## 1NC – CP

#### CP: Member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over reducing intellectual property protections by implementing a one-and-done approach for patent protections. Member nations will support the proposal and adopt the results of consultation.

#### WHO says yes

WHO 06 [(World Health Organization, specialized agency of the United Nations responsible for international public health) “Public health, innovation and intellectual property rights,” Report of the Commission on Intellectual Property Rights, Innovation, and Public Health, 2006] JL

Though difficult to discern from incremental innovation in practice, socalled “evergreening” is importantly different. As usually understood, “evergreening” occurs when, in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term. President Bush, in 2002, provided a working definition while announcing reforms in response to a Federal Trade Commission (FTC) report (73) on delays to the entry of generic products onto the market:

The FTC...discovered that some brand name drug manufacturers may have manipulated the law to delay the approval of competing generic drugs. When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug’s effectiveness … In the meantime, the lower-cost generic drug is shut out of the market … This is not how Congress intended the law to work. Today, I’m taking action to close the loopholes, to promote fair competition and to reduce the cost of prescription drugs in America … These steps we take today will not undermine patent protection. Instead, we are enforcing the original intent of a good law. Our message to brand name manufacturers is clear: you deserve the fair rewards of your research and development; you do not have the right to keep generic drugs off the market for frivolous reasons (81).

Evergreening can occur in a number of ways but typically, as noted by President Bush, it arises when companies file and obtain patents, subsequent to the original patent, on other aspects of the same compound or reformulations of the original compound in ways that might be regarded as of no incremental therapeutic value, but which are nevertheless patentable. For instance, strategies include a similar but different dosage form such as capsules rather than tablets, salts, esters, or crystals (polymorphs) of the same product or other changes dependent on the ingenuity of the formulators and the lawyers. These types of strategies occur in almost all jurisdictions, especially for lucrative products (see Box 4.7) (82, 83).

Where there is a linkage between the patent system and the procedures for approving new drugs (for example, in Canada and the United States), the policy issues take a particular form. In the United States, for instance, the Federal Trade Commission catalogued a number of instances where generic entry was delayed by up to fi ve years by successive stays of up to 30 months on the entry of a generic competitor (see Box 4.7). These stays were provided automatically under the United States law if a brand-holder challenged the generic company for infringement, until the changes announced by President Bush reduced this to one stay only.

These linkage arrangements are essentially supplementary to the patent system. But they alter the way in which the patent system operates for pharmaceutical products.15 Nevertheless, the final decisions on patent validity and infringement cases lie with the courts. This means that any change to tackle evergreening at its roots requires measures to reduce the likelihood of such patents being granted or, if granted, of being upheld in the courts. While, as previously stated, some forms of incremental innovation might be important in terms of patient benefit, faced with the reality of the TRIPS agreement, developing countries need to consider how their own patent laws may deal with this issue. Patents on minor developments are used, often aggressively, by some patent holders to delay or block generic competition. Small and medium-sized generic firms in developing countries, in particular, are generally unable to sustain costly and lengthy legal challenges, and opt to avoid fields where litigation may arise. The outcome may be the reduction or suppression of competition and, in some cases higher prices for patients.

#### Consultation displays strong leadership, authority, and cohesion among member states which are key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

## 1NC – Off

#### Biotech industry strong now.

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] TDI

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A recent report from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### Secondary patents are key to innovation – recouping development costs and new applications of existing medicines

Richards et al 20 [(Kevin T., Associate Solicitor at the US Patent and Trademark Office, former legislative attorney at CRS, JD from UVA School of Law) “Drug Pricing and Pharmaceutical Patenting Practices,” Congressional Research Service, 2/11/2020] JL

Defenders of evergreening respond that the term is "inherently pejorative" because it creates the impression that pharmaceutical companies are exploiting the patent system.157 Defenders contend that there is nothing inherently suspect about secondary patents, which must meet the same requirements for patentability and pass through the same examination procedures as any other patent.158 Indeed, those requirements bar a secondary patent on an obvious variation of the primary patent or on another product or invention already available to the public.159 "[I]t is often the case," defenders contend, "that the value of a follow-on patent is comparable to, or even might exceed, that of a primary patent."160 One example arguably supporting this view is the drug Evista (raloxifine). Evista was "initially studied as a potential treatment for breast cancer" but, in 1997, FDA approved the drug for the prevention of osteoporosis.161 At that time, there were only a few years left on Evista's initial patent, which was filed in 1983.162 If the brand could not patent the new use (i.e., for prevention of osteoporosis), one commentator has argued that insufficient incentives would have existed to make the investment in R&D necessary to bring the drug to market.163

Defenders also argue that the ability to receive a patent on a later-developed formulation provides a significant incentive to address problems with the original formulation. For example, the original formulation of Lumigan, which is used to treat glaucoma, resulted, at times, in sufficiently severe red eye that patients would discontinue its use.164 Researchers subsequently developed an improved formulation with significantly decreased risk of this side effect.165 Defenders of secondary patents contend that without the possibility of patent protection, there would have been little incentive to perform this sort of research due to the significant costs involved.166

Secondary patents are also defended on the grounds of being necessary to recoup development costs. A recent study found that even though the patent term is generally twenty years, delays in PTO and FDA approval can decrease the nominal Orange Book patent term to 15.9 years, and generic competition can result in an effective market exclusivity of only 12.2 years.167 This effective market exclusivity is less than the sixteen years that one commentator suggests is necessary to recoup the brand's fixed costs for research, development, and clinical testing.168

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror.

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### Extinction – defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

## 1NC-Off

#### CP: The member nations of the WTO ought to implement price regulations for medicines.

## 1NC – Case

### 1NC – Framing

**Moral uncertainty means preventing extinction should be our highest priority.  
Bostrom 12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)]  
These reflections on **moral uncertainty suggest** an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might** well **be confused. We may not** nowknow — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet **be able to imagine the best ends** of our journey. **If we are** indeedprofoundly **uncertain** about our ultimate aims,then we should recognize that **there is a great** option **value in preserving** — and ideally improving — **our ability to recognize value and** to **steer the future accordingly. Ensuring** that **there will be a future** version of **humanity** with great powers and a propensity to use them wisely **is** plausibly **the best way** available to us **to increase the probability that the future will contain** a lot of **value.** To do this, we must prevent any existential catastrophe.

**Reducing the risk of extinction is always priority number one.   
Bostrom 12** [Faculty of Philosophy and Oxford Martin School, University of Oxford.], Existential Risk Prevention as Global Priority.  Forthcoming book (Global Policy). MP. http://www.existenti...org/concept.pdfEven if we use the most conservative of these estimates, which entirely ignores the   possibility of space colonization and software minds, **we find that the expected loss of an existential   catastrophe is greater than the value of 10^16 human lives**.  **This implies that the expected value of   reducing existential risk by a mere one millionth of one percentage point is at least a hundred times the   value of a million human lives.**  The more technologically comprehensive estimate of 10  54 humanbrain-emulation subjective life-years (or 10  52  lives of ordinary length) makes the same point even   more starkly.  Even if we give this allegedly lower bound on the cumulative output potential of a   technologically mature civilization a mere 1% chance of being correct, we find that the expected   value of reducing existential risk by a mere one billionth of one billionth of one percentage point is worth   a hundred billion times as much as a billion human lives. **One might consequently argue that even the tiniest reduction of existential risk has an   expected value greater than that of the definite provision of any ordinary good, such as the direct   benefit of saving 1 billion lives.**  And, further, that the absolute value of the indirect effect of saving 1  billion lives on the total cumulative amount of existential riskâ€”positive or negativeâ€”is almost   certainly larger than the positive value of the direct benefit of such an action.

### Advantage 1

#### None of their ev says capabilities to solve superbugs are adequate – if they’re right that superbugs are imminent and deadly, they need to read cards that say we could beat them

#### AMR superbugs have already arrived but new tech makes them preventable

Knoss 18 [(Trent, science writer and beat contact at CU Boulder covering ecology, environmental science, technology, chemistry and engineering, internally cites Peter Otoupal, postdoctoral fellow at Lawrence Berkeley National Laboratory, Ph.D. in Chemical Engineering from CU Boulder) “How to stop an antibiotic-resistant superbug,” CU Boulder Today, 9/3/2018] JL

A genetic disruption strategy developed by CU Boulder researchers effectively stymies the evolution of antibiotic-resistant bacteria such as E. coli, giving scientists a crucial leg up in the ongoing battle against deadly superbugs.

These multidrug-resistant pathogens—which adapt to current antibiotics faster than new ones can be created—infect nearly 2 million people and cause at least 23,000 deaths annually in the U.S., according to data from the Centers for Disease Control.

In an effort to develop a sustainable long-term solution, CU Boulder researchers created the Controlled Hindrance of Adaptation of OrganismS (CHAOS) approach, which uses CRISPR DNA editing techniques to modify multiple gene expressions within the bacteria cells, stunting the pathogen’s central processes and thwarting its ability to evolve defenses.

The findings are outlined today in the journal *Communications Biology*and could open new research avenues on how to best restrict a pathogen’s antibiotic resistance.

“We now have a way to cut off the evolutionary pathways of some of the nastiest bugs and potentially prevent future bugs from emerging at all,” said Peter Otoupal, lead author of the study and a doctoral researcher in CU Boulder’s Department of Chemical and Biological Engineering (CHBE).

The CHAOS research is the culmination of work that began in 2013, when Otoupal and his colleagues began searching for genes that could act as a cellular kill switch for *E. coli*. When the scientists tweaked one gene at a time, the bacteria could adapt and survive. But when they altered two or more genes at once, the cell got weaker.

“We saw that when we tweaked multiple gene expressions at the same time—even genes that would seemingly help the bacteria survive—the bacteria’s fitness dropped dramatically,” Otoupal said.

#### Superbug impact is hype

**Tyson 12**{Greg, syndicated science columnist, PhD student in microbiology (Northwestern), “Tipping Point: The Threat of Antibiotic Resistance,” Helix, 8/17, http://helix.northwestern.edu/article/tipping-point-threat-antibiotic-resistance}

What happens if we stand pat? We won’t return to the Middle Ages, where plague wiped out one third of Europe’s population. The truth is that many of the most dangerous and widespread bacterial pathogens that truly deserve the moniker “superbug” have been tamed, especially in the United States. This is because for the healthy person, pathogens like MRSA are not an immediate threat. But people hospitalized and already sick with other conditions are in danger of contracting bacterial infections we are sometimes powerless to treat. It truly is a shame that we are constantly making medical advances in other fields, but have taken a step back in this area. Some potential solutions include treating infections with multiple antibiotics and offering greater incentives for the pharmaceutical industry to produce these products. Also, more specific therapies directed at toxins the bacteria produce could be used in conjunction with antibiotics to more effectively control infections. Stories about MRSA as a “superbug” are often overblown, causing unnecessary panic among people unlikely to get sick**.** Nevertheless, it rightfully draws attention to a public health problem that requires new solutions. The appropriate response is concern and action. But if we continue to ignore the problem, it can only get worse.

### Advantage 2

#### No evergreening – generic competition occurs after original patents expire but consumers choose to buy follow-on products

Holman 18 [(Christopher M., Professor at the University of Missouri-Kansas City School of Law, where his primary research focus lies at the intersection of intellectual property and biotechnology) “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection,” Intellectual Property Watch, 9/12/2018] JL

Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation.

Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs.’

#### Unpatented medicine cause counterfeits—

Lynbecker 16 [(Kristina M. L. Acri née, an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. Dr. Lybecker’s research analyzes the difficulties of strengthening intellectual property rights protection in developing countries, specifically special problems facing the pharmaceutical industry.) “Counterfeit Medicines and the Role of IP in Patient Safety,” IPWatchDog, 7/27/16. <https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/>] RR

The threat of counterfeit goods took center stage on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). Focusing on trade opportunities and challenges for American businesses in the digital age, Senator Hatch stated:

“The Organization for Economic Co-Operation and Development (OECD) recently released a study that shows that counterfeit products accounted for up to 2.5 percent of world trade, or $461 billion, in 2013. This is a dramatic increase from a 2008 estimate that showed that fake products accounted for less than half that amount. Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France. Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1]

As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals. UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines.

While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3]

[Kristina]

According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5]

While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report,

“INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11]

Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. Without the assurance of quality medicines, access is meaningless. Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need: inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives.

#### **Alt cause – FDA costs – patents actually lower drug costs**

PharmaPatents 15 [“Don’t Blame Patents for High Drug Prices” PharmaPatents, Subsidiary of Foley & Lardner LLP, December 29, 2019] MCM

Before his recent arrest, Martin Shkreli, the former CEO of Turing Pharmaceuticals, gained notoriety for increasing the price of the AIDS drug Daraprim® (pyrimethamine) from about $13.50 to about $750 per pill. He also was reported to be considering a similar price hike for benznidazole, for which his new company, KaloBios Pharmaceuticals, was going to seek FDA approval for treating Chagas disease. Complaints about Shkreli’s drug price hikes often turn into complaints about the supposed pernicious effects of pharmaceutical patents, but you can’t blame patents for Shkreli’s conduct because the patents on pyrimethamine and benznidazole expired long ago. Rather, the recent developments surrounding these drugs illustrate how the market functions without patents.

The Small Patient Population Problem

Pyrimethamine is extremely potent against toxoplasmosis, but the number of people with that disease are (fortunately) few. With such a small potential market and off-patent prices, there was little incentive for generic drug companies to invest the at least $400,000 it can take to obtain FDA approval of a generic drug. Thus, even though the relevant patents expired decades ago, there is only a single FDA-approved supplier of pyrimethamine. Once Turing Pharmaceuticals bought the rights to pyrimethamine and raised the prices to $750 per dose, the missing market incentive suddenly appeared. Express Scripts, the largest U.S. pharmaceutical benefit manager, quickly reached a deal with generic company Imprimis to provide pyrimethamine for $1 a pill.

Like pyrimethamine, benznidazole is an old drug used for a relatively rare infectious disease. Benznidazole treats Chagas disease, which is seen in the U.S. in fewer than 300,000 people. Prior to KalBios, the only way to obtain the drug was through the Centers for Disease Control, which provided it for free. As with pyrimethamine, the small potential market and lack of patent protection to limit market entry make it unsurprising that no generic drug company had sought FDA approval for benznidazole. KaloBios exploited that market vacuum by applying for FDA approval, which would give it market exclusivity and the ability to raise prices, at least temporarily.

Therefore, in both cases, the spike in drug prices was not caused by monopoly power supported by patents, but by monopoly power stemming from the barrier to market entry associated with the requirement for FDA approval.

Patents As Pricing Solution, Not Pricing Problem

The pharmaceutical industry says that patent protection–and the profitable drug pricing patents support–is necessary to provide a return on the significant investment it takes to bring a new drug to market, and to provide resources for investing in further research and development to generate new drugs. Those who advocate for the abolition or curtailment of pharmaceutical patents often do so on the assumption that patents permit unjustifiably high drug prices and prevent competition. But anti-patent advocates forget that patent protection only lasts for a limited time and that the ANDA statutes provide a framework for generic drug companies to enter the market as soon as patents expire or are invalidated.

The recent stories about pyrimethamine and benznidazole show that eliminating patents does not guarantee increased competition and lower drug prices, because no generic competitors emerged in the decades since the patents expired, contrary to the assumptions of anti-patent advocates. If there was not enough incentive to incur the relatively modest costs of regulatory review for generic versions of pyrimethamine and benznidazole, what incentive would there be to cover the much higher costs of developing a new drug?

Without patents to provide temporary market exclusivity to innovators, the pharmaceutical market could become dominated by the first mover and/or lowest marginal cost provider. Such a market structure could result in a small number of providers and monopoly power that is not subject to the limitations of the patent system, especially for drugs with small potential markets. The $13.50 to $750 price hike orchestrated by Martin Shkreli shows the potential consequences of such a patentless system. Those who would eliminate pharmaceutical patents should study pyrimethamine and benznidazole as cautionary tales, and be warned that a pharmaceutical market without the support and limitations of a strong patent system could result in higher drug prices and/or fewer drug choices, which is not what doctors want to order.

#### Alt cause to high drug prices – no price regulations and investor incentives

Kliff 18 [(Sarah, Senior Policy Correspondent at Vox) “The true story of America’s sky-high prescription drug prices” Vox, May 10, 2018] MCM

The prescription is for Humira, an injectable medication used to treat a lot of common conditions like arthritis and psoriasis. Humira is an especially popular medication right now. In 2015, patients all around the world spent $14 billion on Humira prescriptions — that’s roughly the size of Jamaica's entire economy.

Let’s say your doctor appointment is happening in the United Kingdom. There, your Humira prescription will cost, on average, $1,362. If you’re seeing a doctor in Switzerland, the drug runs around $822.

But if you’re seeing a doctor in the United States, your Humira prescription will, on average, run you $2,669.

How does this happen? Why does Humira cost so much more here than it does in other countries?

Humira is the exact same drug whether it’s sold in the United States, in Switzerland, or anywhere else. What’s different about Humira in the United States is the regulatory system we’ve set up around our pharmaceutical industry.

The United States is exceptional in that it does not regulate or negotiate the prices of new prescription drugs when they come onto market. Other countries will task a government agency to meet with pharmaceutical companies and haggle over an appropriate price. These agencies will typically make decisions about whether these new drugs represent any improvement over the old drugs — whether they’re even worth bringing onto the market in the first place. They’ll pore over reams of evidence about drugs’ risks and benefits.

The United States allows drugmakers to set their own prices for a given product — and allows every drug that's proven to be safe come onto market. And the problems that causes are easy to see, from the high copays at the drugstore to the people who can’t afford lifesaving medications.

What’s harder to see is that if we did lower drug prices, we would be making a trade-off. Lowering drug profits would make pharmaceuticals a less desirable industry for investors. And less investment in drugs would mean less research toward new and innovative cures.

There’s this analogy that Craig Garthwaite, a professor at Kellogg School of Management who studies drug prices, gave me that helped make this clear. Think about a venture capitalist who is deciding whether to invest $10 million in a social media app or a cure for pancreatic cancer.

“As you decrease the potential profits I’m going to make from pancreatic cures, I’m going to shift more of my investment over to apps or just keep the money in the bank and earn the money I make there,” Garthwaite says.

Right now America’s high drug prices mean that investing in pharmaceuticals can generate a whole bunch of profits — and that drugs can be too expensive for Americans to afford.

#### Alt causes to high drug prices – insurance industry and cost of research – and new drugs cost more

Baker 17 [(Danial, Director, Drug Information Center, and Professor of Pharmacy Practice, College of Pharmacy, Washington State University Spokane) “High Drug Prices: So Who Is to Blame?” Hospital Pharmacy, January 2017] MCM

The noise level in the news regarding drug prices (eg, EpiPen, generics) has been high. So who's to blame? How about everyone! It is easy to point the finger at few greedy people and the pharmaceutical industry, but the whole system is the problem. This includes patients, the insurance industry, employers, legislators, the board of directors of pharmaceutical companies, CEOs of pharmaceutical companies, and the stockholders of any company associated with the production and pricing of the pharmaceuticals. Each of these has contributed to the problem and is negatively affected, directly and indirectly.

The person most impacted by the high cost of some of the pharmaceuticals is the person who pays cash for medications. The next to be impacted is every taxpayer and business. If the cost of a medication goes up, that increase directly influences the cost of health care for individuals covered by Medicaid, Medicare, other federally assisted programs, and federal employees; but the money to pay for those program does not come from a magic money tree or genie, it comes from money raised by taxes paid by individuals and businesses. The next group to be affected is companies that offer their employees a medical benefit that includes drug coverage. The cost of providing these programs goes up when medication costs go up. The company needs to use more of its income to offset the increased cost. It may shift some or all the increased burden to their employees by decreasing the amount of coverage their program provides, increasing the employees' contribution to offset the expense of the program, or increasing deductibles and/or copays. Also affected are patients who need these medications for the prevention or treatment of various medical conditions.

Some of us are insulated from the true cost of our health care and the cost of medications. The majority of the costs for these health care programs has been covered by our employer or federal programs. For decades, the copay for most medications was relatively low compared to their acquisition cost, therefore the majority of the public did not know the true cost of medications. This trend has been changing through the use of tiered copay systems and formulary placements that are based on cost of the pharmaceutical and its perceived value to the care of the patient.

Another group affected by these higher prices is the health insurance companies, self-insured companies, and managed care organizations. Each of these companies and organizations has to cover the increase in cost somehow. Some of the obvious ways to do this are to increase the price of their insurance plans, decrease the level of service offered by their plans, introduce plans with a higher deductible, and increase copays. Actually, the person most affected by these higher prices, no matter the reason, is the patient or their agent who decided not to fill the prescription because of its price. Even more examples could be identified, but I think I have made my point – high drug prices affect everyone in some manner.

So how do we solve this problem? There is no one answer, because the source of the problem does not come from any one area of the industry. New drugs have almost always come with a higher price to help offset the cost of their research and development and all the others that don't make it to market. Federal price controls could be a possible answer, but that is difficult to implement in a country that prides itself on a free market economy. The insurance industry, pharmacy benefit management companies, and managed care organizations have attempted to control or decrease costs by using formularies, contracting, rebates, and other mechanisms. Even these companies and organizations are negatively impacted by the high inflationary cost of some older medications, especially for those drugs where there is minimal competition, and the high price of some of the new drugs that are not intended for small patient populations (eg, hepatitis C).