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Finding a Regulatory Balance for Genetic Biohacking

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I INTRODUCTION

"Biohacking" has emerged as a cultural and scientific phenomenon. Although there is no consensus on the precise definition of "biohacking," the term generally describes biological investigations and interventions that are conducted outside of institutional scientific settings by individuals who may not have traditional scientific training.[1] Easier access to biological information and resources has enabled biohacking to flourish. Its participants often describe their activities as motivated by a belief in a right to "do science," a high value placed on bodily autonomy, and a view that traditional scientific institutions and regulations have systematically failed to benefit society.[2] It is difficult to quantify the number of individuals worldwide who participate in biohacking, given disagreement about what counts as biohacking, the constant flux of individuals entering and leaving biohacking communities, and the communities' decentralized natures. As one estimate, the DIYbio Google Groups counted over 5,000 members in early 2020.[3] As another estimate, a 2017 Brookings Institute report estimated that there were 30,000 "enthusiasts, followers, biohackers and citizen scientists" in the United States alone.[4]

[*] We thank Barbara Evans, Hank Greely, Max Mehlman, and the participants in the 2019 Petrie Flom Center Annual Conference for thoughtful comments and discussion. We also thank the participants in the 2018 interview study discussed in this chapter for sharing their biohacking and citizen science insights and experiences.

[1] See Amelia Fiske et al., Conceptual and Ethical Considerations for Citizen Science in Biomedicine, in Personal Health Science 195, 198–99, 204 (Nils B. Heyen et al., eds. 2019); see also Barbara J. Evans, Programming Our Genomes, Programming Ourselves: The Moral and Regulatory Limits of Self-Harm in Do-It-Yourself Gene Editing, in Consuming Genetics (I. Glenn Cohen, et al., eds. 2020); Maxwell J. Mehlman and Ronald A. Conlon, Governing Non-Traditional Biology, in Consuming Genetics (I. Glenn Cohen, et al., eds. 2020).

[2] See Lisa C. Ikemoto, DIY Bio: Hacking Life in Biotech's Backyard, 51 U.C.D. L. Rev. 548, 548–54 (2017); Daniel Grushkin et al., Woodrow Wilson Ctr., Seven Myths and Realities About Do-it-Yourself Biology 4 (2013), https://www.wilsoncenter.org/sites/default/files/7_myths_final.pdf.

[3] DIY Google Groups, https://groups.google.com/forum/#!members/diybio.

[4] Bart Kolodziejczyk, Do-It-Yourself Biology Shows Safety Risks of an Open Innovation Movement, Brookings Inst. (Oct. 9, 2017), https://www.brookings.edu/blog/techtank/2017/10/09/do-it-yourself-biology-shows-safety-risks-of-an-open-innovation-movement/.

Molecular genetics – the modification of genetic coding and expression – has become a popular focus of biohacking. Alongside the rise of direct-to-consumer testing services that provide access to raw genetic data, cheap and easy gene-editing techniques, such as CRISPR, are now available. "Genetic biohacking" activities are diverse and include, among other things, modifying algae to glow, altering nonhuman animals to increase their size, and self-injecting nucleotides to genetically enhance muscle growth or to treat HIV or herpes.[5]

At the same time, the November 2018 announcement that a scientist in China used CRISPR to genetically modify viable human embryos – allegedly resulting in the birth of the first "CRISPR babies" – has reinvigorated concerns about the distribution of genetic technologies.[6] For genetic biohacking, these concerns may be heightened by a belief that mechanisms to regulate the activity are absent or inadequate to address its risks. But, as this chapter details, genetic biohacking is likely subject to numerous oversight mechanisms, both public and private.[7] Before calling for additional regulations, regulators and policymakers should evaluate these extant mechanisms.

Some of our assessment is informed by semistructured interviews led by one author (Christi J. Guerrini), from August to December 2018, with thirty-eight individuals who lead, participate in, or study genomic biohacking and other citizen science initiatives.[8] Data were collected and coded according to methods detailed elsewhere;[9] we share select data relevant to regulatory, liability, and safety issues. Although biohacking occurs throughout the world, we focus on the US regulatory environment because the United States is the home of the first community laboratories and where many highly publicized examples of genetic biohacking have occurred.

II GOVERNMENT REGULATION

In the United States, various public laws and regulations govern some aspects of genetic biohacking. These include an appropriations rider in federal law effectively

[5] See Patricia J. Zettler, Christi J. Guerrini & Jacob S. Sherkow, Regulating Genetic Biohacking, 365 Science 34 (2019); see also Alex Pearlman, Biohackers are Using CRISPR on Their DNA and We Can't Stop It, New Scientist (Nov. 15, 2017), https://www.newscientist.com/article/mg23631520-100-biohackers-are-using-crispr-on-their-dna-and-we-cant-stop-it/.

[6] See Eli Y. Adashi & I. Glenn Cohen, The Ethics of Heritable Genome Editing: New Considerations in a Controversial Area, 320 JAMA 2531 (2018); Henry T. Greely, CRISPR'd Babies: Human Germline Genome Editing in the 'He Jiankui Affair', 6 J.L. Biosci. 111 (2019). The scientist was an academic, using professional resources, and is not generally described as having engaged in biohacking. See generally id.

[7] See Christi J. Guerrini, G. Evan Spencer & Patricia J. Zettler, DIY CRISPR, 97 N.C. L. Rev. 1399 (2019).

[8] These interviews were conducted as part of a broader study to understand values, preferences, and processes related to managing the outputs of genomic biohacking and other citizen science initiatives. The study was approved by the Baylor College of Medicine Institutional Review Board (H40925). Data is attributed to interviewees by their assigned interview numbers.

[9] Christi J. Guerrini et al., Core Values of Genomic Citizen Science: Results from an Interview Study BioSocieties (2020), https://doi.org/10.1057/s41292-020-00208-2.

prohibiting research with human embryos that are modified or created to include a heritable genetic modification.[10] There are also laws that regulate environmental impacts,[11] as well as regulations[12] and policies[13] applicable to federally funded research.[14]

Of all federal agencies, the US Food and Drug Administration (FDA) has the most extensive power to regulate the public-health impacts of genetic biohacking. In November 2017, following reports of biohacking by means of genetic self-experimentation, FDA explained its authority over biohacking, stating that it considered "any use of CRISPR/Cas9 gene editing in humans to be gene therapy," subject to the same premarket approval and other requirements that apply to gene therapy products.[15] The agency's jurisdiction is so broad, in part because many things biohackers use – such as raw biological materials, traditional drug products, and biohacking "kits" – are arguably "drugs" under US law.[16] The Federal Food, Drug, and Cosmetic Act (FFDCA) defines drugs as "articles" "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body of man or other animals."[17]

So defined, a product's "intended use" is crucial to placing it within FDA's jurisdiction.[18] The agency may rely on "any relevant source" of evidence to prove a product's intended use, including, for example, statements on a website that a kit can be used to modify a gene, treat an illness, or enhance the body's function. The agency may also determine intended use from nonpublic statements, statements made in the past, and product design.[19] Moreover, distributing products at no charge – which some biohackers do – is not, alone, sufficient to evade FDA's jurisdiction, which requires only that an item, or one of its components, is

[10] Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 734, 132 Stat. 389, 389 (2018).

[11] R. Alta Charo & Henry T. Greely, CRISPR Critters and CRISPR Cracks, 15 Am. J. Bioethics 11, 11–17 (2015).

[12] Protection of Human Subjects, 45 C.F.R. § 46 (2018).

[13] U.S. Dep't Health & Human Serv., NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Apr. 2019), https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html.

[14] Notably, some US institutions interpret federal human research subject protections to cover researchers' participation in their own interventions. See, e.g., Emily Mullin, Who Says You Need Permission to Study Yourself?, Medium (Sept. 27, 2018), https://medium.com/neodotlife/who-says-you-need-permission-to-study-yourself-1c347a25c10c; Johns Hopkins Med. Office of Human Subjects Res., Investigators as Study Participants (Self-Experimentation), Johns Hopkins Med. (July 2005), https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/self_experimentation.html.

[15] FDA, Information About Self-Administration of Gene Therapy (Nov. 21, 2017), https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm1586343.htm.

[16] For a more detailed discussion of FDA's jurisdiction, see Guerrini, Spencer & Zettler, supra note 7.

[17] 21 U.S.C. § 321(g)(1) (2018). Certain kinds of articles – such as human-gene-therapy products – also meet the definition of a biological product in the US Public Health Service Act. 42 U.S.C. § 262(i) (2018).

[18] 21 C.F.R. § 201.128 (2018).

[19] See, e.g., 82 Fed. Reg. 2193, 2199 (Jan. 9, 2017).

distributed across state or national boundaries.[20] As its November 2017 statement indicated, FDA likely has jurisdiction over many materials used in US genetic biohacking activities, especially those promoted on the internet and shipped directly to consumers.

At the same time, FDA lacks jurisdiction over genetic experimentation, including self-experimentation, undertaken with materials distributed without an intent that they be used in humans or animals.[21] DIY CRISPR kits intended only for the modification of bacteria, for example, do not fall within FDA's purview. Likewise, FDA's powers do not extend to simple information about biohacking when it is not provided by or on behalf of distributors of biohacking materials. Although the agency regulates certain information provided by entities marketing products – such as labeling and, in some circumstances, advertising – it does not oversee information about products unconnected to the entities marketing them.[22] Many self-help guides, standards, and FAQs developed by and distributed among biohackers – such as one group's instruction manual for creating an epinephrine autoinjector at home, the "EpiPencil"[23] – thus likely fall outside FDA's authority. Excepting circulation of this kind of information, FDA's authority still applies to many interactions where genetic biohacking materials are exchanged or distributed.[24]

There are benefits to FDA's broad authority. FDA, through its longstanding role in assessing drugs and biological products, has developed expertise to assess the safety and effectiveness of genetic biohacking. This expertise can be used to protect individuals from the distribution of unsafe or ineffective interventions, which may

[20] 21 U.S.C. § 331 (2018).

[21] To be clear, biohacked foods for humans and animals – such as yogurt modified to contain custom bacteria – generally fall within FDA's purview. For more details on FDA's authority over foods, including "biotechnology foods," see National Academies of Sciences, Engineering and Medicine, Preparing for Future Products of Biotechnology 80, 80–86 (2017) and Peter Hutt, Richard Merrill, & Lewis Grossman, Food and Drug Law: Cases and Materials 317, 317–639 (4th ed. 2013).

[22] The extent to which FDA can regulate even information provided by entities marketing products has been the subject of First Amendment challenges in various contexts. For just a small selection of literature discussing this issue, see, e.g., Micah L. Berman, Manipulative Marketing and the First Amendment, 103 Geo. L.J. 497 (2015); Nathan Cortez, Do Graphic Tobacco Warnings Violate the First Amendment?, 64 Hastings L.J. 1467 (2013); Aaron S. Kesselheim & Michelle M. Mello, Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection, 92 N.C. L. Rev. 1539 (2014); Lars Noah, Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA), 21 Health Matrix 31 (2011); Christopher T. Robertson, The Tip of the Iceberg: A First Amendment Right to Promote Drugs Off-Label, 78 Ohio St. L.J. 1019 (2017); Joshua M. Sharfstein & Alta Charo, The Promotion of Medical Products in the 21st Century: Off-Label Marketing and First Amendment Concerns, 314 JAMA 1795 (2015).

[23] Introducing the EpiPencil, Four Thieves Vinegar (Sept. 19, 2016), https://fourthievesvinegar.org/blog/2016/09/introducing-the-epipencil.

[24] Another question that may arise is whether certain genetic interventions are procedures within the practice of medicine and outside FDA oversight. See, e.g., Jordan Paradise, U.S. Regulatory Challenges for Gene Editing, 13 SciTech Lawyer 10, 13 (2016); see also Barbara J. Evans, Distinguishing Product and Practice Regulation in Personalized Medicine, 81 Clinical Pharmacology & Therapeutics 288 (2007). We discuss the blurry line between medical practice and medical products regulation later in this chapter.

be particularly important where patients undertake do-it-yourself (DIY) techniques for conditions that otherwise have available, effective treatments. The lure – and relatively low price – of genetic biohacking materials might result in patients foregoing effective therapeutic options, akin to cancer patients seeking cheaper, albeit ineffective, "alternative therapies." Equally important, FDA plays a critical role in inducing the production of scientifically credible information about interventions by requiring safety and efficacy information prior to distribution.[25] In the absence of oversight, commercial purveyors of reagents and materials for genetic biohacking have every incentive to market their products widely and little incentive to ensure such marketing is supported by robust evidence – similar to makers of tonics, tinctures, and patent medicines in the nineteenth century.[26]

Yet, there are also burdens associated with FDA regulation. For one, as explained by biohackers in interviews, it is difficult to comply with regulations that are incomprehensible to lay persons (or anyone who is not an FDA specialist): "If the laws are just clear for everyone going in, and there's just a place that in plain English they can interpret these things, without paying a lawyer to interpret it, I think we could get along really well and understand where the perimeter is." (Int. 15). Outdated regulatory frameworks also seem to frustrate biohackers' good-faith efforts at compliance. Another interviewee stated: "I think that they don't have a framework to deal with some of these new technologies, so they're trying to fit that into some old ideas on how we regulate things. And I think that that is difficult because it obviously doesn't work" (Int. 37). Other costs of FDA regulation include delayed access to or underinvestment in the development of medical interventions, which has led some patients and their family members to contact biohackers for help. One biohacker described these conversations as follows: "'Hey, I have X genetic disease. Can you fix me?' Or, 'Can you tell me how to fix myself?' You have to tell these people no, and it's heartbreaking." (Int. 5). Although there is no unrestricted legal or ethical right to experimental drugs,[27] there is a vein of US culture that has long emphasized free choice of medical interventions without government interference.[28] Consistent with this "health libertarianism," for example, recently passed state and federal "Right To Try" laws allow patients

[25] See Rebecca S. Eisenberg, The Role of FDA in Innovation Policy, 13 Mich. Telecomm. & Tech. L. Rev. 345, 347 (2007); see also Amy Kapczynski, Dangerous Times: The FDA's Role in Information Production, Past and Future, 102 Minn. L. Rev. 2357 (2018); Catherine M. Sharkey, Direct-to-Consumer Genetic Testing: The FDA's Dual Role As Safety and Health Information Regulator, 68 DePaul L. Rev. 368 (2019).

[26] See generally Joseph Gabriel, Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry (2014).

[27] See Abigail Alliance for Better Access to Dev. Drugs v. von Eschenbach, 495 F.3d 695, 703 (D.C. Cir. 2007); Alex John London, Social Value, Clinical Equipoise, and Research in a Public Health Emergency, 33 Bioethics 326, 326 (2018).

[28] See Lewis A. Grossman, The Origins of American Health Libertarianism, 13 Yale J. Health Pol'y L. & Ethics 76, 80 (2013).

to access experimental interventions without FDA authorization in some contexts.[29]

This reality does not mean that regulators like FDA are unaware of these burdens. Consistent with norms around free choice and the agency's own resource limitations, FDA often chooses not to enforce certain requirements when serious public-safety, health, or welfare risks are not implicated. FDA might therefore exercise such enforcement discretion over genetic biohacking activities that do not pose serious public-health concerns. More practically, it may be difficult for FDA to identify violations by genetic biohackers who work exclusively in private settings and do not publicly discuss their activities.[30] Although a 2013 survey conducted by the Woodrow Wilson Center suggests the number of these individuals may be small,[31] concerns about the safety of their activities may persist if they are – as some have worried[32] — perhaps a little too comfortable working in the legal and ethical margins.

To fill this gap, some states may take steps to regulate genetic biohacking, as California did in August 2019 when it enacted the first "CRISPR law."[33] Consistent with FDA's 2017 statement, the law requires sellers of "gene therapy kit[s]" to inform consumers, on websites and in labeling, that the kits are "not for self-administration."[34] Earlier in 2019, California's Department of Consumer Affairs began to investigate Josiah Zayner, PhD, a well-known biohacker and founder of an online retailer of DIY CRISPR kits, for the "unlicensed practice of medicine."[35] While the line between FDA's jurisdiction and that of state medical boards is, at best, fuzzy, and definitions of

[29] See, e.g., Lewis A. Grossman, AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution, 42 Am. J.L. & Med. 741 (2016); Holly Fernandez Lynch, Patricia J. Zettler & Ameet.Sarpatwari , Promoting Patient Interests in Implementing the Federal Right to Try Act, 320 JAMA 869 (2018); Patricia J. Zettler & Henry T. Greely, The Strange Allure of State Right-to-Try Laws, 174 JAMA Internal Med. 1885 (2014).

[30] See, e.g., Henry T. Greely, Take Care!, STAT (Mar. 14, 2016), https://www.statnews.com/2016/03/14/crispr-do-it-yourself/#Greely.

[31] Cf. Grushkin et al., supra note 2, at 6–7, 9, 15 (reporting that 6 percent of respondents of a survey of biohackers favored complete privacy in response to the question, "What are your feelings about transparency and sharing your work?," and 8 percent reported conducting experiments exclusively at home).

[32] See Ctr. for Global Security Research, Independent Biotechnology: The Innovation-Regulation Dilemma 7 (2016), https://cgsr.llnl.gov/content/assets/docs/Independent_Biotechnology_Workshop_SummaryNOV2016.pdf [hereinafter CGSR].

[33] See Press Release, Sen. Ling Ling Chang, Governor Signs Senator Chang's Bill to Address Human Biohacking (July 31, 2019), https://chang.cssrc.us/content/governor-signs-senator-chang-s-bill-address-human-biohacking.

[34] Cal. Bus. & Prof. Code Ann. § 22949.50 (2020).

[35] Josiah Zayner (@jzayner), Instagram (May 14, 2019), https://www.instagram.com/p/BxdcemZF5uf/?utm_source=ig_twitter_share&igshid=1pkcfktaku9jt; Emily Mullin, Celebrity Biohacker Josiah Zayner is under Investigation for Practicing Medicine Without a License, MIT Tech. Rev. (May 15, 2019), https://www.technologyreview.com/s/613540/celebrity-biohacker-josiah-zayner-is-under-investigation-for-practicing-medicine-without-a/. California's investigation of Dr. Zayner was closed in late 2019. Kristen V. Brown, Biohacker Investigation is Dropped by California Medical Board, Bloomberg (Oct. 19, 2019), https://www.bloomberg.com/news/articles/2019-10-15/biohacker-investigation-is-dropped-by-california-medical-board.

the practice of medicine vary between states, genetic biohacking seems unlikely to qualify as medical practice when it involves only self-experimentation.[36]

In this way, biohacking has now joined other more traditional scientific activities in raising questions about the appropriate intersection of state and FDA regulation.[37] California's efforts raise the specter of state enforcement against genetic biohackers – particularly those who attempt to, or represent that they can, diagnose or treat others' conditions. If medical practice laws do not allow states to reach biohacking, they may seek to regulate biohacking through other means, such as new biohacking-specific legislation. Such developments may be unwise given states' relative lack of expertise in evaluating the safety or effectiveness of the tools of genetic experimentation. In addition, state efforts to regulate biohacking may give unwarranted rhetorical credence to the notion that genetic biohacking is necessarily medical in nature, whereas many biohackers report that their work is not medical but conducted for philosophical, political, recreational, or experimental reasons.[38]

III PRIVATE REGULATION

In addition to being regulated by public agencies, genetic biohacking is also potentially subject to US laws that private actors enforce.[39] Patent owners can impose ethical and public-health restrictions on licensees, such as the Broad Institute's licenses for its CRISPR patents to Monsanto on conditions that Monsanto avoid certain research activities involving human germline cells – eggs and sperm – and tobacco.[40] Patent owners can enforce these restrictions through litigation or the threat of litigation, and even without licenses, they can file lawsuits to prohibit or end conduct posing security, environmental, or public-health risks. Such an approach assumes, of course, that patent owners are aware of such activities and are willing and able to fund such lawsuits. But patent owners of genetic technologies, often active developers themselves, are typically well-positioned to understand their technologies' social and ethical risks. They may also have selfish interests in ensuring that such technologies are developed away from regulatory oversight – interests that would be served by helping to minimize harms to third parties.

In addition, the United States has a robust system of private governance through tort law and tort avoidance. The fear of injuries – and large verdicts from tort suits –

[36] See Patricia J. Zettler, Toward Coherent Federal Oversight of Medicine, 52 San Diego L. Rev. 427, 435 (2015).

[37] See Patricia J. Zettler, Pharmaceutical Federalism, 92 Ind. L.J. 845, 846 (2017).

[38] See Guerrini et al., supra note 9.

[39] See Stephen M. Maurer, Self-Governance in Science 63 (2017).

[40] See Christi J. Guerrini et al., The Rise of the Ethical License, 35 Nature Biotech. 22, 24 (2017); cf. Jorge L. Contreras, Patent Pledges, 47 Ariz. St. L.J. 543, 590–92 (2015) (describing "philanthropic" patent pledges that are made with the outward goal of promoting public welfare).

often drives the development of safety mechanisms for consumer products, from lawnmowers to airplanes.

Distributors of genetic biohacking materials may similarly self-regulate to avoid claims by people injured by genetic biohacking materials, even when distributors may have defenses against such claims – for example, that the injured persons assumed the risks of biohacking. Some biohackers are quite aware of these responsibilities. As one interviewee explained:

> So if you're going to be providing the materials for a gene therapy, you have to be explicitly aware that the second you put it out there, somebody will inevitably use it, and if something goes wrong, it's your fault. I mean, assuming they followed the directions properly and you can only account for user error so much. But assuming everything was done properly, if something goes wrong, it's still your fault. (Int. 26).

Apart from legal mechanisms, participants in biohacking activities can use voluntary mechanisms to promote safety.[41] Many biohacking activities are undertaken in community laboratories that have adopted safety policies[42] consistent with the Biosafety in Microbiological and Biomedical Laboratories guidance document developed by the Centers for Disease Control and the National Institutes of Health.[43] These policies describe rules for handling and disposing of materials, as well as prohibitions of certain activities. Members of community laboratories usually must sign agreements acknowledging safety rules and penalties for noncompliance (including expulsion) and also separately demonstrate their safety knowledge by passing a test or completing a class.[44] Moreover, community laboratories generally endorse the codes of ethics developed by DIYbio.org,[45] which was founded in 2008 "with the mission of establishing a vibrant, productive, and safe community of DIY biologists."[46] Even outside community laboratories, many who engage in biohacking activities prioritize safety. As explained by one interviewee who maintains a home laboratory: "A lot of biohackers, even though it may seem like we're

[41] See Todd Kuiken, Governance: Learn from DIY Biologists, 531 Nature 167, 167 (2016).

[42] See Grushkin et al., supra note 2, at 5.

[43] See U.S. Dep't Health & Human Serv., HHS Publication No. (CDC) 21-1112, Biosafety in Microbiological and Biomedical Laboratories (Deborah E. Wilson & L. Casey Chosewood eds., 5th ed. 2009).

[44] See, e.g., Baltimore under Ground Science Space (BUGSS) Membership Application and Agreement, Baltimore under Ground Science Space, https://bugssonline.org/wp-content/uploads/2018/05/BUGSSmembership-agreement.pdf (last visited Apr. 26, 2021); BioCurious Membership Agreement, BioCurious (June 7, 2017), https://docs.google.com/document/d/e/2PACX-1vQHZZvoERCqR1HJuGTq2-xga-Pip_kl4x5kzMtx08wQAvg6tNE8yxtYjTBTesaE3akEmh7dJJfTkKjj/pub; What Happens After Joining?, BioCurious, https://biocuriosity.wordpress.com/join/what-happens-after-joining/ (last visited Oct. 22, 2020).

[45] Draft DIYbio Code of Ethics from North American Congress, DIYbio (July 2011), https://diybio.org/codes/code-of-ethics-north-america-congress-2011/.

[46] An Institution for the Do-it-Yourself Biologist, DIYbio, https://diybio.org/ (last visited Oct. 22, 2020). As of this writing, the active status of DIYbio is unclear even as its ethics code remains influential.

crazy people, are very conscious of potentials for harm" (Int. 5). Another concurred: "[D]on't hurt other people. I guess that's kind of the rule that a lot of biohackers follow is don't hurt other people." (Int. 1).

Biohackers also rely on each other for materials and information, which in turn discourages secrecy and enables individuals to monitor one another's conduct.[47] Some biohackers might even be described as aggressively public about their activities. One interviewee explained intentionally taking this approach in part to promote safety: "It's kind of this hushed tones, 'don't be too loud or you'll draw attention' kind of thing. I'm not a fan of that because that doesn't make it safe for kids. Kids shouldn't be like: 'Okay, now we're going to close the windows and do some science.' Right. That should never be a thing." (Int.15).

Like government-enforced rules, these private mechanisms present benefits and burdens. On one hand, privately enforced regulatory mechanisms – whether based on law or voluntary codes – are often quicker to respond to concerns than are government processes. Additionally, private entities bear the costs of such enforcement, and, although an expert government regulator may not be involved, this approach draws on the extensive knowledge of patent owners and members of biohacking communities more generally. On the other hand, private actors may not be inclined to regulate conduct that poses risks to the public but not the private actors themselves, leading to socially undesirable outcomes. Private actors also may not be able to afford to undertake consistent enforcement, and penalties – particularly where the underlying "rules" are purely voluntary – may simply be ineffective deterrents. Moreover, in practice, biohackers working outside of community laboratories are subject to few, if any, even voluntary rules.[48]

IV MOVING FORWARD

In the United States, a web of laws, regulations, and norms – if used – could reach a number of genetic biohacking activities. Although there are gaps in both public and private regulatory mechanisms (and questions about how rigorously both are and can be enforced), such problems are not unique to genetic biohacking. Other emergent technologies share genetic biohacking's potential for decentralized manufacturing and DIY applications,[49] including

[47] Cf. CGSR, supra note 32, at 7 (noting that isolation can be an impediment to DIY biology).

[48] However, they may be subject to community safety and ethics norms that are enforced through online platforms where biohackers engage with one another. See, e.g., Biohack.me, https://forum.biohack.me/ (last visited Oct. 22, 2020]); DIYbio Google Groups, https://groups.google.com/forum/#!forum/diybio (last visited Oct. 22, 2020).
Facebook is also a popular online location for biohacker discussion and engagement. See Elliot Roth, A Guide to DIYbio (Updated 2019), Medium (Feb. 16, 2019), https://medium.com/@ThatMrE/a-guide-to-diybio-updated-2019-abd0956cdf74 (noting active biohacker Facebook groups).

[49] See, e.g., Albert C. Lin, Herding Cats: Governing Distributed Innovation, 96 N.C. L. Rev. 945, 946 (2018); see also Maxwell J. Mehlman & Ronald A. Conlon, Governing Non-Traditional Biology, in Consuming Genetics (I. Glenn Cohen, et al., eds. 2020).

neurohacking,[50] fecal microbiota transplantation,[51] and DIY manufacturing of traditional pharmaceuticals (and other products that pose public health risks, such as guns).[52]

Whatever regulatory mechanisms apply to genetic biohacking, they will not achieve perfect compliance. Violations are inevitable. As the announcement of the so-called CRISPR babies underscored, even with significant international agreement about ethical norms if not national prohibitions, "rogue" scientists may nonetheless move forward.[53] Concern that regulators would prohibit genetic biohacking based on a rogue biohacker's actions was a common theme during interviews. As one biohacker explained: "If you do something, you should be held accountable for it. You particularly, not the whole [biohacking] movement. That's the bigger underlying worry, is that the whole movement will be blamed if one person messes up." (Int. 15).

Policymakers, regulators, and private actors should therefore carefully examine how to better enforce existing laws before deciding that additional authority is needed to provide effective oversight of genetic biohacking. As stakeholders work to provide solutions, one important consideration is that FDA, despite its power and expertise, is not the only option for overseeing genetic biohacking's public health impacts. Nor are enforcement actions the only option available to the agency for the authority it does have. Educational and engagement strategies, such as the Woodrow Wilson Center's 2018 workshop that brought together regulators and biohacking supporters to discuss safety and ethical concerns,[54] can supplement FDA oversight where either the agency lacks authority or enforcement actions are unwarranted. Such strategies can help private actors to understand the risks their materials and genetic biohacking activities pose, as well as bolster FDA's role in protecting consumers and fostering innovation. Likewise, public regulators, such as FDA, would benefit from engaging with stakeholders to better understand genetic biohacking activities, their participants' perspectives, and the drawbacks and advantages of self-governance by various genetic biohacking communities.

The agency should understand, however, that regardless of its efforts, some biohackers will resist government regulation. One biohacker summarized this

[50] See Anna Wexler, The Social Context of 'Do-It-Yourself' Brain Stimulation: Neurohackers, Biohackers, and Lifehackers, 11 Frontiers Human Neurosci. 224 (2017).

[51] See Diane Hoffman et al., Improving Regulation of Microbiota Transplants, 358 Science 1390 (2017); Erika Lietzan, Access Before Evidence and the Price of the FDA's New Drug Authorities, 53 U. Rich. L. Rev. 1243 (2019); Rachel E. Sachs & Carolyn A. Edelstein, Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation, 2 J.L. & Biosci. 396 (2015).

[52] See Jenna E. Gallegos et al., The Open Insulin Project: A Case Study for "Biohacked" Medicines, 36 Trends Biotechnol. 1211, 1211 (2018).

[53] R. Alta Charo, Rogues and Regulation of Germline Editing, 380 New Eng. J. Med. 976, 976 (2019).

[54] Todd Kuiken, Eleonore Pauwels & Sarah W. Denton, The Rise of the New Bio-Citizen: Ethics, Legitimacy, and Responsible Governance in Citizen-Driven Biomedical Research and Innovation, Woodrow Wilson Center (July 8, 2018), www.wilsoncenter.org/article/the-rise-the-new-bio-citizen-workshop.

perspective: "The government does not belong in my 'blank'. They don't belong in my bed, they don't belong in my house, they don't belong et cetera. They don't belong in my lab." (Int. 11). Another interviewee lamented:

> Legislation consistently hampers growing industries and biotech is a growing industry, and just like every other technology, it was developed in garages, it was developed in people's kitchens, you know? . . . . That's where innovation has come from. People who are passionate and able to make those things happen. And legislating them and making them hide and not allowing them access to tools and information, all it does is hurt us as a people. (Int. 4)

Indeed, policymakers, regulators, and others should recognize that some current biohacking projects seek to develop innovative solutions to important public-health problems, and other projects may have the potential to lead to unexpected results that may well serve the public health.[55] These consideration are arguably the reasons for the Department of Health and Human Services' open innovation initiatives[56] and FDA's Naloxone App Competition.[57] Biohacking activities may also uncover defects or deficiencies in traditional research protocols, analogous to "white hat" hacking in the computer context.[58] Enjoining such biohacking activities before they can bear fruit seems unwise for innovation policy.

In sum, different kinds of genetic biohacking activities pose different risks and merit different oversight approaches. Permitting the distribution of a DIY copy of a validated (but perhaps expensive) gene-editing technology shown to be safe and effective for a disease, for example, might raise concerns about the quality of the intervention and preserving incentives for innovation for the original creator. Permitting the distribution of a DIY version of an unvalidated gene-editing technology intended to treat a serious disease, on the other hand, would also raise questions about whether patients were receiving a safe and effective treatment or modern-day snake oil. Likewise, genetic biohacking intended to alter an individual's appearance or enhance performance raises different concerns than do interventions intended to

[55] Cf. Nikolaus Franke, Julia Bauer & Philipp Tuertscher, The Seven IP Commandments of a Crowdsourcing Community: How Self-Organized Norms-Based IP Systems Overcome Imitation Problems (working paper), https://www.researchgate.net/profile/Philipp_Tuertscher/publication/281116194_The_seven_IP_commandments_of_a_crowdsourcing_community_How_self-organized_norms-based_IP_systems_overcome_imitation_problems/links/55f29e6f08aedecb6902176c/The-seven-IP-commandments-of-a-crowdsourcing-community-How-self-organized-norms-based-IP-systems-overcome-imitation-problems.pdf (describing a crowdsourcing approach as likely leading to "surprising solutions").

[56] U.S. Dep't of Health & Human Servs., About Open Innovation, https://www.hhs.gov/cto/initiatives/open-innovation/about/index.html (last visited Oct. 22, 2020).

[57] FDA, 2015 Naloxone App Competition (Dec. 16, 2016), https://www.fda.gov/news-events/public-health-focus/2016-naloxone-app-competition.

[58] See Jonathan Sackner-Bernstein, Design of Hack-Resistant Diabetes Devices and Disclosure of Their Cyber Safety, 11 J. Diabetes Sci. Tech. 198, 199 (2017) (describing "white hat" hacking for discovering flaws in an infusion pump).

treat or prevent disease.[59] Policymakers and regulators must assess the validity of concerns about genetic biohacking based on the nature of the risks and benefits that particular activities pose and the likelihood that each will come to pass. Before concluding more regulatory authorities are needed, regulators and policymakers should consider whether existing oversight mechanisms can be used in more effective ways – whether that means better engagement, more or more finely tailored enforcement, or some other approach – to mitigate genetic biohacking's risks while amplifying its potential.

[59] See, e.g., Henry T. Greely, Remarks on Human Biological Enhancement, 56 U. Kan. L. Rev. 1139, 1139 (2008); Matt Lamkin, Regulating Identity: Medical Regulation as Social Control, 2016 B.Y. U. L. Rev. 501, 501 (2016); Gary Marchant et al., Regulatory Frontiers: Integrating Social and Ethical Concerns Into Regulatory Decision-Making for Emerging Technologies, 11 Minn. J.L. Sci. & Tech. 345, 345 (2010); Maxwell J. Mehlman, How Will We Regulate Genetic Enhancement?, 34 Wake Forest L. Rev. 671, 702 (1999).