### Cap

#### Capitalism causes massive violence and inevitable extinction – the role of the ballot is to endorse the best organizational tactics.

Escalante 19 [Alyson Escalante, M.A., Department of Philosophy @ University of Oregon, “Truth and Practice: The Marxist Theory of Knowledge,” 09/08/19, tinyurl.com/8jksnexs] pat

The world we live in today is in a dire state. Climate destruction continues at a fast pace, and every with every passing day, capitalism proves itself to be incapable of addressing this. Capitalist production and its endless drive for resources to match artificial market demands has created a climate crisis that leaves us on the brink of potential extinction.

Governments around the world are turning to far right and fascist leaders to assuage their fears of an uncertain future, and the most marginalized and oppressed suffer because of it. Fascism is on the rise, and history tells us very clearly what that can result in without opposition.

The decaying US empire continues to lash out in violence across the globe in a desperate attempt to re-assert its power and hegemony. Whole countries are destroyed in its desperate bids for more fossil fuels. The world burns from America’s white phosphorus weaponry.

The need for a revolutionary movement capable of replacing capitalism with something better has never been so clear. The choice between socialism or barbarism has never been so stark. More and more people are starting to realize that reform cannot save us, that capitalism and imperialism themselves are the problem, and that we must unite and band together to fight for a better world.

The question then is: how will we know what strategies, what tactics, and what ideas to unite around? If the skeptics and postmodernists are correct that knowledge is always relative and localized, then we cannot built a global and universal strategy to unite around. If they are correct then we are doomed to small acts of localized or individual resistance in the face of apocalypse. To embrace such a vision of the world (with its accompanying epistemological skepticism) is to embrace defeat.

The masses do not want to embrace defeat, they want to know how to fight back. Marxism can provide the tools necessary to engage in that fight.

Marxism, with its self criticism and its insistence on incorporating the valuable ideas of its critics has created a means for unifying workers across the globe with anti-colonial and anti-imperialist struggles. The Marxist belief in the possibility of true ideas, tested and verified in practice, creates the possibility for unity on a global scale. The scientific status of Marxism means that as our climate changes, as our world looks more and more grim, Marxism will adapt through struggle and practice; it will provide us with the ideas and tools we need to fight and win.

There will be no victory for the workers of the world without the ability to wield a revolutionary science. What is at stake in questions of Marxist epistemology is the very possibility of creating a philosophical and scientific basis for revolution. We must defend this possibility. We must defend the scientific status of Marxism, and must insist on the possibility of victory.

#### The aff’s positioning of competition as intrinsic good acts to maintain the stability of capital accumulation.

* AT: Capitalism is when monopoly

Christophers 16 [Brett Christophers, Professor in the Department of Social and Economic Geography at Uppsala University, “The Great Leveler: Capitalism and Competition in the Court of Law,” 2016, Harvard University Press, pp. 8-15, EA]

The aforementioned argument that capitalism has historically migrated from a state of competitiveness to a state of monopoly or oligopoly is deficient in four primary respects, both empirical and conceptual in nature.

First, there is something deeply misleading about the either/or nature of this historical narrative. One of the most important—although rarely acknowledged—of Marx’s insights was that capitalism always, everywhere, requires both. It needs competition, assuredly, not least to drive technological innovation and the reinvestment of profits, and thus growth. But it also needs monopoly—not merely to enhance visibility within and control over otherwise potentially chaotic business environments, but also to underwrite capitalist, market-based trade per se. Not for nothing does David Harvey argue, after Marx, that the “monopoly power of private property” is “both the beginning point and the end point of all capitalist activity.”20 For the legal institution of private property does confer monopoly: the exclusive power to dispose of said property as the owner alone sees fit.

Capital’s seemingly paradoxical need for both competition and monopoly is explored in Chapter 1, which extracts from Marx a conceptualization of capitalism that critically informs the remainder of the book: that of capitalism always, necessarily, teetering on a knife edge, balanced precariously between the contradictory forces of competition and monopoly, and perennially in danger of lapsing too far to one side or the other. “The problem,” Harvey shrewdly observes, “is to keep economic relations competitive enough while sustaining the individual and class monopoly privileges of private property that are the foundation of capitalism as a political-economic system.”21

And it is here that our economic laws crucially enter the picture. In metaphorical terms, the law acts as a powerful leveler: a pincer of sorts on the critical, combustible nexus of monopoly and competition, applicable from one side of the knife edge, the other, or both. Antitrust (competition) law, meaningfully enforced, serves to constrain monopoly power where it coheres too readily, thus boosting competition; IP law acts from the other side, allowing a degree of monopoly power where none “naturally” coheres, and limiting competition in the process. This conceptualization of economic law is sketched out in Chapter 3. Together, such laws help to ensure that over the long term, market-based capitalism is not too competitive (driving down prices and profits) but, in Harvey’s terms, remains competitive enough (avoiding stagnation and rent-seeking). In the process, the laws in question historically have contributed substantially to keeping capitalist accumulation regimes broadly in balance.

At the pivot of this overall mechanism sits the phenomenon of profit. Following the lead of scholars such as Robert Brenner, this book places front and center the relationship between profitability and the interrelated dynamics of competition and monopoly.22 As, indeed, did the classicals: Profit rates were, as Chapter 1 will show, fundamental to their theorization of competition. But it is vital to recognize, as writers such as Keith Cowling have done, that this relationship does not assume a simplistic less-competition-means-more-profit form, isolated as it were from other contributory factors.23 Indeed, the book shows that excesses neither of competitive intensity nor of monopoly power support long-term stability of profit-making and accumulation.

Instead, it leans more toward the type of argument proffered by Gérard Duménil and Dominique Lévy, which is that the dynamics of profitability strongly influence the state’s attempts to regularize regimes of accumulation, and that stabilizing capitalism is thus in no small part a question, ultimately, of stabilizing profitability.24 Or, as David Gordon and coauthors have written, the reproduction of capitalism is “fundamentally conditioned by the level and stability of capitalist profitability. As profits go, in short, so goes the economy.”25 The book’s particular slant on such conceptions is to consider corporate profits more in relative than absolute terms—and relative to, especially, labor and wages. While a comparable focus has recently been adopted by Thomas Piketty in his much discussed Capital in the Twenty-First Century, the inspiration underlying the approach taken here lies much further back in time, in the work in particular of Michal Kalecki.26 For as Kalecki showed both historically and conceptually, the relation of capital with labor, and profit with wages, is centrally implicated in the monopoly-competition relation and the balance that capitalism requires of it. Kalecki, it is fair to say, would have had some very interesting things to say about the Apple wage-suppression antitrust lawsuit.

A second and related problem with the linear historical narrative of from-competition-to-monopoly is its positing of monopoly and competition not only as mutually exclusive alternatives, but as separable ones. Once more, we can turn to Marx for an effective disabusal of this figuring. Monopoly and competition, he argued, are much more closely related, and much more closely connected, than is typically recognized. “Monopoly produces competition, competition produces monopoly,” he maintained, somewhat aphoristically, in a letter he wrote to Pavel Annenkov in 1846.27 Capital not only requires both but is in fact the expression, inter alia, of their synthesis—a synthesis that Marx, in trademark dialectical fashion, described not as a “formula” but as a “movement,” specifically “the movement whereby a true balance is maintained between competition and monopoly.”28 Such movement comprises opposing but connected economic dynamics of centralization and decentralization. When one or the other dynamic becomes disproportionately powerful, Marx argues, the “counteracting tendency” kicks in to return capital to a balanced configuration of monopoly and competition.

This balanced organization of productive forces—always inherently unstable and always prone to knife-edge slippages—is very close to what Edward Chamberlin would later call “monopolistic competition.”29 Such monopolistic competition internalizes monopoly and competition in dialectical relation with one another and is the capitalist norm—and always has been. “The notion of a bygone ‘competitive’ stage of capitalism where firms were price-takers is,” as Duménil and Lévy insist, “a fiction derived from the neoclassical analytical apparatus.”30 Equally fictional, albeit a fiction usually emanating from a very different analytical source, is the notion of a contemporary “monopoly” stage of capitalism absent meaningful competition.31

The historical, U.S.- and U.K.-based narrative related in this book therefore turns on precisely this dialectical, restless synthesis of monopoly and competition, and its ever-evolving, historically and geographically specific forms. In recent years, it is Harvey who has provided the most provocative reading of this dialectic and of its centrality to capitalism. It is, Harvey argues, one of numerous “moving” contradictions that plague the capital form, and with which capital constantly wrestles as it enters into and out of crisis.32 Harvey repeats Marx’s observation that capital requires a balance of competitive and monopolistic forces. He then derives from this postulate the propositions that crisis occurs when such forces become imbalanced—although this is not the only cause of crisis—and that such crisis can only be “fixed” once balance is restored. The result is that capital historically “oscillates” between relative excesses of monopoly and competition, always finding balance hard to achieve, let alone sustain.33 Understanding capital and its historical development in this particular regard, Harvey insists, requires us to recognize “how successful capital has generally been in managing the contradictions between monopoly and competition” and that “it uses crises to do so.”34

Such success, and the role played by crises or by threats thereof, are two of this book’s central, recurring themes. However, Harvey’s framing raises two vital questions that he fails, in his admittedly brief account of monopoly and competition, to answer.

First, how has this success been achieved? “Capital,” Harvey writes, “has organically arrived at a way to balance and rebalance the tendencies towards a monopolistic centralisation and decentralised competition through the crises that arise out of its imbalances.”35 Again, there is no objection here, except to press: “organically,” how? This book fashions an answer. This answer rests on the role of the law. When capital has become sufficiently overcentralized and monopolistic to threaten its own successful, profitable reproduction, antitrust law has been called upon to help restore the necessary degree of balance. This balance will never be perfect and at rest; in a dialectical relation, such as that between monopoly and competition, it never can be. When the dangerous excess has been of competition, by contrast, IP law has come to the rescue. Such laws, needless to say, have not effected this work of rebalancing by themselves, and this book documents their interaction with other pertinent dynamics; but their role has been paramount.

The other problematic question raised by Harvey’s framing brings us directly to our third point of divergence with the Baran and Sweezy or Foster and McChesney reading of capitalist development. Consider here the agency behind the successful, crisis-based management and rebalancing of monopolistic and competitive forces envisioned by Harvey: “capital has been successful . . .”; “capital has arrived at . . .” But what, or who, is this capital, and has its form remained constant? For Harvey, clearly, capital is the capitalist class: those that own the means of production. Yet this singularization of responsibility for regulating and reregulating the core dynamics of the capitalist economy raises all manner of questions that Harvey fails to address. Is this capitalist class homogeneous? Does it share consistent objectives in terms of economic development and management? And even if it does (and of course, it does not), what is its relation with the state and with the different tools of economic regulation, the law among them, that the state uses to govern and shape economic conduct?

If Harvey’s stimulating propositions call for circumspection on account of their simplifying structural abstractions, the connection to the “monopoly capital” thesis is that it too tends to rely upon just such totalizing, even reified, concepts. “Monopoly capital” is itself one such. One of the consistent themes of the tradition renewed by The Endless Crisis—one extending back through Baran and Sweezy’s Monopoly Capital to Rudolf Hilferding’s Finance Capital (1910) and even Lenin’s Imperialism (1917)—is its tendency not only to associate potent monopoly powers with a new stage or phase of capitalism but to depict the latter in terms of a consciously regulated and (centrally) planned system in which market-based competition largely disappears from view.36 For Lenin, this system fused the interests of capital and state (state monopoly capitalism); for Hilferding the fusion was tripartite, with finance capital also integral. But Marx, for all the stereotypes to the contrary, never saw capitalism as such. It was a totality, to be sure, but one that needs to be continually reproduced and reconstituted. This process occurs in and through the disparate actions of government, workers, consumers, businesses, and so on; when such reconstitution occurs in ways that imperil accumulation, crisis looms.

The point of saying all this is not simply to oppugn a totalizing view of “monopoly capital,” but to contrast with it the approach taken in this book, particularly to the law and its mobilization. There is not, and has not been, a single hand on the tiller, for all the obvious importance of the state as the law’s formal originator; there is no single, homogeneous entity pulling the levers, so to speak, of political-economic regulation— no consistent regime of conscious, systematic control. As with other modalities of economic regulation or governance, the law, in practice, does not “work” like that.

For one thing, there is an important difference between the written law and its interpretation. Two courts can interpret and apply the same law or laws in markedly different ways and with very different consequences. Perhaps the clearest example of this, at least in this book (Chapter 6), concerns U.S. antitrust law in the second half of the twentieth century: The nature and degree of enforcement of this law underwent a dramatic transformation in the late 1970s and early 1980s, but the law itself did not materially change. Intellectual training, social and political context, even judicial personality: These variables, and more, all matter to the law’s practical materialization. As such, we must remain constantly alive to the simple fact that, as Peter Carstensen has put it, “court doctrine is not the whole of the law in practice.”37 Relatedly, much of the enforcement of IP rights occurs at a significant remove from courts—specifically in, as argued by William T. Gallagher, the everyday practices of IP owners and their lawyers, whose “negotiations” with alleged infringers take place largely in the “shadow” of IP law.38

For another thing, just as the state never enacts new economic laws in total isolation from the influence and interests of capital, so both capital(s) and state—and indeed other economic agents—use the law to their own ends, and these ends are far from necessarily commensurate. Think, once again, about our two Apple cases. Who, in each case, instigated the legal action? Who put the law to work in their own interests? In the IP case it was Apple itself. In the class-action suit it was labor. But the latter suit was in fact itself based upon a prior government investigation launched by the Department of Justice’s Antitrust Division in 2010.39 Three legal cases, then, all driven by different actors with different motivations, but all revolving around the same political-economic locus: the knotty complex of profit generation and accumulation constituted by Apple Inc. And if the law, together with its agents, is so palpably nonsingular at the scale of the political economy of just one company, on what reasonable grounds could we ever envision it thus—as a vehicle of conscious, unified control—in relation to the political economy of capitalism more widely? The “great leveler” indicated in the book’s title, in short, is not some omnipotent regulator in charge of the law; it is the law per se.

How, then, might we more accurately characterize the human and institutional agency analyzed in the following pages in relation to the law, its mobilization, and its political-economic effects? At a general level, the conclusion reached by Paul David in his examination of the history of IP law fits particularly well: “The complex body of law, judicial interpretation, and administrative practice that one has to grapple with in this field was not created by some rational, consistent, social welfare-maximizing public agency. What one is faced with, instead, is a mixture of the intended and unintended consequences of an undirected historical process on which the varied interests of many parties, acting at different points (some widely separated in time and space), have left an enduring mark.”40 More specifically, however, we will see that although IP and competition laws have indeed performed their work under the influence of varied individuals and groups, the vast majority of the latter are ultimately committed to, and institutionally invested in, the reproduction, in as smooth a fashion as possible, of capitalism in more or less its existing form. And even more specifically, the “smoothness” here alluded to means the reproduction of capitalism especially without the kinds of problems—identified in Chapter 3—that tend to emerge when the necessary balance between monopoly and competition is substantially disrupted.

On all the above grounds, therefore, this book’s argument diverges from that which we find in the all-too-common narrative of competitive capitalism historically segueing into monopoly capitalism. Of course, none of this is to suggest that nothing has changed historically in the capitalist constellation of monopoly-competition structures and dynamics. Far from it. But the book’s fourth and final quarrel with the conventional narrative is that what has substantively, perhaps irrevocably, changed is not the relative levels of competitive intensity and monopoly power—as in, that era had more competition, this one has more monopoly—so much as the source of monopoly powers and the degree of defensibility thereof.

Capitalism, this argument runs, is always characterized by competitive undercurrents; were it not, it would not be capitalism. Meanwhile, and arising partly out of these competitive dynamics (the Marxian argument), there is an endemic drive to fashion monopoly powers. Yet the means of assembly of such powers do not remain constant, and neither does the ability of monopolistic capitalists to defend the powers thus amassed. Capitalists—and indeed the states committed to stabilizing capitalism, with the law one obvious apparatus at their disposal—must constantly find new ways of putting monopoly in place and keeping it there. “As monopoly privileges from one source diminish,” Harvey observes, “so we witness a variety of attempts to preserve and assemble them by other means.”41 Mindful, thus, of Marx’s dictum that the monopoly-versus-competition dualism is a red herring that confuses a dialectical relation for an oppositional one, this book focuses instead on the ways in which the unstable balance between the two forces is maintained—and it posits the law as the primary, necessarily mutable, instrument of such maintenance.

#### Reducing IP protections is used by capitalist nations in the imperial core to claim the moral high ground -- this legitimizes the system and fuels power competition. Newest ev from COVID proves.

Andrea Patanè 21. Marxist, Published: 15 May 2021. “COVID-19 pandemic: patents and profits” <https://www.marxist.com/covid-19-pandemic-patents-and-profits.htm> brett

Far from an act of ‘international solidarity', this latest move from the US government is a calculated political risk, and will be implemented in the interests of US imperialism. A section of the more serious wing of the bourgeoisie understands that a proper economic recovery can happen only if the pandemic is suppressed worldwide. As we have explained elsewhere, wealthy countries risk losing billions of dollars if the pandemic is brought under control only within their own borders, because new variants (like those in India and Brazil) can always mutate elsewhere and reinfect their populations, causing further economic disruption. Therefore, even on a capitalist basis, it is expedient in the long-term for the rich countries to facilitate a global vaccination campaign. Even Pope Francis anointed the demand from his seat in Rome! Biden’s announcement is also an act of vaccine diplomacy. America’s main rivals, China and Russia, have been shoring up their spheres of influence by distributing their Sinopharm and Sputnik V vaccines to poor countries left out by the vaccine nationalism of the US and Europe. Chinese and Russian vaccines have been exported into countries traditionally under western spheres of influence, including Brazil and Hungary. Pushing to waive IP protections on COVID-19 vaccines is therefore partly an effort to push back against the encroachment of rival imperialist powers, which have so far outcompeted Washington in the global vaccination drive. Biden’s announcement is also an attempt to restore the standing and authority of US imperialism on the world stage, which has been bruised by the ‘America First’ vaccine nationalist policy started by Donald Trump, and continued by Biden. According to the FT, Katherine Tai (top US trade envoy) and Jake Sullivan (national security adviser) made the case to Biden that pushing for the waiver “was a low-risk way to secure a diplomatic victory”, after coming under fire for not “respond[ing] quickly enough to the unfolding COVID-19 crisis in India”. Here you have it, straight from the horse’s mouth. Under capitalism, vaccines – rather than providing a way out of the pandemic – are tools for ‘low-risk diplomatic victories’. As if this was some sort of football match between world leaders! In short, Biden is stepping in to prioritise the interests of US imperialism as a whole over the immediate interests of the Big Pharma capitalists. But we should say clearly: this cynical attempt to claim the moral high ground came only after the US used its massive economic clout to secure enough vaccines to inoculate its own population several times over. And in fact, the wartime Defense Production Act is still in effect, which forces US manufacturers to fulfil domestic demands for medical equipment before exports are permitted. This de facto export ban has created bottlenecks in the supply chain that have already undermined the WHO-led COVAX programme to vaccinate poor countries. Rest assured, Biden’s policy remains ‘America First’, just by somewhat more calculated means than his predecessor.

#### Capitalism is unsustainable and causes extinction -- multiple intertwined crises make collapse inevitable which means its try-or-die -- we got charts.

von Weizsäcker and Wijkman ‘17

Ernest Ulrich von Weizsäcker, Professor and Director of the United Nation Centre for Science and Technology for Development, Founder and President of the Wuppertal Institute, Member of the German Bundestag, chairing the Committees on Globalization and the Environment, Dean of the graduate School of Environmental Science and Management at the University of California, appointed Co-Chair of UNEP’s International Resource Panel, Anders Wijkman, chairman of the Swedish Association of Recycling Industries, member of the Board of the Swedish Development Authority (SIDA), appointed chair of the Swedish Cross-Party Committee on Environmental Objectives, member of the European Parliament, Assistant Secretary-General of the United Nations and Policy Director of UNDP, Secretary General of the Swedish Red Cross and Director General of the Swedish Agency for Research Cooperation with Developing Countries, Member of the Swedish Royal Academy of Sciences, the World Future Council and the International Resource Panel, 2017 (“Come On! Capitalism, Short-termism, Population and the Destruction of the Planet – A Report to the Club”, November 11th, Available Online via Subscription to Springer, Accessed 03-20-2018)

1.1 Introduction: The World in Disarray We all know that the world is in crisis. Science tells us that almost half of the top soils on earth have been depleted in the last 150 years1 ; nearly 90% of fish stocks are either overfished or fully fished.2 Climate stability is in real danger (Sects. 1.5 and 3.7); and the earth is now in the sixth mass extinction period in history.3 Perhaps the most accurate account of the ecological situation is the 2012 ‘Imperative to act’,4 launched by all the 18 recipients (till 2012) of the Blue Planet Prize, including Gro Harlem Brundtland, James Hansen, Amory Lovins, James Lovelock and Susan Solomon. Its key message reads, ‘The human ability to do has vastly outstripped the ability to understand. As a result, civilization is faced with a perfect storm of problems, driven by overpopulation, overconsumption by the rich, the use of environmentally malign technologies and gross inequalities’. And further, ‘The rapidly deteriorating biophysical situation is barely recognized by a global society infected by the irrational belief that physical economies can grow forever’. 1.1.1 Different Types of Crisis and a Feeling of Helplessness The crisis is not cyclical but growing. And it is not limited to the nature around us. There are also a social crisis, a political and a cultural crisis, a moral crisis, as well as a crisis of democracy, of ideologies and of the capitalist system. The crisis also consists of deepened poverty in many countries and the loss of jobs for a considerable part of the population worldwide. Billions of people have reached a state of mind where they don’t trust their government anymore.5 Seen from a geographic point of view, symptoms of crisis are found nearly everywhere. The ‘Arab Spring’ was followed by a series of wars and civil wars, serious human rights violations and many millions of refugees. The internal situation is not better in Eritrea, South Sudan, Somalia, Yemen or Honduras. Venezuela and Argentina, once among the richer states of the world, face huge economic challenges, and neighbouring Brazil has gone through many years of recession and political turmoil. Russia and several East European countries are struggling with major economic and political problems in their post-communist phase. Japan finds it difficult to overcome decadelong stagnation, and to deal with the 2011 tsunami and ensuing nuclear disaster. And the temporary economic upswing several African countries have enjoyed lost its dynamism as soon as the prices of mineral resources collapsed, and partly due to very unusual droughts. Land grabbing is plaguing much of Africa, but also other parts of the world, leading to involuntary dislocations of millions of people and the related problems with refugees both within countries and abroad.6 The response of governments has been concentrated, at worst, on managing their own political image, and at best to treat the symptoms of the crisis, not the cause. The problem is that the political class in the whole world is strongly influenced by investors and by powerful private companies. This indicates that the current crisis is also a crisis of global capitalism. Since the 1980s, capitalism has moved from furthering the economic development of countries, regions and the world towards maximizing profits, and then to a large extent profits from speculation. In addition, the capitalism unleashed since 1980 in the Anglo-Saxon world, and since 1990 worldwide, is mainly financial. This trend was supported by excessive deregulation and liberalization of the economy (see Sect. 2.4). The term ‘shareholder value’ popped up in the business pages of the media worldwide, as if that was now the new epiphany and guardrail for all economic action. In reality, it served to narrow business down to short-term gains, often at the expense of social and ecological values. The myth of shareholder value has been effectively debunked in a recent book by Lynn Stout.7 A different, if related, feature of ‘disarray’ is the rise of aggressive, mostly rightwing movements against globalization in OECD countries, often referred to as populism. These have become overt through Brexit and the Trump victory in the United States. As Fareed Zakaria observes, ‘Trump is part of a broad populist

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upsurge running through the Western world. … In most (countries), populism remains an opposition movement, although one that is growing in strength; in others, such as Hungary, it is now the reigning ideology’.8 This phenomenon of right-wing populism can be explained to an extent by the ‘trunk valley of the elephant curve’ (Fig. 1.1) 9 showing the decline of developed world middle classes, during a 20-year period. While more than half of the world’s population was enjoying over 60% income rises, OECD’s middle classes suffered losses caused mainly by the deindustrialization and job losses in major parts of the United States, Britain and other countries. In the United States, the median income increased by a meagre 1.2% since 1979. The stunning income growth on the left-hand side of the curve, the ‘back of the elephant’, lifting some two billion people out of poverty, was caused mainly by China’s and some other countries’ economic success. What remains invisible on the picture is the far end of ‘the trunk of the elephant’: The richest 1% of the world and, more revolting, the richest eight persons of the world now own as much wealth as the poorest half of the world population combined, a figure publicized by Oxfam during the 2017 World Economic Forum.10 The ‘elephant curve’ gives an incomplete picture for a second reason. The Oxford Poverty and Human Development Initiative (OPHI) has proposed a Multidimensional Poverty Index (MPI) going beyond just income and including ten indicators around health, education and living standards. Using that MPI, OPHI counts 1.6 billion people living in ‘multidimensional poverty’ in 2016 – nearly twice as many as the number of people living in extreme poverty measured by income alone.11 Thirdly, the interpretation of the curve requires an analysis of the people in each percentile group. In fact, they tend to move. And the curve does not distinguish those in Russia and East European countries who lost much of their income after 1990 from those in Detroit or middle England who, for very different reasons, also were among the losers.12 Another fact cannot be seen in the picture: the massive shift of money and income from the manufacturing and trade sectors to the financial sector.13 Bruce Bartlett, a senior policy advisor to both the Reagan and Bush administrations, argues that this ‘financialization’ of the economy is the cause of income inequality, falling wages and the poor performance. David Stockman, Reagan’s director of the Office of Management and Budget, agrees, describing our current situation as ‘corrosive financialization that has turned the economy into a giant casino since the 1970s’.14 Populist politicians in the OECD countries see themselves as speaking for the forgotten ‘ordinary’ people and for genuine patriotism, but they tend to fight and antagonize the people representing democratic institutions – what an irony! For the European Union (EU), the strongest trigger for populism has been the millions of refugees who came or would like to come to Europe from the Near East, from Afghanistan and from Africa. Even the most generous European countries have reached their own assumed limits for receiving these masses of refugees. The EU institutions were too weak (not too powerful, as they are depicted by the new nationalists) to deal with the ‘refugee crisis’, resulting eventually in an identity crisis in the EU. Once a success story of an entity ensuring peace and economic development, the EU has lost some of its unifying narrative. The populist right-wing movements or parties see and criticize the EU as the culprit for all kinds of undesired events. The irony is that continuing the success story would require more, not less, powers for the Union. The Union should be entrusted with border protection, a well-funded common asylum and refugee policy to deal with the refugee crisis and maintain the advantages of the Schengen agreement. And for the re-stabilization of the Euro, the EU or at least the Euro zone needs a common fiscal policy, as the new French President Emmanuel Macron is proposing. But it is these very measures of which nationalist populists are most afraid. The EU in its present form is not without shortcomings. Free market principles have come to dominate EU policymaking, leading to a subordination of other policies, like environment. Notably the UK wanted that priority, as it preferred to see the EU chiefly as a union for mutual trade. And the austerity policies pursued have blocked many benign investments and led to unnecessary suffering among tens of millions of Europeans. Such shortcomings, however, should never be used to put in question the overall objectives of the EU – a union of peace, the rule of law, human rights, cultural understanding and sustainability. Addressing the global crisis of democracy, the German Bertelsmann Foundation has published a 3000-page empirical report on progress (or lack thereof) on democracy and a social market economy, as measured by the Bertelsmann Transformation Index (BTI).15 Over the last few years, the report sees a consistent decay of such parameters as civil rights, free and fair elections, freedom of opinion and of press, freedom of assembly and separation of powers. Within the same time frame, the number of countries in which authoritarian, mostly religious, dogmas influence political decision making rose from 22% to 33%. That report was published before the assaults on democracy and civil rights that occurred in summer 2016 in Turkey or the Philippines. Symptoms of tyranny are spreading, including in some of the countries with a solid tradition of freedom and democracy.16 Let us briefly turn to a different kind of crisis. Well, not exactly a crisis but an unpleasant feature in an otherwise fruitful communication tool, the ‘social media’. Aside from being practical and useful for everyday arrangements and exchange of news and reasonable opinions, social media also have become vehicles for enhancing conflicts and vilification of mostly innocent individuals, and for spreading ‘post truth’ nonsense. Much of the contents of social media political conversation is selfenhancing political rubbish, as those media serve as ‘echo chambers’ for networks of like-minded frustrated citizens.17 An empirical study from China found that anger and indignation are the emotions that are most likely to get viral in the social media, meaning they are multiplied faster and stronger than other emotions.18 The Internet and the social media are also vehicles for ‘bots’ (short for robots) that can disrupt or destroy messages, multiply nonsense and create all kinds of mischief. There are dozens of types of malicious bots (and botnets) to harvest email addresses, to grab content of websites and reuse it without permission, to spread viruses and worms, to buy up good seats for entertainment events, to increase views for YouTube videos or to increase traffic counts in order to extract money from advertisers. A more frightening cause of disarray relates to terrorism. In earlier times, humanity’s violent conflicts occurred mostly between different countries. In recent times, systemic and at least partly religious conflicts prevail, using terror attacks with the explicit intention of making people feel insecure. During much of the twentieth century, religions remained quiet, non-aggressive and geographically confined to rather stable territories. This no longer is true. Partly because of globalized populations moving or being forced to leave their home territories, some factions of Islam have expanded geographically and are claiming strong influence over national states, for example, attacking countries like France with its tradition of laicism that does not permit religion to dominate politics. What tends to be underrepresented in the media is the positive role of religions. In Christian-dominated Europe, liberal and tolerant religion became part of the European identity a century after the Enlightenment successfully discredited the earlier doctrinaire, authoritarian and colonialist-missionary manifestations of the faith. During the Cold War, Christian goals of social cohesion helped build the system of ‘Western values’, often described as the social welfare state, or the ‘social market economy’ (for its partial demise, see Sect. 2.4). With a view towards leading Islam into an equally benign and co-operative social role, some Islamic scholars, such as Syrian born Bassam Tibi, call on Muslims in Europe to integrate into democratic society.19 Tibi, however, is not popular among radical Muslims, to put it mildly. But to understand the radicalization of Islam, one must not underestimate the role played by the West, in particular the United States, in interfering with Near Eastern states. Some would say that the troublesome situations mentioned so far, the recurring topics of media headlines, are only the surface of our world’s ‘disarray’. Deeper and more systemic problems include the breath-taking speed of technological development that may very easily run out of control. One trend is digitization that potentially threatens millions of jobs (see Sect. 1.11.4). Another trend or development can be observed in the biological sciences and technologies. The enormous acceleration of genetic engineering through the CRISPR-Cas9 technology20 is causing fears of monster creation or the extinction of species or varieties not seen as valuable under human utilitarian criteria. Generally, a non-specific feeling is spreading that ‘progress’ has scary sides and that the genie may already have left the bottle (see Sect. 1.11.3). No doubt there is a need to analyse and understand the symptoms and roots of the variety of crises, political, economic, social, technological and environmental. It is also important to recognize the extent to which people perceive the various phenomena of disarray and feel disoriented, and to recognize that the reality and the feelings of disarray have a moral and even religious dimension. 1.1.2 Financialization: A Phenomenon of Disarray An important part of the disorientation relates to financial markets. Historians will look back at the last 30 years with concern, when looking at the explosion in bank balance sheets, backed up by declining levels of equity and massive borrowing. One of the results was a temporary private-sector-led boom. The other was a massive increase in the world’s financial sector (finance, insurance, real estate – FIRE), often called financialization, and subsequently the financial crisis of 2008–2009. Excessive risk-taking developed into a crisis that was close to bringing the whole financial system to a halt. When the bubble burst, many governments were forced to step in with broad support programmes. Governments caught by the new mind-set (see Sect. 2.4) were intimately involved in all of this. True, there are many examples of serious malpractices within the private financial sector. But had it not been for the systematic deregulation of the banks by governments, with the purpose of stimulating economic growth by issuing more debt, the situation would have been radically different. The causes behind the crisis were many and varied: – Excessive lending by the banking industry – Lack of action on the part of regulators and central banks to stop (i) excessive lending, (ii) the spread of exotic financial instruments (synthetic assets and bonds, collateralized mortgage obligations/CMOs, structured debt issues, etc.) and (iii) pure speculative transactions – Opaque tax havens, and the absence of a binding legal framework that is accepted and implemented by the international community, in general, and the major jurisdictions and financial centres – Securitization and distribution by investment banks and other financial actors of mortgage-related assets and investment vehicles transferring the credit risk from the original lender to the ultimate bondholders – Failure by some rating agencies and auditing firms to properly assess and report the inherent risks posed by many of the financial products A deeper analysis is presented by economists Anat Admati and Martin Hellwig21 about the main causes behind the financial crisis. Western banks borrowed far too much with far too little equity in their balance sheets to act as a buffer if things went wrong in their business – from trading in the multitrillion-dollar derivatives markets to often reckless lending on real estate. In the decades following the Second World War, banks operated with between 20% and 30% of their liabilities as equity. By 2008, that had shrunk to just 3%. Banks obviously believed that they had invented instruments that removed the risk, allowing them to run their banks with a tenth of the buffer they had before. It proved to be very unrealistic. But they counted with the state to underwrite their risks. Bankers have enriched themselves spectacularly in the process. They made themselves ‘too big to fail’ – and too big to jail. The 2008 financial crisis was mostly caused by that irresponsible greed.22 Yet, in 2009, not only did bankers avoid criminal prosecutions and receive hundreds of billions in government bailouts, but some still paid themselves record bonuses. At the same time, almost nine million households in the United States had to abandon their homes when the value of their houses plummeted and they could no longer service the adjustable-rate mortgages – the so-called foreclosure crisis.23 Financialization refers to the dominance of the financial sector in the global economy and the tendency for accumulated profits (and leverage) to flow into real estate and other speculative investment. Debt is an intrinsic element in this process. In the United States, for example, both household debt and private sector debt more than doubled relative to GDP between 1980 and 2007.24 The same is true for most OECD countries. At the same time, ‘the value of financial assets grew from four times GDP in 1980 to ten times GDP in 2007 and the finance sector’s share of corporate profits grew from about 10% in the early 1980s to almost 40% by 2006’.25 Adair Turner, chair of the UK’s Financial Services Authority in the years following the 2007–2008 crisis, regards unchecked private credit creation as the key system fault that led to that crisis with its devastating consequences.26 From this follows that the financial sector constitutes a significant and increasing risk factor in the economy. The degree of financialization varies from country to country but the increase in the power of finance is general. The current finance sector evolved in the context of the deregulation that gathered pace from the late 1970s and expanded dramatically after the 1999 removal of the separation between commercial and investment banking in the United States.27 This barrier had been put in place in 1933 by the Roosevelt administration in response to the Wall Street Crash of 1929, when a period of rampant credit creation and financial speculation collapsed. Similar speculation preceded the crisis of 2007–2008: The face value of financial products reached US$640 trillion in September 2008, 14 times the GDP of all the countries on earth.28 Lietaer et al.29 compare speculation with ordinary money transfers paying for goods and services: ‘In 2010, the volume of foreign exchange transactions reached $4 trillion per day’, which does not even include derivatives. In comparison, ‘one day’s exports or imports of all goods and services in the world amount to about 2% of those $4 trillion’. Transactions not paying for goods and services, almost by definition are speculative. Such financial products and transactions, the authors continue, lead regularly to monetary crashes, sovereign debt crises and systemic crashes with an average of more than ten countries in crisis every year. One of the consequences of this development is that a significant part of economic growth has been distributed to the wealthy, as mentioned with the new Oxfam figures in the previous subchapter. Practices within the financial sector demonstrate a disregard for the impact they have on both people and the planet. That includes a distinct short-termism, the ratio of banks’ reserves to their loans, the ratio of banks’ lending that support the real economy versus speculation in property and derivatives, unchecked credit creation – in fact money creation – and the failure to account for long-term climate and environmental risks. In the words of Otto Scharmer at MIT,30 ‘We have a system that accumulates oversupply of money in areas that produce high financial and low environmental and social returns, while at the same an undersupply of money in areas that serve important societal investment needs’. The failure to account for environmental risks means that the pressure on already scarce natural resources accelerates – trees are felled, waterways polluted, wetlands drained and the exploitation of oil, gas and coal accelerating, as long as there is demand. It also means that huge savings, among them pension funds, are locked into investments in fossil-based assets. Such assets are increasingly looked upon as high-risk assets (see Sect. 3.4).

#### Vote negative for proletarian internationalism -- only an organized global revolutionary struggle can overcome the destruction of capitalism.

Anastasi et al, 18 (editorial collective of Viewpoint Magazine, a militant research collective working to dialectically bring theory and practice into dialogue by studying cycles of struggle. Alphabetically, members of the editorial collective are as follows: Andrew Anastasi, graduate student in Sociology at CUNY; Cinzia Arruzza, Associate Professor of Philosophy at the New School for Social Research; Robert Cavooris, UC Santa Cruz graduate student and union representative, History of Consciousness Department; Maya Andrea Gonzalez, communist and revolutionary feminist in the Bay Area, graduate student in the Department of History of Consciousness at UC Santa Cruz; Asad Haider, Assistant Professor of Philosophy @ The New School, founding editor of Viewpoint Magazine, PhD in History of Consciousness Department @ UC Santa Cruz; Shuja Haider, widely-published writer and musician based in Brooklyn; Bue Rübner Hansen, writer and activist researcher in the Britain, Barcelona, and in migrant and refugee solidarity movements, PhD from Queen Mary University; Patrick King, graduate student at UC Santa Cruz; Rosa Lee, communist organizer and member of the Viewpoint editorial collective; Ben Mabie, managing editor at Viewpoint and editorial assistant at Verso Books, UCSC graduate; Sarah Mason, member of the Viewpoint editorial collective; Liz Mason-Deese, Assistant Professor, Department of Geography and Geoinformation Science, George Mason University; Dave Mesing, PhD student in Philosophy @ Villanova University; Magally Miranda-Alcazar, Eugene Cota-Robles Fellow and a Ford Foundation Predoctoral Fellow, PhD student in Chicana/o Studies @ UCLA; B.A. from the University of California, Santa Cruz (magna cum laude) with a double major in Community Studies and Feminist Studies, and has been published in The Nation, Verso and the New Left Review; Salar Mohandesi, Assistant Professor of History @ Bowdoin; Gavin Mueller, Lecturer in Media Studies at the University of Amsterdam, former contributing editor @ Jacobin; Evan Calder Williams, writer, translater, and artist, teaches theory at the Center for Curatorial Studies at Bard College and film production at Cooper Union, PhD in Literature from the University of California Santa Cruz and was a Fulbright Fellow in Italy for his research on cinema, industry, and revolt. “Internationalism against Imperialism,” *Viewpoint Magazine*, Issue 6, February 1, 2018, <https://www.viewpointmag.com/2018/02/01/internationalism-against-imperialism/>)

The challenge of reactivating an effective proletarian internationalism is made even more urgent by the aggressive rise of right-wing nationalisms, which have taken a range of organizational and ideological guises. The clarified ideological form of this rightward shift is an emboldened “possessive nationalism” in the North, which revolves around restrictive immigration and trade policies, as responses to the perceived erosion of territorial logics of sovereignty, and the hybridization of the ethno-national community.10 Any prolonged combat against these nativist impulses – especially as they seep into social-democratic or left-liberal parties in Europe and the United States – will need to reinforce the link between migration and imperialism, the former in many ways constituting the reflux of the latter. Here we might center the rich legacy and actuality of migrant struggles for communist politics, and how questions of mobility, control, and dispossession are now at the core of imperialist dynamics. The political and social, informal and formal spaces of migration remain an open field for investigation. As Etienne Balibar noted over 40 years ago, “the concrete knowledge of the causes and effects of immigration is a two-way guiding thread towards an understanding of imperialism,” a methodological linkage which “renders internationalism, more than ever, the very condition of struggles for workers’ liberation.”11 This raises the practical necessity of reconsidering the tactical repertoire and strategic horizons of anti-imperialism. The nearly two-decades-long “War on Terror” – a euphemism for a war on human welfare in the Middle East and a war against Muslims at home – has proven to be a difficult nub for anti-war and anti-militarist activism in “the belly of the beast,” particularly as U.S. violence, amidst ever-shallower domestic hegemony, takes forms other than that of U.S. boots on the ground. The fading – or destruction – of the anti-war movement after 2005, following massive demonstrations against the invasion of Iraq which featured considerable grassroots mobilization, is a critical episode to reflect upon. The ubiquity of manned and unmanned aerial bombardment, the diffuse and often cloaked nature of counterinsurgency operations, the multiplication of U.S. proxies, and dense financial ties have rendered the military conflicts of U.S. empire, perhaps the most visible manifestation of imperialism, an asymmetrical yet constant presence. Any sustained fight against it must be coordinated around several fronts. Recent experiences of mass protest show that a powerful anti-war movement, if it is to reappear, would do so in an altered shape and in close relation to other insurgent forces in society, an extension of their discursive and strategic reach. The high level of organized resistance to militarized border security and repressive immigration policies, the environmentalist/anti-extractivist campaigns around Standing Rock and elsewhere, and the nascent coalitions and activist milieus that have been fortified through the International Women’s Strike initiatives (resonant with calls from Latin America for a new feminist international) indicate a real potential to build a “popular anti-imperialism” from grounded social struggles, connecting the sites of contestation across neo-colonial and imperial frontiers. One can see how this changes the aims and targets of alter-globalization movements, exemplified in the militancy of summit-hopping demos that directly confront leading economic and financial bodies, or in the parallel institution-building and transnational networking of civil society organizations involved in the World Social Forums.12 A more adequate approach to questions of coordination and solidarity across borders would have to probe how political organization is tied to material practices of translation, and recognize that even localized concerns often involve the commonalities and divisions of the global labor force.13 The mutations of class struggle, where the wage-earning proletariat has given way to more diverse social alliances and associations of what Göran Therborn calls the “plebeian strata” or “popular classes,” has provided glimpses of what anti-imperialist mobilization could look like: new strategies of threading upsurges of disruption, combination, and antagonism as they extend over an unstable terrain.14 Today, it is necessary to re-situate the concept and question of imperialism. We agree with Lenin when we recognize that no revolution, even a national one, is possible without grasping the effects of imperialism on any local articulation of the working class. And we further agree that, of course, no national revolution would be sufficient for the goal of communism. In short, we see imperialism as both an obstacle to and enemy of internationalism and we in turn view internationalism as a position to be composed in working class struggle itself. Thus, at the risk of simplifying our approach, we propose that to examine imperialism today is to bring it into the realm of class composition. This can involve no disavowal of the complicated history of Marxism and popular struggle with regard to imperialism, nor a simple repetition of any one of its moments. In our sixth issue of Viewpoint, we instead seek out the possibility of an encounter, bringing together historical accounts, artefacts of struggle, and theoretical interventions past and present. Thus we neither “endorse” all of the positions represented here nor reject those that might be absent from this issue, which is a situated engagement with the problem of opposing imperialism from within American empire; we are proud to offer these contributions as material for the long-term work of thinking and struggling against imperialism in the 21st century.

### 1NC – Robin Feldman

#### **Feldman’s study is wrong.**

Risch et al 17 [Michael Risch, [Lisa Larrimore Ouellette](http://www.law.stanford.edu/profile/lisa-larrimore-ouellette), [Camilla Hrdy](https://www.uakron.edu/law/faculty/directory/profile.dot?u=chrdy), , 11-21-2017, "Data for the Evergreening Debate," No Publication, <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html> ]// lydia

Pharmaceutical companies would like their blockbuster drug exclusivity to last forever. But patents expire and generics enter the marketplace. This ecosystem has led to a battleground, with opposing claims about unfair competition, evergreening, patent misuse, etc. There's a fair amount of data out there, but with respect to evergreening there has been more heat than light. A recent paper by Robin Feldman (Hastings) and Connie Wang (Hastings - student) attempts to change this by gathering data on 16,000 Orange Book entries between 2005 and 2015. For the unaware (and I'll admit that I'm mildly aware), the Orange Book is an FDA listing of all the "exclusivities" that companies claim related to their New Drug Applications (i.e., their drugs). These exclusivities might relate to patents associated with the drug, research related to the drug, approval to use the drug on new populations or for "orphan" (low incident) diseases. Feldman and Wang argue that the Orange Book has been used by companies to "evergreen" their drugs - that is, to extend exclusivity beyond patent expiration. The paper is on [SSRN](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567) and the abstract is here: Why do drug prices remain so high? Even in sub-optimally competitive markets such as health care, one might expect to see some measure of competition, at least in certain circumstances. Although anecdotal evidence has identified instances of evergreening, which can be defined as artificially extending the protection cliff, just how pervasive is such behavior? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry? This study examines all drugs on the market between 2005 and 2015, identifying and analyzing every instance in which the company added new patents or exclusivities. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Key results include: 1) Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. Every year, at least 74% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs; 2) Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once; 3) Once a company starts down this road, there is a tendency to keep returning to the well. Looking at the full group, 80% of those who added protections added more than one, with some becoming serial offenders; 4) The problem is growing across time.I think the data the authors have gathered is extremely important, and I think that their study sheds important light on what happens in the pharmaceutical industry. That said, as I explain below, my takeaways from this paper are much different from theirs. My concerns are fourfold. First, even assuming that every one of the efforts listed by the the study were an attempt to evergreen, I have no sense for whether evergreening actually happened. This study doesn't provide any data about generic entry or pricing. For example, the study describes 13 listings for OxyContin, but I'd bet dollars to donuts that there was plenty of generic oxycodone available. Similarly, many of the new listings are changes from Drug 1.0 to "new and improved!" Drug 2.0. This, of course, has been criticized as anti-competitive (since generics rely on auto-substitution laws), but the study presents no data about whether insurers refuse to pay for Drug 2.0 and instead require the generic, nor does it explain why generics can't do their own advertisements to get doctors to prescribe Drug 1.0. Second, many of these listings and the new patents that go with them are for advances, like extended release and dissolvables. These can be critically important advances, and they are preferred by consumers. Thus, one person's "evergreening" is another person's innovation. I take extended release drugs (and expensive generic) to avoid side effects and I gave my son dissolvable Prevacid when he wouldn't stop crying with GERD (and was glad for it). Without consumer data or patent data, it is impossible to tell just how much evergreening is going on (or how harmful it is). Now, if these patents are obvious because making them dissolvable or extended is easy, I'm all for stripping protection - but that's a different issue. Third, the article speaks of orphan drug approvals as if they are a bad thing. This made me bristle, quite frankly. My mother has an extremely rare autoimmune disease that is very painful. I often wondered, isn't there some incentive to develop drugs to treat it? Turns out there is, and though she got no relief, apparently a bunch of other rare diseases did, and that's the whole point behind orphan drug exclusivity. Concern about this exclusivity seems misguided anyway. If it turns out that drug companies are gaming it and nobody actually needs the drug, then the the loss is not too large, because it's a small population and nobody needs the generic anyway. And if it turns out that they do need it, the Orange Book only limits labeling, and doctors are free to prescribe a generic for off-label use. Without evidence that doctors refuse to do so, there's no real evidence that Orphan exclusivity does much harm. In another personal story, my wife was prescribed a generic drug in a different formulation than the patented tablet for off-label use. Fourth, and most generally, the article speaks of new patents as if there is no innovation. New use discoveries are important. Many of our most important drugs are not for their original uses. As far as I know, generics are not barred from finding new uses and patenting them, either, though admittedly their hands are tied for patient use. So, where the authors see evergreening, I see innovation. Maybe. Maybe it's obvious. But we can't tell that from this high level, and I'm not ready to write it all off as evergreening. It is telling that I was able to provide four personal stories about how supposed evergreening efforts benefited, would have benefited, or did not increase costs for my family or me (and thankfully none of them involved oxycodone). With these concerns stated, I will note one area of agreement - the very narrow range of new drug discovery. It's hard to discover new drugs, and it's expensive. And the results of that show in where the innovative efforts are in this study. So, one of the key questions in my mind is not whether the drug companies are evergreening, but rather whether we are striking the right balance in incentives for brand new drug discovery versus old drug improvement. That, I think, will take a lot more study.

### 1NC – Evergreening

#### Their own “major study” the evergreening database is extremely misleading – the case with ranolazine proves they’re wrong

CIP2 3-4 [C-Ip2, George Mason University, Center for intellectual property x innovation policy, 3-4-2021, "UC Hastings’ Evergreen Drug Patent Search Database: A Look Behind the Statistics Reveals Problems with this Approach to Identifying and Quantifying So-Called “Evergreening”," Center for Intellectual Property x Innovation Policy, <https://cip2.gmu.edu/2021/03/04/uc-hastings-evergreen-drug-patent-search-database-a-look-behind-the-statistics-reveals-problems-with-this-approach-to-identifying-and-quantifying-so-called-evergreening/> ] lydia

We will start with an initial explanation of the methodology underlying the Evergreening Database. As mentioned above, the statistics are derived from out-of-date versions of the FDA’s Orange Book, which is published on the FDA’s website and provides information on patents and “exclusivities” associated with FDA-approved drugs. The exclusivities can be any of a variety of non-patent regulatory exclusivities that Congress created to reward innovators that have achieved certain outcomes that Congress sought to incentivize. Examples include the “NCE exclusivity”—five years of data exclusivity awarded for the initial approval of a new active ingredient, i.e., a “new chemical entity”—and the seven years of orphan drug exclusivity awarded to an innovator that develops a drug for a rare disease or condition. The Orange Book provides a listing of these exclusivities, as well as a list of patents relating to the approved drug (i.e., patents claiming the drug’s active ingredient, formulations of the drug, and methods of using the drug). It also provides expiration dates for the patent and exclusivities. The FDA periodically revises the Orange Book, and when it does, it removes from the lists any patents and exclusivities that have expired. The creators of the Evergreening Database compiled this historical data in a Comma Separated Values file (“the CSV file”). The Database uses the patents and exclusivities derived from the CSV file to generate various statistics for each drug, including a total number of “protections” and “extensions,” as well as the “earliest protection date,” “latest protection date,” and the number of “months of additional protection” (which is the time between the earliest protection date and the latest protection date). Presumably, these statistics are intended to shed some light on the purported evergreening practices of pharmaceutical companies. Now let us turn to ranolazine. The Evergreening Database entry for ranolazine provides the New Drug Application (“NDA”) number for the drug (21526), the branded product name (Ranexa), the name of the innovator company associated with the branded drug (Gilead), and the date of FDA approval (January 27, 2006). The ranolazine entry also provides various statistics derived from the raw data, including the number of “protections” (26) and the amount of “additional protection time” (156 months, i.e., 13 years). This seems to provide an example of evergreening. The statistics appear to show that Gilead gamed the system to “artificially extend the protection horizon of its patents” by 13 years. However, a closer examination of the raw data tells a quite different story. First, what are the 26 purported “protections” that Gilead has apparently secured with respect to Ranexa? Eleven of them are patents that were once listed in the Orange Book for the drug. All the listed patents have expired, so none appear in the current Orange Book. While the Database lists the patents, it does not include expiration dates, which are necessary to understand the “protection time” statistics. Worse, the Database provides no information with respect to the other 15 “protections,” i.e., non-patent exclusivities. With some effort, the missing information can be found in the CSV file. The following step-by-step instructions will hopefully make it easier for others interested in following this path. Beginning on the homepage for the Evergreening Database, click on the “About the Data” hyperlink, which will take you to another page which states: To download the original dataset, that was used to develop the results for the article May Your Drug Price Be Evergreen, along with information about researching the FDA’s Orange Book, please see: Robin Feldman, Identifying Extensions of Protection in Prescription Drugs: Navigating the Data Landscape for Large-Scale Analysis, ANN ARBOR, MI: INTER-UNIVERSITY CONSORTIUM FOR POLITICAL AND SOCIAL RESEARCH (2018), <https://doi.org/10.3886/E104781V2>. Clicking on the “doi.org” link leads to a webpage of “openICPSR,” which describes itself as “a self-publishing repository for social, behavioral, and health sciences research data” and a “service of the Inter-university Consortium for Political and Social Research (ICPSR).” There are several files posted on this webpage, including one entitled Orange\_Book.csv. Users can download this file after registering with openICPSR. The CSV file includes 26 entries for ranolazine that presumably correspond to the 26 “protections” reported in the Database. All 26 protections were based either on the eleven patents or on the NCE exclusivity granted by FDA for the first approval of a new active ingredient. How does that add to 26 protections? Each of the 11 patents was counted twice, once for each approved strength of the drug (which comes in dosages of 500 mg and 1 g). However, marketing approval for two strengths of a drug does not extend the duration of the patents, and it is problematic that the methodology underlying the database results in a doubling of the number of “protections,” with the implication that this constitutes evidence of possible evergreening. One of the patents (U.S. patent number 4,567,264) was counted as three protections, because the duration of that patent was extended by patent term extension (PTE) pursuant to Section 156 of the Patent Act. Congress enacted Section 156 in 1984 as part of the Hatch-Waxman Act for the express purpose of addressing the “distortion” of the patent term experienced by pharmaceutical innovators owing to the lengthy process of achieving FDA marketing approval. Often, by the time a drug has been approved, much (if not all) of the patent term will have elapsed. To compensate for this distortion, Section 156 allows pharmaceutical innovators to extend the duration of one patent covering the drug by a length of time equal to one half of the time between the filing of the Investigational New Drug (IND) application and the submission of an NDA, plus all the time between the submission of the New Drug Application (NDA) and approval of the drug. Pursuant to statute, the maximum amount of PTE that can be awarded under Section 156 is five years, and the amount of PTE awarded can extend the duration of the patent for no longer than 14 years after the drug’s approval date. Five years of PTE was added to U.S. patent number 4,567,264, which claims ranolazine as a composition of matter. Notably, the original expiration date of this patent was in 2003, three years prior to the drug’s initial approval. With the addition of five years of PTE, the patent term was extended to 2008, a little more than two years after the drug was approved for marketing. But since the patent term (including PTE) runs concurrently with the five-year NCE data exclusivity (discussed below), the patent provided no additional exclusivity beyond that already provided by NCE exclusivity. The Database is misleading to the extent that it implies that the award of PTE constitutes an “artificial” extension exclusivity for ranolazine—PTE was created by Congress for this express purpose, and it is available to all innovators who make a new drug available to patients. One of the 26 “protections” was simply a request to delist a patent from the Orange Book. It makes no sense to consider a request to delist a patent as an additional “protection” for the drug, but for some reason that is how it is tallied in the CSV file and Database. To summarize, 24 of the 26 “protections” are accounted for by the 11 patents, including the award of PTE and the request to delist a patent. The remaining two “protections” result from the fact that Gilead received five years of NCE data exclusivity. Like the patents, the NCE exclusivity period was counted twice, once for each approved strength of the drug. Congress created NCE exclusivity as an incentive for pharmaceutical companies to engage in the costly and beneficial activity of securing FDA approval for new pharmaceutical active ingredients, thereby ensuring that innovators receive a minimum of at least five years of exclusivity before any generic company can file an abbreviated NDA (ANDA) seeking approval to market a generic version of the drug. All innovators who succeed in providing a new active ingredient to patients are awarded five years of NCE exclusivity, which runs concurrently with patents. Again, it is misleading for the Database to tally the NCE exclusivity as two additional “protections” for the drug. NCE exclusivity provides a minimum floor of protection for innovators. Now, what about the 11 patents? Are they evidence of evergreening, i.e., artificial extensions of patent protection? In assessing these patents, it is useful to consider the context from which they arose. Ranolazine was initially identified as a drug target by Syntex in the 1980s, and throughout much of the 1980s and 1990s that company conducted extensive studies of the compound for a variety of indications, including Phase II clinical trials testing its safety and efficacy in humans. Unfortunately, these studies failed to result in an approved drug, due at least in part to the fact that ranolazine is rapidly metabolized once ingested, which resulted in inadequate plasma concentrations of the drug in human subjects. Syntex filed a patent application disclosing ranolazine in 1983 that resulted in the issuance of a patent in 1986 claiming the molecule. This is the composition of matter patent mentioned above, the original term of which expired in 2003 but was extended by PTE to 2008. In 1996, Syntex (then a subsidiary of Roche) licensed its rights in ranolazine to another drug company, CV Therapeutics. Researchers at CV Therapeutics succeeded in overcoming the problem of rapid metabolism by developing a sustained-released version of the drug. In 1999, the company filed a patent application disclosing sustained-release ranolazine formulations and methods of using them to treat patients. This application resulted in the issuance of a patent in 2001 claiming methods of using the sustained-release formulation of ranolazine to treat patients suffering from angina (U.S. patent number 6,306,607, the “method of treatment patent.”, which expired in 2019). Note that the method of treatment patent was issued years before the initial FDA approval of ranolazine in 2006, and the initial approval was for the sustained-release ranolazine. Generic versions of ranolazine began entering the market in 2019, shortly before the expiration of the method of treatment patent. What about the other nine? All nine of these patents arose out of continuation applications claiming priority to the original 1999 application and therefore expired on the same day as the method of treatment patent, i.e., 20 years after the filing date of the original parent application. The nine additional patents reflect the fact that the 1999 patent application filed by CV Therapeutics disclosed multiple inventions, addressing different aspects of the company’s discovery of sustained-release ranolazine formulations and their use as therapeutic agents. Patent law’s prohibition against “double patenting” required CV Therapeutics to divide the inventions up into multiple patents, and the PTO examined the various inventions and determined that each merited its own patent. Significantly, because the patents all ran concurrently, and all expired on the same day, they did not extend the period of exclusivity beyond that provided by the initial method of treatment patent. Finally, what of the Database’s assertion that Gilead benefited from 13 years of “additional” protection time for Ranexa? Presumably, this is time gained from “evergreening”; however, the statistics provided by the Database seem suspect, because they report that Ranexa was approved on January 27, 2006 (which is correct), that its “earliest protection date” was May 18, 2006 (less than four months later), and that its “latest protection date” was May 27, 2019 (which is the expiration date for the method of treatment patent). In other words, the total period of exclusivity reported by the Database was a little less than 13 years and four months, almost all of which the Database characterized as “additional protection time.” Why did the Evergreening Database allot ranolazine less than four months of “earliest” protection time? There is no explanation in the Database itself, but the CSV file provides the answer. As mentioned earlier, the CSV file includes three entries for the composition of matter patent, accounting for three of the 26 “protections.” One of those entries lists the “expiration date” for the patent as May 18, 2006. It is this entry in the CSV file that resulted in the Database reporting an “earliest protection date” of May 18, 2006, less than four months after the drug was approved. The latest protection date of May 27, 2019 is the expiration date for the method of treatment patent. The 13 years of “additional protection time” is simply the amount of time between these two dates. There are numerous problems with the methodology used to calculate “additional protection time.” For one thing, the May 18, 2006, expiration date for the composition of matter patent reported in the CSV file is incorrect. The expiration date for the patent was May 18, 2003, and the term was extended by five years of PTE to May 18, 2008 (see the PTO’s Patent Terms Extended Under 35 USC §156, available at <https://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156>, last visited Nov. 29, 2020). The two other entries in the CSV file for the composition of matter patent provide expiration dates of May 18, 2007. We assume that the creators of the Database intended to populate the CSV file with the original expiration date of the patent and the PTE-extended expiration date, but for some reason they got the years wrong—i.e., the actual years were 2003 and 2008, and the creators of the Database erroneously reported them as 2006 and 2007. However, because they used the erroneous May 18, 2006 expiration date as the “earliest protection date” for ranolazine, the Database allows for less than four months of “earliest” protection time and counted the remaining 13 years of protection provided by the method of treatment patent as “additional.” In fact, if they had used the correct original expiration date for the composition of matter patent, the result would have been an “earliest protection date” that preceded the approval date of the drug, resulting in zero days of initial protection. This illustrates how misleading it would be to assume there is any connection between the “additional protection time” reported in the Database and evergreening activity. In short, when we look at the raw data underlying the misleading statistics presented by the Database, we see that the innovator enjoyed a little over 13 years of patent protection, based on patents that arose out of the critical inventive activity that enabled CV Therapeutics to transform a failed drug candidate into a successful human therapeutic. Is 13 years of patent protection excessive for ranolazine? We would argue that it is not, particularly when one considers the huge investment and risk that was involved in bringing the drug to market. And Congress did not think so when it enacted Section 156, explicitly allowing pharmaceutical companies to extend the expiration date of their patents up to a maximum of 14 years after initial approval of the drug. The patent system appears to have worked exactly as Congress intended, with all patents and exclusivities expiring and generic versions of the drug entering the market approximately 13 years after the initial approval of Ranexa.

#### Prefer legal studies.

Parker and Mooney 7 [Scott and Kevin; “Is ‘evergreening’ a cause for concern? A legal perspective,” Journal of Commercial Biotechnology; 2007; <https://link.springer.com/article/10.1057/palgrave.jcb.3050066>] Justin

THE LEGAL BACKGROUND The patent system provides an incentive for companies to incur the cost and risk of research by providing the time-limited exclusive right to commercialise a patented product. At the heart of the patent system in the UK (and all other fully TRIPs compliant countries) is the requirement that to qualify for the monopoly right that the patent confers (20 years from the date of filing the patent application) the invention covered by the patent must be novel, non-obvious (ie it involves an inventive step) and capable of industrial application (‘utility’ or ‘usefulness’ in the US). The novelty and inventiveness of the patent is evaluated against the ‘state of the art’, which consists in general of every item of information which has ever been made available to the public by any kind of publication, or by use, anywhere in the world, at any point in time before the first filing date of the patent. It is a basic principle of patent law that once details of a product have entered the public domain (by being published anywhere without patent protection, or when any patents for the product or proposal expire or lapse), then everyone has freedom to use that information and any obvious developments of it. So before assuming that any new development relating to a known compound can be patented, we have to ask: 1 Is this new? Any previous publication or use, no matter how obscure, of the same invention destroys novelty and prevents a patent being issued or, if issued in ignorance of such a publication, this will subsequently cause the patent to be declared invalid if sought to be enforced. 2 Is there an inventive step? A patent cannot be granted for anything which is simply an obvious development or variant on any individual piece of information which is part of the state of the art. It is no answer that the piece of information in question may never have come to the attention of the fictitious ‘person skilled in the art’ who is central to any determination of ‘obviousness’. 3 Is there a proposed industrial application for the invention (in the broad sense of having some useful purpose)? The invention does not have to demonstrate an improvement on what is already known, but it cannot be speculative. It must have a use. For example, a DNA sequence for a recombinant gene fragment with a well-defined function is a patentable invention whereas a DNA sequence alone without any indication of function or of its useful attributes is not. 4 Does the patent describe how to put the invention into effect? The patent must be ‘enabling’; it must add to public knowledge, and contribute in its own right to the state of the art. In this way each new patent moves the frontier of the state of the art forward and makes it more difficult to find improvements which are neither old nor obvious. This disclosure enables third parties to implement the invention once the patent has expired and, is the consideration (in the legal sense) for the monopoly right granted by a patent. HOW THE PATENT SYSTEM DEALS WITH ‘EVERGREENING’ The criteria of patentability set out above apply equally to all inventions from the most basic mechanical patent to the most complex microelectronic or biotechnological invention. Similarly patent law does not distinguish between the invention of a wholly new product and inventions relating to improvements upon an existing product. The same criteria for patentability apply. ‘Double patenting’ is prohibited. That is to say the same invention cannot be covered by more than one patent. Thus for an improvement upon an existing pharmaceutical product to be patentable in its own right it will need to satisfy the criteria of novelty and non-obviousness taking into account the earlier product and all that is known about it in the public domain at the time that the second patent is applied for. If a patent is granted in respect of this improvement it will only cover the improvement to which it relates and will not extend to the originator product. That is to say a patent for a new product in a class will always be broader than any subsequent patent covering an improvement, modification or derivative of that product and so the exclusivity granted is in broad terms commensurate with the scope of the scientific advance that it reflects. An important corollary to the prohibition on ‘double patenting’ is that a patent covering an improved version of a pharmaceutical (or any other) product does not preclude a generic company from copying all forms of the originator product once the patents protecting these forms have expired. For example, if a company selling a patented pharmaceutical reformulates that product as a syrup for paediatric administration and then patents the new formulation, generic competition to the original adult formulation will be possible once the patents covering it expire or are invalidated. The existence of the patent on the paediatric formulation will not delay or prevent generic competition on the original formulation. The innovator company will, however, continue to have the exclusive right to sell the paediatric formulation for the remainder of the life of the patent covering this specific improvement. If in the above example the improvement made is not a paediatric formulation but a slow release formulation that allows once daily dosing and so improves patient compliance as a result of increased convenience, doctors and patients will have a choice between generic versions of the original formulation or the new once-daily product once any patent on the original formulation expires. The patents on the slow release formulation will not delay or prevent marketing of the original formulation. The market will then decide whether the benefits offered by the improved formulation make it worth paying for in the face of cheaper versions of the original product. The answer to this question will inevitably vary from market to market and between different patient populations. Either way the patient would appear to benefit from the increased choice available. A simple and further example of this is ibuprofen. The supermarket shelf carries premium-priced ibuprofen formulations which typically are quicker acting or easier to take than the traditional tablet. These formulations may be patent protected. Customers can, however, decide for themselves whether the added benefit is worth the extra cost. The patents do not prevent anybody from buying the ordinary, cheapest kind of tablet. Reference to patents covering the colour and scoring of tablets has been made in several articles criticising the pharmaceutical industry (without the specific patents that are complained of being identified).4 It is informative to consider how the patent system would apply to such ‘developments’. To the best of the authors’ knowledge no patents have ever been granted for the colour of pharmaceutical products. In fact, since UK patent law (and most others) expressly excludes the patenting of ‘aesthetic creations’ the colour of a pharmaceutical product could only ever be patentable if either: (a) it could be established that the colour itself produces a technical effect, such as a therapeutic benefit caused by increased compliance, that is novel and not obvious; or (b) that the means of obtaining that colour, the manufacturing process of colouring the tablet, is itself novel and not obvious. It goes without saying that for a ‘pink pill’ patent application the technical effect, novelty and inventiveness would be scrutinised carefully. Nevertheless, the application would be looked at on its own facts and applying the patentability criteria described above. Similarly, as regards the scoring of tablets, the same standard of patentability and scrutiny must be satisfied. It would need to be established that tablets had never been scored in this way before and that to do so was not an obvious departure from what has gone before. Without further investigation it should not be assumed that such an invention would be of no value to patients (eg it could be that compliance among children would be improved if the tablet is more cleanly cut as a result of the means of scoring employed). There are plenty of examples of developments (reformulations, new salts, combinations and the like) that have real therapeutic benefit but which at first blush may seem trivial. Again, the more minor that a variation is (eg a pink tablet or means of scoring the tablet) the more narrow the relevant patent protection will be and the easier it should be for a competitor to design around the patent without needing to seek to invalidate it. For example, if a patent is (or has been) granted that covers a particular colour of tablet or a particular means of scoring such tablet then such a patent would not stop a competitor from marketing (respectively) a different colour tablet or a tablet that is not scored or that is scored in a different way. In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent ‘evergreening’. It allows the use of ‘old’ technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of ‘minor variations’ is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace. ‘STRATEGIC PATENTING’ A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a ‘patent thicket’ that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as ‘strategic patenting’.5 Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself. This is a serious charge that deserves to be looked at in more detail. Of course, pharmaceutical and biotechnology companies (like companies in all other R&D-based industries) have patenting strategies. In no other industry is there any suggestion that companies should restrict themselves to patenting inventions that meet some higher standard over and above the basic criteria for patentability or that companies should not seek protection for certain types of technological advance or that exceeding a certain number of patents in a technical area is per se reprehensible. When one considers that intellectual property rights are the life-blood that propels pharmaceutical advances in the private sector (and to an increasing extent in the public sector as well) and takes into account the sums that are typically spent on a new product during the 10–15-year-period from discovery through pre-clinical and clinical trials to regulatory approval and market launch, any company that did not do all that it could to protect its inventions would be acting negligently towards its shareholders. On the subject of patenting strategies in the pharmaceutical industry the UK Patents Court judge Mr Justice Jacob (now Lord Justice Jacob) said in the case of Synthon v SmithKline Beecham ‘I ask myself whether SB have done anything blameworthy…and I cannot see that they have. On the contrary, so far as I can see, they have employed competent and careful patent agents to obtain for them the best patent position which they think they can get. It may be good, it may be bad, but they are doing their job and I see no criticism whatever in the conduct of SB’.6 If one accepts that the nature of pharmaceutical and biotechnological innovation (as with other R&D based industries) is most often incremental and cumulative then it follows that the patent system should reflect this reality. This is indeed the case. As we have seen above, the patent system does not distinguish between ‘breakthroughs’ and ‘incremental improvements’ in terms of the patentability requirements that apply. At the same time a greater reward (a broader patent) is granted in respect of the ground breaking research than for inventions directed at solving further technical hurdles and optimisation of the initial invention. In the experience of the authors most of the patents that have been challenged by generic companies wishing to enter the market were applied for during the development of the originator product rather than once it has been established as a commercial success. This reflects the organic process of drug discovery and development and the time lag between drug discovery development, clinical testing and regulatory approval (ie that inventions are made in overcoming the various technical challenges faced during drug development). Nevertheless, some innovations are made at a later stage. For example, it may be that it is only after the product has been prescribed to a population of patients post-launch that it will become evident that further improvements need to be made to improve efficacy, deal with a compliance (or other) problem or expand the target patient population or disease indications. Such improvements may stem from greater experience of the product, problems unexpectedly encountered in particular patient populations or other advances made in the field. Given that the purpose of the patent system is to encourage innovation and (in the pharmaceutical sector) to lead to better medicines, it would be strange indeed if this incentive was removed or diminished once the first product of a particular type has been launched.

#### Evergreening is good---your authors misunderstand it.

Banana 19 [BananaIP; “DEMYSTIFYING THE EVERGREEN MYTH,” Executive Office of the President of the United States; 7/19/19—originally appeared 5/19/14; [https://www.bananaip.com/ip-news-center/chapter-iii-demystifying-evergreen-myth-comprehending-apprehension-apprehending-comprehension/]](https://www.bananaip.com/ip-news-center/chapter-iii-demystifying-evergreen-myth-comprehending-apprehension-apprehending-comprehension/%5d) Justin

Evergreening is like any other business strategy that market players would adopt to seek a competitive edge in the market. It doesn’t stop anyone from making the product claimed in the expired patent, but only makes sure that they can differentiate themselves from the other generic products through incremental inventions. More often than not, the R&D efforts and investments that go into the making of these incremental inventions can be very high and their results invaluable for treatment.

One of the rationales of the patent system is to incentivize innovation which is believed to lead to the progress in technology. A patent application is published 18 months after it is filed so as to ensure that the knowledge in the patent is made public for aspiring inventors to design around and build on it. Anyone, including the owner of an existing patent and their competitors, is free to invest in research in this direction as early as 18 months from the filing of such a patent. If a competitor files for an incremental patent, it is branded as innovation, but when a patent holder files for an incremental patent, it is looked upon as innovation leading to life cycle management or Evergreening.

In most parts of the world, life cycle management is considered as positive development. However, to the frustration of many pharmaceutical companies, symbolically represented by Bayer, life cycle management is quite a tricky business in India, thanks to the infamous Section 3(d) of the Indian Patent Act, often alluded to as the anti-evergreening law, which bears the burden of keeping a check on incremental pharmaceutical inventions that add no therapeutic value. Section 3(d) states that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant” is not patentable.

### 1NC – Superbugs/Disease

#### Their OWN ev literally proves squo solves— we read blue

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].

#### Worst possible diseases don’t cause extinction

Owen Cotton-**Barratt 17**, et al, PhD in Pure Mathematics, Oxford, Lecturer in Mathematics at Oxford, Research Associate at the Future of Humanity Institute, 2/3/2017, Existential Risk: Diplomacy and Governance, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf

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

#### Even if a pandemic is virulent AND lethal enough, it burns out

York 14 (Ian, Virologist, 6-4-14, “Why don't diseases completely wipe out species?”, http://www.quora.com/Why-dont-diseases-completely-wipe-out-species)

But mostly diseases don't drive species extinct. There are several reasons for that. For one, the most dangerous diseases are those that spread from one individual to another. If the disease is highly lethal, then the population drops, and it becomes less likely that individuals will contact each other during the infectious phase. Highly contagious diseases tend to burn themselves out that way.

Probably the main reason is variation. Within the host and the pathogen population there will be a wide range of variants. Some hosts may be naturally resistant. Some pathogens will be less virulent. And either alone or in combination, you end up with infected individuals who survive.

### 1NC – Health diplomacy

#### They can’t resolve neglected areas just by having more innovation – nothing abt the aff changes the distribution globally.

#### Capitalism ensures science diplomacy will be exploited by wealthy nations to

#### Science diplomacy is more likely to increase conflict – innovation rate & political interests

Dickson 09 [David Dickson David Dickson has been the Chief Executive Officer and President of McDermott International, Inc. since December 16, 2013. Mr. Dickson served as the Chief Operating Officer and Executive Vice from October 31, 2013, to December 16, 2013. He served as the Chief Executive Officer and President of Global Industries Ltd.] The limits of science diplomacy, 4-6-2009, SciDev.Net, accessed 8-26-2021 https://www.scidev.net/global/editorials/the-limits-of-science-diplomacy///ramamurty

But whether scientific cooperation can become a precursor for political collaboration is less evident. For example, despite hopes that the Middle East synchrotron would help bring peace to the region, several countries have been reluctant to support it until the Palestine problem is resolved. Indeed, one speaker at the London meeting (organised by the UK's Royal Society and the American Association for the Advancement of Science) even suggested that the changes scientific innovations bring inevitably lead to turbulence and upheaval. In such a context, viewing science as a driver for peace may be wishful thinking. Conflicting ethos Perhaps the most contentious area discussed at the meeting was how science diplomacy can frame developed countries' efforts to help build scientific capacity in the developing world. There is little to quarrel with in collaborative efforts that are put forward with a genuine desire for partnership. Indeed, partnership — whether between individuals, institutions or countries — is the new buzzword in the "science for development" community. But true partnership requires transparent relations between partners who are prepared to meet as equals. And that goes against diplomats' implicit role: to promote and defend their own countries' interests. John Beddington, the British government's chief scientific adviser, may have been a bit harsh when he told the meeting that a diplomat is someone who is "sent abroad to lie for his country". But he touched a raw nerve. Worlds apart yet co-dependent The truth is that science and politics make an uneasy alliance. Both need the other. Politicians need science to achieve their goals, whether social, economic or — unfortunately — military; scientists need political support to fund their research. But they also occupy different universes. Politics is, at root, about exercising power by one means or another. Science is — or should be — about pursuing robust knowledge that can be put to useful purposes. A strategy for promoting science diplomacy that respects these differences deserves support. Particularly so if it focuses on ways to leverage political and financial backing for science's more humanitarian goals, such as tackling climate change or reducing world poverty. But a commitment to science diplomacy that ignores the differences — acting for example as if science can substitute politics (or perhaps more worryingly, vice versa), is dangerous.

#### Empirically denied

Patman 17 [Robert G. Patman is professor of politics and director of international studies at the University of Otago, New Zealand. He is coeditor of the Praeger Security International series Ethics of American Foreign Policy.], “Donald Trump, climate denial and other obstacles to science diplomacy,” https://www.noted.co.nz/currently/science/donald-trump-climate-denial-and-other-obstacles-to-science-diplomacy/, mm

The term science diplomacy has entered the vocabulary of policymakers, scientists and scholars of international relations. It refers to the way states use scientific knowledge to address problems and to build international partnerships to deal with some of the planet’s most urgent challenges. Science diplomacy’s direct relationship with government interests and goals distinguishes it from other forms of international scientific co-operation, which are driven by research or commercial imperatives and often occur without direct state participation. In 2008, the American Association for the Advancement of Science (AAAS) established the Centre for Science Diplomacy, which sought to use science “to build bridges between countries and to promote scientific co-operation as an essential element of foreign policy”. Two years later, the AAAS and the Royal Society in the United Kingdom produced a report called New Frontiers in Science Diplomacy: Navigating the Changing Balance of Power. And in the past six years, research institutions and universities, including my own, have hosted conferences on science diplomacy. The United Nations and the European Union, along with the US, the UK, Switzerland, Germany, Japan and New Zealand, have collaborated in building policymaking capacity to conduct science diplomacy. In particular, the New Zealand Government’s chief science adviser, Professor Sir Peter Gluckman, has worked to establish an International Network of Government Science Advice. In August 2014, the first international meeting on science advice to governments was held in Auckland. It was attended by more than 240 delegates from 44 countries. Furthermore, in 2015, the US National Academy of Sciences released its own assessment of science in the US Department of State in a study entitled Diplomacy for the 21st Century: Embedding a Culture of Science and Technology Throughout the Department of State. The results have been mixed. Science diplomacy has been used to initiate and manage large-scale international science projects. In the Asia-Pacific region, the Square Kilometre Array (SKA) project is a multilateral diplomatic effort aimed at extending scientific collaboration to establish a large radio telescope that will dramatically improve human capabilities to survey space. The development of SKA will intensify next year, incorporating antennas in open areas, free from radio noise, that will relay information to central cores in Australia and South Africa. The project’s headquarters are at the Jodrell Bank Observatory in Cheshire, England. New Zealand is a partner of Australia in this project, and some 20 countries, including India and China, are participating and sharing the estimated €2 billion (NZ$3 billion) cost. The SKA project aims “to provide answers to fundamental questions” about general relativity, galaxy evolution, cosmic magnetism, the cosmic dawn and extraterrestrial life. This is one way in which diplomacy can expand the scope of scientific collaboration. Since the signing of the Antarctic Treaty in 1959, nations with a presence in Antarctica have largely embraced scientific co-operation and the area has become something of a peace zone. In 2016, after five years of diplomatic negotiations, 25 nations agreed to establish the world’s largest marine protection park in the Ross Sea. By contrast, science diplomacy has notably failed to address global warming. The Intergovernmental Panel on Climate Change, an international group of more than 2000 scientists established in 1988, concluded that not only was global warming perhaps the most significant threat to the planet, but also that the culprit was atmospheric greenhouse gas generated by human activities: industrial pollution, traffic emissions and intensive farming. International treaties designed to limit greenhouse-gas emissions were signed at successive high-profile meetings at the United Nations Framework Convention on Climate Change in Rio de Janeiro, Kyoto, Copenhagen and, most recently, Paris. To date, however, little has been achieved and the targets set are woefully short of what scientists say is needed. Climate diplomacy has faced two obstacles. President George W Bush and, more recently, president-elect Donald Trump have found it politically and economically expedient to ignore or dispute the evidence. In particular, Trump has repeatedly described climate change as a “hoax” and nominated a climate-change denier, Oklahoma Attorney General Scott Pruitt, as the head of the Environmental Protection Agency. Moreover, diplomats have often lacked a clear grasp of the scientific evidence and negotiated in an incremental fashion at odds with the “tipping-point” nature of the threat. In short, many of the planet’s major problems – in climate, food, water, energy and health – are of global proportions and almost all are linked, in some way, to science and technology. Yet many states still cling to the Westphalian doctrine of unfettered sovereignty.

### 1NC – Innovation

#### Innovation high now – their ev is 2020 ours is this year

Kenan 6-9, The Frank Hawkins Kenan Institute of Private Enterprise develops and promotes innovative, market-based solutions to vital economic issues. With the belief that private enterprise is the cornerstone of a prosperous and free society, the institute fosters the entrepreneurial spirit to stimulate economic prosperity and improve the lives of people in North Carolina, across the country and around the world. Kenan Institute, 6-9-21, “Turbocharging Healthcare Innovation” <https://kenaninstitute.unc.edu/kenan-insight/turbocharging-healthcare-innovation/> brett

As COVID-19 began to spread around the globe, companies and entrepreneurs stepped up to develop new technologies and redeploy existing technologies in their portfolio to tackle the disease and cope with the constraints it brought. The pandemic forced telemedicine into the mainstream and brought mRNA vaccine technology to the forefront. At the same time, new technologies such as CRISPR gene editing and artificial intelligence (AI) approaches have been finding their niche for speeding up drug discovery and development.

Healthcare innovation was already on the fast train before the pandemic. Now, it’s been turbocharged. In this Kenan Insight, we explore why the 2021 Trends in Entrepreneurship Report names emerging technology in the healthcare industry as a key trend for entrepreneurship, along with some of the challenges that come with fast-moving technology advances.

A trajectory of explosive growth

The healthcare industry has experienced extraordinary growth over the past four decades. Big pharma is driving much of this boom, accounting for 10% of the U.S. economy’s overall R&D spending at the end of 2020.1 The medical device industry, expected to generate $54.5 billion over the next four years, is another important player.2 This growth is catching the attention of investors. In 2020, health tech startups raised approximately $14 billion in venture capital funding, nearly double that of 2019.3 CB Insights estimates there are now 51 healthcare unicorns, defined as startups valued at $1 billion or more.

Health-tech venture funding reached record levels in 2020

Chart, bar chart, histogram

Description automatically generated

Source: Deloitte analysis of Rock Health’s Digital Health Funding Database

Innovation is a critical driver in the healthcare sector. Increasing rates of innovation can be seen in the sharp rise of U.S. patents granted for pharmaceuticals and medical devices in recent years. Between 2013 and 2019, more than 60,000 pharmaceutical patents and more than 125,000 medical device patents were granted.4 Today, there are more than 18,500 drugs at various stages of the development process worldwide.5

Maturing technologies

The increasing numbers of patent applications, clinical trials and collaborations are leading indicators of a vibrant and growing biopharmaceutical ecosystem. However, the proliferation of innovation tools, rather than just innovative products, is what will allow the next generation of pharmaceutical drugs to be discovered more quickly and more efficiently, to provide more effective treatments and to target diseases that have so far evaded our collective intervention efforts. As scientists learn more about human genes and their connection to diseases, these insights can feed into tools that make drug R&D faster, less expensive and more precise.

AI technology has matured to the point where it can now be used reliably to analyze huge amounts of data and solve extremely complex problems. This has made AI attractive to the pharmaceutical industry as a tool that can enable more efficient identification of new drugs and drug targets. In 2020, drug discovery was the focus area that received the most private AI investment, with more than $13.8 billion invested globally. This was 4.5 times higher than the total for 2019.6

CRISPR gene editing is another hot technology that is enabling the development of more innovative and accurate therapeutic strategies. This tool is making it easier to determine the genes and proteins that cause or prevent disease and thus to identify new targets for potential drugs. As of the second quarter of 2020, there were 724 active companies around the world focused on using or developing CRISPR technology and almost 50 clinical trials involving CRISPR.7

#### Turn— one-and-done patents decrease innovation and they don’t solve

Holman 20 Chris Holman [Professor of Law, University of Missouri-Kansas City School of Law], February 7, 2020, , "Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection," Geneva Network, <https://geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/> // EH

Patent law is primarily concerned with rewarding and enhancing the creation of useful inventions. It is not an instrument that has been specifically designed to address crucial problems relating to ethics, access, health, competition and human rights policies. This is particularly true for the bio-pharmaceutical sector. It is therefore crucial that patent offices and courts continue to assess the inventiveness of all inventions, including inventions arising out of follow-on pharmaceutical innovation, based on the specific features of that invention when compared to the relevant prior art, rather than adopting the sort of technology-specific presumptions against patentability endorsed by the Guidelines. In cases where there are legitimate concerns that patents are being misused in a manner that restricts access to medicine, then that misuse should be addressed directly, rather than through a broadside attack on the patenting of follow-on pharmaceutical innovation in toto. If the patent system is being misused in a manner that is anticompetitive, then antitrust and competition laws should be invoked to address the problem directly. If certain specific types of patent enforcement activities are deemed problematic, they too can be addressed directly. The US patent statute, for example, already provides an exemption from liability for doctors who use a patented method of medical treatment. This addresses concerns about doctors potentially being sued without depriving medical innovators of patents (which would still be enforceable against a competing medical device company, for example). It would be a mistake to upset the delicate balance of innovation policy embodied in the current consensus patent regime – to do so poses a grave risk of greatly diminishing the pipeline of future medicinal breakthroughs.

#### No link— HIV/AIDS proves follow-on increases innovation

Holman 20 Chris Holman [Professor of Law, University of Missouri-Kansas City School of Law], February 7, 2020, , "Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection," Geneva Network, <https://geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/> // EH

The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

#### The alt drives far better innovation than the AFF

Alexander 14 - acclaimed political commentator whose work is regularly praised by top academics (Scott, <https://slatestarcodex.com/2014/09/24/book-review-red-plenty/>, emuse)

There’s a very settled modern explanation of the conflict between capitalism and communism. Capitalism is good at growing the economy and making countries rich. Communism is good at caring for the poor and promoting equality. So your choice between capitalism and communism is a trade-off between those two things. But for at least the first fifty years of the Cold War, the Soviets would not have come close to granting you that these are the premises on which the battle must be fought. They were officially quite certain that any day now Communism was going to prove itself better at economic growth, better at making people rich quickly, than capitalism. Even unofficially, most of their leaders and economists were pretty certain of it. And for a little while, even their capitalist enemies secretly worried they were right. The arguments are easy to understand. Under capitalism, plutocrats use the profits of industry to buy giant yachts for themselves. Under communism, the profits can be reinvested back into the industry to build more factories or to make production more efficient, increasing growth rate. Under capitalism, everyone is competing with each other, and much of your budget is spent on zero-sum games like advertising and marketing and sales to give you a leg up over your competition. Under communism, there is no need to play these zero-sum games and that part of the budget can be reinvested to grow the industry more quickly. Under capitalism, everyone is working against everyone else. If Ford discovers a clever new car-manufacturing technique, their first impulse is to patent it so GM can’t use it, and GM’s first impulse is to hire thousands of lawyers to try to thwart that attempt. Under communism, everyone is working together, so if one car-manufacturing collective discovers a new technique they send their blueprints to all the other car-manufacturing collectives in order to help them out. So in capitalism, each company will possess a few individual advances, but under communism every collective will have every advance, and so be more productive. These arguments make a lot of sense to me, and they definitely made sense to the Communists of the first half of the 20th century. As a result, they were confident of overtaking capitalism. They realized that they’d started with a [disadvantage] – czarist Russia had been dirt poor and almost without an industrial base – and that they’d faced a further [disadvantage] in having the Nazis burn half their country during World War II – but they figured as soon as they overcame these [disadvantages] their natural advantages would let them leap ahead of the West in only a couple of decades. The great Russian advances of the 50s – Sputnik, Gagarin, etc – were seen as evidence that this was already starting to come true in certain fields. And then it all went wrong. II. Grant that communism really does have the above advantages over capitalism. What advantage does capitalism have? The classic answer is that during communism no one wants to work hard. They do as little as they can get away with, then slack off because they don’t reap the rewards of their own labor. Red Plenty doesn’t really have theses. In fact, it’s not really a non-fiction work at all. It’s a dramatized series of episodes in the lives of Russian workers, politicians, and academics, intended to come together to paint a picture of how the Soviet economy worked. But if I can impose a thesis upon the text, I don’t think it agreed with this. In certain cases, Russians were very well-incentivized by things like “We will kill you unless you meet the production target”. Later, when the state became less murder-happy, the threat of death faded to threats of demotions, ruined careers, and transfer to backwater provinces. And there were equal incentives, in the form of promotion or transfer to a desirable location such as Moscow, for overperformance. There were even monetary bonuses, although money bought a lot less than it did in capitalist countries and was universally considered inferior to status in terms of purchasing power. Yes, there were [Goodhart’s Law](http://en.wikipedia.org/wiki/Goodhart%27s_law) type issues going on – if you’re being judged per product, better produce ten million defective products than 9,999,999 excellent products – but that wasn’t the crux of the problem. Red Plenty presented the problem with the Soviet economy primarily as one of allocation. You could have a perfectly good factory that could be producing lots of useful things if only you had one extra eensy-weensy part, but unless the higher-ups had allocated you that part, you were out of luck. If that part happened to break, getting a new one would depend on how much clout you (and your superiors) pulled versus how much clout other people who wanted parts (and their superiors) held. The book illustrated this reality with a series of stories (I’m not sure how many of these were true, versus useful dramatizations). In one, a pig farmer in Siberia needed wood in order to build sties for his pigs so they wouldn’t freeze – if they froze, he would fail to meet his production target and his career would be ruined. The government, which mostly dealt with pig farming in more temperate areas, hadn’t accounted for this and so hadn’t allocated him any wood, and he didn’t have enough clout with officials to request some. A factory nearby had extra wood they weren’t using and were going to burn because it was too much trouble to figure out how to get it back to the government for re-allocation. The farmer bought the wood from the factory in an under-the-table deal. He was caught, which usually wouldn’t have been a problem because everybody did this sort of thing and it was kind of the “smoking marijuana while white” of Soviet offenses. But at that particular moment the Party higher-ups in the area wanted to make an example of someone in order to look like they were on top of their game to their higher-ups. The pig farmer was sentenced to years of hard labor. A tire factory had been assigned a tire-making machine that could make 100,000 tires a year, but the government had gotten confused and assigned them a production quota of 150,000 tires a year. The factory leaders were stuck, because if they tried to correct the government they would look like they were challenging their superiors and get in trouble, but if they failed to meet the impossible quota, they would all get demoted and their careers would come to an end. They learned that the tire-making-machine-making company had recently invented a new model that really could make 150,000 tires a year. In the spirit of [Chen Sheng](http://en.wikipedia.org/wiki/Dazexiang_Uprising), they decided that since the penalty for missing their quota was something terrible and the penalty for sabotage was also something terrible, they might as well take their chances and destroy their own machinery in the hopes the government sent them the new improved machine as a replacement. To their delight, the government believed their story about an “accident” and allotted them a new tire-making machine. However, the tire-making-machine-making company had decided to cancel production of their new model. You see, the new model, although more powerful, weighed less than the old machine, and the government was measuring their production by kilogram of machine. So it was easier for them to just continue making the old less powerful machine. The tire factory was allocated another machine that could only make 100,000 tires a year and was back in the same quandary they’d started with. It’s easy to see how all of these problems could have been solved (or would never have come up) in a capitalist economy, with its use of prices set by supply and demand as an allocation mechanism. And it’s easy to see how thoroughly the Soviet economy was sabotaging itself by avoiding such prices. III. The “hero” of Red Plenty – although most of the vignettes didn’t involve him directly – was Leonid Kantorovich, a Soviet mathematician who thought he could solve the problem. He invented the technique of [linear programming](http://en.wikipedia.org/wiki/Linear_programming), a method of solving optimization problems perfectly suited to allocating resources throughout an economy. He immediately realized its potential and wrote a nice letter to Stalin politely suggesting his current method of doing economics was wrong and he could do better – this during a time when everyone else in Russia was desperately trying to avoid having Stalin notice them because he tended to kill anyone he noticed. Luckily the letter was intercepted by a kindly mid-level official, who kept it away from Stalin and warehoused Kantorovich in a university somewhere. During the “Khruschev thaw”, Kantorovich started getting some more politically adept followers, the higher-ups started taking note, and there was a real movement to get his ideas implemented. A few industries were run on Kantorovichian principles as a test case and seemed to do pretty well. There was an inevitable backlash. Opponents accused the linear programmers of being capitalists-in-disguise, which wasn’t helped by their use of something called “shadow prices”. But the combination of their own political adeptness and some high-level support from Khruschev – who alone of all the Soviet leaders seemed to really believe in his own cause and be a pretty okay guy – put them within arm’s reach of getting their plans implemented. But when elements of linear programming were adopted, they were adopted piecemeal and toothless. The book places the blame on Alexei Kosygen, who implemented [a bunch of economic reforms that failed](http://en.wikipedia.org/wiki/1965_Soviet_economic_reform), in a chapter that makes it clear exactly how constrained the Soviet leadership really was. You hear about Stalin, you imagine these guys having total power, but in reality they walked a narrow line, and all these “shadow prices” required more political capital than they were willing to mobilize, even when they thought Kantorovich might have a point. IV. In the end, I was left with two contradictory impressions from the book. First, amazement that the Soviet economy got as far as it did, given how incredibly screwed up it was. You hear about how many stupid things were going on at every level, and you think: This was the country that built Sputnik and Mir? This was the country that almost buried us beneath the tide of history? It is a credit to the Russian people that they were able to build so much as a screwdriver in such conditions, let alone a space station. But second, a sense of what could have been. What if Stalin hadn’t murdered most of the competent people? What if entire fields of science hadn’t been banned for silly reasons? What if Kantorovich had been able to make the Soviet leadership base its economic planning around linear programming? How might history have turned out differently? One of the book’s most frequently-hammered-in points was that there was was a brief moment, back during the 1950s, when everything seemed to be going right for Russia. Its year-on-year GDP growth (as estimated by impartial outside observers) was somewhere between 7 to 10%. Starvation was going down. Luxuries were going up. Kantorovich was fixing entire industries with his linear programming methods. Then Khruschev made a serious of crazy loose cannon decisions, he was ousted by Brezhnev, Kantorovich was pushed aside and ignored, the “Khruschev thaw” was reversed and tightened up again, and everything stagnated for the next twenty years. If Khruschev had stuck around, if Kantorovich had succeeded, might the common knowledge that Communism is terrible at producing material prosperity look a little different?