### Setcol k

#### The fueling and protecting the American economy creates violence against natives – injecting economic cost benefit rationale into ecological context crowds out other ways of knowing/valuing outside of the discourse of western civilization

Barry ‘04 (John, Reader in Political Theory in the School of Politics, Queen’s University Belfast, ”From environmental politics to the politics of the environment The pacification and Normalization of environmentalism?”, Liberal Democracy and Environmentalism: The End of Environmentalism? By M. Wissenburg , p.188-9)

In the privilege accorded to science and the 'scientific method' within modern societies, we can find roots of the dominance of economic forms of reasoning and thinking within contemporary capitalist liberal democratic nation-states. Its predominance as the central form of knowledge (along with natural science) used by state actors, bureaucracies and leaders to make decisions, implement policies and propose reforms, while of course not eliminating other forms of knowledge and bases for making political judgement, has had a profound effect on the environment and social-environmental relations. As Francis Bacon, one of the founders of the modern scientific method and worldview, noted, 'knowledge is power', and this is particularly true in respect to the natural sciences and economic science. At the same time, economic forms of thinking do not simply express themselves within state policy-making, but can also seep into 'ordinary' or 'common sense' modes of thinking. While the powerful effect of economic reasoning on modern perceptions of the environment and its official (and unofficial) influence on state decision-making which affects the environment, cannot be overestimated, I will limit my discussion to a few salient points.

Economic forms of reasoning and argumentation heavily influence political debate over environmental issues within public policy. Precisely because of the dominance of economic considerations in public policy-making, environmental issues are often translated into 'economic' problems and courses of action pursued on the basis of the economic costs or benefits of the environmental issue in question. There is a lot of strategic advantage in using economic forms of argumentation in advancing the case for environmental protection, since one is speaking a language politicians and policy-makers understand (see, for example, Pearce 1992: 8).

This is not to deny the importance of economic considerations, but simply to note how an economic approach to and understanding of social-environmental problems can (and does) "crowd out1 non-economic forms of environmental valuation and argumentation. The privileged position occupied by economics in environmental policy-making has the effect of drowning out other 'voices', other forms of reasoning, valuing and thinking about the environment. This economistic monologue (as opposed to a genuine dialogue), holds a fortiori, if as noted in the case above, that environmental decision-making is made in non-deliberative or discursive institutional settings.

Economic reasoning, methodology, rationality and forms of valuing the natural environment can be regarded as not simply the language of power in policy-making, but the grammar of power. What is meant by this is that economic theory functions as the dominant way in which environmental policy-making is debated, thought about and ultimately decided. In this sense it constitutes the very 'rules of the game' in the same way as grammar has rules for the correct use of language. Thus, those who either do not know or refuse to accept this particular grammar (such as non-economic arguments for environmental preservation) are at a severe disadvantage in trying to influence environmental policy-making within the current institutional framework.

#### Settlers use pathologizing narratives of “*vulnerable populations*” to shift responsibility of settler colonial violence – the AFF’s upholds the settler structure we’ve problematized

Patel 14 – PhD in Curriculum Development at Boston College [Lisa (Leigh) Patel (2014), Countering Coloniality in Educational Research: From Ownership to Answerability, Educational Studies, 50:4, 357-377, DOI: 10.1080/00131946.2014.924942, Accesed via Taylor Francis Online] Eagan – mads

Educational research displays parallels to the nation’s durable settler-slave Indigenous relationships through many aspects of research. First is what cultural groups are likely to be researched, racially minoritized and low-income, versus those conducting the research. Educational research, in many ways, relies on vulnerable populations to justify various foci in funding streams and publications through the justification of potential impact at improving said vulnerable populations’ conditions (Daza 2013b; Tuck 2009). But one of the net effects of the predominance of this justificatory lens is a pathologization of particular populations that essentializes human conditions, often obscuring information that may not fit the justificatory frame of at-riskness. This is a trope that has been critiqued by scholars within and outside the field of education. Psychologist Carl Hart addressed this trend to pathologize, explaining why the field of psychology may have long-standing misperceptions about the causes and potential influences on drug addiction: “There’s a skewed focus on pathology. We scientists know that we get more money if we keep telling Congress that we’re solving this terrible problem. We’ve played a less than honorable role in the war on drugs” (Hart, as quoted in Tierney 2013, para 20). When such frames are pervasively rewarded through grant structures and funding and resultant publications, coloniality persists in the relation between subject and researcher. In the field of educational research, and indeed in most applied social science fields, there is a great deal of research studying why everyone else does not achieve at the levels of economically privileged White populations. Most empirical studies close their findings with implications, and in studies of lack of achievement, the most common suggestion is for interventions for various populations who do not enjoy the safety, security, and flourishing historically experienced by upper and middle-class White settler populations. In fact, only the at-risk, those in need of intervention, are studied. Those who benefit from preferential spots in society are not generally studied, and because of that silencing, they are recentered as the norm. When the privileged are studied, though, it has often been from the episteme of what they’ve done well, to then apply such practice as an intervention to others (e.g., Duckworth et al. 2011), rather than from the stance of how interlocking forms of societal privilege have led to privileged social status. Meanwhile, those struggling are spotlighted as the area of need, not a system that comprehensively functions to secure and refresh higher status for those already holding power and marginalize nondominant populations. This insight is not a new one, nor has it gone unchallenged. In 1899, W. E. B. DuBois reversed this pathologizing gaze in his comprehensive analysis of the social, cultural, and economics conditions offered a systemic understanding of African Americans in turn of the 20th century urban Philadelphia. This stance echoes productively in research that studies up and across liminality to, in part, shed light on colonial structures (Daza 2006; McCarty and Lee 2014; Nader 1972). Despite such early and strong examples of systemfocused research, the dominant approach has been to focus on the neediness of dispossessed populations. This is not to say that there are not material needs that Native peoples, urban populations, populations of color, and poor populations face in educational and other social settings but, rather, that acritical and ahistorical educational research is complicit in the maintenance of these realities by consistently justifying its work through the lens of the achievement gap, rather than being grounded in the political, economic, and historical infrastructure of inequity (Ladson-Billings 2006). Instead of focusing attention on the malignancy of this system, the trend has been to focus (pathologizing) attention on the lower strata and how to provide them with experiences that mimic those in the upper strata, echoing the pattern of erasing to replace. For example, the current context of growing numbers of immigrants from non-English-speaking homes has led to a plethora of educational research studies investigating how to make these populations fluent in standard academic English as quickly and as efficiently as possible. Such studies and policies work from a tacit premise of meritocracy that, given the preferred linguistic and cultural practices, success and safety in society is available (McNamee and Miller 2004; Patel 2009), latent only because of the lack of these skills. Although fundamentally flawed with an even superficial understanding of the history of formal education in the United States (Bowles and Gintis 1976), this predominant focus on the transmittal of standard academic English also echoes the genealogy of settler colonialism through a contemporary coloniality that seeks to erase in order to replace, but with a replacement that cannot provide access to higher status, ultimately reseating those with higher status.

#### **Focusing on American Economic fluctuations is unethical – requires violence to Indigenous nations**

Byrd ‘11 (Jodi A., (Chickasaw), assistant professor of American Indian studies and English at the University of Illinois at Urbana-Champaign, The Transit of Empire: Indigenous Critiques of Colonialism, pg. xxiii-xxvii)

That the continued colonization of American Indian nations, peoples, and lands provides the United States the economic and material resources needed to cast its imperialist gaze globally is a fact that is simultaneously obvious within—and yet continually obscured by—what is essentially a settler colony’s national construction of itself as an ever more perfect multicultural, multiracial democracy. As the United States constructs a Manichean allegory of settler democracy through which imperialism can finally be brought humanely and justifiably to the world through discourses of “fighting them there so we don’t fight them here,” the status of American Indians as sovereign nations colonized by the United States continues to haunt and inflect its raison d’etre.

#### Settler colonialism is both a both a structure and an event. The globalization of settler colonialism necessitates the 1AC as part of its attempt to complete the unfinished settler colonial project that converges symbiotically with militarism. The conditional imposition of debt repayment supplants this construction of settler de facto sovereignty that overcodes that of other nations.

Kim 18 [Jodi Kim Social Text 135 • Vol. 36, No. 2 • June 2018 Settler Modernity, Debt Imperialism, and the Necropolitics of the Promise] ChefDON//mads

This essay offers an investigation of US settler colonialism and military empire, a conjunction theorized as settler modernity, in the post–World War II era. It argues that settler modernity is an ensemble of relations significantly structured and continually reproduced through manifold regimes, relations, and forms of debt, and in particular through debt imperialism. Debt imperialism, as the essay elaborates, is a kind of temporal exception. It is a multiscalar process through which the United States imposes imperial power by rolling over its significant national debt indefinitely and not conforming to the homogeneous time of repayment that it imposes on others. This linking of debt and imperialism, indeed the ability to leverage great indebtedness into a form of imperialism, demonstrates how debt can function in such manifold and counterintuitive ways because it is not simply a financial economy. It is also crucially a figurative economy or narrative structure. The debt relation thus indexes something much broader than the sum of money owed. Indeed, it is a broader social relation, production of subjectivity, sleight of hand, and creation of a temporal exception through which US settler modernity functions and continually attempts to re-create itself. In this varied relation, debt curiously emerges in two seemingly antonymous forms: as a form of imperialism, on the one hand, and as a form of freedom, emancipation, or liberation, on the other. I focus on Asia and the Pacific as a crucial site where we witness a violent and specifically militarized convergence of these arrangements in the post–World War II conjuncture, when the US settler state also becomes a military empire. Transpacific connections within Asia, the Pacific, and the United States, the making of multiple Asian and Pacific Islander diasporas, subimperial dynamics and desires among Asian and Pacific regions and nations, and decolonial aspirations among the peoples of colonized territories are all animated by what might be called a colonial and gendered racial transpacific debt relation and militarism. I ask, moreover, how debt functions as a necropolitical regime for those impoverished, gendered racial, and colonized nations and subjects whose promissory notes must be fully repaid with interest. How has US settler modernity been constituted by this usurious necropolitics of the promise, even as it continually confers upon itself the temporal exception of debt imperialism, or the right not to keep its promises or even to evade the very need to promise? This analysis reveals that what is at stake in US settler modernity is not only the elision of conquest and genocide as the conditions of possibility for military empire, economic power, and the avowed defense of liberal democracy but also the attempt to possess metapolitical authority. Metapolitical authority, as distinct from mere political authority, is the ability to define and prescribe the very content and scope of “law” and “politics.”1 In invoking Asia and the Pacific as a site, it is not my intent to flatten the vast and complex heterogeneities and hierarchies within it, nor is it my intent to reproduce limitations in the frameworks of American studies, Asian American studies, Asian Pacific American studies, and Asian studies that are not sufficiently attentive to work in Native Pacific and Indigenous studies. Rather, my intent and hope are to interrogate the very production of the Asia-Pacific by the United States as a site of strategic interest. This geopolitical and geohistorical production calls for a relational analysis of distinct yet related forms of colonial domination — settler colonialism and military empire in particular — rather than a focus on one form that tends to elide the other. The United States as the literal testing ground for biopolitical tactics and technologies that are geopolitically and militarily projected abroad has produced and continues to produce Native displacement and dispossession, and that geopolitical and military projection abroad in Asia and the Pacific in turn produces Asian and Indigenous Pacific Islander migration. Indeed, as Jodi A. Byrd asks, “Given all these difficulties, how might we place the arrivals of peoples through choice and by force into historical relationship with indigenous peoples and theorize those arrivals in ways that are legible but still attuned to the conditions of settler colonialism?”2 In theorizing, then, the nexus of US settler colonialism and military empire in Asia and the Pacific as settler modernity, I also amplify Alyosha Goldstein’s contention that focusing exclusively on imperialism and empire can risk obscuring how territorial seizure, occupation, and expansion, differential modes of governance, and their attendant justifications remain the conditions of possibility for more indirect forms of rule, the vast network of military encampments, and global economies.3 Moreover, this essay understands settler colonialism and military empire as an ensemble of relations that continually need to re-create and renovate themselves, for they are incomplete and unexhausted projects.4 Indeed, the continual violence generated by settler colonialism and military empire is a mark or index of their very incompletion, as are the solidarities, oppositions, and continued survivals of communities and peoples against whom (and often ostensibly on behalf of whom) such violence is waged. I build on Patrick Wolfe’s important conceptualization of settler colonialism as a “logic of elimination” whose dominant feature is the acquisition of land (via the elimination of the Indigenous population and its replacement with the settler population) rather than the surplus value derived from mixing native labor with land. As such, for Wolfe, settler colonialism is a structure and not an event.5 Yet, insofar as settler colonialism is not a fait accompli but, rather, a process that requires continual renewal and renovation, I comprehend it as both a structure and an event. I link it, moreover, to military empire, observing how the United States is at once a settler state and an imperial power whose militarist logics condense in a particularly heightened form specifically in Asia and the Pacific. Yet still, as Iyko Day and others have importantly argued, we need to go beyond a binary theory of settler colonialism structured around a settler-Indigenous dialectic. Day maps out “the triangulation of Native, alien, and settler positions” in North America with an attentiveness to how divergent conditions of both forced and voluntary migration are significant features of US settler colonialism.6

**The alternative is unyielding decolonization—reject any and all attempts at reformism and assimilation**

**Walia ‘12** (Harsha, South Asian organizer and writer based in Vancouver Coast Salish Territories, “Moving Beyond a Politics of Solidarity Towards a Practice of Decolonization,” Jan 5, www.peopleofcolororganize.com/analysis/theory/moving-beyond-politics-solidarity-practice-decolonization/) \*\*\*We don’t endorse ableist language.

Decolonization is as much a process as a goal. It requires a profound re-centring of Indigenous worldviews in our movements for political liberation, social transformation, renewed cultural kinships, **and the development of an economic system that serves rather than threatens our collective life on this planet.** As stated by Toronto-based activist Syed Hussan “Decolonization is a dramatic re-imagining of relationships with land, people and the state. Much of this requires study, it requires conversation, it is a practice, **it is an unlearning**.” It is a positive sign that a growing number of social movements are recognizing that Indigenous self- determination must become the foundation for all our broader social-justice mobilizing. Indigenous peoples are the most impacted by the pillage of lands, experience disproportionate poverty and homelessness, are over-represented in statistics of missing and murdered women, and are the primary targets of repressive policing and prosecutions in the criminal injustice system. Rather than being treated as a single issue within a laundry list of demands, Indigenous self-determination is increasingly understood as intertwined with struggles against racism, poverty, police violence, war and occupation, violence against women, and environmental justice. Intersectional approaches can, however, subordinate and compartmentalize Indigenous struggle within the machinery of existing Leftist narratives: anarchists point to the anti-authoritarian tendencies within Indigenous communities, environmentalists highlight the connection to land that Indigenous communities have, anti-racists subsume Indigenous people into the broader discourse about systemic oppression, and women’s organizations point to relentless violence borne by Indigenous women in discussions about patriarchy. We have to be cautious to avoid replicating the state’s assimilationist model of liberal pluralism, whereby Indigenous identities are forced to fit within our existing groups and narratives. The inherent right to traditional lands and to self-determination is expressed collectively and should not be subsumed within the discourse of individual or human rights. Furthermore, it is imperative to understand being Indigenous as not just an identity but a way of life, which is intricately connected to Indigenous people’s relationship to the land and all its inhabitants. Indigenous struggle cannot simply be accommodated within other struggles; it demands solidarity on its own terms.

### FWRK

#### The role of the ballot should be the team who best deconstructs and combats settler colonialism.

#### You should view the 1ac as a research project, in which we test the represenatations of the aff and the epistemology of the aff.

#### Its better for debate – the aff will never actually happen in the real world, and testing the actual education and representations of the 1ac changes our views of the realworld and allows us to get more education.

**The central question of this debate is that the exclusion of the indigenous provides the ontological grounding for modern sovereignty - any analysis which fails to foreground these histories is doomed to reproduce the horrors of colonialism**

Also makes an indict of security rhetoric; war allows the sovereign colonizer to continue its violent imposition

**Byrd ‘11**(Jodi, Chickasaaw and Asst. Prof of American Indian Studies and English at the University of Illinois at Urbana-Champaign, *The Transit of Empire: Indigenous Critics of Colonialism*, p. xvii-xxi)

1. The Transit of Empire begins with a network of conflicting definitions to reflect upon the cultural and political modes of "Indianness" regulated and produced by U.S. settler imperialism née colonialism. Primarily, this book is essayistic, provisional, and some of its readings and conclusions often defy the expected affective common sense of liberal multiculturalism invested in acknowledgements, recognitions, equality, and equivalences. Transit is slightly provocative, an incomplete point of entry, and its provenance might be more suited to diaspora studies and border-crossings than to a notion such as indigeneity that is often taken as rooted and static, located in a discrete place. Steven Salaita's The Holy Land in Transit denotes transit alternately as the function of an alliance between United States and Israeli settler colonialisms that map old world sacred names onto new world sacred sites, a comparative approach to American Indian and Palestinian literatures, and finally a gesture towards the ways in which peoples have been forced to move and relocate.' Gerald Vizenor's work offers another way to frame modes of indigeneity in his concept of transmotion that he defines as a "sense of native motion and an active presence (that) is sui generis sovereignty. Native transmotion is survivance, a reciprocal use of nature, not a monotheistic, territorial sovereignty. Native stories of survivance are the creases of transmotion and sovereignty." Those creases, according to Vizenor, are apprehended in the complementarities of stories, associations, intimacies, and reincarnations that resist absence and possession. 2 The Chickasaws have a migration story that we tell. In search of a new homeland, twin brothers, Chikasah and Chatah, were charged with leading the people as they traveled across the land. Ababinili had given them a sacred pole, the lrohta falaya, that would point the way. After each day of travel, Chikasah would plant the long pole in the earth, and each morning the brothers would rise to find the pole leaning eastward in the directionthey needed to travelled by a white dog and the Milky Way, the brothers and the people traveled for years, always following the direction of the pole. Until one morning. At sunrise, the brothers awoke to find the pole standing almost straight upright. Chatah insisted that the pole confirmed that their travels were done, but Chikasah disagreed and argued that the pole still leaned, that there was still further to go. After continued debate, the question was put to the people-those who agreed with Chatah would stay and make a life there as Choctaws, in the lands that would become central Mississippi and those who sided with Chikasah would travel further east to finally live in what is now northern Mississippi. Chickasaw sovereignty is, according to our national motto, unconquered and unconquerable. It is contrary and stubborn. But the creases of Chickasaw movement demonstrate how sovereignty is found in diplomacy and disagreement, through relation, kinship, and intimacy. And in an act of interpretation. To be in transit is to be active presence in a world of relational move ments and countermovements. To be in transit is to exist relationally, multiply. There is more than one way to frame the concerns of The Transit of Empire and more than one way to enter into the possibilities that transit might allow for comparative studies. On the one hand, I am seeking to join ongoing conversations about sovereignty, power, and indigeneity—and the epistemological debates that each of these terms engender—within and across disparate and at times incommensurable disciplines and geographies. American studies, queer studies, postcolonial studies, American Indian studies, and area studies have all attempted to apprehend injury and redress, melancholy and grief that exist in the distances and sutures of state recognitions and belongings. Those distances and sutures of recognitions and belongings, melancholy and grief, take this book from the worlds of Southeastern Indians to Hawai’i. from the Poston War Relocation Center to Jonestown. Guyana, in order to consider how ideas of “Indianness” have created conditions of possibility for U.S. empire to manifest its intent. As liberal multicultural settler colonialism attempts to flex the exceptions and exclusions that first constituted the United States to now provisionally indude those people othered and abjected from the nation-state's origins, it instead creates a cacophony of moral claims that help to deflect progressive and transformative activism from dismantling the ongoing conditions of colonialism that continue to make the United States a desired state formation within which to be included. **That cacophony of competing struggles** for hegemony within and outside institutions of power, no matter how those struggles might challenge the state through loci of **race, class, gender, and sexuality**, **serves to misdirect and cloud attention** from the underlying structures of settler colonialism that made the United States possible as oppressor in the first place. As a result, the cacophony produced through U.S. colonialism and imperialism domestically and abroad often coerces struggles for social justice for queers, racial minorities, and immigrants into complicity with settler colonialism. This book, on the other hand, is also interested in the quandaries poststructuralism has left us: the traces of indigenous savagery and "Indianness" that stand a priori prior to theorizations of origin, history, freedom, constraint, and difference.' These traces of "Indianness" are vitally important to understanding how power and domination have been articulated and practiced by empire, and yet because they are traces, they have often remained deactivated as a point of critical inquiry as theory has transited across disciplines and schools. Indianness can be felt and intuited as a presence, and yet apprehending it as a process is difficult, if not impossible, precisely because Indianness has served as the field through which structures have always already been produced. Within the matrix of critical theory, lndianness moves not through absence but through reiteration, through meme, as theories circulate and fracture, quote and build. The prior ontological concerns that interpellate Indianness and savagery as ethnographic evidence and example, lamentable and tragic loss, are deferred through repetitions. How we have come to know intimacy, kinship, and identity within an empire born out of settler colonialism is predicated upon discourses of indigenous displacements that remain within the present everydayness of settler colonialism, even if its constellations have been naturalized by hegemony and even as its oppressive logics are expanded to contain more and more historical experiences. I hope to show through the juridical, cultural, and literary readings within this book that indigenous critical theory provides alternatives to the entanglements of race and colonialism, intimacy and relationship that continue to preoccupy poststructuralist and postcolonial studies. The stakes could not be greater, given that currently U.S. empire has manifested its face to the world as a war machine that strips life even as it demands racialized and gendered normativities. The post-9/11 national rhetorics of grief, homeland, pain, terrorism, and security have given rise to what Judith Butler describes as a process through which the Other becomes unreal. “The derealization of the ‘Other’” Butler writes, “means that it is neither alive nor dead, but interminably spectral. The infinite paranoia that imagines the war against terrorism as a war without end will be one that justifies itself endlessly in relation to the spectral infinity of its enemy, regardless of whether or not there are established grounds to suspect the continuing operation of terror cells with violent aims.”4 But this process of derealization that Butler marks in the post-9/11 grief that swept the United States, one could argue, has been functioning in Atlantic and Pacific "New Worlds" since 1492. As Geonpul scholar Aileen Moreton-Robinson argues, discourses of security are "deployed in response to a perceived threat of invasion and dispossession from Indigenous people; and in the process, paranoid patriarchal white sovereignty manages its anxiety over dispossession and threat through a “pathological relationship to indigenous sovereignty.” In the United States, **the Indian is the original enemy combatant who cannot be grieved**. Within dominant discourses of postracial identity that depend on the derealization of the Other, desires for amnesty and security from the contradictory and violent occupations of colonialist wars exist in a world where, as Gayatri Chakravorty Spivak points out, "metropolitan multiculturalism-the latter phase of dominant postcolonialism-precomprehends U.S. manifest destiny as transformed asylum for the rest of the world."6 As a result, the Indian is left nowhere and everywhere within the ontological premises through which U.S. empire orients, imagines, and critiques itself. The Transit of Empire, then, might best be understood as a series of preliminary reflections on how ideas of Indians and Indianness have served as the ontological ground through which U.S. settler colonialism enacts itself as settler imperialism at this crucial moment in history when everything appears to be headed towards collapse.

### Case

#### Read the evidence – none of it is specific to the aff – its about IP laws broadly, that should trigger the internal link

#### No warrant for why future pandemics cause extinction

#### No bioterrorism---empirics and technical barriers.

Blum & Neumann 20, \*former Head of Laboratory at the Organisation for the Prohibition of Chemical Weapons. He holds a PhD in Biochemistry from the University of Frankfurt, \*\*Professor of Security Studies at King’s College London, and served as Director of its International Centre for the Study of Radicalisation from 2008-18.. (Marc-Michael & Peter, 6-22-2020, "Corona and Bioterrorism: How Serious Is the Threat?", *War on the Rocks*, https://warontherocks.com/2020/06/corona-and-bioterrorism-how-serious-is-the-threat/)

The novel coronavirus pandemic has put the threat of bioterrorism back in the spotlight. White supremacist chat rooms are teeming with talk about “biological warfare.” ISIL even called the virus “one of Allah’s soldiers” because of its devastating effect on Western countries. According to a recent memo by the U.S. Department of Homeland Security, terrorists are “[making] bioterrorism a popular topic among themselves.” Both the United Nations and the Council of Europe have warned of bioterrorist attacks.

How serious is the threat? There is a long history of terrorists being fascinated by biological weapons, but it is also one of failures. For the vast majority, the technical challenges associated with weaponizing biological agents have proven insurmountable. The only reason this could change is if terrorists were to receive support from a state. Rather than panic about terrorists engaging in biological warfare, governments should be vigilant, secure their own facilities, and focus on strengthening international diplomacy.

A History of Failures

Biological warfare, which uses organisms and pathogens to cause disease, is nearly as old as war itself. The first known use of biological agents as a weapon dates back to 600 B.C., when an ancient Greek leader poisoned his enemies’ water supply. Throughout the Middle Ages, especially during the time of the Black Death, it was common to hurl infected corpses into besieged cities. And during the two world wars, all major powers maintained biological weapons programs (although only Japan used them in combat).

Among terrorists, however, the use of biological weapons has been rarer, although groups from nearly all ideological persuasions have contemplated it. Recent examples include a plot to contaminate Chicago’s water supply in the 1970s; food poisoning by a religious cult in Oregon in the 1980s; and the stockpiling of ricin by members of the Minnesota Patriot Council during the 1990s. No one died in any of these instances.

The same is true for the biological warfare programs of al-Qaeda and the Islamic State group. Both groups have sought to buy, steal, or develop biological agents. For al-Qaeda, this seems to have been a priority in the 1990s, when its program was overseen by (then) deputy leader Ayman al-Zawahiri, a trained physician. With the Islamic State, evidence dates back to 2014, when Iraqi forces discovered thousands of files related to biological warfare on a detainee’s laptop.

Yet none of these efforts succeeded. The only al-Qaeda plot in which bioterrorism featured prominently — the so-called “ricin plot” in England in 2002 — was interrupted at such an early stage that none of the toxin had actually been produced. The Islamic State’s most serious attempt, in 2017, involved a small amount of ricin, whose only fatality was the hamster on which it was tested. Of the tens of thousands of people that jihadists have murdered, not a single one has died from biological agents.

It may be no accident that the most lethal bioterrorist attack in recent decades was perpetrated by a scientist and government employee. In late 2001, the offices of several U.S. senators and news organizations received so-called “anthrax letters,” which killed five people and injured 17. Following years of investigation, the FBI identified the sender as Bruce Ivins, a PhD microbiologist and senior researcher at the U.S. Army’s Medical Research Institute of Infectious Diseases. Unlike the others, he was no amateur or hoaxer, but a trained expert with years of experience and full access to the world’s largest repository of lethal biological agents.

Technical Challenges

Ivins’ case helps to explain why so many would-be bioterrorists have failed. At a technical level, launching a sophisticated, large-scale bioterrorist attack involves a toxin or a pathogen — generally a bacterium or a virus — which needs to be isolated and disseminated. But this is more difficult than it seems. As well as advanced training in biology or chemistry, isolating the agent requires significant experience. It also has to be done in a safe, contained environment, to stop it from spreading within the terrorist group. Contrary to what al-Qaeda said in one of its online magazines, you can’t just make a (biological) weapon “in the kitchen of your mom!”

In addition, there is the challenge of dissemination. Unless the agent is super-contagious, a powerful biological attack relies on a large number of initial infections in perfect conditions. In the case of the bacterium anthrax, for example, only spores of a particular size are likely to be effective in certain kinds of weather. State-sponsored programs often needed years of testing and experimentation to understand how their weapons could be used. Though not impossible, it is unlikely that terrorist groups possess the resources, stable environment, and patience to do likewise.

#### No extinction from disease.

Barratt 17, PhD in Pure Mathematics, Lecturer in Mathematics at Oxford, Research Associate at the Future of Humanity Institute. (Owen Cotton-Barratt et al, “Existential Risk: Diplomacy and Governance”, pg. 9, <https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf>)

1.1.3 Engineered pandemics

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

#### Patent evergreening thumps any chance of innovation – companies will literally just get another patent

Arnold Ventures, 9/24/20, Arnold Ventures is a philanthropy dedicated to tackling some of the most pressing problems in the United States. We invest in sustainable change, building it from the ground up based on research, deep thinking, and a strong foundation of evidence. We drive public conversation, craft policy, and inspire action through education and advocacy. “’Evergreening’ Stunts Competition, Costs Consumers and Taxpayers”, Arnold Ventures, <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/> //Eagan AE

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.”

#### Innovation strong now thanks to patents

**Ezell and Stevens 20** [Philip Stevens is the executive director of the Geneva Network, which he founded in 2015. He is also a senior fellow at the Institute for Democracy and Economic Affairs, Malaysia. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division. Philip has also worked as director of policy for International Policy Network, a United Kingdom-based think tank, as well as holding research positions with the Adam Smith Institute and Reform—both public policy think tanks in London. He holds degrees from the London School of Economics and the University of Durham, United Kingdom. Stephen J. Ezell is ITIF vice president for Global Innovation Policy and focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale, 2012). "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" Information Technology & Innovation Foundation, February 3, 2020 https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work]

Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over $1.36 trillion in R&D in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, 943 new active substances have been introduced globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than 500 new medicines since 2000 alone. And these medicines are getting to more individuals: Global medicine use in 2020 will reach 4.5 trillion doses, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the world’s most intractable diseases, including cancer and Alzheimer’s.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved 41 new medicines (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through enhanced clinical efficacy (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, or better treatment for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39

#### Patents aren't the barrier to access in developing countries -- numerous alt causes

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What about [In] lower- and middle-income countries, where public health coverage is often minimal and most health spending comes out of individuals’ pockets? Here, the real problem is not so much drug pricing, but a lack of coverage. For instance, a survey of 33 low-income countries found that out-of-pocket payments represent more than half of total health expenditures.64 As a result, many people struggle to afford even cheap essential medicines that have been off-patent for decades, let alone far more expensive physician fees and hospital costs. And while delinkage proponents assert the high cost of medicines as key a rationale for their proposals, the reality is the far bigger challenge in developing nations is with access to health care services in general, and access to needed medicines in particular. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.65 A 2014 WHO study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.66 More than 80 countries fail to meet the basic threshold of 23 skilled health professionals per 10,000 people.67 In other instances, individuals lack access to essential medicines, with their cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.68 A 2009 survey of 36 countries found that 15 common generic medicines listed on the WHO Essential Medicines list were frequently unavailable in either the public or private sectors, with regional availability ranging from 29 percent in Africa to 54 percent in the Americas.69 Again, cost remains only part of the problem. Indeed, the vast majority of drugs—at least 90 percent—currently on WHO’s Essential Medicines list are off-patent.70 Yet essential generic medicines are frequently unavailable or unaffordable.71 The problem, in much larger part, stems from countries’ underdeveloped health systems and many people living in rural areas, far from care. In fact, approximately 70 percent of the world’s poor live in rural areas, where it becomes very difficult to cost-effectively deliver health care services and supplies. Improving health coverage and health systems is the answer to better health care in these countries. And of course, boosting productivity and per capita incomes in these nations, in large part through helping all industries—traded and non-traded alike—become more productive is the ultimate solution.72

#### Strong IP protections key to innovation

**Ezell and Stevens 20** [Philip Stevens is the executive director of the Geneva Network, which he founded in 2015. He is also a senior fellow at the Institute for Democracy and Economic Affairs, Malaysia. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division. Philip has also worked as director of policy for International Policy Network, a United Kingdom-based think tank, as well as holding research positions with the Adam Smith Institute and Reform—both public policy think tanks in London. He holds degrees from the London School of Economics and the University of Durham, United Kingdom. Stephen J. Ezell is ITIF vice president for Global Innovation Policy and focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale, 2012). "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" Information Technology & Innovation Foundation, February 3, 2020 https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work]

As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary to induce companies to invest in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investments.42 Indeed, it’s the ability to recoup fixed costs, not just marginal costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, there would be no new drugs developed, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $3.2 billion.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the confidence to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, in the global public’s long-term interests. Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48

#### Drug companies are voluntarily expanding access through donations and tiered pricing.

Donald **McNeil 19** [science reporter for NYT "Drug Companies Are Focusing on the Poor After Decades of Ignoring Them" The New York Times, June 24, 2019 https://www.nytimes.com/2019/06/24/health/drugs-poor-countries-africa.html]

Twenty years ago, thousands of Africans died of AIDS each day as pharmaceutical companies looked on, murmuring sympathy but claiming that they could not afford to cut the prices of their $15,000-a-year H.I.V. drugs. It’s hard to imagine such a nightmare unfolding today. Vast changes have swept the drug industry over the last two decades. Powerful medicines once available only in rich countries are distributed in the most remote regions of the globe, saving millions of lives each year. Nearly 20 million Africans are now on H.I.V. treatment — for less than $100 a year. Top-quality drugs for malaria, tuberculosis, hepatitis C and some cancers are now sold at rock-bottom prices in poor countries. Once demonized as immoral profiteers, many of the world’s biggest 20 pharmaceutical companies now boast about how they help poor countries and fight neglected diseases. They compete on the Access to Medicine Index, which scores their charitable efforts. Several of them even cooperate with the Indian generics companies they once dismissed as “pirates” by sub-licensing patents so the generics makers can produce cheap drugs for Africa, Asia and Latin America.

#### Even with a patent, substitutes exist.

**Ezell and Stevens 20** [Philip Stevens is the executive director of the Geneva Network, which he founded in 2015. He is also a senior fellow at the Institute for Democracy and Economic Affairs, Malaysia. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division. Philip has also worked as director of policy for International Policy Network, a United Kingdom-based think tank, as well as holding research positions with the Adam Smith Institute and Reform—both public policy think tanks in London. He holds degrees from the London School of Economics and the University of Durham, United Kingdom. Stephen J. Ezell is ITIF vice president for Global Innovation Policy and focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale, 2012). "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" Information Technology & Innovation Foundation, February 3, 2020 https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work]

“The obvious answer is that the benefits from eliminating drug patents would be much smaller than predicted by the prize literature, and there might not be any benefits at all,” argues Benjamin Roin of the MIT Sloan School of Management.63 Professor Roin points out that patents are frequently mischaracterized as giving the right to monopoly profits, effectively forcing consumers to pay the full monopoly price of medicines. In reality, patents grant no such right, merely giving the right to exclude others from copying a specific patented product, and even then only for a limited period of time. Moreover, while patents do provide temporary exclusive rights, there are usually many substitutes and alternatives to a patented product that make market monopoly very rare and always, if they exist, temporary. Markets for products covered by IP are often intensely competitive, because there are usually many substitutes and alternatives. This is particularly true of medicine.

Prices declining now.

Thomas B. **Cueni 17** [Director General at the International Federation of Pharmaceutical Manufacturers & Associations, interviewed by John Zarocostas "Perspectives on access to medicines and IP rights" WIPO Magazine, December 2017 https://www.wipo.int/wipo\_magazine/en/2017/06/article\_0002.html]

Thomas Cueni: I understand concerns surrounding the cost of individual drugs and that companies have to justify the value they bring, but I believe the price debate is overblown. On aggregate there is no sign that drug costs are out of control. The latest OECD data, for example, show that between 2009 and 2015, there was a 0.5 percent annual reduction in per capita expenditure for pharmaceuticals. More importantly, expenditures on health should be seen as an investment towards increased welfare, productivity and economic growth. They should not be seen exclusively as a fiscal cost at a given point in time. The research-based biopharmaceutical industry is delivering breakthrough medicines for patients. Over the last 10 years, we have seen dramatic improvements in treatments for HIV, HCV (hepatitis C), oncology and many rare diseases that have transformed the lives of patients. The wider developments driving healthcare spending, and the systemic challenges that limit access to high-quality, safe and effective medicines around the world, need to be considered.

#### Generic drugs in developing countries are low-quality -- they are actively harmful and create drug-resistant infections – turns case

Katherine **Eban 19** ["How Some Generic Drugs Could Do More Harm Than Good" republished in TIME, May 17, 2019. Adapted from an excerpt of Bottle of Lies: The Inside Story of the Generic Drug Boom by Katherine Eban with permission from Ecco, an imprint of HarperCollins Publishers. Copyright © 2019 by Katherine Eban. All rights reserved. https://time.com/5590602/generic-drugs-quality-risk/]

Most people assume that a drug is a drug — that Lipitor, for example, or a generic version, is the same anywhere in the world, so long as it’s made by a reputable drug company that has been inspected and approved by regulators. That, at least, is the logic that has driven the global generic-drug revolution: that drug companies in countries like India and China can make low-cost, high-quality drugs for markets around the world. These companies have been hailed as public-health heroes and global equalizers, by making the same cures available to the wealthy and impoverished. But many of the generic drug companies that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely adjust their manufacturing standards depending on the country buying their drugs, a practice that could endanger not just those who take the lower-quality medicine but the population at large. These companies send their highest-quality drugs to markets with the most vigilant regulators, such as the U.S. and the European Union. They send their worst drugs — made with lower-quality ingredients and less scrupulous testing — to countries with the weakest review. The U.S. drug supply is not immune to quality crises — over the last ten months, dozens of versions of the generic blood pressure drugs valsartan, losartan and irbesartan have been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained a probable carcinogen once used in the production of liquid rocket fuel. But the patients who suffer most are those in so-called “R.O.W. markets” — the generic-drug industry’s shorthand for “Rest of World.” In swaths of Africa, Southeast Asia and other areas with developing markets, some generic drug companies have made a cold calculation: they can sell their cheapest drugs where they will be least likely to get caught. In Africa, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive. But Africa soon became an avenue “to send anything at all,” said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. The poor quality has affected every type of medication, and the adverse impact on health has been “astronomical,” he told me. Multiple doctors I spoke to throughout the continent said they have adjusted their medical treatment in response, sometimes tripling recommended doses to produce a therapeutic effect. Dr. Gordon Donnir, former head of the psychiatry department at the Komfo Anokye teaching hospital in Kumasi, treats middle-class Ghanaians in his private practice and says that almost all the drugs his patients take are substandard, leading him to increase his patients’ doses significantly. While his European colleagues typically prescribe 2.5 milligrams of haloperidol (a generic form of Haldol) several times a day to treat psychosis, he’ll prescribe 10 milligrams, also several times a day, because he knows the 2.5 milligrams “won’t do anything.” Donnir once gave ten times the typical dose of generic Diazepam, an anti-anxiety drug, to a 15-year-old boy, an amount that should have knocked him out. The patient was “still smiling,” Donnir said. Many hospitals also keep a stash of what they call “fancy” drugs — either brand-name drugs or higher-quality generics — to treat patients who should have recovered after a round of treatment but didn’t. Confronted with the ailing boy at the Mulago hospital, Westerberg’s colleagues swapped in the more expensive version of ceftriaxone and added more drugs to the treatment plan. But it was too late. In the second week of his treatment, the boy was declared brain dead. Westerberg’s Ugandan colleagues were not surprised. Their patients frequently died when treated with drugs that should have saved them. And there were not enough “fancy” drugs to go around, making every day an exercise in pharmaceutical triage. It was also hard to keep track of which generics were safe and which were not to be trusted, said one doctor in Western Uganda: “It’s anesthesia today, ceftriaxone tomorrow, amoxicillin the next day.” Westerberg, shaken by his newfound knowledge, flew back to Canada and teamed up with a Canadian respiratory therapist, Jason Nickerson, who’d had similar experiences with bad medicine in Ghana. They decided to test the chemical properties of the generic ceftriaxone that had been implicated in the Ugandan boy’s death. Another of Westerberg’s colleagues brought him a vial from the Mulago hospital pharmacy. The drug had been made by a manufacturer in northern China, which also exported to the U.S. and other developed markets. But when they tested the ceftriaxone at Nickerson’s lab, it contained less than half the active drug ingredient stated on the label. At such low concentration, the drug was basically useless, Nickerson said. He and Westerberg published a case report in the CDC’s Morbidity and Mortality Weekly Report. Although they couldn’t say with certainty that the boy had died due to substandard ceftriaxone, their report offered compelling evidence that he had. Some companies claim that, while their drugs are all high-quality, there may be some variance in how they are produced because regulations differ from market to market. But Patrick H. Lukulay, former vice president of global health impact programs for USP (formerly U.S. Pharmacopeia), one of the world’s top pharmaceutical standard-setting organizations, calls that argument “totally garbage.” For any given drug, he says, “There’s only one standard, and that standard was set by the originator,” meaning the brand-name company that developed the product. It’s not just those in developing markets who should be alarmed. Often, substandard drugs do not contain enough active ingredient to effectively cure sick patients. But they do contain enough to kill off the weakest microbes while leaving the strongest intact. These surviving microbes go on to reproduce, creating a new generation of pathogens capable of resisting even fully potent, properly made medicine. In 2011, during an outbreak of drug-resistant malaria on the Thailand-Cambodia border, USP’s chief of party in Indonesia Christopher Raymond strongly suspected substandard drugs as a culprit. Treating patients with drugs that contain a little bit of active ingredient, as he put it, is like “putting out fire with gasoline.” USP is so concerned about this issue that in 2017 it launched a center called the Quality Institute, which funds research into the link between drug quality and resistance. In late 2018, Boston University biomedical engineering professor Muhammad Zaman studied a commonly used antibiotic called rifampicin that, if not manufactured properly, yields a chemical substance called rifampicin quinone when it degrades. When Zaman subjected bacteria to this substance, it developed mutations that helped it resist rifampicin and other similar drugs. Zaman concluded from his work that substandard drugs are an “independent pillar” in the global menace of drug resistance. The low cost of generic drugs makes them essential to global public health. But **if** those **bargain drugs are of low quality, they do more harm than good.** For years, politicians, regulators and aid workers have focused on ensuring access to these drugs. Going forward, they must place equal value on quality, through an exacting program of unannounced inspections, routine testing of drugs already on the market and strict legal enforcement against companies manufacturing subpar medicine. One model is the airline industry, which through international laws and treaties, has established clear global standards for aviation safety. Without something similar for safe and effective drugs, the twin forces of subpar medicine and growing drug resistance will be so destructive that developed countries won’t be able to ignore them. As Elizabeth Pisani, an epidemiologist who has studied drug quality in Indonesia, put it, “The fact is, pathogens know no borders.”

#### 10. TURN: Innovation lowers the price of existing drugs.

Stephen **Moore and** Steve **Forbes 18** [Stephen Moore is the Distinguished Visiting Fellow for Project for Economic Growth at The Heritage Foundation. "Foreign Price Controls Jeopardize Global Health and Raise Drug Costs for Americans" Committee to Unleash Prosperity, JULY 2018 https://web.archive.org/web/20200522024422/https://committeetounleashprosperity.com/wp-content/uploads/2018/07/CTUP\_WhitePaper\_Moore\_Jul2018.pdf]

To equalize the costs of drug development, the Trump administration has proposed a series of reforms to lower drug prices for Americans. Here’s where innovation deserves another look, because pharmaceutical R&D isn’t just the key to unlocking new cures: it’s also one of the main ways of reducing prices for existing drugs, by encouraging competition in the marketplace. Conversely, while some of the White House’s proposed reforms make sense, there is a danger that lowering prices and thus profits with artificial price controls here at home will chase investment outside the U.S. and slow the development of new drugs. In fact, this could paradoxically raise health care costs for several reasons. First, research has shown that the entry of a new drug into the marketplace, often with additional benefits in the form of increased efficacy or tolerability, forces down the prices of other drugs in the same therapeutic class—**even before their patents have expired**. This is because, as physicians begin to sign prescriptions for the new entrant, insurers, pharmacy benefit managers and other intermediaries take advantage of this new competitor product to negotiate better deals for existing drugs. Similarly the introduction of several “me-too” or “follow on” drugs with comparable efficacy diminishes differentiation for each, reducing the price premium drug makers can demand for them.13,14,15 One of the most spectacular examples of the impact of new entrants on drug prices in recent years came in the fast-growing field of Hepatitis C treatments. Following Gilead’s introduction of the breakthrough Hepatitis C cure Sovaldi in 2013, competitors rushed a number of drugs exploiting the same underlying biological mechanism to market, resulting in dramatic price drops across the entire therapeutic class. This competition has resulted in rebates and discounts ranging from about 22 percent in 2014 to about 40-65 percent today.16,17 This analysis doesn’t include the overall cost savings projected from curing 2.9 million Americans with chronic Hepatitis C, including hospital stays and transplant costs, estimated at $100.3 billion in the U.S.18 Hepatitis C drugs are just one of the more dramatic cases of new entrants bringing down prices by offering cheaper alternatives in the same therapeutic class. One study found that seven new “follow-on” drugs developed to treat conditions including nonHodgkin’s lymphoma, ovarian cancer, psoriasis, and Huntington’s disease offered discounts over the incumbent drug ranging from 21 percent to 61 percent.19