### 1AC Framework

#### Ethics must solve the internalism-externalism paradox—either reasons for action are based on an agent’s internal motivation, or on a priori objective reasons. However, both of these accounts fail since internal motivations are contingent and arbitrary, while external reasons beg the question of a source for these reasons. The solution is constitutivism, or the idea that ethics must be based on the nature of agency. Only this can solve the paradox—concerns derived from the nature of agents are objective and non-optional, yet are motivational for all agents.

#### Thus, the meta ethic is constitutivism.

#### Prefer

#### [1] Agency is the only non-optional enterprise—everything is part of it. Every action part of an optional enterprise is part of agency. This round is part of my identity as a debater, but it’s also engagement in agency.

#### [2] Regress—trying to escape agency necessitates using rational reflection about what I ought to do, which is part of agency.

#### Next, reason is constitutive of action

#### [1] Decision making—Agents have infinite ends available to pursue but have a limited means to pursue them—that requires reason to choose which ends to pursue.

#### [2] Action theory—any action can be divided into infinite states of affairs—only intent can unify our action into intended means and ends. Takes out util—there would be infinite states of affairs we would have to evaluate.

#### Only reasons that can be universalized across all actions can be constitutive of agency since agency is the ability to set and pursue ends—that means reasons that can’t be universalized can’t be applied to all instances of agency. There’s no prior distinction between agents so everyone must be able to will a maxim universally.

#### Coercion isn’t universalizable—willing your own freedom while violating someone else’s is a conceptual contradiction.

Engstrom [Stephen Engstrom, (Professor of Philosophy @ the University of Pittsburgh) "Universal Legislation as the Form of Practical Knowledge" http://www.academia.edu/4512762/Universal\_Legislation\_As\_the\_Form\_of\_Practical\_Knowledge, DOA:5-5-2018 // WWBW]

Given the preceding considerations, it’s a straightforward matter to see how **a maxim of action that assaults the freedom of others** with a view to furthering one’s own ends results in a contradiction when we attempt to will it as a universal law in accordance with the foregoing account of the formula of universal law. Such a maxim **would lie in a practical judgment that deems it good on the whole to act to limit others’ outer freedom**, and hence their self-sufficiency, their capacity to realize their ends, **where doing so augments, or extends, one’s own outer freedom** and so also one’s own self-sufficiency.  Now on the interpretation we’ve been entertaining, applying the formula of universal law involves considering whether it’s possible for every person—every subject capable of practical judgment—to share the practical judgment asserting the goodness of every person’s acting according to the maxim in question. Thus in the present case the application of the formula involves considering whether it’s possible for every person to deem good every person’s acting to limit others’ freedom, where practicable, with a view to augmenting their own freedom. Since here **all persons are** on the one hand **deeming good both the limitation of others’ freedom and the extension of their own freedom, while** on the other hand, insofar as they agree with the similar judgments of others, **also deeming good the limitation of their own freedom and the extension of others’ freedom, they are all deeming good both the extension and the limitation of both their own and others’ freedom. These judgments are inconsistent** insofar as the extension of a person’s outer freedom is incompatible with the limitation of that same freedom.

#### **But, rights claims are not enforceable in the state of nature because of the problem of assurance—without the state, there is nothing that can ensure rights will be enforced. Exempting yourself from the state is impossible since any disagreement would be willing coercion.**

Ripstein 04 [Arthur Ripstein, (University Professor of Law and Philosophy, [University of Toronto](https://scholar.google.com/citations?view_op=view_org&hl=en&org=8515235176732148308)) "Authority and Coercion" Philosophy & Public Affairs, 32: 2–35, 2004, http://onlinelibrary.wiley.com/doi/10.1111/j.1467-6486.2004.00003.x/abstract, DOA:12-16-2017 // WWBW]

Kant explains the need for the three branches of government in Rousseau’s vocabulary of the “general will.” Kant finds this concept helpful, since it manages to capture the way in which the specificity of the law and the monopoly on [the law’s] its enforcement do not thereby make it the unilateral imposition of one person’s will upon another. Instead, it is what Kant calls an “omnilateral” will, since all must agree to set up procedures that will make right possible. All must agree, because without such procedures, equal freedom is impossible, and so the external freedom of each is impossible. But the sense in which they must agree is not just that they should agree; it is that they cannot object to being forced to accept those procedures, because any objection would be nothing more than an assertion of the right to use force against others unilaterally. Once the concept of the General Will is introduced, it provides further constraints on the possibility of a rightful condition, and even explains the ways in which a state can legitimately coerce its citizens for reasons other than the redress of private wrongs. Kant’s treatment of these issues of “Public Right” has struck many readers as somewhat perfunctory, especially after his meticulously detailed, if not always transparent, treatment of private right. He treats these issues as he does because he takes them to follow directly from the institution of a social contract. The details of his arguments need not concern us here, because he does not claim that these exhaust the further powers of the state. Instead, he puts them forward as additional powers a state must have if it is to create a rightful condition, and it is the structure of that argument that is of concern here.

#### Thus, the standard is consistency with the omnilateral will.

#### Impact Calculus—

#### 1] Side-constraint –

#### A] a just government may only protect the rights of its agents and nothing else. Other moral problems aren’t obligatory

#### B] is-ought gap – even if something is bad, it doesn’t logically follow that we ought not do it – that’s why we do immoral things even though we know its bad.

#### Prefer additionally:

#### 1] In setting an end, any agent must regard freedom as a necessary good. This is a side constraint on ends-based theories—if freedom is not a necessary good, then other agents can impede on the ends you set.

Gewirth 84 bracketed for grammar and gendered language [Alan Gewirth, () "The Ontological Basis of Natural Law: A Critique and an Alternative" American Journal Of Jurisprudence: Vol. 29: Iss. 1 Article 5, 1984, https://scholarship.law.nd.edu/ajj/vol29/iss1/5/, DOA:9-10-2018 // WWBW]

Let me briefly sketch the main line of argument that leads to this conclusion. As I have said, the argument is based on the generic features of human action. To begin with, **every agent acts for purposes [t]he[y] regards as good. Hence, [t]he[y] must regard as necessary goods the freedom and well being that [is] are the** generic features and **necessary conditions of his action and successful action in general**. From this, it follows that **every agent logically must hold or accept that he has rights to these conditions.** For **if he were to deny that he has these rights, then he would have to admit that it is permissible for other persons to remove from him the very conditions of freedom** and well-being **that, as an agent, he must have. But it is contradictory for him to hold both that he must have these conditions and also that he may not have them.** Hence, on pain of self-contradiction, every agent must accept that he has rights to freedom and well-being. Moreover, **every agent must further admit that all other agents also have those rights, since all other actual or prospective agents have the same general characteristics of agency on which he must ground his own right-claims.** What I am saying, then, is that **every agent, simply by virtue of being an agent, must regard his freedom and well being as necessary goods and must hold that** he and **all** other actual or prospective **agents have rights to these necessary goods.** Hence, every agent, on pain of self-contradiction, must accept the following principle: Act in accord with the generic rights of your recipients as well as of yourself. The generic rights are rights to the generic features of action, freedom, and well-being. I call this the Principle of Generic Consistency (PGC), because it combines the formal consideration of consistency with the material consideration of the generic features and rights of action.

#### 2] The Kantian subject is the opposite of abstract and embraces an embodied subject—universalizability is essential to mutual recognition of others.

**Farr 1** Arnold Farr (prof of phil @ UKentucky, focusing on German idealism, philosophy of race, postmodernism, psychoanalysis, and liberation philosophy). “Can a Philosophy of Race Afford to Abandon the Kantian Categorical Imperative?” JOURNAL of SOCIAL PHILOSOPHY, Vol. 33 No. 1, Spring 2002, 17–32.

**“One** of the most popular **criticism**s **of Kant’s moral philosophy is that it is too formalistic.**13 That is, the universal nature of the categorical imperative leaves it devoid of content. Such a principle is useless since moral decisions are made by concrete individuals in a concrete, historical, and social situation. This type of criticism lies behind Lewis Gordon’s rejection of any attempt to ground an antiracist position on Kantian principles. The rejection of universal principles for the sake of emphasizing the historical embeddedness of the human agent is widespread in recent philosophy and social theory. I will argue here on Kantian grounds that **although a distinction between the universal and the concrete is** a **valid** distinction, **the unity of the two is required for** an understanding of human **agency.** The attack on Kantian formalism began with Hegel’s criticism of the Kantian philosophy.14 The list of contemporary theorists who follow Hegel’s line of criticism is far too long to deal with in the scope of this paper. Although these theorists may approach the problem of Kantian formalism from a variety of angles, the spirit of their criticism is basically the same: The universality of the categorical imperative is an abstraction from one’s empirical conditions. **Kant is** often **accused of making the moral agent an abstract, empty**, noumenal **subject. Nothing could be further from the truth. The Kantian subject is** an **embodied**, empirical, concrete subject. However, this concrete subject has a dual nature. Kant claims in the Critique of Pure Reason as well as in the Grounding that human beings have an intelligible and empirical character.15 It is impossible to understand and do justice to Kant’s moral theory without taking seriously the relation between these two characters. The very concept of morality is impossible without the tension between the two. By “empirical character” Kant simply means that we have a sensual nature. We are physical creatures with physical drives or desires. **The** very **fact that I cannot simply satisfy my desires without considering the rightness** or wrongness **of my actions suggests that my empirical character must be held in check** by something, or else I behave like a Freudian id. My empiri- cal character must be held in check **by my intelligible character**, which is the legislative activity of practical reason. It is through our intelligible character that **we formulate principles that keep our** empirical **impulses in check.** The categorical imperative is the supreme principle of morality that is constructed by the moral agent in his/her moment of self-transcendence. What I have called self-transcendence may be best explained in the following passage by Onora O’Neill: In restricting our maxims to those that meet the test of the categorical imperative we refuse to base our lives on maxims that necessarily make our own case an exception. The reason why a universilizability criterion is morally signiﬁcant is that it makes our own case no special exception (G, IV, 404). In accepting the Categorical Imperative we accept the moral reality of other selves, and hence the possibility (not, note, the reality) of a moral community. **The Formula of Universal Law enjoins no more than that we act only on maxims that are open to others also.**16 O’Neill’s description of the universalizability criterion includes the notion of self-transcendence that I am working to explicate here to the extent that like self-transcendence, universalizable moral principles require that the individ- ual think beyond his or her own particular desires. **The individual is not allowed to exclude others as** rational **moral agents** who have the right to act as he acts in a given situation. For example, if I decide to use another person merely as a means for my own end I must recognize the other person’s right to do the same to me. I cannot consistently will that I use another as a means only and will that I not be used in the same manner by another. **Hence,** the **universalizability** criterion **is a principle of consistency and** a principle of **inclusion.** That is, in choosing my maxims **I** attempt to **include the perspective of other moral agents.**

#### 3] Performativity—freedom is the key to the process of justification of arguments. Willing that we should abide by their ethical theory presupposes that we own ourselves in the first place. Thus, it is logically incoherent to justify a standard without first willing that we can pursue ends free from others.

#### 4] Isolating unconditional worth within the other is uniquely liberatory and the basis from which other theories begin, so my offense turns and outweighs yours.

Farr 2 [Arnold Farr [Professor of philosophy at University of Kentucky, focusing on German idealism, philosophy of race, postmodernism, psychoanalysis, and liberation philosophy]. “Can a Philosophy of Race Afford to Abandon the Kantian Categorical Imperative?” JOURNAL of SOCIAL PHILOSOPHY. Vol. 33, No. 1. Spring 2002.]

Whereas most criticisms are aimed at the formulation of universal law and the formula of autonomy, our analysis here will focus on the formula of an end in itself and the formula of the kingdom of ends, since we have already addressed the problem of universality. The latter will be discussed ﬁrst. At issue here is what Kant means by “kingdom of ends.” Kant writes: “By ‘kingdom’ I understand a systematic union of different rational beings through common laws.”32 The above passage indicates that Kant recognizes different, perhaps different kinds, of rational beings; however, the problem for most critics of Kant lies in the assumption that Kant suggests that the “kingdom of ends” requires that we abstract from personal differences and content of private ends. The Kantian conception of rational beings requires such an abstraction. Some feminists and philosophers of race have found this abstract notion of rational beings problematic because they take it to mean that rationality is necessarily white, male, and European.33 Hence, the systematic union of rational beings can mean only the systematic union of white, European males. I ﬁnd this interpretation of Kant’s moral theory quite puzzling. Surely another interpretation is available. That is, the implication that in Kant’s philosophy, rationality can only apply to white, European males does not seem to be the only alternative. The problem seems to lie in the requirement of abstraction. There are two ways of looking at the abstraction requirement that I think are faithful to Kant’s text and that overcome the criticisms of this requirement. First, the abstraction requirement may be best understood as a demand for intersubjectivity or recognition. Second, it may be understood as an attempt to avoid ethical egoism in determining maxims for our actions. It is unfortunate that Kant never worked out a theory of intersubjectivity, as did his successors Fichte and Hegel. However, this is not to say that there is not in Kant’s philosophy a tacit theory of intersubjectivity or recognition. The abstraction requirement simply demands that in the midst of our concrete differences we recognize ourselves in the other and the other in ourselves. That is, we recognize in others the humanity that we have in common. Recognition of our common humanity is at the same time recognition of rationality in the other. We recognize in the other the capacity for selfdetermination and the capacity to legislate for a kingdom of ends. This brings us to the second interpretation of the abstraction requirement. To avoid ethical egoism one must abstract from (think beyond) one’s own personal interest and subjective maxims. That is, the categorical imperative requires that I recognize that I am a member of the realm of rational beings. Hence, I organize my maxims in consideration of other rational beings. Under such a principle other people cannot be treated merely as a means for my end but must be treated as ends in themselves. The merit of the categorical imperative for a philosophy of race is that it contravenes racist ideology to the extent that racist ideology is based on the use of persons of a different race as a means to an end rather than as ends in themselves. Embedded in the formulation of an end in itself and the formula of the kingdom of ends is the recognition of the common hope for humanity. That is, maxims ought to be chosen on the basis of an ideal, a hope for the amelioration of humanity. This ideal or ethical commonwealth (as Kant calls it in the Religion) is the kingdom of ends.34 Although the merits of Kant’s moral theory may be recognizable at this point, we are still in a bit of a bind. It still seems problematic that the moral theory of a racist is essentially an antiracist theory. Further, what shall we do with Henry Louis Gates’s suggestion that we use the Observations on the Feeling of the Beautiful and Sublime to deconstruct the Grounding? What I have tried to suggest is that instead of abandoning the categorical imperative we should attempt to deepen our understanding of it and its place in Kant’s critical philosophy. A deeper reading of the Grounding and Kant’s philosophy in general may produce the deconstruction35 suggested by Gates. However, a text is not necessarily deconstructed by reading it against another. Texts often deconstruct themselves if read properly. To be sure, the best way to understand a text is to read it in context. Hence, if the Grounding is read within the context of the critical philosophy, the tools for a deconstruction of the text are provided by its context and the tensions within the text. Gates is right to suggest that the Grounding must be deconstructed. However, this deconstruction requires much more than reading the Observations on the Feeling of the Beautiful and Sublime against the Grounding. It requires a complete engagement with the critical philosophy. Such an engagement discloses some of Kant’s very signiﬁcant claims about humanity and the practical role of reason. With this disclosure, deconstruction of the Grounding can begin. What deconstruction will reveal is not necessarily the inconsistency of Kant’s moral philosophy or the racist or sexist nature of the categorical imperative, but rather, it will disclose the disunity between Kant’s theory and his own feelings about blacks and women. Although the theory is consistent and emancipatory and should apply to all persons, Kant the man has his own personal and moral problems. Although Kant’s attitude toward people of African descent was deplorable, it would be equally deplorable to reject the categorical imperative without ﬁrst exploring its emancipatory potential.

### Advocacy

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

#### The Plan solves Evergreening.

Feldman 3 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.

### 1AC – Contention

#### 1] Evergreening – exploitation of patents is anti-ethical to the intrinsic nature of medical duty – that affirms.

McHenry 6, Leemon. "Ethical issues in psychopharmacology." Journal of Medical Ethics 32.7 (2006): 405-410.

It is often claimed that corporations that are profit driven could not be expected to behave in any other manner than they do. The nature of business demands maximisation of the market share and shareholder value. **Pharmaceutical companies**, however, **present** themselves **as responsible producers of healthcare products**. The **very nature** of the product **involves trust** in the science that produced it **and** an **ethical commitment to** the **wellbeing of the patients** who are their consumers. Despite appearances, nothing of this sort is true in the pharmaceutical industry. As we have seen above, the serotonin hypothesis sold to consumers of pharmaceuticals is flawed. Making questionable claims for the efficacy and safety of SSRIs involves the pharmaceutical companies in further deception. Expanding the market for these drugs by creating dubious disease categories and then luring vulnerable individuals into SSRI therapy by direct to consumer advertising would represent, if perpetrated by a doctor, an abuse of the trust implicit in the relationship between patient and doctor. I do not argue that SSRIs should be withdrawn from the market thus depriving clinicians and patients of this therapeutic option. Rather I argue that **full disclosure** of the data for efficacy and safety **is a basic moral obligation** of the pharmaceutical industry. Until such data is available to the public, prescribing clinicians and patients are relying on drug promotion rather than rigorous science. When **Kant discusses** the **motivation of acting from duty** **as opposed to** the motivation of **self interest**, he mentions the case of the merchant who keeps a fixed price for everyone so that a child who buys from him pays the same price as everyone else.53 The **only actions that have moral worth are those done from the motive of duty alone**. And similarly, **only when** the **pharmaceutical companies act from** the motive of **duty** in fully disclosing all information they possess about the risks and benefits of their drugs **do their actions have any moral worth**. The SSRI marketing story provides a lens through which we can view a much larger problem. The **integrity of medicine is endangered by** an industry that profits from illness and distorts the process of scientific inquiry by marketing strategy, public relations campaigns, and the **sheer power of buying influence** in high places. The House of Commons health committee in the UK has made the point: “It is not in the long term interest of industry for prescribers and the public to lose faith in it. We need an industry which is led by the values of scientists not those of its marketing force” (House of Commons health committee,23 p 6). Medicine desperately needs to win back the territory lost to business. If and when it does, it is not likely to be a result of industry and government regulators facing up to the problems, but rather a matter of the sheer weight of legal actions filed by victims and public outcry about the moral concerns of the sort raised in this paper.

#### 2] IPR is nonuniversalizable and interferes with the freedom of people who need medicine

Merges 11 [(Robert, Wilson Sonsini Goodrich & Rosati Professor of Law and Technology, University of California, Berkeley, School of Law) “Justifying Intellectual Property,” Harvard University Press, 2011]

Under Kant’s Universal Principle of Right (UPR), “laws secure our right to external freedom of choice to the extent that this freedom is compatible with everyone else’s freedom of choice under a universal law.”8 As I explained in Chapter 3, Kant’s theory of property rights expresses a special instance of this general principle: property is widely available, yet denied when individual appropriation interferes with the freedom of others. Kant says that although the need for robust property drives the formation of civil society, property rights are nonetheless subject to this “universalizing” principle. Under the operation of the UPR, property rights are constrained: they must not be so broad that they interfere with the freedom of fellow citizens. In a Kantian state, individual property is both necessary— to promote autonomy and self- development; see Chapter 3— and necessarily restricted under the UPR.9

Death is the ultimate restraint on autonomy; there is no more “self” to guide after a person dies. So when a claim to property by person A leads to the death of person B, Kant’s Universal Principle would seem to rebut that claim. As with other issues, however, Kant’s views in this regard are not so simple. In par tic u lar, he expressed complex views on the legal defense of “necessity,” which bears a close resemblance to the property- limiting principle I am attributing to him here.10 Kant says, in effect, that in at least one important example of necessity— where A kills B, or at least puts B in immediate grave danger, to save A’s own life— one who commits a necessary act is culpable but not punishable.11 As with so much in the Kantian canon, there is a great deal of debate over just what Kant was trying to say about necessity. One view— at least as plausible as most others, and more plausible than some— holds that Kant thought of necessity as something like an excuse or defense: a wrong act is not made right by necessity, but it is insulated from formal legal liability.12 This view, well described by among others the Kant scholar Arthur Ripstein, depends on the distinction between formal, positive law (“external,” in Kant’s terminology; see Chapter 3) and “internal” morality. Property for Kant is an absolute right, and taking it without permission is always objectively wrong. But at the same time, some takings are not punishable by the state because they fall outside the proper bounds of legitimate lawmaking.

Because Kant did not explicitly discuss the necessity defense as it pertains to property rights, any application of his thinking to the case of pharmaceutical patents can only be speculation. Even so, there is one point to make. As I explained in some detail in Chapter 3, there is generally a high degree of symmetry between Kant’s thinking on law and3 his theory of property. The UPR is a good example; as I explained in Chapter 3, the idea that property can extend only up to the point that it interferes with the freedom of others is simply one specific application of the general Kantian take on law and freedom. Thus, the analysis of the pharmaceutical patents problem would turn on the issue of property’s effect on the freedom of those suffering from treatable diseases. To put it simply, it is difficult to be sure of the exact conclusion Kant would reach with regard to the issue, but I am sure that the analysis would turn on the freedom- restricting qualities of pharmaceutical patents. It is hard to know the right answer, but not hard to pose the right question: should property extend so far as to cut off or restrain the freedom of those who might be treated?

### 1AC: Innovation

#### The Advantage is Innovation -

#### 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 1 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.

#### We control Uniqueness – up to 80% of all new patents are not new drugs but old ones.

Feldman 2 Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)//sid

The study results demonstrate definitively that the pharmaceutical industry has strayed far from the patent system's intended design. The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free zones. Moreover, the incidence of such behavior has steadily increased between 2005 and 2015, especially on the patent front and for certain highly valuable exclusivities. Most troubling, the data suggest that the current state of affairs **is harming innovation** in tangible ways. Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—drug companies are focusing their time and effort extending **the patent life of old products**. This, of course, is not the innovation one would hope for. The greatest creativity at pharmaceutical **companies should be in the lab, not in the legal department**.115 The following sections describe the results obtained through our analysis in detail, but below are the key takeaways from the study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% of the drugs associated with new patents in the FDA’s records **were not new drugs** coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost 40% of all drugs available on the market created additional market barriers by **having patents or exclusivities added** to them. Many of the drugs adding to the Orange Book are ‘serial offenders’—returning to the well repeatedly for new patents and exclusivities. Of the drugs that had an addition to the Orange Book, 80% of those had an addition to the Orange Book on more than one occasion, and almost half of these drugs had additions to the Orange Book on four or more occasions. The number of drugs with a high quantity of added patents in a single year has substantially increased. For example, the number of drugs with three or more patents added to them in one year has doubled. Similarly, the number of drugs with five or more added patents has also doubled. Overall, the quantity of patents added to the Orange Book has more than doubled, increasing from 349 patents added in the year 2005 to 723 in 2015. The number of drugs that had a patent added to them in the Orange Book almost doubled. There were striking increases in certain exclusivities, such as orphan drug exclusivity, new patient population exclusivity, and new product exclusivity. In particular, the number of drugs with an added orphan drug exclusivity tripled. In addition, the number of times a use code was added to a patent more than tripled, suggesting that this has become a new favored game. To provide a broad sense of the types of metrics we are using, some could be characterized as ‘intensity’ measures, which capture the breadth and depth of patent and exclusivity activity in the industry. Another set of our metrics can be characterized as ‘temporal’ measures, which evaluate whether there are any trends in the behavior under examination across time during our 11-year timeframe from 2005 to 2015.

#### 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

#### Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

#### Expanding breadth of Pharma Innovation into neglected diseases results in global linkages that revitalizes global health diplomacy.

Hotez 16, Peter J. Blue marble health: an innovative plan to fight diseases of the poor amid wealth. JHU Press, 2016. (Sabin Vaccine Institute and Texas Children’s Hospital Center for Vaccine Development, Departments of Pediatrics and Molecular Virology and Microbiology)//Elmer

We also need to better understand how these NTDs are actually transmitted within US borders, and I think it is extremely important to learn more about the links between these diseases and poverty. As I noted earlier, a drive through Houston’s Fifth Ward provides some insights, as one can quickly identify predisposing risk factors, including stray animals, dilapidated houses without window screens, standing water and discarded tires, and other evi- dence of environmental degradation, but we need to conduct careful epidemiological studies to really understand the links between poverty and NTDs, as well as animal reservoirs for illnesses such as Chagas disease and others. All of this presents an important research and development agenda for the **NTDs** in the United States. There are no point-of-care diagnostic tests available for most of the NTDs endemic to the nation, so blood from pa- tients must be sent to the CD С or other specialty research laboratories in order to establish a diagnosis for these conditions. As I sometimes point out to general audiences, when you go to your physician and get blood work done, there is no box to check off for toxocariasis or Chagas disease as there is for blood chemistries or other routine tests. We need diagnostic tests that are easily accessible to physicians and nurses. We also need new and improved treatments and vaccines. Because the NTDs are poverty-related diseases, they often fly below the radar screen of the major pharmaceutical companies and are not prioritized. Thus, the drugs used to treat these illnesses are not widely available, so typically the CDC has to be contacted in order to access them. In addition, many of these medicines were developed decades ago and produce a lot of side effects. For instance, the two medicines for Chagas disease—benznidazole and nifurtimox—cause skin rashes, diarrhea, and other unpleasant or even dangerous symptoms and illnesses. Patients using these medications have to interrupt their treatments up to 20% of the time. Moreover, these drugs cannot be used by pregnant women. Currently, new innovations for NTDs like Chagas dis- multinational ease still rely on nonprofit PDPs. The Geneva-based Drugs pharmaceutical for Neglected Diseases Initiative is leading efforts to de- companies have velop new and safer Chagas disease medicines [60], while shown little or modest at our National School of Tropical Medicine the Sab in interest in American Vaccine Institute and Texas Childrens Hospital Center for NTDs. As a result, new Vaccine Development (Sabin PDP) is working to develop products are being a therapeutic vaccine that could be used alongside exist- developed in the ing treatments [61]. These efforts rely on major philan- nonprofit sector. thropic donors. In our case at the Sabin PDP, they include the Kleberg Foundation, the Carlos Slim Foundation, the Southwest Electronic Energy Medical Research Institute, and Texas Childrens Hospital. Summary Points 1. In the United States, 45.3 million people live below the poverty line, roughly the same number of impoverished Americans alive during the early 1960s when Michael Harrington wrote The Other America. Approximately 20 million Americans now live in extreme poverty at one-half the US poverty level, and approximately 5 million are living on less than $2 per day 2. American poverty concentrates in specific areas, especially in southern states, with Texas having the largest numbers who live in poverty Important areas in the South include the Gulf Coast, border areas with Mexico, the Mississippi Delta, and Appalachia. 3. Approximately 12 million Americans are infected with NTDs, led by toxocariasis and trichomoniasis—which disproportionately affect African Americans—and Chagas disease (American trypanosomiasis) and cysticercosis—which disproportionately affect people of Hispanic origin. Toxoplasmosis is another important NTD. Toxocariasis, cysticercosis, and toxocariasis exert important mental health effects on impoverished Americans. Many of these NTDs are transmitted within US borders (autochthonous infections). 4. Arboviral infections are also important NTDs, led by dengue fever in Gulf Coastal areas and West Nile virus infection. WNV can cause chronic, persistent viral infections linked to chronic neurologic and renal disease. 5. There is an urgent need to promote awareness about the NTDs, especially for physicians and other health-care providers. 6. New policies are needed to expand surveillance for the NTDs affecting the United States. New legislation has been adopted in Texas, while additional bills are being introduced in the US Congress. Epidemiological studies are also needed to better understand how these diseases are transmitted and how they are linked to extreme poverty in the American South and elsewhere. 7. There is an urgent need for new “control tools” for American NTDs, including point-of-care diagnostics, antiparasitic and antiviral drugs, and vaccines. Many of these products are being developed by nonprofit PDPs rather than pharmaceutical companies. he G20 "A Theory of Justice" In his landmark 1971 book A Theory of Justice, the Harvard political philosopher John Rawls articulates two overriding principles of a just and fair society, namely, (1) “equality in the assignment of basic rights and duties” and (2) allowance of some social and economic inequalities, but only if they ultimately benefit “the least advantaged members of society” [1]. In terms of Rawls’s worldview, I believe that finding widespread NTDs among the extreme poor (and least-advantaged) who live amidst wealth—the central tenet of blue marble health—might represent one of the most jarring affronts to what he terms “justice as fairness” Because NTDs are now widespread among the leastadvantaged members of the worlds wealthiest economies, and they represent a major basis for thwarting their future growth, it is urgent for these nations, especially the G20 countries, to adopt strong internal policies to combat these diseases. I envision a three-pronged strategy to best address the G20 s (and Nigeria’s) poorest citizens afflicted by NTDs: 1. Each of the G20 nations and Nigeria has the capacity to fully understand the extent of these diseases within their own borders and then provide their own impoverished populations access to essential medicines used in mass drug administration to target helminth infections, in addition to trachoma, leprosy, yaws and scabies, and to provide treatments for other high-disease burden NTDs, including leishmaniasis and Chagas disease. The G20 countries and Nigeria Three major steps are required to effectively address blue marble health. 141 142 Blue Marble Health need to allocate resources and implement programs to achieve universal coverage for these diseases. 2. Each of the G20 nations and Nigeria has the capacity to conduct research and development for new NTD biotechnologies; they need to allocate resources toward this goal. 3. Both activities should be conducted within an overall framework of health system strengthening. Mass Drug Administration in the G20 A good place to revisit MDA among the G20 countries is to more closely examine the six G20 countries with positive worm indices—Brazil, China, India, Indonesia, Mexico, and South Africa—in addition to Nigeria. Together these countries account for one-half of the worlds helminth infections [2]. An analysis of WHO s PCT database reveals that most of these nations are severely underachieving when it comes to providing MDA for people who require regular and periodic treatment for their intestinal helminth infections, schistosomiasis, and LF. Shown in table 11.1 is WHO’s estimate of the percentage that received treatment in 2013 [3-5]. Overall, the G20 nations affected by helminth infections and Nigeria perform poorly when it comes to treating their affected populations through MDA. In terms of specific countries in Latin America, Brazil is reaching only approximately one-third of its children and population at risk. And although Mexico provides complete coverage for intestinal worms, it—as previously mentioned—neither diagnoses nor treats hundreds of thousands (and possibly millions) of people with Chagas disease. In Africa, Nigeria’s MDA reaches less than 25% of its children at risk for helminth infections, and there is no information about schistosomiasis coverage in South Africa forthcoming from WHO. However, as Dr. Eyrun Kjetland (who works extensively in South Africa) has pointed out, female genital schistosomiasis remains widespread there, in part because praziquantel has been mostly unavailable in the country, owing to its drug importation laws. Schistosomiasis and other NTDs are still found among the poor in the Kingdom of Saudi Arabia. The entire MENA region severely underdiagnoses most of its NTDs, including leishmaniasis. In Asia, Indonesia largely does not promote widespread deworming for its children, and only a small percentage of its population receives treatment for LF, while India does only marginally better. Indonesia also suffers from high rates of yaws, which can also be targeted by MDA using the antibiotic azithromycin. Similarly in India, the vast majority of its children do not have access to regular and periodic deworming, and only about one-half of the population receives MDA for LF. India also has the worlds largest numbers of leprosy cases. This disease can also be attacked through MDA using a multidrug therapy regimen. WHO does not present information on China, either because it has not been determined or is unavailable. However, China has made great strides in reducing its schistosomiasis prevalence since 1949, and it has eliminated LF. Similarly, Japan and South Korea have achieved significant success both in economic development and in reducing or eliminating its NTDs. 144 Blue Marble Health Key common factors for poor performance in meeting MDA targets are vast geographies, decentralization of health care, inadequate resource allocation, and lack of political will. Overall, the six G20 countries with positive worm indices, together with Nigeria, have the means and capacity to eliminate LF within their own borders, while greatly reducing the disease burdens of their intestinal helminth infections and schistosomiasis through MDA. Some of the key common factors for poor performance in meeting MDA targets are vast geographies, decentralization of health care that results in fragmentation of drug delivery, inadequate resource allocation, and lack of political will and commitment. What about G20 countries affected by NTDs but without a positive worm index? In the United States, the 12 million Americans infected and living with NTDs are largely unrecognized, undiagnosed, and untreated. The United States also does very little in terms of conducting active surveillance for Chagas disease (and other major NTDs), and only a tiny percentage of its population receives access to diagnosis and treatment—the same is true for Argentina. In both North America and Europe, toxocariasis and other parasitic zoonotic infections are seldom diagnosed and treated. Minimal information is available on eastern ------------------- Europeans, Turks, and Russians with intestinal worms or zoonotic NTDs or their access to diagnosis and treatment. NTDs remain widespread among Aboriginal Australians, including intestinal helminth infections and scabies—both of which can be targeted through MDA. Thus, the current status of access to essential medicines for people living in poverty and with NTDs among the G20 countries and Nigeria can be summarized as abysmal. The fact that so few are being treated through MDA programs is especially sad, given its low costs. As previ- ------------------- ously mentioned, there are approximately 1.07 billion treatments required among the populations at greatest risk in the G20 countries and Nigeria. At a cost of 50 cents per person per year, approximately $500 million would be required—that is, a dollar amount representing a tiny percentage (<0.001%) of the $65 trillion combined economy of these countries. The bottom line is that each of these nations has the internal capacity to provide these low-cost treatments to its impoverished populations. WHO has now launched a Universal Health Coverage (UHC) initiative that builds on its 1978 “Health for All” Alma-Ata declaration and the MillenThe current status of access to essential medicines for people living in poverty and with NTDs among the G20 countries and Nigeria can be summarized as abysmal. The G20 145 nium Development Goals, with a focus on protecting the health of the worlds most economically vulnerable populations. The activities highlighted here clearly fall within WHO s UHC mandate. Research and Development for New Control Tools and Biotechnologies For many of the leading NTDs—including vector-borne diseases such as dengue, leishmaniasis, Chagas disease, African sleeping sickness, and malaria, and also some helminth infections such as hookworm, schistosomiasis, onchocerciasis, and foodborne trematodiases—there are equally urgent needs to develop new drugs, diagnostics, and vaccines. Each year, the Australian policy group known as Policy Cures publishes an annual G-FINDER Report that measures the global investment in new technologies for neglected diseases, defining them broadly to include both the NTDs and the “big three” diseases: HIV/ AIDS, ТВ, and malaria [6]. For the year 2014, G-FINDER determined that approximately $3.37 billion was invested globally in neglected disease R&D technology, with most of that support going toward the big three diseases [6]. A look at total government support for neglected disease R&D, almost all of it from G20 countries, is also interesting. The public sector provided 64% of the total funding, and the United States provided two-thirds of that funding, mostly from the US National Institutes of Health [6]. In all, 71% of the total government funding for neglected diseases comes from the United States, European Commission, and United Kingdom. However, as the G-FINDER Report points out, these absolute numbers do not consider the GDPs of these nations. In terms of public funding relative to GDP ratios, countries such as Ireland, Denmark, Norway, and Argentina do particularly well in this regard [6]. Shown in table 11.2 are selected estimates from G-FINDER of the percentage of their GDP that various governments have devoted to R&D on Of government funding for neglected diseases R&D, a whopping 71% comes from the United States, European Commission, and United Kingdom. We need greater involvement and support from the remainder of the G20 countries, including positive worm index G20 countries— Brazil, China, India, Indonesia, Mexico, and South Africa, in addition to Nigeria. 146 Blue Marble Health Although NTDs and other poverty-related diseases account for almost 14% of the global disease burden, they receive only a bit more than 1% of the global health-related R&D funds. neglected diseases. Using data from the G-FINDER Report combined with GDP information, I calculate that the world spends approximately 0.0028% of its GDP on neglected diseases R&D. Only three G20 countries—United States, United Kingdom, and Australia—match or exceed that percentage, ------------------- although India and France come close to it. The worstperforming countries were China and Japan. However, in 2013 the Japanese government, together with Japans major pharmaceutical companies and the Bill & Melinda Gates Foundation, formed a partnership known as the Global Health Innovative Technology (GHIT) Fund for supporting PDPs and other entities to develop and shape new biotechnologies for neglected diseases, with an emphasis on NTDs [7, 8]. China is a different matter. The New York Times has reported that China paid out $86.3 billion in foreign investments in the year 2013 [9], with much of that spent in fragile nations where health systems are broken and NTDs are widespread. Clearly, China needs to allocate some of those funds to neglected diseases, either for MDA or new technologies. In addition, the nation of Brazil could easily increase its global contribution to NTD technologies by ю -fold in order to match higher-performing nations in this regard. Germany is now looking at supporting NTD technologies as part of an overarching G7 initiative on NTDs. In 2011, the German government launched a policy roadmap for neglected and poverty-related diseases [10]. Indeed, a recent analysis conducted by German investigators has found although NTDs ------------------- and other poverty-related diseases account for almost 14% of the global disease burden, they receive only a bit more than 1% of the global health-related R&D funds [11]. As shown in figure 11.1, by presenting R&D expenditures for a particular disease divided by the disability adjusted life years (DALYs) it is possible to get a sense of ------------------- diseases that are especially underfunded—even compared with other NTDS—such as the intestinal helminth infections and other neglected enteric diseases, as well as rheumatic fever [11]. Such data argue for the great urgency needed in addressing these health disparities by increasing R&D funding and support. Recently, the Dutch and German governments and the European Union (EU) have established important initiatives to support NTD R&D. The Dutch Ministry of Foreign Affairs, for instance, has been a major partner in our human hookworm vaccine initiative, while the EU has an important Frameworks Program 7 (FP7) for supporting new technologies [12], including a HOOKVAC Consortium of partners organized through the Amster dam Institute of Global Health and Development [13]. Most recently, the EU has established an ambitious Horizon 2020 program for expanding R&D in Europe, including NTD R&D activities [14], on top of a European and Developing Countries Clinical Trials Partnership (EDCTP) for clinically evaluating new NTD technologies [15]. New German government funding for NTD R&D funding was just announced. These Dutch, German, and EU initiatives represent an important advance for shaping the next generation of products to treat and prevent NTDs. Yet another aspect of blue marble health is the rise in comorbid conditions between the NTDs, the big three diseases, and the noncommunicable diseases. Impoverished and neglected populations in the G20 countries and Nigeria are facing a double hit resulting from the convergence of NTDs and NCDs. For instance, in Texas, Mexico, and India (but presumably elsewhere) they include both ТВ and diabetes interactions and, lately, dengue and diabetes interactions. In South Africa, HIV/AIDS now flourishes amidst the high prevalence of female genital schistosomiasis. Studying the pathogenesis and epidemiology of these comorbid interactions will also be an important theme in the coming years. Shaping a Policy for the G20 The G20 began meeting in 2008 in response to that years global recession and have since convened in a summit each year to discuss the major policy issues of the day [16]. At the 2015 G20 Summit held in Turkey, the major areas of broad emphasis included strengthening the global recovery and enhancing resilience, while ensuring sustainability [17]. Clearly, lifting the bottom segments of their populations out of poverty through NTD control and elimination could fall within the G20 remit. It is imperative that the six member nations with positive worm indices commit to providing total MDA coverage for their populations affected by the major helminth infections, and also that the four Western Hemispheric countries step up surveillance, diagnosis, and treatment for Chagas disease. Leishmaniasis, both kala-azar and the cutaneous form, also represent major NTDs affecting the G20, and these diseases need to be targeted for control and elimination. The US, Dutch, German, and Japanese governments, along with the EU, stand out for their contributions toward supporting product development to counter NTDs, 150 Blue Marble Health Equally important is the R&D agenda. There are some obvious underachievers among the G20 countries that must step up and contribute to R&D for new drug, diagnostic, and vaccine products to fight the neglected diseases [18]. Toward that aim, several investigators have proposed the establishment of R&D funds to support neglected disease research. They include a global vaccine development fund [19] and a general biomedical R&D fund focused on antimicrobial resistance, emerging infectious diseases, and neglected diseases [20]. Both proposals are thoughtful, have a lot of merit, and need to be considered, but I offer an alternative or complementary solution. In 2013, the World Health Assembly passed a resolution (66.22) that proposes a “strategic work plan” to achieve sustainable funding for health R&D that could emphasize NTDs. The plan commits the director-general of the World Health Organization to establish a global “observatory” in order to identify gaps and opportunities for health R&D related to neglected diseases [21]. Through a pooled fund managed by WHO-TDR (a special program on tropical disease research and training), several pilot projects are now being supported [22]. Given that todays neglected disease R&D support comes mostly from the United States—and indeed mostly from a single agency, the National Institutes of Health—it is difficult to envision how such a fund would be created without calling on the NIH yet again. Realistically, it is unlikely the NIH leadership or the well-established community of US scientists would be willing to cede control of NIH budgets to an international body. Instead, I think it is worth considering the possibility of having each of the G20 countries establish its own version of the Japanese GHIT Fund, which builds on indigenous scientists and academic institutions and their own pharmaceutical industries. A Chinese or South Korean version of GHIT for example could become a vital and important institution. Creating twenty separate innovation funds could achieve the same goals as a global fund, while simultaneously ensuring national ownership and capacity building for indigenous academic and industrial institutions. Many of them could develop and shape new biotechnologies in collaboration with the 16 international PDPs. This approach would be especially useful for the less developed G20 countries, including Brazil, Global funds for R&D are an option. An attractive alternative is to create national funds for product development R&D in each of the G20 countries and Nigeria—ones that resemble those put forward by the Dutch and Japanese governments. The G20 151 India, Indonesia, and Mexico. These nations have indigenous vaccine manufacturers, which are represented by the Developing Country Vaccine Manufacturers Network, and therefore have a level of sophistication for producing next-generation NTD vaccines. Still another option is for smaller groups of G20 countries to come together to support R&D investments. The EU’s programs for new NTD technologies highlighted above represent important examples. In addition, if institutions from China and India (both rivals and neighbors) collaborated in the area of neglected diseases [23], some important NTD problems affecting Asia could be solved in the coming years. The United States has potential to extend its outreach on NTDs by collaborating with other G20 nations in the Americas or other countries [24]. As a UN agency, WHO could certainly partner with one or more of these G20 NTD R&D investment funds, especially through its global health R&D observatory mechanism. Another key United Nations agency might include WIPO—the World Intellectual Property Organization. Through the Patent Cooperation Treaty mechanism, the Geneva-based WIPO represents one of the few revenue-generating UN agencies. In 2011, in collaboration with BIO Ventures for Global Health, it established WIPO Re:Search to facilitate the development of products to combat NTDs by bringing together major pharmaceutical companies and academic investigators working on these diseases [25]. As a revenue-generating UN agency under the charismatic leadership of Francis Gurry, WIPO has the potential to expand this remit to support NTD product R&D. Looking beyond the G20 The major NTDs linked to wealthy countries and blue marble health could also be addressed by nongovernmental organizations, including faith-based groups. For example, in 2011 the Pew Research Centers Forum on Religion and Public Life reported that the center of the worlds Christian-majority countries has shifted from Europe and North America to the Global South, meaning Africa, Asia, and Central and South America [26]. Thus, countries such as Brazil, Philippines, Angola, Democratic Republic of Congo, and Papua New Guinea now have some of the highest percentages of Christian populations. As shown in table 11.3, from an analysis published in PLOS NTDs I found that almost all of the world s Chagas disease cases and African trypanosomiasis (sleeping sickness) can be found in Christian-majority countries, in addition to almost one-half of the schistosomiasis cases [26]. These findings suggest the possibility of bringing in new actors to combat NTDs. They could include the Vatican and Pope Francis, especially given the new popes renewed commitment to impoverished populations [19]. The Orthodox Christian Church also has opportunities to highlight NTDs in countries such as Ethiopia or those in the Middle East, as do many Christian faith-based organizations and universities. The G20 153 Summary Points 1. The six G20 countries with positive worm indices—Brazil, China, India, Indonesia, Mexico, and South Africa, together with Nigeria, have the means and capacity to eliminate LF within their own borders, while greatly reducing the disease burdens of their intestinal helminth infections and schistosomiasis through MDA. 2. G20 countries without classical worm indices, including the United States, also need to find mechanisms for promoting surveillance and access to essential medicine options for the poor living with NTDs within their own borders. 3. The G20 countries also have important biotechnology capabilities, which have yet to be adequately tapped for producing new NTD diagnostics, drugs, and vaccines. Beyond the United States, European nations, Australia, and Japan, they also include Brazil, China, India, Indonesia, Mexico, Russian Federation, Saudi Arabia, South Africa, and South Korea. 4. Yet another aspect of blue marble health is the rise in comorbid conditions between the NTDs, the big three diseases, and the NCDs. 5. The EU and the Dutch and German governments have launched important NTD technology initiatives, as has the Japanese government and its partners through a new GHIT Fund. These activities support PDPs committed to NTDs as well as indigenous academic institutions and industrial organizations. 6. Large G20 economies such as Brazil and China must increase their global commitment to support new NTD technologies and R&D. 7. There are opportunities to link these new investments with parallel activities ongoing at two UN agencies, namely, WHO and WIPO. 8. These topics should be highlighted at future G20 summits. 9. Faith-based organizations could have a future role. For instance, the Vatican and related entities have opportunities to expand commitments to control those NTDs that are found to be prevalent among Christian-majority countries. Central to the blue marble health concept is that each of the G20 nations and Nigeria need to take greater responsibility for their own neglected diseases and neglected populations. Doing so could result in the control or elimination of one-half or more of the planets NTDs, with substantial gains made against HIV/AIDS, ТВ, and malaria. Thus, while programs of overseas development assistance devoted to health, such as PEPFAR, GFATM, PMI, and USAID’s NTD Program, in which the worlds richest countries provide support to the poorest nations for their neglected diseases, must continue and should even expand, we need increasingly to recognize the hidden burden of neglected diseases among the poor living in wealthy countries. As a first step, we must expand initiatives that raise awareness about the problem of NTDs within each of the G20 countries and Nigeria. The Global Network for NTDs linked to the Sabin Vaccine Institute has been working closely with the governments of India and Nigeria, respectively, in order to explain the opportunity for mass drug administration and its potential impact on health and economic development. MDA coverage rates are disappointingly low in these nations, especially for intestinal helminth infections and LF, as well as for schistosomiasis in the case of Nigeria. An extraordinary finding is that at least three nations with positive worm indices—India, Pakistan, and China—also maintain nuclear stockpiles [1]. Could the scientific horsepower of these nuclear states be partly redirected toward reducing endemic NTDs at home? 154 A Framework for Science and Vaccine Diplomacy 155 Outside of India and Nigeria, there is a need to promote NTD awareness in each of the G20 countries. For example, in the United States, our National School of Tropical Medicine has been highlighting the plight of some 12 million Americans living with NTDs. We have now worked with the Texas Legislature to enact a bill for NTD surveillance in suspected high-prevalence areas. However, similar initiatives need to be enacted across the G20 nations, including the European Union. In addition, international cooperation between the different G20 nations and Nigeria could be critical in achieving higher population coverage for MDA. For instance, China, despite its billions of dollars of business investments in sub-Saharan Africa, has not yet promoted NTD control efforts there. Yet China has tre- mendous expertise in MDA for NTDs and could provide Africa with valuable advice in this area. China was the first country to eliminate LF and has achieved successes in re- ducing its burden of schistosomiasis more than ю -fold since the 1949 revolution. China could also share its best practices with neighboring India, where NTDs remain practically ubiquitous [ 2]. Similarly, Japan and South Korea have made great gains toward eliminating intestinal helminth infections, while the former has also successfully eliminated LF and schistosomiasis. International cooperation between these three East Asian nations and Nigeria, or with the G20 countries with positive worm indices, especially India, Indonesia, and Brazil (where they are the highest), could result in important, positive health and economic gains. Each of these activities represents examples of what some refer to as global health diplomacy. Global Health Diplomacy My former colleague at Yale University, Ilona Kickbusch, currently the director of the Global Health Programme at the Graduate Institute of International and Development Studies in Geneva, has provided several working definitions of global health diplomacy, including efforts to “position health in foreign policy negotiations,” together with the establishment of global health governance initiatives [3]. Indeed, the creation of the GAVI Alliance, GFATM, UN AIDS, and other Geneva-based organizations might be considered vital examples of organizations created under the auspices of global health diplomacy, with the first two created following the 2000 Millennial Development Goals. The MDGs themselves represent an important framework for global health diplomacy, and arguably the most successful. Since 2005, several global health diplomacy initiatives have been enacted that could facilitate NTD activities among the G20 and Nigeria, although most of these actions are more focused on emerging viral infections of pandemic potential rather than the widespread chronic and debilitating NTDs. The International Health Regulations (IHR) were enacted in 2005 as a binding legal mechanism for all member states of WHO and focused on responses to acute public health emergencies [4]. IHR demands that countries report outbreaks and other public health events, while WHO responds with measures to uphold and enforce global health security [4]. IHR also establishes an emergency committee that advises the WHO director-general on whether an unexpected event should be considered a public health emergency. It also provides recommendations on initial steps for travel restrictions, surveillance, and infection control. With the possible exception of dengue fever, it is not clear how IHR will substantively address the NTDs or other blue marble health conditions. Moreover, even with IHR in place, the global response to the 2014 emergence of Ebola in West Africa was slow and inadequate and led to a catastrophic outbreak in the fall of that year [5]. This failure may require future revisions in the IHR, as recently recommended in a 2015 Lancet article by Lawrence Gostin and his colleagues at Georgetown University [6]. The Global Health Security Agenda (GHSA) is an interagency initiative of the US government conducted in partnership with other nations and international organizations, including WHO [7]. GHSA is also focused on preventing or reducing the impact of epidemics and outbreaks of pandemic potential, such as H7N9 influenza virus or MERS coronavirus, as well as detecting emerging threats and implementing rapid and effective responses. In some respects, GHSA represents the US component or response to IHR. It also covers intentional or accidental releases of dangerous infectious disease pathogens. Global Health 203s and The Lancet Commission were launched in 2013, coinciding with the twentieth anniversary of a landmark 1993 World Development Report that helped to ignite international efforts to link investments in health with economic development [8]. The Lancet Commission identifies four key messages and actions: (1) the substantial economic return on investing in health, which can be as much as 24% in low- and middle-income countries; (2) implementation of a “grand convergence” in global health through scale-up of health technologies and strengthening health systems by the year 2035; (3) fiscal policies such as taxation of tobacco and reduction of subsidies for fossil fuels, which represent powerful forces or “levers” for elected leaders; and (4) universal health coverage as an efficient mechanism to improve health as well as to provide “financial protection” [8]. The Addis Ababa Action Agenda (AAAA) is the product of the first of three international meetings for implementing the UN s 2015 Sustainable Development Goals. However, health is at present only a minor component of the AAAA. Indeed, the SDGs have been criticized because health is now only 1 of the 17 goals, whereas it was front and center among the 2000 MDGs. So far, the AAAAs recommendations have included the promotion of the health systems strengthening component of the GFATM and GAVI Alliance and the establishment of a Global Financing Facility (GFF) for womens and childrens health that would go hand-inhand with the UN secretary generals new Global Strategy for Every Woman Every Child [9]. The emphasis of these initiatives is to reduce preventable maternal, child, and adolescent deaths by 2030. Despite the evidence that hookworm infection and Chagas disease rank among the leading complications of pregnancy among women living in poverty in low- and middle-income countries, while female genital schistosomiasis is among sub-Saharan Africa’s most common gynecologic condition, there is not yet a specific mention of NTDs in the AAAA or GFF. Ultimately, the G20 nations can identify ways to address blue marble health disparities under the auspices of the SDGs or the global health diplomacy initiatives highlighted above. However, at present there is no specific mandate for them to do so. Vaccine Science Diplomacy Concurrently, the G20 nations have opportunities to collaborate in scientific activities leading to the development of new drugs, diagnostics, and vaccines. I have used the term “vaccine science diplomacy” to refer to inter- national scientific codevelopment of lifesaving vaccines between scientists of different nations, but particularly from nations with strained or evenly openly contentious international relations. The best historical example of vaccine science diplomacy is the codevelopment of the oral polio vaccine, led on the American side by Dr. Albert B. Sabin, and his Soviet virologist counterparts, including Dr. Mikhail Petrovich Chumakov [3]. In modern times there is potential interest in explor ing vaccine science diplomacy opportunities between the United States and some of the worlds Muslim-majority nations belonging to the Organisation of Islamic Cooperation [10,11]. OIC countries include most of the Middle East and North Africa, as well as some highly populated Southeast Asian nations, including Bangladesh, Indonesia, and Malaysia, as well as most of central Asia. New estimates that we published in PLOS NTDs in 2015 indicate that the 30 most-populated OIC countries account for 35% of the worlds helminth infections comprising the global Worm Index, including 50% of the worlds children who require MDA for schistosomiasis [11]. Given that approximately 1.5 billion people live in OIC countries, or about 20% of the global population, helminth infections appear to disproportionately affect the health and economic development of Muslim-majority countries, as does leishmaniasis, trachoma, and possibly other NTDs [11]. As shown in figure 12.1, there is also tight inverse association between the worm index and human development index in the Muslim world [11]. OIC nations with strong infrastructures in science and biotechnology are potentially attractive candidates to pursue joint vaccine science diplomacy initiatives with the United States. Here the idea would be to promote scientific collaborations between US scientists and scientists from selected OIC countries in order to create new NTD technologies for some of the worst-off Muslim-majority countries. The “worst-off” might include OIC countries at the high end of the worm index, including Mali, Cote d’Ivoire, Mozambique, Cameroon, Burkina Faso, and Niger, as well as Nigeria [11].

#### Solves hotspot escalation

Nang and Martin 17, Roberto N., and Keith Martin. "Global health diplomacy: A new strategic defense pillar." Military medicine 182.1-2 (2017): 1456-1460. (MC, Global Health Division, Uniformed Services University of the Health Sciences)//Elmer

INTRODUCTION: FORCE IF NECESSARY BUT NOT NECESSARILY FORCE The world appears unhinged. Instability from the Middle East, Caucasus, Africa, and Central America to Asia abound. The Study of Terrorism and Response to Terrorism database identified fewer than 300 major terrorist incidents between 1998 and 2004 in the Middle East and North Africa. In 2013, they listed 4,650 such incidents.1 Quieter cracks tear at the fabric of South America and parts of Asia. Although geographically distinct, many of these areas of instability share underlying causes that give rise to threats to the United States and the global community. Human-generated causes include corruption, poor governance, absence of the rule of law, violence, gross human rights abuses, climate change, environmental degradation, a weak civil society, and a lack of professional capabilities across skill sets within the government departments needed to effectively manage the operations of a well-run state.2 Natural causes include disasters, disease, demographic changes, and limited access to the resources essential for life. When these human or natural causes create conditions that result in poor provision of, or unequal access to essential services, such as water, food, shelter, health services, education, and economic opportunity, people lose confidence in government and hope for their children and their future. They become restless, demonstrate, can become violent and overthrow their governments (such as the self-immolation of Mohamed Bouazizi, the Tunisian cart vendor, which sparked 35 more selfimmolations by extralegal businessmen and started the Arab Spring), or can result in mass migrations.3 Desperate human security, conditions create desperate people undermining stability and creating even more demands from host nation governments and governments in neighboring states. Although force and counter terrorism programs are sometimes needed to address security threats, enormous opportunities are available to use nonkinetic capabilities within the Department of Defense (DoD), Department of State, U.S. Agency for International Development, other U.S. Government agencies, and civilian organizations to address the underlying causes of instability. Global health diplomacy is an underutilized strategic asset to do this. At a far lower cost, it will save lives, decrease economic losses, reduce the need for kinetic military operations, increase security cooperation, improve diplomatic relations, encourage trade, and create the foundations for longterm stability. HEALTH IS A NATIONAL SECURITY IMPERATIVE—DISTANT HEALTH THREATS ARE GLOBAL THREATS Health is a national security imperative. The second- and thirdorder effects of a strategic health or global health issue that severely impacts and overwhelms the stability of a far-distant nation can have broad and multiplying effects that transcend boundaries and can become regional and global security threats. When human immunodeficiency virus/acquired immunodeficiency syndrome first started to be seen in the United States, there were U.S. leaders that were not too concerned about its impact on the general public, alluding to the fact that it was a disease that mostly affected the four H’s: homosexuals, heroin addicts, hemophiliacs, and Haitians.4 From its first known cases in 1981 up to 2013, human immunodeficiency virus has infected almost 78 million people and killed about 39 million.5 The Chernobyl power plant accident that occurred on October 26, 1986, was a catastrophic nuclear accident. Several studies have been done to estimate the increase in health effects and cancer-related morbidity and mortality in Europe.6 Communicable diseases can be easily carried from a distant area of the world to a teeming metropolis within 24 hours because of the ease and affordability of plane travel. The interconnectedness of countries as a result of trade has its drawbacks— biological or chemical contamination of food or products commonly occur across oceans and continents.7 Noncommunicable diseases are also affecting not just high income countries but also low-to-middle income countries. Ubiquitous exports of fast-food meals, high-fructose drinks, and salty, fried foods have contributed to a tremendous increase in obesity and hypertension.8 Obese and sedentary populations negatively impact the workforce of a nation and its productivity. The offices of military personnel and readiness cite obesity as the number one disqualifying reason for new recruits.9 Twenty seven percent of the U.S. young adults are not fit to serve in the military.10 Addiction to illegal drugs is an important global health threat. The problems created by the manufacture of opium in Afghanistan, methamphetamine in Mexico, and cocaine in Peru and Columbia create tremendous and devastating health effects, loss of productivity, social disruptions, breed corruption in a nation’s military and police forces, and create turbulent violence all along its wake, both in the countries manufacturing the drugs and the countries importing them. Weather forecasters often discuss the multiplying effects that the fluttering of a butterfly’s wings in one country may have on the regional weather of another distant country. Global health professionals and more and more of our military and political leaders are now concerned that the disease that we see in a child in Africa or a pig in Asia may have tremendous impacts on the public health, economic productivity, military readiness, and strategic security interests of their nation. In addition, a weak health and political system anywhere can be a threat everywhere. LINKAGES: GLOBAL HEALTH, SECURITY, AND STRATEGIC CHALLENGES Global health encompasses the basic needs required for human security: respect for people’s universal rights, personal protection, the rule of law, access to food, water, health care, education, basic infrastructure, and shelter.11 Their absence leaves populations vulnerable to the depredations of insurgent groups and corrupt, venal cabals that can hijack a region or state for the benefit of themselves and a select group of people. This creates an environment of the privileged and abused, the included and excluded, and an environment ripe for insecurity and conflict.12 For a nation to provide the environment where people’s basic needs can be met requires capabilities within their governing infrastructure and communities. This includes management, finance, education, social sciences, law,medicine, public health, engineering, veterinary medicine, agronomy, and more. Their absence [undermines] ~~cripples~~ a nation’s ability to support a foundation for human security and stability, inhibits its ability to thrive in good times, and respond effectively to natural and man-made threats in bad times. It **breeds corruption**, poverty, poor health outcomes, spread of lethal diseases, gross **human rights abuses and conflict. This we have seen played out with grim efficiency in Afghanistan, Pakistan, Iraq, Syria, Sudan, Democratic Republic of the Congo, Central African Republic, Libya, Yemen, Somalia, Nigeria, Honduras, and beyond**. All have had disastrous regional effects, many have created direct threats to U.S. interests. Islamic State in Iraq and Syria was borne out of the brutal kleptocracy of Assad’s Syria and a destructive government in Iraq. Al-Shabaab was created in the failed state of Somalia. Boko Haram grew in the destitute and neglected regions of northern Nigeria. Al Qaeda and the Taliban secured a haven in the lawless western regions of Pakistan. Weak governments in Central America created a fertile ground for organized criminal gangs to terrorize the populace and profiteer off the illegal drug trade that destroys lives, and drives people to desperately flee northward into the United States. Insurgencies, terrorist organizations, and other nonstate actors thrive in the presence of an incompetent or abusive state government that violates segments of its citizenry and fails to provide an environment where peoples’ rights are protected and their basic needs met. These groups divine counter narratives that take advantage of people’s lack of hope and fears. They create a refuge and an outlet for people’s rage. Such messages and place of belonging can be a powerfulmagnet for youths, the poor, and the disenfranchised,who see little hope in the future. Security threats are not only manmade but also can come from nature. The international community’s failure to dramatically reduce our carbon footprint leaves us vulnerable to an increasing number of extreme weather events that threaten everything from coastal communities to food and water security. This will amplify existing tensions over natural resources and could result in the forced migrations of massive numbers of vulnerable people. The world’s population is expected to reach 9 billion by 2030. The growth will primarily occur in cities in the developing world most of which already have fractured or nonexistent infrastructure. Climate change will have a dramatic effect on densely populated poor urban areas, especially those in arid zones and in littoral areas. This is a recipe for disaster. Environmental degradation is also increasing the spread of infectious diseases and facilitating zoonoses to jump the species barrier and infect humans. The Ebola outbreak, like severe acute respiratory syndrome and H1N1 before it, is part of a long list of diseases that have infected humans from an animal reservoir with devastating impact. Many zoonoses exist and more will come. Using history’s guide, the next pandemic will likely be a zoonotic agent. Recognizing this, the United States last year led the creation of the Global Health Security Agenda to prevent, detect, and respond to deadly disease outbreaks.13 Though accepted by many countries, it has been implemented by few. No amount of force can resolve these challenges. However, global health diplomacy, exercised through civil-military and military-military programs, is a promising strategic tool that should be employed to address these wicked strategic or global health problems and improve domestic and international security. AN OPPORTUNITY TO ACT Despite a growing level of interest in academia and government agencies, there is little agreement on how to define “global health diplomacy.”14 Michaud defined it as “international diplomatic activities that (directly or indirectly) address issues of global health importance, and is concerned with how and why global health issues play out in a foreign policy context.”14 The World Health Organization (WHO) states that it “brings together the disciplines of public health, international affairs, management, law, and economics, and focuses on negotiations that shape and manage the global policy environment for health.”15 We summarize global health diplomacy as the application of a broad range of skill sets to cooperatively improve human security throughout the world. A vital area of focus must be to strengthen public service, governance capabilities, and civil society in unstable regions. Doing so will enable nations to create an environment where their citizens’ basic needs can be met, universal rights respected, and the ability to hold a government to account, secure. This includes building and retaining capabilities to manage effective, noncorrupt, justice, finance, health, education, defense, public works, and environmental departments. The absence of these structures cripples a country’s ability to govern itself and leaves it vulnerable to the causes of instability, both human and natural. The United States, by virtue of its strengths across diplomacy, defense, development, trade, and its inherent domestic civilian capabilities, has an opportunity to exercise its leadership and mobilize these assets. Using global health diplomacy to comprehensively strengthen public service and governance capabilities has been chronically neglected by the international development community. It needs a leader to start this process and the United States has the ability and authority to do so in the national and international interest.

### Underview

#### 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] Ideal theory is best

#### a) action theory – we’d constantly be fixing injustices as a precondition to ethical action so we never get to the bottom of what is actually ethical

#### b) 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

#### c) every ethical theory can be misused – but that isn’t a problem with ethical principles, that is a problem with us – also means we should reclaim the true function of these ethical concepts in places like debate to challenge the way they are misunderstood

#### d) real world injustices need universal ideal principles to ground them and explain why they are wrong. Saying 100 lives still assumes 1+1 = 2 which requires a priori rules.

# 1AR

### Presumption and Permissibility affirm

**Permissibility and presumption affirm**

**1] Paralysis- otherwise we would not be able to justify morally neutral actions like drinking water since there isn’t a prohibition and we would needlessly have to prove an obligation.**

**2] Trivialism- statements are true until proven false, if I told you my name you’d believe me.**

#### 3] Affirming is harder - A] 7-4-6-3-time skew makes every 1ar speech a time crunch that can’t justify a proactive obligation B] They know the aff but we don’t know the NC so the burden is on them. Structural skew O/W on reversibility since it can’t be changed.

#### 4] Negation Theory- Negating requires a complete absence of an existing obligation

Negate [is to]: to deny the existence of

That’s Dictionary.com- “Negate” https://www.dictionary.com/browse/negate.

### Fairness/Theory O/W Trix

#### The shell comes prior to [Apriories, Truth Testing ROTB, Trix nonsense] - 6 justifications

#### 1] Truth Testing- absent legitimate clash over the issues it makes it impossible to test the truth value of their arguments which is a side constraint on deliberation

#### 2] The shell indicts your ability to read these arguments in the first place which means you can’t weigh them

#### 3] You need an external body to verify whether your theory is correct. Anything else leads to self-justified truths that and psychopathic lying which prevents rigorous testing. Testing outweighs because it’s the constitutive purpose of debate

#### 4] Constitutivism- fairness is a constitutive process of debate proven by us following speech times, disclosing, flipping before round, etc. Their [trix arguments] assume the ballot which we have proven are constrained by procedural rules. Independently Constitutivism outweighs all other offense since it’s inescapable and affects how we play the game

#### 5] Inclusion- Only our model of debate creates a more inclusive atmosphere that allows for contestation and competitive equity. Inclusion should be used as an impact filter to all their arguments since accessibility controls the internal link to being able to debate in the first place

#### 6] Time Skew- Reading the shell means we took time to read the shell so we couldn’t mind sweep their arguments and respond to all of them in a technically efficient manner.

## K

### 1AR – AT: Ballot Link

#### The Ballot Link – it’s non-unique – the judge has to vote for someone so both sides “call” for the Ballot. We don’t link since we don’t think voting Aff will do anything other than cause us to win, the Alternative links more since you’ve invested symbolic power in the “No” of the Ballot.

### 1AR – AT: Fulfil the Lack Link

#### They say we attempt to overcome our lack through reducing IP – 1] No Link – we don’t think the Plan is a end-all-be-all – it’s obviously incomplete BUT it doesn’t deny that certain medical innovations can minimize the global harms of suffering and 2] Turn – Pharmaceutical companies profit-driven motives attempt to fulfill the lack w/ money – the Plan disrupts that and says there are other ways to relate and engage the world which is good.

### 1AR – AT: Themi Impact

#### They say Themi – 1] This is about “willful ignorance” so the Perm solves it, 2] Non-Unique DA - Empirically proven to be non-unique – at what point does denial of the lack cause Extinction – scenario specificity should filter probability, and 3] We’re not “doing more moral things”, we’re negative State Action which isn’t a transgression.