] *See* Naomi Cahn & Sonia M. Suter, *The Art of Regulating ART*, 96 CHI.-KENT. L. REV. 29, 58 (2022).

[30] *See id.*

[31] *See* ENRÍQUEZ, *supra* note 1, at 300-01.

[32] *Id.* at 301-04.

[33] We have provided more details about such a continuum of approaches elsewhere, and this is a summary. *See* Cahn & Suter, *supra* note 29.

[34] Maartje Schermer, *Reprogenetic Technologies Between Private Choice and Public Good, in* HUMAN FLOURISHING IN AN AGE OF GENE EDITING, 212, 220-21 (Erik Parens & Josephine Johnston eds., 2019).

adoption market,[35] as well as to the existing market for in vitro fertilization and donor gametes.[36]

This model does not preclude regulation to monitor and penalize potential abuse of the market, such as through oversight of false claims, although such monitoring need not address safety testing, anti-discrimination, or other principles. If efficient, the market would self-regulate, with disreputable sellers being driven out through competition (or tort suits), and the market itself ensuring a reasonable price.

Such a market facilitates choice and innovation without stifling the development of new technologies.[37] Yet it also has drawbacks. First, many will be priced out of GGE, increasing the economic inequities already associated with access to reproductive technologies. Relatedly, it might lead to discrimination based on finances or sexual identity, for example, or decisions about which conditions to eliminate using the technology.

B. *Professional Organizations Guidelines*

An incremental step (towards government regulation) would allow professional organizations to establish either binding or advisory guidelines.[38] Professionals in the field, on this view, are best able to determine and protect against risks of the technology and support the needs of patients.[39] This involves deference to scientists, a concept that Enríquez might appreciate (although does not promote).

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[35] *See* Elisabeth M. Landes & Richard A. Posner, *The Economics of the Baby Shortage*, 7 J. LEGAL STUD. 323 (1978) (developing a model of supply and demand for babies for adoption under then existing pattern of regulation, showing how that regulation created a baby shortage by preventing a free market from equilibrating the demand for and supply of babies for adoption).

[36] *E.g.*,. NAOMI R. CAHN, TEST TUBE FAMILIES: WHY THE FERTILITY MARKET NEEDS LEGAL REGULATION (2009); Naomi Cahn & Sonia Suter, *Sperm Donation Is Largely Unregulated, But that Could Soon Change as Lawsuits Multiply*, CONVERSATION (Jan. 18, 2022), https://theconversation.com/sperm-donation-is-largely-unregulated-but-that-could-soon-change-as-lawsuits-multiply-174389

[37] *See* Julia D. Mahoney & Gil Siegal, *Beyond Nature? Genomic Modification and the Future of Humanity*, 81 LAW & CONTEMP. PROBS. 195, 211-12 (2018) (describing how government, nonprofit organizations, and profit-seeking firms all play important roles in biomedicine and offering suggestions for adapting biomedical oversight to present day realities); Michelle Bayefsky, *Who Should Regulate Preimplantation Genetic Diagnosis in the United States?*, 20 AMA J. ETHICS 1160, 1164 (2018) (providing an overview of professional self-regulation of preimplantation genetic diagnosis in the United States).

[38] *See* Myrisha S. Lewis, *Is Germline Gene Editing Exceptional?*, 51 SETON HALL L. REV. 735, 740 (2021) (arguing that regulatory treatment of gene editing in the United States should be similar to that of traditional IVF, "which is subject to physician self-regulation and state laws addressing the practice of medicine").

[39] Bayefsky, *supra* note 37**Error! Bookmark not defined.**, at 1164.

The logical entity is the American Society for Reproductive Medicine ("ASRM"), the professional organization for reproductive endocrinologists, which has already established professional norms for the types of practices that might engage in GGE.[40] ASRM could provide guidelines or more stringent oversight, complete with mandated reporting of guideline violations to federal or state authorities.

As with the free market system, downsides to this option include the lack of enforcement authority. Coupled with mandated reporting obligations and some limited state oversight, however, this objection could be allayed. Other objections concern the potential for discrimination by providers and, more fundamentally, the misalignment of interests with practitioners' presumable desire to facilitate increased usage of the technology and the public's potentially differing concern with possible ethical issues.

C. *The FDA*

One step further along the regulatory continuum would be, as Enríquez—and others—suggests, regulation through the FDA.[41] Enríquez traces the history of the FDA's earlier and more limited authority from the late nineteenth century to its more expansive role today. As the basis for the FDA's authority over GGE, Enríquez relies not just on the FDA's enabling statute but also on the *United States v. Regenerative Sciences LLC* opinion.[42] Arguing that the FDA's current gene therapy protocol is inadequate,[43] and that the FDA's lack of clear statement of authority over non-therapeutic gene therapy is problematic, he proposes instead that the FDA assert authority over any aspect of GGE, regardless of the potential use of such manipulations.[44] Although *Regenerative Sciences* covered somatic stem-cell therapy, he argues that its principles should apply more broadly.

Enríquez does address—and reject—potential legal objections to the FDA's assertion of authority, including whether GGE falls within its authority to regulate drugs, biological products, or medical devices, as well as the current limits on GGE and the argument that GGE simply involves the practice of

[40] *E.g.*, *Ethics Committee Opinions*, AM. SOC'Y REPRODUCTIVE MED., https://www.asrm.org/news-and-publications/ethics-committee-documents/ [https://perma.cc/B663-SJPF] (last visited Jan. 18, 2022); *Practice Committee Documents*, AM. SOC'Y REPRODUCTIVE MED., https://www.asrm.org/news-and-publications/practice-committee-documents/ [https://perma.cc/HF54-ZCKY] (last visited Jan. 18, 2022).

[41] *See* Yaniv Heled, *The Regulation of Genetic Aspects of Donated Reproductive Tissue—The Need for Federal Regulation*, 11 COLUM. SCI. & TECH. L. REV. 243, 289 (2010).

[42] *See* ENRÍQUEZ, *supra* note 1, at 301-04 (citing United States v. Regenerative Sciences LLC, 741 F.3d 1314 (D.C. Cir. 2014).

[43] *Id.* at 299-300.

[44] *Id.* at 300.

medicine.[45] It's important to note additional criticisms of the FDA that potentially undermine its legitimacy (although they, too, can be addressed).

First, some scholars point to the FDA's lack of insulation from politics.[46] Second, the FDA process is potentially cumbersome and sometimes secretive.[47] During the COVID-19 pandemic, the FDA was frequently faulted for delayed responses.[48] Moreover, the FDA does not specialize in reproductive or germline technology. Finally, its focus on safety means that it may not be adequately responsive to the technology's broader social or ethical implications.[49]

D. *Banning GGE*

The most restrictive approach is some form of moratorium or ban on the use of GGE.[50] This could cover both research and clinical uses of these technologies or just clinical uses. The justification is that further research is needed to address questions about safety and ethical implications before any use can be authorized.

Even if a ban is global in reach, there will still be a black market that would foster a variety of potentially unethical uses.[51] Moreover, given the very premise of *Rewriting Nature*, the technology is startling in its potential therapeutic scope, and a moratorium would prevent responsible development of a technology that has enormous potential.

Ultimately, like Enríquez, we agree that the FDA or a comparable federal entity, perhaps one similar to the British Human Fertilisation and Embryology Authority, should regulate all forms of gene editing.[52] Such a system could build on the strength of the free market and the expertise of professional organizations by fostering further development in line with scientific recommendations, yet also with sensitivity to ethical and moral issues.

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[45] *Id.* at 307-12.

[46] *E.g.,* Eli Y. Adashi, Rohit S. Rajan & I. Glenn Cohen, *When Science and Politics Collide: Enhancing the FDA*, 364 SCIENCE 628, 629 (2019).

[47] *E.g.*, Myrisha S. Lewis, *How Subterranean Regulation Hinders Innovation in Assisted Reproductive Technology*, 39 CARDOZO L. REV. 1239, 1288-90 (2018).

[48] *E.g.*, David Leonhardt, *Booster Confusion,* N.Y. TIMES (Oct. 20, 2021), https://www.nytimes.com/2021/10/15/briefing/johnson-and-johnson-booster-fda.html.

[49] Bob Zhao, *Mitochondrial Replacement Therapy and the Regulation of Reproductive Genetic Technologies in the United States*, 15 DUKE L. & TECH. REV. 121, 130 (2017) ("[B]ecause the FDA's mandate is limited to issues related to safety and efficacy, considerations regarding the "well-being" of the research participants and of society will be neglected under the FDA's authority.").

[50] Eric Lander, Françoise Baylis, Feng Zhang, Emmanuelle Charpentier, Paul Berg, Catherine Bourgain, Bärbel Friedrich, J. Keith Joung, Jinsong Li, David Liu, Luigi Naldini, Jing-Bao Nie, Renzong Qiu, Bettina Schoene-Seifert, Feng Shao, Sharon Terry, Wensheng Wei & Ernst-Ludwing Winnacker, Comment, *Adopt a Moratorium on Heritable Genome Editing*, 567 NATURE 165, 165 (2019).

[51] *See* ENRÍQUEZ, *supra* note 1, at 313.

[52] *See* Cahn & Suter, *supra* note 29, at 70.