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AN INTRODUCTION TO PERSONAL GROWTH BETS: USING CONTRACT LAW TO LOSE WEIGHT AND QUIT SMOKING

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Self-improvement is hard. Whether losing weight or quitting smoking, individuals have a difficult time honoring their commitments, especially if the only person they are disappointing is themselves. In this Article, we introduce a new legal mechanism for incentivizing personal growth. We describe this mechanism as a personal growth contract, which allows an individual to make an enforceable agreement with either a counterparty or himself with the aim of self-improvement. We propose the use of smart contracts to help execute unilateral personal growth contracts. Our conclusion is that personal growth contracts should be presumptively legal, provided they do not violate some otherwise applicable public policy or law.

AN INTRODUCTION TO PERSONAL GROWTH BETS: USING CONTRACT LAW TO LOSE WEIGHT AND QUIT SMOKING

Max Raskin[1] *& Jack Millman*[2][3]

INTRODUCTION

People often want to improve themselves. But whether it's quitting smoking or losing weight, self-improvement is difficult. The idea for this Article came from a very real practice of its authors to make self-improvement a little bit easier.

Over the course of our friendship, each of us has had personal goals related to our growth as individuals. As a way of incentivizing this development and completing these goals, we would participate in what we called "personal growth bets" with each other. These bets can, and have, dealt with any number of goals, but the canonical example is weight loss. For example, a rough outline of such a bet would be: if Max does not lose 10 pounds over the next six months, he must pay Jack $1,000. Whereas, if he does lose the weight, Jack must buy Max a steak dinner.

A vast amount of psychological research, as well as simple intuition, supports the conclusion that incentives matter. If someone knows he will either lose or make a meaningful amount of money related to a goal within his control, he is more likely to exert the effort. That does not mean incentives always work, but they have a real effect on the margins.[4]

These personal growth bets involve three parties: (1) the aspirant, (2) the monitor, and (3) the enforcer. The aspirant seeks to achieve a certain goal but does not fully trust himself, so he tries to bind his future

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[4] *See* Leslie John, George Loewenstein, et. al., *Financial Incentives for Extended Weight Loss: A Randomized, Controlled Trial*, 26 J. OF GEN. INTERNAL MED. 621, 621-26 (2011); ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS 5 (Adam Smith ed., 5th ed. 1789).

self with some type of present commitment to either action or inaction. For the weight loss bet, that commitment is to forfeit $1,000 if the aspirant does not lose 10 pounds. But the aspirant needs someone to monitor his future self to verify whether the commitment is satisfied (i.e., to ensure he actually loses ten pounds), and then enforce the bet if the future self fails (i.e., to ensure the $1,000 is forfeited). As will be explained below, a new technology called "smart contracts" can serve the roles of enforcer and monitor, allowing an aspirant to effectively bind his future self without the need to involve another person.

This Article argues that a personal growth bet is best described legally as a contract. These bets fit the traditional definition of a contract—legally recognized promises to act or refrain from acting in a specified way.[5] They are not exactly "bets," because the outcome is not uncertain in the same way most bets' outcomes are. Like any contract, it is within the power of at least one of the parties to ensure that the bargained-for outcome occurs.[6] These "bets" also allow a party to accomplish his *ex ante* goal through legal commitment, which is a defining feature of contracts.[7]

We will therefore describe such personal growth bets as personal growth contracts, but they differ from standard commercial contracts in several important ways. *First*, the agreement principally involves only one party. A person's present self seeks to make a commitment that leaves his future self better off and tries to bind his future self through some kind of monetary penalty or restraint on liberty. The monitoring and enforcement services generally require other parties, but as discussed more below, these services are just transaction costs tacked on to the real unilateral agreement. It is our belief that technology has advanced such that other parties may not be needed to execute the monitoring and enforcement functions. *Second*, the aspirant's present self almost never wants to permit amendment of the contract after the initial terms are agreed to. But traditional contract law generally does

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[5] *See, e.g.*, RESTATEMENT (SECOND) OF CONTRACTS § 1 cmt. d (AM. L. INST. 1981).

[6] Compare with Nevada gambling law, which defines a wager as a sum of money or representative of value that is risked on an occurrence for which the outcome is uncertain. To be sure, someone could overestimate his ability to lose weight or build a house in a given time period, for instance, and no amount of willpower on his part could bend the physical laws of the universe. In this case, individuals who regularly overestimate their abilities will have deterrence that makes this overestimation costly. These are still contracts, although fall into the category where performance is impossible.

[7] *See generally Philosophy of Contract Law*, STAN. ENCYCLOPEDIA OF PHIL. (Nov. 23, 2021), https://plato.stanford.edu/entries/contract-law/#:~:text=The%20first%2C%20and%20most%20famous,promoting%20efficient%20investment%20and%20exchange.

allow parties to modify contracts after the fact.[8] This creates issues if the aspirant's future self changes his mind because, of course, the entire point of the bet is that the aspirant's present self is worried about the actions of his future self. *Third*, these types of personal growth bets interact oddly with the idea of "efficient breaches," i.e., situations where a party believes it is better off paying damages rather than performing the contract.[9] Some may object to bets with specific performance components because they could lead to cases where individuals prevent their future selves from engaging in activities that would make the person better off (because one's future self would be better off by breaching). Others may object to bets with monetary components because efficient breach theory would suggest an aspirant might often be justified in paying the money and engaging in the prohibited behavior, which just leaves the aspirant worse-off than had he not ever made the bet. One's view of this turns on whether the aspirant's present self has a more accurate assessment of the benefits and costs—perhaps because the future self will misjudge the costs—or if the aspirant is being unrealistic about the costs and benefits of achieving a desired future outcome.

These differences from traditional contracts can make it difficult to find a good monitor and enforcer for a personal growth bet. One can be fortunate—like the authors—and find friends willing to take on these roles. But this is a big commitment for a friend to take on, and it can put them in an awkward spot if the bet fails.[10] On the other hand, if the threat of enforcement is not serious, the purpose of the bet quickly falls apart.

One solution might be an impersonal third-party monitoring and enforcement service. These services do exist.[11] Users of these services commit to a goal—such as weight loss—and have to pay pledge amounts if they fail to adhere to the goal. But, although these services monitor one's progress, they rely on self-reporting. This works for many users,[12] but others might need a more aggressive monitor—particularly if the temptation is great. A final possible monitor and enforcer is the government.[13] In some situations, the government permits an aspirant

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[8] *See infra* Part III.A.
[9] *See infra* Part III.B.
[10] For a contract to be legally enforceable, there must generally be mutual consideration, and so one needs to find a friend willing to commit some consideration to help his friend achieve his goals, e.g., the purchasing of a steak dinner in our case. And of course, even if that consideration exists, most friends will not actually go to court to enforce the bet if the aspirant fails to follow through.
[11] *See infra* Part I.B.
[12] Dreeves, *Combatting Cheating*, BEEMINDER BLOG (Aug. 23, 2013), https://blog.beeminder.com/cheating/.
[13] *See infra* Part II.A.

to pre-commit and legally enforces this commitment—a powerful example is so-called "self-exclusion" laws that allow a person to ban himself from casinos. People may exclude themselves from a casino or online gaming site, and the casino will expel them if they are found violating this "law."[14] The gaming entity can also be required to check identification and confirm if someone is on an exclusion list. But of course, the government is generally not in the personal growth space, nor should it be given the unintended consequences and inefficiencies stemming from government's involvement.[15]

The practice of individuals turning to third parties to help enforce their personal growth goals is at least as old as the mythical Trojan War. In the Greek epic The *Odyssey*, the hero Ulysses wants to hear the beautiful songs of creatures called Sirens but knows that doing so would lead his future self to death on the rocks below. So, he demands his sailors tie him tightly to the mast of his ship and then plug their own ears with beeswax so they won't be tempted themselves. When Ulysses hears the Sirens' song, he begs his sailors to untie him, but they only bind him tighter. Only when Ulysses is no longer in danger do the sailors release him. This so-called "Ulysses pact" involves third parties—in this case, the sailors. Third parties complicate things if the third parties turn out to be unreliable. A Ulysses pact with oneself, however, avoids this problem, but also raises some important questions about the nature of contract law.

There is a novel solution to some of these problems: smart contracts. Smart contracts are agreements wherein execution is automated, usually by computers.[16] Thanks to the rise of smart contracts, it is now possible to enter into a personal growth contract with oneself. When combined with interconnected devices capable of monitoring performance and enforcing breaches, smart contracts have made it possible for individuals to make commitments with their financial assets in a way that incentivizes their behavior without the need of a counterparty. Instead, technology permits automated devices to fulfill the roles of enforcer and monitor. Thus, aspirants' *ex ante* decisions to bind their future selves cannot be easily undone and therefore form the basis of a self-enforcing contract. The ability to commit financial assets

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[14] *See infra* Part I.C.; *see also Responsible Gaming Regulations and Statutes Guide*, AM. GAMING ASS'N (Sept. 1, 2022), https://www.americangaming.org/wp-content/uploads/2019/09/AGA-Responsible-Gaming-Regs-Book_FINAL.pdf.
[15] *See generally* MARIO J. RIZZO & GLEN WHITMAN, ESCAPING PATERNALISM (Timur Kuran & Peter J. Boettke eds., Cambridge Univ. Press 2020).
[16] *See* Max Raskin, *The Law and Legality of Smart Contracts*, 1 GEO. L. TECH. REV. 304 (2017).

to deterministic and automated processes has enabled a whole new world of possibilities. Many of these possibilities are already realities, such as the permanent destruction of digital assets or the minting of finite non-fungible tokens (NFTs). But self-contracting is a novel application of smart contracts that has not been explored in depth in either the legal or popular literature.[17]

One of the fundamental principles of a contract is that it is an agreement between at least two parties. The promises we make to ourselves, such as to quit smoking or lose weight, are informal and have not historically been enforced by the legal system. These promises are not enforced because if someone breaks a promise to himself, he would have to take himself to court and sue for damages—a nonsensical scenario.

Despite these issues, we side with Ulysses. We believe a person's aspirations are worthy of legal protection—even against his future self. Because these contracts are really between an aspirant's present self and an aspirant's future self, the law should permit self-contracting through smart contracts. These contracts avoid both the problems with informal monitors and enforcers and the problems with formal monitors and enforcers, while still allowing a person to achieve a better version of himself. This Article aims to put forth a coherent framework for how Ulysses contracts like our own personal growth bets may be made and executed through the use of blockchain technology.

Part I of this Article defines personal growth bets in more detail and discusses the concepts of aspirant, monitor, and enforcer. It also considers the circumstances under which we might want a person's present self to be able to bind that person's future self. Part I then examines existing private mechanisms for monitoring and enforcement, as well as the concept of "commitment bonds," through which an individual makes a commitment and agrees to pay money if he fails to meet it. The buyer of the bond receives the money if the individual fails. Part I also reviews state and federal laws that support personal growth commitments. Finally, Part I discusses issues with the current types of monitors and enforcers (informal private, formal private, and government). These issues fall into two categories: (1) general problems

[17] Part of the reason for this dearth of legal analysis is that these bets simply are not that popular. In addition to the high transaction costs of finding a counterparty, individuals generally are not interested in "gamifying" their self-growth. This is not only because of the inherent psychological discomfort in tying oneself to the mast—the kind of forethought many do not have or want—but also the time and energy spent to find escrow and other technical services to execute the bet.

with the monitors and enforcers and (2) specific kinds of precommitment actions the monitors and enforcers are ill-equipped to handle.

Part II proposes smart contracts as a solution to some of these problems. After explaining how smart contracts function, we go through potential upsides, such as reduced transaction costs, guaranteed enforcement, and automatic monitoring. We also review some potential downsides—such as a loss of flexibility if unexpected circumstances arise.

Finally, Part III explains how smart contracts executing personal growth bets fit into existing law. Certain assumptions about contract law would need to shift to accommodate self-executing smart contracts. The basic legal conclusion of this Article is that self-contracts should not be discouraged by courts, legislators, or regulators. To the extent courts can exercise power over these contracts, they should not do so unless there is some deeply compelling reason. The general rule in a free society is that individuals should be allowed to enter into consensual contractual relationships with one another and that such relationships provide mutual benefits to both parties. This rule should apply with equal force where the counterparty is not another individual but instead one's future self.

Above all, this paper hopes to introduce the concept of the personal growth bet in the hopes that our readers will use them, making the world a better place.[18] As far as we are aware, this is the first self-help law review article.[19] Or at least, the first self-help law review article involving smart contracts.

I. BACKGROUND

A. Defining Personal Growth Bets

"Personal growth bets," as we use the term in this Article, are a mechanism for self-improvement wherein an individual makes an agreement to act or refrain from acting in a way that furthers his personal goals. If he does not follow through with his end of the bargain, the consequence is usually forfeiting some predetermined amount of money. This is a fun exercise with one's friends, but has not been the subject of

[18] This assumes our readers' accomplishment of their personal goals will lead to good in the world. For the evil readers of ours, please stop reading.

[19] We do not refer here to the legal concept of self-help, but rather to a genre of literature typified by such writers as Tony Robbins and Dale Carnegie.

much legal analysis, even though companies now exist that help individuals implement the concept.[20]

These contracts have all the elements traditionally required to establish a legally enforceable contract: offer, acceptance[21], and consideration.[22] Take the example of the personal growth bet involving weight loss. The contract terms are that one party must lose 10 pounds in six months. If the weight is not lost, he must pay $1,000 and if it is lost, his counterparty must buy him a steak dinner.

It is the general rule that for a contract to be enforceable there must be consideration.[23] Consideration is an act or forbearance made in exchange for an act or forbearance of another.[24] In our weight loss contract, there is consideration in the form of an action (i.e., losing weight) and the purchase of a steak dinner if the action is completed.

Another element of this contract is a liquidated damages clause—in this case the $1,000 payment in case the weight goal is not reached. A liquidated damages clause sets out a specific penalty for breach, and is arguably the key provision of this type of contract, as it determines the costs of breach, and therefore the operative incentives. Liquidated damages clauses are the subject of much legal literature, but it suffices here to say that they are presumptively legal.[25] The other elements of a contract can easily be included in this bet, such as capacity to contract,[26] as well as offer and acceptance.

The traditional form of this contract occurs bilaterally or trilaterally. Two parties contract with one another or involve a third

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[20] *See infra* Part I.B.

[21] It may be argued that there is no acceptance in such an agreement because one is binding one's future self without his consent. The trouble with this argument is that it proves too much—all contracts bind one's future self without his consent. *See generally* Robert Nozick, *Philosophical Explanations*, (Feb. 7, 2019) https://scholar.harvard.edu/files/sberker/files/phil169-meeting2.pdf.

[22] *See* RESTATEMENT (SECOND) OF CONTRACTS § 24 (defining "offer"), 50 (defining "acceptance"), 71 (defining "consideration"); for an overview of each of these elements in the context of an actual dispute, see Allied Steel and Conveyors, Inc. v. Ford Motor Co., 277 F.2d 907 (6th Cir. 1960).

[23] *See infra* Part IV.C.

[24] *See* RESTATEMENT (SECOND) OF CONTRACTS § 71; Hamer v. Sidway, 11 N.Y.S. 182 (N.Y. Sup. Ct. 1890).

[25] *See* Luke C. Tompkins, *Issues Impacting Enforceability of Liquidated Damages in Construction Contracts*, 10 NAT'L L. REV. 297 (2020).

[26] *See* RESTATEMENT (SECOND) OF CONTRACTS: CAPACITY TO CONTRACT § 12 ("No one can be bound by contract who has no legal capacity to incur at least voidable contractual duties. Capacity to contract may be partial and its existence in respect of a particular transaction may depend upon the nature of the transaction or upon other circumstances. A natural person who manifests assent to a transaction has full legal capacity to incur contractual duties thereby unless he is under guardianship, or an infant, or mentally ill or defective, or intoxicated.").

party who helps facilitate the contract, such as an escrow agent or a beneficiary like an anti-charity.[27]

B. Monitoring and Enforcement Through Private Parties

There are a number of mechanisms—both speculative and already existing—for monitoring and enforcing personal growth bets.

On the speculative side, Professors Abramowicz and Ayres propose an instrument called the commitment bond that is designed to create incentives for commitment to a course of action or inaction.[28] But there are also real-world companies that currently act as counterparties in personal growth bets and provide monitoring and enforcement services. We will first discuss these current examples and then move to the realm of speculation.

1. Accountability Apps

Many companies involved in personal growth bets advertise themselves as "accountability apps" that help users practice self-discipline and achieve their individual goals. These apps share a number of features: there is an aspirant who specifies a personal goal and pledges a monetary sum, a monitor (either a trusted third party selected by the aspirant or other health monitoring apps), and an enforcer—the app itself. Below are some examples of such services.

StickK:[29] one of the more popular accountability apps, StickK works by having users sign a "Commitment Contract"—a binding agreement with themselves. First, the user defines his own goal. StickK offers information on and preset contracts for a variety of goals, including those related to exercise and fitness, health and lifestyle, weight loss, family and relationships, money and finance, education, sustainability, and hobbies and recreation.[30] However, a user can specify any kind of goal in his customized Commitment Contract. Next, the user decides what the stakes of his "personal bet" will be.[31] Like the goal itself, the stakes

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[27] An anti-charity is an organization selected by a donor or a counterparty to whom money is forfeited if certain goals are not met. For instance, a pro-life individual would have to give to NARAL or an anti-gun activist would have to donate to the NRA.
[28] Michael Abramowicz & Ian Ayres, *Commitment Bonds*, 100 GEO. L.J. 605 (2012).
[29] *See* STICKK, https://www.stickk.com/ (last visited Sept. 15, 2022).
[30] *See How It Works*, STICKK, https://www.stickk.com/ (last visited Nov. 26, 2022).
[31] *See Know Yourself*, STICKK, https://www.stickk.com/ (last visited Nov. 26, 2022).

can be customized by the user, though StickK suggests imposing financial stakes.[32]

The app monitors the user's progress toward achieving his goal through the user's submission of self-reports, and, if the user chooses, through a "referee."[33] A referee—an individual designated by the user—determines whether the self-report was genuine or not.[34] If the user fails to meet his goal, the payment method they provided will be charged the amount of money specified in the Commitment Contract. The destination of the forfeited money is also up to the user: he can send it to a charity or another person.[35] Interestingly, the "Terms and Conditions" of the Commitment Contract describe the contract as being between the user and StickK.[36]

GoFkingDoIt**:[37] similar to StickK, this app employs a straightforward accountability mechanism: users enter a goal, provide a deadline, put some amount of money on the line, and provide the contact information for a friend to help keep them accountable by acting as a "supervisor" (not unlike the "referee" in StickK). The website gives examples of real users' contracts, including "I will finish my paper or pay $100" and "I will run a marathon or pay $50."[38] When the deadline arrives, the supervisor is asked to confirm whether the user completed the goal.[39] If the user did not, he forfeits the amount of money he pledged (which is charged to the payment method the user has provided).

Beeminder:[40] as with both StickK and GoF**kingDoIt, Beeminder is an app that allows users to bet their own money on their own achievement of a goal. Unlike the others, though, Beeminder does not require the aspirant to designate a third-party "referee" or "supervisor" to validate successful achievement of a goal. Instead, the app connects to other tracking apps like Fitbit, Apple Health, and Strava. The app's set-up is familiar: the user defines a goal, sets a deadline, and pledges money. The

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[32] *Id.* (explaining that StickK's internal data shows that imposing "financial stakes increase[s] your chances of success by up to 3x").
[33] *How it Works*, https://stickk.zendesk.com/hc/en-us/articles/206833157-How-it-Works (last visited Nov. 26, 2022).
[34] *Id.*
[35] *See What is StickK?*, STICKK, https://stickk.zendesk.com/hc/en-us/articles/206109308-What-is-stickK- (last visited Nov. 26, 2022).
[36] *See Terms of Use*, STICKK, https://www.stickk.com/faq/tou (last visited Nov. 26, 2022).
[37] *See* GOF**KINGDOIT, https://gof**kingdoit.com/ (last visited Sept. 15, 2022).
[38] *Id.*
[39] *Id.*
[40] *See* BEEMINDER, https://www.beeminder.com/ (last visited Sept. 15, 2022).

goals a user can set are more limited on Beeminder: they must be "graphable," because the app generates a trajectory based on the user's starting point, end goal, and specified time frame. The user then signs a contract that commits him to paying if he goes "off track"—i.e., if he veers too far off the trajectory.[41] Each time the user strays from his trajectory line, the amount he must pay increases. Because of this structure, the "pledge amount" is not a fixed value, but rather a "pledge schedule," which the user can customize within limits. Monitoring is done through a combination of self-reporting (e.g., Beeminder will "ask" how much the aspirant weighs) and synchronization with other monitoring apps that can automatically send data to Beeminder. The forfeited funds go to Beeminder.[42]

2. Commitment Bonds

In addition to the above companies, theoretical instruments called "commitment bonds" have been proposed and analyzed as a potential enforcement mechanism.[43] This new type of bond is structured around an individual's commitment to a certain action or inaction and Abramowicz and Ayres were explicit in their hopes that this would be a mechanism for individuals, organizations, and government to "tie themselves to the mast."[44]

Instead of putting money in an escrow account that is forfeited in the case of non-performance (as in the case of accountability apps), in a commitment bond, an individual "sells the right to receive any forfeited funds to a third party."[45] The buyer of the bond is "contractually designated as the recipient of any amounts the bond seller forfeits."[46] As outlined in their article, there are many interesting observations regarding the pricing of these bonds that demonstrate how theoretically a market could exist in such assets.

These bonds differ in one crucial way from the third-party services outlined in the previous section. Abramowicz and Ayres would describe the previous escrow-forfeiture arrangement as a "one-way ratchet" that only offers the potential of loss.[47] The commitment bond allows the

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[41] *See FAQ*, BEEMINDER, https://www.beeminder.com/faq#qcom (last visited Nov. 26, 2022).
[42] *Id.*
[43] Michael Abramowicz & Ian Ayres, *Commitment Bonds*, 100 GEO. L.J. 605 (2012).
[44] *Id.* at 606.
[45] *Id.*
[46] *Id.*
[47] *Id.* at 608

aspirant to actually make money if there is a willing counterparty on the other side to purchase the bond.[48]

Still, the commitment bond is similar to existing services in that it requires the existence of a counterparty, who must act as an enforcer and monitor. Another individual or institution must be willing to purchase the bond in the hopes that the aspirant does not achieve his goals. As discussed below, this creates perverse incentives, especially if there is no countervailing force like friendship on the part of the buyer.[49]

It is worth noting that the commitment bond has not caught on as a device for commitment.[50] We are unable to find any meaningful adoption of commitment bonds by individuals, governments, or corporate entities, and we are unaware of any secondary market on which they are traded.

Both third-party services and the commitment bond involve a contract with a counterparty. This counterparty is incentivized to monitor performance, though each method has a slightly different way of doing so. For our purposes, it is relevant that the monitoring falls along a spectrum, with the total excision of human reporting at one extreme and complete reliance on the aspirant himself at the other. The use of "referees" or "supervisors" that are designated by the aspirant falls closer to the self-reporting end of the spectrum, while integration with tracking apps or hired monitors falls closer to the other end. As will be discussed below, the existence of counterparties necessarily raises the costs of transacting.

C. Government Regulation of Personal Commitments

Personal growth bets are a kind of "precommitment"—a concept whose difficulties have been analyzed before.[51] But, as discussed, a personal growth bet can also be thought of as a contract, which have, in some instances, been recognized by the law. That is, there are legal

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[48] *See id.* at 610.

[49] Someone wouldn't want a company incentivized to prevent him from achieving his personal goals.

[50] Another interesting commitment device that has not caught on is the "anti-insurance" contract proposed by Cooter and Porat in 2002. Robert Cooter & Ariel Porat, *Anti-Insurance*, 31 J. LEGAL STUD. 203, 204 (2002). Anti-insurance operates by having payments for the promisor's breach made to a third party instead of to the promisee. *Id.* at 203. This increases the incentives for promisees to commit to the contract and not abandon once it becomes clear that performance is not 100% possible. *See id.* at 203–04.

[51] *See* John A. Robertson, *"Paying the Alligator": Precommitment in Law, Bioethics, and Constitutions*, 81 TEX. L. REV 1729 (2003) (analyzing precommitments in international law, norms and restrictions in bioethics, and constitutional governance).

mechanisms by which individuals may, in the present, commit their future selves to taking or refraining from taking a specific action. There are a handful of examples of so-called "self-restriction" laws, and they are worth discussing given that they illustrate how the government can take on the role of enforcer and monitor or compel private parties to take on those roles.[52] They also demonstrate that our concept of self-contracting is neither legally novel, nor practically infeasible.

1. Casino Laws ("Self-Exclusion Laws")

A number of states have gambling self-exclusion statutes.[53] These laws allow individuals to voluntarily place themselves on an exclusion list.[54] Casinos are required by law to expel individuals on this list from the establishment.[55] Missouri was the first state to pass such a law, but the majority of states now have some form of a self-exclusion program.[56] One author describes the origin story of Missouri's law as follows:

> [Missouri added its self-exclusion law] at the behest of a citizen who saw himself as a compulsive gambler whose self-control was insufficient to keep him from entering casinos when his compulsion flared up. Nor, apparently, did it suffice simply to ask the casinos to exclude him. Reaching agreement with each casino individually would be time-consuming, and because the casino would merely

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[52] Cecil VanDevender, Note, *How Self-Restriction Laws Can Influence Societal Norms and Address Problems of Bounded Rationality*, 96 GEO. L.J. 1775, 1777 (2008).
[53] California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Missouri, Montana, New Jersey, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, Virginia, Washington, West Virginia, and Washington D.C. *See, e,g.*, ARIZ. ADMIN. CODE § 19-4-150 (2021); *Responsible Gaming Regulations and Statutes Guide*, AM. GAMING ASS'N (Sept. 1, 2022), https://www.americangaming.org/resources/responsible-gaming-regulations-and-statutes-guide/.
[54] Connecticut, for example, requires casino and gaming operators to "[e]stablish a voluntary self-exclusion process to allow a person to (A) exclude himself or herself from establishing an account, (B) exclude himself or herself from placing wagers through an account, or (C) limit the amount such person may spend using such an account." CONN. GEN. STAT. § 12-863 (2022).
[55] *See, e.g.*, 11 VA. ADMIN. CODE § 5-90-100 (2022) ("3. If an individual on the voluntary exclusion list is found on the premises of a facility, the facility operator: a. Shall immediately notify the department; and b. May pursue criminal charges against the individual for trespassing or any other appropriate criminal charge. 4. A facility operator may not: a. Permit an individual on the voluntary exclusion list to: 1. Enter the facility; or 2. Play a casino game.").
[56] *Supra* note 53 (listing states).

> be promising to exclude him, and not entering into a contract (because it would not be giving up anything as consideration), he would naturally doubt the vigor with which they would enforce this promise (businesses rarely being inclined to kick out their most spendthrift customers as soon as they walk in the door).[57]

While the mechanics of the self-exclusion program vary by state, there are some common features. First, the individual must demonstrate that they are acting both voluntarily and sincerely making the decision to self-exclude; often, he must meet with gaming personnel to complete the process and must have a witness or notary present.[58] The identifying information of the individual is then shared with gambling facilities within the state and used to keep him out. Casinos, for their part, are required to develop internal controls to identify and expel such individuals[59]—in this way, the casinos act as both monitors and enforcers. If an individual on the self-exclusion list violates the prohibition by entering a gambling establishment, he is removed, forced to forfeit any winnings, and, in some states, charged with criminal trespassing.[60]

Getting off of a self-exclusion list also varies by state. In Missouri, once an individual places himself on the list, he is on it for life.[61] Other states allow the individual to choose the length of the exclusion (sometimes from a pre-set menu of options, e.g., 5, 10, or 15 years), after which he is automatically removed from the list.[62] Still, others require the individual to petition for removal, but only after a requisite number of years has passed (as determined by the state).[63]

2. Covenant Marriage Laws

A second type of "self-restriction law" is a covenant marriage—a marital arrangement whereby both spouses agree, through the marriage

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[57] VanDevender, *supra* note 52, at 1779–80.
[58] *See* Andy Rhea, *Voluntary Self-Exclusion Lists: How They Work and Potential Problems*, 9 GAMING L. REV. 462, 464 (2005); ILL. ADMIN. CODE tit 11, § 1770.240 (2008).
[59] *Id.*
[60] *Id.* at 464–65; VanDevender, *supra* note 52, at 1781.
[61] VanDevender, *supra* note 52, at 1780.
[62] *Id.* at 1780–81.
[63] *Id.* at 1780.

contract, to "renounce[] their right to no-fault divorce and adopt[] certain legal duties to one another."[64]

Covenant marriage laws are far less ubiquitous than casino self-exclusion laws; they are recognized in only Arizona,[65] Arkansas,[66] and Louisiana.[67] While covenant marriage serves an expressive function—signaling a couple's intention to remain married their entire lives—it has real legal ramifications. Namely, the couple cannot get a divorce other than for a limited number of reasons (adultery, conviction of a serious crime, abuse, substance abuse, etc.).[68]

A covenant marriage, therefore, allows individuals to deprive their future selves of a right they would otherwise have, i.e., no-fault divorce. As with casino self-exclusion laws, covenant marriages must be entered into voluntarily. In all three states where covenant marriage is allowed, the couple must receive premarital counseling before they will be permitted to enter into a covenant marriage. They must also sign a "Declaration of Intent" agreeing to such terms.

3. Psychiatric Advance Directives and Do Not Resuscitate Orders

While not quite a self-restriction law, psychiatric advance directives ("PAD") represent a legally binding precommitment. A PAD is "a legal tool that allows a person with mental illness to state their preferences for treatment in advance of a crisis."[69] A PAD usually has an advance instruction and also provides for a healthcare power of attorney for an individual who will have decision-making authority in the event of a psychiatric emergency.[70] A PAD can only be entered into by an adult of sound mind, and goes into effect when that adult is deemed by a physician or psychologist to be incapable of making decisions for themselves.[71]

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[64] *Id.* at 1789.
[65] ARIZ. REV. STAT. ANN. § 25-901 (2023).
[66] ARK. CODE. ANN. § 9-11-803 (2020).
[67] *Covenant Marriage*, LA. DEP'T HEALTH, https://ldh.la.gov/page/695 (last visited Apr. 16, 2023).
[68] *See Covenant Marriage Information*, ARIZ. COURT HELP (Mar. 10, 2022), https://azcourthelp.org/topics/marriage/covenant-marriage.
[69] *See* SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMIN., A PRACTICAL GUIDE TO PSYCHIATRIC ADVANCE DIRECTIVES (2019), https://www.samhsa.gov/sites/default/files/a_practical_guide_to_psychiatric_advance_directives.pdf.
[70] *Id.*
[71] *Id.*

Do Not Resuscitate Orders (DNRs) are another form of legally binding healthcare precommitments that have life-and-death consequences. In a DNR an individual will commit his future self to refusing life-saving medical treatment. An individual, who is incapacitated, with no ability to consent or refuse treatment, will use a prior commitment from his past self to inform doctors of his current preferences. Federal law requires certain medical institutions to provide information to patients on their options with respect to medical precommitment.[72]

D. Issues with Third-Party Counterparties

Although numerous people seek self-improvement in the United States,[73] issues with each type of monitor and enforcer prevent personal growth contracts from being anything more than a niche activity. Informal monitors and enforcers, like good friends, can provide a lot of flexibility in how a bet is monitored and enforced, but there is significant downside in the form of damage to the personal relationship or an unwillingness to enforce the contract if the aspirant fails. Formal monitors eliminate the risk of damaging a personal relationship and add credibility to enforcement, but greatly increase transaction costs and often cannot effectively monitor. Government enforcement also carries enforcement credibility, and the government can require other parties to monitor, but in most circumstances, laws governing personal growth would be extremely inefficient, inflexible, or otherwise problematic.

First, one could use an informal monitor and enforcer like a friend. The benefit of going through an informal counterparty is that it avoids the expenses inherent in other methods. However, common sense suggests the problems this creates. One problem is that this places a high burden on the informal party, often a friend, who has to do the work to monitor the bet, intervene if the bet goes off-track, and then enforce the bet against an unfulfilled aspirant if it all goes wrong. A second problem

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[72] *The Patient Self-Determination Act (PSDA)*, AM. CANCER SOC'Y (June 15, 2009), https://www.cancer.org/treatment/treatments-and-side-effects/planning-managing/advance-directives.html?sitearea=MIT [https://web.archive.org/web/20100222233709/http://www.cancer.org/docroot/MIT/content/MIT_3_2X_The_Patient_Self-Determination_Act.asp?sitearea=MIT].

[73] John LaRosa, *$10.4 Billion Self-Improvement Market Pivots to Virtual Delivery During the Pandemic*, MARKET RESEARCH.COM (Aug. 2, 2021), https://blog.marketresearch.com/10.4-billion-self-improvement-market-pivots-to-virtual-delivery-during-the-pandemic.

is that it may damage the personal relationship if the transaction goes awry. We need no citations[74] to make the observation that if two friends make a bet with significant stakes and the outcome is not how the aspirant hoped, this can lead to some serious problems. The friend acting as enforcer must decide how much he actually wants to push to collect (or refuse to return) the money. But, the weaker the threat of enforcement, the weaker the chance the ropes binding our would-be Ulysses hold.

Second, one could use a formal private monitor, like one of the services discussed earlier. A benefit of using such a service would be that there would be no risk of damaging a personal relationship. And there would be much more certainty about enforcement. However, there would be some downsides relative to the informal monitors and enforcers. For one, using a third-party service introduces transaction costs of paying the third party. And many of the third-party services require the aspirant to fill out the details of the progress of the bet, opening it to manipulation. Additionally, the third-party services have other limits, such as only permitting certain types of bets.

This private monitor and enforcer could also take advantage of informal dispute mechanism systems. In a number of areas of law,[75] alternative dispute resolution mechanisms—e.g., private mediation, arbitration, or restorative justice processes—have become increasingly prevalent, though they are certainly not new. Indeed, the Federal Arbitration Act has, since 1925, provided for judicial enforcement of private arbitration agreements.[76] Arbitration, like other alternative dispute resolution mechanisms, has a number of benefits: the absence of government involvement provides a level of flexibility; the parties can tailor the procedure to their particular needs; parties can usually obtain a resolution more expeditiously than through traditional litigation, and often at a cheaper price.[77] In the international context, arbitration is a popular choice because it provides a neutral decision maker who can

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[74] *But see* Orin S. Kerr, *A Theory of Law*, 16 GREEN BAG 2D 111 (2012).
[75] For example, arbitration is common in international commercial law, labor law, securities regulation, and family law. *See Alternative Dispute Resolution*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/alternative_dispute_resolution (last visited Apr. 16, 2023); *see also* Joan F. Kessler, Allan R. Koritzinsky & Stephen W. Schlissel, *Why Arbitrate Family Law Matters*, 14 J. AM. ACAD. MATRIMONIAL L. 333 (1997); *see generally* GARY B. BORN, INTERNATIONAL ARBITRATION: LAW & PRACTICE (3d ed. 2021).
[76] 9 U.S.C. §§ 1–16.
[77] *Arbitration vs. Litigation: The Differences*, THOMSON REUTERS (Oct. 4, 2022), https://legal.thomsonreuters.com/blog/arbitration-vs-litigation-the-differences/.

apply internationally neutral procedural rules.[78] However, arbitration is not without costs. Because the process happens behind closed doors, the decision does not create a precedent that will bind future parties—and while this may be a benefit from the perspective of the parties to the arbitration, it arguably hinders the development of the *corpus juris*. For employees subject to mandatory arbitration with corporations, they may be restricted from raising claims under a number of federal employment statutes.[79] Additionally, there is some evidence that arbitration tends to favor corporate parties, so defendants who have an incentive to collect payment may try to game the system.[80]

Third, one could contract the problem out to the government. There would be several benefits. There should be no question about the threat of enforcement. And the government could enforce non-damages forms of relief such as casino-exclusion-like laws. However, there would be numerous downsides that likely preclude using the government for most personal growth bets. One could be the very high-transaction costs of using government agents to act as monitors and enforcers. For a few categories of bets (reducing gambling or alcohol consumption), it may be possible to shift the cost to private parties, but in most cases the private sector would be better able to provide the service. That is because the system would have to be one-size-fits-all and relatively inflexible (for example, consider covenant marriage laws).

II. SMART CONTRACTS: A SOLUTION FOR SELF-CONTRACTS

A. An Alternative Framework: Self-Contracts

We propose a newer form of this contract that occurs unilaterally and we describe as a "self-contract." On its face, the concept of a self-contract is a contradiction. As discussed above, the traditional view of contracts defines them as *mutual* promises enforceable by law.[81] This typically means that there are at least two parties who enter into an agreement — a "meeting *of two* minds" to perform certain acts (or forbearances).

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[78] *See* BORN & RUTLEDGE, INTERNATIONAL CIVIL LITIGATION IN U.S. COURTS 1149–62 (6th ed. 2018).
[79] STONE & COLVIN, THE ARBITRATION EPIDEMIC: MANDATORY ARBITRATION DEPRIVES WORKERS AND CONSUMERS OF THEIR RIGHTS (2015), https://files.epi.org/2015/arbitration-epidemic.pdf.
[80] *Id.*
[81] *See* RESTATEMENT (SECOND) OF CONTRACTS § 17(1) (1977) ("[T]he formation of a contract requires a bargain in which there is a manifestation of mutual assent to the exchange and a consideration.").

In most circumstances, it is true that the idea of a self-contract is contradictory. Suppose Max writes a "contract" with himself that says, "If Max does not lose 10 pounds by January 1st, Max will have to pay Max's designated charity $1,000." Supposing this "contract" is breached, what remedy does Day 1 Max have against Day 365 Max? Day 1 Max is the one with the claim because Day 365 Max is in breach, but because it is Day 365 Max who has the actual ability to bring the claim in court (because Day 1 Max no longer exists), and since Day 365 Max has already made the decision not to bring the claim, the concept is nonsensical. But, let us note something important—the reason why the concept is nonsensical is not because there is anything wrong with treating Day 1 Max and Day 365 Max as two contracting parties;[82] it is nonsensical because, as a technical matter, there is no way to empower Day 1 Max to bring or enforce a claim. The hallmark of a right is the ability to enforce it, and Day 1 Max is powerless. This is where a new invention called smart contract changes the situation.

Now it may be said that we are simply replacing one form of law professor pipe dream (i.e., the commitment bond) with another that will also not catch on (i.e., the self-contract). The response to this is that self-contracts have already caught on[83], and their aims are often to further personal commitments. Similarly, the use of smart contracts today in many financial transactions, including art markets, demonstrates the use of technical precommitment as a popular tool.

Aspects of many cryptocurrencies incorporate the self-contract and have simply not been labeled as such. Let us take for example what is called a "multi-signature wallet" on the bitcoin network. The bitcoin network uses public key-private key cryptography to establish ownership of bitcoin.[84] When an individual has possession of a private key, he is able to transfer bitcoin, and therefore possession of a private key establishes possession of a bitcoin.[85] But there are more complex ways of creating a private key, namely what are referred to as "multi-signature" wallets.[86] These wallets essentially divide a private key into a certain

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[82] This does bring up an issue of Day 365 Max not being a party to the original contract because he is non-existent at the point of the contracting, so he cannot give his consent. Framing these contracts as bilateral agreements does not make sense.
[83] *See infra* Section I.B.1.
[84] *See* SATOSHI NAKAMOTO, BITCOIN: A PEER-TO-PEER ELECTRONIC CASH SYSTEM (2008).
[85] *See* Gunnar Lindqvist et al., *How Do Bitcoin Users Manage Their Private Keys?*, 7TH INT'L WORKSHOP ON SOCIO-TECH. PERSPECTIVE IN I.S. DEV. Oct. 11-12, 2021 at 11, ("Private keys provide bitcoin ownership and can create Bitcoin addresses and digital signatures for transactions on the Bitcoin blockchain.").
[86] *See* Colin Harper, *Multisignature Wallets Can Keep Your Coins Safer (If You Use Them Right)*, COINDESK (Feb. 9, 2023, 8:17 AM),

number and require a certain number of those sub-keys to transfer bitcoin.[87] For example, a private key may be divided into three and two of the sub-keys are needed to transfer bitcoin.[88] This system is used in a number of different applications, but primarily it is thought as a mechanism for increasing security by involving multiple parties in the ownership and transfer of bitcoin.[89] Escrow services, for instance, use this multi-signature technology.[90]

For our purposes, however, what is important is that many cryptocurrenciesrepresent an existing form of self-contracts for commitment purposes. When an individual takes his bitcoin private key and divides it, he is "tying himself to the mast."

B. Smart Contracts Overview

A smart contract is an agreement whose execution is automated. One powerful example of a smart contract is the vending machine.[91] A vending machine has been defined as "self-contained automatic machines that dispense goods or provide services when coins are inserted."[92] In other words, a vending machine is a device that automates performance of a sales contract by tendering a good once the offer for the good has been accepted through performance. To illustrate, suppose a vending machine contains an offer on the part of the seller to tender one can of Coke in exchange for 10 U.S. dollars.[93] Once the buyer accepts the offer by inserting money into the machine, the machine executes the contract by dispensing the can of Coke. The reason this contract is "smart" is that once the offer has been accepted and the contract formed, no human activity is needed to perform the contract, and the agreement is executed automatically by a machine.

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https://www.coindesk.com/tech/2020/11/10/multisignature-wallets-can-keep-your-coins-safer-if-you-use-them-right/.

[87] *Id.*

[88] *Id.*

[89] *See* Freeman Law, *Cryptocurrency Transactions: Multi-Signature Arrangements Explained*, FREEMAN L. INSIGHTS BLOG (Nov. 11, 2022, 5:10 PM), https://freemanlaw.com/cryptocurrency-transactions-multi-signature-arrangements-explained/ ("Multi-signature transactions provide an increased level of security.").

[90] *Id.* ("A common use of the multi-sig approach is the 'Multisig Escrow'—a trading arrangement designed to offer security to both buyers and sellers.").

[91] *See* Nick Szabo, *Formalizing and Securing Relationships on Public Networks*, 3 (1997), http://myinstantid.com/szabo.pdf; *see also* Raskin, *supra* note 16.

[92] *See* KERRY SEGRAVE, VENDING MACHINES: AN AMERICAN SOCIAL HISTORY (MCFARLAND & CO. 2002).

[93] Given central banks' tendencies to inflate, and our desire for this paper to remain fresh and relevant in the future, we have assumed a higher price of Coke than exists at the time of publication.

These contracts are distinct from traditional contracts where the parties themselves are required to act or refrain from acting in order to ensure completion of the agreement. For example, in a contract to build a house, a general contractor and his subcontractors must build the house themselves. Human action is required.[94] Not so with the smart contract. In the smart contract, once the agreement has been made, performance is automated.

Automation can exist in a number of forms. As in the case of a vending machine, one method of automation is through a physical device. Another example of a physical device instantiating a smart contract is a "starter interrupter" device. These devices prevent ignition of an automobile and are used by creditors to render their collateral, i.e., the vehicle, non-functional if the debtor is not in compliance with the terms of his financing arrangement.[95]

Another method of automation is computer code linked to digital financial assets.[96] Computer programming languages are highly amenable to contract creation execution because the foundation of computer logic is "if/then" statements. This is also the foundation of contractual thinking. For example, *if* a debtor is in default, *then* his secured collateral returns to the creditor.

Smart contracts executed by computers must translate the terms of agreement into computer-readable and executable programs. A vending machine is an example of this. Inside of the vending machine is a system of computers and physical devices that instantiate the terms of the contract. The computer program directs machinery by using a system of if/then statements combined with Boolean operators.

Connecting contract terms to physical instruments involved in the performance of the contract is termed "contractware."[97] Contractware is defined as the physical or digital instantiation of a computer-decipherable contract.[98] In other words, contractware is a device that control some object connected to the performance of a contract. In the case of the vending machine, the innards of the machine, including the device that dispenses the Coke, is contractware. To give a fanciful

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[94] Even in the case of a spot transaction, like a sale at a cash register, a human must hand over payment and human must make the goods available.
[95] *See* Kwesi D. Atta-Krah, *Preventing a Boom from Turning Bust: Regulators Should Turn Their Attention to Starter Interrupt Devices Before the Subprime Auto Lending Bubble Bursts*, 101 IOWA L. REV. 1187, 1191 (2015).
[96] It is worth noting that cryptocurrency is not the only digital financial asset. Most of the money base today does not, in fact, come in the form of physical dollar bills, but rather exists digitally as accounting conventions governed by the Federal Reserve.
[97] *See* Raskin, *supra* note 16, at 307.
[98] *Id.* at 312.

dystopian example, take the case of a debtor wished to secure lower interest rates and was willing to install a bomb in his skull such that it would explode if he missed a payment or tried to remove it. The bomb-computer device would be an example of contractware because it helps to ensure performance in the real world of a contract between the debtor and creditor.

1. Blockchains and Immutability

Until recently, smart contracts and their contractware was most commonly seen in vending machines.[99] But the rise of blockchain technology has enabled the use of contractware in financial transactions.

This was achieved through the use of public key-cryptography. Digital currencies like bitcoin or Ether are financial assets, but their technical specifications distinguish them from other financial assets. We will proceed with bitcoin for an overview of what makes cryptographically-secured digital assets unique, but many digital assets share the same structure.

Bitcoin exists in bitcoin addresses, which can be thought of as accounts. This public address has an associated private key. A user who possesses the private key associated with the public address can authorize transactions to send funds from one address to another.

Each address' balance can be viewed on a ledger called the blockchain, which is a public recording of all bitcoin addresses and all transactions between those addresses. This ledger is public and can be viewed by anyone who downloads the blockchain.[100] To use a helpful analogy, a bitcoin address is like a safety deposit box on the Internet that is made of glass. Anyone can see what is inside any safety deposit box by viewing its public address, but only an individual with the private key associated with a particular box can open the box and send its contents to another box.

A blockchain operates such that once a decision is made on behalf of an owner to send funds, those funds are irrevocably sent. The sending of funds is immutable and recorded forever on the ledger.[101] If an

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[99] For more on the radical history of the vending machine, *see id.* at 315.

[100] *See* DYLAN YAGA ET AL., BLOCKCHAIN TECHNOLOGY OVERVIEW, NISTIR 8202 5 (Oct. 2018), available at https://nvlpubs.nist.gov/nistpubs/ir/2018/nist.ir.8202.pdf ("Permissionless blockchain platforms are often open source software, freely available to anyone who wishes to download them.").

[101] *Id.* at 46 ("Once data is recorded in a blockchain, that data is usually there forever[.]").

individual sends his savings from one safety deposit box to another that he does not own, he no longer controls those funds. It is practically impossible to undo a transaction by rewriting a blockchain[102]—this is the entire point of the blockchain schema of operation.

This immutability also serves as the basis for smart contracts existing on a blockchain. Just as the command to send funds exists on the blockchain, so too do more complex commands that involve concepts like making payment conditional on certain occurrences. The ability of blockchains to execute conditional commands is the basis of smart contract technology. The Ethereum blockchain was in large part designed to execute these more complex conditional statements in an immutable fashion.[103] Indeed, an entire programming language, Solidity, was created solely to write smart contracts on the Ethereum blockchain.[104] This programming language enables a more complex set of contracts.

One example of such a contract enabled by blockchains is the decentralized escrow contact. In most instances, a third party service acts as the intermediary between two parties to execute an escrow contract.[105] A buyer of a house, for instance, deposits money into the third party's account, and the funds are not released until the third party makes a judgment that the seller has done what he needs to do per the terms of the contract (i.e., provide the buyer with possession).

Escrow services that exist on blockchains remove this third party from the equation. The buyer of an asset sends his money to a public address that is encoded with certain conditionals that release the funds to the buyer only if those conditions are met. Unlike the third party that uses its judgment to determine whether funds are released, in a smart contract escrow service, what is called an "oracle" makes a determination whether certain conditions are met, and the funds are then sent automatically, without having to rely on a third party.

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[102] *Id.* at 1 ("At their basic level, [blockchains] enable a community of users to record transactions in a shared ledger within that community, such that under normal operation of the blockchain network no transaction can be changed once published.").
[103] *See* Vitalik Buterin, *Ethereum: A Next-Generation Smart Contract and Decentralized Application Platform*, ETHEREUM (2014), https://ethereum.org/669c9e2e2027310b6b3cdce6e1c52962/Ethereum_Whitepaper_-_Buterin_2014.pdf.
[104] *See Solidity*, ETHEREUM, https://docs.soliditylang.org/en/v0.8.17/ (last visited Sept. 15, 2022).
[105] *See* Troy Segal, *Understanding the Escrow Process and Requirements*, INVESTOPEDIA (last updated June 13, 2022), https://www.investopedia.com/mortgage/escrow-process-requirements/.

A blockchain oracle is a method of connecting a smart contract to real world information.[106] This is most often accomplished through programs called application programming interfaces ("APIs"). APIs are a method for computers to talk to one another automatically.[107] The publisher of certain real-world information will use an API to connect to other computers that are interested in that information. For instance, the federal government's National Weather Service has an API that includes daily temperature readings from around the country.[108] Likewise, various stock markets have APIs that relay information about stock prices through the day.[109]

Now, we can tie everything together to show how a smart contract bet can be executed without the use of a third party. Let us suppose two individuals made a bet using a smart contract about the temperature on a given date in New York City. In a world where they use a third-party escrow service to settle the bet, the third party would use some method of determining the temperature and then use its judgment to determine whether the conditions had been satisfied such that one person won. An oracle, however, would operate automatically by connecting to the National Weather Service's API that publishes the daily temperature in Central Park.[110]

The oracle connected to the National Weather Service would automatically inform the public address, which has been encoded with a smart contract, what the temperature was. As stipulated by the immutable if/then statements, a party would be the winner of the bet and the funds would be automatically released once the data was published.

It is a hop, skip, and a jump from bilateral bets about the temperature in Central Park to a person making a bet with himself about

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[106] *See What Is a Blockchain Oracle?*, CHAINLINK (last updated Sept. 14, 2021), https://chain.link/education/blockchain-oracles.

[107] *See What Is an API?*, AMAZON, https://aws.amazon.com/what-is/api/ (last visited Sept. 15, 2022).

[108] *See* National Weather Service, *API Web Service*, NAT'L OCEANIC & ATMOSPHERIC ADMIN., https://www.weather.gov/documentation/services-web-api (last visited Sept. 15, 2022).

[109] *See* United Fintech, *Everything You Need to Know About Stock Market APIs*, UNITED FINTECH BLOG (Aug. 25, 2021), https://unitedfintech.com/blog/everything-about-stock-market-apis/. *See also* NEW YORK STOCK EXCHANGE, https://www.nyse.com/market-data/real-time (last visited Sept. 15, 2022); NASDAQ, https://data.nasdaq.com/tools/api (last visited Sept. 15, 2022).

[110] There is some question as to the honesty of oracles—like all technology, APIs can be manipulated. For instance, hackers could change the National Weather Service's data or the government itself could publish corrupt data. Dealing with corrupt oracles is beyond the scope of this paper, but suffice it to say that there are many novel technical workarounds to such problems.

his weight, and then verifying with an oracle connected to an API published by an Internet-connected scale.

2. Strong and Weak Smart Contracts

Before assessing the legality of smart contracts for personal bets, there is one more concept that must be introduced: the distinction between strong and weak smart contracts.

Not all smart contracts are created equally; they exist along a spectrum of how "smart" they are. This spectrum classifies smart contracts according to their cost of revocation and modification.[111] Smart contracts are said to be stronger when these costs are higher, and they are said to be weaker when these costs are lower.[112]

The above bomb-in-skull example that a debtor would use to obtain a lower interest rate from a creditor would be a strong smart contract because if one tries to modify or revoke the contract by surgically removing the device, the bomb will explode. There is an infinitely high cost of revocation to the debtor and so this would be deemed a strong smart contract.

On the other end of the spectrum is a weak smart contract. An example of this would be a standing purchase order with Amazon. Suppose an individual has a standing order to buy paper towels once a month from Amazon. Once the contract is formed, it executes automatically through Amazon's distribution system. There may be human beings at the last mile, but given their relative lack of autonomy over the execution of the contract, this could be considered a smart contract of sorts.

The reason is that if the buyer realizes he no longer needs paper towels that month and tries to revoke the order, there is a point at which Amazon cannot stop performance. Suppose the hour before the paper towels were scheduled to be delivered, the buyer tried to cancel the order—it is true that Amazon could refund him after the fact and demand a return, but the paper towels would likely still be delivered. It is not a strong smart contract, however, because Amazon has a number of ways to prevent the automatic execution of the contract. If the order was canceled early enough the company could instruct their robots not to execute certain commands to get the paper towels. It is a weak smart

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[111] *See* Max Raskin, *The Law and Legality of Smart Contracts*, 1 GEO. L. TECH. REV. 304, 310 (2017).
[112] *See id.*

contract in the sense that there are many ways the parties can get out of it without a high cost.

Courts may not be in the business of modifying or revoking contracts, but it is important to them that they have the ability to do so.[113] This is why the existence of strong smart contracts pose a greater challenge than weak smart contracts to the government and its legal system. These distinctions and the approach of the legal system to strong and weak smart contracts will be important when thinking about personal growth bets.

3. Unilateral Smart Contracts for Personal Growth Bets

With the above, we can proceed to describe a unilateral smart contract used for a personal growth bet.

Any unilateral personal growth contract has two legs that mimic the two sides of a bilateral contract. The first leg is the action or inaction that is the aim of the contract. The second leg is the consequence of performance or breach of the terms.

For example, an individual who wants to stop smoking will define the first leg of the contract as abstaining from smoking cigarettes for 30 days following execution of the contract. The second leg will be that if the individual does not stop smoking cigarettes for the next 30 days, then he will forfeit $10,000. The terms of this contract are fairly straightforward and if two parties were to enter into this contract, as seen above, it would be a legally enforceable contract.[114]

By removing the counterparty from the contract, the dual problems of monitoring and enforcement arise.

Counterparties have incentives to monitor performance. Whether it is a homeowner monitoring compliance by a general contractor or an employer monitoring his employees' timecards, parties to a contract are incentivized to ensure performance from their counterparties.

In the case of a bilateral non-smoking contract, the counterparty who will win $10,000 if the individual smokes is incentivized to monitor the individual's behavior. One website, funded by the National Institutes of Health, provides breathalyzers to detect carbon monoxide to ensure compliance with the terms of the agreement.[115] Smokers have elevated

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[113] *See infra* Part III.A.

[114] There may be a question of adequate consideration on the part of the friend who is acting as the monitor or enforcer, but this can be easily rectified by his staking $10 in the case of his friend accomplishing his bet—serving the role of the steak dinner in our personal example.

[115] *See* QUITBET, https://www.quit.bet/ (last visited Sept. 15, 2022).

levels of carbon monoxide in their exhaled breaths. The organization established a threshold of 6 parts per million, such that if a breathalyzer detects 7 or more parts per million of carbon monoxide, he will be considered having smoked.

The important thing to note here is that monitoring involves some interaction between the contract and the real world. The contract lays out certain events or non-events that trigger certain conditional clauses of the contract. Determining whether those events or non-events happened is a central part of the contract. For any contract to be enforced, determining whether events occur is of paramount importance, but it is a condition often taken for granted because of the presence of a highly incentivized counterparty.

The second important aspect of a contract that becomes problematic without a counterparty is enforcement after either performance or breach. When a party to a contract breaches, a counterparty has legal and non-legal remedies available to him.[116] A wide variety of non-legal recourse is available to an aggravated party, ranging from civil discussion[117] to extreme social pressure.[118] Legal recourse in this context normally entails the use of the court system to sue for breach of contract. Without a counterparty, the concept of suing for breach is nonsensical. No one either would or could take himself to court. The reason he would not is because any of the damages he would sue for, e.g., forfeiting money, he would be either willing or not willing to pay himself.[119] If he was unwilling, he would not bring himself to court because the end of a successful case would be his paying himself the money. If he was willing, he would simply forfeit the money without

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[116] *See* RESTATEMENT (SECOND) OF CONTS. § 1 (AM. L. INST. 1981) ("A contract is a promise or a set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty."); UCC §§ 2-708, 2-713, 2-716 (AM. L. INST. & UNIF. L. COMM'N 2021).

[117] Civil discussion can occur informally between the parties, or as a formal type of alternate dispute resolution known as mediation. *See Mediation*, NEW YORK STATE UNIFIED COURT SYSTEM, https://ww2.nycourts.gov/ip/adr/mediation#:~:text=In%20mediation%2C%20a%20person%20called,or%20wrong%20in%20the%20past (last visited Apr. 5, 2023).

[118] In a recent high-profile contract dispute, video game developer Epic Games provoked a public shaming campaign against its counterparty, Apple. *See* Gene Park, *'Fortnite' Is Trying to Change Public Opinion About Apple. But Small Developers Are Lost in the Debate.*, WASH. POST (Aug. 21, 2020), https://www.washingtonpost.com/video-games/2020/08/21/fortnite-is-trying-change-public-opinion-about-apple-small-developers-are-lost-debate/ ("Epic Games continue[d] this momentum of publicly shaming Apple by announcing a #FreeFortnite tournament[.]").

[119] This assumes there is no third party to act as a party to the suit.

going to court. And anyway, a court would never entertain a person suing himself.[120]

What follows is an outline for a non-smoking smart contract, which solves the problems of both enforcement and monitoring. The smart contract is set up first with a public bitcoin address that is created by the aspirant or a third-party service.[121] The aspirant then sends $10,000 worth of some digital currency to that address.[122] The address is encoded with an oracle that is connected to the API of a breathalyzer. To ensure that there is no cheating, the device can either be housed in a healthcare facility or use some technology like facial recognition to ensure no tampering or fraud.

Then a series of if/then statements are encoded onto the public address. The primary statement might read: "*If* a carbon monoxide reading over a threshold level is detected at any of the readings during the 30 days, *then* the $10,000 is forfeited." A number of conditions would be written into the code that would evolve over time—how often a reading must be registered—how to deal with impossibility of a breathalyzer reading in the case of emergency, etc. As most individuals do not write code, it is likely that such smart contract software bases would exist in services or as open-source projects.

This contract is just one of many that are possible. The crux of the development of such contracts will be the appetite of the aspirants as well as the ability for oracles to enable individuals to take monitoring and enforcement into their own hands. The following section addresses the legality of such contracts.

4. Normative Case

There is nothing doctrinally challenging about the use of smart contracts in personal growth bets. They can be characterized as unilateral or "self-contracts" and then can be analyzed within the corpus of traditional contract law.

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[120] *But see* Christopher Coble, *Can You Sue Yourself? In Fatal Car Crash Case, Utah Court Says Yes*, FINDLAW: COURTSIDE (last updated Mar. 21, 2019), https://www.findlaw.com/legalblogs/courtside/can-you-sue-yourself-in-fatal-car-crash-case-utah-court-says-yes/.

[121] It may seem paradoxical to use a third-party service to execute a unilateral bet, but given the open-source nature of the code, these third-party coders are really just acting as agents for the aspirant.

[122] Given the volatility of digital assets, there are a number of hedging mechanisms, including stablecoins, that exist to ensure the constancy of the $10,000.

One of the first principles of contract law is a presumption that contracts ought to be enforced.[123] This presumption is not absolute and there are a number of doctrines and rules that courts use to prevent the enforcement of otherwise legal contracts.[124] As shown above, there is no structural reason why smart contracts cannot be formal contracts; they contain the requisite consideration and other elements of a valid contract, including offer and acceptance. Therefore, the presumption is that they should be enforced and not voided by the state, either through the courts or the legislature's police power.

There are, however, exceptions that the state uses to void otherwise legitimate contracts.[125] For our purposes, the relevant one here is a court's invalidation of a contract on public policy grounds. The idea behind invalidating a contract on public policy grounds is that even though the two parties make and formalize a bargain that they believe *ex ante* will be of mutual benefit, there are other parties involved that are harmed and therefore the state has the power[126] to invalidate those contracts.[127]

A classic example of such a contract would be a sales contract with a citizen in a country that has been embargoed. Even though an American buyer and a Cuban seller may execute an otherwise legitimate contract for the sale of cigars, because the United States has a policy of embargoing Cuba and there exist laws that establish this policy, a court will invalidate a contract between two willing parties on the grounds that it is illegal. Courts can also make determinations that certain contracts violate public policy without an explicit determination by a legislature.[128]

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[123] *See, e.g.*, Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A., 188 F. Supp. 2d 115, 123 (D. Mass. 2002) ("The Court presumes that, if a contract was formed in this case (which is assumed to be true for purposes of summary judgment), the parties expected it to be enforced.").

[124] United States v. Bethlehem Steel Corp., 315 U.S. 289, 326 (1942) (Frankfurter, J., dissenting) ("[I]s there any principle which is more familiar or more firmly embedded in the history of Anglo-American law than the basic doctrine that the courts will not permit themselves to be used as instruments of inequity and injustice? Does any principle in our law have more universal application than the doctrine that courts will not enforce transactions in which the relative positions of the parties are such that one has unconscionably taken advantage of the necessities of the other? These principles are not foreign to the law of contracts. . .. More specifically, the courts generally refuse to lend themselves to the enforcement of a 'bargain' in which one party has unjustly taken advantage of the economic necessities of the other.").

[125] By legitimate, we mean under principles inherent in the nature of the contract itself under established principles of contract law.

[126] As a positive matter.

[127] *See* RESTATEMENT (SECOND) OF CONTS. § 179 (AM. L. INST. 1981).

[128] *See id.*; *see, e.g.*, Henningsen v. Bloomfield Motors, Inc., 161 A.2d 69 (N.J. 1960) (striking warranty provision in a contract for the sale of a car where the car manufacturing industry operated as an effective oligopoly).

In a traditional contract, which has no self-enforcing mechanisms, neither courts nor police are needed to ensure that the contract is not executed. This is because many steps of human action are still needed to make the contract a reality and at each step along the way, either law enforcement or the courts can step in to invalidate the contract. The mere writing of a contract that says "Bob will sell Alice 10 pounds of heroin" is not as problematic as taking actual steps to make the contract a reality, for instance, by planting opium poppy seeds or manufacturing heroin. Law enforcement does not have such a problem with the writing and executing of contracts that are contrary to public policy because there is ample ability to invalidate the contract down the road after concrete actions have been taken.[129]

This is not the case with smart contracts. Because smart contracts aim to excise human performance from their operation, law enforcement and the state, generally, should have more of an issue with their "mere" creation. Another way to think of this is that the concrete actions that are problematic from the point of view of the state are taken before the offer and acceptance of the smart contract. The actual creation of the contract can pose problems.[130]

As with all regulation, there are two possible methods for regulating smart contracts—through *ex ante* and *ex post* regulation and enforcement. In a free society, the general method of regulation and law enforcement is through *ex post* actions by the state.[131] This is to say that governments generally do not require individuals to seek permission before acting, even if those actions *could* be illegal.

Take the example of a cigarette vending machine, which, as we have discussed above, is a classic example of a strong smart contract. As of the time of writing, cigarettes by themselves are not illegal. Vending machines are not illegal either. But the United States federal government has a policy of not allowing individuals under the age of 21 to purchase

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[129] *See* RESTATEMENT (SECOND) OF CONTS. § 178 (AM. L. INST. 1981) ("A promise or other term of an agreement is unenforceable on grounds of public policy if legislation provides that it is unenforceable or the interest in its enforcement is clearly outweighed in the circumstances by a public policy against the enforcement of such terms.").

[130] *See, e.g.*, *U.S. Treasury Sanctions Notorious Virtual Currency Mixer Tornado Cash*, U.S. DEP'T OF THE TREASURY (Aug. 8, 2022), https://home.treasury.gov/news/press-releases/jy0916 (describing actions taken against a developer's creation of a decentralized service that the state viewed as contrary to law and public policy).

[131] *See generally* Samuel Issacharoff, *Regulating After the Fact*, 56 DEPAUL L. REV. 375 (2007).

cigarettes. These facts taken together pose a conceptual problem for cigarette vending machines as a smart contract.

The United Kingdom, for instance, has banned cigarette vending machines.[132] Different states in the United States have different approaches, but New York City, for instance, has banned their use in public places.[133] Bans on the use of these smart contracts demonstrate that certain strong smart contracts fall within the ambit of the state's police power.[134] The cost of revocation or modification for certain smart contracts are so high that governments have made a determination that their mere existence should be prohibited.

For example, an individual about to drive a car could potentially commit the crime of drunk driving. Driving under the influence of alcohol is a crime that could be regulated either before or after the crime takes place—either though an *ex ante* regulation or *ex post* policing. There exist devices called ignition interlock devices that prevent cars from starting unless the driver's breath-alcohol level is below a certain threshold.[135] Some private bus companies use these devices to ensure that their drivers are not driving drunk and endangering their passengers. But the government does not generally require these devices in every car,[136] and has instead opted for an *ex post* policing regime for the crime of drunk driving. Police monitor the roads and only when a certain threshold of suspicion is met for a search does law enforcement police the crime.

It is important to note here that *ex ante* prohibitions are certainly the exception to the general rule of *ex post* enforcement. There are very

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[132] *See Cigarette Vending Machines Banned in Eng.*, BBC (Oct. 1, 2011), https://www.bbc.com/news/uk-15132529.

[133] *See* Eric Pace, *N.Y.C. Moves Against Cigarette Machines*, N.Y. TIMES (Oct. 16, 1990), https://www.nytimes.com/1990/10/16/nyregion/new-york-city-moves-against-cigarette-machines.html.

[134] An interesting analogue is developing in the case of Tornado Cash, where courts will have to determine whether a smart contract executing a certain money transaction is per se problematic. *See* Jerry Brito & Peter Van Valkenburgh, *Coin Center Is Suing OFAC Over its Tornado Cash Sanction*, COIN CENTER (Oct. 12, 2022), https://www.coincenter.org/coin-center-is-suing-ofac-over-its-tornado-cash-sanction/.

[135] *See What Is an Ignition Interlock Device?*, INTOXALOCK, https://www.intoxalock.com/ignition-interlock-devices/what-is-an-ignition-interlock-device/ (last visited Apr. 9, 2023).

[136] There are instances, however, where state legislatures have made the determination that repeat DUI offenders shall be required to have such devices in their vehicles. *See, e.g.*, *New York Enforces Mandatory Interlock Device Use for All DUI Offenders*, LERNER & LERNER, P.C., https://www.lernerandlerner.com/articles/new-york-enforces-mandatory-interlock-device-use/#:~:text=New%20York%20mandates%20that%20all,National%20Conference%20on%20State%20Legislatures (last visited Sept. 15, 2022).

few devices in society that are *per se* illegal. Even for cigarette vending machines, there is no outright ban, as they are allowed in establishments where patrons must be 21 years or older to enter. Another example of *ex ante* regulation is with respect to certain classes of firearms. Fully automatic weapons, like machine guns, are generally prohibited for private ownership in the United States.[137] A very strict preclearance regime exists, and only certain licensed individuals are allowed to own such automatic weapons.[138] But millions of pistols and rifles are not illegal in the United States and their ownership is constitutionally protected, even though they can be used to commit crimes.[139] It is true that a preclearance regime with varying degrees of strictness exists in many states, but the objects themselves have not been banned.

Turning to personal growth bets, using the above framework, there should be a strong presumption to allow the use of smart contracts in personal growth bets. As mentioned above, there are two aspects of smart contracts in personal growth bets that differentiate them from traditional contracts with counterparties. These two areas of monitoring and enforcement are the two areas that the state may object to on public policy grounds.

Let us tweak the example of the non-smoking personal growth bet and turn it into a non-drinking personal growth bet. An individual sets up a smart contract such that if his blood alcohol level ever goes above .02, he will forfeit $10,000. In this bet, an individual will need an oracle to monitor his blood alcohol level. This is not technically difficult and would be similar to diabetic individuals who have blood sugar monitors attached to them perpetually. This monitor will act as an oracle and be connected to a digital currency account. The smart contract will be set up such that the value of the escrow account will be either donated or destroyed if the conditions are not met.

There is nothing inherently problematic about this contract from a legal perspective.[140] There are ways in which this contract could,

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[137] *See, e.g.*, N.Y. PENAL LAW § 265.02(2), (3) (McKinney 2022).
[138] Peter Suciu, *Yes, Machine Guns Are 'Legal' (But Here Comes All the Catches)*, NAT'L INT. (July 2, 2020), https://nationalinterest.org/blog/reboot/yes-machine-guns-are-legal-here-comes-all-catches-163921.
[139] New York State Rifle & Pistol Association, Inc. v. Bruen, 142 S. Ct. 2111 (2022).
[140] One possible objection is that the forfeiting of currency poses a problem to the central bank's control of the money supply. It is illegal to burn federal reserve notes, i.e., U.S. dollars. 18 U.S.C. § 333. Stemming from this, it is impermissible to instruct an executor of an estate to burn one's estate. *See* RESTATEMENT (SECOND) OF TRUSTS, § 124 cmt. G (AM. L. INST. 1959) (describing "capricious purposes"); *see also* Everman v. Mercantile Trust Co., 524 S.W.2d 210 (Mo. App. 1975) (citing the Restatement section); In re Scott's Will, 386, 93 N. W. 109 (Minn. 1903) (citing the Restatement section and Evermen). To begin with, if the personal growth bet is denominated in

however, become problematic. Suppose instead of forfeiting money, an individual, so committed to sobriety, set up his monitoring device to include a cyanide pump such that he would be injected with cyanide if a BAL of over .08 was detected. The government would obviously not allow this contract, *ex ante*.

This demonstrates a spectrum of contractware that instantiates contracts. A general rule can be gleaned from the above examples and existing legislation: a smart contract executing a unilateral personal growth bet should be presumptively allowed so long as the damages for breach do not violate an otherwise applicable law. Any regulation of such contracts and the technology making them a reality should be done *ex post*, if at all.

The most powerful existing precedent for such a rule is the self-exclusion rules mentioned above. The most important thing to note about the existence of these laws is that they explicitly recognize the use of punishment to give precedence to a person's earlier will over his later will. In some sense, all contracts do this, but these laws are unique in that they are a close example to a self-contract because there is really no third party involved.[141]

These laws also prevent a person from doing something that otherwise would be permitted. Like all contracts, personal growth bets involve taking on additional obligations. A general contractor does not have to build a house, but when he agrees to take on the obligation, we give this agreement legal force. So too with self-exclusion laws. An individual does not have to ban himself from a casino, but once he does, we give legal force to this commitment. The same holds for unilateral smart contracts. An individual does not have to commit to sobriety or weight loss, but once he does, we give the contract legal force.

Another thing to note about self-exclusion laws is that there is nothing inherently illegal or against public policy to prevent an individual from entering a casino. So long as the casino is not running afoul of any anti-discrimination laws, they are allowed to refuse entry to whomever they decide.[142] Thus, the punishment does not involve anything illegal.

U.S. dollars, there are many workarounds to this rule. An individual could simply lock his currency in a digital safe that scrambles its password if the conditions are not met. Secondly, if the bet is denominated in a digital currency, the statute does not apply.

[141] It is true that self-exclusion laws bind third parties, i.e., the casinos. In this sense, the unilateral smart contract for personal growth bets is actually less problematic because they do not use state power to bind non-parties to the contract.

[142] *See* Madden v. Queens Cnty. Jockey Club, 72 N.E.2d 697, 698 (N.Y. 1947) ("In our opinion [the racetrack operator] has the power . . . to exclude others solely of his own

This rule can be applied to the above case of the personal growth bet to avoid alcohol consumption. Two consequences were proposed—one in which money was forfeited and the other in which cyanide was injected if a BAL above a certain number was detected. In the first case, it is clear that the contract should be presumptively allowed and any technology instantiating the contract should be allowed because there is no law against an individual giving his money away.[143]

On the other hand, there are many laws against suicide and promoting suicide,[144] which would make this hypothetical cyanide device likely illegal. In a world where the state has arrogated to itself the police power, it would be within its right to police the existence of the technology that instantiates the contract. As a practical matter, this means the ability to ban the devices like automatic syringe injectors.

This is a relatively bright line and will allow individuals to take on obligations that may not be strictly illegal but may be extremely unpleasant. Some may want to extend the rule beyond protecting bodily integrity and move towards protecting property or economic value. Those who believe in the concept of efficient breach will want to draw this line in a different manner. To these critics, there is a great deal of economic loss that will be created if we make it functionally impossible to breach a contract, even with oneself. To take a fanciful example, suppose an individual who has committed to sobriety through a smart contract is presented with the opportunity to enter a beer drinking contest. The prize for this contest is one million dollars. While *ex ante* he committed to not drinking, the possibility for efficient breach is presented. It makes sense to breach if the individual only staked $10,000 to forfeit, but at a certain point there are circumstances that the individual *ex ante* did not consider that if he did, he would have been okay with his breach. Depending on the stakes, smart contracts make such a breach impossible.

This is not a reason to prohibit such contracts. Such a rule would prove too much as it would allow the state to intervene in any instance where an individual was generating economic loss. Commitment is always difficult because circumstances change.

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volition, as long as the exclusion is not founded on race, creed, color or national origin.").

[143] More problematic would be an individual who commits to burning his money instead of donating it. This would appear to violate 18 U.S.C. § 333, which prohibits the destruction of Federal Reserve notes. *See* 18 U.S.C. § 333. There is, however, a simple workaround, which is to convert the U.S. dollars into bitcoin or some other crypto currency and then destroy the value that way.

[144] *E.g.*, N.Y. PENAL LAW § 120.30 (McKinney 1967).

III. RETHINKING CONTRACT LAW

Should one accept the normative case for self-contracts for personal growth—and, as discussed above, we very much believe one should—then several long-standing contract law doctrines such as the presumption of post-execution modification and consideration requirements will need to be modified. These modifications not only permit the creation of value-adding self-contracts (which is good), but are also consistent with these long-standing doctrines once one conceives of the present self as a separate party from the future self.

A. Restricting Post-Contract Amendment

An obvious doctrine that jurisdictions would need to adjust is the traditional rule that parties can always amend a contract after its initial execution if they all agree.[145]

In the standard two or more parties contracting scenario, the parties are almost always around to consent (as successors are generally appointed if the original party dies or goes out of business). But, for self-contracts, where the parties are one's past self (at the time of contracting) and future (now-current) self, one party, the past self, is not available to consent. Further, permitting the future self to amend would often defeat the purpose of the bet, just as permitting Ulysses to change the terms of his arrangement the moment he hears the Sirens is ill-advised.

But never permitting amendment would also produce undesirable results, especially in cases where unexpected events making meeting the commitment far more difficult or impossible than the past self would have expected (e.g., a commitment to run a marathon followed by contracting a serious illness). After all, there are a number of good reasons parties may wish to modify an existing, enforceable contract, which support the traditional rule. First, no party has the ability to foresee any and all contingencies that may materialize after the contract is signed. What may have been an efficient and value maximizing allocation of risks *ex ante* may subsequently prove to be inefficient; reestablishing an efficient allocation might require modification. Contract law may want to facilitate such a modification.

It should be noted, however, that even in traditional multi-party contracts the story may not always be so benign. If, after a contract is

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[145] *See* RESTATEMENT (SECOND) OF CONTS. § 89 (AM. L. INST. 1981); U.C.C. §2-209 (AM. L. INST. & UNIF. L. COMM'N 2021).

signed, one party is in a position to "hold up" the other—for example, when the party being held up has made a transaction-specific investment that can't be transferred, and which he can only recover if the other party performs—the law may want to prevent modifications (to deter such opportunism).[146]

When it comes to self-contracts, a possible solution would be to create a default rule that such contracts cannot be modified absent circumstances a reasonable person would deem to have made the original goals of the aspirant impossible or impractical. This would not defeat the purpose of the smart contract as long as the costs of revocation still remain high (i.e., requiring that the aspirant go to arbitration and show impossibility or impracticability by a preponderance of the evidence). At common law, modifications to existing contracts would only be upheld if they were supported by some additional consideration (i.e., the promisor must promise something in addition to his existing obligation).[147] This reflected the concern that a modification without additional consideration was likely to be a "hold-up" situation.[148] The Restatement Second of Contracts strikes a balance between the common law rule and the desire to facilitate benign amendments, allowing modifications that are "fair and equitable in view of the circumstances."[149] If, for example, A agrees, by written contract, to dig an inground pool for B for a stated price, but unexpectedly encounters solid rock which will make the job much more difficult, A and B may orally agree to modify the contract by reasonably increasing the price. B would be bound to this amount. Similarly, the Uniform Commercial Code permits modifications made in good faith.[150]

In addition, a contract can differentiate between knowable circumstances that create impracticability problems and unknowable unforeseen circumstances. Take the example of the starter interrupter devices mentioned above. An example of a knowable frustration to a contract is the length of time a secured creditor must wait until he is allowed to repossess property. This time could change, but it could be written into the code that an oracle will consult with legislative pronouncements that are published online. An unknowable frustration would be something like Congress' enactment making it much more

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[146] For the classic case on this point, *see* Alaska Packers Ass'n v. Domenico, 177 F. 99 (9th Cir. 1902).
[147] This is called the pre-existing duty doctrine. *See Pre-Existing Duty Doctrine*, LEGAL INFO. INST., https://www.law.cornell.ed, (last visited Apr. 9, 2023).
[148] RESTATEMENT (SECOND) OF CONTS. § 89 (AM L. INST. 1981).
[149] *Id.*
[150] U.C.C. § 2-209 (AM. L. INST. & UNIF. L. COMM'N 2021).

difficult to foreclose on military veterans.[151] This is unknowable in our terminology because it is a criterion, unlike time-to-repossess, that did not exist at the time of the contract's drafting. This is why it makes sense to have human judgment still involved in some way.

B. No Efficient Breach, Only Specific Performance

Another area of the doctrine that may need to be adjusted for smart self-executing contracts is the practice of so-called "efficient breach." Efficient breach describes a situation where a party to a contract voluntarily ceases performance and pays damages because to perform the contract would result in an "economic" loss to both parties involved. Under an efficient breach theory, courts should treat contractual obligation not as obligation to perform in all circumstances, but as an obligation to choose between performance and compensatory damages.

Proponents of this theory contend that giving a promisor the choice between performance and breaching-and-payment results in a more efficient outcome. This is because the promisee is fully compensated in either case, while the promisor is better off if he does not have to perform but can pay damages instead.[152] The promisor will only exercise his breach-and-pay option if he gains more from a third party or alternative course of action than he would have from the original promisee or promise. A third party, too, is better off because he has now secured a performance that he previously did not have.

Let us take Richard Posner's famous example:

> Suppose I sign a contract to deliver 100,000 custom-ground widgets at $.10 apiece to A, for use in his boiler factory. After I have delivered 10,000, B comes to me, explains that he desperately needs 25,000 custom-ground widgets at once since otherwise he will be forced to close

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[151] Forclosure Relief and Extension for Servicemembers Act of 2017, S. 1661, 115th Cong. (2017).

[152] The earliest scholarship putting forward the concept of efficient breach was Birmingham. *See* Robert L. Birmingham, *Breach of Contract, Damage Measures, and Economic Efficiency*, 24 RUTGERS L. REV. 273, 284 (1970) ("Repudiation of obligations should be encouraged where the where the promisor is able to profit from his default after placing his promisee in as good a position as he would have occupied had performance been rendered."). It has been perhaps most famously championed by Posner. *See* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW (Little, Brown and Co. ed. 3d ed. 1986). *But see* Ian R. Macneil, *Efficient Breach of Contract: Circles in the Sky*, 68 VA. L. REV. 947 (1982) (arguing that permitting breach is not the only way to achieve an efficient result).

> his pianola factory at great cost, and offers me $.15 apiece for 25,000 widgets. I sell him the widgets and as a result do not complete timely delivery to A, who sustains $1000 in damages from my breach. Having obtained an additional profit of $1250 on the sale to B, I am better off even after reimbursing A for his loss. Society is also better off. Since B was willing to pay me $.15 per widget, it must mean that each widget was worth at least $.15 to him. But it was worth only $.14 to A – $.10, what he paid, plus $.04 ($1000 divided by 25,000), his expected profit. Thus, the breach resulted in a transfer of the 25,000 widgets from a lower valued to a higher valued use.[153]

Suppose, however, that the boiler factory owner *ex ante* sensed that he could have holdout value and to protect this value had his widgets designed with in such as way so as they could never be used outside of his own boiler facility, frustrating the purposes of the pianola producer. On Posner's theory, this forethought of tying his widgets to the mast would be inefficient.

This is a fanciful example, to be sure, but it illustrates an important point: the use of technology combined with *ex ante* desires can raise the cost of efficient breach to be prohibitively high. These costs effectively serve as liquidated damages clauses that must be enforced given the nature of the technology installed.

Depending on the strength of the smart contract and the contractware instantiating the contract, the costs to modify may make efficient breach impossible. This bolsters at least one vision of contract law that finds promises important in their own right.[154] Indeed, it adheres more closely to the view of vocal critics of efficient breach theory who argue that, to the extent that efficient breach encourages parties to breach their contractual obligations, it may undermine important societal understandings of promise by allowing promisors to "profit from the unilateral exercise of their power to perform or not."[155] Should not

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[153] RICHARD POSNER, ECONOMIC ANALYSIS OF THE LAW 151 (Aspen, 8th ed. 2011).
[154] CHARLES FRIED, CONTRACT AS PROMISE: A THEORY OF CONTRACTUAL OBLIGATION (Harv. Univ. Press 1981).
[155] Richard R. W. Brooks, *The Efficient Performance Hypothesis*, 116 YALE L.J. 568, 572–73 (2006). *See also* Daniel Friedmann, *The Efficient Breach Fallacy*, 18 J. LEGAL STUD. 1 (1989); Peter Linzer, *On the Amorality of Contract Remedies—Efficiency, Equity, and the Second "Restatement"*, 81 COLUM. L. REV. 111, 112 (1981) (arguing that "it is both fair and appropriate to hold people to promises that they freely made," and that, as such, the concept of efficient breach is an amoral one).

the promisee, a victim of the intentional breach, receive a portion of that profit?[156]

An intentional breach of contract—however "efficient" it may be—seems to conflict "with a basic premise of both the common law and other Western legal systems, namely, that property (including contractual rights) is not to be taken and given to another without the owner's consent."[157] Further, without some assurance that a counterparty may not ultimately hold up their end of the bargain if it finds a more lucrative alternative, one may, ex ante, be deterred from entering into otherwise profitable transactions.

In the case of a personal growth bet, efficient breach may be justified if the aspirant picks a number that raises the cost of breach to the appropriate amount, thus aligning his future incentives with the desired outcome, and then circumstances justify a breach. For example, a proper personal growth bet contract should raise the cost of a pleasurable vice (e.g., smoking cigars) to a high enough amount to properly account for otherwise unaccounted for negative externalities (e.g., cancer). A properly aligned bet would therefore eliminate issues such as hyperbolic discounting by an aspirant's future self.[158] However, it may still justify occasional breaches, such as enjoying a fantastic cigar with friends for a special occasion. This is true even though most people would not make a personal growth bet contemplating efficient breach because the whole point of the contract is to achieve some purpose. But, this is true for all contracts *ex ante*. Although in the case of the personal growth bet, the concept of efficient breach seems more egregious than in a world where businessmen deal with widgets.

However, in other situations the aspirant may desire to eliminate any risk of a future breach, such as with Ulysses and the Sirens. In that case, the penalty would have to be so high as to make breach ruinous, with the only escape hatch an unalterable default rule permitting breach if fulfillment of the contract is impactable or impossible. One may not want to permit efficient breaches in such a case, because the purpose of the bet is to ensure no breach occurs.

Finally, jurisdictions may want to permit forms of injunctive relief. This would be similar to casino exclusion laws, except the aspirant

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[156] Brooks, *supra* note 155, at 573.
[157] Friedmann, *supra* note 155, at 13-14.
[158] Hyperbolic discounting occurs when a person greatly discounts the future cost of taking an action in favor of the immediate benefits, leading to serious long-term regret. *See* Mario J. Rizzo & Douglas Glen Whitman, *The Knowledge Problem of New Paternalism*, 2009 BYU L. REV. 905, 924-28 (2009) (discussing hyperbolic discounting issues).

would have more flexibility in selecting which type of activity he or she would be prohibited from engaging in. In some cases, this might be preferable to a ruinously high monetary penalty, which might leave a person both destitute and then willing to engage in the prohibited behavior. However, this raises the concerns with government enforcement discussed above, including issues with using of force and state power to enforce the injunction.

This Article takes no position on the efficient breach debate but recognizes that some smart contracts may be designed to make efficient breach prohibitively expensive, and whether we should permit such a contract will be a difficult issue.

C. Consideration and One-Sided Contracts

Another area of the doctrine that would need modified is the requirement for consideration. Under the common law, for a valid contract to exist, there must be an offer, an acceptance, and consideration. Consideration requires that "a performance or a return promise must be bargained for," and may take the form of an act, forbearance, or change to a legal relationship.[159] Consideration serves to distinguish between contracts—i.e., bargained-for exchanges—and gifts.

For example, if A promises to gift $10 to B, there is no consideration for A's promise—even if B relied on that promise.[160] Similarly, if A agrees to give B a $1,000 gratuitous loan, B's promise to accept the loan is not consideration for A's promise to make it.[161] This distinction matters: in order for an agreement to have legal force—for there to be legal remedies for breach—there must be consideration.[162] In

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[159] *See* RESTATEMENT (SECOND) OF CONT. § 71:

> (1) To constitute consideration, a performance or a return promise must be bargained for
>
> (2) A performance or return promise is bargained for if it is sought by the promisor in exchange for his promise and is given by the promise in exchange for that promise
>
> (3) The performance may consist of
>
> a. An act other than a promise, or
>
> b. A forbearance, or
>
> c. The creation, modification, or destruction of a legal relation
>
> (4) The performance or return promise may be given to the promisor or to some other person. It may be given by the promise or by some other person.

[160] *Id.* at § 71 cmt. b. illus. 2.

[161] *Id.* at § 71 cmt. b. illus. 8.

[162] *See* RESTATEMENT (SECOND) OF CONTS. § 1 (AM L. INST. 1981) ("A contract is a promise or a set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty.").

this way, consideration is proof that a contract exists; it draws a line between those promises that are enforceable, and those which are not.[163]

Consideration serves a number of important purposes, purposes that should be considered for self-contracts. First, as discussed above, consideration differentiates between contracts and gifts, the latter of which is not generally considered to be the kind of thing the law enforces.[164] Second, requiring consideration prevents hasty or joke promises from being enforced.[165] Third, consideration signals a change made (in behavior) in return for a promise, which might itself reflect the parties' *ex ante* belief that the exchange was worth engaging in—that is, that it was value-maximizing. Consistent with an economic view of contract law, we want to enforce promises that appear to be value maximizing for both parties; consideration serves as a proxy for that.

In the case of the personal growth bet, consideration should be considered to exist only if clear benefits for the future aspirant exist at the time the aspirant makes the contract. The consideration is not for the monitoring and enforcing, which is only a means to the end of achieving the goal. The actual consideration is the benefit the future aspirant will achieve, paying the price of the threatened penalty. Therefore, a personal growth contract should only be enforceable if it provides real benefits to a future self.

One may also argue that the lack of "real" consideration in personal growth contracts shows they are outside the scope of the legal system, similar to gifts. However, the difference with gifts is that personal growth contracts share the same characteristics as contracts when it comes to their seriousness or attempt at creating additional future value through voluntary exchange. First, going through the formalities of creating a smart contract is and would be similar to a real contract (specific terms, specific penalty for breach, method of enforcement), as opposed to a hasty joke or comment. Second, people generally enter into personal growth contracts to create future value (especially if contracts are enforced only if the future self-benefits), making them more akin to value-creating contracts than one-sided gifts.

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[163] Lon Fuller, *Consideration and Form*, 41 COLUM. L. REV. 799, 800 (1941) (explaining that consideration serves an "evidentiary function," providing evidence of the existence of a contract in the event of dispute). However, note that some promises that lack consideration may still be enforced through the doctrine of promissory estoppel. *See* RESTATEMENT (SECOND) OF CONTS. § 90 (AM L. INST. 1981).

[164] *See* Henry Winthrop Ballantine, *Mutuality and Consideration*, 28 HARV. L. REV. 121 (1914); *see also* Fuller, *supra* note 163.

[165] Fuller, *supra* note 163, at 800 (describing the "cautionary function" of consideration).

CONCLUSION

For those who read just the abstract and conclusion, we hope you take away one thing from this article: personal growth bets are a powerful tool for making life better. By staking money on achieving a personal goal, whether it is losing weight or writing a law review article, a person is more incentivized to accomplish that goal. Those incentives lead to real world improvements.

Existing contract law doctrines lend a great deal of support to making these bets legally enforceable. These bets, which can be described as personal growth contracts, contain all of the necessary elements of a legally enforceable contract. While such contracts can be made with counterparties, including existing companies, involving counterparties necessarily increases transaction cost and adds another layer to what should be a *self*-improvement process.

This added cost is the reason why we propose using smart contracts for personal growth bets. Smart contracts excise (to varying degrees) human discretion in the performance of a contract. They allow an individual to tie himself to the mast and enforce the *ex-ante* bargain with an individual's aspirational self.

To be sure, this program is a speculative and aspirational one—smart contracts are only in the beginning phases of their development as a legal and business tool, even if they have a long and rich history of use without doctrine or formal recognition.

We encourage software developers to build tools around smart contracts for personal growth. This is a worthwhile goal because the personal growth bet is a powerful concept that does not take much upfront cost to radically change a person's life. We hope that the personal growth bet will catch on and grow in popularity because it truly is a tool that can make life better.

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ARTICLES

THE CODE OF LIFE AND DEATH

Braden R. Leach

Biotechnology is advancing at an astonishing clip, but our safeguards are decades behind. Given new technologies and economies of scale, it is possible for nefarious actors to assemble deadly viruses from scratch using synthetic DNA ordered off the internet.

The Select Agents statute helps to prevent malicious actors from acquiring dangerous pathogens, but the Department of Health and Human Services has interpreted it to not cover synthetic DNA. Recognizing the gap, HHS issued guidance recommending that gene synthesis companies verify their customers to ensure their legitimacy and screen genetic sequences for matches to pathogen sequences.

Unsurprisingly, voluntary guidance has not inspired full adherence. I argue that HHS should require providers to screen the sequences they provide and that it has the statutory authority to do so. This would improve security and level the playing field.

But it would not be enough. Private companies are not in the best position to perform background checks on their customers, and their economic incentives point the other way. I propose a novel license regime, where every buyer and seller of synthetic DNA and gene synthesis equipment would need to undergo a background check before transacting. In a world where biotechnology will only grow cheaper and easier to use, open access is untenable.

Informed by experts at the frontlines of science, industry, and security, this article advances novel regulatory solutions to counter the risks posed by dual-use biotechnology. If the US wishes to protect its people and remain the leader in the field, it must control who can access the code of life and death.

THE CODE OF LIFE AND DEATH

Braden R. Leach[1]

INTRODUCTION

We are living in a new biotechnological age. Better gene sequencing, synthesis, and assembly methods have given us previously unimaginable abilities to manipulate living organisms.[2] Vaccine platforms have accelerated vaccine development, machine learning has revolutionized protein prediction and design, and gene drives may soon eradicate mosquitos that transmit deadly diseases.[3] The emerging bioeconomy promises "innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security."[4]

A major part of this advance is the new field of synthetic biology, which aims to make life easier to manipulate "so that biological traits, functions, and products can be programmed like a computer."[5] By applying engineering principles to biology, we can redesign organisms to create biofuels, biomaterials, and cheaper pharmaceuticals.[6] In 2012, the World Economic Forum ranked synthetic biology as the second key technology for the 21st century, right after informatics.[7]

Given new techniques and economies of scale, business is booming. In the past twenty years, the cost of gene synthesis has fallen

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[1] J.D. 2022, University of California, Berkeley, School of Law; Visiting Scholar at the Johns Hopkins Center for Health Security. I would like to thank Dr. Gigi Gronvall, Dr. Michael Montague, Dr. Richard Bruns, and Doni Bloomfield for sharing their insights. All views and mistakes are my own.

[2] Sam Weiss. Evans et al., *Embrace Experimentation in Biosecurity Governance*, 368 SCIENCE 6487, 138 (2020).

[3] Luke Kemp et al., *Bioengineering Horizon Scan 2020*, ELIFE, 2 (2020).

[4] Exec. Order No. 14081, 87 Fed. Reg. 56849 Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy (September 12, 2022).

[5] Gigi Kwik Gronvall, *US Competitiveness in Synthetic Biology*, 13 HEALTH SEC. no. 6, 378, 378 (2015).

[6] *Synthetic Biology*, NAT'L HUM. GENOME RSCH. INST. (Aug. 14, 2019), https://perma.cc/DM8U-6CE7; Ahmad S. Khalil & James J. Collins, *Synthetic Biology: Applications Come of Age*, 11 NATURE REV. GENETICS 367, 367 (2010).

[7] Global Agenda Council on Emerging Technologies, *The Top 10 Emerging Technologies for 2012*, WORLD ECON. FORUM (Feb. 15, 2012) https://www.weforum.org/agenda/2012/02/the-2012-top-10-emerging-technologies/.

from hundreds of dollars per base pair to fractions of cents.[8] Synthetic DNA generated more than $3.6 billion in 2021[9] and is modeled to reach around $10.6 billion by 2030.[10] While the North American region currently has the largest revenue share, the Asia Pacific region is estimated to grow the fastest this decade.[11]

The cheapest way to obtain DNA is to order gene-length sequences from a commercial gene synthesis company.[12] A researcher could also start with short DNA or RNA sequences (called oligonucleotides, or oligos for short) and chemically stitch them together.[13] Improvements in gene synthesizer machines will allow researchers to assemble longer and longer genetic sequences in-house.[14]

New synthetic biology technology and techniques are destroying barriers to entry.[15] Previously, DNA synthesis required university-level implements and expertise, but now "anyone with a laptop computer can access public DNA sequence databases on the Internet, access free DNA design software, and place an order for synthesized DNA for delivery."[16]

But like all technologies, biotechnology can be used for good or for ill. This is known as the dual-use problem.[17]

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[8] Amanda Kobokovich et. al., *Strengthening Security for Gene Synthesis: Recommendations for Governance*, 17 HEALTH SEC. no. 6, 424 (2019) [hereinafter Center for Health Security].

[9] *Synthetic Biology Market by Tools (Oligonucleotides, Enzymes, Synthetic Cells), Technology (Genome Engineering, Bioinformatics), Applications (Tissue Regeneration, Biofuel, Food, Agriculture, Consumer Care, Environmental) – Global Forecast to 2027*, MKTS. & MKTS. https://www.marketsandmarkets.com/Market-Reports/synthetic-biology-market-889.html; *Synthetic Biology Market Size, Share & Trends Analysis Report By Product (Enzymes, Cloning Technologies Kits), By Technology (PCR, NGS), By Application (Non-healthcare, Healthcare), By End-use, And Segment Forecasts, 2022–2030*, GRAND VIEW RSCH., https://www.grandviewresearch.com/industry-analysis/synthetic-biology-market. These figures include both single- and double-stranded DNA.

[10] *Gene Synthesis Market Size to Hit US$ 10.58 Billion by 2030,* BIOSPACE, (May 3, 2022) https://www.biospace.com/article/gene-synthesis-market-size-to-hit-us-10-58-billion-by-2030/?keywords=IO+Biotech. Synthetic DNA made up the lion's share of the broader synthetic biology market in 2020. *Id.*

[11] *Id.*

[12] Nicole H. Kalupa, *Black Biology: Genetic Engineering, the Future of Bioterrorism, and the Need for Greater International and Community Regulation of Synthetic Biology*, 34 WIS. INT'L L.J. 952, 964 (2017).

[13] *Id.*

[14] *Id.*

[15] GEORGE M. CHURCH & ED REGIS, REGENESIS: HOW SYNTHETIC BIOLOGY WILL REINVENT NATURE AND OURSELVES 158 (2012).

[16] Michele S. Garfinkel et. al., *Synthetic Genomics, Options for Governance*, 5 BIOSEC. AND BIOTERRORISM: BIODEF. STRATEGY, PRAC., AND SCI., 359, 360 (2007).

[17] *See, e.g.*, Gregory D. Koblentz, *Biosecurity Reconsidered: Calibrating Biological Threats and Responses*, 34 INT'L SEC. no. 4, 96, 101 (Spring 2010) ("Biology and biotechnology are subject to a powerful dual-use dilemma: the skills, materials, and

I. THE THREAT

Biological weapons are "the poor man's atom bomb."[18] Whereas nuclear weapons require specialized facilities and materials that are difficult and expensive to produce, biological weapons can be made with readily available materials and equipment.[19] Dr. George Church explains that bioweapons are "potentially more dangerous than chemical or nuclear weaponry, since organisms can self-replicate, spread rapidly throughout the world, and mutate and evolve on their own."[20] And given that synthetic biology has made contorting nature simpler and cheaper, the poor man's atom bomb is much more achievable than even a few decades ago.[21]

Although biological attack may ring of science-fiction, it has been attempted and perpetrated throughout recorded history.[22] The Mongol army likely catapulted dead plague victims over the city walls of Caffa in 1346, colonial militias sent blankets from smallpox hospitals to American Indians, a German spy attempted to infect Allied livestock during World War I, Imperial Japan used bioweapons against the Chinese during World War II, and the South African apartheid regime weaponized HIV and Ebola.[23] The United States, the United Kingdom, and the Soviet Union all had major bioweapons programs in the 20th Century, and the Soviet Union's clandestine program was active until the early 1990s, two decades after it had signed a treaty prohibiting them.[24] As we shall see, nation states are not the only ones who have pursued bioweapons.

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technology to conduct civilian activities such as biomedical research and pharmaceutical production can also be used to produce biological weapons.").

[18] Michael P. Scharf, *Clear and Present Danger: Enforcing the International Ban on Biological and Chemical Weapons Through Sanctions, Use of Force, and Criminalization*, 20 MICH. J. INT'L L. 477, 497 (1999).

[19] *See* Matthew S. Halpin, *Biological Warfare: The Weaponization of Naturally-Occurring Biological Diseases*, 16 HOUS. J. HEALTH L. & POL'Y 259, 266 (2016).

[20] CHURCH & REGIS, *supra* note 15, at 230–32.

[21] *Id.* at 477; Rob Reid, *Deterrence – and the Undeterrable*, MEDIUM (Oct. 11, 2018), https://gen.medium.com/how-tech-empowers-dangerous-lone-wolves-50fa0365335 [https://perma.cc/A53W-S6YT].

[22] *See* MICHAEL T. OSTERHOLM & MARK OLSHAKER, DEADLIEST ENEMY: OUR WAR AGAINST KILLER GERMS 128 (2017).

[23] *See id.*; *see also* MALCOLM DANDO, BIOTERROR AND BIOWARFARE 24 (2006) (explaining that from 1939 to 1942, Imperial Japan's Unit 731 perpetrated a series of "large-scale biological weapons attacks in China," weaponizing cholera, paratyphoid A, anthrax, and plague).

[24] Benjamin D. Trump et al., *Building Biosecurity for Synthetic Biology*, 16 MOLECULAR SYS. BIOLOGY 1, 2 (2020).

A. Non-State Actors

Terrorist organizations have also demonstrated a keen interest.[25] Al-Qaeda investigated the possibility of weaponizing anthrax but the technological challenges proved too much.[26] The Aum Shinrikyo cult pursued bioweapons before turning to chemical weapons, deploying sarin gas in the subways of Tokyo and killing thirteen.[27] While there is no evidence that the Islamic State ever sought bioweapons, its apocalyptic ideology, attempted genocide of the Yazidis in Iraq, use of chemical weapons, and weaponization of commercial drones suggest that it would not be morally opposed. Just as of 2010, fifteen terrorist organizations had showcased an interest in acquiring bioweapons.[28]

On the home front in 1995, a scientist with ties to white supremacist groups obtained three vials of the bacteria that causes plague.[29] Shortly after the 9/11 attacks, anthrax letters to Congress and the media caused five deaths, incurred a billion dollars in cleanup costs, disrupted the US Postal Service, and shuttered Senate offices for almost three months.[30] After a five-year manhunt, the FBI concluded that US government scientist Dr. Bruce Ivins was responsible, though he committed suicide before he could be indicted.[31]

Although we may wish we lived in a different world, the one we inhabit includes some sociopathic individuals and apocalyptic terrorist groups who may try to engineer plagues.[32] And bioweapons will only

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[25] Koblentz, *supra* note 17, at 114; *see also* NATIONAL BIODEFENSE STRATEGY AND IMPLEMENTATION PLAN: FOR COUNTERING BIOLOGICAL THREATS, ENHANCING PANDEMIC PREPAREDNESS, AND ACHIEVING GLOBAL HEALTH SECURITY, WHITE HOUSE 6 (Oct. 2022) ("Multiple nations have pursued clandestine biological weapons programs, and a number of terrorist groups have sought to acquire biological weapons. In addition, advances in biotechnology, including synthetic biology, are making it easier to develop and use biological agents as weapons."); *id.* at 8 ("terrorist groups have found value in pursuing biological weapons, and there can be no confidence that will change in the future").

[26] Koblentz, *supra* note 17, at 104.

[27] *Id.*

[28] *Id.* at 114.

[29] NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, SEQUENCE-BASED CLASSIFICATION OF SELECT AGENTS: A BRIGHTER LINE 19 (2010) [hereinafter *Brighter Line*].

[30] OSTERHOLM & OLSHAKER, *supra* note 22, at 127.

[31] Koblentz, *supra* note 17, at 115. Ivins worked at the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID), the military's "premier biodefense research facility." *Id. See also* CHRISTIAN ENEMARK, BIOSECURITY DILEMMAS: DREADED DISEASES, ETHICAL RESPONSES, AND THE HEALTH OF NATIONS 38–39 (2017) (detailing the 1995 and 2001 incidents).

[32] Koblentz, *supra* note 17, at 98, 115.

become more compelling to non-state actors.[33] Synthetic DNA has already become incredibly cheap and widespread, and new technologies and techniques will only make it easier to manipulate. Further advances will reduce barriers and increase the pool of individuals who can effectuate harm.[34]

B. Nefarious Paths

Malicious actors could take several different approaches to obtain a bioweapon. They could acquire a deadly pathogen from nature, steal it from a lab, or create a pathogen from scratch using synthetic DNA.[35]

The acquisition of pathogens from nature or from a lab used to be the easier paths, but technological developments have altered the calculus.[36] The de novo synthesis of known pathogens, particularly small viruses, is listed as one of the most pressing biodefense risks according to the 2018 National Academies of Sciences report.[37] And pathogens' genetic sequences are freely available on the internet.[38]

Scientists have repeatedly shown that synthesizing at least some viruses is doable. It has been demonstrated in "the construction of poliovirus, the 1918 influenza virus, and most recently, the virus that causes horsepox," a close cousin of smallpox.[39] For instance, in 2018, Canadian researchers reconstituted an extinct horsepox virus for only $100,000 using mail-order DNA.[40]

To be sure, pathogen synthesis is not something that just anyone can accomplish. It is still thought to be very difficult to synthesize long

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[33] *Id.* at 117.
[34] NATIONAL BIODEFENSE STRATEGY, *supra* note 25, at 8.
[35] Diane DiEuliis et al., *Biosecurity Implications for the Synthesis of Horsepox, an Orthopoxvirus*, 15 HEALTH SEC. 6, 630 (2017).
[36] *See also* Diane DiEuliis et al., *Options for Synthetic DNA Order Screening, Revisited,* 2 MSPHERE 4, 1, 1 (2017) ("using DNA synthesis technologies, a nefarious actor would not need direct access to certain pathogens but could chemically synthesize them using sequence information freely available on the Internet. Once synthesized, they could be 'booted up' to become infectious.").
[37] National Academies of Sciences, *Biodefense in the Age of Synthetic Biology* 39–40, 117 (2018) [hereinafter NAS Report].
[38] DiEuliis et al., *supra* note 36, at 1.
[39] *Id.*; *see also* Koblentz, *supra* note 17, at 101 (stating that poliovirus was built from scratch for the first time in 2002).
[40] Kai Kupferschmidt, *How Canadian Researchers Reconstituted an Extinct Pox Virus for $100,000 Using Mail-Order DNA*, SCIENCE (July 6, 2017) https://www.science.org/content/article/how-canadian-researchers-reconstituted-extinct-poxvirus-100000-using-mail-order-dna.

bacterial genomes, which is why small viruses pose the greater risk.[41] However, Dr. Kevin Esvelt at MIT estimates that at least 30,000 individuals worldwide possess the laboratory skills to follow "public step-by-step protocols to obtain any influenza virus with a published genome sequence from commercially available synthetic DNA."[42]

Furthermore, there are some cases where viral synthesis is likely easier than rummaging around in nature or perpetrating a lab heist. For example, the World Health Organization declared smallpox (variola virus) eradicated from nature in 1980 and now it is held tightly at only two locations in the world—the CDC headquarters in Atlanta and the Vector lab in Novosibirsk, Russia.[43] If terrorists wanted smallpox, they would likely try to build it.[44]

Once an aspiring bioterrorist acquired a deadly pathogen, he could engineer it to make it even more harmful. Modifications could increase "infectivity, virulence, pathogenicity, transmissibility, and/or stability;" make them resistant to vaccines, antivirals, or antibiotics; or allow them to avoid detection or diagnosis.[45]

Another tactic would be to hybridize the pathogen with DNA from other organisms to create a "chimera," although this would require more expertise and effort.[46] A third possibility would be to design a completely

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[41] *See, e.g.*, Center for Health Security, *supra* note 8, at 420 ("At this time, concerns about misuse of gene synthesis to make entire pathogens from scratch are almost entirely limited to viruses. Synthesis of whole cellular genomes, bacterial or fungal, is a much more challenging task that has only been accomplished by a few groups.").

[42] Kevin Esvelt, *How a Deliberate Pandemic Could Crush Societies and What to do About It*, BULLETIN OF THE ATOMIC SCIENTISTS (Nov. 15, 2022). His estimation is based on the number of doctoral degrees conferred in the relevant fields. He also notes that as larger viruses are more difficult to assemble, the number of people capable of synthesizing "coronaviruses and paramyxoviruses such as MERS and measles" are likely only in the "single-digit thousands," and "only one or two hundred are likely capable of assembling huge poxviruses such as variola, the causative agent of smallpox." *Id. See also* MICHAEL T. OSTERHOLM & MARK OLSHAKER, DEADLIEST ENEMY: OUR WAR AGAINST KILLER GERMS 129–30 (2017). ("Tools to fundamentally alter how a virus or bacteria kills, or even potentially transmits, that did not exist in 2001 are now in the hands of many thousands of scientists in universities . . . and commercial labs.").

[43] DiEuliis, *supra* note 35, at 630.

[44] *Id.*

[45] Jesse Kirkpatrick et al., *Editing Biosecurity: Needs and Strategies for Governing Genome Editing* 50, GEORGE MASON UNIV, & STANFORD UNIV. (Dec. 2018) [hereinafter GEORGE MASON & STANFORD].

[46] *See, e.g.*, *Brighter Line*, *supra* note 29, at 112–13 ("Non-trivial chimeric constructions (more wholesale rearrangement and 'assembly' of parts from different organisms into a novel whole) are extraordinarily challenging and would almost certainly require large laboratory resources and iterative optimization in an experimental testing program in susceptible hosts . . .").

novel pathogen, though this is likely still extremely difficult.[47] The most pressing concerns are the synthesis of known pathogens (with blueprints available online) and their relatively simple modifications.

C. Weapons of Mass Destruction

Upon the advent of CRISPR—which allows for the editing of genetic code similarly to copying and pasting in a word document—James Clapper, then-Director of the Office of National Intelligence, grabbed national security headlines by referring to this tool as a Weapon of Mass Destruction.[48]

While the anthrax attacks only killed five, there is little reason to hope that the next attack will be so limited. Unfortunately, "gene editing technologies and an expanding convergence between biotechnology and information technology have enabled precision manipulation of biology, which creates opportunities for harm only wished for during Cold War bioweapons programs."[49] According to one analysis, "the versatility, flexibility, and precision offered by new genome editing techniques, such as CRISPR, increases the attack surface, which encompasses the number, accessibility, and severity of vulnerabilities that could be exploited to cause harm."[50] If a misanthropic group had the resources to design, build, test, and iterate, the result could be catastrophic.

Former US Navy Secretary Richard Danzig has thought much about the risk of catastrophic bioterrorism. Writing back in 2003, he made the case that sophisticated plots would not involve one isolated attack, but a campaign of them over time.[51] Dr. Esvelt has imagined that terrorists could attack multiple travel hubs simultaneously using multiple pathogens, causing scarcely imaginable chaos.[52] To make the illustration more vivid, he notes that if a single terrorist were to release a

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[47] *Id.* at 112. We can view these options "in order of increasing technical difficulty, and therefore decreasing likelihood: *modified* pathogens; *chimeric* pathogens; and *designed* pathogens."
[48] Diane DiEuliis, *Key national security questions for the future of synthetic biology*, 43 FLETCHER F. WORLD AFF. 127, 128 (2019).
[49] DiEuliis et al., *supra* note 36, at 1.
[50] Kirkpatrick et al, *supra* note 43, at 2.
[51] DANDO, *supra* note 23, at 125 (citing Richard Danzig, *Catastrophic Bioterrorism – What is to be Done?*, WASHINGTON: CTR. FOR TECH. AND NAT'L SEC. POL'Y (2003)).
[52] Esvelt, *supra* note 42, at 2.

virus equivalent to SARS-CoV-2, he would have killed more people than he would have by detonating a nuclear warhead in a dense city.[53]

Even that is scarcely the worst-case scenario. We live in a globalized world, where disease could travel to every corner of the earth before the infected even show symptoms.[54] If an engineered virus spread as easily as the omicron variant, but had the lethality of smallpox, which killed about 30% of those it infected, "the subsequent loss of essential workers could trigger the collapse of food, water, and power distribution networks—and with them, societies."[55]

While natural pandemics continue to pose a substantial threat, we must realize that the next global event could be manmade.[56]

D. Biosecurity & Risk Regulation

Biosecurity is the project of keeping people safe from both natural and manmade disease.[57] (This term is often confused with "biosafety," which is concerned with preventing lab accidents.[58]) In the last two to three decades, the US government has explicitly come to view pandemic disease as a national security threat.[59]

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[53] *Id.* at 2. Several other scientists have depicted Esvelt as a scaremonger, but "many agree that *some* kind of security for synthetic DNA is warranted." *See* Michael Schulson,
Experts debate the risks of made-to-order DNA, UNDARK (Dec. 21, 2022) https://undark.org/2022/12/21/experts-debate-the-risks-of-made-to-order-dna/.
[54] OSTERHOLM & OLSHAKER, *supra* note 42 at 131. For instance, after SARS "emerged from rural China in February 2003, it spread to five countries within twenty-four hours and another twenty countries on five continents within two months." Koblentz, *supra* note 17, at 103. Dr. Koblentz argues that "four trends . . . have increased the risks posed by biological threats: advances in science and technology, the emergence of new diseases, globalization, and the changing nature of conflict." *Id.* at 98.
[55] Esvelt, *supra* note 42, at 2.
[56] Jaime M. Yassif et al., *Strengthening global systems to prevent and respond to high-consequence biological threats*, NUCLEAR THREAT INITIATIVE 4 (Nov. 2021).
[57] ENEMARK, *supra* note 31, at xvi. Narrower definitions only capture manmade disease. *See* Koblentz, *supra* note 17, at 107.
[58] *See, e.g.*, National Research Council of the National Academies of Sciences, RESPONSIBLE RSCH. WITH BIOLOGICAL SELECT AGENTS AND TOXINS 27 (2009).
[59] *See, e.g.*, David P. Fidler, *Public Health and National Security in the Global Age: Infectious Diseases, Bioterrorism, and Realpolitik*, 35 GEO. WASH. INT'L L. REV. 787, 793 (2003) (describing, for instance, that the CIA's National Intelligence Council "issued a report in January 2000 entitled *The Global Infectious Disease Threat and Its Implications for the United States*, which presented infectious diseases as a national security threat") (internal citation omitted); James G. Hodge Jr. & Kim Weidenaar, *Public Health Emergencies as Threats to National Security*, 9 J. NAT'L SEC. L. & POL'Y 81, 84 (2017) (noting that the federal government has "repeatedly classified public health crises not just as emergencies, but also as threats to national security").

Improving biosecurity will not involve just one silver bullet. Instead, scholars have framed the goal in terms of a "layered defense" or a "web of prevention."[60] Building a hearty, layered defense (or a tensile web, whichever you prefer) is the best we can hope for to prevent catastrophes and respond effectively.[61] This essay is particularly concerned with one especially low-hanging fruit—"people should not be able to easily order the DNA encoding smallpox from the internet."[62]

But when is regulation justified to mitigate risks? Cass Sunstein has argued that "[w]hen risks have catastrophic worst-case scenarios, it makes sense to pay special attention to those risks, even when existing information does not enable regulators to make a reliable judgment about the probability that the worst-case scenarios will occur."[63] Similarly, Richard Posner has admonished that "catastrophic risks—in the sense of low-probability events that if they occur will inflict catastrophic harm—are, despite their low probability, well worth the careful attention of policymakers."[64] Posner includes bioterrorism among these risks.[65]

These suggestions are sensible. Framed oppositely, it would be foolish to regulate only when probabilities are certain or known to be high when the potential magnitude of harm is vast.[66] But regardless of

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[60] *See generally* DANDO, *supra* note 23, at 129–145 (describing different parts of the web of prevention).

[61] *See id.* at 139 (arguing that we cannot "cover all possible contingencies," but each improvement adds difficulty and helps to deter attacks); *id.* at 144 ("the aim is to make it as difficult as possible" to make "hostile use of biological agents.").

[62] Center for Health Security, *supra* note 8, at 425.

[63] Cass R. Sunstein, *The Catastrophic Harm Precautionary Principle*, 6 ISSUES LEGAL SCHOLARSHIP [i], 1–2 (2007); *see also* Cass R. Sunstein, *Irreversible and Catastrophic*, 91 CORNELL L. REV. 841, 841 (2006) ("when catastrophic outcomes are possible, it makes sense to take special precautions against the worst-case scenarios—the Catastrophic Harm Precautionary Principle.").

[64] Richard A. Posner, *Efficient Responses to Catastrophic Risk*, 6 CHI. J. INT'L L. 511, 525 (2006).

[65] *See also id.* at 515–16 ("The probability of bioterrorism or nuclear terrorism, for example, cannot be quantified, but we have some sense of the range of possible losses that such terrorism would inflict (there really is no upper limit short of the extinction of the human race). We can infer from this that even if the probability of such a terrorist attack is small, the expected cost—the product of the probability of the attack and of the consequences if the attack occurs—probably is quite high.").

[66] A quick caveat: I am not suggesting that we slight "normal" public health problems and devote all our attention to catastrophic bioterrorism. They both deserve more careful attention. Interestingly, some tactics would provide a dual benefit. For instance, improving our ability to detect and respond to infectious diseases would help mitigate both natural and manmade diseases.

whether one is a fan of the precautionary principle or not, my proposed solutions do not hinge on it.[67]

E. US Policy

Simply put, "governments are still imposing old rules on a new technology, an insufficient strategy to provide security in the future."[68] This is unsurprising, given the lightning pace of scientific and technological development. Moreover, the problem is complex and multidisciplinary, existing at the intersection of science, technology, law, and economics. Any legal solutions must take all into account.

This issue has received very little attention in the legal literature. Although several efforts have captured the overall problem, there is a dearth of pragmatic solutions.[69] This essay aims to fill that gap.

After analyzing domestic law, I conclude that the *de facto* self-regulation regime for commercial DNA synthesis is deeply inadequate. The Federal Select Agents Program does not address the synthesis of pathogens from scratch, and it will only grow more outdated as biotechnology improves. Any viable solution must focus on preventing

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[67] A proponent of the strong version of the precautionary principle would demand that synthetic biology be blocked until its proponents could show that it was safe, which would be impossible because DNA is dual use. No one is urging this. *See* Jonathan B. Wiener, *Precaution in a Multirisk World*, HUMAN AND ECOLOGICAL RISK ASSESSMENT: THEORY AND PRACTICE 1509, 1521 (2002). Professor Wiener argues that the precautionary principle is too simple in a world of multiple risks and advocates an "optimal precaution" approach that weighs tradeoffs, considers the risks created by regulation, and tries to minimize overall risk. *See id.* at 1511, 1520. *See also* Jonathan B. Wiener, *The Tragedy of the Uncommons: On the Politics of Apocalypse*, 7 GLOBAL POLICY 67, 76 (May 2016) (finding "the conventional view that the public demands more risk protection while experts urge less turns out to apply to unusual but experienced (available) risks, whereas for both familiar routine risks, and ultra-low-frequency (unexperienced) catastrophic risks, it is not the public demanding more protection, but experts.").

[68] Benjamin D. Trump et al., *Building Biosecurity for Synthetic Biology*, 16 MOLECULAR SYSTEMS BIOLOGY (2020); *see also* Megan J. Palmer et al., *A More Systematic Approach to Biological Risk*, 350 SCIENCE 6267, 1471 (Dec. 2015) (our strategies for "managing biological risk in emerging technologies have not matured much in the last 40 years."); OSTERHOLM & OLSHAKER, *supra* note 42, at 129 ("In spite of biological warfare's long history and our experience of it in my lifetime, in the more than a decade and a half since the 2001 anthrax attack, our state of unreadiness and denial has remained more or less the same.").

[69] *See, e.g.*, Stephen M. Maurer, *End of the Beginning or Beginning of the End - Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It*, 45 VAL. U. L. REV. 1387 (2011); Braden Leach, *Necessary Measures: Synthetic Biology & the Biological Weapons Convention*, 25. STAN. TECH. L. REV. 141 (2021); Kalupa, supra note 12 at 964.

malicious individuals and entities from easily acquiring gene synthesis materials, including synthetic DNA and related equipment.[70]

I make two major policy prescriptions. First, The Department of Health and Human Services (HHS) should require that gene synthesis companies screen customers' DNA orders for matches to dangerous pathogens. I argue that HHS already has the statutory authority to do so. Second, the US should adopt a license system for buyers and sellers of synthetic DNA. In its simplest formulation, everyone transacting in synthetic DNA and gene synthesis equipment should have to undergo a brief background check. This would erect a necessary barrier to mitigate facile access to powerful dual-use materials.

This essay proceeds in eight parts. In Part II, I summarize the state of US law. In Parts III through V, I explain why HHS should require genetic sequence screening, argue that it already has the statutory authority to do so, and analyze specific policy elements. Part VI argues that the US should implement a license regime for the gene synthesis ecosystem. Part VII builds out the regime, and Part VIII addresses plausible concerns. Part IX briefly concludes.

II. CURRENT LAW

The US primarily relies upon the Federal Select Agents Program ("FSAP") to protect the populace from biological harm. This section surveys the legal landscape and points out its obvious weaknesses given technological progress.

A. Background

The Biological Weapons Convention[71] ("BWC") and its implementing legislation[72] form the backdrop of US biosecurity law.[73] The US signed the BWC in 1972, the Senate ratified it in 1974 (giving

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[70] National Biodefense Strategy, *supra* note 25, at 9 ("No longer confined to sophisticated research laboratories, these technologies are being developed and utilized all over the world, and the necessary expertise, materials, and equipment are widely available.").

[71] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction." Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163 [hereinafter BWC].

[72] Biological Weapons Anti-Terrorism Act of 1989, Pub. L. No. 101-298, 104 Stat. 201 (codified as amended at 18 U.S.C. §§ 175–178); *see specifically* § 2, Purpose and Intent.

[73] *Brighter Line*, *supra* note 29, at 157–58.

advice and consent required under Article II of the Constitution),[74] and President Ford signed the instruments of ratification in 1975, whereafter it entered into force with respect to the United States.[75] It was the first multilateral disarmament treaty to ban states from developing and using an entire category of weapons of mass destruction.[76]

The Biological Weapons Anti-Terrorism Act of 1989 implemented the BWC into federal law.[77] It also sought to "protect the United States against the threat of biological terrorism"[78] by authorizing criminal sanctions for developing bioweapons, allowing the government to seize bioweapons, and providing a cause of action for the US to seek injunctions against violators.[79] The Patriot Act of 2001 beefed up the criminal code for those attempting to acquire bioweapons.[80]

B. Federal Select Agents Program

In part because a white supremacist got his hands on plague bacteria in 1995, the US passed the Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA).[81] This was the first list-based attempt at regulating harmful biological agents.[82]

Following the double-blow of 9/11 and the anthrax attacks, Congress passed the Bioterrorism Act of 2002.[83] This law built upon

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[74] *See* Biological Weapons Anti-Terrorism Act of 1989 § 2(a).
[75] *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Status of the Treaty,* UN OFF. FOR DISARMAMENT AFFS., https://perma.cc/U5WA-BGGE (archived Nov. 3, 2021). There are currently 183 State Parties and 109 State Signatories.
[76] *See* Matthew S. Halpin, *Biological Warfare: The Weaponization of Naturally Occurring Biological Diseases*, 16 HOUS. J. HEALTH L. & POL'Y 259, 276–77 (2016); BWC, *supra* note 71.
[77] Biological Weapons Anti-Terrorism Act of 1989 § 2.
[78] Biological Weapons Anti-Terrorism Act of 1989 § 2(a)(2).
[79] 18 U.S.C. §§ 175–177.
[80] Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Pub. L. 107–56, 115 Stat. 272. The Patriot Act expanded some criminal code provisions built by the Biological Weapons Act. *See Brighter Line*, *supra* note 29, at 158.
[81] Pub. L. 104–132, 110 Stat. 1214 (1996). Scholars have noted that the government has often responded in a "reactive manner to counter that particular event," rather than look at what is most likely to happen in the future. *See* Diane DiEuliis et al., *Biodefense Policy Analysis—A Systems-Based Approach*, 17 HEALTH SEC. No. 2, 83, 84–85 (2019) [hereinafter *Biodefense Policy*].
[82] *Brighter Line*, *supra* note 29, at 158. Congress tasked the HHS Secretary with issuing regulations governing "the transport of biological agents with the potential to pose a severe threat to public health and safety through their use in bioterrorism." *Id.*
[83] *See* Public Health Security and Bioterrorism Preparedness and Response Act, known as the Bioterrorism Act of 2002, Pub. L. 107–188, 116 Stat. 594.

AEDPA and created the FSAP we know today.[84] Under this regime, the Centers for Disease Control (with authority delegated from HHS) and Department of Agriculture regulate the possession, use, and transfer of "select agents."[85] This is a list of bacteria, viruses, and fungi that have been determined to pose a severe threat to public health.[86]

However, neither agency has regulated synthetic biology materials.[87] (I will use the term "synthetic biology materials" to encompass synthetic DNA and RNA and the equipment used to make them). They seem to believe that their statutory authority does not extend that far.[88]

Since viruses can be made from scratch, the FSAP no longer provides a "compelling management plan."[89] According to a National Academy of Sciences report, "overreliance on the Select Agent list is a systemic weakness affecting many aspects of the United States' current biodefense mitigation capability."[90]

C. 2010 HHS Guidance

Concerned about the "potential misuse of [gene synthesis] products to bypass existing regulatory controls," HHS issued voluntary

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[84] *See* 42 C.F.R. § 73.2 (2005) (Purpose & Scope) ("This part implements the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins.").

[85] This regulatory patchwork is shared between the HHS/CDC and USDA/APHIS. AEDPA tasked the HHS Secretary with issuing regulations governing "the transport of biological agents with the potential to pose a severe threat to public health and safety through their use in bioterrorism," which HHS delegated to the CDC. Pub. L. 104–132, 110 Stat. 1214. The Bioterrorism Act of 2002 then gave the U.S. Department of Agriculture, through its Animal and Plant Health Inspection Service ("APHIS"), the authority to regulate the possession, use, and transfer of biological agents that relate to plant and animal health and products, complementing the authority granted to CDC for human pathogens. Pub. L. 107–188, 116 Stat. 594. The "select agent" regulations are codified in 42 C.F.R. § 73 (2021), 9 C.F.R. § 121 (2021), and 7 C.F.R. § 331 (2021).

[86] *See Brighter Line*, *supra* note 29, at 159.

[87] *See* 7 C.F.R. § 331 (2021); 9 C.F.R. § 121 (2021); 42 C.F.R. § 73 (2021).

[88] *See, e.g.*, CDC, *Applicability of the Select Agent Regulations to Issues of Synthetic Genomics*, https://osp.od.nih.gov/wpcontent/uploads/Applicability_of_the_Select_Agents_Regulations_to_Issues_of_Synthetic_Genomics.pdf.

[89] Palmer et. al, *supra* note 68, at 1472. Scholars at the Johns Hopkins Center for Health Security note that since "biosecurity controls in the United States and many other nations are primarily based on pathogen access," "gene synthesis technologies undercut these protections." Center for Health Security, *supra* note 8, at 420.

[90] NAS REPORT, *supra* note 37, at 102 ("[O]verreliance on the Select Agent list is a systemic weakness affecting many aspects of the United States' current biodefense mitigation capability.").

guidelines for commercial gene synthesis providers in 2010.[91] This guidance has two basic recommendations: sequence screening and customer verification.[92]

Sequence screening means using software to analyze whether DNA sequences are close matches to pathogen sequences. The guidance encourages providers to screen double-stranded DNA orders longer than 200 base pairs for suspicious orders. It recommends cross-checking all orders against the FSAP list, and for international orders, against the Commerce Control List (CCL) as well. Suspicious orders are to be reported to the FBI Weapons of Mass Destruction Directorate.[93]

As for customer verification, the guidance encourages providers to ensure that their customers are "legitimate," i.e., real and peaceful. Providers have a preexisting legal obligation not to do business with customers that are on a prohibited person or entity list.[94]

In sum, providers are encouraged to screen sequences, but they are not required to, and so long as customers are not on a list of malefactors, providers can still sell them genes.

D. Self-Regulation

In the absence of actual regulation, the gene synthesis industry has engaged in limited self-regulation. The International Gene Synthesis Consortium ("IGSC") is an industry group that was formed to "design and apply a common protocol to screen both the sequences of synthetic gene orders and the customers who place them."[95] Companies in the IGSC voluntarily screen DNA orders over 200 base pairs and are supposed to alert other members of their industry group when they receive a

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[91] Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA, 75 Fed. Reg. 62820–03 (Oct. 13, 2010) [2010 HHS Guidance].
[92] *Id.*
[93] *Id.*
[94] These include the Department of Treasury Office of Foreign Assets Control (OFAC) list of Specially Designated Nationals and Blocked Persons (SDN List), the Department of State list of individuals engaged in proliferation activities, and the Department of Commerce Denied Persons List (DPL). *Id.*
[95] *About IGSC,* INT'L GENE SYNTHESIS CONSORTIUM, https://genesynthesisconsortium.org/ (last visited Feb. 25, 2023). IGSC members purportedly screen for US Select Agents, US Commerce Control List (CCL) controlled sequences, Australia Group list agents, and European Union (EU) list sequences.

suspicious order.[96] But implementing the IGSC standards are at each company's discretion and there is no compliance mechanism.[97]

IGSC members allegedly constitute 80% of the commercial gene-synthesis market worldwide, though there is reason to be suspicious of this statistic.[98] In 2013, the group had seven members and as of late 2022, it had twenty-three members.[99] Throughout this entire period, the organization has professed that it encompasses "approximately" 80% of the global market, even as companies have sprouted prodigiously in South Korea and China.[100]

While most prominent US companies screen DNA sequences—presumably because they view it to be in their enlightened self-interest—it is unclear how many US customers are getting their gene products from non-screening providers in the US and overseas.[101] Many smaller US companies do not screen their orders.[102]

Customer verification is undoubtedly even worse off. While it is relatively cheap and simple to run sequences through automated screening software, investigating customers is time-consuming, expensive, and places companies at a competitive disadvantage.[103]

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[96] Diane DiEuliis et al., *supra* note 36, at 1 ("Gene synthesis providers affiliated with the International Gene Synthesis Consortium voluntarily screen double-stranded DNA synthesis orders over 200 [base pairs] to check for matches to regulated pathogens and to screen customers . . . oligonucleotides and tracts of DNA less than 200 [base pairs] are not screened."). IGSC precautions exceed the HHS Guidelines.

[97] GEORGE MASON & STANFORD, *supra* note 45, at 14.

[98] *Id.*

[99] SARAH R. CARTER & ROBERT M. FRIEDMAN, DNA SYNTHESIS AND BIOSECURITY: LESSONS LEARNED AND OPTIONS FOR THE FUTURE, J. CRAIG VENTER INSTITUTE 10 (Oct. 2015) (internal citations omitted) [hereinafter VENTER REPORT].

[100] Whereas the 2010 HHS Guidance listed roughly 45 companies with gene synthesis capabilities, more than 320 companies are now relevant to the field according to recent market research. Center for Health Security, *supra* note 8, at 424. While U.S. companies initially dominated, "international players, particularly Chinese companies, are rapidly increasing their share of the market." VENTER REPORT, *supra* note 99, at 15; *see also* Trump, *supra* note 24, at 4 ("Saudi Arabia is funding research to develop microbial cell factories to produce fuels and chemicals, while Singapore is investing considerable resources into life and environmental sciences research. The Chinese Academy of Sciences is establishing an Institute of Synthetic Biology, which is tasked with the dual responsibilities of fostering roadmaps for future development while establishing safety and security norms for researchers at Chinese institutions.").

[101] *See* DiEuliis, *supra* note 36 at 1–2; VENTER REPORT, *supra* note 99, at 17 ("Although most U.S.- and E.U.-based DNA providers (the IGSC members plus others) follow the recommendations of the HHS Guidance, there are many providers that do not. We spoke with at least two companies that rely on the trust developed with their customers and only rarely screen DNA sequences.").

[102] *See* DiEuliis, *supra* note 36, at 2–3.

[103] *Id.* at 2 ("the HHS Guidance and screening dsDNA orders are increasingly facing serious challenges to their relevance and impact. One challenge is its cost to companies: costs for DNA synthesis continue to decrease, while screening remains

Immaculately trained bio-informaticists must review orders that raise red flags and follow up with customers, which may include verifying addresses and affiliations and analyzing past orders.[104] These costs get baked into the final prices that customers pay. Companies that do not investigate customers (or do so poorly) can offer lower prices and quicker turnarounds.

Thus, according to a 2015 report by the J. Craig Venter Institute, US providers likely "perform only the legally required minimal customer screening using government watch lists . . . [and] [o]utside the U.S. and Europe, there may be even fewer companies practicing biosecurity screening procedures."[105]

One analysis painted a rosy picture of the status quo, noting that this "partnership" between government and industry "has been reasonably successful to date because established companies are highly motivated to prevent any biosecurity mishaps that could implicate their firms or their industry."[106] After all, in "conversations with industry representatives, we repeatedly heard their concern that any biosecurity lapse on their part could result in a public outcry, legal liability, and/or government action that would severely restrict not only an individual company but the industry as a whole with national and international significance."[107]

Fear of public opprobrium, liability, and regulation are powerful motivators, but so is profit. Given that bioterrorism is rare, most firms that seek to maximize margins and market share will not devote more than a pittance of their resources to security.

Under the self-regulation regime, maligned actors can simply buy DNA from the providers that do not screen. And unless they are on a list of bad guys, they are probably in the clear.

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relatively constant, making screening costs an increasingly larger percentage of total costs. In particular, some orders are not clearly problematic but require a highly trained person to make a judgment about proceeding; these ambiguous orders make up a majority of sequence screening costs. Companies that screen risk becoming uncompetitive.").

[104] Center for Health Security, *supra* note 8, at 424 ("The primary cost of screening a sequence, regardless of length, is in human analyst time in the event of a positive sequence match to a threat-list sequence.").

[105] VENTER REPORT, *supra* note 99, at 17.

[106] VENTER REPORT, *supra* note 99, at 8.

[107] *Id.*

E. 2022 HHS Proposed Guidance

HHS recently issued unfinalized, revised guidance.[108] The 2022 guidance attempts to patch many holes from the 2010 document, though it remains nonbinding. In the next section, I will argue that this fact alone makes it inescapably flawed, but for now I will limit myself to the proposed upgrades.

Like the original guidance, "a primary goal is to minimize the risk that unauthorized individuals or individuals with malicious intent will use nucleic acid synthesis technologies to obtain organisms for which possession, use, and transfer is regulated by FSAP and CCL."[109] But it has an additional, "parallel" goal: "limit[ing] the potential for individuals with malicious intent to use synthetic oligonucleotides to create novel high-risk pathogens using sequences from unregulated organisms."[110] In other words, HHS has its eyes beyond the *select* agents paradigm and is worrying about entirely new pathogens as well. The 2022 guidance also:

- Extends beyond "Providers" to include "Third-Party Vendors, Institutions, Principal Users, and End Users."
- Expands the guidance beyond double-stranded DNA over 200 bases to "include both DNA and RNA, as well as both single- and double-stranded oligonucleotides."
- Lowers the screening threshold from 200 base pairs to "50 base pairs or longer if ordered in quantities of less than one micromole, or lengths 20 bp or longer if ordered in quantities of one micromole or greater."
- Recommends that providers of benchtop synthesizers screen customers, track transfers, screen sequences over the internet, verify users, and log data.[111]

The HHS Assistant Secretary of Preparedness and Response is clearly apprised of the threat. Later I will evaluate each of these issues in turn.

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[108] Screening Framework Guidance for Providers and Users of Synthetic Oligonucleotides, 87 Fed. Reg. 25495–499 (Published April 29, 2022) [hereinafter 2022 HHS Guidance].
[109] *Id.* at 25496–97.
[110] *Id.* at 25497.
[111] *Id.* at 25497–98.

F. California Legislation

California was the first state in the union to regulate gene synthesis to any degree, and as of late 2022, it remains the only one to have done so.

After a more ambitious bill was vetoed by Governor Newsom in 2021, a narrower one made it past his desk in the 2022 legislative session.[112] The statute provides that the California State University system "shall" develop "systemwide guidance for purchasing" gene synthesis equipment or products from providers, whereas the University of California system is merely requested to do so.[113] This provision, situated peculiarly in California's Education Code, is weak medicine. Whether other states will follow California's lead or take larger steps is anyone's guess.

III. SEQUENCE SCREENING REQUIREMENT

This section will briefly lay out why a sequence screening mandate is necessary. Later I will show that requiring companies to investigate their customers would be unwise because companies would be incentivized to perform the cheapest compliance possible, resulting in pointless security theater.

We now live in an age where synthetic DNA is widely available, viruses can be built from scratch, and pathogens can be modified with synthetic DNA. Bioweapon development is criminalized in the US, but as Professor Christian Enemark notes, "the length of time it took the FBI to complete its investigation [into the anthrax attacks] is a factor weighing strongly against the deterrent value of arrest and punishment."[114] Our regulatory apparatus must adapt.

An obvious place to start is to implement a sequence screening requirement for commercial gene synthesis providers. Companies should be required to run customer DNA orders through a database of Select Agent pathogens to make sure they are not unwittingly assisting in

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[112] The vetoed bill would have required all gene synthesis providers and gene synthesis equipment manufacturers operating in California to be a member of the IGSC or have their screening protocols verified by the State Department of Public Health. It would have also required all recipients of state funding to purchase only from IGSC members or verified manufacturers. A.B. 70, 2021–2022 Assemb., Reg. Sess. (Cal. 2021).

[113] CAL. EDUC. CODE § 66361(a) (West 2022).

[114] ENEMARK, *supra* note 31, at 49; *see also id.* at 38 (explaining that the investigation involved "over ten thousand witness interviews, eighty site searches, review of twenty-six thousand emails, analysis of four million megabytes of computer memory, and the issuing of nearly six thousand grand jury subpoenas.").

bioweapon development. HHS could enforce its rule via audits or investigations and impose liability for noncompliance, which I will discuss in greater depth later.

The fundamental benefit of screening is that it will make acquiring dangerous pathogens more difficult.[115] We should not want nefarious actors to have easy access to "genetic material that could be used to construct pathogenic viruses, including smallpox, Ebola, or influenza."[116] Preventing gene synthesis products from being "easily and directly misused" will also serve as a deterrent.[117] If the costs of pursuing this approach are perceived to be too high, then nefarious actors will steer clear. Additionally, screening may be useful for biosafety efforts "if it prevents imprudent and unsafe ordering of genes from dangerous pathogens without due consideration of risks."[118]

One could argue that the HHS guidance is sufficient because most large US companies follow it. But many smaller companies do not, so individuals can simply buy DNA from the providers that do not screen.[119] A national requirement would remove these weak links.

Companies that already screen may even prefer a mandate because it would level the playing field.[120] Their competitors could not cut costs by neglecting security. And even for newer market entrants, running orders through screening software is unlikely to pose serious burdens, especially if NGOs provide the software for free.[121]

Though screening will make it harder for non-state actors to easily assemble malicious viruses, it will not erase the possibility of biological attacks.[122] State-sponsored actors are "unlikely to be detected or deterred by gene synthesis screening controls, given that they would presumably

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[115] Center for Health Security, *supra* note 8, at 427.
[116] Gigi K. Gronvall, *Needed: Stricter Screening of Gene Synthesis Orders, Customers*, STAT+ (Oct. 5, 2022), https://www.statnews.com/2022/10/05/gene-synthesis-suppliers-tighter-screening-orders-customers/.
[117] Center for Health Security, *supra* note 8, at 427.
[118] *Id.* at 426.
[119] *See* DiEuliis et al., *supra* note 36, at 1; VENTER REPORT, *supra* note 99, at 17.
[120] This is much more desirable than a patchwork of state laws. The only state law on the books is California's, which is a partial solution at best. The California approach only requires that California State University researchers buy synthetic DNA from companies that are members of the IGSC. CAL. EDUC. CODE § 66361(a) (West 2022). Recall that industry group members theoretically do a minimum level of sequence screening and customer verification. But there is no compliance mechanism, economic incentives disfavor customer verification, and whatever verification is performed by less capable private companies. Regulating via an industry group is also deeply questionable from a rent-seeking standpoint.
[121] *See* UNDARK, *supra* note 53.
[122] *See* Center for Health Security, *supra* note 8, at 427.

have their own capacities."[123] Non-state actors in other countries may also be able to acquire unscreened DNA, but the US has the largest market and its efforts can help to create norms or rules worldwide. The goal is not complete victory—which is impossible—but meaningful gains that make bioweapon development harder.[124]

IV. HHS HAS STATUTORY AUTHORITY

HHS has the authority to mandate sequence screening under 42 U.S.C. § 262a, titled "Enhanced Control of Dangerous Biological Agents and Toxins."[125] HHS's authority stems straightforwardly from subsection (c) concerning the possession and use of listed agents, and subsection (b) regarding transfers of listed agents.[126] These subsections' broad authority defeat any narrower interpretation.

Under HHS's current reading, this section only accounts for synthetic DNA if it encodes for a *complete* listed pathogen.[127] But HHS has not imposed any barriers to accessing synthetic DNA, so this reading has no teeth. HHS's interpretation is at odds with the broad delegations of authority in subsections (b) and (c).[128]

A. HHS Shall Govern the Possession and Use of Select Agents

Subsection (a) requires that the Secretary "establish and maintain" a list of agents with the "potential to pose a severe threat to public health and safety."[129] This is the authority for the Select Agents list. Subsection (b) requires the Secretary to regulate "transfers of listed agents and toxins."[130] Then, subsection (c) requires the Secretary to regulate their possession and use.[131]

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[123] *Id.* at 425.
[124] *See, e.g.*, *National Biodefense Strategy*, *supra* note 25, at 11 ("Deter, detect, degrade, disrupt, deny, or otherwise prevent nation-state and non-state actors' attempts to pursue, acquire, or use biological weapons, related materials, or their means of delivery.").
[125] 42 U.S.C. § 262a. This section is part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
[126] 42 U.S.C. § 262a (b), (c).
[127] *See* 42 U.S.C. § 262a; 42 C.F.R. §§ 73.2, 73.3. The Select Agent framework has thus far been interpreted to cover the creation, transfer, and possession of *complete* synthetic genomes on the Select Agents list, not just those of "viable" Select Agents. CDC, *supra* note 88.
[128] *See* 42 U.S.C. § 262a; 42 C.F.R. § 73.3.
[129] 42 U.S.C. § 262a(a).
[130] 42 U.S.C. § 262a(b).
[131] 42 U.S.C. § 262a(c).

Subsection (c) provides that the "Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, *including* the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect the public health and safety."[132]

Requiring gene synthesis companies to screen their orders for matches to select agents is plainly a procedure "governing" the "possession and use" of select agents.[133] To put it bluntly, it governs who can have and use them. The subsection's broad language easily allows for such an application; in the words of Justice Scalia, "Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion."[134] And importantly, Congress's use of the word "including" shows that HHS is not limited to governing possession and use by regulating transfers.[135] It has other means at its disposal.

Indeed, Congress was worried about this very issue in 2002 when it created the Select Agents Program. In the same piece of legislation, Congress amended the criminal code sections regarding biological weapons.[136] It amended the definition of "biological agent" to include "any naturally occurring, bioengineered or *synthesized component* of any such microorganism or infectious substance . . . ."[137] And Congress imported this definition of "biological agent" into section 262a.[138] This definition provides strong evidence that subsection (c) empowers the HHS Secretary to regulate "synthesized component[s]" of select agents to prevent terrorists from possessing or using the complete products.[139]

HHS's own guidance documents also support this reading. For instance, the 2010 Guidance states that:

> [t]he directed synthesis of polynucleotides could enable individuals not authorized to *possess* Select Agents (or, for international orders, those items listed on the CCL) to *obtain* them through transactions with providers of synthetic [double-stranded] DNA. Such synthesis obviates

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[132] *Id.* (emphasis added).
[133] *See id.*
[134] City of Arlington v. FCC, 569 U.S. 290, 296 (2013).
[135] 42 U.S.C. § 262a(c).
[136] 18 U.S.C. § 178(1); *see also* 42 C.F.R. § 73.1.
[137] 18 U.S.C. § 178(1) (emphasis added) (Congress similarly amended the definition of "toxin." in section 2)); *see also* 42 C.F.R. § 73.1.
[138] 42 U.S.C. § 262a(l).
[139] *Id.*; 18 U.S.C. § 178(1).

> the need for *access* to the naturally occurring agents or naturally occurring genetic material from these agents, thereby greatly expanding the potential *availability* of these agents."[140]

Similarly, the 2022 Guidance notes that "[p]urchasing or synthesizing oligonucleotides could enable individuals without a legitimate and peaceful purpose to *possess* genetic sequences that would pose risks if misused.[141]

An opponent might argue that the statute only addresses the possession of *complete* select agents, and screening would merely serve to prevent the dissemination of their components. If a provider sent a customer part of the smallpox genome, the argument would go, then that individual would not possess smallpox. But because one can possess smallpox by ordering its pieces and fitting them together, this narrow interpretation defangs subsection (c) and overlooks that "biological agent[s]" include their "synthesized component[s]."[142] A skeptic might also argue that Section 262a provides an exhaustive list of security measures, leaving no room for a screening requirement.[143] But this interpretation ignores the word "including" in subsection (c).[144] Limiting the possession and use of select agents by regulating transfers is the floor, not the ceiling.

A screening requirement is straightforwardly permissible under 42 U.S.C. § 262a(c). HHS's hands are not tied.[145]

B. HHS Shall Prevent Access to Select Agents

In addition, HHS can require screening under subsection (b). Subsection (b) states that the "Secretary shall by regulation provide for -- (1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins . . . (2) the establishment and enforcement of safeguard and security measures to *prevent access to*

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[140] 2010 HHS Guidance, *supra* note 91, at 2 (emphasis added).
[141] 2022 HHS Guidance, *supra* note 108, at 25495 (emphasis added).
[142] 42 U.S.C. § 262a(c), (l).
[143] For instance, subsections (d) and (e) require those seeking to work with select agents to register and HHS to maintain a database of registered persons, the select agents they possess, and where transfers are made to. Subsection (f) allows for inspections, (g) creates exemptions, and so on. 42 U.S.C. § 262a(d)–(g).
[144] 42 U.S.C. § 262a(c); *see, e.g.*, Google LLC v. Oracle Am., Inc., 141 S. Ct. 1183, 1197 (2021) (noting a provision's use of "include" and "including" and determining that "the provision's list of factors is not exhaustive").
[145] *See id.*

such agents and toxins for use in domestic or international terrorism or for any other criminal purpose . . . ."[146]

Requiring gene synthesis companies to screen for select agents is a reasonable way to "prevent access to" select agents.[147] It would cause companies not to transfer them, in whole or in part. This is consistent with the broad language of subsection (b)(2), which provides a purpose to be achieved (preventing terrorists and criminals from accessing select agents), instead a specific process to be employed.[148]

So too here, HHS's guidance supports this interpretation. The "primary goal" of the 2010 Guidance was to "minimize the risk that unauthorized individuals or individuals with malicious intent will *obtain* 'toxins and agents of concern' through the use of nucleic acid synthesis technologies."[149] The 2022 Guidance reiterated this, where a "primary goal is to minimize the risk that unauthorized individuals or individuals with malicious intent will use nucleic acid synthesis technologies to *obtain* organisms for which possession, use, and transfer is regulated by FSAP and CCL."[150] The whole point of the guidance is preventing unauthorized or malicious "access" to select agents.[151]

Again, a skeptic might argue that subsection (b) only gives HHS authority to regulate the transfer of *complete* listed agents, not their genetic components, given its subtitle of "Regulation of transfers of listed agents and toxins."[152] However, this interpretation undercuts the operative language in subsection (b)(2), which requires establishing security measures to prevent access to select agents by terrorists and criminals.[153] It also renders the part of the definition of "biological agent" that includes "bioengineered or synthesized component[s]" meaningless.[154]

In conclusion, HHS can mandate sequence screening under 42 U.S.C. § 262a.

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[146] 42 U.S.C. § 262a (b) (emphasis added).
[147] *See id.*
[148] *Id.*
[149] 2010 HHS Guidance, *supra* note 91, at 3 (emphasis added).
[150] 2022 HHS Guidance, *supra* note 108, at 25496-497 (emphasis added).
[151] *Id.*
[152] 42 U.S.C. § 262a (b).
[153] *Id.*
[154] *Id.* § 262a(l)(1) (incorporating the definition from 18 U.S.C. § 178(1)).

V. SEQUENCE SCREENING POLICY

The concept is straightforward: commercial DNA orders should be screened to prevent facile access to pathogen sequences. But the biosecurity literature evinces disagreement about the specifics.

It is undesirable to be too loose on security or too burdensome on industry. A catastrophe could take countless lives, but over-regulation could kill the goose that lays the golden egg. This section will explain the advantages and shortcomings of various approaches and offer tentative conclusions.

A. Synthesizers

Benchtop synthesizers ought to be regulated. As the name implies, these are machines that produce synthetic DNA in-house, obviating the need to order DNA from commercial providers.[155] Oligo synthesizers, which can print short sequences of single-stranded DNA, have been around for decades and are available on eBay.[156] Gene synthesizers, which can print long strands of double-stranded DNA, are relatively new.[157] These powerful, dual-use machines should be a top priority.

The 2022 Guidance states that benchtop equipment should be designed to have internet connectivity to screen sequences, authenticate legitimate users, and log printed sequence data that the manufacturer is to receive.[158] If the user were not authenticated or tried to print pathogen sequences, the device would not print. Others have considered the possibility of kill-switches.[159] Technical solutions should be paired with a license regime, which I will detail below.

B. Line Drawing

One key dilemma is assigning the minimum sequence length for screening. This choice will majorly affect the screening costs for gene synthesis companies. If the bar is set too high, then the risks of evasion

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[155] *See* Center for Health Security, *supra* note 8, at 423.
[156] *Id.; see also* VENTER REPORT, *supra* note 99, at 20 n.20.
[157] Center for Health Security, *supra* note 8, at 423.
[158] HHS 2022 Guidance, *supra* note 108, at 25497–98.
[159] *See* Center for Health Security, *supra* note 8, at 427. Such "built-in biosecurity controls" could take several forms. For example, "if a researcher wished to create a gene synthesis product that matched a virus on the Select Agents list, the researcher would encounter a non-skippable message on their synthesizer with instructions to contact the provider company for a clearance code to proceed.

increase, but if the bar is set too low, it would also capture synthetic DNA customers who are not trying to build genes.[160]

The 2010 HHS guidance only applied to double-stranded DNA over 200 base pairs.[161] This line was likely drawn as a compromise between security and economic feasibility. The 2022 Guidance recommends screening all DNA over 50 bases long, including single-stranded oligos.[162] It lowers the threshold even further—to 20 bases—if customers order a large enough batch.[163]

The impetus for lowering the threshold is that scientific advancements have made it simpler, cheaper, and more reliable to assemble gene-length sequences from these small pieces.[164] This has created a loophole.[165] Instead of ordering a long sequence that would be screened by most US companies, one could chop it up into smaller pieces, evade screening, and then put the pieces together.

However, lowering the threshold to 50 bases may not be economically feasible for providers. It would vastly increase the number of sequences to be screened, it would apply to more providers (and more types of providers), and it would likely generate lots of false positives because shorter sequences are more likely to be shared with nonpathogens.[166] Scientists at the J. Craig Venter Institute have estimated that the "lessons learned by DNA providers from screening [double-stranded] DNA suggest that screening oligos with a similar

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[160] *See* VENTER REPORT, *supra* note 99, at 19–20; Center for Health Security, *supra* note 8, at 421–22. Scientists at the J. Craig Venter Institute offered a potential solution hinging on what the oligos are likely to be used for. Most oligos are used for polymerase chain reaction (PCR) or gene sequencing purposes, not for gene synthesis. These tend to be short—under 30 bases— and orders tend to have only a few oligos. In contrast, oligos used for gene synthesis are generally 60 bases long (but can be as small as 40 bases), and orders tend to be larger. The HHS recommendation for a 50-base threshold apparently hit the middle of the target.

[161] 2010 HHS Guidance, *supra* note 91, at 10.

[162] 2022 HHS Guidance, *supra* note 108, at 25496.

[163] The full requirement is as follows: "*Synthetic oligonucleotides subject to screening:* DNA or RNA, single- or double-stranded, of lengths 50 base pairs (bp) or longer if ordered in quantities of less than one micromole, or lengths 20 bp or longer if ordered in quantities of one micromole or greater." *Id.* (emphasis in original)

[164] *See,* James Diggans & Emily Leproust, *Next Steps for Access to Safe, Secure DNA Synthesis*, 7 FRONTIERS IN BIOENGINEERING AND BIOTECHNOLOGY 86, 3 (Apr. 2019) (noting that "capacity for generating enormous, diverse pools of oligo-length sequences has grown while lower-cost methods for assembling high-quality, gene-length sequences from oligo pools have been developed and matured.") (internal citations omitted). *See also* Center for Health Security, *supra* note 8, at 421-22.

[165] Diggans & Leproust, *supra* note 165, at 3; *see also* Center for Health Security, *supra* note 8, at 427 ("As technologies that rely on oligonucleotide synthesis to assemble larger pieces of DNA become more common, the need for screening lengths of DNA less than 200 nucleotides in length becomes more important.").

[166] Diggans & Leproust, *supra* note 165, at 3; DiEuliis et al., *supra* note 36, at 2.

procedure would be untenable."[167] Other researchers also see oligo screening as cost prohibitive.[168] Overly burdensome asks, in the name of security, could run the gene synthesis industry into the ground.

Although several ideas have been tossed around, they all ignore the most obvious solution—better customer verification.[169]

C. Export and Import Controls

US customers should not be able to circumvent screening by ordering from overseas providers, nor should US companies be able to sell unscreened DNA overseas.

The Commerce Department's Bureau of Industry and Security ("BIS") is responsible for regulating dual-use exports.[170] Under the Export Administration Act, the BIS administers the Export Administration Regulations ("EAR").[171] For our purposes, the EAR implements the Australia Group's Control List, which harmonizes participant states' export controls on pathogens and equipment that could be used to manufacture bioweapons.[172] All Australia Group members, including the US, agree to require entities within their jurisdiction to receive a license before exporting materials on the Control List.[173]

Accordingly, the EAR's Commerce Control List ("CCL") enumerates items subject to licensing requirements, including certain

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[167] VENTER REPORT, *supra* note 99, at 19.
[168] *See* DiEuliis et al., *supra* note 36, at 2.
[169] The Nuclear Threat Initiative endorsed oligo screening but suggested that it be paired with additional resources, tools, and incentives for adherence. *See* Nuclear Threat Initiative, *supra* note 56, at 19-20. James Diggans and Emily Leproust propose screening oligo batches using advanced computational methods that try to predict the puzzle box image that the puzzle pieces will create. *See* Diggans & Leproust, *supra* note 165, at 3. Scholars at the Johns Hopkins Center for Health Security recommend that the government should "fund the development of screening methodologies and standards that could allow for the cost-effective screening of oligonucleotides." Center for Health Security, *supra* note 8, at 427.
[170] *See, e.g.*, Jennifer Feldman, *Trusted Customers in a Distrusted Country: Liberalizing Dual-Use Exports to China While Safeguarding National Security*, 20 FED. CIR. B.J. 337, 343-44 (2010) (describing the dual-use export regime).
[171] *See* Export Administration Act of 1979, Pub. L. No. 96-72, 93 Stat. 503 (expired 1994); 15 C.F.R. §§ 730-774. It has been propped up through executive orders. *See* 15 C.F.R. § 730.
[172] The Australia Group is a multilateral export control regime designed to mitigate the proliferation of biological and chemical weapons. Since 1985, the organization has grown to include 42 participant states plus the European Union. *See Introduction,* AUSTRALIA GROUP, https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/introduction.html (last visited Feb. 28, 2023).
[173] *Id.*

pathogens and related equipment.[174] Recent additions include gene synthesizers and genetic sequencing software.[175] Regarding pathogens, the CCL encompasses human, animal, and plant pathogens that are on the Select Agent and Australia Group lists, including synthesized ones.[176] Under the CCL criteria, "genes" that are "specific to" controlled viruses or bacteria are also subject to licensing,[177] but gene *fragments* ostensibly are not.[178]

Critically, the only way to know if controlled genes require an export license is through sequence screening.[179] Gene synthesis companies must run customer orders through screening software to determine whether controlled genes are present. The extent to which US companies comply with this implicit screening requirement for exports is unclear. By contrast, an *explicit* screening rule that applies to domestic and foreign orders alike would be a salutary improvement. The US could also suggest amending the Australia Group Control List to include gene *fragments* that are "specific to" controlled viruses or bacteria, to mitigate

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[174] *See* Commerce Control List, 15 C.F.R. § 774, supp. 1, Category 1.

[175] *See* THE COMMERCE CONTROL LIST, CORPORATE COUNSEL'S GUIDE TO EXPORT CONTROL, App'x Y (2nd ed., last updated Nov. 2022); *see also,* BIS *Considers Export Controls on Neurotechnology and Adds New Controls on Genetic Sequencing Software and Intrusion Software,* DORSEY (Nov. 9, 2021) https://www.dorsey.com/newsresources/publications/client-alerts/2021/11/new-export-controls-on-neurotechnology. ECCN 2B352.j covers "genetic sequencing assemblers and synthesizers that are automated and can generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run." Oligo synthesizers are therefore not covered. The newest rule implements an amendment to the Australia Group treaty and covers software designed for gene synthesizers if it is "capable of designing and building functional genetic elements from digital sequence data." ECCN 2D352. These licensing requirements only apply to states subject to restrictions based on chemical and biological weapons and anti-terrorism reasons.

[176] *See* THE COMMERCE CONTROL LIST, CORPORATE COUNSEL'S GUIDE TO EXPORT CONTROL, App'x Y (2nd ed., last updated Nov. 2022). Export Control Classification Number (ECCN) 1C351 contains human and animal pathogens, and ECCN 1C354 lists plant pathogens. The Select Agents lists largely overlap but they are not the same. For instance, yellow fever virus is on the Australia Group list but not the Select Agent list.

[177] *Id.* Genes of regulated human, animal, or plant pathogens require an export license if they meet the criteria in ECCN 1C353. Whereas all genes "specific to" controlled viruses require a license, bacterial genes only require a license if they are unique to controlled species and "could endow or enhance pathogenicity" or "[i]n itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health."

[178] One prominent gene synthesis company rationally interpreted the phrase "gene or genes" to exclude gene fragments. *See* James Diggans, *Synthetic Gene-Length DNA: Evolving Export Control Concerns*, TWIST BIOSCIENCE (July 2019).

[179] *See* Piers Millett & Paul Rutten, *COVID-19, SARS-CoV-2, and Export Controls*, 18 HEALTH SEC. 4, 333 (2020) (explaining that some "gene synthesis companies . . . screen their orders, including against export control lists" which entails translating the "lists of controlled pathogens . . . into a database of controlled sequences").

the uninhibited export of gene fragments that can be "trivially assembled into controlled genes."[180]

On the import side, the US should impose a permit requirement for genetic materials coming from non-Australia Group states.[181] Permits would certify that gene products were sold by a screening provider, and that the provider found no sequences of concern. Unscreened genetic materials would be turned away. This rule could be implemented as a Department of Homeland Security, US Customs and Border Protection regulation.[182]

D. Setting a Floor

The US can require that companies screen for specific pathogens without prescribing a certain database that must be used.[183] The screening floor should encompass regulated pathogens—those on the FSAP and CCL lists—and then companies, universities, and defense professionals can innovate beyond that if they wish.[184]

Some have suggested that all companies should use a central screening database, but this may be unwise.[185] Although it could save companies time and money, it would be prone to evasion.[186]

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[180] James Diggans, *Synthetic Gene-Length DNA: Evolving Export Control Concerns*, TWIST BIOSCIENCE (July 2019). The US might also suggest a method whereby Australia Group members could exchange information regarding their sequence screening practices. This would encourage states to enforce export controls for genetic materials.

[181] *See* 42 C.F.R. § 71.54 (Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors); U.S. Customs and Border Protection, *Importing Biological Materials into the United States*, (Dec. 21, 2022), https://www.cbp.gov/trade/basic-import-export/importing-biological-materials-united-states.

[182] Synthesized components of microorganisms are already encompassed in the definition of "biological materials" that require inspection. *See* U.S. Customs and Border Protection, *Guidance: Clearance of Biological Materials by U.S. Customs and Border Protection-Procedures and Requirements* (Feb. 13, 2023), https://content.govdelivery.com/bulletins/gd/USDHSCBP-3488069?wgt_ref=USDHSCBP_WIDGET_2.

[183] Center for Health Security, *supra* note 8, at 426.

[184] *See id.* The incentive for innovation is that better screening software can reduce companies' costs. For instance, many pathogens contain "housekeeping" genes, which code for basic biological functions, and can be found in other non-pathogenic organisms. A customer order may trip red flags just because it happens to share a housekeeping gene with a pathogen. Rooting out some of these sequences would reduce ambiguities and employee time sinks.

[185] *See* VENTER REPORT, *supra* note 99, at 186.

[186] *See* Center for Health Security, *supra* note 8, at 426.

Concentrated efforts may be devoted to cracking one lock, and once cracked, every provider would be compromised.[187]

Screening software has developed in tandem with the synthetic DNA market, with Battelle Memorial Institute's "ThreatSEQ" being a notable example.[188] The Intelligence Advanced Research Projects Activity (IARPA) has a sequence screening project as well.[189] The market appears to be providing solid services, though the government may wish to provide its own software for free to upstart companies.

E. New Pathogens

The 2022 (unfinalized) guidance worries that malicious individuals may try to create *novel* pathogens using sequences from "unregulated organisms" "that could contribute to pathogenicity or harm."[190] So, HHS asks that providers develop screening methods to encompass these sequences.[191]

This recommendation should not be transmuted into binding regulation. First and most importantly, requiring this would exceed the scope of HHS' statutory authority.[192] Congress specified a list-based approach, so requiring providers to go beyond the list of specified pathogens into the realm of "unregulated organisms" is out of bounds.[193]

Second, this would be extremely technically difficult, which HHS acknowledges.[194] Predicting traits such as pathogenicity and transmissibility from DNA source code "is a prediction problem of the greatest complexity."[195] According to a special committee tasked with

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[187] *See id.* For instance, Dr. George Church recommended creating a centralized, non-profit DNA clearinghouse set up by a federal agency. Companies that receive suspicious DNA orders would be required to report them to the clearinghouse. Staff would make an immediate preliminary assessment and then search their system for similar or related DNA orders from other vendors. However, this sequence-centric approach would be resource intensive, inefficient, and arguably infeasible as the base pair threshold for screening is lowered.

[188] *Id.* at 424.

[189] *Id.* at 424–25. IARPA's program is known as "Functional Genomic and Computational Assessment of Threats (FunGCAT)," which "aims to improve gene synthesis screening to alert providers to sequences of concern."

[190] 2022 HHS Guidance, *supra* note 108, at 25496–97.

[191] *Id.* at 25497.

[192] *See* 42 U.S.C. § 262a.

[193] 2022 HHS Guidance, *supra* note 108, at 25498. HHS likely recognized that this is beyond its statutory authority by referring to "unregulated" organisms.

[194] *Id.* HHS notes that such a database "may not yet exist," but "encourages the development of such a database . . . provided that measures are taken to prevent such a database from being misused."

[195] *Brighter Line*, *supra* note 29, at 2. Certain genes may serve very different functions in different organisms. And the same gene, in the same organism, can lead to different

examining the Select Agent regulations, these traits "cannot plausibly be predicted with the degree of certainty required for regulatory purposes, either now or in the foreseeable future."[196]

Finally, this could lead to massive information hazards.[197] Knowledge about how pathogens cause harm can be used to fight disease or inflict it.[198] Thus, the same information sets that would allow for advanced screening could be used to design new pathogens. The special committee stated that because "prediction and design go hand in hand," "accurate computational prediction of Select Agent characteristics from genome sequences enables computational design and optimization of bioweapon genome sequences."[199]

VI. BEYOND SELECT AGENTS: A LICENSE REGIME

Almost anyone can buy synthetic DNA online, to be delivered in two business days. I have argued that this is untenable and will only grow more so as biotechnology marches on. The FSAP, though it remains necessary, does not fully account for this problem. And while a sequence screening requirement is necessary, it is not sufficient. Companies' economic incentives disfavor customer investigation. If we take incentives seriously, we realize that many companies are unlikely to do this task well, or at all.

Thus, Congress should pass a law creating a license regime administered by HHS.[200] As with the FSAP, buyers and sellers of

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traits under different environmental conditions. Complex interactions between genes can lead to emergent traits, such that the whole cannot be predicted by merely summing the parts. Predicting the harmful properties of pathogens using only their DNA "will require an extraordinarily detailed understanding of host, pathogen, and environment interactions integrated at the systems, organism, population, and ecosystem levels."

[196] *Id.* at 2.

[197] Nick Bostrom defines an information hazard as "a risk that arises from the dissemination of (true) information that may cause harm or enable some agent to cause harm." Nick Bostrom, *Information Hazards: A Typology of Potential Harms from Knowledge*. REVIEW OF CONTEMPORARY PHILOSOPHY 10, 44–79 (2011).

[198] *See, e.g.*, Gregory Lewis et al., *Information Hazards in Biotechnology*, 39 RISK ANALYSIS 5, 975 (2019) (biological knowledge is "increasingly the object of greatest security concern").

[199] *Brighter Line*, *supra* note 29, at 6. Similarly, NTI bio experts think that "broader distribution of a biorisk database is appropriate when it is limited to established virulence factors from regulated pathogens or listed toxins that are already found in publicly available resources." In other words, we should limit ourselves to information that is already out there. *See* NUCLEAR THREAT INITIATIVE, *supra* note 56.

[200] Although HHS could try to implement a license regime under existing statutory authority, using similar arguments to those I gave above, it would likely be found ultra vires. While sequence screening involves hunting for regulated sequences and only

synthetic biology materials would need to undergo a background check by the FBI to receive a license. Gene synthesis companies would be required to verify each customer's license, and middlemen would be required to verify their customers' licenses as well. This would provide accountability from producer to end-user. Licenses would also be required to buy and sell synthesizers.

This is a necessary and perhaps inevitable first line of defense. Although several scholars have suggested a license regime, this is the first effort to give it a fuller treatment.[201]

As a matter of political feasibility, it is worth mentioning that this solution could receive the net support of industry. Although gene synthesis companies would have to verify licenses, they may prefer the ease and information that licenses would provide. The government would be shouldering part of the security burden, instead of leaving it solely to industry.

As creating and editing life becomes even easier, so does creating bioweapons. The government must control who can access precursor materials. A license system would be the most efficient and comprehensive way to accomplish this.

This section provides four policy arguments favoring a license regime. First, companies' economic incentives direct against customer investigation. Second, the government is better at doing it. Third, customer investigation has a relative advantage to sequence screening. And fourth, this solution would help fill many important gaps. The following section will address the specific elements of a license regime.

A. Economic Incentives Disfavor Customer Investigation

Let us look closely at how (some) gene synthesis companies voluntarily screen and investigate. After a customer submits a DNA order, the provider runs the ordered sequences through a database of

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burdens those trying to purchase those sequences, a license regime would apply to the broader gene synthesis ecosystem. The breadth of such a program would likely exceed the commands in 42 U.S.C. § 262a.

[201] In 2009, Professor Stephen Maurer wrote that "[t]he most obvious way to control synthetic DNA is to license the equipment and reagents that make it." Stephen M. Maurer, *End of the Beginning or Beginning of the End? Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It*, 45 VAL. U. L. REV. 1387, 1421 (2011) (citing Robert Carlson, *Synthetic Biology 1.0*, FUTUREBRIEF (2005), (discussing licensing of scientists); MICHELE GARFINKEL ET AL., SYNTHETIC GENOMICS: OPTIONS FOR GOVERNANCE, at ii (2007) (describing options for registering synthesis machines and owners and people who purchase reagents); George M. Church, *A Synthetic Bio-Hazard Non-Proliferation Proposal* (Aug. 6, 2004) (discussing licensing scheme for reagents and instruments).

listed pathogens. If there are no "hits," the company ships the order. If there are, the provider follows up with the customer.[202] This means asking questions like: who are you? What is your address? What projects are you working on? The company may try to corroborate answers using databases of registered businesses and web searches. After this follow up, almost all orders are shipped, including ones with pathogen matches.[203] If concerns were not ameliorated, the provider contacts the FBI WMD Directorate.[204]

Although a sequence may have triggered further review, the ultimate decision of whether to ship the product turned on a customer investigation.[205] This is the most important part of the process. But as it stands, companies' profit motives point the other way.

The main reason a voluntary approach is inadequate is that it runs against powerful economic incentives.[206] While the cost of gene synthesis has plummeted dramatically due to technological advances and economies of scale, the cost of customer verification has remained relatively fixed.[207] This is because it requires the time and energy of exquisitely trained and well paid experts.[208] Companies bear high costs,

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[202] *See* Center for Health Security, *supra* note 8, at 424 ("Even with this low rate of flagged orders, the cost to dsDNA providers to screen and follow up on these orders will become increasingly burdensome as the profit per base falls. To make up for the decrease in cost per base, companies will have to accept, and therefore screen, more orders").

[203] *See, e.g.*, DiEuliis, *supra* note 36, at 3 ("it is unknown how many synthesis orders are flagged for further screening, whether customer screening accomplishes much of the same goals as sequence screening, or how many orders are currently referred to authorities. Customer screening is undeniably important . . .").

[204] VENTER REPORT, *supra* note 99, at 8.

[205] This portion of the essay benefitted enormously from conversations with Dr. Michael Montague.

[206] *See, e.g.*, Diggans & Leproust, *supra* note 171, at 4 ("Especially for companies whose business model focuses on thin margins or low volume, the current economics (even with extensive IGSC advice and support) strongly disincentivize screening.").

[207] *See id.* at 2 ("As scale drives down cost per base pair, the relatively fixed cost of screening plays a more direct role in overall price. These costs are driven by both customer and sequence screening—commercially-available customer screening solutions still require a great deal of manual review of false positive findings. These false positives create a floor on the possible reduction in labor cost of new customer onboarding").

[208] *See, e.g.*, Center for Health Security *supra* note 8, at 424 ("Compared to the time required for customer follow-up, the time required for sequence screening is relatively small—on the order of minutes. Red hits can take several hours to resolve during the customer follow-up phase, because the information needed to verify and then complete these orders cannot be gleaned from a database but rather must be gathered from the customer. Thus, the customer screening and follow-up component of biosecurity controls for the dsDNA provider will continue to represent a nontrivial burden on overhead costs of gene synthesis.").

which get translated into higher prices, which in turn make companies less competitive.

The little research available strongly suggests that companies are not willing to sacrifice their competitiveness, which squares with common sense. Several large companies have readily admitted that they only exclude customers if they are found on a list of prohibited persons, and smaller companies are unlikely to do more.[209]

Companies that investigate customers are at a competitive disadvantage.[210] A license system fixes this problem by putting it in the hands of the government. And companies may prefer it that way.

B. The Government Is Better at Background Checks

As I alluded, customer investigation is essentially a background check. This is a quintessential law enforcement task. Since the FBI Criminal Justice Information Services Division already does background checks for those who work with dangerous pathogens under FSAP, it is the obvious candidate to do background checks here as well.[211]

While the FBI is relatively good at performing background checks, gene synthesis companies, resellers, and device manufacturers are less adept.[212] The FBI has trained investigators and powerful databases at its disposal; private companies only have publicly available information and the customer's word, and they are disincentivized from investigating at all. This point hardly merits elaboration.

To the extent that companies *do* investigate customers, a license system would remove much of these costs. Companies would not need to devote time and money to researching basic customer information. Instead, companies would focus on the more specialized task of

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[209] VENTER REPORT, *supra* note 99, at 17.

[210] *See, e.g.*, VENTER REPORT, *supra* note 99, at 12 (finding that while only 5% of orders to IGSC companies raise flags, the cost of investigating these is exorbitant for most companies); Diggans & Leproust, *supra* note 171, at 2 ("Twist Bioscience (a member company and officer of the IGSC) has witnessed first-hand how challenging some of the Guidance recommendations can become at increasing scale. Those difficulties must be surmounted while maintaining customer and sequence screening accuracy and still achieving the tight delivery timelines demanded by fierce competition within the global DNA synthesis industry").

[211] *See* 42 C.F.R. § 73.10.

[212] The 2022 HHS Guidance encourages all sellers (including gene synthesis providers, resellers, and device manufacturers) to know their buyer; know if the product contains sequences of concern, and if so, notify the customer; and if follow-up screening does not placate concerns about an order, report it to the FBI. *See* 2022 HHS Guidance, *supra* note 108, at 25497.

determining whether customers have good reasons for receiving flagged orders.

Concentrating this task into one government agency would be more efficient than having dispersed companies do it, each with a handful of scientists-turned-detectives. Since this is a matter of national security, it makes sense to give this task to the government.

C. Relative Advantage of Customer Verification

The biosecurity literature devotes much more attention to technical sequence screening solutions than customer verification.[213] This is unsurprising given that most contributors are scientists and technologists. But customer verification has a relative advantage over sequence screening, because technical advances are rendering sequence screening less effective and more expensive.[214]

Let us take a few examples. New synthesis techniques are making it easier to assemble genomes using smaller and smaller pieces (oligos), meaning we would need to screen vastly more sequences to keep up.[215] The advance of benchtop synthesis devices will allow more DNA to be printed in-house, instead of being ordered from synthesis companies, which will go unscreened unless something is done.[216]

One more extreme example to drill home the point. In addition to the four DNA bases that we learned about in biology (A, T, G, & C), scientists "have been expanding the language of DNA . . . by adding in new bases (S, B, P, and Z)."[217] There are four new letters and more to come! But if customers order sequences containing new bases, these

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[213] *But see* Diggans & Leproust, *supra* note 164, at 4 (arguing that the commandment to "know your customer" "should apply more broadly and explicitly to the entire synthetic biology industry and supply chain").

[214] *See* Center for Health Security, *supra* note 8, at 421 ("Since 2010, there have been technical advances that challenge or evade the biosecurity benefits of gene synthesis screening protocols. It is now more straightforward to assemble large pieces of genetic material using methods other than purchasing screened DNA synthesis products. . . Some of the most important advances that diminish the effectiveness of current gene synthesis screening approaches are Gibson Assembly, enzymatic assembly of DNA, genetic recoding, CRISPR, and a new type of desktop DNA synthesizer, a product that is just on the horizon").

[215] *See id.* at 421 ("Gibson Assembly is a widely used synthetic biology technique that can be used to rapidly and accurately assemble large genetic fragments from oligonucleotide fragments or from single-stranded or double-stranded DNA oligonucleotides. Using Gibson Assembly, smaller pieces of DNA (which are now unscreened) may be assembled to construct much larger fragments").

[216] *See id.* at 423. While less-capable oligo synthesizers have been around for decades, more capable gene synthesizers are gaining popularity and becoming more widespread.

[217] *See id.* at 422.

sequences "may be inscrutable to the gene synthesis provider."[218] Such "genetic recoding" means that customers could encrypt their orders, and sequence screening would need to decrypt it to be effective.[219]

The obvious lesson to draw is that it is easier to investigate the customer rather than decrypt the puzzle. I am not saying that technical sequence screening solutions are not worth thinking about; they are. But as sequence screening grows more difficult and provides less coverage, it becomes relatively more efficient to focus on the customer end.

While technology is progressing rapidly, people will stay the same. And whereas the biosecurity literature focuses on technical solutions, this essay aims for common sense.

D. Gap Filling

Verifying mystery customers is the most glaring gap. Under the self-regulation regime, some gene synthesis companies do nothing to verify their customers or do very little. A license regime would patch this hole by ensuring that customers pass a legitimacy test.

A license system would also go a long way toward correcting the venue-shopping problem. Like the legal analog, where lawyers file cases in, or transfer cases to, venues they perceive as advantageous, bad actors wishing to acquire dangerous pathogens can submit orders to the weakest link.[220] A license system would deter and weed out malicious actors from the start.

In the same vein, a license system would largely address the issue of circumvention—evading detection by ordering smaller bits of DNA from multiple manufacturers. Circumvention would be much less of a concern with an ex-ante license requirement because it would not be possible to fly totally under the radar.

A license requirement would even partially address the future problem of novel pathogen design. An individual would have to qualify for a license before they could order any DNA, including sequences that pose risks without raising alarms.

One can observe a common thread. A license regime creates an upfront barrier that would mitigate a host of bad downstream consequences.[221] If it was well built, it would stop most malicious

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[218] *Id.*
[219] *Id.*
[220] *See id.* at 425.
[221] A bonus is that it could provide a check on potentially irresponsible research. If a privately funded lab was studying a dangerous pathogen not on the FSAP list, it may be able to entirely evade federal oversight. *See* Ryan Ritterson et al., *A Call for a*

individuals that tried to climb over it.[222] And though it would be overly optimistic to say that it could never be scaled, the fact of its existence would deter many attempts to begin with.

VII. LICENSE REGIME ELEMENTS

Congress should pass a law creating the framework for a license regime. Like the FSAP, it should be administered by HHS and background checks should be performed by the FBI. This section takes a stab at the elements of a successful license system.

Much of this proposal is modeled after the FSAP, which has a sophisticated license architecture.[223] However, it avoids many of the FSAP's most burdensome attributes, which have engendered understandable scrutiny from the research community.[224] Many of the hoops from the FSAP approval process associated with dangerous pathogen research—like preparing a security plan, biosafety plan, and incident response plan—are inapplicable here.[225] Nor would licensed parties need to keep a running inventory of stock, "perhaps the most controversial element" of the FSAP because it is very hard to tally reproducing organisms.[226] Synthetic DNA is dead for the time being.

This proposal also borrows from the REAL ID Act, legislation that requires minimum identification standards to improve national

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National Agency for Biorisk Management, 20 HEALTH SEC. 2, 188 (2022). This could be true even if it were modifying the pathogen to make it more transmissible or more pathogenic, and even if researchers had a criminal background or a known association with terrorists. *Id*. To the extent the lab required synthetic DNA, a license regime would inject some scrutiny into the situation.

[222] *See also* Posner, *supra* note 64, at 524 ("one must also bear in mind that expenditures used to combat bioterrorism do more than prevent mega-attacks; the lesser attacks, which would still be very costly, both singly and cumulatively, would also be prevented").

[223] *See* 42 C.F.R. § 73.

[224] Even though the FSAP aimed not to unduly burden legitimate research, many believe it did just that. *See, e.g*., *Brighter Line*, supra note 29, at 20, 29–31 ("Paradoxically, the designation of these organisms and toxins as Select Agents put considerable burden on the scientific community to conduct this research while simultaneously adhering to costly and rigorous standards for security and accountability"); ENEMARK, *supra* note 31, at 55 (describing the "secure or stifle" tradeoff, and noting that after 2002 "there was a steep decline in the number of [scientific papers on the anthrax and ebola viruses] per million dollars of US government funding").

[225] *See* 42 C.F.R. §§ 73.7(g); 73.11; 73.12; 73.14. To handle Select Agents, there are additional hurdles that do not concern us here. These include "controlled access to facilities, physical security, inventory control, and site-specific risk assessments." *Brighter Line*, supra note 29 at 109.

[226] *Brighter Line*, *supra* note 29, at 23.

security.[227] Compliant licenses will soon be necessary to board federally regulated commercial aircraft, enter nuclear power plants, and access certain other federal facilities.[228] Whereas the REAL ID requirements will stretch to hundreds of millions of people traveling the skies, this is a more targeted approach.

A. License Requirement

The Select Agent regulations prohibit the possession, use, or transfer of Select Agents without a certificate of registration issued by the HHS Secretary.[229] So too here, the possession and use of synthetic biology materials (synthetic DNA/RNA and benchtop synthesizers) without a license would be prohibited, as would transferring them to an unlicensed party.[230]

B. Line Drawing

It is undesirable to draw too large of a circle. Licenses should be required for actors in the gene synthesis ecosystem, and ideally not be necessary for those who use synthetic DNA for other purposes such as PCR or gene sequencing. Happily, we have a rule of thumb to differentiate these purposes.

Remember, most single-stranded (oligo) sequences are ordered for PCR or sequencing, not for gene synthesis.[231] These orders tend to include sequences under 30 bases, whereas those used for gene synthesis are longer, between 40 and 60 bases.[232] Thus, it may make sense that a license requirement would only apply to DNA orders equal to or greater than 40 bases. This would avoid capturing an unnecessary segment of the synthetic DNA industry.

Admittedly, there is no bright line at forty bases.[233] It is still possible to synthesize genes with smaller pieces. Although this policy would be slightly over- and under-inclusive, it tries to strike a balance. A stricter policy would impose a license requirement on all synthetic DNA, regardless of length.

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[227] REAL ID Act of 2005, Pub. L. 109–13, Div. B (May 11, 2005). The Department of Homeland Security oversees its implementation.
[228] *Id.*
[229] 42 C.F.R. §§ 73.7(a); 73.16. Individuals and entities can also be exempted under § 73.5.
[230] *See id.*
[231] *See* VENTER REPORT, *supra* note 99, at 19–20.
[232] *See id.*
[233] *See id.*

C. Security Risk Assessment

Those seeking to do research with Select Agents must undergo a background check, called a "security risk assessment," by the FBI's Criminal Justice Information Services Division every three years.[234] Then the HHS Secretary must approve the individual or entity, the Responsible Official, and the individual who controls or owns the entity.[235]

This process tries to achieve "personnel reliability."[236] Under the Patriot Act, an application may be denied if the individual has been indicted or convicted of a crime punishable by imprisonment for greater than one year, has been dishonorably discharged from the military, is a fugitive from justice, is a current user of illegal drugs, has been committed to a mental institution, is illegally in the US, or is an alien national (not a lawful permanent resident) of a country officially designated as a state sponsor of terrorism.[237] To be clear, foreign nationals are eligible, as are those with mental illnesses that have voluntarily received treatment or been hospitalized.[238]

Under the Bioterrorism Act, an individual may also be denied if he is "reasonably suspected" of having committed certain crimes, been knowingly involved in a terrorist organization or an organization that commits crimes of violence, or is an agent of a foreign power.[239] Finally, an applicant can be denied if it is "necessary to protect the public health and safety," a catch-all provision.[240] Denied applicants may appeal.[241]

Arguably, the background check to receive a synthetic biology license should be less onerous than with FSAP because the risks are less direct. Researchers that work with dangerous pathogens pose a greater security risk than those that *could* build them, which still requires considerable skill.

As a floor, assessments should verify that applicants are who they say they are, confirm the basics of their identities, and acquire information about the types of work they perform.[242] This should be done

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[234] 42 C.F.R. § 73.10. Certificates used to be valid for five years, but this was decreased to three years in 2012. ENEMARK, *supra* note 31, at 52.
[235] § 73.7(d)(1).
[236] *See* RESPONSIBLE RESEARCH, *supra* note 58, at 47–48, 59.
[237] *Brighter Line*, *supra* note 29, at 20.
[238] RESPONSIBLE RESEARCH, *supra* note 58, at 47, 78.
[239] 42 C.F.R. § 73.8(a)(2).
[240] 42 C.F.R. § 73.8(a)(3), (4).
[241] 42 C.F.R. § 73.20.
[242] *See e.g.*, Department of Homeland Security, *REAL ID Requirements*, U.S. DEP'T HOMELAND SEC., https://www.dhs.gov/real-id/real-id-faqs ("At a minimum, you must

with overseas customers as well.[243] A more rigorous approach would aim for personnel reliability, using the criteria from FSAP. The lessons learned from its implementation should be applied.[244]

D. Responsible Official

Duplicating the "Responsible Official" approach from FSAP would further promote accountability.[245] Each licensed entity would need to designate a Responsible Official (or several) to ensure compliance.[246] Putting responsibility on their shoulders would foster ownership and incentivize careful monitoring.[247]

E. Chain-Linked Transactions

Every entity transferring synthetic biology materials would need to ensure that their counterpart had a valid license. This is particularly important because genetic materials and equipment often do not go straight from point A to point B.[248]

The 2022 HHS Guidance hopes that gene synthesis companies will verify the "end-user" of their products, but this is difficult when there are middlemen.[249] And again, companies are unlikely to go far out of

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provide documentation showing: 1) Full Legal Name; 2) Date of Birth; 3) Social Security Number; 4) Two Proofs of Address of Principal Residence; and 5) Lawful Status"); Maurer, *supra* note 69, at 22 ("Companies should also check shipping addresses to make sure that they correspond to registered businesses, internationally-recognized academic institutions, or similarly legitimate organizations").

[243] *See, e.g.*, Maurer, *supra* note 69, at 24 ("US and European gene synthesis companies find it prohibitively expensive to investigate customers in the developing world. Government can potentially fill this gap by investigating and licensing customers. Such a system would be similar to the 'Expert Traveler' lists currently found in US airports").

[244] *See generally* RESPONSIBLE RESEARCH, *supra* note 58, at 73–103 (recommending some changes to the personnel reliability process); *see, e.g.*, *id.* at 78 (recommending a broader appeal process for those denied for past criminal offenses).

[245] 42 C.F.R. §§ 73.7(c); 73.9.

[246] *Id.* §§ 73.7(c); 73.9.

[247] *See, e.g.*, *Biodefense Policy*, *supra* note 81, at 89, 92 = (recommending centralizing compliance activities in an institution); Rebecca L. Morvitz et al., *Promoting Biosecurity by Professionalizing Biosecurity*, 367 SCIENCE 6480, 856 (2020) (recommending a credentialing process to help address biosecurity gaps in their home institutions and collaborate with others at other institutions); *see* Kirsten X. Jacobsen et al., *Biosecurity in Emerging Life Sciences Technologies, A Canadian Public Health Perspective*, 2 FRONTIERS IN PUB. HEALTH 198, 1 (urging that labs be licensed and that a "qualified biological safety officer (BSO) would be designated for each institution.").

[248] Center for Health Security, *supra* note 8, at 425.

[249] *See* 2022 HHS Guidance, *supra* note 108; *see also* Sarah Carter & Diane DiEuliis, *Mapping the Synthetic Biology Industry: Implications for Biosecurity*, 17 HEALTH SEC. 5, 403, 405 (2019) ("[I]t is likely that many more synthetic biology companies

their way when it cuts into their bottom line. A simple solution is to require verification at every step.

This is similar to the FSAP's "chain of custody" requirement.[250] There, the CDC requires that transferring laboratories are registered and report each transfer.[251] So too here, the transferring parties should be required to verify that their counterpart is licensed and record the transaction. License security features can help prevent tampering and protect privacy.[252] Reporting transactions to the regulator seems excessive, except perhaps for sales of powerful synthesizers.

F. Records, Investigations, Revocation, & Notice

Each transfer would be recorded, and all licensees would be required to maintain a complete record for a certain duration. The FSAP requires that records be kept for three years, which seems to roughly balance accountability and hardship.[253]

As with the FSAP, investigations would help to catch violators before a catastrophe, and aid in attribution and prosecution efforts if something goes wrong.[254] The regulator would have the authority to conduct audits on suspected noncompliance without notice.[255]

If a party failed an investigation or audit, the regulator could revoke their license.[256] An appeal process would be available to rectify regulatory mistakes and abuses.[257]

And like the FSAP, licensees would be required to notify the authorities if synthetic biology materials were lost or stolen.[258]

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will be established, increasing the potential that the end user will be even further removed from the production of synthetic DNA.").

[250] *Brighter Line*, *supra* note 29, at 158.

[251] *Brighter Line*, *supra* note 29, at 109–10 (citing NRC 2009).

[252] *See* REAL ID Act of 2005, § 202(b)(8)-(9), 49 U.S.C. § 30301; Manoj Govindaiah, *Driver Licensing Under the REAL ID Act: Can Current Technology Balance Security and Privacy?, 2006* U. ILL. J.L. TECH. & POL'Y 201, 206–13 (2006).

[253] 42 C.F.R. § 73.17.

[254] *See Brighter Line*, *supra* note 29, at 23; *see also* RESPONSIBLE RESEARCH, *supra* note 58, at 52 (explaining that the FBI is automatically notified if an individual with a favorable security risk assessment is arrested or checked against databases).

[255] *See* 42 C.F.R. § 73.18. This could involve peeking at companies' logged records and copying them. If the authority wished, they could attempt a sting operation. Depending on the level of funding, the regime could also incorporate periodic or random audits.

[256] *Id.* at § 73.8.

[257] *Id.* at § 73.20.

[258] *See id.* at § 73.19.

G. Liability

Liability would be the backbone of a license regime, providing desired incentives and deterring and punishing noncompliance.

The FSAP allows the Inspector General of HHS to impose civil penalties,[259] and the Biological Weapons Act allows for criminal penalties.[260] If a *restricted* person possesses or transports Select Agents, they can face fines, imprisonment up to ten years, or both.[261] Criminal liability is lesser for an *unregistered* person; they can face fines, imprisonment up to five years, or both.[262]

Likewise, transfers of synthetic biology materials to restricted persons, and possession by restricted persons, should be criminalized. Providers and intermediaries can easily determine whether a customer is on a restricted list, so imposing criminal penalties would deter recklessness. Providing synthetic biology materials to someone for the purpose of developing a bioweapon is already criminalized.[263]

However, criminal penalties seem too punitive for transfers to or use by unregistered persons. As powerful as these technologies are, they pose a less direct threat to national security than complete pathogens. Significant civil penalties would likely be sufficient. Because noncompliance could range from a one-off mistake to a pattern of evasion, and as different players in the industry have varyingly deep pockets, penalties could be determined on a case-by-case basis by the HHS Inspector General. Another option is to predefine penalties as a fraction of entities' annual gross income. This would be persuasive to large corporations and avoid dooming startups.

H. Grace Period & Automatic Approvals

To achieve a smooth transition from the wild west to a license system, the law should include an ample grace period. It would likely take a few years to issue (and appropriately deny) a great number of licenses.[264]

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[259] *Id.* at § 73.21(a).
[260] 18 U.S.C. § 175b.
[261] *Id.* at § 175b(a).
[262] *Id.* at (b), (c).
[263] 18 U.S.C. § 175.
[264] For instance, the REAL ID Act was passed in 2005, but the enforcement date is May 7, 2025. *See REAL ID Frequently Asked Questions*, U.S. DEP'T OF HOMELAND SEC., https://www.dhs.gov/real-id/real-id-faqs (accessed Jan. 4, 2023). However, the grace period here should be much shorter since it involves far fewer licenses and no coordination with states.

Researchers who are already certified to work with Select Agents would automatically be approved, because another round of vetting would be redundant. The same could also apply to US government employees that have already undergone background checks.

I. Options: Red-Teaming and Tiers

Obviously, it should not be easy for a nefarious actor to obtain a license. The license regime should be stress-tested to make sure that it works. One way to do this is via red teaming—purposefully trying to exploit the system to make it stronger.[265] The government could partner with sophisticated white-hat actors to periodically reevaluate the system and patch holes.

Another feature of a license regime could be creating tiers based on different levels of risk.[266] Like the FSAP, which differentiate pathogens into several tiers based on their dangerousness and potential for misuse, the license regime could require greater or lesser burdens.[267] For instance, possessing a potent gene synthesizer may deserve heightened scrutiny.

Thus concludes my attempt to outline the basic elements of a license regime. These recommendations should be taken with a grain of salt; more input by scientists, lawyers, law enforcement and intelligence experts, and private companies would undoubtedly create a stronger product.[268]

VIII. COUNTERARGUMENTS

This section will consider the best arguments against a license regime and provide counterarguments. The chief complaint I anticipate

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[265] *See*, *e.g.*, Maurer, *supra* note 69, at 23 ("In the long run, it may also be important for customers to know when companies do not screen. This can be done by testing company systems with 'red team' orders for dangerous sequences. Government is the most natural provider for this kind of testing.").

[266] *See generally* Alexander Kelle, *Synthetic Biology and Biosecurity*, 10 EMBO REPORTS (2009) (describing how different synthetic biology subfields have different security implications).

[267] *See, e.g.*, DiEuliis et al., *supra* note 81, at 89 (noting that the FSAP regulations were updated in 2012 to include enhanced biosecurity measures for Tier 1 agents).

[268] *See also* Jesse Bloom, *A Plea for Making Virus Research Safer*, N.Y. TIMES (Oct. 30, 2022) ("Some virologists think we should have the final say, since we're the ones with technical expertise. I only partially agree. I'm a scientist. My dad is a scientist. My wife is a scientist. Most of my friends are scientists. I obviously think scientists are great. But we're susceptible to the same professional and personal biases as anyone else and can lack a holistic view. The French statesman Georges Clemenceau said, 'War is too important to be left to the generals.'").

is that it would constitute over-regulation. The argument from the other side is that it would be easily evadable and not worth the effort. Both are unpersuasive.

A. Overly Burdensome

Perhaps a license regime would just mire a prosocial industry in unnecessary red tape. Large US companies already screen sequences and we have no evidence that self-regulation has faltered. A license system would increase transaction costs, deter innovation, and dampen the burgeoning bioeconomy.

The "unnecessary" part of the argument is unpersuasive because companies' economic incentives direct against customer verification. I have endeavored to show that this investigative component is important and necessary. However, the added burden should be taken seriously.

The FSAP provides a useful point of reference. The stringency of these regulations may have hampered helpful research and deterred scientists from going down this road in the first place.[269] However, I have emphasized that the most burdensome aspects of the FSAP are not needed here. Written biosecurity and biosafety plans are unnecessary, as are running stocks of inventory. I have also argued that background checks should be less onerous because the risks are more attenuated.[270]

Even so, this proposal casts a wide net. Since synthetic DNA can be used for many purposes, it is difficult to craft an instrument that does not touch various industries that use it.[271] I have recommended that licenses only be required for synthetic DNA orders equal to or greater than forty base pairs to narrow its reach. It is also helpful that the customer base for synthetic DNA is currently "dominated by companies," which are easier to verify than individuals.[272]

As of 2009, the average turnaround time for a security risk assessment in FSAP was only a month.[273] During the initial phase when many assessments were needed, the wait time was only two months.[274]

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[269] *See* ENEMARK, *supra* note 31, at 55; *Brighter Line*, *supra* note 29, at 24; DiEuliis, *supra* note 81, at 94.
[270] One implication might be that license holders only need to renew their license every five years instead of every three years, as in the FSAP.
[271] These industries include pharmaceuticals, chemicals, fuels, agriculture, food, materials, and consumer products. Carter & DiEuliis, *supra* note 250, at 404.
[272] *See id.* at 405. A decade ago, the field was dominated by individual researchers in academic settings.
[273] RESPONSIBLE RESEARCH, *supra* note 58, at 48.
[274] *Id.* at 48–49.

Here, a generous implementation period could help ensure that companies are not halted in their tracks and would minimize downsides.

What if greater securitization deters the next Steve Jobs from going into biology? Well, if Steve is seriously interested, he will be willing to jump through a few hoops to pursue his dreams. A more serious answer is that our open access approach is unsustainable as dual-use biotechnology keeps improving.

The emerging bioeconomy will be overwhelmingly good for society. Innovations will improve medicine, energy, and agriculture. But since biotechnology can be misused, it would be a mistake to continue our *laissez-faire* approach. We must try to strike a balance between innovation and security.[275] A moderate investment to curb the risk of potentially catastrophic bioterrorism is money well spent.

B. Ineffective Security

Conversely, one might worry that a license system would not provide meaningful security or deterrence. Nefarious individuals could sneak through the license approval process, bribe or threaten license holders, or order synthetic DNA from abroad.

It goes without saying that a license regime should be as bulletproof as possible. I have shown that background checks by the FBI are preferrable to those by private companies, who are incentivized not to do them. Red teaming could help find and patch weaknesses.

Licenses would not annul the benefits of sequence screening; they would provide an additional layer of defense. To the extent that companies verify customers, they would no longer need to investigate basic information, though they should still have in-house experts examine DNA orders that raise flags and contact customers to interrogate their purpose.

Of course, a well-resourced actor with firm intentions could still acquire dangerous materials from overseas. But as the world leader in biotechnology, the US arguably has an obligation to be the first mover. Doing so would give it leverage to encourage security efforts elsewhere, including China, which aims to become the new frontrunner in synthetic

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[275] *See also* Executive Order, *supra* note 4, at 2 ("Simultaneously, we must take concrete steps to reduce biological risks associated with advances in biotechnology. We need to invest in and promote biosafety and biosecurity to ensure that biotechnology is developed and deployed in ways that align with United States principles and values and international best practices, and not in ways that lead to accidental or deliberate harm to people, animals, or the environment.").

biology.[276] International solutions could include revamping the Biological Weapons Convention or writing a new multilateral treaty, creating a new international organization, or simply exercising soft power and developing norms. If the US acts first and exerts tactical pressure, it can reduce global risks.[277]

CONCLUSION

Dual-use biotechnology is a moving target. Any regulatory solutions are fraught with uncertainty and impervious to straightforward cost-benefit analysis.[278] But these difficulties should not breed inaction. The synthetic biology self-regulation regime must give way.

The US should require that gene synthesis companies screen the DNA sequences they provide to help prevent facile misuse. It should also implement a license regime to help verify customers and ensure their legitimacy. As biotechnologies become cheaper and even more powerful, it is hard to imagine a desirable future where anyone can get their hands on synthetic DNA and the machines that make it.

Though gene synthesis security efforts are not a panacea, preventing gene synthesis materials from being "easily and directly misused" is a goal worth achieving.[279]

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[276] *See* Center for Health Security, *supra* note 8, at 427; REPORT TO CONGRESS OF THE U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION 8 (Nov. 2021). China passed its first comprehensive biosecurity law in 2021, but it is too early to know its implications. *See* Huigang Liang et al., *Significance of and Outlook for the Biosecurity Law of the People's Republic of China*, J. OF BIOSAFETY AND BIOSECURITY 3, 46–50 (2021).

[277] *See also* Jonathan B. Wiener, *The Diffusion of Regulatory Oversight*, in THE GLOBALIZATION OF COST-BENEFIT ANALYSIS IN ENVIRONMENTAL POLICY 128 (Michael A. Livermore & Richard L. Revesz, eds., Oxford Univ. Press, 2013) (internal citations omitted) ("legal scholars came to appreciate that legal evolution also occurs through the exchange of legal concepts across legal systems via borrowing, also called "hybridization."").

[278] *See* Daniel A. Farber, *Uncertainty*, 99 GEO. L.J. 901, 903, 946–49 (2011).

[279] *See* Gigi K. Gronvall, *Safety, Security, and Serving the Public Interest in Synthetic Biology*, 45 J. OF INDUS. MICROBIOLOGY & BIOTECHNOLOGY 463, 464–65 (2018).

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ARTICLES

THE HIGH COST OF PHARMACEUTICAL ACQUISITIONS: INCREASING SOCIAL WELFARE OR FURTHERING INEQUALITY?

Timothy J. Haltermann

THE HIGH COST OF PHARMACEUTICAL ACQUISITIONS: INCREASING SOCIAL WELFARE OR FURTHERING INEQUALITY?

*Timothy J. Haltermann**

INTRODUCTION

Global sales of pharmaceuticals reached over $1 trillion annually each of the past three years and the trajectory of growth is expected to continue in the coming years.[1] In the United States alone, pharmaceutical sales topped $500 billion in each of the past two years, making it the largest market in the world.[2] The importance of the pharmaceutical market was thrust into the spotlight during the COVID-19 pandemic, as both policymakers and individual companies raced to provide access to life saving medicine to those in need. Large pharmaceutical companies engaged in partnerships with small research start-ups, developing breakthrough vaccines that reached the market in record time.[3] Two of the leading vaccine manufacturers, Pfizer and Moderna, are projected to approach $50 billion in sales in 2022 alone.[4]

News publications have been replete with headlines about astronomically high costs to consumers for essential treatments over the past decade, featuring stories about EpiPens and insulin.[5] The increase

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[1] Matej Mikulic, *Global Pharmaceutical Sales from 2017 to 2021, By Region,* STATISTA, (Jul. 27, 2022), https://www.statista.com/statistics/272181/world-pharmaceutical-sales-by-region/.

[2] *See id.*

[3] Desma Polydorou et al., *Transatlantic Enforcers Working Group on Pharmaceutical Mergers: Reimagining Innovation May Have Side Effects*, 36 ANTITRUST 70, 70 (2021).

[4] Spencer Kimball, *What's next for Pfizer, Moderna, beyond their projected $51 billion combined Covid vaccine sales this year*, CNBC, (Mar. 3, 2022, 6:13 PM), https://www.cnbc.com/2022/03/03/covid-pfizer-moderna-project-51-billion-in-combined-vaccine-sales-this-year.html.

[5] *See, e.g.*, Lisa Rapaport, *Another look at the surge in EpiPen costs,* REUTERS, (Mar. 27, 2017, 6:03 PM), https://www.reuters.com/article/us-health-epipen-costs/another-look-at-the-surge-in-epipen-costs-idUSKBN16Y24O (explaining how generic drugmaker Mylan increased the list price of the EpiPen from $94 to $609, resulting in a 535 percent price hike for patients out-of-pocket spending from 2007 to 2014); Steve Inskeep & Allison Aubrey, *Insulin costs increased 600% over the last 20*

in innovation and resulting market dominance of large pharmaceutical companies has brought with it renewed scrutiny from regulators about pricing concerns. In response to increasing prescription drug prices for many Americans, President Biden and Congress worked to include drug pricing reform in the Inflation Reduction Act of 2022 ("IRA").[6] Under the IRA, the Secretary of the Department of Health and Human Services is empowered to establish a "Drug Price Negotiation Program," under which he shall negotiate prescription drug prices and enter into agreements with manufacturers of selected drugs.[7] Regardless if it were the correct normative approach to reduce prices for consumers, the current administration took a substantial step to address the concern over individual social welfare, likely coming at the expense of future profits for pharmaceutical companies.

Amidst concerns over future regulation and the sustainability of profits from existing products, pharmaceutical companies have turned largely to mergers and acquisitions ("M&A") to supplement their own internal research and development ("R&D") and to find the next "blockbuster" drug. Over the past few decades, spending on R&D has increased dramatically, and on average, pharmaceutical companies spent approximately one quarter of their revenues on R&D in 2019.[8] The disproportionate spending on R&D appears logical when considering the "costly and uncertain process" of developing a drug that passes all milestones during clinical trials and is granted approval by the United States Food and Drug Administration ("FDA").[9] According to research done by the Congressional Budget Office, only 12 percent of drugs that enter clinical trials are approved by the FDA, and the cost of R&D spending on an individual approved drug can be as high as $2 billion.[10] Large pharmaceutical companies have turned to small biotechnology

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years. States aim to curb the price, NPR, (Sept. 12, 2022, 5:07 AM), https://www.npr.org/2022/09/12/1122311443/insulin-costs-increased-600-over-the-last-20-years-states-aim-to-curb-the-price#:~:text=The%20price%20of%20insulin%20remains,patients%20ration%20this%20lifesaving%20drug (discussing how insulin manufacturers have increased prices by 600% over the course of the past twenty years).

[6] *The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans*, CTR. FOR MEDICARE & MEDICAID SERV., (Oct. 5, 2022), https://www.cms.gov/newsroom/fact-sheets/inflation-reduction-act-lowers-health-care-costs-millions-americans.

[7] 42 U.S.C. § 1320f.

[8] *Research and Development in the Pharmaceutical Industry*, CONG. BUDGET OFF. 1 (Apr. 2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf. The share of revenue devoted to R&D expenses is larger than other innovative industries, including the expenses for "semiconductors, technology hardware, and software."

[9] *Id.* at 2.

[10] *Id.*

startups and partnerships with nonprofit research institutions as a means of outsourcing R&D to those who have the ability to specialize on certain biological processes or individual small molecules, and have the flexibility to research in the manner they see fit.[11] Given the high cost associated with developing new drugs, and the risk of failure in one or more stages of development, smaller startup companies are incentivized to engage in transactions with larger incumbent firms in order to commercialize new products.[12]

While the value of M&A to large pharmaceutical companies and their shareholders has been debated for years, both scholars and regulatory officials have begun to focus on whether consolidation between firms will harm innovation, and thus negatively impact downstream social welfare for individuals.[13] The debate intensified following the release of a working paper by economists Colleen Cunningham, Florian Ederer, and Song Ma, which introduced the concept of "killer acquisitions" – an incumbent firm acquires a nascent competitor with the motivation of terminating development in order to reduce competition to its existing or pipeline products.[14] While subsequent research papers have begun to echo similar concerns over the anticompetitive nature of M&A in the pharmaceutical industry, others have discussed the problems associated with proving such phenomena exist.[15] To explore the issue further, leading antitrust authorities, including the FTC, the European Commission ("EC"), the Department of

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[11] *See* Joanna Shepherd, *Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*, 21 J. HEALTH CARE L. & POL'Y 1, 1–10, (2018); *see also* Constance E. Bagley & Christina D. Tavrnø, *Pharmaceutical Public-Private Partnerships in the United States and Europe: Moving from the Bench to the Bedside* (discussing the encouragement of legally binding partnerships between private pharmaceutical companies and public research institutions or private universities utilizing public grants to incentivize innovation and increase the likelihood of successful commercialization of new drugs).

[12] *See* Shepherd, *supra* note 11, at 9–10.

[13] *Id.* at 1–2.

[14] *See* Collen Cunningham et al., *Killer Acquisitions*, Vol. 129, No. 3 J. POL. ECON. 649 (Mar. 2021).

[15] *See, e.g.*, W. Robert Majure et al., *Evaluating innovation theories of harm in merger review: economic frameworks and difficulties*, CORNERSTONE RSCH., (Aug. 2021), https://www.cornerstone.com/wp-content/uploads/2022/01/Evaluating-innovation-theories-of-harm-in-merger-review.pdf (addressing the difficulties in finding evidence and supporting empirical measurement in proving harm to innovation); Patricia M. Danzon & Michael A. Carrier, *The Neglected Concern of Firm Size in Pharmaceutical Mergers*, 84 ANTITRUST L.J. 487 (2022) (introducing the "neglected concern of firm size" in pharmaceutical mergers and suggesting that antitrust authorities should differentiate between large firms and others when conducting merger review).

Justice Antitrust Division ("DOJ"), the Canadian Competition Bureau, and the United Kingdom's Competition and Markets Authority ("CMA"), issued a notice seeking public comment on how to best inform their approaches to analyzing pharmaceutical mergers.[16]

While the concentration of market power may lead to increased prices in the short term for consumers, antitrust authorities should be wary of examining the deleterious effects on innovation as a standalone theory of harm because countervailing interests in synergy and innovation stemming from pharmaceutical M&A may increase total consumer surplus in the long run.[17] Additionally, the current patent system, which provides a limited term of monopoly for patent holders, and requires companies to license existing products or face liability for patent infringement, provides consistent incentives for large pharmaceutical companies to acquire new products and ideas through acquisition, rather than through organic development.[18] Many startup biotechnology companies develop specifically for the purpose of selling the business in order to profit, instead of adopting the role of a true competitor to larger incumbent firms.[19] In examining the actual effect on competition resulting from an acquisition, the counterfactual world is not observable, and it would be impossible to predict a nascent company's future effects on competition.[20]

Instead, this note will argue that government and regulatory authorities should focus on easing access to downstream innovation by broadening research exemptions to patent infringement. Part I of this note will focus on the current state of patent protection and exclusivity afforded to pharmaceutical companies. Part II will discuss incentives

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[16] *Multilateral Pharmaceutical Merger Task Force Seeks Public Input*, FED. TRADE COMM'N. (May 11, 2021), https://www.ftc.gov/news-events/press-releases/2021/05/multilateral-pharmaceutical-merger-task-forceseeks-public-input. The Task Force sought comment on seven questions on the effects of pharmaceutical mergers. These included: "(1) [w]hat theories of harm should enforcement agencies consider . . .?; (2) [w]hat is the full range of a pharmaceutical merger's effects on innovation?;... and (6) [w]hat types of remedies would work . . .?"

[17] *See generally* Robert D. Cooter & Uri Y. Hacohen, *Progress in the Useful Arts: Foundations of Patent Law in Growth Economics*, 22 YALE J. L. & TECH. 191 (2020). This article outlines that the purpose of the patent law system is to "increase economic growth through innovation." Using the constitutional background as a basis for policy, the authors note that social welfare can increase exponentially from innovation, outweighing any losses from inefficiency or inequality stemming from reallocation of resources.

[18] *See* Matthew J. Higgins & Daniel Rodriguez, *The Outsourcing of R&D Through Acquisitions in the Pharmaceutical Industry*, 80 J. FIN. ECON. 351 (2006).

[19] *See* Cooter & Hacohen, *supra* note 17, at 197–98.

[20] John M. Yun, *Are We Dropping the Crystal Ball? Understanding Nascent and Potential Competition in Antitrust*, 104 MARQ. L. Rev. 613, 636–42 (2021).

created that lead rational actors to engage in M&A instead of through internal R&D. Part III will address the development of innovation as a standalone theory of harm in merger review, and the fallacies associated with labeling certain transactions as "killer acquisitions." Finally, Part IV of the note will look at the intersection of pharmaceutical transactions and intellectual property protection, and how encouragement of collaboration between firms may offset the negative externalities associated with high costs to consumers and terminated R&D projects.

I. EXCLUSIVE RIGHTS IN PHARMACEUTICALS

A. Patent Protection

Congress was granted the power under the Constitution to "promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive right to their . . . [d]iscoveries."[21] While the theoretical underpinning for the United States patent system is vague, it is best understood as providing incentives to stimulate innovation and thus improve human welfare.[22] Generally, patent owners are entitled to exclude competitors from "making, using, or selling the patented invention" for a period lasting 20 years after the filing date of the patent application—patents create a short-term monopoly for their holder.[23] The grant of exclusivity is codified in statute under the Patent Act of 1952 ("Patent Act")[24], most recently amended by the Leahy-Smith America Invents Act ("AIA").[25] Under 35 U.S.C. § 101, any person who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . ." is eligible to qualify for a utility patent.[26] In the context of pharmaceuticals, patents may claim "compounds . . ., a method of using

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[21] U.S. CONST. art. I, § 8, cl. 8.
[22] *See* Christopher Buccafusco & Jonathan S. Masur, *Drugs, Patents, and Well-Being*, 98 WASH. U. L. REV. 1403, 1404 (2021).
[23] *Id.* at 1404–05.
[24] *See generally* Patent Act of 1952, 35 U.S.C. §§ 1–390.
[25] Pub. L. No. 112-29, 125 Stat. 284 (2011). The AIA was a groundbreaking development in US patent law, as it changed the prior "first-to-invent" rules to a "first-inventor-to-file" system. After the effective date of March 16, 2013, priority was given to the inventor who filed her patent application with the United States Patent and Trademark Office ("USPTO"), instead of relying on a claimed date of invention. The USPTO instituted the new system, among other changes, to provide "greater transparency, objectivity, predictability, and simplicity in patentability determinations." *See Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act*, 37 C.F.R. Part 1 (2013).
[26] 35 U.S.C. § 101.

the product, a method of making or administering the product, or a very of other patentable inventions relating to a drug or biologic."[27] After filing a patent with the USPTO, a patent examiner will determine if the claimed invention is (1) directed at patentable subject matter, (2) new, (3) nonobvious, and (4) useful.[28]

Once a valid patent has been granted by the USPTO, the holder of the patent has the exclusive right to make, use, sell, or import the invention within the United States until the expiration of the patent term or the patent is invalidated.[29] Thus, any person who "makes, uses, offers to sell, or sells any patented invention" infringes that patent, and may be liable for damages, and may be enjoined from its use.[30] Additionally, a patent holder may license a right in the patent to another, authorize the use of the patented material and waiving liability for patent infringement.[31] Due to the limited duration of exclusive rights to a pharmaceutical compound, and the profitability of exclusive use and marketing, patent holders have strong incentives to enforce their rights, and new competitors (often generic drug manufacturers) seek to invalidate the claimed patent. Under the statutory text, patents are governed by federal law, and federal district courts have jurisdiction in adjudicating any disputes.[32] All appeals from patent matters are heard by the United States Court of Appeals for the Federal Circuit.[33]

While the term for a patent is 20 years starting from the date of application, pharmaceutical companies can apply for patent term adjustments. These modifications to the standard term include time to account for excessive delays in examination at the USPTO, or delay resulting from obtaining marketing approval, typically approval by the FDA.[34] The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") sought to address distortions to patent terms associated with obtaining regulatory approval prior to marketing a drug.[35] Since a patent owner loses a period of the patent term following application, but before approval, the owner can apply for a patent term

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[27] *Drug Prices: The Role of Patents and Regulatory Exclusivities*, CONG. RSCH. SERV. 2 (2021) [hereinafter *Role of Patents and Exclusivities*].
[28] 35 U.S.C. § 101–03.
[29] *Role of Patents and Exclusivities*, *supra* note 27, at 25.
[30] 35 U.S.C. § 271(a).
[31] *Id.* at § 271(d).
[32] 28 U.S.C. § 1338.
[33] *Id.* at § 1295(a)(1).
[34] *Role of Patents and Exclusivities*, *supra* note 27, at 26.
[35] United States Patent and Trademark Office, *Patent Term Extension for Delays at Other Agencies Under 35 U.S.C.156*, Manual of Patent Examining Procedure § 2750 (9th ed. 2020).

extension ("PTE").[36] The grant of a PTE shall "not exceed 5 years from the date of expiration of the original patent term."[37]

While claiming a specific compound for the active ingredient within a pharmaceutical product typically provides the broadest breadth of protection, companies often seek to provide additional exclusivity through a variety of other patents. Pharmaceutical companies employ different filing strategies for their patent portfolio, but many apply for patent protection on different features of a drug or biologic beyond the initial claims.[38] These can include:

> 1. Formulations of a pharmaceutical (e.g., an administrable form and dosage, or a combination of active and other ingredients);
> 2. Methods of using the pharmaceutical (e.g., an indication or use of the drug for treating a particular disease);
> 3. Technologies and methods used to administer the pharmaceutical (e.g., an inhaler or injector device);
> 4. Technologies and methods for manufacturing the pharmaceutical (e.g., a manufacturing process); or
> 5. Other chemicals related to the active ingredient, such as crystalline forms, polymorphs, intermediaries, salts, and metabolites.[39]

Critics of strong intellectual property rights under the current system often highlight the multitude of patents on a single pharmaceutical product as an attempt to circumvent the normal patent process to extend the effective life of exclusivity.[40] Two of the most frequently cited criticisms are so-called patent "evergreening" and "patent thickets."[41] Patent "evergreening" is the practice of "filing for new patents on secondary features of a pharmaceutical as earlier patents expire," functionally extending the 20-year term of exclusivity through secondary patents.[42] "Patent thickets" refer to the filing strategy of certain pharmaceutical companies referring to the filing of numerous

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[36] 35 U.S.C. § 156.
[37] *Id.* at § 156(d)(5)(E)(i).
[38] *Role of Patents and Exclusivities*, *supra* note 27, at 28–29.
[39] *Id.* at 29.
[40] *See* Cooter & Hacohen, *supra* note 17, at 193 (explaining recent criticism of patent rights during both the Obama and Trump administration, which led to increased involvement from Congress).
[41] *Role of Patents and Exclusivities*, *supra* note 27, at 2.
[42] *Id.*

overlapping patents for the same pharmaceutical, creating a robust patent portfolio and thereby deterring competition through the risk of infringement.[43]

B. FDA Approval and Regulatory Exclusivity

When considering the development of a new drug or biologic, pharmaceutical companies must comply with the Federal Food, Drug and Cosmetic Act ("FD&C Act"), which governs the manufacture and distribution of pharmaceutical drugs.[44] In order to protect public health, new drugs and biologics must obtain FDA approval before they are marketed within the United States.[45] In order to meet the FDA guidelines, a company must submit a New Drug Application ("NDA").[46] The FDA has three main considerations in approving an application: (1) whether the drug is safe and effective in its proposed use; (2) whether the drug's proposed labeling is appropriate; and (3) whether the methods used in manufacturing the drug are adequate to preserve the drug's identity, strength, quality and purity.[47] While the FDA seeks to encourage and incentivize innovation through new treatments, it must balance the benefits of the proposed treatment with the associated harms and risks to the health of consumers.[48]

Before the drug will ever be introduced to the consuming market, a pharmaceutical company must demonstrate the "drug's safety and effectiveness for humans . . . "through clinical trials."[49] Clinical trials can be burdensome for those seeking approval from the FDA, and the selection of appropriate candidates is often a long and arduous process. Clinical testing occurs in three separate phases: phase I trials introduce the investigational new drug into a small population of humans, and phase II and III trials more thoroughly examine the efficacy of a new drug, and expand the study to a larger number of participants.[50]

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[43] *Id.*
[44] *See* 21 U.S.C. Ch. 9, Subch. V.
[45] 21 U.S.C. § 355(a) (regulating the approval of new drugs before introduction into commerce); 21 U.S.C. § 262(a) (forbidding introduction of biological products into commerce that do not comply with stated terms).
[46] *New Drug Application (NDA)*, FDA (Jan. 21, 2022), https://cacmap.fda.gov/drugs/types-applications/new-drug-application-nda#:~:text=The%20NDA%20application%20is%20the%20vehicle%20through%20which,New%20Drug%20%28IND%29%20become%20part%20of%20the%20NDA.
[47] *Id.*
[48] *Id.*
[49] *Role of Patents and Exclusivities*, *supra* note 27, at 11–12.
[50] For a further breakdown of the phases of clinical studies, *see* 21 C.F.R. § 312.21.

Following the amendment to the FD&C Act in 1962, the size of the population participating in clinical trials has expanded dramatically, making it more difficult to garner support from investors and outside parties.[51] In addition to the size of the trials, "the costs of recruiting patients, the length of the clinical trial period, and the number and complexity of clinical tests used in clinical trials have increased over time."[52] With the increased time and cost associated with clinical trials, it has raised development costs of each new drug to over $2 billion.[53] At the same time, companies have little guarantee of success, as FDA estimates predict that only 10 percent of new drugs entering testing will ever reach the market.[54] As new drugs become increasingly specialized, and courses of treatment reflect personalized characteristics, these requirements will only become more difficult for pharmaceutical manufacturers to meet.[55]

While the hurdles pharmaceutical companies must face to obtain FDA approval remain burdensome, they continue to face competition from non-brand name drug manufacturers (generic manufacturers).[56] Following the passage of the Hatch-Waxman Act, generic drug makers were empowered to compete with brand name pharmaceutical companies through the introduction of the abbreviated new drug application ("ANDA").[57] Instead of having to conduct their own clinical trials, ANDAs require only that a generic manufacturer conduct studies to show that a proposed drug is pharmaceutically equivalent to the marketed drug, and meets a certain level of bioequivalence.[58] This new pathway reduces the amount of time for a generic manufacturer to bring a new drug into the market, typically when a brand name drug is nearing the expiration of its main compound patent. The newfound competition drastically increases the availability of medication within the market and

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[51] Shepherd, *supra* note 11, at 4.
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *See, e.g.*, Sara Ponziani et al., *Antibody-Drug Conjugates: The New Frontier of Chemotherapy*, INT'L J. MOLECULAR SCI. (2020). The article discusses the novel use of antibody-drug conjugates ("ADCs"), which have become one of the most promising developments in cancer treatments. The ADCs selectively target antigens on tumor cells that are expressed at higher levels than normal cells. The treatments are often more effective in patients who exhibit higher levels of expression of certain cells, and results may vary significantly based on the presence of specific antigens. The changes in level in response have garnered the attention of numerous scientists and may lead to more "personalized medicine" in the future.
[56] Shepherd, *supra* note 11, at 4.
[57] *Role of Patents and Exclusivities*, *supra* note 27, at 13.
[58] *Id.*

reduces the cost of the drug to consumers—the profits of a patent owner will face a steep decline upon the entry of even the first competitor.[59]

While increasing availability of medicine to individuals, and subsequently reducing costs has become of paramount importance to many, federal law attempts to balance this interest with stimulating innovation.[60] In order to incentivize firms to undertake the arduous process of obtaining approval for a new drug, federal law provides regulatory exclusivity that "limits the FDA's ability to approve generic drugs and biosimilars . . ."[61] Commentators refer generally to two types of exclusivity: (1) data exclusivity, which "precludes other applicants from relying on the FDA's safety and effectiveness findings . . ." for a marketed product (i.e., clinical trial data), and (2) marketing exclusivity, which "precludes [the] FDA from approving any other application for the same pharmaceutical product and use . . .."[62] For an applicant who files a drug that contains a new chemical entity, meaning it contains a new active ingredient, data exclusivity will be awarded for "five years from the date of the approval of the application."[63] In the case of an NDA that contains an approved chemical entity, but is sufficiently changes from an approved drug, it is granted a period of "three years from the date of the approval of the application" for data exclusivity.[64] Finally, the Hatch-Waxman Act provides a 180-day exclusivity for the first generic manufacturer who successfully files an ANDA.[65]

II. INCENTIVES FOR CONSOLIDATION

A. Economists' Perspective

Economists have long theorized over the effect that competition among firms will have on innovation and the ways in which it will impact social welfare.[66] Two of the most prolific models from which antitrust authorities have modeled merger review guidelines were advanced by

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[59] Cooter & Hacohen, *supra* note 17, at 231–32.
[60] *Role of Patents and Exclusivities*, *supra* note 27, at 16.
[61] *Id.*
[62] *Id.*
[63] 21 U.S.C. § 355(c)(3)(E)(ii).
[64] *Id.* at § 355(c)(3)(E)(iii).
[65] 21 U.S.C. § 355(j)(5)(B)(iv). *See* Shepherd, *supra* note 11, at 9 (explaining that if a generic company can bring a drug to market during a period of 180-day exclusivity, in which no other generic competitors can market their drug, it will result in substantial profits).
[66] Majure et al., *supra* note 2, at 1.

Kenneth Arrow and Joseph Schumpeter.[67] Schumpeter espoused that concentrating resources between firms into oligopolies may actually promote innovation by creating market power and the ability to leverage economies of scale.[68] Arrow was critical of this approach and responded by noting that monopolistic behavior may stifle innovation.[69] Instead, he thought that competition among firms would incentivize companies to pursue further advances that a single firm would be unwilling to develop.[70] While there has been no general consensus among academics, economists have often noted confounding variables in examining the effects of competition on innovation.[71]

Carl Shapiro attempted to find compatibility between the competing theories in his chapter "Competition and Innovation: Did Arrow Hit the Bull's Eye."[72] He provides three guiding principles that may be utilized to examine innovation: (1) the contestability principle, (2) the appropriability principle, and (3) the synergies principle.[73] He defines contestability as "[t]he prospect of gaining or protecting profitable sales by providing greater value to customers," which would increase overall innovation.[74] By providing a more valuable product to consumers, examined based on the nature of ex post product market competition, a firm would be more likely to capture profits from the endeavor.[75] Appropriability "focuses on the extent to which a successful innovator can capture the social benefits resulting from its innovation."[76] In practice, appropriability requires that a firm be able to exploit its competitive advantage, and differentiate its profits from competitors.[77] Finally, the synergies principle explains that "[c]ombining complementary assets enhances innovation capabilities and thus spurs innovation."[78] Shapiro notes that the synergies resulting from business combinations is uniquely important in industries where value is derived from systems that incorporate multiple components—downstream innovation may require previous knowledge or technology to build upon

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[67] Polydorou et al., *supra* note 3, at 70.
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] Majure et al, *supra* note 2, at 1.
[72] Carl Shapiro, *Competition and Innovation: Did Arrow Hit the Bull's Eye*, THE RATE AND DIRECTION OF INVENTIVE ACTIVITY REVISITED, 361–404 (Josh Lerner & Scott Stern eds., 2012).
[73] *Id.* at 364–65.
[74] *Id.* at 364.
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *Id.* at 365.

prior work.[79] While contestability and appropriability offer *incentive* to innovate, synergies focuses on a firm's *ability* to innovate.[80]

B. Competition in the Pharmaceutical Industry

Over the past two decades, the pharmaceutical industry has produced groundbreaking new medicines that have fundamentally changed the way that society treats illnesses that have crippled the lives of individuals for centuries. Promising advances in immunotherapy provide courses of treatment for patients suffering from cancer[81] and novel vaccines allow a barrier of protection against COVID-19.[82] Given the rapid advancement in science and massive shifts in R&D efforts to produce new drugs, the expectation would be for new companies to emerge as frontrunners in the industry, backed by large profits stemming from their innovation. In the opposite fashion, the pharmaceutical industry has been shaped by the persistence of the same list of large firms over the years.[83] In fact, the top 20 pharmaceutical firms of 2009 are remarkably similar to the top 20 firms in 2019, with only a few new companies emerging as powerhouses in the industry.[84] Explaining the continued dominance of a few firms is the "extensive, industry-wide pattern of acquisition" as large firms seeks to enhance their product pipeline and R&D that supplement a lack of organic development.[85]

Examining this phenomenon using Shapiro's framework, it is clear that all three of his stated principles are acting in the market. For contestability, when a popular new drug is introduced to the public, the demand for life-saving treatment will be overwhelming. Consider two drugs: Drug A and Drug B. Drug A is remarkably effective at treating a disease and produces little to no side effects within patients. Conversely,

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[79] *Id.*
[80] *Id.*
[81] *See, e.g.*, Sofia Farkona et al., *Cancer Immunotherapy: The Beginning of the End of Cancer?*, 14 BMC MED. (2016). Scientists have long sought to exploit the human immune system as a means of treating tumors and malignant cells. Through the discovery of specific antibodies, current research focuses on targeting antibodies with immune cells to either stimulate or inhibit immune responses in the body. In combination with other therapies, immunotherapy has become increasingly effective in treating various forms of cancer, including melanoma.
[82] *See Decades in the Making*: *mRNA COVID-19 Vaccines*, NAT'L INST. HEALTH (last visited Jan. 7, 2023) for a discussion on the development of mRNA vaccines. FDA-approved mRNA vaccines have been essential in saving millions of lives during the COVID-19 pandemic and may be further researched for application to other illnesses.
[83] Danzon & Carrier, *supra* note 15, at 493.
[84] *Id.* at 493–94.
[85] *Id.* at 495.

Drug B is a similar treatment for a given disease, but clinical trials show less efficacy and countless negative side effects. When given open competition on the market, rational doctors and patients will choose Drug A on every occasion, leading to a wave of sales derived from the inherent value of the drug, and it will likely become a blockbuster treatment for a pharmaceutical company. While in the ideal world, firm profits will reflect the value to consumers, it is evident that this will not always be the case because companies still have to satisfy the principle of appropriability. In order to profit from Drug A, a company will have to successfully obtain patent protection for its invention, meet all of the stringent criteria for FDA approval including clinical trials, and will only be able to exploit its protection for a period of 20 years (often less after navigating the process of regulatory approval). Even if a small firm were able to produce the next miracle treatment, it is unlikely that it would be able to capture profits from its invention by navigating through the unwieldy and costly process. Given the average cost of developing a new drug is estimated at $2 billion,[86] the hurdles eliminate competition from the vast majority of firms in the market, even before the entry of generic manufacturers.

Next, consider a scenario where Drug A provides benefits beyond just its use for treatment of a single indication. Instead, it provides a mechanism of action that other researchers can base their own novel drugs off, leading to a "series of possible discoveries."[87] Introducing this complication into the hypothetical dilutes the current appropriability of a single breakthrough, as subsequent discoveries become more profitable and leaving the original discovery obsolete. Instead, profits are most efficiently realized through synergy between firms, as researchers collaborate to produce the most effective treatment possible. Cooter and Hacohen describe this effect as the "fertility principle:" an innovation that "can be used to create another innovation."[88] Given the complexity associated with the development of pharmaceuticals and the need for prior innovations to lead to downstream development, it seems more appropriate to focus on "increased human welfare" writ large, rather than on market power of a specific firm.[89]

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[86] *Research and Development in the Pharmaceutical Industry*, *supra* note 8, at 2.
[87] Majure et al., *supra* note 2, at 1.
[88] Cooter & Hacohen, *supra* note 17, at 205–06.
[89] *See id.* at 208–10.

C. Pathways to Innovation

While smaller startup companies, such as biotechnology firms, suffer from an inability to compete with incumbent firms to bring new drugs to market, they act as a primary source of R&D in the pharmaceutical industry.[90] In fact, internal R&D has been completely overtaken in the market as "three-fourths of new drugs are externally-sourced."[91] While traditional pharmaceutical companies have often focused on synthetic chemical entities, consisting mostly of small molecules, biotech companies focus on applying elements of living cells to new treatments (e.g., antibodies that target specific antigens).[92] Larger incumbent firms offer a pathway to bring new drugs to market as they "devote significant efforts to [] clinical testing, marketing, manufacturing, and distribution of drugs.[93] Given the increasing importance of smaller firms in the market, it becomes important to define the "current drug innovation ecosystem," in which larger firms must seek acquisitions, joint ventures, and licenses in order to continue their drug development pipelines.[94]

In her article, Shepherd describes four attributes that give biotech companies a comparative advantage over large pharmaceutical companies in early-stage drug development.[95] First, she notes that startup companies typically operate on a much smaller scale when conducting R&D and developing new treatments.[96] The small organizational structure gives the firm the important flexibility needed to pursue risks that may be unsuccessful, and could not be considered at a larger firm due to their need to act in the best interests of shareholders.[97] Second, biotech companies enjoy close partnerships with nonprofit research institutions, where some of the country's leading scientists can pursue academic research without the worry of commercialization.[98] Additionally, the Bayh-Doyle Act of 1980 allows non-government entities to apply for patents resulting from programs that receive federal funding.[99] Third, due to their significant risk, but

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[90] Shepherd, *supra* note 11, at 2.
[91] *Id.*
[92] *Id.* at 17.
[93] *Id.*
[94] *Id.* at 16–18.
[95] *Id.* at 21–23.
[96] *Id.* at 21.
[97] *Id.*
[98] *Id.*
[99] *Id.* at 18. *See* 35 U.S.C. § 202(a) (allowing nonprofit organizations or small businesses to "elect to retain title to any subject invention").

potentially substantial upside, biotech firms often receive their funding from venture capitalists ("VCs") or private equity firms.[100] While the steady stream of capital allows smaller firms to pursue goals that would otherwise be unattainable, many VCs push the ventures toward an exit from the market, either through sale of the company or licensure of the invention.[101] Finally, the culture of creativity and innovation, coupled with significantly less bureaucratic oversight, attracts some of the nation's brightest researchers to smaller companies.[102] Indeed, when discussing killer acquisitions, Cunningham et al. considered that large pharmaceutical companies may acquire smaller firms in order to benefit from the human capital.[103] Interestingly, their data supports the proposition that only a relatively small number of researchers stay at the acquiring firm post-acquisition, reflecting the interest in remaining at smaller, more flexible companies.[104]

D. Issues for Large Pharmaceutical Companies

While acquisition can provide significant benefits for smaller startups, it has become critical for large firms to continue their commercial success. Higgins and Rodriguez postulated that M&A is most likely to occur in large pharmaceutical companies that have exhibited "deteriorating R&D productivity," especially when companies consider acquiring research-intensive firms.[105] They outline numerous options considered by pharmaceutical companies facing declines in productivity: (1) supplement internal R&D efforts through acquisition of smaller companies, (2) engage in large horizontal mergers to achieve greater economies of scale (3) acquire mature existing products through licensing agreements, (4) attempt to increase internal R&D efforts

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[100] Shepherd, *supra* note 11, at 22.
[101] For a full discussion on the motivations of VCs to force startup companies to sell to larger firms, *see generally* Mark A. Lemley & Andrew McCreary, *Exit Strategy*, 101 B.U. L. REV. 1 (2020). Similar to the pharmaceutical industry, technology companies in Silicon Valley face the pressures of accepting money from VCs who seek large returns on their initial investment. The article proposes changing incentives to maximize the number of startups that continue operations, finding different sources of funding for projects to relieve pressures, and providing regulatory responses that deter such action. While there are fundamental differences between the types of investment in small pharmaceutical companies and technology platforms, there is significant overlap and lessons to be learned from examining the nature of capital being infused in the firms.
[102] Shepherd, *supra* note 11, at 22.
[103] Cunningham et al., *supra* note 14, at 5.
[104] *Id.*
[105] Higgins & Rodriguez, *supra* note 18, at 352.

organically, (5) increase activity through alliances, or (6) change their fundamental business model.[106] In determining what type of acquisition may be the most advantageous for pipeline development, pharmaceutical companies face a significant challenge in information asymmetry—given the early stages of product development, it is often impossible to predict which research projects will be successful or result in overlap with existing products within a portfolio.[107]

One measure frequently used by both investors and academics as a proxy for real value in a pharmaceutical company is by looking at the number of successful patents that a company owns.[108] Given the tendency of pharmaceutical companies to deter patent infringement through a plethora of patents for features other than a new compound, it is often an unreliable measure of the actual value of a pharmaceutical company.[109] Instead of using a discrete number of patents as an index, subsequent studies instead used patent citations as indicative of social value, theorizing that highly-cited patents were more impactful on the industry, and would be used as prior art in subsequent patent applications.[110] While a patent-citation index may provide a useful approximation for those seeking to evaluate the patent portfolio of a company, the data is often based only on published materials, such as the FDA Orange Book[111] or the USPTO website.[112]

III. M&A IN THE PHARMACEUTICAL INDUSTRY

A. Merger Review

Blockbuster pharmaceutical acquisitions have become the norm within the industry, as large firms frequently engage in horizontal

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[106] *Id.* at 354.
[107] *Id.* at 356.
[108] *See* Polydorou et al., *supra* note 3, at 75.
[109] *See* DAVID S. ABRAMS & BHAVEN N. SAMPAT, PHARMACEUTICAL PATENT CITATIONS AND REAL VALUE, 1–3 (2017).
[110] *See id.* at 3.
[111] *See Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book*, FDA, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last visited Mar. 5, 2023). The publication, commonly known as the "Orange Book" provides a comprehensive list of drug products approved by the FDA and related patent and exclusivity information. This database is a useful starting point, but does not include those drugs that have not received approval from the FDA and does not include information about biologic products.
[112] *See* Abrams & Sampat, *supra* note 109, at 4.

mergers to maintain their dominance.[113] The advent of the twenty-first century saw massive deals from Pfizer, Merck, Bristol-Myers Squibb ("BMS"), and AbbVie, each to acquire leading products on the market that produced massive profits through global sales.[114] Following the massive influx of revenue from sales of COVID-19 vaccines and other anti-viral drugs, pharmaceutical companies have continued to seek new companies to expand upon their existing product pipeline.[115] As larger incumbent firms continue to swallow smaller startup companies, academics and regulators have become increasingly concerned with the anticompetitive nature of the transactions, especially when existing products overlap with those in the target company.[116] Interestingly, despite broader concerns about consolidation in the pharmaceutical industry and rising prices, essentially no transaction has been blocked by the FTC.[117] According to a study by the American Antirust Institute from 1994 to 2020, the FTC "challenged 67 pharmaceutical mergers worth over $900 billion, moved to block only one, and settled virtually all the remainder subject to divestitures."[118]

While M&A can provide positive social benefits, the FTC recognizes that "[s]ome mergers change market dynamics in ways that can lead to higher prices, fewer or lower-quality goods or services, or less innovation."[119] Under traditional merger review, M&A is prohibited under section 7 of the Clayton Act when it "substantially lessen[s] competition or tend[s] to create a monopoly."[120] Combinations of all types can cause harm to consumers, but the largest antitrust concerns arise when mergers are proposed between direct competitors in the same

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[113] Danzon & Carrier, *supra* note 15, at 493.
[114] *Id.* For example, Pfizer acquired Warner-Lambert to obtain Lipitor, and upon its patent expiration, acquired Wyeth to add Prevnar to its portfolio. Merck acquired Schering-Plough and benefited from an unexpected blockbuster cancer treatment in Keytruda. *Id.*
[115] *See, e.g.*, Rebecca Robbins & Peter S. Goodman, *Pfizer Reaps Hundreds of Millions in Profits from Covid Vaccine,* NY TIMES (May 5, 2022), https://www.nytimes.com/2021/05/04/business/pfizer-covid-vaccine-profits.html; George Budwell, *Biopharma's 5 Biggest M&A Deals of 2022*, BIOSPACE (Dec. 23, 2022), https://www.biospace.com/article/biopharma-s-5-biggest-m-and-a-deals-of-2022/.
[116] *See* Polydorou et al., *supra* note 3, at 71–73.
[117] *See* Danzon & Carrier, *supra* note 15, at 488–89.
[118] *Id.* at 489 (quoting Diana L. Moss*, From Competition to Conspiracy: Assessing the Federal Trade Commission's Merger Policy in the Pharmaceutical Sector 10,* AM. ANTITRUST INST. (Sept. 3, 2020)).
[119] *Mergers, Guide to Antitrust Laws*, FTC, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/mergers (last visited Jan. 8, 2023).
[120] 15 U.S.C. § 14.

industry.[121] Additionally, the Hart-Scott-Rodino Antitrust Improvements Act of 1976 imposed a pre-merger notification requirement to both the DOJ Antitrust Division and the FTC when the proposed transaction exceeds $200 million.[122] As a result, the pre-merger notice allows regulators to challenge mergers before they are consummated, often resulting in abandonment or divestiture, while those that fall below the dollar threshold are not subject to scrutiny.[123]

While competition authorities have varied in their approaches to considerations of harm in pharmaceutical mergers, the traditional practice was "almost exclusively concerned . . . with existing products, or those contemplated in the merging firms' pipelines."[124] This understanding acknowledges the fact that mergers may increase innovation by providing changes in investment incentives—such as shared intellectual property between firms about knowledge of disease targets, or by implementing next generation or lower cost technologies—and thus there should be a "neutral rather than negative presumption . . . for merger innovation efforts."[125] In the United States, the FTC historically focused on Phase III pipeline products when considering remedies (e.g., divestiture), but has also considered products in the FDA pipeline, including those in the pre-clinical stages.[126] While the FTC has often been unwilling to challenge pharmaceutical mergers, in recent years a number of commissioners have notably dissented from the majority calling for further innovation activism.[127] In his dissenting statement in *AbbVie/Allergan*, Commissioner Rohit Chopra issued a grave warning, stating that "[t]he agency's default strategy of requiring merging parties to divest overlapping drugs is narrow, flawed, and ineffective."[128] It allows "pharmaceutical companies to further exploit

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[121] *Mergers, supra* note 119; *see also* Danzon & Carrier, *supra* note 15, at 490 (discussing how a merger of two large firms in the pharmaceutical sector negatively impacts the industry by harming competitors and consumers, reducing incentives to innovate, and entrenching the acquiring firms position in the market).
[122] 15 U.S.C. §§ 18(a)–(b).
[123] Amy C. Madl, *Killing Innovation? Antitrust Implications of Killer Acquisitions*, 38 YALE J. ON REG. BULL. 28, 40 (2020).
[124] Polydorou et al., *supra* note 3, at 70.
[125] *Id.* at 72.
[126] *Id.* (explaining the current state of the FTC approach to innovation in pharmaceutical mergers). In contrast, the EC has codified a four-level approach, examining: (1) overlaps between existing products; (2) overlaps between existing and pipeline products, and between pipeline products and those in advanced stages of development; (3) loss of innovation competition resulting from changes in pipeline products with existing products; and (4) loss of innovation competition resulting from a structural reduction of the overall level of innovation. *See id.* at 73.
[127] *Id.*
[128] Dissenting Statement of Commissioner Rohit Chopra at 2, AbbVie, Inc./Allergan

their dominance, block new entrants, and harm patients in need of life-saving drugs."[129]

B. Innovation as a Theory of Harm

Given the increasing concern with M&A activity in the pharmaceutical industry, leading antitrust enforcers across Europe and North America have banded together to assess the "full range of a pharmaceutical merger's effects on innovation[.]"[130] While other industries may follow a deterministic process with discrete inputs and observable outputs, it is seemingly impossible to derive the value of future innovation from early-stage developments.[131] In their article, Majure et al. discuss the complications in observing effects on innovation stemming from evidence and measurement.[132] First, attempts to provide a singular model for examining mergers may be ineffective because innovation is not a homogenous subject.[133] Instead, a transaction may harm consumers by producing fewer cost-reducing technologies, raise prices, or a firm may abandon plans to develop future products.[134] In order to appropriately quantify changes in the level of future innovation, experts must provide a specific model for each characteristic, backed with empirical evidence focusing on that attribute.[135] Second, changes in innovation within pharmaceutical companies do not directly correspond to changes in social welfare as directly as other factors (e.g., prices).[136]

Aside from the difficulty in choosing an accurate model, it is equally problematic to find appropriate metrics from which regulators can determine what type of activity would be anticompetitive. Polydorou et al. explain that authorities have previously used both past product launches and patent citation indexes as measures of innovation

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plc, FTC File No. 191-0169 (May 5, 2020).

[129] *Id.*

[130] Polydorou et al., *supra* note 3, at 71.

[131] *See* Majure et al., *supra* note 15, at 1.

[132] *Id.* at 2.

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] *Id.*; *see also* Shepherd, *supra* note 11, at 6–28. Professor Shepherd argues that in the current drug innovation ecosystem, M&A will not stifle innovation. Since most R&D occurs outside the purview of large pharmaceutical companies, it is "largely missing the point" to focus on organic R&D efforts. In addition, social welfare is more directly impacted by other critical factors, such as competition from generic manufacturers, pharmacy benefit managers who administer prescription drug coverage for Americans with health insurance, and the costs associated of compliance with FDA guidelines.

potential.[137] While some correlation may exist, it is difficult to examine backward-looking measures for future innovation, as pharmaceutical companies often acquire nascent or early-stage pipeline products.[138] In these cases, past product launches and patent citations would not accurately reflect the impact on future product development.[139] Another measure that has been considered is outsized valuations, meaning that a high deal value may be suspect, giving the impression that the acquiring company overpaid in order to hinder competition.[140] However, attempting to determine the motive of executives and business development teams is a fruitless endeavor, as there are numerous justifications for acquisitions that are considered a "rational business decision."[141] Finally, regulators often turn to internal communications as evidence of innovative intentions.[142] However, this again may be misleading, as the authors note that "[d]ocuments may be created by people without the necessary knowledge or authority to implement the ideas they contain, may represent early thinking that was quickly rejected, or may have been created to 'sell' a certain view of the world to a specific audience."[143]

C. Killer Acquisitions?

In their frequently cited paper *Killer Acquisitions*, Cunningham et al. discuss the possibility that drugs acquired through acquisition are less likely to be developed when they overlap with an existing product in the acquirer's portfolio.[144] Citing Arrow, the authors hypothesize that an incumbent acquirer will have reduced incentives to continue a project if it directly competes with, or substitutes for, an existing project.[145] To qualify as an "overlapping acquisition," a competing product must be in the same therapeutic class (i.e., used to treat a particular disease) and must use the same mechanism of action to treat the patient (i.e., how the drug is delivered).[146] The paper suggests three main objectives from the

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[137] Polydorou et al., *supra* note 3, at 74–75.
[138] *Id.*
[139] *Id.*
[140] *Id.* at 75.
[141] Madl, *supra* note 123, at 31.
[142] Polydorou et al., *supra* note 3, at 75.
[143] *Id.*
[144] Cunningham et al., *supra* note 14, at 650.
[145] *Id.* at 651 (citing Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 622 (Princeton Univ. Press, 1962)).
[146] *Id.* at 652.

research: (1) to highlight that killer acquisitions are a fundamental impediment to corporate innovation, as firms seek to protect existing profits; (2) the effect of such acquisitions on innovation in the pharmaceutical industry, where future discoveries have a crucial link to social welfare; and (3) that this trend leads to consolidation of firms within the industry, as incumbents reduce competition by acquiring nascent companies to deter future competition.[147] According to the empirical data, acquisitions motivated by efforts to hinder the development of overlapping products occur at an estimated rate of approximately 7 percent per year.[148]

While Cunningham et al. come to the conclusion that killer acquisitions will have a negative effect on consumer surplus, both through decreasing the number of drugs sold and increased prices,[149] they recognize that there may be alternative explanations for the trend.[150] Importantly, the authors discuss optimal project selection as a motivation behind terminating future development of a product post-acquisition, although they remain skeptical of its importance.[151] The brief discussion neglects to consider that the majority of acquisitions that take place are of smaller biotechnology companies, whose product pipelines include many promising drug candidates at varying stages of clinical development. An acquiring firm, similar to other investors, takes a gamble on numerous drugs with the hope that a small number of those products will be a commercial success, or a "blockbuster" drug.[152] Furthermore, an acquiring firm may gain invaluable *negative* information about specific drug candidates or mechanisms of action that lack functionality.[153] Finally, Cunningham et al. explain that acquiring companies do not redeploy drugs in their own internal projects post-acquisition, finding that future projects largely do not share chemical similarities to drugs acquired from the target.[154] While the authors use a period of five years after the acquisition date in order to observe

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[147] *Id.* at 655.
[148] *Id.* at 692.
[149] *Id.* at 694.
[150] *Id.* at 687–91. The paper focuses five alternative explanations for the phenomenon: (1) informational asymmetries in the acquisition market, (2) optimal project selection, (3) redeployment of technologies, (4) redeployment of human capital, and (5) salvage acquisitions. While recognizing varying incentives among acquiring firms, the authors explain that it is unlikely these play a substantial role in practice. *Id.*
[151] Cunningham et al., *supra* note 14, at 688.
[152] *See* Shepherd, *supra* note 11, at 22–25 (explaining that acquisition, licensing, and collaboration with biotech companies allow large pharmaceutical companies to develop specialized medicines).
[153] Madl, *supra* note 123, at 38.
[154] Cunningham et al., *supra* note 14, at 688.

similarities in molecular structure, this notably fails to account for the fact that the development process often "take[s] a decade or more."[155] Increasingly, pharmaceutical companies have sought to take advantage of initial breakthroughs by employing combination therapies, often finding new indications that benefit from similar courses of treatment.[156]

IV. INCREASING DOWNSTREAM INNOVATION

While increasing scrutiny on M&A in the pharmaceutical industry may lead to fewer consummated transactions and lower costs for consumers in some cases, it will also have the unwanted effect of reducing total consumer surplus as investors shy away from infusing capital into drug development. Allowing companies to set prices at levels that exceed the cost of manufacturing yields profit and higher profits increase the incentive to innovate.[157] While there is certainly a tradeoff between access to healthcare and incentives to innovate, society will benefit when the rate of innovation exceeds any losses from inefficiency in the market (e.g., discontinuation of certain products).[158] Instead of focusing on the acquisitions of products in the development pipeline—an essential element of the structure of the current innovative ecosystem[159]—government authorities should reduce barriers to innovation by expanding exemptions from patent infringement for follow-on research.

A. Justifications for Exemptions from Patent Infringement

According to the Constitution, Congress is authorized to make patent law to "promote the Progress of Science and useful Arts."[160] According to Cooter and Hacohen, lawmakers can only fulfill this constitutional purpose by effecting *progress*, measured by the increased quality of life of individuals in the aggregate.[161] Bearing on economic principles, the pair defines two fundamental precepts of patent law

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[155] CONG. BUDGET OFF., *supra* note 8, at 5.
[156] *See, e.g.*, Reza Bayat Mokhtari et al., *Combination Therapy in Combating Cancer*, 8 ONCOTARGET 38022, 38022 (2017), https://pubmed.ncbi.nlm.nih.gov/28410237/ (discussing combination therapy, a method of treatment that combines two or more therapeutic agents, as increasing efficacy in the treatment of certain cancers).
[157] Cooter & Hacohen, *supra* note 17, at 196.
[158] *See id.*
[159] Shepherd, *supra* note 11, at 16–25.
[160] U.S. CONST. art. I, § 8, cl. 8.
[161] *See* Cooter & Hacohen, *supra* note 17, at 193.

policy: the "separation principle" and the "overtaking principle."[162] First, the separation principle denotes that patent protection should be "strong against using an innovation to consume or produce, and weak against using an innovation to innovate."[163] A patent serves the purpose of allowing its inventor to reap profits from their innovation; when a consumer purchases that invention, wealth is transferred from the individual to the inventor, providing incentives for reinvestment and future innovation.[164] Conversely, when the innovation is used by a subsequent inventor to produce their own innovation, wealth is transferred between two parties both seeking to provide novel inventions, likely reducing overall consumer surplus through deadweight loss and inefficiency in the form of transaction costs.[165] Second, the overtaking principle explains that the welfare gains from the exponential growth stemming from innovation will outweigh any losses from static inefficiencies in the market.[166] Therefore, "in the absence of aggravating circumstances, escalated consumer products' prices should not justify reform" within the traditional structure of exclusivity for innovators.[167]

In a recent article, Professor Janet Freilich outlines that, due to the sequential nature of discovery, the patent system may provide a fundamental roadblock to downstream innovation, as future experimentation often falls within the scope of an upstream patent.[168] In some cases, scientists "cannot conduct even the most basic research towards downstream technologies without addressing the upstream patent."[169] The structure of the patent system leaves open three possibilities: (1) the innovator licenses the upstream patent (which can have the negative effect of notifying other researchers about future intentions); (2) the party infringes a blocking patent; or (3) research is done outside the scope of an existing patent, which is not defined as patent infringement.[170] While other scholarship has reflected the viewpoint that these possibilities hinder research from taking place, Professor Freilich explains it instead provides incentives for research to take place in areas that are exempt from patent infringement.[171] While

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[162] *Id.* at 195–97.
[163] *Id.* at 195.
[164] *Id.*
[165] *Id.*
[166] *Id.* at 196.
[167] *See id.*
[168] Janet Freilich, *Paths to Downstream Innovation*, 55 U.C. DAVIS. L. REV. 2209, 2211–12 (2022).
[169] *Id.* at 2209.
[170] *Id.* at 2212.
[171] *Id.*

patents do not provide "a near-total block" to future innovation, they "pull downstream research along haphazard and arbitrary paths."[172] Instead of incentivizing discrepancies between different research projects, regulators should reshape the patent system to ensure that society is taking advantage of all future innovation to increase human welfare.

B. Common Law Research Exemption

Justice Story famously advanced the theory that using patented technology to experiment should not be included within the scope of patent infringement, which has provided a basis for research exemptions in the common law.[173] He argued that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[174] While there has been little Congressional action to address a basic scientific research exemption from patent infringement, subsequent case law has confirmed that such a principle exists.[175] In *Poppenhusen v. Falke*, the court stated that "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee."[176] The common law research exemption has slowly been eroded over the years, culminating in a decision from the Federal Circuit in *Madey v. Duke University*.[177] There, the court determined that experiments conducted by the research institution using a patented laser did not qualify for the experimental use defense, as the projects "unmistakably further[ed] the institution's legitimate business objectives."[178] Duke University had conducted the experiments with the goal of gaining notoriety, which the court proposed could be used to obtain federal grants and was used in recruiting both faculty and students.[179]

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[172] *Id.*
[173] *See* Whittemore v. Cutter, 29 F. Cas. 1120, 1120–23 (C.C.D. Mass. 1813).
[174] *Id.* at 1121.
[175] Jorge A. Goldstein, *The Law on Research Exceptions – Common Law Exceptions*, U.S. BIOTECHNOLOGY PAT. L. § 12:35 (2022).
[176] *Id.* (quoting Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D. N.Y. 1861)).
[177] Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002).
[178] *Id.* at 1362.
[179] *Id.*

C. Other Exceptions to Infringement

Professor Freilich discusses numerous other ways that research may fall outside the scope of patent infringement, and how arbitrary lines provide differing incentives for downstream innovation.[180] In the context of pharmaceuticals, one of the other most important exemptions from patent infringement is a safe harbor provided by Congress, known commonly as a "Bolar Exception." In response to the ruling in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[181] Congress included a provision in the Hatch-Waxman Act that exempted experimental use from patent infringement when the relevant research was used to obtain approval by the FDA prior to marketing.[182] The statute states that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . ."[183] While many assumed that the statutory safe harbor was meant exclusively for generic drug manufacturers in order to obtain regulatory approval before the expiration of a patent, the Supreme Court repudiated this view.[184] The Court explained that Congress did not limit the exemption to developing information for submission to the FDA in the process of generic drug approval—"it exempted from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs."[185]

The practical effect of the safe harbor provided under section 271(e)(1) is that large swaths of life sciences research is exempted from patent infringement, including preclinical studies and other testing on drugs that is "reasonably related" to regulatory approval.[186] However, the

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[180] *See* Freilich, *supra* note 168, at 2225–50. The article gives a full discussion of downstream research that is considered "not infringement" and compares such activity to things that qualify as "infringement." Importantly, she highlights specific areas of research that can produce innovation without infringing on a patent owners exclusivity, including (1) new methods of using an existing product, (2) research on commercially available products, (3) late-stage life sciences research, (4) research at state universities, (5) research outside the jurisdiction of the United States, (5) thinking about hypotheses, (6) secret research, (7) low-cost research, and (8) research in areas where patent rights are not voluntarily enforced. *Id.*

[181] Roche Prod., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).

[182] 35 U.S.C.A. § 271(e)(1) (Westlaw through Pub. L. No. 111—148).

[183] *Id.*

[184] *See* Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 206 (2005).

[185] *Id.* (Emphasis included).

[186] Freilich, *supra* note 168, at 2231.

exception does not cover all downstream research in the pharmaceutical sector, such as basic scientific research, where a clinical candidate has not yet been selected.[187] Additionally, the safe harbor has not been expanded to areas where regulatory approval by the FDA or other agencies is not required, leaving out advances in adjacent fields that may provide technological innovation that can reduce the costs to develop certain drugs.[188]

D. Reduced Cost to Innovate Increases Social Welfare

While pharmaceutical M&A may have anticompetitive effects on the market, the difficulties in quantifying which transactions qualify, the costs associated with enforcement, and the reduced incentives to innovate, make merger review an inefficient method of addressing costs to consumers. Instead, regulatory authorities should focus on reducing hurdles to competition through patent further exemptions to patent infringement, and encouragement of collaboration between parties that have little to no desire to commercialize products. The Bolar Exception under Section 271(e)(1) provides a method for generic competition to enter the market sooner, effectively reducing the prices of brand name drugs earlier in their life cycle. Moreover, private, non-profit research institutions should be protected in conducting groundbreaking research, so long as there are no extenuating circumstances that make clear the primary goal is commercialization. Partnerships between research institutions and small startup companies have proven exceptionally successful and provide glamorous targets for acquisition and development by large companies.[189]

CONCLUSION

The COVID-19 pandemic highlighted the importance of cooperation between the pharmaceutical industry, healthcare providers, and government officials. Barriers to access can leave individuals without life-saving treatments that can be a determinative factor in whether that

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[187] *Id.* at 2232.
[188] *Id.*
[189] *See, e.g.*, Heather McKenzie, *Merck's Molnupiravir: When a Private-Public Partnership Bears Fruit*, BIOSPACE (Nov. 3, 2022), https://www.biospace.com/article/merck-s-molnupiravir-when-a-private-public-partnership-bears-fruit-/ (examining the successful partnership between Merck, Emory University, and Ridgeback Biotherapeutics in producing a "miracle drug" used to treat COVID-19).

person lives or dies. Highlighted by media stories and quick jabs from politicians, large pharmaceutical companies have carried much of the blame for inefficiencies in the prescription drug market and increasing prices that effectively limit lower-income individuals from receiving the care they need. While increasing scrutiny from antitrust authorities may provide a feasible solution to the problem, it will only increase the costs for M&A to occur in the pharmaceutical industry. Likely, these costs will be passed onto consumers, or reduce the incentive for innovation of future miracle treatments. It is nearly impossible to delineate ascertainable metrics to use in merger review, and thus innovation as a standalone theory of harm will prove too difficult for regulators to practically enforce.

While the current innovation ecosystem—where smaller startup and biotechnology firms, backed by venture capitalists, are acquired by larger incumbent firms—may leave many uneasy, it is a necessary evil to allow continued growth in the area. Specialization within in smaller firms allows treatment for rare diseases and small populations, who may otherwise be left without any treatment. Policymakers should instead focus on ways to encourage collaboration and innovation partnerships, through expanding exemptions to patent infringement. Given the limited term of patent protection, executives in pharmaceutical companies recognize that the only way to maintain success is by developing a robust product pipeline. In a world where M&A is the primary source of development for incumbent firms, the focus should be on providing resources to startup companies and non-profit research institutions, with the hope that the next breakthrough idea will be acquired and commercialized by a large company. While the current patent system may not provide the ideal solution for intellectual property protection, there are avenues to increase social welfare dramatically.

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ARTICLES

A SLEEPING GIANT: MHEALTH APPLICATIONS, THE GDPR, AND THE NEED FOR FEDERAL PRIVACY REGULATION IN THE UNITED STATES

Kali Peeples

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INTRODUCTION

The creation and evolution of the smartphone has ushered in a technological marvel that is a double-edged sword: mobile health applications (mHealth apps).[1] While this digitized tool enables people to access healthcare from the palms of their hands to track potentially life-threatening ailments or other health-related concerns,[2] mHealth also necessitates the uploading of personal information to online databases that are ripe with privacy issues. As mHealth becomes more integrated within society and healthcare, it is imperative to highlight how privacy legislation from around the world is aiming to combat these issues to create a safe environment for consumers. An analysis of privacy regulation concerning mHealth apps is a multifaceted process that requires the examination of changes within not only the healthcare space but also the technological world, as well as the legislative history and intent of various nations.

Part I focuses on the development and rapid creation of mHealth apps within the past decade. Part II seeks to illustrate the distinct privacy

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[1] Barbara Fox, *Mobile Medical Apps: Where Health and Internet Privacy Law Meet*, 14 HOUS. J. HEALTH L. & POL'Y 193, 193 (2014); *see also* Anne Marie Helm & Daniel Georgatos, *Privacy and MHealth: How Mobile Health "Apps" Fit into a Privacy Framework Not Limited to HIPAA*, 64 SYRACUSE L. REV. 131, 134 (2014) ("mHealth occurs when a provider of healthcare services uses connected and interactive mobile computing to produce, access, transmit, or store data for the provision of healthcare services to patients, or when a patient or consumer uses connected and interactive mobile computing to produce, access, transmit, store, or otherwise share data for a health-related purpose.").

[2] David Smahel, Steriani Elvasky & Hana Machackova, *Functions of mHealth Applications: A User's Perspective*, 25(3) HEALTH INFORMATICS J. 1065, 1065 (2017).

concerns of mHealth apps by concentrating on the evolution of the physician-patient dynamic and the digitalization and personalization of healthcare. Once the privacy issues of mHealth are illustrated, this piece turns to privacy legislation from multiple countries that aim to combat these concerns. Part III concentrates on the current American piecemeal approach of having federal acts and state-specific privacy laws to protect American consumers. As this deficient approach does not account for the vast array of different types of mHealth apps, nor the plethora of information that each app gathers, Part IV looks towards Europe for a potential solution. This part details the European Union's General Data Protection Regulation and how this regulation assigns extra protections and privileges to sensitive health data. As European Union countries can enact stricter provisions where the General Data Protection Regulation falls silent, Part IV also examines Germany's conservative approach regarding health data privacy protections, as well as Finland's liberal approach.

The main issue being addressed in this paper is whether the United States should create nationwide legislation that directly relates to mHealth data protection or continue with a self-regulatory method. Part V illustrates the pros and cons of each argument to determine which approach will sufficiently address American consumers' concerns surrounding the protection of their health data. Ultimately, this piece argues that the United States should create legislation that resembles the European Union's General Data Protection Regulation to account for the rapidly evolving technological world.

I. THE EVOLUTION OF DIGITAL HEALTHCARE AND MHEALTH APPS

Technology, especially through the use of smartphones, has become embedded in almost every individual's life. From 2010 to 2016, the use of smartphones within the United States increased from 35% to 77%.[3] In 2020 alone, over 90,000 mHealth apps were created and developed for online stores, totaling to an average of almost 250 new mHealth apps every day.[4] By 2021, there were more than 300,000

[3] Aisha T. Langford, Craig A. Solid, Ebony Scott, Meeki Lad, Eli Maayan, Stephen K. Williams & Azizi A Seixas, *Mobile Phone Ownership, Health Apps, and Tablet Use in US Adults with a Self-Reported History of Hypertension: Cross-Sectional Study*, 7(1) JMIR MHEALTH & UHEALTH 1, 2 (2019).

[4] Emily May, *How Digital Health Apps are Empowering Patients*, DELOITTE (Oct. 19, 2021), https://www2.deloitte.com/us/en/blog/health-care-blog/2021/how-digital-health-apps-are-empowering-patients.html.

mHealth apps available on online stores.[5] While many apps were initially created to help monitor chronic health conditions, such as diabetes, obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD), and obesity, a significant boom in the mHealth industry came from the development of applications focused on preventative care, such as dieting and fitness.[6]

Now, mHealth apps can be split into two categories: consumer apps and provider apps.[7] Consumer apps can be characterized as health and wellness apps that are "designed for consumers who want to track and/or analyze their health on a personal level;" this includes apps that "support diet and exercise programs, reference aids, symptom checkers, and self-diagnostic tools, as well as those with more specific functions like pregnancy trackers and sleep-and-relaxation aids."[8] Provider apps are mHealth apps that are specifically related to medical providers, and these apps relay information about clinical decisions, patient diagnoses, treatments, and remote patient monitoring to both the medical professionals and their patients.[9] The multitude of mHealth apps that have flooded online markets has had a profound effect on not only people's relationships with technology and their doctors, but also on doctors', and potentially app developers', responsibilities and duties to their clients and consumers.

II. MHEALTH AND PRIVACY CONCERNS

Privacy is an ever-changing legal space that evolves not only with time but also with the development of new technologies. Legal scholars and law makers have struggled with protecting the privacy of individuals as privacy covers a wide range of issues that cannot simply be fixed by a "one size fits all" solution; rather, as leading privacy scholar Daniel J. Solove suggests, it is imperative to acknowledge specific privacy concerns of a given field and address them directly.[10] For mHealth, there are six specific privacy concerns: (1) surveillance through the collection of information by either "overt or secret means";[11] (2) improper protection of sensitive information by digital security lapses or illicit use of

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[5] *Id.*; *see also* Trix Mulder, *Health Apps, Their Privacy Policies and the GDPR*, 10 EUR. J. L. & TECH. 1, 2(2019).
[6] Fox, *supra* note 1, at 195-96.
[7] Helm & Georgatos, *supra* note 1, at 137-38.
[8] *Id.*
[9] *Id.* at 138.
[10] Daniel J. Solove, *A Taxonomy of Privacy*, 153 U. PENN. L. REV. 477, 481 (2006).
[11] Helm & Georgatos, *supra* note 1, at 139.

information;[12] (3) identification of private information to specific individuals;[13] (4) unsanctioned secondary use (when collected information is used for an unknown and unauthorized purpose);[14] (5) aggregation of small bits of information that ultimately add up to a holistic medical record;[15] and (6) disclosure of "true but sensitive information."[16] These six privacy points can be summarized by a conclusion with two key contentions: mHealth privacy concerns relate to the *sensitive nature of the data* being analyzed and the means by which this data is *collected, processed, and disseminated*.[17] While these concerns about the handling of sensitive medical data have been addressed in the past through the oaths of medical professionals and the standardization of medical treatment, technology has caused these checks to become obsolete. Thus, to understand why a sound and cohesive privacy regulation is needed for mHealth apps, it is crucial to understand how the healthcare landscape has changed.

A. Protection of Sensitive Information and the Hippocratic Oath

Created in the fourth century, and continued to be used today,[18] the Hippocratic Oath is the main vehicle by which a doctor vows to protect the confidentiality and privacy concerns of their patients.[19] This oath has become a foundational element in numerous codes of ethics,

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[12] *Id.* at 139-40.
[13] *Id.* at 140.
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.* at 139.
[18] A modern rendition of the Hippocratic Oath states, "I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow . . . *I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know* . . . . I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick . . . . May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help." Louis Lasagna, *The Hippocratic Oath: Modern Version*, PBS NOVA, https://www.pbs.org/wgbh/nova/doctors/oath_modern.html (last visited Jan. 21, 2023) (emphasis added).
[19] Mark Rothstein, *The Hippocratic Bargain and Health Information Technology*, 38(1) J. L. MED. ETHICS 7, 7 (2010). *But see id.* (cautioning that, while the Oath aims to protect privacy concerns, ancient Greece had different notions of privacy as "[p]hysicians took histories, examined patients, gave prognoses, and practiced surgery in public or in houses as relatives and strangers looked on").

including the 1984 American Medical Association's code of ethics.[20] According to scholar Mark Rothstein, the Oath establishes a type of "bargain;" this bargain can be summarized as:

> Allow me to examine you in ways that you would never permit any stranger, and tell me the most sensitive information about your body, mind, emotions, and lifestyle. These intrusions upon your privacy are essential in providing you with sound medical care. If you provide me with this intimate access to your person, I promise to maintain your secrets for as long as I live and to disclose them only if directed by you or others you have authorized.[21]

The Hippocratic Oath, and thus this bargain, has rapidly evolved throughout the years. What has initially started out as a physician-patient relationship that consisted solely of one healthcare practitioner has evolved into a type of patient care that involves a diverse array of medical professionals from numerous specialties in order for individuals to receive proper medical treatment.[22] Now, a concern about having a sole practitioner knowing a person's medical ailments has transmogrified into having multiple individuals, including but not limited to technicians, laboratory and pharmacy staff, physical therapists, and other specialists, being involved in a patient's treatment, thereby subjecting more people to the Hippocratic Oath.[23] Technology, while drastically improving the quality of medical care since the time of Hippocrates, has only complicated the physician-patient dynamic further. As such, some medical professionals have called for the revision of the Hippocratic Oath with the rise of Big Data.[24] These professionals seek to amend the Oath by (1) including language that addresses the data obtained by both researchers and patients themselves since data is no longer collected by just physicians, (2) the specific acknowledgement of preventative health care rather than just "sick care," (3) the digital technology, such as algorithms, used for diagnoses, and (4) the explicit statement that doctors will aim to protect patient *data*.[25]

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[20] *Id.*
[21] *Id.* at 7-8.
[22] *Id.* at 8.
[23] *Id.*
[24] *See generally* Bertalan Meskó & Brennan Spiegel, *A Revised Hippocratic Oath for the Era of Digital Health*, 24(9) J. MED. INTERNET RSCH. 1, 2 (2022).
[25] *Id.* at 2-3.

It is important to note that the developers of mHealth apps are not expected to partake in the Hippocratic Oath as they are not doctors. Therefore, these proposed revisions still will not correct the growing concern of mHealth apps. Some advocate for a "digital Hippocratic Oath" which would force "digital health innovators to embrace regulation" that "hold[s] apps up to a standard of conduct."[26] However, it may be more beneficial to enact strict privacy legislation that imposes fines for misconduct to truly ensure that app developers are exercising the utmost care with their customers' health data.

B. Personalized Medicine and the Mystery of Black-Box Treatment Plans

Another aspect that has revolutionized modern healthcare is the concept of personalized medicine. Personalized medicine can be characterized as the nexus between Big Data and Big Health; this form of healthcare incorporates personal information derived from various types of medical tests, and other relevant data points, to create treatment plans tailored to individual patients.[27] The benefits to personalized health are immeasurable. By individualizing medicine, health practitioners can create "more precise marker-assisted diagnos[es,]" as well as "safer and more effective treatment[s],"[28] for patients while simultaneously "lower[ing] costs and improv[ing] the efficiency of the healthcare system."[29] This phenomenon enables "pharmaceutical and biotechnology industries [to] focus drug development efforts on

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[26] Laura Lovett, *Aneesh Chopra Urges Innovators to Embrace 'Digital Hippocratic Oath'*, HEALTHCARE IT NEWS (Apr. 2, 2018, 9:45 AM), https://www.healthcareitnews.com/news/aneesh-chopra-urges-innovators-embrace-digital-hippocratic-oath.

[27] W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 420 (2015); *see also* Isaac S. Chan & Geoffrey S. Ginsburg, *Personalized Medicine: Progress and Promise*, 12 ANN. REV. GENOMICS & HUM. GENETICS 217 (2011) (explaining that personalized medicine takes into account family health history, health risk assessments, genomic information, including genome-wide variation, transcriptomics (the "genome-wide study of RNA expression levels in a cell, tissue or biological fluid"), metabolomics (the analysis of "changes in the nonprotein small molecules related to a biological or physiological state" through the use of mass spectroscopy and nuclear magnetic resonance spectroscopy), epigenomics ("the genetic programing that occurs predominantly as a consequence of DNA methylation (194)"), and, lastly, proteomics (the "large scale study of proteins"), to determine susceptibility to diseases, cancer, and more).

[28] Geoffrey S. Ginsburg & Jeanette J. McCarthy, *Personalized Medicine: Revolutionizing Drug Discovery and Patient Care*, 19 TRENDS BIOTECHNOLOGY 491, 495 (2001).

[29] Price II, *supra* note 27, at 427.

subpopulations who have the same critical genetic variants,"[30] thereby creating benefits for not only the sole patient being treated but thousands of genetically-similar individuals.

Personalized medicine can be divided into two categories: "[e]xplicit personalized medicine" and "black-box medicine."[31] Explicit personalized medicine uses scientific data and clinical research to analyze biological relationships to hypothesize the potential outcomes of medical treatments for individual patients.[32] This first category of personalized medicine is explicit because the data points and clinical research that was used in determining a treatment plan allows practitioners to understand why a patient is being treated in a particular way. Where major concern lies, however, is what W. Nicholson Price II labels as black-box medicine.

Black-box medicine can be defined as a system in which "opaque computational algorithms" are used to create a personalized medical plan "based on relationships which are *not* understood and often not identified."[33] This implicit personalized medicine regime utilizes large and broad data sets to make predications and treatment plans "without explicitly identifying or understanding those connections."[34] By uploading health information about a patient, or even family medical history, computers now have the ability to create a treatment plan that can be sent directly to a patient. This new ability is in sharp contrast from having a doctor explain a treatment method face-to-face with a patient explaining why the patient should be treated in a particular way. However, computers are unable to complete this task unless they have access a concerningly large amount of health information from all over the world.

An additional concern is the actual opacity of black-box medicine. Patients, including users of mHealth apps, do not understand how the algorithms work or how the algorithms create their final findings. So, not only do patients and app users not understand how the treatment is created, but these individuals do not know which data points are being used to make health-related analyses. It begs the question: how much information are these computers using and are users giving the computers more information than necessary?[35]

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[30] *Id.*
[31] *Id.* at 425.
[32] *Id.* at 427.
[33] *Id.* at 425.
[34] *Id.* at 429-30.
[35] A potential concern is that this uneasiness about black-box medicine may inevitably evolve into concerns about algorithmic contracts. As the world increasingly becomes

The final line of defense for these concerns is privacy law, specifically in relation to mHealth apps. If mHealth apps are not subjected to the Hippocratic Oath, and the computers generating health treatments are utilizing health data points in a way unbeknownst to both medical professionals and those being treated, there must be a way to vigilantly protect the sensitive medical information of those in need of healthcare treatments. This problem has only been exacerbated after the Covid-19 pandemic as telehealth and mHealth treatments have become more accessible and utilized.[36] The United States must review its existing policies surrounding the protection of digital health information. Additionally, it will be beneficial to analyze and compare how other regions of the world are approaching this issue as well. Specifically, the United Sates should look to the European Union (EU) and their use of the General Data Protection Regulation (GDPR) as a potential example of how to enact all-encompassing privacy regulations, as the GDPR has been regarded as successful in forcing companies in becoming more aware and cautious when handling consumer data.[37]

III. U.S. APPROACH TO PRIVACY FOR MHEALTH DATA PROTECTION

Currently, the United States does not have nationwide data privacy legislation.[38] Rather, "the federal regulations [concerning mHealth privacy] are so piecemeal that nearly every state has enacted its

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digitalized, and black-box medicine becomes more institutionalized due to its efficient nature, computers will begin to determine what information they need and do not need. This in turn may affect the terms of contracts. Since doctors will rely on algorithms to determine treatment plans, it is foreseeable that the medical and digital health fields will come to rely on algorithms for contract formation. These algorithmic contracts, similar to that of black-box medicine, are "not analyzable simply as the sum of their inputs" as they are derived from complex variables that are inputted into computational relationships. Lauren Henry Scholz, *Algorithmic Contracts*, 20 STAN. TECH. L. REV. 128, 135 (2017). While there are mutual assent concerns over black-box algorithmic contracts, thereby making them likely unenforceable, it is imperative to keep these potential algorithmic contractual concerns in the background of a privacy analysis so that computers do not enable the release of private health information to potential third parties or collect more information than what is needed to determine a treatment plan.

[36] *See generally* Tsion H. Tebeje & Jorn Klein, *Applications of e-Health to Support Person-Centered Health Care at the Time of COVID-19 Pandemic*, 27 TELEMEDICINE & E-HEALTH 150 (2021). *See also* Bokolo Anthony Jnr, *Implications of Telehealth and Digital Care Solutions During COVID-19 Pandemic: A Qualitative Literature Review*, 46 INFORMATICS FOR HEALTH & SOC. CARE 68, 68 (2021).

[37] Ilse Heine, *3 Years Later: An Analysis of GDPR Enforcement*, CTR. FOR STRATEGIC & INT'L STU. (Sept. 13, 2021), https://www.csis.org/blogs/strategic-technologies-blog/3-years-later-analysis-gdpr-enforcement.

[38] Shaun G. Jamison, *Creating a National Data Privacy Law for the United States*, 10 CYBARIS, AN INTELL. PROP. L. REV. 1, 3 (2019).

own regulations to provide additional privacy protections for personal data, health information, and genetic information."[39] The United States, as a whole, presently relies on the Health Insurance Portability and Accountability Act (HIPAA), the Federal Trade Commission (FTC), and the Food & Drug Administration (FDA) when navigating privacy and health data.[40]

A. HIPAA: The Privacy Rule & the Security Rule

In 1996, HIPPA was passed to "to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes."[41] It is currently the main federal statute that relates to mHealth, especially after the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule) was passed.[42] According to the U.S. Department of Health & Human Services (HSS), the Privacy Rule "establishes national standards to protect individuals' medical records and other individually identifiable health information," also known as personal health information, and "applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically."[43] Personal health information (PHI) is any

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[39] Marilyn Cech, *Genetic Privacy in the "Big Biology" Era: The "Autonomous" Human Subject*, 70 HASTINGS L.J. 851, 867-68 (2019).

[40] The FDA has a very limited view of what constitutes a medical device (e.g., mHealth apps). Since the software of some of these mHealth applications do not fall under the definition of "device" in the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA will refrain from regulating them as devices. For the mHealth applications that could function as medical devices but pose a low risk to the public, the FDA will most likely exercise enforcement discretion over them rather than enforce the FD&C Act. U.S. FOOD & DRUG ADMIN., Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, 1, 2 (Sept. 28, 2022), https://www.fda.gov/media/80958/download; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399i (2021).

[41] Preamble, Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

[42] Helm & Georgatos, *supra* note 1, at 152.

[43] *The HIPAA Privacy Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Mar. 31, 2022), https://www.hhs.gov/hipaa/for-professionals/privacy/index.html ("The Rule requires appropriate safeguards to protect the privacy of protected health information and sets limits and conditions on the uses and disclosures that may be made of such information without an individual's authorization. The Rule also gives individuals rights over their protected health information, including rights to examine and obtain a copy of their health records, to direct a covered entity to transmit to a third party an

information that relates to someone's previous or current health conditions, the healthcare treatment someone is receiving, or any payment in regards to health procedures both in the past or present; essentially, PHI is defined as any sensitive health information by which an individual could be identified.[44] HIPAA further protects PHI through the Security Standards for the Protection of Electronic Protected Health Information (the Security Rule). The Security Rule specifically protects PHI that is "held or transferred in electronic form" (e-PHI).[45] The creation of both the Privacy Rule and the Security Rule was a response by the HSS to the growing concern of the healthcare industry becoming reliant on technology to complete basic functions.[46] These rules were seen as compromises that enable healthcare providers to continue using new technologies that make their profession more efficient, while simultaneously protecting the health information of patients.[47] With this being said, there are important limitations to HIPAA in regard to mHealth.

There are two specific concerns with HIPAA's Privacy and Security rules. First, these rules only apply to "covered entities."[48] According to HSS, covered entities refer to "health plans, health care clearinghouses, and [] any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA."[49] mHealth app developers are not specifically listed, therefore, they may not be subjected to HIPAA standards. Second, the Privacy and Security Rules refer to e-PHI that is identifiable; e-PHI that has been made to be anonymous or in the public domain do not apply to the rules.[50] While it could be argued that deidentified information can protect users, this claim is not necessarily true.

First, it is false to proclaim that just because health information has been wiped from identifiers that the information cannot be traced back to the individual from which the information is derived, as scientists

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electronic copy of their protected health information in an electronic health record, and to request corrections.").

[44] *Summary of the HIPAA Privacy Rule,* U.S. DEP'T OF HEALTH & HUM. SERVS (Oct. 19, 2022), https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html.

[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] Cech, *supra* note 39, at 869.

[49] *Summary of the HIPAA Privacy Rule*, *supra* note 44.

[50] Cech, *supra* note 39, at 869.

have proven this time and time again.[51] Second, covered entities are able to disclose this "deidentified" information,[52] which in turn creates a multi-billion dollar marketplace where third-party buyers and sellers trade health information, even though one could potentially still identify someone with this information.[53] Third, insurance companies have the ability to discriminate based on deidentified information that was collected from the public domain.[54] Thus, these concerns regarding covered entities and the handling of deidentified information can be combined into the troubling conclusion that "HIPAA governs what covered entities do, not what becomes of personal information once it leaves the covered entities' control."[55] It is also important to note that an additional limitation of HIPAA is that it only addresses the e-PHI that alludes to treatment and not the surplus information that mHealth apps can gather that does not necessarily pertain to the health treatment that one is seeking, such as geo-location, usage, and more. Therefore, while HIPAA offers some protection with respect to an individual's e-PHI, it is sorely inadequate when put into context with mHealth apps.

B. FTC & mHealth

The Federal Trade Commission (FTC)'s mission is to "[protect] the public from deceptive or unfair business practices and from unfair

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[51] Melissa Gymerk et al., *Identifying Personal Genomes by Surname Inference*, 339 SCI. 321, 324 (2013) (detailing how the use of a free and publicly accessible Internet resources, as well as the use of a surname inference, led to the identification of nearly 50 individuals whose information was supposed to be anonymous on genetic genealogy databases); Luc Rocher et al., *Estimating the Success of Re-Identifications in Incomplete Datasets Using Generative Models*, 10 NATURE COMMC'NS. 1, 5 (2019) (demonstrating how 99.98% of the people in Massachusetts can be re-identified by using 15 demographic attributes from "deidentified" datasets); *see* Katharine Miller, *De-Identifying Medical Patient Data Doesn't Protect Our Privacy*, STAN. UNIV. HUMAN-CENTERED A.I. (Jul. 19, 2021), https://hai.stanford.edu/news/de-identifying-medical-patient-data-doesnt-protect-our-privacy (". . . [I]t is never possible to guarantee that de-identified data can't or won't be re-identified. That's because de-identification is not anonymization. . . . In addition, since HIPAA was passed in 1996, artificial intelligence has only gotten better at identifying people using facial recognition, genetic information, iris scans, and even gait.").

[52] Cech, *supra* note 39, at 869.

[53] Christina Farr, *Hospital Execs Say They Are Getting Flooded with Requests for Your Health Data*, CNBC (Dec. 18, 2019, 8:27 AM), https://www.cnbc.com/2019/12/18/hospital-execs-say-theyre-flooded-with-requests-for-your-health-data.html.

[54] Cech, *supra* note 39, at 869; *see also* Marshall Allen, *Health Insurers Are Vacuuming Up Details About You—And It Could Raise Your Rates*, PROPUBLICA (Jul. 17, 2018, 5:00 AM), https://www.propublica.org/article/health-insurers-are-vacuuming-up-details-about-you-and-it-could-raise-your-rates.

[55] Fox, *supra* note 1, at 214.

methods of competition through law enforcement, advocacy, research, and education."[56] Anti-competitive concerns stem from "platform dynamics (e.g., Apple, Google, etc.) and how a powerful few corporations might hold consumers captive, monopolize the entirety of a mobile device user's experience, control consumer access to apps or data they generate, limit the rate of innovation or app options by dictating app features, and more."[57] Privacy concerns, such as lax data security and privacy measures, can also be calculated when determining if an entity is acting unfairly.[58] While some have argued that mHealth privacy concerns should be governed by more specific statues, like HIPAA or the Health Information Technology for Economic and Clinical Health Act (HITECH), the FTC has stated that the commission has "concurrent and complementary jurisdiction" in health privacy cases.[59] Therefore, the FTC has ability to rule on mHealth apps that have inadequate security features.[60]

The FTC also provides guides where mHealth app developers can determine which federal laws and regulations their app may be subjected to.[61] These guides provide information about HIPAA, the Federal Food, Drug, and Cosmetic Act (FD&C Act),[62] the 21st Century Cures Act,[63] the HHS Office of the National Coordinator for Health Information Technology (ONC)'s "information blocking" regulations,[64] the FTC's Health Breach Notification Rule,[65] and the Children's Online Privacy

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[56] FED. TRADE COMM'N, ABOUT THE FTC, https://www.ftc.gov/about-ftc (last visited April 18, 2023).
[57] Jennifer K. Wagner, *The Federal Trade Commission and Consumer Protections for Mobile Heath Apps*, 48 J. L. MED. & ETHICS 103, 105 (2020).
[58] *Id.*
[59] Helm & Georgatos, *supra* note 1, at 163 (citing Respondent LabMD, Inc.'s Motion to Dismiss the Complaint with Prejudice and Stay Administrative Proceedings at 9, *In the Matter of LabMD, Inc.,* No. 9357, F.T.C. (Aug. 28, 2013)).
[60] *Id.*
[61] Mobile Health App Interactive Tool, FED. TRADE COMM'N, (Dec. 2022) https://www.ftc.gov/business-guidance/resources/mobile-health-apps-interactive-tool.
[62] *Id.* ("When a software function is intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the human body, the software function is a device under section 201(h) of the FD&C Act, if it is not a software function excluded from the device definition by the 21st Century Cures Act.").
[63] 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).
[64] Information blocking is a practice that "is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information" by either health care providers, health IT developers, or by a health information network. *Id.* at § 4004, 130 Stat. 1176.
[65] The Health Breach Notification Rule requires "entities covered by the Rule to provide notifications to consumers, the FTC, and, in some cases, the media, following certain breaches of personal health record information," and applies to other mHealth

Protection Act (COPPA).[66] It is important to note, however, that use of these guides is not required by law, thus it is up to the developer's discretion of whether or not to utilize the tools provided by the FTC.[67]

Major concerns with the FTC's regulations of privacy issues in mHealth apps lie in its reliance on laws that use broad standards for issues like consumer protection.[68] As technology becomes more advanced and nuanced, there is the possibility that broad rules such as the ones used by the FTC will become outdated, thereby challenging the FTC's authority on privacy issues.[69] Additionally, some have argued that FTC's inability to immediately fine an offending organization makes the FTC a poor deterrent mechanism for privacy concerns.[70]

C. State Privacy Laws

Since there is a lack of a nationally recognized and comprehensive data privacy law in the United States, the states themselves are free to create privacy regulation on their own terms. Often, these State regulations vary depending on region or the types of data that they apply to.[71] Notable states that have created comprehensive consumer data privacy laws are California,[72] Colorado,[73] Connecticut,[74] Utah,[75] and

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apps as they act as quasi-healthcare providers by "furnishing health services or supplies" to consumers. Mobile Health App Interactive Tool, *supra* note 61.

[66] COPPA gives parents the ability to oversee the collection of personal information from their children. It specifically applies to any internet source that is aimed at children under thirteen, and the operator of such source has access to the personal information of a child, including photos, videos, geolocation, and more. Children's Online Privacy Protection Act of 1998, 15 U.S.C. §§ 6501-6505 (1998).

[67] Mobile Health App Interactive Tool, *supra* note 61.

[68] Helm & Georgatos, *supra* note 1, at 163.

[69] *Id.*

[70] Jamison, *supra* note 38, at 8.

[71] Thorin Klosowski, *The State of Consumer Data Privacy Laws in the US (And Why It Matters)*, N.Y. TIMES (Sept. 6, 2021), https://www.nytimes.com/wirecutter/blog/state-of-privacy-laws-in-us/. Please note that this piece was written before the enactment of the My Health My Data Act in Washington State. This broad Act aims to increase the obligations of non-HIPAA covered entities that handle sensitive consumer health data. Future analysis is required to see the effects and reliability of this Act as most of the Act's provisions will come into effect in 2024. Yana Komsitsky & Neeka Hodaie, *Washington's "My Health My Data" Act*, SEYFARTH SHAW LLP (Apr. 25, 2023), https://www.seyfarth.com/news-insights/washingtons-my-health-my-data-act.html.

[72] California Consumer Privacy Act of 2018, CAL. CIV. CODE §§ 1798.100-1798.199.100 (West 2018). [hereinafter CCPA].

[73] Colorado Privacy Act, COLO. REV. STAT. §§6-1-1301-6-1-1313 (2021).

[74] An Act Concerning Personal Data Privacy and Online Monitoring, CONN. GEN. STAT. § 22-15 (2022) (effective July 1, 2023).

[75] Utah Consumer Privacy Act, UTAH CODE ANN. §§13-61-101-13-61-404 (West 2022) (effective Dec. 31, 2023).

Virginia.[76] As California's legislation has been enacted the longest, it is the most useful tool to analyze state privacy regulation with respect to mHealth.

The California Consumer Protection Act (CCPA) is the closest U.S. act to resemble the rules and regulations of the GDPR.[77] It specifically concerns itself with protection of the personal information of the residents of California and defines personal information as any "information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, *with a particular consumer or household*."[78] The CCPA focuses on granting five essential rights with respect to data privacy in California; according to the Act, Californians are entitled to i) know what information about them are being collected, ii) know if their information is being bought, sold, or disclosed to other individuals, iii) refuse data collection or processing, iv) access their own personal data, and, lastly, v) be free from discrimination if they were to exercise one of their privacy rights.[79] Violations regarding the processing of personal information or preventing an individual from invoking their privacy rights may result in fines, thus major multinational corporations have changed their behaviors to be in accordance with the CCPA.[80] For health data specifically, the CCPA requires that companies provide an opportunity for consumers to opt out of the sale of their data.[81] Lastly, an additional Californian privacy act, the California Privacy Rights Act (CPRA), works tangentially with the CCPA to mandate data impact assessments for companies handling personal information, as well as mandate the minimization of the collection of one's personal data as much as possible.[82]

There has recently been a focus on the privacy issues concerning mobile applications in California. Californian Attorney General Rob

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[76] Consumer Data Protection Act, VA. CODE ANN. §§ 59.1-575-59.1-585 (2023).
[77] Cech, *supra* note 39, at 884.
[78] CCPA, *supra* note 72, at § 1798.140(v)(1) (emphasis added). This Californian definition of "personal information" provides a broader category than what is actually afforded under the GDPR, as explained in Part IV, as it also includes information about consumer households. Cech, *supra* note 39, at 884.
[79] Cech, *supra* note 39, at 884.
[80] Hannah K. Galvin & Paul R. DeMuro, *Developments in Privacy and Data Ownership in Mobile Health Technologies, 2016-2019*, 29(1) Y.B. MED. INFORMATICS 32, 34 (2020).
[81] Danielle Feingold, *Digital Health Companies and Data Protection: Ensuring Compliance with Continually Evolving, Piecemeal State Regulations Surrounding Data Use and Data Subject Rights*, 31 ANNALS HEALTH L. ADVANCE DIRECTIVE 147, 158-59 (2021).
[82] *Id.* at 157.

Bonta conducted an investigation regarding the privacy policies of certain mobile apps, and the investigation resulted in a wide range of companies from various sectors being notified that their mobile applications failed to comply with the CCPA.[83] The sweep focused on failed consumer opt-out requests, the lack of a mechanism to stop the sale of data, failed processing of consumer requests, and more.[84] When speaking about the importance of privacy regulation for mobile apps, Attorney General Bonta stated,

> [Every day] businesses must honor Californians' right to opt out and delete personal information, including when those requests are made through an authorized agent[,] particularly given the wide array of sensitive information that these apps can access from our phones and other mobile devices. I urge the tech industry to innovate for good — including developing and adopting user-enabled global privacy controls for mobile operating systems that allow consumers to stop apps from selling their data.[85]

IV. EU AND THE GDPR

Enacted on May 25th, 2018, the GDPR was created as a means to promote uniformity and harmonization of data protection and privacy laws within the European Union.[86] According to Article 4 of the GDPR, "personal data" is any identifiable information relating to a person, such as a name, identification number, or any factor that relates specifically to a person's physical, physiological, genetic, mental, economic, cultural or social identity."[87] Health data occupies a specific subset of the GDPR's personal data as it is categorized as "sensitive data." Sensitive data encompasses information that refers to an individual's genetic data, biometric data, "racial or ethnic origin, political opinions, religious or

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[83] *Ahead of Data Privacy Day, Attorney General Bonta Focuses on Mobile Applications' Compliance with the California Consumer Privacy Act*, STATE CALI. DEP'T JUST. (Jan. 27, 2023), https://oag.ca.gov/news/press-releases/ahead-data-privacy-day-attorney-general-bonta-focuses-mobile-applications'.
[84] *Id.*
[85] *Id.*
[86] Council Regulation 2016/679, Regulation on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of such Data, 2016 O.J. (L. 119) 1 [hereinafter GDPR].
[87] Achilleas Papageorgiou et al., *Security and Privacy Analysis of Mobile Health Applications: The Alarming State of Practice*, 6 INST. ELEC. AND ELECS. ENG'R ACCESS 9390, 9400 (2018).

philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life."[88] The GDPR mandates that companies handling any sort of sensitive data act responsibly so that consumers have the ability to access and understand what data is being collected from them, why the data is being processed, and who is collecting such information.[89] Consequently, the definitions for personal data and health data are intentionally broad so that the GDPR is applicable to not only to companies producing medical devices, but also to the developers of commercial apps for wearable-medical devices, such as a fitness watch, that could potentially handle sensitive data.[90]

A notable aspect of the GDPR is that the regulation has established certain rights that individuals are entitled to when their personal data is being handled. Examples of these rights include: (1) an explanation as to why their data is being used; (2) the requirement of affirmative consent to process personal data; (3) withdrawal of consent to use personal data; (4) the ability to access personal data in a "readable and accessible format;" (5) the erasure of personal data ("a right to be forgotten"); and (6) the ability to transfer data to another provider ("right of portability").[91] The GDPR also mandates that entities obtain consent before any data is handled,[92] and provide "at least one of the six legal bases for processing data."[93] Failure to comply with the GDPR standards will result in high fines.[94] Additionally, companies must provide data impact assessments to regulators if they are to process data that would "present a high risk to the rights of [the] persons" from whom they are collecting data from.[95] Lastly, the GDPR mandates that data controllers exercise a principle called "data minimization," where essentially collectors limit the amount of information that they gather from an

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[88] *Id.* at 9401.
[89] T. Mulder & M. Tudorica, *Privacy Policies, Cross-Border Health Data and the GDPR,* 28(3) INFO. & COMMC'NS. TECH. L. 261, 262 (2019).
[90] *Id.* at 264.
[91] Feingold, *supra* note 81, at 153; *see generally* GDPR, *supra* note 86.
[92] According to Article 4 of the GDPR, consent is "any freely given, specific, informed and unambiguous indication of a data subject's wishes by which he or she, by a statement or by clear affirmative action, signifies agreement to the processing of personal data relating to him or her." GDPR, *supra* note 86, at art. 4(11).
[93] Feingold, *supra* note 81, at 153.
[94] *See* GDPR, *supra* note 86, at art. 83.
[95] Feingold, *supra* note 81, at 153-54 (citing Meg Leta Jones & Margot E. Kaminski, *An American's Guide to the GDPR*, 98 DENV. L. REV. 93, 118 (2020)) ("The data auditing and related impact assessment requirements ensure the adequate involvement of citizens in managing their data and promote corporate accountability of data processing.").

individual to only the amount necessary to complete their specified task.[96]

Not only does the GDPR place a great emphasis on consent, but there are other conditions that the GDPR forces companies to comply with that are of great importance. One of these conditions is the use of clear and plain language.[97] The second condition is transparency, which is crucial as a person needs to know who is handling their data, as well as what their risks, rules, safeguards and rights are.[98] Lastly, the final component of the GDPR that is of extreme importance is the ease by which an individual can protect their sensitive health data when it crosses borders.[99] Health data is in constant flux; the transfer of data can simply be from a wearable device to an online server, or on a much broader scale, such as the uploading of sensitive information in one country to the database of a company located in a different country. As stated by some privacy scholars, "[o]ne of the consequences of the electronic capturing of personal data via modern technologies is that, due to the very nature of these modern technologies, data may be located and stored anywhere in the world."[100] Understandably, the creators of the GDPR were worried about not only the transfer of data between EU countries, but also the transfer of data about EU citizens to countries located outside of the EU. As such, the GDPR mandates that non-EU companies must still comply with the GDPR's sensitive data regulations when handling the data of subjects within the EU.[101]

While the GDPR establishes EU standards of how to treat health data, member states are still able to adopt state-specific privacy legislation so long as it is compatible with the GDPR regulations.[102] As

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[96] GDPR, *supra* note 86, at art. 5(1)(c).
[97] *Id.* at art. 7(2).
[98] Mulder & Tudorica, *supra* note 89, at 268. An added component to the transparency aspect of the GDPR is that companies must also make individuals aware that they can exercise their rights when it pertains to the protection and use of their personal data. *Id.* at 269.
[99] *Id.* at 271.
[100] *Id.*
[101] *Id.* at 272.
[102] *See, e.g.*, Fruzsina Molnár-Gábor et al., *Harmonization after the GDPR? Divergences in the Rules for Genetic and Health Data Sharing in Four Member States and Ways to Overcome Them by EU Measures: Insights from Germany, Greece, Latvia and Sweden*, 84 SEMINARS CANCER BIOLOGY 271, 272-73 (2022) (comparing the health data protection laws of different EU countries, such as Germany's Federal Data Protection Act (BDSG), Greece's Greek Data Protection Act (DPA), Lativa's Personal Data Processing Law (PDPL), and both of Sweden's Patient Data Act (PDA) and Swedish Ethical Review Act (ERA)).

such, there are some wide variances between how health data is handled by EU countries.[103] Some of which are detailed below.

A. A Conservative Approach: Germany

The German Federal Data Protection Law (BDSG) and the Bundestag Data Protection Adaptation and Implementation Act EU (DSAnpUG-EU) are the official German legal adaptations of the GDPR.[104] Like the GDPR, the BDSG places health data under a special category of personal data, and only enables the processing of this data when it is "strictly necessary for the performance of the controller's task."[105] The BDSG mandates that certain safeguards are implemented when handling special personal data, like health data. Examples of such safeguards include: (1) the identification of specific requirements for data security/protection; (2) time limits for the amount of time it takes to determine relevance and subsequent erasure; (3) easy determination of who is handling special data; (4) restriction of who can handle special data; (5) separation of processing special data from other types of personal data; (6) deidentification of special data; (7) encryption of special data; or the (8) implementation of specific standards to make certain that special data is being handled lawfully.[106] Additionally, the BDSG also delineates the rights of data subjects with respect to data processing,[107] requirements for the security of data processing,[108] notification procedures for a personal data breach,[109] rules for conducting a data protection impact assessment,[110] and much more. Lastly, the BDSG imposes strict rules for consent, such as having "explicit" consent for special personal data.[111] Such safeguards and

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[103] Marieke Bak et al., *You Can't Have AI Both Ways: Balancing Health Data Privacy and Access Fairly*, 13 FRONTIERS IN GENETICS 1, 2 (2022).
[104] Fruzsina Molnár-Gábor, *Germany: A Fair Balance Between Scientific Freedom and Data Subjects' Rights?*, 137 HUMAN GENETICS 619, 619 (2018).
[105] Bundesdatenschutzgesetz (BDSG) "Federal Data Protection Act of 30 June 2017" (Federal Law Gazette I p. 2097), as last amended by Article 10 of the Act of 23 June 2021 (Federal Law Gazette I, p. 1858; 2022 I p. 1045) (Ger.), https://www.gesetze-im-internet.de/englisch_bdsg/englisch_bdsg.pdf ("'[D]ata concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.").
[106] *Id.* at pt 3, ch. 2 §48.
[107] *Id.* at pt 3, ch. 2 §55.
[108] *Id.* at pt 3, ch. 2 §64.
[109] *Id.* at pt 3, ch. 2 §§65; 66.
[110] *Id.* at pt 3, ch. 2 §67.
[111] *Id.* at pt 3, ch. 2 §51.

procedures are one of many ways in which Germany exceeds the minimum set of protections enforced by the GDPR.[112] Note that depending on the health service that a mHealth app provides, there may be more regulations that the developer can be subject to, and failure to comply with these regulations may result in sanctions or fines up to EUR 20 million.[113]

Implemented on June 27th, 2019, the DSAnpUG-EU was intended to reconcile the nearly 154 federal laws from the BDSG with the changes to the GDPR over the previous few years.[114] Major changes to the BDSG include the increased minimum number of employees, from ten to twenty, who are hired to processes personal data, and simplified consent requirements from employees within the scope of their employment.[115] The DSAnpUG-EU also includes the addition of another provision of permission when processing special health data; according to the new law, non-public bodies may be able to process special data only when it is "absolutely necessary for reasons of substantial public interest."[116]

B. A Liberal Approach: Finland

With respect to mHealth apps, the Data Protection Act of Finland (DPA) and the Act on the Secondary Use of Health and Social Data (ASUHSD) are the most useful to analyze for data protection for health

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[112] Anna Essén et al., *Health App Policy: International Comparison of Nine Countries' Approaches*, 31 NPJ DIGIT. MED. 1, 6 (2022); *see also* David Raj Nijhawan*, The Emperor Has No Clothes: A Critique of Applying the European Union Approach to Privacy Regulation in the United States*, 56 VAND. L. REV. 939 (2003) (explaining the Germany, much like France, have stricter laws than other EU-member states). *But see The New German Privacy Act*, Deloitte, https://www2.deloitte.com/dl/en/pages/legal/articles/neues-bundesdatenschutzgesetz.html (last visited Jan. 31,2023, 6:48 AM) (explaining that differing German and EU laws cause uncertainty for data controllers and processors, and that the GDPR is the superior rule of law, thus causing national laws to only be generated when the GDPR provides opening clauses).

[113] Jana Grieb et al., *Digital Health Laws and Regulations Germany*, ICLG (Feb. 24, 2022), https://iclg.com/practice-areas/digital-health-laws-and-regulations/germany#.

[114] Detlev Gabel, *German Bundestag Passes Second Act on the Adaptation of Data Protection Law to the GDPR*, WHITE & CASE (Jul. 19, 2019), https://www.whitecase.com/insight-alert/german-bundestag-passes-second-act-adaptation-data-protection-law-gdpr.

[115] *Id.*

[116] Lars Lensdorf, *German Bundestag Approves 2nd German Data Protection Adaptation Act ("2nd DSAnpUG"): Summary of Significant Changes for German Data Protection Laws*, COVINGTON: INSIDE PRIVACY (Jul. 3, 2019), https://www.insideprivacy.com/eu-data-protection/german-bundestag-approves-2nd-german-data-protection-adaptation-act-2nd-dsanpug-summary-of-significant-changes-for-german-data-protection-laws/.

information. [117] The DPA, like the BDSG, supplements the EU's GDPR. However, unlike its German counterpart, the DPA does not explicitly describe personal data protection.[118] In fact, the main intention of the DPA is to "reduce special regulation" so that Finland is more reliant on the general articles of the GDPR.[119] When necessary, Finland uses sector-specific regulations to deal with particular subsets of data protection, such as the ASUHSD.

The ASUHSD was created to "facilitate the effective and safe processing and access to the personal social and health data for steering, supervision, research, statistics and development in the health and social sector."[120] Secondary use is when the data collected from an individual, in this instance health data, is used for a reason other than the primary justification for the collection of the data.[121] What is unique about this Act is that it creates an "established IT ecosystem," known as Findata,[122] that facilitates the transfer of social and health care information from data controllers that were responsible for the primary purpose of processing to other public or private entities that obtain a fixed-term revocable license.[123] Findata differs from other EU member states' centralized data

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[117] Tietosuojalaki [Data Protection Act] (Finlex 1050/2018) (Fin.), https://www.finlex.fi/en/laki/kaannokset/2018/en20181050.pdf; Laki Sosiaali- Ja Terveystietojen Toissijaisesta Käytöstä [Act on Secondary Use of Social and Health Data](Finlex, 552/2019), https://stm.fi/documents/1271139/1365571/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data/a2bca08c-d067-3e54-45d1-18096de0ed76/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data.pdf.

[118] Päivi Korpisaari, *Finland: A Brief Overview of the GDPR Implementation*, 5 EUR. DATA PROT. L. REV. 232, 232 (2019).

[119] *Id.* at 233. Germany's BDSG can be seen to do the opposite; the BDSG can be construed as a mechanism that is seeks to impose extra restrictions than what the GDPR stipulates. *GDPR in Germany: What You Need to Know in 2022*, PANDECTES (Jan. 2, 2022), https://pandectes.io/blog/gdpr-in-germany-what-you-need-to-know-in-2022/.

[120] *Secondary Use of Health and Social Data*, MINISTRY OF SOCIAL AFFAIRS AND HEALTH, https://stm.fi/en/secondary-use-of-health-and-social-data (last visited Jan. 31, 2023).

[121] *Id.* The types of secondary uses that are authorized through the ASUHSD are "scientific research, statistics, development and innovation operations, steering and supervision by authorities, planning and reporting duty of an authority, education and knowledge management." *Act on the Secondary Use of Health and Social Data*, UNIV. E. FIN. LIBR., https://www.uef.fi/en/library/act-on-the-secondary-use-of-health-and-social-data (last visited Feb. 1, 2023).

[122] *See generally Services for Customers*, FINDATA, https://findata.fi/en/services-for-customers/ (last visited Feb. 1, 2023).

[123] Joonas Dammert, *Finland: Parliament Approves New Act on the Secondary Use of Social and Health Care Personal Data*, DLA PIPER (Apr. 8, 2019), https://blogs.dlapiper.com/privacymatters/finland-parliament-approves-new-act-on-the-secondary-use-of-social-and-health-care-personal-data/; *see also GA4GH GDPR Brief: The Finnish Secondary Use Act 2019 (May 2020 Bonus Brief)*, GLOB. ALL. FOR

systems by how it labels accessible data. Findata labels accessible data in numerous ways. The labels can be generated by either using a patient's full name, a patient's national civic number/patient ID, an algorithmic pseudonym of the patient's name, an algorithmic pseudonym of the patient's ID number, a pseudonym from other factors, or by using completely anonymized data.[124]

Finland, like other EU member states, continues to prioritize data subjects' consent with the ASUHSD. First, explicit consent is needed for any secondary use pertaining to innovation or development activities.[125] Second, data users have the ability to contact the employees of Findata to either alter or withdraw their secondary use consent.[126] Third, the data subject must consent to both Findata *and* the secondary user; this can be done either simultaneously when the data subject consents to the primary data controller using their data, or by having the data user consent to the primary data controller first and expressing consent to Findata and the secondary user later on.[127] It is important to note that the above illustrations are specifically in relation to secondary use.[128] The Finnish stance towards secondary use can be construed as a liberal one; the ASUSHD is essentially "a national policy oriented towards big data and open data to transform the technical and governance infrastructure for AI and other computer science research."[129] Some EU countries, like Germany, do not currently have a nationally-recognized process for secondary use due to concerns about consent, the use of personal health data, and more.[130]

GENOMICS & HEALTH (May 21, 2020), https://www.ga4gh.org/news/ga4gh-gdpr-brief-the-finnish-secondary-use-act-2019-may-2020-bonus-brief/ (explaining the creation of Findata in 2020 to handle the requests for secondary use of social and health data).

[124] Eur. Comm'n, Consumers, Health, Agric. and Food Exec. Agency, Assessment of the EU Member States' Rules on Health Data in the Light of GDPR, No SC 2019 70 02 in the Context of the Single Framework Contract Chafea/2018/Health/03, at 111-12, (2021) https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf.

[125] Dammert, *supra* note 123.

[126] *Id.*

[127] *Id.*

[128] For example, "[i]n Finland, consent is not legally required for including personal data in national health registries." Bak, *supra* note 103, at 2.

[129] *Id.*

[130] *See generally* Sven Zenker et al.*, Data Protection-Compliant Broad Consent for Secondary Use of Health Care Data and Human Biosamples for (Bio)Medical Research: Towards a New German National Standard*, 131 J. BIOMEDICAL INFORMATICS 104096, 2-8 (2022).

V. THE ULTIMATE CHOICE: EU'S GDPR PATH OR THE ROAD LESS TRAVELED

As Big Data becomes more pervasive in society's daily activities and functions, the United States is faced with the dilemma of finding the best approach to protect American citizens' data. Two of the major arguments within this debate is whether the United States should adopt a comprehensive data policy like the EU's GDPR, or if the United States should adopt an approach that is uniquely its own by allowing States to choose what data protection policies they want to enact for their residents. Therefore, it is necessary to weigh the pros and cons of the application of the GDPR approach to the American legal regime, especially with respect to health data and mHealth apps.

There are many beneficial aspects to adopting a comprehensive, national standard for data privacy in the United States. As not only healthcare but other daily functions become digitized, the United States will have to start concerning itself with multiple entities having access to people's sensitive data. Currently, the United States has adopted a data privacy approach that focuses on direct consumer relationships, thus making the policy vulnerable to unregulated third parties partaking in data processing.[131] In contrast, the EU's GDPR focuses on the personal data itself and not the entity that is controlling it, which in turn subjects even third parties to fall under the jurisdiction of the GDPR due to the sensitive nature of the data that they are handling.[132]

If the United States were to adopt a GDPR approach to privacy regulation, there are two benefits that could arise relating to third parties. First, the United States would not have to create additional legislation to account for third-party users, saving time and money for the legislative branch. Second, since many third-party companies are already changing their approach to data processing to accommodate the demands of the GDPR, creating legislation that mimics the GDPR could save money for multinational businesses, promote international business relations, and

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[131] Jones & Kaminski, *supra* note 95, at 107; *see* Jill McKeon, *The Quest to Improve Security, Privacy of Third-Party Health Apps*, TECHTARGET: HEALTH IT SECURITY (Apr. 12, 2022), https://healthitsecurity.com/features/the-quest-to-improve-security-privacy-of-third-party-health-apps (noting that the "onus should not be on the individual" to find the most secure health app because they are the ones in need of finding healthcare, and that third-party privacy concerns expose the shortcomings of HIPAA).

[132] Jones & Kaminski, *supra* note 95, at 107.

provide clarity and foster transparency about third parties for data subjects and consumers.[133]

Another benefit derived from having federal legislation based on the GDPR is that rather than having too many drastically different state laws, there would be a minimum standard for privacy protection that all States would have to adhere to. Instead of relying on various acts and governmental organizations, like HIPPA, the FTC, or the FDA, the federal government can address all types of privacy concerns through one act. If States are still concerned about potential gaps in a federal act, they would have the ability to address those concerns in state-specific acts, similar to how EU-member states, like Germany and Finland, have their own privacy legislation. Having a national standard for privacy regulation will only reiterate the basic protections that Americans should be afforded with respect to their sensitive health data. It will also provide clarification about how American companies, and companies that operate in the United States, should treat and handle their consumers' data. Thus, mHealth app developers will understand American expectations of how to treat the data that they collect, especially regarding data sharing rights, opt-in consent, data minimization, and nondiscrimination for those who utilize their privacy rights.[134] Ultimately, a connection between the GDPR and U.S.-based privacy legislation will promote simplicity and standardization for companies and consumers all over the world.[135]

With all of this being said, the GDPR is not the perfect solution to the ever-growing list of privacy concerns. Some scholars have already determined that the GDPR, or any GDPR-like legislation, would be inadequate in solving the United States' privacy concerns.[136] There are three specific concerns about a GDPR-like federal privacy law in the U.S. The first is that a GDPR approach to privacy protection would interfere with American's First Amendment-protected right to the free flow of information.[137] Many companies rely on the easy transfer of information to successfully function; the GDPR, while well-intended, poses more obstacles in such movement. This creates concerns of having too much government involvement in the affairs of American citizens and

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[133] Piotr Foitzik, *What You Must Know About 'Third Parties' Under GDPR and CCPA*, INT'L ASS'N PRIVACY PROS. (Nov. 26, 2019), https://iapp.org/news/a/what-you-must-know-about-third-parties-under-the-gdpr-ccpa/.
[134] Klosowski, *supra* note 71.
[135] *See generally* Foitzik, *supra* note 133.
[136] Nijhawan, *supra* note 112, at 944.
[137] *Id.* at 959.

companies,[138] the movement of lower quality information due to consumers' veto power against data collection,[139] and more. Essentially, the application of a GDPR approach to the U.S. would be "a problematic situation in the U.S., because the EU method of registering data processing activities does not align with American values of minimal government intrusion into the private sphere."[140]

The second concern is related specifically to digital health and, thus, mHealth apps. The GDPR has been criticized to be rooted in preconceived notions of data privacy, thereby making it incompatible with how digital health currently operates and how digital health will evolve.[141] For example, as seen with black-box medicine, healthcare providers have become reliant on the use of algorithms. As such, "personal health data collected for machine learning can be put to extensive uses that cannot be specifically identified and explicitly articulated to the data subject at the time of collection… as machine learning algorithms 'learn and develop' and hence are not necessarily directed by their programmers."[142] Therefore, digital health is already in contention with the GDPR data protection principles of data minimization and transparency. Another example of the GDPR's inadequacy with regard to mHealth apps is that the distinction between personal data and sensitive data can easily be blurred which undermines the protection enumerated in the EU legislation.[143] For instance, seemingly unrelated and unimportant data, like shopping records and lifestyle habits, could be linked to important information, such as an individual's health status; even if a mHealth app company were to treat both data sets differently, the company could still ultimately have the ability to create inferences about the innocuous data to create accurate assumptions about a consumer's sensitive information.[144]

Lastly, a critique about the American implementation of a GDPR-like legislation is that it will ultimately not influence American citizens anyway due to the "privacy paradox." The privacy paradox is when individuals, while valuing their right to privacy, ultimately make decisions that put their privacy at risk with respect to modern

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[138] *Id.* at 961-62.
[139] *Id.* at 964.
[140] *Id.* at 967 (citing Paul Rose, Comment, *A Market Response to the European Union Directive on Privacy,* 4 UCLA J. INT'L L. & FOREIGN AFF. 445, 469-70 (1999/2000)).
[141] *See* Luca Marelli, Elisa Lievevrouw & Ine Van Hoyweghen, *Fit for Purpose? The GDPR and the Governance of European Digital Health*, 41 POL'Y STUD. 447, 452 (2020).
[142] *Id.* at 453.
[143] *Id.* at 455.
[144] *Id.*

technologies.[145] Examples of this phenomenon can be seen when consumers agree to a company's privacy policies without reading them, resulting in the consumer not knowing what happens to their data when it is processed by the company. While individuals claim to be concerned about how companies are handling their data, they actually do very little to combat those concerns in real life.[146] There is an argument that people are more cautious when the data concerns sensitive information, like health data, however, such individuals continue to use mHealth apps anyway despite there being a lack of strong privacy regulations in the United States. Therefore, rather than create completely new privacy laws, there could be an argument that the current system in place in the U.S. is sufficient enough to give consumers adequate peace of mind to continue to engage with mHealth apps, while simultaneously regulating companies on how they treat health data.

CONCLUSION

While the concerns illustrated by critics of the GDPR are legitimate, it is imperative that the United States establishes a minimum baseline of protection for the privacy concerns of American citizens with a federal privacy law. As technology continues to advance, and people become more reliant on smartphones, telehealth, and personalized medicine, sensitive health information is put more at risk from inadequate security provisions of primary data controllers, third-party handlers, and from discrimination. This is especially concerning since the U.S. judiciary and legislative branches have recently made monumental decisions regarding healthcare. In a post-*Dobbs v. Jackson Women's Health Organization* world,[147] for example, some individuals that use menstrual-tracking apps, fertility-tracking apps, or any type of app that tracks one's location are worried that the potential information that these apps could provide may result in either public shaming or even criminal actions. This is not hard to imagine as data brokers have already been seen to sell information pertaining to when individuals visited a Planned Parenthood and included information in the sale regarding how long they stayed, from where they came, and where they traveled to after

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[145] Mulder & Tudorica, *supra* note 89, at 266.
[146] Tanja Schroeder, Maximilian Haug & Heiko Gewald, *Data Privacy Concerns Using mHealth Apps and Smart Speakers: Comparative Interview Study Among Mature Adults*, 6(6) JMIR FORMATIVE RSCH. 1, 3 (2022).
[147] *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, (2022).

their visit.[148] Additionally, the leaking of personal health information from mHealth apps could affect an individual's ability to obtain a job, insurance, or monetary aid due to discrimination based on their data.[149] Therefore, a comprehensive federal privacy regulation must be implemented in the United States.

As previously mentioned, if States are concerned about the federal privacy law not affording enough protection, they should be able to enact additional provisions within their states to put those concerns at ease, especially with respect to sensitive data. It is not the ceiling of privacy protection that Americans should be concerned about; it is the floor. The United States must enact a minimum set of protections for its citizens that deals with privacy as a whole, not by acts here and there that tangentially allude to privacy concerns. This need is only more prevalent when taken into context with mHealth. mHealth app developers are not bound by centuries-old oaths of confidentiality. Rather, they are subjected to the whims and needs of computer-generated algorithms to develop personalized healthcare. These developers have access to millions of people's sensitive information which can easily be transferred with a simple sale. That is a lot of unrestricted power to have, thus there must be a governmental check on the actions of these mHealth app developers.

Ultimately, it is the federal government's responsibility to protect the rights of its citizens. With respect to mHealth and privacy, the only way this can be achieved is through federal privacy policies, similar to that of the GDPR. Not only will it be more efficient for American health

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[148] Jay Edelson, *Post-Dobbs*, *Your Private Data Will Be Used Against You*, BLOOMBERG LAW: US LAW WEEK (Sept. 22, 2022, 4:00 AM), https://news.bloomberglaw.com/us-law-week/post-dobbs-your-private-data-will-be-used-against-you; *see also* Justin Sherman, *The Data Broker Caught Running Anti-Abortion Ads—to People Sitting in Clinic*s, LAWFARE (Sept. 19, 2022, 8:31 AM), https://www.lawfareblog.com/data-broker-caught-running-anti-abortion-ads—-people-sitting-clinics; *see* Holly Barker, *Nebraska Abortion Probe and Search Warrants for Data: Explained*, BLOOMBERG LAW (Aug. 12, 2022, 10:33 AM), https://www.bloomberglaw.com/bloomberglawnews/health-law-and-business/XABPUQAK000000?bna_news_filter=health-law-and-business#jcite (explaining Meta Platforms Inc.'s response to receiving warrants, which did not specifically mention abortions, to provide information about a woman suspected of committing a serious crime, which ultimately resulted in her and her daughter being charged with an illegal abortion in Nebraska).

[149] *See generally* Alexandra Heidel & Christian Hagist, *Potential Benefits and Risks Resulting from the Introduction of Health Apps and Wearables Into the German Statutory Health Care System: Scoping Review*, 8(9) JMIR MHEALTH & UHEALTH 1, 6 (2020) (detailing how chronically-ill individuals are worried that health insurance companies would discriminate against them if the insurance company were to access their health data).

providers, app developers, and consumers, but it will enable millions of people access to healthcare without sacrificing their right to privacy.

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ARTICLES

THE PRICE OF COMPETITION: ANALYZING ANTICOMPETITIVE TACTICS IN PHARMACEUTICAL MARKETS DURING THE HATCH-WAXMAN ERA

William Ulrich

THE PRICE OF COMPETITION: ANALYZING ANTICOMPETITIVE TACTICS IN PHARMACEUTICAL MARKETS DURING THE HATCH-WAXMAN ERA

William Ulrich[*]

INTRODUCTION

For nearly forty years, the Hatch-Waxman system for expediting approval of generic drugs has brought increased levels of competition to the pharmaceutical markets, lowering drug prices for all consumers. On its face, the Hatch-Waxman Act has enjoyed extraordinary success. Today, nearly 90% of prescriptions are filled with generic pharmaceuticals, with around 80% of all brand-name pharmaceuticals having a generic competitor.[1] Despite this success, anecdotal evidence in recent years suggests new forms of strategic behaviors designed to block generic entry are on the rise.[2]

From highly publicized congressional hearings to high profile press articles and outrage from various presidential candidates on the topic, the rising price of pharmaceuticals has led to public outcry. For example, Turing CEO Martin Shkreli and his company riveted the nation after increasing the price of a drug from $13.50 per tablet to $750 per tablet, an action that eventually led to congressional hearings on the topic.[3] Additionally, pharmaceutical manufacturers' tactics relating to specialty pharmacies and price increases have drawn notice from federal prosecutors, further underscoring the rise of new forms of strategic, anticompetitive behaviors.[4]

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[1] *See* Robin Feldman, *Captive Generics: The Wolf in Sheep's Clothing*, 59 HARV. J. LEG. 383, 384 (2022) [hereinafter Feldman, *Captive Generics*].

[2] *See, e.g.*, Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 499, 524–54 (2016) [hereinafter Feldman, *Drug Wars*] (pointing out various anticompetitive tactics, including use of the administrative process, regulatory schemes, and drug modification to block or delay generic entry into the market).

[3] *See* Robin Feldman, et. al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 42 (2017) [hereinafter Feldman, *Citizen's Pathway Gone Astray*]; *see also* Feldman, *Drug Wars*, *supra* note 2, at 536–38.

[4] *See* Feldman, *Drug Wars*, *supra* note 2, at 538–39.

It is not difficult to understand the motivation behind such behaviors. If a brand-name pharmaceutical manufacturer can delay generic entry for a blockbuster drug—even by just a mere month or two—it stands to earn hundreds of millions of dollars in additional revenue.[5] With a significant amount of dollars at stake, brand-name manufacturers have a powerful incentive to keep searching for new methods of delaying generic competition into the market. From society's standpoint, this is directly contrary to what one would prefer: instead of brand-name manufacturers using their resources in search of new pathways for treating disease, they instead search for new pathways of blocking competition.[6] Thus, in order to keep the generic system on track, it is critical to expose the various avenues of generic delay.

Part I of this Note briefly describes the generic entry process as prescribed by the Hatch-Waxman Act. Part II details four well-known tactics used by brand-name manufacturers to block or delay the entry of generic competition, highlighting how the tactics are successful. Part III concludes by examining the nature of the various problems and arguing that the first step towards ending the different forms of anticompetitive behavior is through increased disclosure requirements.

I. THE HATCH-WAXMAN SYSTEM

Since 1984, the United States prescription drug market has been governed by the Drug Price Competition and Patent Term Restoration Act, more commonly known as the Hatch-Waxman Act.[7]

A. Before the Hatch-Waxman Act

Prior to 1984, a pharmaceutical manufacturer that sought to sell a new prescription drug looked to the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act (FDCA) for guidance, the most significant piece of federal legislation affecting the pharmaceutical market at the time.[8] Giving power to the Food and Drug Administration (FDA) to require pharmaceutical manufactures to prove that their drugs

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[5] *Id.* at 503 n.23 (highlighting examples of the revenue generated by blockbuster drugs).
[6] *See* Feldman, *Citizen's Pathways Gone Astray*, *supra* note 3, at 43.
[7] Pub. L. No. 98-417, 98 Stat. 1585 (1984).
[8] Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Act Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 Yale J. Health, Pol'y, L. & Ethics 293, 297 (2015).

were safe and efficacious,[9] the Kefauver-Harris Amendments thrust the FDA into the gatekeeper role responsible for verifying the effectiveness of new prescription drugs.[10] From the requirements of multiple premarket clinical trials of the drug[11] to the submission of a New Drug Application (NDA) following a successful clinical trial process,[12] the FDA's approval process created an expensive endeavor for any pharmaceutical manufacturer looking to sell a new prescription drug.[13]

While the FDA's process ensured the safety of new drugs, from a competition perspective, the process had a significant flaw: generic manufacturers could not easily enter the market once a drug's patent expired. Because the full clinical trial process was also applicable to any new generic prescriptions as well, it was a significant investment for a generic manufacturer to bring its own drug to market.[14] Further, courts failed to recognize the experimental use defense to patent infringement liability with respect to pharmaceuticals.[15] By requiring the generic manufacturer to either wait until the patents on the brand-name drug expired before starting the clinical trial process or risk liability by conducting clinical trials during the term of the patent,[16] the courts had effectively extended the exclusivity periods for brand-name manufacturers, dampening the market for generics even further.[17] By the late 1970s, about 150 brand-name drugs lacked generic counterparts despite being off-patent, with generics accounting for only 19% of all prescriptions.[18]

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[9] *See* S. Rep. No. 87-1744 (1962).
[10] Kesselheim, *supra* note 8, at 298.
[11] Part 130—New Drugs: Procedural and Interpretive Regulations; Investigational Use, 28 Fed. Reg. 179 (Jan. 8, 1963) (codified at 21 C.F.R. pt. 130.3).
[12] *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 335(b) (2021).
[13] *See* Kesselheim, *supra* note 8, at 298.
[14] *Id.*
[15] *Id.* at 299–300.
[16] *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that pre-expiration testing of patent-protected brand-name drugs was not covered under any experimental use defense to liability for infringement because of the definite, cognizable, and substantial commercial purposes of Bolar's actions); *see also* Pfizer, Inc. v. Int'l Rectifier Corp., 545 F. Supp. 486 (C.D. Cal. 1980) (rejecting the use of patented doxycycline tablets without authorization of the patent holder for purposes of gaining FDA approval).
[17] *See* Kesselheim, *supra* note 8, at 300.
[18] *Id.*; *see also* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

B. Background and Goals of the Hatch-Waxman Act

It is against this backdrop that the Hatch-Waxman Act came into force. Looking to bolster both the brand-name and generic drug industries, the Hatch-Waxman Act intended to make low-cost generics more widely available while—arguably more important—maintaining proper incentives for innovation.[19] To achieve this end, the Act contained four major subcategories of provisions:

> (1) creation of a separate abbreviated FDA approval pathway for generic drugs proven to be pharmaceutically equivalent and bioequivalent to their brand-name counterparts; (2) a system to adjudicate generic manufacturers' challenges to brand-name drug manufacturers' market exclusivity; (3) assurance of competition-free periods for innovative drug approvals; and (4) extensions of brand-name market exclusivity.[20]

Title I of the Hatch-Waxman Act eliminated the long and expensive clinical trial requirement for generic manufacturers looking to launch new generics on the market, instead creating the Abbreviated New Drug Application (ANDA) pathway: the formalized and expedited system granted FDA approval upon proof that the generic drug was both pharmaceutically equivalent and bioequivalent to the brand-name counterpart.[21] By allowing generic manufacturers to focus on making their drugs as inexpensively and high-quality as possible, the clear intention of the Act was to lower drug prices for consumers.[22] Additionally, the Act eliminated brand-name manufacturers' ability to sue for patent infringement while generic manufacturers tested their drugs for bioequivalence before the expiration of the brand-name manufacturers' patent, allowing for ANDAs to be prepared and submitted to the FDA without additional delay.[23]

The second requirement of the Act—legal certification regarding the status of the patents protecting the brand-name drug—created a

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[19] *See* Kesselheim, supra note 8, at 301; *see also* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 389 (1999).
[20] *See* Kesselheim, *supra* note 8, at 301.
[21] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98–417, § 101, 98 Stat. 1585, 1585–92 (1984) (codified as amended at 21 U.S.C. § 3550) (2012)).
[22] H.R. REP. NO. 98–857(11), at 29–32 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2713–16.
[23] 35 U.S.C. § 271(e)(1) (2012).

system where generic manufacturers could challenge brand-name manufacturers' patents.[24] Known as a "Paragraph IV" certification, a generic manufacturer seeking to market its drug must certify with the FDA that its version does not infringe the patents of the brand-name drug, or that the brand-name drug's patents are invalid.[25] Interestingly, an ANDA submission containing a Paragraph IV certification is deemed an act of patent infringement by the statute, giving the brand-name manufacturer forty-five days to initiate a lawsuit for alleged infringement.[26] If initiated, the brand-name manufacturer's lawsuit generates an automatic thirty-month stay of the ANDA proceeding, preventing the generic drug from obtaining FDA approval.[27] If patent litigation is not completed by the end of the thirty months, the generic manufacturer becomes eligible again to obtain FDA approval, albeit at risk depending on the outcome of the litigation.[28]

Upon a successful determination that the brand-name manufacturer's patents are invalid or not infringed, the generic manufacturer is awarded a six-month period of market exclusivity, the key incentive that promotes generic manufacturers to challenge brand-name manufacturers' patents.[29]

While the Hatch-Waxman Act incentivized the challenging of brand-name manufacturers' patents by the granting of the six-month period of market exclusivity for a successful challenger, it still provided assurance that brand-name manufacturers would enjoy guaranteed minimum periods of exclusivity.[30] By mandating that the ANDA process for specific types of pharmaceuticals called new molecular entities (NMEs)[31] not start until five years after FDA approval of the NME, the Act guarantees manufacturers—even without a patent—at least the five years of market exclusivity to recoup research and development costs and obtain profits.[32] For non-NME pharmaceuticals, like applications for new uses or new formulations of previously approved drugs, the

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[24] *See* Kesselheim, *supra* note 8, at 302–03.
[25] *Id.* at 303.
[26] 35 U.S.C. § 271(e)(2) (2012).
[27] 21 U.S.C. § 355(j)(5)(B)(iii) (2012).
[28] *Id.*
[29] § 355(j)(5)(B)(iv); *see* Kesselheim, *supra* note 8, at 304.
[30] *See* Kesselheim, *supra* note 8, at 305.
[31] *Id.* A new molecular entity is a pharmaceutical that contains active parts that have not previously been approved by the FDA. *Novel Drug Approvals for 2022*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022 (last visited Aug. 4, 2023).
[32] *Id.*; *see* Hatch-Waxman Act, § 355(j)(5)(F)(ii).

manufacturers receive three years of market exclusivity.[33] Coupled with the thirty-month stay on Paragraph IV certifications, most NMEs can expect at least seven-and-a-half years of market exclusivity while other non-NME pharmaceuticals can expect at least five-and-a-half years of market exclusivity.[34]

To further incentivize new development by brand-name manufacturers, Title II of the Hatch-Waxman Act grants "patent term restoration" to approved pharmaceuticals, additional time that is added to the term of the patent to account for the time lost during the clinical testing phases and FDA review period.[35] By calculating the time between the various filings with the FDA and the time during which the FDA reviewed the NDA, the patent term is extended accordingly.[36] Overall, the brand-name manufacturer can extend the patent term for a maximum of fourteen years from the date of the drug's FDA approval, depending on the length of the approval process.[37]

In sum, by providing a method for generic manufacturers to challenge brand-name manufacturers' patents and by providing for a six-month period of exclusivity in certain circumstances for the first generic company to file for FDA approval, the Hatch-Waxman Act greatly incentivized generic drug competition. Today, approximately 90% of all prescribed non-biologic[38] drugs are generics, with the average generic costing upwards of 90% less than its branded counterpart.[39] Considering these numbers, it is easily said that the Hatch-Waxman Act directly contributed to a revolution in the United States pharmaceutical markets, transforming the environment from a brand-name dominated market in the early 1980s to the present day where the vast majority of prescriptions are filled by generic drugs.

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[33] § 355 (j)(5)(F)(iii).
[34] *Id.*
[35] *See* 35 U.S.C. § 154(a) (2012). Because the patent term today runs twenty years from the date of filing the patent application, a large portion of the patent term is lost when brand-name manufacturers seek to bring a new drug to market. *See* Kesselheim, *supra* note 8, at 306.
[36] 35 U.S.C. § 156(c).
[37] § 156(c)(3) & (g)(6).
[38] *See* Feldman, *Captive Generics*, *supra* note 1, at 384.
[39] *Id.*; *Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA): Hearing Before the H. Comm. on Oversight & Gov't Reform*, 114th Cong. 1 (chart 1) (2016) (statement of Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin.).

II. TACTICS FOR DELAY

By greatly incentivizing generic drug competition in the pharmaceutical industry, the obvious goal of the Hatch-Waxman Act is to lower prescription drug prices. Because the entry of a generic greatly reduces the price of the brand-name counterpart, brand-name manufacturers stand to lose billions of dollars whenever a generic manufacturer seeks to challenge their patents through Paragraph IV certifications.[40] Not surprisingly, this has led brand-name manufacturers to try everything and anything to get the competitive, or what some might say, anticompetitive, edge: pay-for-delay, citizen petitions, product hopping, and "authorized" generics are all strategies employed by brand-name manufacturers to keep generic competitors out of the market for as long as possible.[41]

A. Pay-for-Delay

The first, and rather simple, tactic employed by brand-name pharmaceutical manufacturers is to "pay" the generic manufacturer to abstain from releasing the generic drug onto market. Known as "pay-for-delay" agreements, by offering the competing generic manufacturer something of value in exchange for a promise to not enter the market, the brand-name manufacturer essentially pays off the competition to maintain its exclusive position in the market.[42] From the generic manufacturer's viewpoint, pay-for-delay agreements are mutually advantageous. By receiving an immediate financial benefit—while also avoiding costly patent infringement litigation—the generic manufacturer receives an instantaneous and sizable return while avoiding significant costs in the process.[43] Further, depending on the agreement, the generic

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[40] *See* Feldman, *Captive Generics*, *supra* note 1, at 384–85. It has been estimated that brand-name manufacturers lose out on over $1 trillion in revenue over the course of a decade. *See* Evan Hoffman, *Competitive Dynamics of the Generic Drug Manufacturing Industry*, 52 BUS. ECON. 68, 69 (2017).

[41] *See* Feldman, *Captive Generics*, *supra* note 1, at 385. The result on drug prices has been felt by consumers: based on analysis of Medicare patients, it was found that the average dosage-unit price of common brand-name drugs increased by 313% between 2010 and 2017, even accounting for rebates. *See* Robin Feldman, *The Devil in the Tiers*, 8 J.L. & BIOSCIENCES 1, 19 (2021).

[42] *See* Robin Feldman, *The Pricetag of "Pay-for-Delay,"* 23 COLUM. SCI. & TECH. L. REV. 1, 4 (2022) [hereinafter Feldman, *Pricetag*]. *See generally* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1153 (2006).

[43] *See* Feldman, *Pricetag*, *supra* note 42, at 10.

manufacturer may still retain most of the benefits granted by the Hatch-Waxman scheme.[44]

Because both the generic and brand-name manufacturers stand to gain in pay-for-delay agreements, it is not hard to see why the agreements are successful. A simple example underscores this point: take an agreement in which the generic manufacturer is compensated in exchange for the promise not to file a Paragraph IV certification with the FDA.[45] Assuming there is not a second generic manufacturer looking to file with the FDA during the term of delay, the generic manufacturer still maintains the 180-day first-to-file market exclusivity period when it does enter the market at the expiration of the pay-for-delay agreement.[46] Thus, not only does the generic manufacturer reap the rewards of the first-filer status under the Hatch-Waxman regime, but it is also able to cash in on a serious payday in the meantime.[47]

Normally, payments in exchange for refraining from entering a given market are considered clear antitrust violations.[48] However, when one party to the agreement holds a valid patent, the analysis is different: patent holders generally have a "lawful right to exclude others from the market" until the patent expires, thus exempting the patent holder from antitrust scrutiny.[49] Free from the fear of antitrust scrutiny, the law prior to 2013 enabled brand-name manufacturers—who almost always held patents over their drugs—with the freedom to negotiate agreements with generic manufacturers, ensuring they remained the sole supplier in the given market. However, in 2013, the legal landscape surrounding pay-

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[44] *Id.*

[45] It is important to note that the deal set out in this example is highly simplified. In reality, pay-for-delay agreements are structured in much more complex ways. Straight money in exchange for a promise not to enter the market faces significant legal obstacles, which are later discussed in this section.

[46] Feldman, *Pricetag*, *supra* note 42, at 10.

[47] Additionally, because the generic manufacturer still maintains its 180-day first-filer market exclusivity period during the term of the pay-for-delay agreement, it can be argued that a bottleneck is created for any subsequent generic manufacturers, further disincentivizing additional generic entry into the market. *Id.*

[48] *Id.* at 12; *see also* 15 U.S.C. §1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.").

[49] FTC v. Actavis, Inc., 570 U.S. 136, 146 (2013) (quoting FTC v. Watson Pharms., Inc. 667 F.3d 1298, 1307, 1310 (11th Cir. 2012), *rev'd and remanded sub nom.* FTC v. Actavis, Inc. 570 U.S. 136 (2013)). This view is not without critics: because both the brand-name and generic manufacturer hold direct control over the market for a particular drug, with the powerless consumer bearing the cost, some commentators have argued that pay-for-delay settlements are clear infringements of Section I of the Sherman Act and should be considered a form of illegal monopolization. *See* Hemphill, *supra* note 42, at 1596.

for-delay agreements and patent holders changed when the Supreme Court weighed in on the issue.[50]

In addressing whether pay-for-delay agreements are contestable under antitrust principles, even when one party is the holder of a valid patent, the Supreme Court opened the door in *FTC v. Actavis, Inc.*[51] After filing a New Drug Application in 1999, Solvay Pharmaceuticals, a brand-name manufacturer, received FDA approval in 2000 to sell AndroGel, its brand-name topical testosterone drug. A patent over the drug was later obtained in 2003, granting the company exclusive rights set to expire in 2021.[52]

It was not long until Solvay faced threat of competition: Actavis, Inc., Paddock Laboratories, and Par Pharmaceuticals—all generic manufacturers—each filed their own Abbreviated New Drug Applications with the FDA in 2003, the same year Solvay received patent protection over its branded drug.[53] In standard Hatch-Waxman fashion, Solvay initiated Paragraph IV litigation against the generic manufacturers, triggering the thirty-month stay in the generic approval process. Rather interestingly, after the thirty-month stay expired in 2006, but before the Paragraph IV patent litigation ended, Solvay settled with the generic manufacturers.[54] With each generic manufacturer agreeing to promote Solvay's brand-name drug in exchange for a yearly cash payment, the settlements were structured as mere marketing contracts.[55] However, each settlement contained a key condition: that to delay entry of the respective generic drugs into the market.[56]

In response to the settlement, in January 2009, the FTC launched a lawsuit against Solvay, Actavis, Paddock, and Par, alleging that the companies violated Section 5 of the FTC Act prohibiting unfair or

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[50] *See* FTC v. Actavis, Inc. 570 U.S. 136 (2013).
[51] *Id.*
[52] *Id.* at 144.
[53] *Id.* at 144–45.
[54] *Id.* at 145. Following the expiration of the thirty-month stay in the generic approval process in 2006, Actavis's generic had been approved by the FDA. Had Solvay's patent been found to either be invalid, unenforceable, or not infringed, Actavis would have been free to launch its generic into the market. Thus, given that the Paragraph IV patent litigation was still in progress and Solvay's status as sole manufacturer of AndroGel was in jeopardy, Solvay faced great pressure to settle. *See id.*
[55] *Id.* at 145. Specifically, Actavis agreed to not enter the market with its generic until August 31, 2015—just shy of five-and-a-half-years before Solvay's patent expired—and to promote Solvay's AndroGel to doctors in exchange for $19 million to $30 million per year for nine years. Paddock Laboratories agreed to not enter the market and to promote AndroGel for $12 million per year, and Par Pharmaceuticals agreed to not enter the market and to promote AndroGel for $60 million per year. *Id.*
[56] *Id.*

deceptive practices.[57] In affirming the district court's dismissal of the complaint, the Court of the Appeals for the Eleventh Circuit relied on Solvay's status as a patent holder to conclude it had the lawful right to exclude others from the market until the patent expired.[58] While the appellate court did apply the law at the time, the Supreme Court did not agree; in a 5–3 decision written by Justice Breyer, the Court of Appeals for the Eleventh Circuit was reversed. Ultimately finding that pay-for-delay settlements are open to antitrust scrutiny,[59] the majority held that the Rule of Reason test should be employed to determine whether such settlements between brand-name and generic pharmaceutical manufacturers violate antitrust law.[60] Stressing that it was not necessary for courts to determine whether a patent was valid to assess whether a settlement had anticompetitive effects, the Court clearly articulated that reverse payment settlements were not immune from antitrust scrutiny even when they fell within the scope of the exclusionary potential of the patent.[61] Thus, in holding the way it did, the Supreme Court opened the door to future antitrust allegations against pharmaceutical manufacturers engaging in pay-for-delay agreements.

B. Citizen's Petitions

Brand-name pharmaceutical manufacturers stand to reap sizable gains during their time of market exclusivity. Therefore, at the threat of competition from generic manufacturers, brand-name manufacturers are greatly incentivized to delay competition from entering the market as

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[57] *Id.; see also* Federal Trade Commission Act of 1914, 15 U.S.C. § 45(a)(1) (2006) (prohibiting "unfair or deceptive business practices in or affecting commerce").
[58] *Actavis, Inc.*, 570 U.S. at 146. Recall, this is not the norm when it comes to anticompetitive actions taken by businesses. Without the presence of the patent, the settlement reached between Solvay and the three generic manufacturers would be in clear violation of the Sherman Act.
[59] *Id.* at 147–48.
[60] *Id.* at 159. The Rule of Reason formulation is best described in the 1918 *Board of Trade of City of Chicago v. United States* case: "The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its conditions before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable.
The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences." Bd. of Trade of Chicago v. United States, 246 U.S. 231, 238 (1918).
[61] *Actavis, Inc.*, 570 U.S. at 158–59.

long as possible, even if that delay is only a couple months.[62] With pay-for-delay agreements being subject to increased levels of scrutiny, brand-name manufacturers have expanded their arsenal when it comes to gaining a competitive edge through use of citizen's petitions.

Mandated by Congress' passage of the Administrative Procedure Act, citizen's petitions require federal agencies to create formal routes for members of the public to petition an agency to change, amend, or repeal an agency rule.[63] As applied to the FDA—the agency tasked with drug approval—the petitions may "request the Commissioner of Food and Drugs to . . . (issue, amend, or revoke a regulation or order to take or refrain from any other form of administrative action)."[64] In communicating all the factual and legal grounds for the petition and providing all the relevant information—including environmental and economic impact sections if necessary—the citizen's petition process, in theory, is a useful method for the public to communicate its concerns to the FDA.[65] However, this process can be, and has been, used for ulterior motives: the stifling of competition via brand-name pharmaceutical manufacturers as "concerned citizens" challenging generic manufacturers' Abbreviated New Drug Applications.[66] While it can be difficult to distinguish between petitions that raise important and necessary issues from those that carry anticompetitive underpinnings, the result is generally beneficial to the brand-name manufacturer: the stopping or delaying of approval of the generic manufacturer's drug.[67]

As an example of a questionable citizen's petition, consider one filed by Mutual Pharmaceuticals in 2007. As a generic manufacturer itself, Mutual was the first to receive FDA approval in 2004 to sell its generic version of felodipine, a blood pressure medicine.[68] Then, in the first quarter of 2007, Mylan, another generic manufacturer, sought FDA approval to sell its own version of generic felodipine.[69] Only a few months

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[62] For example, the top-selling drug in the United States in 2014, Gilead's Hepatitis C Drug, Sovaldi, earned about $1.98 billion in sales every three months. In the event of a generic competitor, even a modest 10% price drop would be worth $198 million for three months. *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 43.
[63] 5 U.S.C. § 553(e) (2012 & Supp. III 2015).
[64] 21 C.F.R § 10.30(b)(3) (2016).
[65] *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 52.
[66] *Id.* (explaining that the brand-name manufacturer commonly employs a variety of different arguments, ranging from direct attacks against the generic manufacturer's application and its bioequivalence or clinical data to appeals to safety, calls to preserve or add new exclusivities for the brand-name drug, and more).
[67] *Id.*
[68] *Id.* at 53.
[69] *Id.* It is important to consider that Mylan was the second generic manufacturer to seek approval with the FDA, with the first being Mutual. This meant Mylan was a

later, Mutual filed a citizen's petition that sought to delay other generic manufacturers from gaining FDA approval for other versions of generic felodipine.[70]

Citing concerns with the current product label, Mutual's petition was based on a 2001 study that examined the effects of certain types of orange juice on the absorption of the drug.[71] Ultimately denying Mutual's petition for a failure on the part of the study to raise serious safety concerns, the FDA's response was laced with skepticism towards Mutual's claims, and even towards its motives.[72]

At face value, Mutual's petition does not appear concerning because it was swiftly exposed and discarded. Relative to the aforementioned pay-for-delay agreements, this seems trivial at best. One may ask, does the citizen's petition system really pose a serious threat to competition in pharmaceutical markets?

In short, there is more to the citizen's petition process than meets the eye. The denial of Mutual's petition was April 17, 2008, the same date in which Mylan's generic version of felodipine was approved.[73] While it cannot be said for certain, these chains of events strongly suggest Mutual's petition was one of the last barriers to Mylan's ultimate approval.[74] Thus, it appears Mutual was successful in delaying the approval of the second generic, and direct competitor, for felodipine through its citizen's petition of questionable merit.[75]

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direct threat to the economic benefits Mutual was feeling after being the first generic to enter the market, also giving Mutual further reasons to be aware of Mylan's filing with the FDA.

[70] *See* Letter from Janet Woodcock, Dir. Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Robert Dettery, Vice President, Regulatory Affairs, Mut. Pharm. Co. (Apr. 17, 2008), https://www.regulations.gov/document?D=FDA-2007-P-0123-0009 [hereinafter *Response*].

[71] *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 52–53. Rather conveniently, as a currently approved seller of generic felodipine, Mutual would be free to continue selling using the existing labels during the FDA's review process. *Id.* at 53.

[72] *See* Response, *supra* note 70, at 4. For example, the response commented on how the 2001 study was published well before Mutual's own generic application, yet Mutual claimed to not have become aware of the 2001 study until 2007 and there was the threat of competition. *Id.* at 3.

[73] *Id.* at 1.

[74] *See Id.*

[75] For the effects on cost for consumers, sales of Plendil—the brand-name version of felodipine—still totaled $251 million in 2017, even with the presence of two generic versions on the market for the majority of year. Thus, the brand-name manufacturer's success in the relative highly competitive market further shows Mutual stood to make millions even by a slight one-month or two-month delay in the approval of the second generic manufacturer. Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 54; *see also* Michael Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 252 (2012) (detailing a citizen petition delayed the generic

Examining historical trends in the use of citizen's petitions further shines light on the issue, suggesting that petitions like Mutual Pharmaceuticals' are not one-off events. The early 2000s saw an increase in the number of total yearly citizen's petitions, along with the number of petitions that had the potential to delay generic entry into the market.[76] In 2010, over 20% of citizen's petitions filed had the potential to delay generic entry into the market, with percentages consistently reaching the high teens in preceding and subsequent years.[77] As to the specific filing time of the petitions in relation to the timeline of the FDA generic drug approval process, the majority were filed less than six months from the date of the generic drug's approval.[78] Considering that the average length of time from generic filing to approval is about four years, the fact that most citizen's petitions are filed less than six months from approval is telling: by raising concerns at the last minute, rather than early or midway through the approval process, these petitions clearly have the potential to extend the length of the generic approval process and delay market entry of generic competition.[79]

C. Product Hopping

As previously mentioned, once a generic enters the market, sales and profits for the brand-name counterpart drop significantly. Further, even in the event a physician prescribes a brand-name drug when a generic equivalent is readily available, brand-name manufacturers still do not benefit. Known as Drug Product Selection (DPS) laws, every state permits pharmacists to fill physician-prescribed brand-name drugs with the generic equivalent instead, provided there is a generic equivalent available for the prescribed brand-name drug.[80] While great for generic

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version of the depression drug Welbutrin XL by 133 days, which cost consumers roughly $600 million).

[76] *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 71.

[77] *Id.* at 72.

[78] *Id.* at 75.

[79] *Id.* To further expand on this point, the FDA employs a 180-day time limit for responding to citizen's petitions. This 180-day period—which equates to six months—aligns with the category in which potentially delaying petitions were filed, that between 0–6 months before generic approval. This strongly supports the conclusion that many of the citizen's petitions may be the last barrier to final generic approval. *Id.* at 77.

[80] *See* Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. *1471, *1479–480 (2008); *see* Alison Masson & Robert L. Steiner, FTC, Generic Substitution and Prescription
Drug Prices: Economic Effects of State Drug Product Selection Laws 1 n.l; *see* Bureau of Consumer Prot.,

manufacturers, the brand-name manufacturers had a response of their own: product hopping.

Recall that, through the Abbreviated New Drug Application pathway, the Hatch-Waxman Act eliminated the long and expensive clinical trial requirement for generic drugs, instead only requiring proof that the new generic drug was both pharmaceutically equivalent and bioequivalent to the brand-name counterpart.[81] It then follows that if the brand-name manufacturer alters the formulation of the drug such that a new version is no longer bioequivalent to the old version, the brand-name manufacturer creates a situation where the generic drug of the old formulation is also not bioequivalent to the new formulation either.[82] Thus, because the new brand-name drug and the generic drug are no longer bioequivalent, pharmacists are no longer able to substitute the generic equivalent for the brand-name drug when physicians prescribe the brand-name drug.[83] To further suppress the generic, if the brand-name manufacturer kills demand for its old formulation—meaning physicians no longer prescribe it—the brand-name manufacturer likewise kills demand for the rival generic.[84]

When the brand-name manufacturer alters the formulation of its drug, the generic manufacturer has limited options, each with only mild benefits. First, in the effort to continue enjoying the valuable sales-generating generic substitution, the generic manufacturer can follow the "hop," developing a new generic version of the new formulation. However, this requires starting the drug development process from square one again: the generic manufacturer must first develop the generic version of the new formulation and then proceed through the

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FTC, Drug Product Selection 155–62 (1979) (examining the differences between major types of state DPS laws); *see also* Eric L. Cramer & Daniel Berger, *The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs*, 39 U.S.F. L. REV. 81, 116 n.116 (2004) (distinguishing state DPS laws that merely permit pharmacists to substitute generics for brand-name drugs from state DPS laws that require pharmacists to substitute generics).

[81] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98–417, § 101, 98 Stat. 1585, 1585–92 (1984) (codified as amended at 21 U.S.C. § 3550) (2012)).

[82] *See* Cheng, *supra* note 80, at 1488.

[83] *Id.*; *see also* Guy V. Amoresano, *Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground*, 62 FOOD & DRUG L.J. 249, 251 (2007) (describing that the "reformulation strategy . . . prevents [generic] drug[s] from being dispensed by pharmacists as an AB-rated substitute to fill prescriptions written for the brand drug [when the new formulation is prescribed]").

[84] *See* Cheng, *supra* note 80, at 1488. This is because the generic drug no longer receives the benefit of the state DPS law.

ANDA approval process again.[85] By subjecting the generic manufacturer to the relatively time-consuming approval process for a second time—and potentially a new round of patent litigation—the brand-name "product hopper" enjoys several more years of insulation from generic competition, leading to sizable gains.[86] Even if the generic manufacturer is successful in "hopping" to the new formulation, nothing is stopping the brand-name manufacturer from "hopping" again onto a third formulation, requiring the generic manufacturer to repeat the approval for a third time.[87] A second, alternative approach to following the product hop involves the generic manufacturer selling its version of the old formulation under its own separate brand name.[88] However, as the ensuing example will demonstrate, it is not common for the generic manufacturer's branded version of the old formulation to succeed, as the generic manufacturer's advertising and marketing abilities commonly pale in comparison to the rival brand-name manufacturer's abilities.[89]

In 1998, Abbott Laboratories, with assistance from Fournier Industrie et Sante, marketed TriCor, the branded version of the cholesterol-lowering drug fenofibrate.[90] Then, only one year later in 2000, Teva Pharmaceutical, a generic manufacturer, filed its own ANDA, looking to launch its own generic into the market. Likely in response to the ANDA filing, Abbott and Fournier in 2001 altered the TriCor formulation, changing the product from a capsule to a new tablet formulation. Additionally, the original capsule formulation was removed by Abbott and Fournier from the market, meaning Teva's generic, which was an equivalent of the original capsule formulation, could not receive the benefit of state DPS laws.[91] Through the product hop, Abbott and

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[85] *Id.* For a broader overview of the process, *see supra* notes 22–26 and accompanying text.
[86] *Id.* Recall, if the brand-name manufacturer induces patent infringement litigation in a timely manner, it can trigger a thirty month stay, barring the generic manufacturer from the market. 21 U.S.C. § 355(j)(5)(B)(iii) (2012); *see also* Hemphill, *supra* note 42, at 1566 (explaining how the delay may last more than three years).
[87] *See* Cheng, *supra* note 80, at 1489.
[88] *Id.* at 1495.
[89] *Id.* Because brand-name pharmaceutical manufacturers typically have far greater resources available than the generic counterpart, the brand-name manufacturer easily diverts consumers to its new formulation, instead of the branded generic released by the generic manufacturer.
[90] *Id.* at 1491. TriCor was highly successful, with annual sales hovering around $750 million per year. *Id.*
[91] *Id.* at 1492.

Fournier had successful prevented Teva from benefiting from generic substitution of TriCor.[92]

However, Teva did not backdown easily: electing the first option mentioned above, Teva followed the hop itself and again applied for FDA approval, this time in 2002.[93] Then, like before, Abbott and Fournier hopped again, this time developing a new tablet formulation for TriCor that did not need to be taken with food.[94] Again removing the old formulation from the market, Abbott and Fournier were successful in hindering the competition, with nearly 100% of patients on the old formulation switching to the second, new formulation.[95] Instead of following the hop a second time, Teva elected the second option mentioned above and decided to market the generic formulation under its own brand name, Lofibra.[96] However, due to its limited marketing ability coupled with the lack of generic substitution, Teva's sales of Lofibra were a fraction when compared to Abbott's and Fournier's sales: only about $4 million per year. [97]

Having effectively eliminated generic competition, Abbott and Fournier highlight the anticompetitive nature of product hopping while also showing the extent to which brand-name pharmaceutical manufacturers will go to prevent generics from entering the market.[98] The problem in preventing this type of behavior is that brand-name manufacturers are under little legal obligation to help their generic competitors by restricting formulation changes that in theory better meet consumer preferences.[99] Further, a brand-name manufacturer is under no obligation to continuing the sale of old formulations of its drugs.[100]

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[92] Had Abbott and Fournier not altered the formulation of TriCor, then whenever TriCor was prescribed by physicians, Teva would receive benefit of the DPS laws, resulting in its generic being substituted in place of the branded TriCor.
[93] *See* Cheng, *supra* note 80, at 1493.
[94] *Id.*
[95] *Id.*
[96] *Id.* This action taken by Teva was necessary as, similar to before, it could no longer rely on generic substitution to fuel sales because Abbott's and Fournier's new formulation was no longer bioequivalent to Teva's second generic.
[97] *Id.*; *see also* Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 416 (D. Del. 2006).
[98] Importantly, Abbott's and Fournier's actions did not escape antitrust scrutiny. *See* Abbott Labs., 432 F.Supp. 2d at 413. In opting against a *per se* legal approach in determining the legality of the product hopping, the Court instead weighed the modification's anticompetitive effects to see if they outweighed its benefits. *Id.* at 422. Thus, like challenges to the pay-for-delay agreements, product hopping issues tend to result in lengthy and expensive litigation.
[99] *See* Cheng, *supra* note 80, at 1494.
[100] *Id.* at 1495. *See also* Image Tech. Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1216 (9th Cir. 1997) (highlighting that there was "no reported case in which a court has imposed antitrust liability for a unilateral refusal to sell or license a patent or

D. Authorized Generics

To achieve its goal of increasing the number of generic pharmaceuticals on the market, the Hatch-Waxman Act, through its central incentive—the 180-day exclusivity period awarded to the first generic manufacturer to file a Paragraph IV certification and win regulatory approval—has achieved success.[101] However, that is not to say the Hatch-Waxman Act is without flaw: the 180-day exclusivity period has a significant carve-out, that of the brand-name manufacturer itself.[102] By simply notifying the FDA—neither an Abbreviated New Drug Application or separate New Drug Application is required—the brand-name manufacturer is able to side-step the generic manufacturer's 180-day exclusivity period and create direct competition in the generic market immediately via use of the "authorized" generic.[103]

At first glance, one might see no harm in allowing these "authorized" generics—generic versions of brand-name drugs coming directly from the brand-name manufacturer itself—to encroach on one of the most significant benefits to being the first generic manufacturer to enter the market. After all, the introduction of not one, but two generic versions of the branded drug only seem to spur competition in the market, not hinder it. While it does seem strange that a unique carve-out has been given to brand-name manufacturers—who already possess significant leverage—should it matter that the source of the "authorized," and second generic on the market, is the brand-name manufacturer itself, and not another purely-generic manufacturer?

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copyright"); *In re* Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1328 (Fed. Cir. 2000) (holding that patent holders are immune from antitrust claims for their refusals to license or use their patent rights).

[101] *See* Feldman, *supra* note 1, at 390. In 1995, 43% of all dispensed prescription drugs were generics. This number increased to 89% in 2016, showcasing how the Hatch-Waxman Act has altered the pharmaceutical landscape since its inception. *Id.*

[102] *Id.* This was not without challenge, however. In 2004, Teva Pharmaceuticals and Mylan, both generic drug manufacturers, filed petitions with the FDA that requested the agency prohibit distribution of generics produced by the brand-name manufacturers during the 180-day exclusive period. After the FDA rejected the petitions, two legal challenges followed. *Id.* at 391. The Court of Appeals for the D.C. Circuit agreed with the FDA's interpretation of the Hatch-Waxman Act, holding that the Act does not prohibit New Drug Application holders from marketing captive generics during the exclusivity period. Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 55 (D.C. Cir. 2005). Similarly, the Court of Appeals for the Fourth Circuit affirmed that the Hatch-Waxman Act does not give the FDA the power to ban generics produced by the brand-name manufacturer during the 180-day exclusivity period. Mylan Pharm., Inc. v. U.S. FDA, 454 F.3d 270, 271 (4th Cir. 2006). With *Teva* and *Mylan* both backing the FDA, federal courts helped cement authorized generics as a fixture in the pharmaceutical industry.

[103] Feldman, *supra* note 1, at 390.

The simple answer is yes, it does matter that the source of the generic is the brand-name manufacturer itself. First, when comparing drug markets containing an authorized generic with those markets that do not, the markets with the authorized generic tend to have increased prices for both the generic and brand-name version of the drug.[104] While brand-name drug prices tend to increase over time due to natural inflationary effects—whether or not an authorized generic is present in the market—it appears the presence of an authorized generics accelerates the price increase significantly.[105] Second, and more concerning, the presence of an authorized generic generally inflated the price of the generic competitors in its first three years on the market, resulting in markedly higher generic drug prices for consumers.[106] Clearly, the presence of a direct generic competitor decreases sales of the true generic. Thus, in order to compensate for the lower sales, a higher price is necessary.[107]

Along with the effects on net generic prices, the presence of an authorized generic tends to alter the composition of generic drug markets.[108] It was found that as other true generics are approved and launch into a particular drug market, they cut into other true generics'—and not the authorized generic's—market share, leaving the authorized generic's share unaltered.[109] This strongly suggests authorized generics are better than true generics at penetrating generic markets, likely due the sales and marketing relationships cultivated through their brand-name drugs and market prowess. Thus, it is evident that the presence of authorized generics in generic drug markets has undesirable effects, with the most concerning being the effect on generic drug prices.

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[104] *Id.* at 415.
[105] *Id.* at 416. When an authorized generic was not present in a particular market, the brand-name drug net price rose an average of 6% in the first three years following the launch of a true generic. Conversely, when an authorized generic was present, the growth in the net price of the brand-name drug increased to 21%. *Id. See also* Inmaculada Hernandez et al., *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018*, 323 JAMA 854, 854 (2000) (researching the changes in brand-name drug net prices from 2007 through 2018).
[106] *See* Feldman, *supra* note 1, at 416. In the first year, true generics generally saw an increase of around 11% due to the presence of an authorized generic. The price of the true generic generally saw an additional 4% increase in net price when an authorized generic was available. *Id.*
[107] *Id.* at 417.
[108] *Id.* at 408. For example, generic manufacturers generally saw a 22% decrease in combined market share over the first three years due to presence of an authorized generic. *Id.*
[109] *Id.*

III. MOVING FORWARD

As discussed in Part III.A, the Supreme Court opened pharmaceutical manufacturers up to antitrust liability when evaluating pay-for-delay settlements, even when they fell within the scope of the exclusionary potential of a patent.[110] However, it is not clear that the standard for evaluating behavior under the Sherman Act—the Rule of Reason test—is a meaningful limit on brand-name manufacturers engaging in anticompetitive behavior.[111] By simply not offering cash, it appears brand-name manufacturers may be successful in side-stepping the restrictions implemented by the courts.[112]

As discussed in Part III.B, the citizen petition system allows for the possibility of abuse by pharmaceutical manufacturers, allowing for the warping of the system meant to serve as a check on the FDA into a method of delaying competition. The challenge is distinguishing petitions seeking to raise valid concerns, from those that only carry the appearance of validity and nothing more. Thus, absent change to the

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[110] *See* FTC v. Actavis, Inc., 570 U.S. 136 (2013).

[111] Some commentators have described the Rule of Reason test as complex and burdensome, placing a high burden on the plaintiff. *See* Feldman, *Pricetag*, *supra* note 42, at 13. Although some do argue that *Actavis* has resulted in the end of pay-for-delay, others note that *Actavis* only further incentivized pharmaceutical manufacturers to create more complex agreements in an effort to sidestep antitrust scrutiny. *See* Lauren Krickl & Matthew Avery, *Roberts Was Wrong: Increased Scrutiny After* FTC v. Actavis *Has Accelerated Generic Competition*, 19 VA. J.L. & TECH. 509, 547 (2015); *see also* Feldman, *Pricetag*, *supra* note 42, at 12. Some argue that the FTC's observation of a decline in anticompetitive pay-for-delay agreements post-*Actavis* largely stemmed from its inability to categorize most settlements between brand-name and generic manufacturers, not because the actual number of agreements was declining. *See* Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 260–65 (2019).

[112] Because of the way lower courts have applied the language of *Actavis*, a plaintiff is generally required to show that the generic manufacturer agreed to not use the patented, brand-name drug and that the generic manufacturer received an unexplained payment from the brand-name manufacturer. Thus, alternative agreements that achieve the same anticompetitive outcomes may pass through the courts without challenge due to cleverly drafted contracts that do not allow for unexplained payments from the brand-name manufacturer. *See* Aaron Edlin, et al., *Activating Actavis*, 28 ANTITRUST 16, 18 (2013). For example, the brand-name manufacturer could "overpay" the generic manufacturer for marketing services the generic manufacturer is not equipped to tender, much like Solvay's agreements with Actavis, Paddock, and Par. Additionally, the brand-name manufacturer could allow the generic manufacturer to make and sell other drugs in its portfolio, thus diverting the competition to a different drug market. *See* Feldman, *Pricetag*, *supra* note 42, at 15. Further strategies include leveraging the threat of introducing an authorized generic to compete directly with the generic manufacturer's drug during the 180-day exclusivity period. By agreeing not to market its own generic, the brand-name manufacturer effectively pays for the generic manufacturer's delay into the market. *See generally* Feldman, *Captive Generics*, *supra* note 1.

current system, petitions filed for the purpose of delaying entry of generic competition are free to exist without penalty to those that file them.[113]

As discussed in Part III.C, product hopping by brand-name manufacturers seriously undercuts the success of a generic drug once launched on the market, forcing generic manufacturers to adapt or risk being left behind. Further, brand-name manufacturers are under little legal obligation to help their generic competitors by restricting formula changes, nor are they under any obligation to continue the sale of old formulations of the branded drugs after a new formulation has been developed.[114] Thus, actions outside the judiciary are essential to curb the practice.[115]

As discussed in Part III.D, the Hatch-Waxman Act's failure to prevent brand-name manufacturers from launching their own generics into the market during the 180-day exclusivity period awarded to the first generic filer poses unique threats to the composition of generic drug markets. Given that the interpretation of the Hatch-Waxman Act seems settled,[116] like that of product hopping, actions outside the judiciary are necessary to resolve the issue.

A. Disclosure as the First Step

From pay-for-delay agreements to questionable citizen petitions to product hopping and finally authorized generics, it is clear brand-name pharmaceutical manufacturers are willing to go to great lengths to prevent competition from entering the market. The benefit to the brand-

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[113] Although the FDA does have the power to summarily deny any petition filed with the primary purpose of delaying generic approval if the petition does not also raise valid scientific or regulatory concerns, it is not difficult for petitioners to weave seemingly valid concerns into the petitions. Further, it is not common for the FDA to summarily deny petitions, failing to do so even once from 2007 through 2014. *See* 21 U.S.C. §355(q)(1)(E) (2012); *See also* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 88.

[114] *See* Cheng, *supra* note 80, at 1494. *See also* Image Tech. Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1216 (9th Cir. 1997); In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1326 (Fed. Cir. 2000).

[115] Although brand-name manufacturers still are open to antitrust litigation, because of courts' failure to apply a *per se* rule against product hopping, any attempts to police brand-name manufacturers' actions will require significant resources, in the form of time and money. *See generally* Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006).

[116] *See* Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 55 (D.C. Cir. 2005) (holding that the Hatch-Waxman Act does not prohibit New Drug Application holders from marketing captive generics during the exclusivity period); *see* Mylan Pharm., Inc. v. U.S. FDA, 454 F.3d 270, 271 (4th Cir. 2006) (holding the Hatch-Waxman Act does give the FDA the power to ban generics produced by the brand-name manufacturer during the 180-day exclusivity period).

name manufacturers is so great, that—in the words of one expert on the topic— "significant effort by competition authorities" is required to prevent the issues.[117] However, given that brand-name pharmaceutical manufacturers possess great leverage coupled with tremendous resources, they have the unique ability to bend and adapt in response to whatever the judiciary or legislature throws their way. Thus, in order to begin to remedy the higher prices caused by the anticompetitive tactics discussed, more specific and detailed information on each of the four issues is required. The following text outlines legislative and regulatory solutions meant to help remedy all four issues discussed.

Outside the obvious band-aid type legislative solutions that immediately address the raised issues,[118] the crucial first step towards eliminating the anticompetitive practices altogether is robust transparency mandates. Whether achieved through legislative or regulatory action, by forcing pharmaceutical manufacturers to reveal information whenever engaging in an action related to the release of a drug into the market, critical insight on the various anticompetitive practices will be gained.[119] Thus, by shining a light directly on the actions of brand-name manufacturers, legislators and regulators will then have the knowledge to cure the current anticompetitive practices while—more importantly—also remaining flexible to bend and adopt to any future

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[117] *See* Feldman, *Pricetag*, *supra* note 42, at 43.

[118] To curb the practice of pay-for-delay, the incentive structure of the Hatch-Waxman Act could be altered. For example, legislation could be enacted that strips the first generic filer of the 180-day exclusivity period in the event that patent infringement between the brand-name and generic manufacturer settles. *See* Feldman, *Pricetag*, *supra* note 42, at 46–47. To curb the practice abusive citizen petitions, a simple ban preventing competitors from filing citizen petitions related to generic applications would solve the issue. *See* Feldman, *Citizen's Pathway Gone Astray*, *supra* note 3, at 86–87. To curb the practice of product hopping, alterations to state DPS laws could provide for approved generics to still receive the benefit of the DPS laws with respect to the new formulations of the brand-name drug, provided the reason for the formula alteration was not due to some underlying problem with the original. To curb the practice of brand-name manufacturers releasing authorized generics during the first-filer generic's 180 exclusivity period, legislation could be enacted that simply prohibits brand-name manufacturers from releasing their generics into the market during that time. *See* Feldman, *Captive Generics*, *supra* note 1, at 420–21. Although the aforementioned solutions would have immediate effects, with time, pharmaceutical manufacturers will likely devise methods for curtailing the solutions. Thus, solutions that cut to the root of the issue are necessary to completely prevent the issues.

[119] Additionally, increased disclosure will result in increased public scrutiny of pharmaceutical manufacturer's actions. Although pharmaceutical companies generally are already under a microscope by the public and lawmakers, it is clear the current disclosure requirements are insufficient for drawing necessary information to effectively circumvent the issues. *See* Feldman, *Drug Wars*, *supra* note 2 and accompanying text; *See also* Feldman, *Pricetag*, *supra* note 42, at 47.

anticompetitive practices devised in response to future changes in the law.

Similar to how original proponents of federal securities legislation observed something was adrift with unregulated public company disclosure practices,[120] the current opacity of information with regard to pay-for-delay settlements, citizen petitions, product hopping, and authorized generics accentuates failure in pharmaceutical markets.

For example, by requiring strict disclosure requirements whenever a brand-name manufacturer settles an infringement lawsuit with a generic manufacturer, concrete data regarding the value of the agreement and the drug products at issue will become easily accessible. This in turn will fuel outside investigators, like antitrust enforcers and civil attorneys, that will hold the brand-name manufacturers accountable for their anticompetitive tactics. Similarly, increased information will help curb abusive citizen petitions by allowing the FDA to quickly dismiss those that lack merit.[121] With respect to product hopping, explicit acknowledgement of the effects of minute formulation changes by the brand-name manufacturers will draw scrutiny, while also drawing increased awareness of the practice.[122] And lastly, detailed information highlighting every connection a brand-name manufacturer has with the corresponding generic market for its brand-name drug will provide invaluable information for legislators and regulators to craft law ensuring the integrity of generic drug markets.[123]

In addition to the benefits gained from the specific information disclosed, the requirement of disclosure itself serves as an important check on pharmaceutical companies. As evidenced in federal securities law, a failure to comply with the disclosure requirements allows individual investors to bring direct civil lawsuits to hold the company's

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[120] *See generally* Michael D. Guttentag, *An Argument for Imposing Disclosure Requirements on Public Companies*, 32 FLA. ST. U. L. REV. 123 (2004).

[121] Additionally, regulation allowing the FDA to impose penalties on citizen petitions which lack merit would further strengthen the disclosure requirement, reducing the number of citizen petitions which have the potential for generic delay.

[122] Further, disclosure requirements by generic manufacturers with respect to the number of sales generated from state DPS laws will provide increased ammunition for outside investigators to bring lawsuits holding brand-name manufacturers to account for their actions.

[123] Although a generic directly authorized by the brand-name manufacturer is the most explicit example of a brand-name manufacturer's influence on the generic market, increased information will help shine light on other more complex and nonobvious arrangements—like multi-company licensing arrangements touching other drugs in a brand-name manufacturer's portfolio—currently in place. Then, once the true scope of the issue is evident, further legislation and regulation is possible.

managers in check.[124] Applying this theory to the proposed disclosure requirements for pharmaceutical manufacturers, a failure to comply with such disclosure requirements will open the manufacturer up to civil liability. Further, the mere failure to comply will prove valuable by providing outside investigators with easy targets to scrutinize and challenge. Thus, brand-name manufacturers will have a great inventive to comply to avoid further scrutiny.

B. Limitations

First, legislation or regulation mandating robust disclosure requirements will not lead to immediate solutions. Moreover, it will likely take years of disclosure to properly craft specialized legislation and regulations that eradicate the anticompetitive practices altogether. Thus, in the meantime, brand-name manufacturers remain free to engage in the anticompetitive practices, with consumers suffering in the form of increased drug prices.

Second, increased disclosure requirements will increase operating and litigation costs on pharmaceutical manufacturers. Much like how publicly traded companies are subject to the added cost of producing audited financial documents, pharmaceutical manufacturers will incur higher legal costs to ensure compliance with the disclosure requirements. Similarly, any instance of suspected non-compliance will result in costly litigation expenses for the manufacturers. This in turn will result in higher drug prices for consumers to compensate for the added costs.

CONCLUSION

The Hatch-Waxman Act relies on a series of important incentives to achieve its goal of promoting generic competition in pharmaceutical markets, while simultaneously balancing brand-name manufacturers' interest in profit. Although profit motive is a powerful incentive for innovation, it also incentivizes those with leverage—the brand-name manufacturers—to hijack the system directly responsible for their decreased profits by means of generic drug competition. Instead of facilitating the end of improper pharmaceutical patents, mutually beneficial pay-for-delay agreements are entered into that only serve to keep brand-name drug prices higher for longer. Instead of accepting defeat, the citizen petition process is warped to further delay generic

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[124] *See generally* Janet Cooper Alexander, *Do the Merits Matter? A Study of Settlements in Securities Class Actions*, 43 STAN. L. REV. 497 (1991).

entry in any way possible. Instead of pursuing real innovation, resources are devoted to creating trivial variations in drug composition to eliminate generic competitors. And finally, instead of allowing true competition, authorized generics are launched to alter the composition of generic drug markets.

As one expert in the field noted, "[t]he law must become as nimble and creative as these complex schemes."[125] Thus, to discourage the increasingly complex anticompetitive maneuvers by brand-name manufacturers, increased and recurring information is essential. By shining light directly on the harmful tactics and drawing scrutiny upon companies that employ such tactics, the stage for future change is set. Only then will the anticompetitive practices be ended once and for all.

[125] *See* Feldman, *Pricetag*, *supra* note 42, at 48.