#### Theory after phil

### FW

#### Perspectivism is true –

#### 1] Opacity – we can never access another person’s perspective because we can never fully understand who someone else is or what they think. Every truth I create cannot be universalized because I can’t guarantee that they will create the same truth because they do what they want.

#### 2] Resolvability – Centuries of moral debate proves we can’t come to an objectively correct answer so it has to be indexed to individual subjects. High school debaters can’t come to a correct conclusion on their own and moral dilemmas are too complicated to “solve” in 45 minutes, so you should prefer a perspectivist account.

#### 3] Subjectivity only has meaning when it interacts with other machines – there are no intrinsic values and a failure to recognize that stratifies subjects and reifies violence.

**Malins 04** [Brackets Original. Peta Malins (Program Manager of the Bachelor of Legal and Dispute Studies and a Lecturer in Criminology and Justice Studies @ RMIT University). “Machinic Assemblages: Deleuze, Guattari and an Ethico-Aesthetics of Drug Use”. The University of Melbourne. 2004. Accessed 2/19/21. http://janushead.org/wp-content/uploads/2020/06/Malins.pdf //Xu]

As an assemblage, a [drug using body] has only itself, in connection with other assemblages and in relation to other bodies without organs. We will never ask what a [drug using body] means, as signified or signifier; we will not look for anything to understand in it. We will ask what it functions with, in connection with what other things it does or does not transmit intensities, in which other multiplicities its own are inserted and metamorphosed, and with what bodies without organs it makes its own converge. A [drug using body] exists only through the outside and on the outside. A [drug using body] itself is a little machine (Deleuze and Guattari, 1988: 4)1 The work of Deleuze and Guattari is perhaps best conceived of as a ‘tool box’2 –as a collection of machinic concepts that can be plugged into other machines or concepts and made to work. This is how I approach their writing, and why–despite initial misgivings–I have transformed the above excerpt (surreptitiously replacing the concept ‘book’ with ‘drug using body’) to suit the purposes of this paper. In making this transformation, I soon discovered that it became a perfect little language-machine: not only articulating where I want to take the concept of drug use, but also [through its parentheses] expressing the open applicability of Deleuze and Guattari’s work. Insert body of choice: a sexual body; a bicycle, a language; a body of art; a film–the excerpt works for them all. In this openly mutating state the passage introduces some of the key concepts in Deleuze and Guattari’s philosophical project: becomings, rhizomatic connections, and multiplicities. It also, more explicitly, outlines their project to take thought (and ethics) away from internal meanings, causes, and essences, and toward surface effects, intensities and flows. However it is the particular concept of the body activated by the excerpt–the concept of the body as machinic assemblage–that I find most useful to the task of rethinking drug use. It is a concept that unravels the modern fantasy of the body as a stable, unified, bounded entity, and gives a language to the multitude of connections that bodies form with other bodies (human and otherwise). A body’s function or potential or ‘meaning’ becomes entirely dependent on which other bodies or machines it forms an assemblage with. Colebrook’s (2002) example of the bicycle is useful here: a bicycle is a machine that doesn’t begin to work or have a particular meaning until it connects up with another machine. When it connects up with a cyclist, it becomes a vehicle; when is placed in a gallery, it becomes an artwork. A cigarette is similarly multiple: when smoked it becomes a drug; when held seductively at the end of ones fingertips it becomes an object of beauty; when shown in a film it becomes a plot device (Klein, 1993). And a drug using body is no different: when it connects up to bicycle, it becomes a cyclist; to a cigarette, a smoker; to LSD, a tripper. The drug using body is multiple. While numerous writers have begun to make movements toward rethinking drug use via Deleuze and Guattari3 , very few have explored this intersection in detail4 . In this paper I will map out some of the specific implications of rethinking the drug using body in this way. I will begin by exploring what happens to the subject (the ‘drug user’, the ‘addict’) when the body becomes a multiplicity. Like Deleuze and Guattari: I will not ask what a drug using body ‘means’ or signifies; but rather, what affects its assemblages produce and what flows of desire they cut off (its components and affects). I will then explore Deleuze and Guattari’s own particularly bleak conception of drug-use, arguing that the pessimism it engenders can be strategically sidestepped using Deleuze and Guattari’s other philosophical tools. I will explore how we might productively approach drug use via a Deleuzian ethics, and will argue for a specific ethical rethinking of drug use according to the concepts of the machinic assemblage and rhizomatic multiplicities. A strategy with implications not only for social policy, but also for how we understand ourselves. And who we might become. Subjectivity and the drug using body Bodies that fall prey to transcendence are reduced to what seems to persist across their alterations. Their very corporeality is stripped from them, in favor of a supposed substrate–soul, subjectivity, personality, identity–which in fact is no foundation at all, but an end effect, the infolding of a forcibly regularized outside. (Massumi, 1992: 112) For Deleuze and Guattari a body (human, animal, social, chemical) has no interior truth or meaning; it exists only through its external connections and affects. They write: We know nothing about a body until we know what it can do, in other words, what its affects are, how they can or cannot enter into composition with other affects, with the affects of another body. (ATP5 : 257) So where does this leave the subject? And identity? If we are to talk only of the drug using body and its multiplicities–where does the ‘drug user’ or ‘addict’ disappear to? For Deleuze and Guattari the subject is nothing more (and nothing less) than a particular way in which bodies have become organised and stratified in the post-Enlightenment social world. In order to comprehend the ‘human’ body, the social world (or socius) reduces the complexity and chaos of an ever-changing multiplicity of bodily flux to discrete categories of meaning and constancy. Bodies become ordered and delimited according to hierarchical binary presuppositions: human/animal, man/woman, healthy/unhealthy, lawful/criminal, hetero/gay, clean/junkie. Binaries that bodies never fully correspond to: No real body ever entirely coincides with either category. A body only approaches its assigned category as a limit: it becomes more or less “feminine” or more or less “masculine” depending on the degree to which it conforms to the connections and trajectories laid out for it by society… “Man” and “Woman” as such have no reality other than that of logical abstraction. (Massumi, 1992: 86) Yet when bodies fall outside these binaries, or try to claim a different identity, they are rarely granted anything outside a third term (‘bi-sexual’, ‘reformedsmoker’) that remains reliant upon, and limited to, those binary relations. Multiplicities reduced to binaries and trinities. Manifold potential reduced to a discrete set of bodily possibilities. You will be a boy or a girl; a smoker or a non-smoker; a civilized human being (with all bodily parts fulfilling civilized ‘human’ functions)’ or an animal. Your choice. You will subscribe to modern selfhood (and all its bodily and linguistic demands) or you’ll be rejected: You will be organized, you will be an organism, you will articulate your body–otherwise you’re just depraved. You will be signifier and signified, interpreter and interpreted–otherwise you’re just a deviant. You will be a subject, nailed down as one, a subject of the enunciation recoiled into a subject of the statement–otherwise you’re just a tramp. (ATP: 159)

**This commits us to practical deliberation as the method of moral inquiry   
Serra 09**Juan Pablo Serra. What Is and What Should Pragmatic Ethics Be? Some Remarks on Recent Scholarship*.* EUROPEAN JOURNAL OF PRAGMATISM AND AMERICAN PHILOSOPHY. 2009. Francisco de Vitoria College, Humanities Department, Faculty member. https://journals.openedition.org/ejpap/905

This separation of theory and practice runs parallel to another split, namely, that of ethics and morals or, better put, of ethical theory and moral practice. Peirce denies that morality is subject to rationality and thinks that ethics is valuable as a science in a broad sense. But he also regards ethics as a science which bears on human conduct only indirectly, through the examination of past actions and the self-correction of the self in view of future action. In addition, ethics would be a normative knowledge only in so far as it analyzes the adjustment of actions to ends and in so far as it studies the general way in which a good life can be lived. In morals Peirce appeals to instinct and sentiment, and in ethics he recommends the use of logical thinking —just as scientists do. However, even within the framework of his system, it’s not obvious that scientists may so easily set aside their instincts —in fact, instinct (or ‘rational instinct’ as he called it in 1908) plays a significant role in the economy of re- search. Moreover, the statement that in moral issues there may be no possibility of carrying out an inquiry that is truth-oriented is not an uncontroversial one. After all, moral inquiry is performed in a deliberative way, weighing up argumentations, beliefs and principles, and comparing them either with their probable or conceivable consequences or with lived as well as possible experiences that can be forceful or impinge upon the deliberative subject in such a way as to acquire the compulsory resistance due to reality. As Misak puts it succint- ly, “the practice of moral deliberation is responsive to experience, reason, argument, and thought experiments... Such responsiveness is part of what it is to make a moral decision and part of what it is to try to live a moral life” (2000: 52)3. Likewise, this same deliberative activity implies an effort to acquire habits, beliefs and principles that contribute to a truly free deliberation which, in turn, can result in creative conclusions. For Peirce, as you get more habit-governed, you become more creative and free, and your selfhood acquires plas- ticity and receptiveness to experience4. Vincent Colapietro has referred to Peirce’s description of human reason in terms of a deliberative rationality (1999: 24). Also, in another place he has explained that deliberation for Peirce is a process of preparation for future action which has to do with the checking of previous acts, the rehearsal in imagination of different roads to be followed by possible conduct and the nurturing of ideals (Colapietro 1997: 270, 281). It is precisely this experi- ment carried out within imagination that generates habits, because, as Peirce says in “A Survey of Pragmaticism”, “it is not the muscular action but the accompanying inward ef- forts, the acts of imagination, that produce the habit” (CP 5.479, 1907). Habits are regular ways of thinking, perceiving and interpreting that generate actions. As such, habits have a huge influence on human behavior, manifest themselves in the con- crete things we do and, at the same time, are formed within those same activities. Even more, according to Peirce, the activity takes the form of experimentation in the inner world; and the conclusion (if it comes to a definite conclusion), is that under given conditions, the interpreter will have formed the habit of acting in a given way whenever he may desire a given kind of result. The real and living logical conclusion is that habit (CP 5.491, 1907). Much more evidence could be given to support the view that habits are virtually decided (CP 2.435, c.1893) and also that intelligence comprises inward or potential actions that in- fluence the formation of habits (CP 6.286, 1893). Suffice it to say that, according to Peirce, deliberation is a function of the imagination, and that imagination is in itself an experiment which may have unexpected consequences that impose themselves upon the deliberative subject.

#### Thus, the standard is consistency with pragmatic deliberation.

#### Impact Calc – deliberation is procedural, which means that agents ought to act in a deliberative fashion by employing the pragmatic procedure of deliberation, not the substance or conditions where deliberation can arise. To clarify, consequences are a sequencing question.

#### 1] Pluralistic Materialism – other theories rely on minimalistic criteria; our framework understands knowledge as changing and uses experience to base social change and revise ideas. Glaude 7Eddie S. (Eddie S. Glaude Jr. is the African-American chair of the Center for African-American Studies and the William S. Tod Professor of Religion and African-American Studies at Princeton University.) In a Shade of Blue : Pragmatism and the Politics of Black America. University of Chicago Press, 2007. EBSCOhost. (5-7)

In a Shade of Blue is my contribution to the tradition I have just sketched. My aim is to think through some of the more pressing conceptual problems confronting African American political life, and I do so as a Deweyan prag-matist. I should say a bit about what I mean by this self-description. John Dewey thought of philosophy as a form of cultural and social criticism. He held the view that philosophy, properly understood as a mode of wis-dom, ought to aid us in our efforts to overcome problematic situations and worrisome circumstances. The principal charge of the philosopher, then, is to deal with the problems of human beings, not simply with the problems of philosophers. For Dewey, over the course of his long career, this involved bridging the divide between science, broadly understood, and morals—a divide he traced to a conception of experience that has led philosophers over the centuries to tilt after windmills. Dewey declared, “The problem of restoring integration and co-operation between man’s beliefs about the world in which he lives and his beliefs about values and purposes that should direct his conduct is the deepest problem of any philosophy that is not isolated from life.”9Dewey bases this conclusion on several features of his philosophy: (1) anti foundationalism, (2) experimentalism, (3) contextualism, and (4) soli-darity.10 Antifoundationalism, of course, is the rejection of foundations of knowledge that are beyond question. Dewey, by contrast, understands knowledge to be the fruit of our undertakings as we seek “the enrichment of our immediate experience through the control over action it exercises.”11He insists that we turn our attention from supposed givens to actual consequences, pursuing a future fundamentally grounded in values shaped by experience and realized in our actions. This view makes clear the experimental function of knowledge. Dewey emphasized that knowledge entails efforts to control and select future experience and that we are always con-fronted with the possibility of error when we act. We experiment or tinker, with the understanding that all facts are fallible and, as such, occasionally afford us the opportunity for revision.12Contextualism refers to an understanding of beliefs, choices, and actions as historically conditioned. Dewey held the view that inquiry, or the pursuit of knowledge, is value-laden, in the sense that we come to problems with interests and habits that orient us one way or another, and that such pursuits are also situational, in the sense that “knowledge is pursued and produced somewhere, some when, and by someone.”13Finally, solidarity captures the associational and cooperative dimensions of Dewey’s thinking. Dewey conceives of his pragmatism as “an instrument of social improvement” aimed principally at expanding democratic life and broadening the ground of individual self-development.14Democracy, for him, constitutes more than a body of formal procedures; it is a form of life that requires constant attention if we are to secure the ideals that purportedly animate it. Individuality is understood as developing one’s unique capacities within the context of one’s social relations and one’s community. The formation of the democratic character so important to our form of associated living involves, then, a caring disposition toward the plight of our fellows and a watchful concern for the well-being of our democratic life.

#### 2] Best studies prove pluralistic tendencies are inevitable

Polzler 19[Thomas Pölzler and Jennifer Cole Wright- “Empirical research on folk moral objectivism” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6686698/> NCBI. Published July 5th 2019]

Examining these studies' results more closely, however, makes it less clear whether this interpretation is appropriate (Pölzler, 2018b). Take again Goodwin and Darley's study. In this study, almost 30% of subjects' responses to the disagreement measure and almost 50% of their responses to the truth‐aptness measure fell on the option that the researchers took to be indicative of subjectivism (Goodwin & Darley, 2008, pp. 1347, 1351). Moreover, while some moral statements were dominantly classified as objective (e.g., the above statement about robbery), many others were dominantly classified as nonobjective (e.g., the stem cell research statement). This suggests that subjects in Goodwin and Darley's study may have actually favored what Wright, Grandjean, and McWhite (2013) called “metaethical pluralism,” i.e., they sometimes sided with objectivism and other times with nonobjectivism. More recent studies have by and large confirmed this hypothesis of folk metaethical pluralism. Wright et al. (2013) and Wright, McWhite, and Grandjean (2014), for example, replicated Goodwin and Darley's results, using the exact same measures, but letting subjects classify the presented statements as moral and nonmoral themselves. Objectivity ratings for statements that were dominantly self‐classified as moral varied between as little as 5% and as much as 85%. Research based on different measures yielded high proportions of intrapersonal variation as well (e.g., Beebe, 2014; Beebe, Qiaoan, Wysocki, & Endara, 2015; Beebe & Sackris, 2016; Fisher, Knobe, Strickland, & Keil, 2017; Goodwin & Darley, 2012; Heiphetz & Young, 2017; Wright, 2018; Zijlstra, forthcoming‐a).2

#### 3] **Frameworks all share equal value. Weighing between them becomes infinitely regressive as it presupposes there is a higher metric to determine who has the better justifications. That means contestation is vacuous which means a locus of moral duty is sufficient since it has an uncontested obligatory power.**

#### 4] Performativity- when you enter debate, you presume that you can discuss the topic because of deliberation. This means denial of my framework is impossible and all objections should be ignored on face because responding to my framework requires my framework to do so.

#### 5] Topic Lit – a pluralistic foundation is a meta-concern for the particularities of IP – 2 warrants. TJFS first frameworks are essentially T debates about the word ought which proves the better model of debate is what matters.

Kanning 12 [Michael A. Kanning (Graduate School at University of South Florida). “A Philosophical Analysis of Intellectual Property: In Defense of Instrumentalism”. A thesis submitted in partial fulfillment of the requirements for the degree of Master of Arts Department of Philosophy College of Arts and Sciences University of South Florida. January 2012. Accessed 8/22/21. <https://digitalcommons.usf.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=5290&context=etd> //Xu]

In response to the insufficiencies of the classical arguments, recent works have offered a pluralistic theory of intellectual property. David Resnik suggests two positive reasons for adopting a pluralistic theory that adopts multiple normative foundations and justifying principles. First, because intellectual property is a broad and diverse field that encompasses different kinds of right that apply to different kinds of things, it is reasonable that different arguments are used to account for the diverse practices individually. Second, a pluralist theory allows for fruitful public discourse concerning intellectual property in a globalized world, where the participants in that discourse come from “different ethnic and cultural backgrounds and have different moral, philosophical and religious beliefs” (Resnik 331). A pluralistic account can overcome these disputes over foundations by encouraging a more contextual approach. To resolve IP disputes using the pluralist approach, “one must weigh and balance the different values that are at stake in the situation and determine which one should have priority” (331). How the values in a particular scenario are “ranked” can vary from one case to another. What is it then, that determines the ranking? Resnik suggests that contextual factors will make it clear what should be emphasized. As examples he suggests that in disputes about patents, utility should be emphasized because “the legal and social function of the patent system is to promote the progress of science and the natural arts”. In allocations of “intellectual credit” (i.e. academic citation practices, moral rights of authors), the interests that authors and creators have in being treated fairly should be of the highest importance (331). In these examples, though, it seems equally plausible that other values could be emphasized. Patents could be guided by an emphasis on the moral rights of the creator - they could be of unlimited term, for instance, and “intellectual credit” could be guided by utilitarian concerns (it might be that the art word would flourish if copying and imitation were totally unrestricted, both as law and in everyday practice). So what is it that guides the selection of emphasis in these cases?

#### 6] Causal relationships are complex which necessitates a pragmatic orientation towards international politics

Cairney and Geyer 17 [Paul Cairney (Department of History and Politics, University of Stirling, Great Britain) and Robert Geyer (Department of Politics, Philosophy and Religion, Lancaster University, Great Britain). “A critical Discussion of Complexity Theory: How does 'Complexity Thinking' improve our Understanding of Politics and Policymaking?” Complexity, Governance & Networks – Vol. 3, No 2 (2017), p. 1-11. Accessed 9/3/21. <https://core.ac.uk/download/pdf/77611972.pdf> //Xu]

In other words, a key challenge for complexity is its lack of a clearly developed normative framework. From a complexity perspective, so long as a system maintains core boundaries, is relatively stable and open, and encourages a wide variety of interactions, a plethora of particular structures and outcomes are possible. Detailed practical interventions and/or normative choices are uncertain. Yet, society (amplified by the mass media and willing political actors) continues to try to reassert a more causal/modernist policy position: someone must be in control and in democracies this should be our democratic representatives (and the bureaucratic machinery of national/regional/local policy that it is supposed to control). This implies a limited view of democracy where: The trend in political life is to insist on controlling responsibility by tightening the external standards of accountability. Yet the real problem of our public life is the failure of responsibility, not accountability. Increasing demands for accountability often obscure actual responsibility and enhance the gap between responsibility and accountability. (Ansell, 2011, p. 134) This dilemma of normative choice and democratic responsibility is not new and something that a variety of philosophic traditions have been wrestling with throughout the past two centuries – for example pragmatist philosophy (see the work of Dewey in particular). More recently, there has been a growing exploration of the overlaps between pragmatism and complexity. These overlaps have been touched upon by academics in different fields (Doll et al. 2005; Rescher 2003), but most importantly by the policy informed work of Sanderson (2002, 2006, 2009). For Sanderson, Dewey provided three relevant contributions. First, Dewey’s commitment to a continued “scientific” search for the “truth” through an engaged, democratic and open approach leads to policy making that is based on the best evidence “while recognising that such evidence does not constitute the final word” (Sanderson, 2009, p. 710). Second, mirroring the earlier Labour Government’s focus on “what works,” Deweyian pragmatism encouraged policy makers to view their actions as “policy hypotheses” that must be continually tested with the best evidence available and through democratic societal debate. Third, Sanderson pointed out that pragmatism: leads us to recognise that policy making is not a ‘technical’ exercise in instrumental rationality but rather a domain of ‘practical reason’… we are not just concerned with the ‘instrumental’ notion of ‘what works’ but rather with a broader ‘practical’ notion of what is ‘appropriate’ in the circumstances. (p. 711) Similar to complexity, pragmatism is based on an engaged view of democracy and society that does not know or propose a final societal outcome but knows that the best way forward is through an open, educated, democratic society engaged in continual learning and dialogue with itself (free expression, debate, speech and interaction) and its governmental structures. Pragmatism is the philosophy of “evolutionary learning” and “democratic experimentalism” (Ansell, 2011, p. 5). In essence, complexity provides a meta-theoretical position, linking the natural and human societies, while pragmatism provides a justification and framework for societal/public action in a complex and uncertain world. It is based on a reasonably optimistic vision of human rationality and a belief in that ability of well-intentioned individuals and societies to progress, in a generally positive direction, through discussion, learning, experimentation, debate and interaction. Being pragmatic in politics is not easy. It may be sensible to produce a range of measures based on a more realistic policymaking philosophy, and potential strategies include: relying less on centrally driven targets, and punitive performance management, in favour of giving local bodies more freedom to adapt to their environment; trial-and-error projects, that can provide lessons and be adopted or rejected quickly; and, to teach policymakers about complexity so that they are less surprised when things go wrong. Yet, as Tenbensel (2015) makes clear, these strategies should not be selected simply because we reject a caricature of top-down policymaking. One of the best practical applications of complexity and systems inspired policy thinking is found in the excellent 2011 UK Munro Review of Child Protection. Following a string of highprofile child abuse cases, Professor Eileen Munro was asked to carry out a wide-ranging and indepth review of UK child protection policy. Inspired by systems and complexity thinking, Munro produced an impressive document that highlighted the failings of the former well-intentioned but misguided approach that resulted in a tick-box culture and a loss of focus on the needs of the child. These weaknesses were further amplified by a media and public culture which demanded that ‘lessons must be learned’ and some individual or process must take responsibility/blame. The core problem, which the Review made clear, was that in highly complex situations there are no simple solutions, lines of responsibility or easy targets to blame. What made this situation even worse was a knee-jerk governmental response that demanded ever-growing targeting and audit regimes to show that “lessons” had really been learned. The difficulty, as the Munro Review aptly demonstrated, was that this did little for the actual protection of children, while greatly complicating the policy process of child protection. Hence, one of the key conclusions of her report was that there needed to be a radical reduction in central prescription in order to help social workers move from a compliance to a learning culture, and that we had to recognize that the larger societal pressures to find “someone to blame” (amplified by the mass media) misshaped the policy response to child protection.

#### 7] Ideal theory is good

#### 1] measurement – non-ideal theory is constantly changing and can’t challenge oppression since its impossible to measure something with a changing yardstick

#### 2] every theory can be misused – but that is a problem with us not with ethics which means we should reclaim the true function in places like debate to challenge the way they are misunderstood

#### 3] relevance – every society has different injustices that occur – the resolution is a universal values statement which means you cannot universalize any theory under nonideal theory

### Affirm

#### 1] IP laws prioritize uniformity and predictability as a method of homogenizing knowledge and refusing experimentation.

Wu 14 [Tim Wu (Julius Silver Professor of Law, Science and Technology at Columbia University). “Intellectual Property Experimentalism By Way of Competition Law”. Columbia Law School. 2014. Accessed 8/16/21. <https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=2843&context=faculty_scholarship> //Xu]

The goals of uniformity and predictability has had its clearest implications at the international level. Unlike competition law, which varies significantly between OECD nations, over the last several decades all of the IP laws have become subject to a much stronger and geographically broader web of harmonizing international agreements, on multinational, regional and bilateral levels. The general aim of these treaties is to homogenize the world’s IP regimes, reducing or eliminating geographical variation. All of the major laws are the subject of longstanding global treaties specifying minimum protections (The Berne and Paris conventions), which were fortified in 1994 by the addition of an intellectual property agreement to the World Trade Organization, and further strengthened by numerous bilateral treaties since then. And of course the World Trade Organization, unlike the informal organizations common to competition law, has the power to punish deviations from the intellectual property treaties with serious trade sanctions. The pattern can also be observed at the national level. Both in Europe and the United States the last few decades have witnessed many important measures taken to create uniformity. In the United States, a single appeals court, the Federal Circuit, has heard the nation’s appeals in patent cases since 1982 in an effort to bring greater uniformity to the patent law. Though proposals for constructing a uniform patent court akin to the Federal Circuit in the European Union have been unsuccessful so far,26 the European Patent Convention, founded in 1973, provides a common application for the prosecution of patents in each of the member states.27 In short, stronger protection of uniform rights has been the clear trajectory of the intellectual property laws over the last few decades. That tendency is sharply at odds with the predispositions of the competition laws. The dichotomy I am suggesting here is, of course, not absolute. In certain areas of the competition law, one can sense the influence of a vested rights theory, in, for example, the resistance to breakups of dominant terms, even if the economic case for doing so might be quite strong. And there are areas in IP law, like the American fair use doctrine (a judicial and scholarly favorite), which have, in fact, served as important outlets for judicial tinkering in the face of changing conditions. For example the famous Sony decision, blessing the VCR, broke with prevalent copyright doctrine, arguably as a reaction to perceived technological necessity.28 Similarly, following a decade of bad press, Congress, the courts, and the American Patent Office have begun to make adjustments with American patent law. An example is the new post-grant review process, which includes a particular provision targeted at business method patents. Nonetheless it would be hard to describe the intellectual culture of either the intellectual property laws as truly committed to experimental improvement of the law. It would be even harder to describe competition law as devoted to the protection of fundamental rights. We are left with a divergence in intellectual cultures with broad implications for just about every advanced economy in the world. IV. USING ANTITRUST FOR PATENT EXPERIMENTALISM AT THE UNITED STATES SUPREME COURT I believe there is a need for a more experimentalist approach to the intellectual property laws, and particularly to the patent laws. The law, I believe, needs better mechanisms not simply to celebrate its successes, but to correct its errors, both specific and general. One way this might be achieved is to act within the structure and institutions of the laws themselves; as just discussed, this is a project underway in certain respects. But the other path is to rely on the competition laws as a kind of oversight and adjustment mechanism for the intellectual property laws.

#### 2] IP is an encroachment on the intellectual commons – expansionist tendencies threaten discursive expression and the cultivation of potentiality.

Barron 11 [Anne Barron (Law Department, London School of Economics and Political Science). ”Kant, copyright and communicative freedom.” Law and philosophy. pp. 1- 48. 2011. Accessed 8/22/21. <http://eprints.lse.ac.uk/37521/1/Kant_Copyright_and_Communicative_Freedom_%28lsero%29.pdf> //Xu]

This assumption is contested in a large literature (and an associated political movement) that has emerged by way of a backlash against IP expansionism and the hegemony of its justificatory theory. Here the category of the ‘public domain’ plays a key role. In ordinary parlance, information is said to be in the public domain when it is publicly available, i.e. not secret. In the context of the contemporary resistance to IP expansionism, however, it generally refers to “information resources that are unencumbered by intellectual property rights”5 as well as being publicly available in that sense. Defenders of this public domain argue strenuously against its colonization via the ‘second enclosure movement’6 that they claim is represented by IP expansionism and legitimated by neoclassical economic theory. They argue for a positive re-valuation of non-propertized ‘information resources’: overcoming the negative representation of the public domain as a kind of wasteland, “a sad jumble of things that don’t deserve to be protected by intellectual property laws or … a netherworld where old information goes to die,”7 as one sympathetic commentator has put it. There is now a well-established tendency to conceptualize the public domain as a kind of cultural ‘environment,’8 which in turn has yielded calls for strategies of ‘environmental preservation’ analogous to those around which the environmental movement took shape in the 1970s. Yet these tendencies are frequently underpinned by concerns to emphasize the economic value of the public domain and the inefficiencies that can result from privatizing its contents, and this tends only to reinforce liberal-utilitarianism’s hegemony as the privileged lens through which to view copyright law and the fields that it affects.9 So while it is easy to be sympathetic towards the general ambition underlying these arguments, the arguments themselves have not so far been premised on a particularly rich understanding of what ‘culture’ is, what its social dynamics are, and what exactly, therefore, is threatened by IP expansionism in general and copyright expansionism in particular. This article forms part of an ongoing project to address these questions. One promising starting point from which to begin to address them is the idea that an author is a kind of speaker (i.e. one who creates works with a view to communicating with a public), that ‘culture’ is the realm in which dialogue between speakers occurs, and that copyright law rightly forms part of the legal framework that facilitates this dialogue. Theorists of copyright law who adopt this starting point frequently assume that authorial rights (as well as limits on these rights) are legitimated by a more general individual right to freedom of expression, with copyright law – as the United States Supreme Court famously put it in 1985 – serving as the ‘engine’ of free expression by establishing marketable rights in expressive products.10 On this standard liberal view, culture is envisioned on the model of a ‘marketplace of ideas’, underpinned by an actual market in authors’ works, which in turn is underpinned in various ways by law. In so far as copyright law helps to produce the conditions in which competitive markets in authors’ works can flourish, it is said to be consistent with freedom of expression.11 Its recent expansionary tendencies – which have made copyrights ever less like the limited property rights they were originally designed to be, and ever more like rights of absolute dominion over intellectual creations – have yielded a standard diagnosis of how copyright law can threaten freedom of expression. Given the oligopolistic structure of markets for cultural commodities, bloated copyrights produce a ‘permission culture’ that chills expression (since permission to use copyright material as raw material for follow-on creativity “is not often granted to the critical or independent”).12 The negative liberty of individuals is thereby endangered; some have argued that space for the self-cultivation of each individual’s potentialities (‘autonomy’ as understood within the tradition that includes J.S. Mill and Joseph Raz) is also restricted.13 Consequently, the benefits that accrue to society as a whole from the clamour of competing claims and perspectives – a diversity of opinions and forms of creativity, information which is reliable because tested in the heat of public debate, the dissemination of knowledge, a more effective democracy – are diminished. From the perspective of this liberalism, a free culture emerges from the freedoms of individuals to say what they choose to say and experience what others choose to say, unhindered in either dimension by intellectual property rights unless aggregate welfare (or on the Razian view, liberal-democratic culture as a ‘common good’)14 is thereby advanced.

### **Method**

#### 1] 1AR theory is legit – anything else means infinite abuse

#### – drop the debater – 1AR is too short to make up for the time trade-off

#### – no RVIs – 6 min 2NR means they can brute force me every time

#### – competing interps – reasonability narrows the theory debate to one issue of brightline, making it easy for the Neg to collapse to the issue in the long 2NR

#### – 1AR theory is the highest layer – the NC has 7 minutes to be abusive and 6 minutes to leverage the abuse against 1A theory in the 2N, making checking abuse lexically impossible

#### 2] Give me new weighing in the 2AR for 1AR shells – I don’t know what arguments will be read in the 2NR so 1AR weighing is impossible as I don’t know what to weigh against.

#### Interp: Debaters must show-up to the tech-check at the NSDA campus

#### Violation: They were late, screenshots in doc

Graphical user interface

Description automatically generated

#### 1] Tech issues – testing tech pre-round is key to functional debates like audio quality and sound settings. O/Ws A] Sequencing – controls the internal link to other standards B] Reversibility – you could get disqualified for being late.

#### 2] Prep Skew – I had to spend 15 minutes checking my tech while they could be prepping which irreparably skews the burdens in their favor. O/Ws on structural abuse since it’s the only verifiable impact.

#### No RVI’s on 1AC Theory- A] Incentivizes a 7 min collapse in the 1NC which destroys the short 1ar B] Moots all the time we spend reading the 1ac

#### 1AC Theory is DTD—its key to making sure they’re held accountable

#### Competing interps on 1AC Theory- A] 7 minutes is more than enough time to robustly justify their counter interp B] Gives us the opportunity to flesh out our model of debate since it’s introduced earlier in the aff

#### 3] P and P affirm

#### 1] Epistemics – we wouldn’t be able to start a strand of reasoning since we’d have to question that reason.

#### 2] Illogical – presuming statements false is illogical since you can’t say things like P and ~P are both wrong.

#### 3] Presuming obligations is logically safer since it’s better to be supererogatory than fail to meet an obligation.

### Advantage

#### Plan – The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by implementing a one-and-done approach.

#### We are in an innovation crisis – new drugs are not being developed in favor of re-purposing old drugs to infinitely extend patent expiration.

Feldman 19 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

Drug companies **have brought great innovations** to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. **But that’s not happening**. Instead, drug companies build massive patent walls around their products, extending the protection **over and over again**. Some modern drugs have an avalanche of U.S. patents, with expiration dates **staggered across time**. For example, the rheumatoid arthritis drug Humira is **protected by more than 100 patents**. Walls like that **are insurmountable**. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, **more than three-quarters** of the drugs associated with new patents **were not new ones** coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be **obtained on minor tweaks** such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit.

#### The only major study confirms our Internal Link – Evergreening decimates competition by resulting in functional monopolies

Arnold Ventures 20 9-24-2020 "'Evergreening' Stunts Competition, Costs Consumers and Taxpayers" <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/> (Arnold Ventures is focused on evidence-based giving in a wide range of categories including: criminal justice, education, health care, and public finance)//Elmer

In 2011, Elsa Dixler was diagnosed with multiple myeloma. That August, she was prescribed Revlimid, a drug that had come on the market six years earlier. By January 2012, she went into full remission, where she has remained since. So long as Revlimid retains its effectiveness, she will take it for the rest of her life. “I was able to go back to work, see my daughter receive her Ph.D, and have a pretty normal life,” said Dixler, a Brooklyn resident who is now 74. “So, on the one hand, I feel enormously grateful.” But Dixler’s normal life has come at a steep financial cost to her family and to taxpayers. Revlimid typically costs nearly $800 per capsule, and Dixler takes one capsule per day for 21 days, then seven days off, and then resumes her daily dose, requiring 273 capsules a year. Since retiring from The New York Times at the end of 2017, she has been on Medicare. Dixler entered the Part D coverage gap (known as the donut hole) “within minutes,” she said. She estimates that adding her deductible, her copayment of $12,000, and what her Part D insurance provider pays totals approximately $197,500 a year. Revlimid should have **been subject to competition** from generic drug makers starting in 2009, bringing down its cost by many orders of magnitude. But by obtaining **27 additional patents**, eight orphan drug exclusivities and 91 total additional protections from the U.S. Food and Drug Administration (FDA) since Revlimid’s introduction in 2005, its manufacturer, Celgene, has extended the drug’s **monopoly** **period** **by 18 years** — through March 8, 2028. “I cannot fathom the immorality of a business that relies on **squeezing people with cancer**,” Dixler said, noting her astonishment that Revlimid has obtained orphan drug protections when it treats a disease that is not rare and does not serve a very limited population. She also observed that Revlimid’s underlying drug is thalidomide, which has been around for decades. “They didn’t invent a new drug, rather, they found a new use for it,” she said. “The cost of Revlimid has imposed constraints on our retirement,” Dixler said, “but when I hear other people’s stories, I feel very lucky. A lot of people have been devastated financially.” Revlimid is a case study in a process known as “evergreening” — artificially sustaining a monopoly for years and even decades by manipulating intellectual property laws and regulations. Evergreening is most commonly used with blockbuster drugs generating the highest prices and profits. **Of the roughly 100 best-selling drugs, more than 70 percent have extended their protection** from competition at least once. More than half have extended the protection cliff multiple times. The true scope and cost of evergreening has been brought into sharper focus by a groundbreaking, publicly available, comprehensive database released Thursday by the Center for Innovation at the University of California Hastings College of Law and supported by Arnold Ventures. **The Evergreen Drug Patent Search is the first database to exhaustively track the patent protections filed by pharmaceutical companies**. Using data from 2005 to 2018 on brand-name drugs listed in the FDA’s Orange Book — a listing of relevant patents for brand name, small molecule drugs — it demonstrates the full extent of how evergreening has been used by Big Pharma to prolong patents and delay the entry of generic, lower-cost competition. “Competition is the backbone of the U.S. economy,” said Professor Robin Feldman, Director of the UC Hastings Center for Innovation, who spearheaded the database’s creation. “But it’s not what we’re seeing in the drug industry. “With evergreening, pharmaceutical companies repeatedly make slight, often trivial, modifications to drugs, dosage levels, delivery systems or other aspects to obtain new protections,” she said. “They pile these protections on over and over again — so often that 78 percent of the drugs associated with new patents were not new drugs coming on the market, but existing drugs.” Competition is the backbone of the U.S. economy. But it’s not what we’re **seeing in the drug industry**. Professor Robin Feldman Director of the UC Hastings Center for Innovation In recent decades, evergreening has systematically undermined the Drug Price Competition and Patent Term Restoration Act of 1984, which created the generic drug industry. Commonly known as the Hatch-Waxman Act, it established a new patent and market exclusivity regime in which new drugs are protected from competition for a specified period of time sufficient to allow manufacturers to recoup their investments and earn a reasonable profit. When that protection expires, generic drug makers are incentivized to enter the market through a streamlined regulatory and judicial process. Drug prices typically drop by as much as 20 percent when the first generic enters the market**, and with more than one generic manufacturer, prices can plummet by 80 to 85 percent**. “Hatch-Waxman created an innovation/reward/competition cycle, but it’s been distorted into an innovation/reward/more reward cycle,” Feldman said. “To paraphrase something a former FDA commissioner once said, the greatest creativity in Big Pharma should come from the research and development departments, not from the legal and marketing departments.” Feldman led the development of the Evergreen Drug Patent Search in response to repeated requests from Congressional committees, members of Congress, state regulators and journalists for information about specific drugs and companies. “We want to make it so anyone can have the question about drug protections at their fingertips whenever they want,” Feldman said. “It’s designed to be easy and user-friendly, and to enhance public understanding about how competition may be limited rather than enhanced through the drug patent system.” The **database** was **created through** a painstaking process of **combing** through **160,000 data points** **to examine every instance where a pharmaceutical company added a new drug patent or exclusivity**. “Most of it was done by hand,” Feldman said, “with multiple people reviewing it at every stage. And along the way we repeatedly made conservative choices. **We erred on the side of underrepresenting the evergreen gain** to be sure we were as fair and reasonable as possible.” Among the 2,065 drugs covered in Evergreen Drug Patent Search, there are many examples of the evergreening strategy used by pharma to delay the entry of competition, especially generics, often for widely prescribed drugs, including those used to treat heartburn, chronic pain, and opioid addiction. Nexium Before Nexium, there was Prilosec, a popular drug to treat gastroesophageal reflux disease (GERD). But its patent exclusivity was due to expire in April 2001. In the late 1990s, with a precipitous drop in revenue looming, Prilosec’s manufacturer, AstraZeneca, decided to develop a replacement drug. Using “one-half of the Prilosec molecule — an isomer of it,” the result was Nexium, which received approval in February 2001. Essentially an evergreened version of Prilosec, Nexium’s exclusivity was then extended by more than 15 years, as AstraZeneca received 97 protections stemming from 16 patents. These included revised dosages, compounds, and formulations. Feldman said that tinkering changes such as Nexium’s do not involve the substantial research and development required for a new drug, nor do they constitute true innovations, yet for a decade and a half, patients and taxpayers were forced to pay far more than was warranted for GERD relief. In fact, in 2016 — one year after patent exclusivity expired — Nexium still topped all drugs in Medicare Part D spending, totaling $1.06 billion. Suboxone Use of this combination of buprenorphine and naloxone for treating opioid addiction has exploded in the wake of the opioid epidemic. Since its approval, Suboxone’s manufacturer, Reckitt Benckiser (now operating as Indivior), extended its protection cliff eight times, gaining nearly two extra decades of exclusivity through early 2030. The drug maker gained six patents for creating a film version of the drug — notably around the time protection was expiring for its tablet version. (The therapeutic benefits of the film and tablet are identical.) An earlier version of Suboxone also obtained an orphan drug designation, despite an opioid epidemic that has expanded Suboxone’s customer base to millions of potential customers. Suboxone generates more than $1 billion in annual revenue and ranks among the 40 top-selling drugs in the U.S. Truvada When Truvada, commonly referred to as PrEP, was approved in 2004, this HIV-prevention drug was a breakthrough. But 16 years later — and 14 years after its original exclusivity was to expire — it retains its monopoly status. Truvada’s manufacturer, Gilead, has received 15 patents and 120 protections since it came on the market, extending its exclusivity for more than 17 years, until July 3, 2024. In countries where generic Truvada is available, PrEP costs $100 or less per month, compared to $1,600 to $2,000 in the U.S. As a result, Truvada is unaffordable to many people **who need protection from HIV**. Barred from access, they are left vulnerable to infection. “We’re establishing a precedent that a pharmaceutical company can charge whatever it wants even as it allows an epidemic to continue, and the government refuses to intervene,” said James Krellenstein, co-founder of the group PrEP4All. “That should scare every American. If it’s HIV today, it will be another disease tomorrow.” EpiPen First approved in 1987, the EpiPen has saved the lives of countless numbers of people with deadly allergies. But it is protected from competition until 2025 — 38 years after its introduction — because its owner, Mylan, has filed five patents, four since 2010, all involving tweaks to the automatic injector. The actual medication used, epinephrine, has existed for more than a century — the innovation here is in the delivery device. Because these small changes to the injector have maintained its monopoly for so long, the cost of an EpiPen package (containing two injectors) has risen from $94 when Mylan purchased the device to between $650 and $700 today. For many people, especially parents of children with severe reactions to common allergens like peanuts, EpiPen’s increasing price tag imposes an onerous financial burden. What Can Be Done As the Evergreen Drug Patent Search makes clear, the positive impact of Hatch-Waxman has been steadily and severely eroded by a regulatory system vulnerable to increasingly sophisticated forms of manipulation. “You might say that the patent and regulatory system has been weaponized,” Feldman said. “When billions of dollars are at stake, there’s a lot of money available to look for ways to exploit the legal system. And companies have become adept at this, as our work has found.” There are several key steps that Congress could take to restore the balance between innovation and competition that is the key to a successful prescription drug regulatory process. These may include: Imposing restrictions on the number of patents that prescription drug manufacturers can defend in court to discourage the use of anticompetitive patent thickets. Limiting the patentability of so-called secondary patents — which don’t improve the safety or efficacy of a drug — through patent and exclusivity reform. Reforming the 180-day generic exclusivity, which can currently be abused to block other competitive therapies. “**The Evergreen Drug Patent Search provides the publicly available, evidence-based foundation that defines the extent of the problem**, and it can be used to develop policies that solve the problem of anti-competitive patent abuses,” said Kristi Martin, VP of Drug Pricing at Arnold Ventures. “Our incentives have gotten out of whack,” Martin said. “The luxury of monopoly protection should only be provided to innovations that provide meaningful benefits in saving lives, curing illnesses, or improving the quality of people’s lives. It should not be provided to those gaming the system. If we can change that, we can save consumers, employers, and taxpayers many billions of dollars while increasing the incentives for pharmaceutical companies to achieve breakthroughs."

#### Only innovation now solves AMR super-bugs -- timeframe’s key.

Sobti 19 [Dr. Navjot Kaur Sobti is an internal medicine resident physician at Dartmouth-Hitchcock-Medical Center/Dartmouth School of Medicine and a member of the ABC News Medical Unit. May 1, 2019. “Amid superbug crisis, scientists urge innovation”. <https://abcnews.go.com/Health/amidst-superbug-crisis-scientists-urge-innovation/story?id=62763415>] Dhruv

[The United Nations](https://abcnews.go.com/Politics/amal-clooney-angelina-jolie-speak-us-weighed-vetoing/story?id=62574726) has called antimicrobial resistance a “global crisis.” With the [rise in superbugs](https://abcnews.go.com/Health/superbug-fungus-global-health-threat-600-us-infected/story?id=62297532) across the globe, common infections are becoming harder to treat, and lifesaving procedures riskier to perform. Drug-resistant infections result in about 700,000 deaths per year, with at least 230,000 of those deaths due to multidrug resistant tuberculosis, [according to a groundbreaking report from the World Health Organization (WHO).](https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1) Given that antibiotic resistance is present in every country, antimicrobial resistance (AMR) now represents a global health crisis, according to the UN, which has urged immediate, coordinated and global action to prevent a potentially devastating health and financial crisis. With the rising rates of AMR -- including antivirals, antibiotics, and antifungals -- estimates from the WHO show that AMR may cause 10 million deaths every year by 2050, send 24 million people into extreme poverty by 2030, and lead to a financial crisis as severe as the on the U.S. experienced in 2008. Antimicrobial resistance develops when germs like bacteria and fungi are able to “defeat the drugs designed to kill them,” according to the Centers for Disease Control and Prevention. Through a biologic “survival of the fittest,” germs that are not killed by antimicrobials and continue to grow. WHO explains that “poor infection control, inadequate sanitary conditions and inappropriate food handling encourage the spread” of AMR, which can lead to “superbugs.” Those superbugs require powerful and oftentimes more expensive antimicrobials to treat. Examples of superbugs are far and wide, and can range from drug-resistant bacteria like Pseudomonas aeruginosa and Staphylococcus aureus to fungi like Candida. These bugs can cause illnesses that range from pneumonia to urinary tract and sexually transmitted infections. According to the WHO, AMR has caused complications for nearly 500,000 people with tuberculosis, and a number of people with HIV and malaria. The people at the [highest risk for AMR](https://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed) are those with chronic diseases, people living in nursing homes, hospitalized in the ICU or undergoing life-saving treatments such as organ transplantation and cancer therapy. These people often develop infections, which can become antimicrobial-resistant, rendering them difficult, if not impossible, to treat. [(MORE: Melissa Rivers talks about her father's suicide with Dr. Jennifer Ashton)](https://abcnews.go.com/Health/melissa-rivers-talks-fathers-suicide-dr-jennifer-ashton/story?id=62733179&cid=clicksource_26_null_headlines_hed) The CDC notes that “antibiotic resistance has the potential to affect people at any stage of life,” including the “healthcare, veterinary, and agriculture industries, making it one of the world’s most urgent public health problems." AMR can cause prolonged hospital stays, billions of dollars in healthcare costs, disability, and potentially, death. “The most important thing is to understand and embrace the interconnectedness of all of this,” said Dr. Robert Redfield, director of the CDC, in a recent interview with ABC News’ Dr. Jennifer Ashton. It’s not just our countries that are connected.” Research has shown that superbugs like Candida auris “came from multiple places, at the same time. It wasn’t just one organism that [evolved]” in a single location, Redfield added. Given longstanding concerns about antimicrobial misuse leading to AMR, physicians have embraced a medical approach called antibiotic stewardship. This encourages physicians to carefully evaluate which antibiotic is most appropriate for their patient, and discontinue it once it is no longer medically needed. WHO has also highlighted that the inappropriate use of antimicrobials in agriculture -- such as on farms and in animals -- may be an underappreciated cause of AMR. Noting these trends, the WHO has urged for “coordinated action...to minimize the emergence and spread of antimicrobial resistance.” It urges all countries to make national action plans, with a focus on the development of new antimicrobial medications, vaccines, and careful antimicrobial use. Redfield emphasized the importance of vaccination during the global superbug crisis, stating that “the only way we have to eliminate an infection is vaccination.” He added that investing in innovation is key to solving the crisis. While WHO continues to advocate for superbug awareness, they warn that AMR has reversed “a century of progress in health.” The WHO added that “the challenges of antimicrobial resistance” are “not insurmountable,” and that coordinated action will “help to save millions of lives, preserve antimicrobials for generations to come and secure the future from drug-resistant diseases.”

#### Extinction - generic defense doesn’t apply.

Srivatsa 17 Kadiyali Srivatsa 1-12-2017 “Superbug Pandemics and How to Prevent Them” <https://www.the-american-interest.com/2017/01/12/superbug-pandemics-and-how-to-prevent-them/> (doctor, inventor, and publisher. He worked in acute and intensive pediatric care in British hospitals)//Elmer

It is by now no secret that the human species is locked in a race of its own making with “superbugs.” Indeed, if popular science fiction is a measure of awareness, the theme has pervaded English-language literature from Michael Crichton’s 1969 Andromeda Strain all the way to Emily St. John Mandel’s 2014 Station Eleven and beyond. By a combination of massive inadvertence and what can only be called stupidity, we must now invent new and effective antibiotics faster than deadly bacteria evolve—and regrettably, they are rapidly doing so with our help. I do not exclude the possibility that bad actors might deliberately engineer deadly superbugs.1 But even if that does not happen, humanity faces an existential threat largely of its own making in the absence of malign intentions. As threats go, this one is entirely predictable. The concept of a “black swan,” Nassim Nicholas Taleb’s term for low-probability but high-impact events, has become widely known in recent years. Taleb did not invent the concept; he only gave it a catchy name to help mainly business executives who know little of statistics or probability. Many have embraced the “black swan” label the way children embrace holiday gifts, which are often bobbles of little value, except to them. But the threat of inadvertent pandemics is not a “black swan” because its probability is not low. If one likes catchy labels, it better fits the term “gray rhino,” which, explains Michele Wucker, is a high-probability, high-impact event that people manage to ignore anyway for a raft of social-psychological reasons.2 A pandemic is a quintessential gray rhino, for it is no longer a matter of if but of when it will challenge us—and of how prepared we are to deal with it when it happens. We have certainly been warned. The curse we have created was understood as a possibility from the very outset, when seventy years ago Sir Alexander Fleming, the discoverer of penicillin, predicted antibiotic resistance. When interviewed for a 2015 article, “The Most Predictable Disaster in the History of the Human Race, ” Bill Gates pointed out that one of the costliest disasters of the 20th century, worse even than World War I, was the Spanish Flu pandemic of 1918-19. As the author of the article, Ezra Klein, put it: “No one can say we weren’t warned. And warned. And warned. A pandemic disease is the most predictable catastrophe in the history of the human race, if only because it has happened to the human race so many, many times before.”3 Even with effective new medicines, if we can devise them, we must contain outbreaks of bacterial disease fast, lest they get out of control. In other words, we have a social-organizational challenge before us as well as a strictly medical one. That means getting sufficient amounts of medicine into the right hands and in the right places, but it also means educating people and enabling them to communicate with each other to prevent any outbreak from spreading widely. Responsible governments and cooperative organizations have options in that regard, but even individuals can contribute something. To that end, as a medical doctor I have created a computer app that promises to be useful in that regard—of which more in a moment. But first let us review the situation, for while it has become well known to many people, there is a general resistance to acknowledging the severity and imminence of the danger. What Are the Problems? Bacteria are among the oldest living things on the planet. They are masters of survival and can be found everywhere. Billions of them live on and in every one of us, many of them helping our bodies to run smoothly and stay healthy. Most bacteria that are not helpful to us are at least harmless, but some are not. They invade our cells, spread quickly, and cause havoc that we refer to generically as disease. Millions of people used to die every year as a result of bacterial infections, until we developed antibiotics. These wonder drugs revolutionized medicine, but one can have too much of a good thing. Doctors have used antibiotics recklessly, prescribing them for just about everything, and in the process helped to create strains of bacteria that are resistant to the medicines we have. We even give antibiotics to cattle that are not sick and use them to fatten chickens. Companies large and small still mindlessly market antimicrobial products for hands and home, claiming that they kill bacteria and viruses. They do more harm than good because the low concentrations of antimicrobials that these products contain tend to kill friendly bacteria (not viruses at all), and so clear the way for the mass multiplication of surviving unfriendly bacteria. Perhaps even worse, hospitals have deployed antimicrobial products on an industrial scale for a long time now, the result being a sharp rise in iatrogenic bacterial illnesses. Overuse of antibiotics and commercial products containing them has helped superbugs to evolve. We now increasingly face microorganisms that cannot be killed by antibiotics, antifungals, antivirals, or any other chemical weapon we throw at them. Pandemics are the major risk we run as a result, but it is not the only one. Overuse of antibiotics by doctors, homemakers, and hospital managers could mean that, in the not-too-distant future, something as simple as a minor cut could again become life-threatening if it becomes infected. Few non-medical professionals are aware that antibiotics are the foundation on which nearly all of modern medicine rests. Cancer therapy, organ transplants, surgeries minor and major, and even childbirth all rely on antibiotics to prevent infections. If infections become untreatable we stand to lose most of the medical advances we have made over the past fifty years. And the problem is already here. In the summer of 2011, a 43-year-old woman with complications from a lung transplant was transferred from a New York City hospital to the Clinical Center at the National Institutes of Health (NIH), in Bethesda, Maryland. She had a highly resistant superbug known as Klebsiella pneumoniae carbapenemase (KPC). The patient was treated and eventually discharged after doctors concluded that they had contained the infection. A few weeks later, a 34-year-old man with a tumor and no known link to the woman contracted KPC while at the hospital. During the course of the next few months, several more NIH patients presented with KPC. Doctors attacked the outbreak with combinations of antibiotics, including a supposedly powerful experimental drug. A separate intensive care unit for KPC patients was set up and robots disinfected empty rooms, but the infection still spread beyond the intensive care area. Several patients died and then suddenly all was silent on the KPC front, with doctors convinced they had seen the last of the dangerous bacterium. They couldn’t have been more mistaken. A year later, a young man with complications from a bone marrow transplant arrived at NIH. He became infected with KPC and died. This superbug is now present in hospitals in most, if not all U.S. states. This is not good. This past year an outbreak of CRE (carbapenem-resistant enterobacteriaceae) linked to contaminated medical equipment infected 11 patients and killed two in Los Angeles area hospitals. This family of bacteria has evolved resistance to all antibiotics, including the powerful carbapenem antibiotics that are often used as a last resort against serious infections. They are now so resilient that it is virtually impossible to remove them from medical tools such as catheters and breathing tubes placed into the body, even after cleaning. Then we have gonorrhea, chlamydia, and other sexually transmitted diseases that we cannot treat and that are spreading all over the world. Anyone who has sex can catch these infections, and because most people may not exhibit any symptoms they spread infections without anyone knowing about it. Sexually transmitted diseases used to be treatable with antibiotics, but in recent years we have witnessed the rise of multi-drug resistant STDs. Untreated gonorrhea can lead to infertility in men and women and blindness and other congenital defect in babies. As is well known, too, we have witnessed many cases of drug-resistant pneumonia. These problems have arisen in part because of simple mistakes healthcare professionals repeatedly make. Let me explain. Neither superbugs nor common bacterial infections produce any special symptoms indicative of their cause. Rashes, fevers, sneezing, runny noses, ear pain, diarrhea, vomiting, coughing, fatigue, and weakness are signs of common and minor illnesses as well as uncommonly deadly ones. Therefore, the major problem for clinicians is to identify a common symptom that may potentially be an early sign of a major infection that could result in an epidemic. We know that dangerous infections in any given geographical area do not start at the same time. They start with one victim and gradually spread. But that victim is only one among hundreds of patients a doctor will typically see, so many doctors will miss patients presenting with infections that are serious. They will probably identify diseases that kill fast, but slow-spreading infections such as skin infections that can lead to septicemia are rarely diagnosed early. In addition, I have seen doctors treating eczema with antibiotic cream, even though they know that bacteria are resistant to the majority of these drugs. This sort of action encourages simple infections to spread locally, because patients are therefore not instructed to take other, more useful precautions. On top of that, some people are frivolous about infections and assume doctors are exaggerating the threat. And some people are selfish. Once I was called to see a passenger during a flight who had symptoms consistent with infection. He boarded the plane with these symptoms, but began to feel much worse during the flight. I was scared, knowing how infections such as Ebola can spread. This made me think about a way to screen passengers before they board a flight. Airlines could refund a traveler’s ticket, or issue a replacement, in case of sickness—which is not the policy now. We currently have no method to block infectious travelers from boarding flights, and there are no changes in the incentive system to enable conscientious passengers to avoid losing their money if they responsibly miss a flight because of illness. Speaking of selfishness, I once saw a mother drop her daughter off at school with a serious bout of impetigo on her face. When I asked her why she had brought her daughter to school with a contagious infection, she said she could not spare the time to keep her at home or take her to the doctor. By allowing this child to contact other children, a simple infection can become a major threat. Fortunately, I could see the rash on the girl’s face, but other kids in schools may have rashes we cannot see. Incorrect diagnosis of skin problems and mistaken use of antibiotics to treat them is common all over the world, and so we are continually creating superbugs in our communities. Similarly, chest infections, sore throats, and illnesses diagnosed as colds that unnecessarily treated with antibiotics are also a major threat. By prescribing antibiotics for viral infections, we are not only helping bacteria develop resistance, but we are also polluting the environment when these drugs are passed in urine and feces. All of this helps resistant bacteria to spread in the community and become an epidemic. Ebola is very difficult to transmit because people who are contagious have visible and unusual symptoms. However, the emerging infections and pandemics of the future may not have visible symptoms, and they could break out in highly populous countries such as India and China that send thousands of travelers all over the world every day. When a person is infected with a contagious disease, he or she can expect to pass the illness on to an average of two people. This is called the “reproduction number.” Two is not that high a number as these things go; some diseases have far greater rates of infection. The SARS virus had a reproduction number of four. Measles has a reproduction number of 18. One person traveling as an airplane passenger and carrying an infection similar to Ebola can infect three to five people sitting nearby, ten if he or she walks to the toilet. The study that highlighted this was published in a medical journal a few years ago, but the airline industry has not implemented any changes or introduced screening to prevent the spread of infections by air travel passengers, a major vehicle for the rapid spread of disease. It is scary to think that nobody knows what will happen when the world faces a lethal disease we’re not used to, perhaps with a reproduction number of five or eight or even ten. What if it starts in a megacity? What if, unlike Ebola, it’s contagious before patients show obvious symptoms? Past experience isn’t comforting. In 2009, H1N1 flu spread around the world before we even knew it existed. The Questions Remains Why do seemingly intelligent people repeatedly do such collectively stupid things? How did we allow this to happen? The answer is disarmingly simple. It is because people are incentivized to prioritize short-term benefits over long-term considerations. It is what social scientists have called a “logic of collective action” problem. Everyone has his or her specialized niche interest: doctors their patients’ approval, business and airline executives their shareholders’ earnings, hospitals their reputations for best-practice hygienics, homemakers their obligation to keep their own families from illness. But no one owns the longer-term consequences for hundreds of millions of people who are irrelevant to satisfying these short-term concerns. Here is an example. At a recent Superbug Super Drug conference in London that I attended, scientists, health agencies, and pharmaceutical companies were vastly more concerned with investing millions of dollars in efforts to invent another antibiotic, claiming that this has to be the way forward. Money was the most pressing issue because, as everyone at the conference knew, for many years pharmaceutical companies have been pulling back from antibiotics research because they can’t see a profit in it. Development costs run into billions of dollars, yet there is no guarantee that any new drug will successfully fight infections. At the same conference Dr. Lloyd Czaplewski spoke about alternatives to antibiotics, in case we cannot come up with new ones fast enough to outrun superbug evolution. But he omitted mention of preventive strategies that use the internet or communication software to help reduce the spread of infections among families, communities, and countries. It is madness that we don’t have a concrete second-best alternative to new antibiotics, because we need them and we need them quickly. Of course, this is why we have governments, which have been known occasionally in the past as commonwealths. Governments are supposed to look out for the wider, common interests of society that niche-interested professionals take no responsibility for, and that includes public health. It is why nearly every nation’s government has an official who is analogous to the U.S. Surgeon General, and nearly every one has a public health service of some kind. Alas, national governments do not always function as they should. Several years ago physician and former Republican Senator Bill Frist submitted a proposal to the Senate for a U.S. Medical Expeditionary Corps. This would have been a specialized organization that could coordinate and execute rapid responses to global health emergencies such as Ebola. Nothing came of it, because Dr. Frist’s fellow politicians were either too shortsighted or too dimwitted to understand why it was a good idea. Or perhaps they simply realized that they could not benefit politically from supporting it. Plenty of mistakes continue to be made. In 2015, a particularly infectious form of bird flu ripped through 14 U.S. states, leading farmers to preventively slaughter nearly 40 million birds. The result of such callous and unnecessary acts is that, instead of exhausting themselves in the host population of birds, the viruses quickly find alternative hosts in which to survive, and could therefore easily mutate into a form that can infect humans. Earlier, during the 1980s, AIDS garnered more public attention because a handful of rich and famous people were infected, and because the campaign to eradicate it dovetailed with and boosted the political campaign on behalf of homosexual rights. Methicillin resistant Staphylococcus aureus (MRSA) in hospitals, by far the bigger threat at the time, was virtually ignored. Some doctors knew that MRSA would bring us to our knees and kill millions of people worldwide, but pharmaceutical companies and device and equipment manufacturers ignored these doctors and the thousands of patients dying in hospitals as a result of MRSA. They prioritized the wrong thing, and government did not correct the error. And that is partly how antibiotic-resistant infection went from an obscure hospital problem to an incipient global pandemic. Politics well outside the United States plays several other roles in the budding problem that we are confronting. Countries often will not admit they have a problem and request help because of the possible financial implications in terms of investment and travel. Guinea did not declare the Ebola epidemic early on and Chinese leaders, worried about trade and tourism, lied for months in 2002 about the presence of the SARS virus. In 2004, when avian influenza first surfaced in Thailand, officials there displayed a similar reluctance to release information. Hospitals in some countries, including India, are managed and often owned by doctors. They refuse to share information about existing infections and often categorically deny they have a problem. Reporting infections to public health authorities is not mandatory, and so hospitals that fail to say anything are not penalized. Even now, the WHO and the CDC do not have accurate and up-to-date information about the spread of E. coli or other infections, and part of the reason is that for-profit hospitals are reluctant to do anything to diminish their bottom line. Syria and Yemen are among those countries that are so weak and fragmented that they cannot effectively coordinate public healthcare. But their governments are also hostile to external organizations that offer relief. Part of the reason is xenophobia, but part is that this makes the government look bad. Relatedly, most poor-nation governments do not trust the efficacy of international institutions, and think that cooperating with them amounts to a re-importation of imperialism. They would rather their own people suffer and die than ask for needed help. That brings us to the level of international public health governance. Alas, sometimes poor-country governments estimate the efficacy of international institutions accurately. The WHO’s Ebola response in 2014-15 was a disaster. The organization was slow to declare a public health emergency even after public warnings from Médecins Sans Frontières, some of whose doctors had already died on the front line. The outbreak killed more than 28,000 people, far more than would have been the case had it been quickly identified. This isn’t just an issue of bureaucratic incompetence. The WHO is under-resourced for the problems it is meant to solve. Funding comes from voluntary donations, and there is no mechanism by which it can quickly scale up its efforts during an emergency. The result is that its response to the next major disease outbreak is likely to be as inadequate as were its responses to Ebola, H1N1, and SARS. Stakeholders admit that we need another mechanism, and most experts agree that the world needs some kind of emergency response team for dangerous diseases. But no one knows how to set one up amid the dysfunctional global governance structures that presently exist. Maybe they should turn to Bill Frist, whose basic concept was sound; if the U.S. government will not act, perhaps some other governments will, and use the UN system to do so. But as things stand, we lack a health equivalent of the military reserve. Neither government leaders nor doctors can mobilize a team of experts to contain infections. People who want to volunteer, whether for government or NGO efforts, are not paid and the rules, if any, are sketchy about what we do with them when they return from a mission. Are employers going to take them back? What are the quarantine rules? It is all completely ad hoc, meaning that humanity lacks the tools it needs to protect itself. And note, by the way, the contrast between how governments prepare for facing pandemics and how they prepare for making war. War is not more deadly to the human race than pandemics, but national defense against armed aggression is much better planned for than defense against threats to public health. There is a wealth of rules regarding it, too. Human beings study and plan for war, which kills people both deliberately and accidentally, but they do not invest comparable effort planning for pandemics, which are liable to kill orders of magnitude more people. To the mind of a medical doctor, this is strange. Creating Conditions for Infections to Spread Superbug infections spread for several interlocking reasons. Some are medical-epidemiological. Most of the infections of the past thirty years have started in one place and in one family. As already noted, they spread because many infectious diseases are highly contagious before the onset of symptoms, and because it is difficult to prevent patients who know they are sick from going to hospitals, work, and school, or from traveling further afield. But again, one reason for the problem is political, not medical. Many governments have no strategies in place to prevent pandemics because they are unwilling to tell their people how infections spread. They don’t want to worry people with such talk; it will make them, they fear, unpopular. So governments may have mountains of bureaucracy with great heaps of rules and regulations concerning public health, but they are generally unwilling to trust their own citizens to use common sense on their own behalf. This, too, seems very strange. Until now, no one has come forward to help us develop strategies to educate people how to identify and prevent the spread of infection to their families and communities. The majority of stakeholders have also been oblivious to the use of new technologies to help reduce the spread of these infections. There are some exceptions. In a fun blog post called Preparedness 101: Zombie Apocalypse, the CDC uses the threat of a zombie outbreak as a metaphor to encourage people to prepare for emergencies, including pandemics. It is well meaning and insightful, yet when my colleagues and I try to discuss ways of scaling up the CDC’s example with doctors and nurses, they shut down. Nobody plans for an actual crisis partly because it is too scary and hence paralyzing to think about. But it is also because it is not most health professionals’ job; it is not what they are trained and paid to do. It is always someone else’s job, except that it has turned out to be nobody’s job. Worse, the situation is not static. While we sit paralyzed, superbugs are evolving. Epidemiological models now predict how an algorithmic process of disease spread will move through the modern world. All urban centers around the entire globe can become infected within sixty days because we move around and cross borders much more than our ancestors did, thanks to air travel. A new pandemic could start crossing borders before we even know it exists. A flu-like disease could kill more than 33 million people in 250 days.3

#### The Plan solves Evergreening.

Feldman 2 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

I believe that one period of protection **should be enough**. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by a “one-and-done” approach** for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but **not all of the above** and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through **legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

#### Reforming the Patent Process would lower Drug Prices and incentivize Pharma Innovation by revitalizing the Market.

Stanbrook 13, Matthew B. "Limiting “evergreening” for a better balance of drug innovation incentives." (2013): 939-939. (MD (University of Toronto) PhD (University of Toronto))//Elmer

At issue in the Indian case was “evergreening,” a now widespread practice by the pharmaceutical industry designed to extend the monopoly on an existing drug by modifying it and seeking new patents.2 Currently, half of all drugs patented in Canada have multiple subsequent patents, extending the lifetime of the original patent by about 8 years.3 Manufacturers, in defence of these practices, predictably tout the advantages of new versions of their products, which often represent more potent isomers or salts of the original drugs, longer-lasting formulations or improved delivery systems that make adherence easier or more convenient. But the new versions are by definition “**me too” drugs**, and demonstration that the resulting **incremental benefits** in efficacy and safety are clinically meaningful **is often lacking**. Moreover, the original drugs have often been “blockbusters” used for years to improve the health of millions of patients. It seems hard to argue convincingly why such beneficial drugs require an upgrade, often just before their patents expire. Rather than the marginal benefits accrued from tinkering with already effective agents, patients worldwide are in desperate need of new classes of pharmaceuticals for the great many health conditions for which treatments are presently inadequate or entirely lacking. But developing truly innovative drugs is undeniably a high-risk venture. It is important and necessary that pharmaceutical companies continue to take these risks, because they are usually the only entities with sufficient resources to do so. Therefore, companies must continue to perceive **sufficient incentives** to continue investing in innovation. Indeed, there is evidence that the prospect of future evergreening has become part of the incentive calculation for innovative drug development.4 But surely it is perverse to extend unpredictably a period of patent protection that the government intended to be clearly defined and predictable, and to maintain incentives that drive companies to divert their **drug-development resources away from innovation**. **Current patent legislation may not be optimal** for striking the right balance between encouraging innovation and facilitating profiteering. Given the broad societal importance of patent legislation, ongoing research to enable active governance of this issue should be a national priority. In the last decade, Canada’s laws have been among the friendliest toward evergreening in the world.5 We should now reflect on whether this is really in our national interest. Governments, including Canada’s, would do well to take inspiration from India’s example and tighten regulations that currently facilitate evergreening. This might involve **denying future patents for modifications** that currently would receive one. An overall reduction in the duration of all secondary patents on a therapy might also be considered. Globally, a more flexible and individualized approach to the length of drug patents might be a more effective strategy to align corporate incentives with population health needs. Limits on evergreening would likely reduce the **extensive patent litigation** that contributes to the **high prices of generic drugs** in Canada.3 Reducing economic pressure on generic drug companies may facilitate current provincial initiatives to lower generic drug prices. As opportunities to generate revenue from evergreening are eliminated, research-based pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits.

#### Pharma Innovation solves Bioterrorism.

Marjanovic and Feijao 20 Sonja Marjanovic and Carolina Feijao May 2020 "Pharmaceutical Innovation for Infectious Disease Management" <https://www.rand.org/content/dam/rand/pubs/perspectives/PEA400/PEA407-1/RAND_PEA407-1.pdf> (directs RAND Europe's portfolio of research in the field of healthcare innovation, industry and policy)//Elmer

We need to **ensure** **scalable and sustainable** **approaches for pharmaceutical innovation** **in response to** infectious disease **threats to public health** As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. **Infectious agents such as** **anthrax, smallpox and tularemia** could **present threats in a bioterrorism context**.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the **expertise, networks and infrastructure** that industry has within its reach, as well as public expectations and the moral imperative, **make pharmaceutical companies** and the wider life sciences sector an **indispensable** partner **in the search for solutions** that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation **in response to** infectious **disease threats** to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic.

#### Bioterrorism causes Extinction – overcomes any conventional defense.

Walsh 19, Bryan. End Times: A Brief Guide to the End of the World. Hachette Books, 2019. (Future Correspondent for Axios, Editor of the Science and Technology Publication OneZero, Former Senior and International Editor at Time Magazine, BA from Princeton University)//Elmer

I’ve lived through disease outbreaks, and in the previous chapter I showed just how unprepared we are to face a widespread pandemic of flu or another new pathogen like SARS. But a deliberate outbreak caused by an engineered pathogen would be far worse. We would face the same agonizing decisions that must be made during a natural pandemic: whether to ban travel from affected regions, how to keep overburdened hospitals working as the rolls of the sick grew, how to accelerate the development and distribution of vaccines and drugs. To that dire list add the terror that would spread once it became clear that the death and disease in our midst was not the random work of nature, but a deliberate act of malice. We’re scared of disease outbreaks and we’re scared of terrorism—put them together and you have a formula for chaos. As deadly and as disruptive as a conventional bioterror incident would be, an attack that employed existing pathogens could only spread so far, limited by the same laws of evolution that circumscribe natural disease outbreaks. But a virus engineered in a lab to break those laws could spread faster and kill quicker than anything that would emerge out of nature. It can be designed to evade medical countermeasures, frustrating doctors’ attempts to diagnose cases and treat patients. If health officials manage to stamp out the outbreak, it could be reintroduced into the public again and again. It could, with the right mix of genetic traits, even wipe us off the planet, making engineered viruses a genuine existential threat. And such an attack may not even be that difficult to carry out. Thanks to advances in biotechnology that have rapidly reduced the skill level and funding needed to perform gene editing and engineering, what might have once required the work of an army of virologists employed by a nation-state could soon be done by a handful of talented and trained individuals. Or maybe just one. When Melinda Gates was asked at the South by Southwest conference in 2018 to identify what she saw as the biggest threat facing the world over the next decade, she didn’t hesitate: “A bioterrorism event. Definitely.”2 She’s far from alone. In 2016, President Obama’s director of national intelligence James Clapper identified CRISPR as a “weapon of mass destruction,” a category usually reserved for known nightmares like nuclear bombs and chemical weapons. A 2018 report from the National Academies of Sciences concluded that biotechnology had rewritten what was possible in creating new weapons, while also increasing the range of people capable of carrying out such attacks.3 That’s a fatal combination, one that plausibly threatens the future of humanity like nothing else. “The existential threat that would be most available for someone, if they felt like doing something, would be a bioweapon,” said Eric Klien, founder of the Lifeboat Foundation, a nonprofit dedicated to helping humanity survive existential risks. “It would not be hard for a small group of people, maybe even just two or three people, to kill a hundred million people using a bioweapon. There are probably a million people currently on the planet who would have the technical knowledge to pull this off. It’s actually surprising that it hasn’t happened yet.”