### 1

#### Counterplan: High-income country governments, backed by the United States, should provide all necessary funding and technology to build manufacturing capacity for emergency use listing medicines during public health emergencies of international concern, fund research and development of those medicines, make advance purchase commitments of those medicines, and buy large number of doses of those medicines at a set price.

Lindsay 6/11 - Brink Lindsay, Brookings, 6-11, 2021, Why intellectual property and pandemics don’t mix, https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/

Waiving patent protections is certainly no panacea. What is needed most urgently is a massive drive of technology transfer, capacity expansion, and supply line coordination to bring vaccine supply in line with global demand. Dispensing with patents in no way obviates the need for governments to fund and oversee this effort.¶ Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is¶ currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference.¶ Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time.¶ The Nature of the Patent Bargain¶ When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs.¶ Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices.¶ The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment.¶ For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology.¶ Unfortunately, the U.S. patent system at present is out of balance. Over the past few decades, the expansion of patentability to include software and business methods as well as a general relaxation of patenting requirements have led to wildly excessive growth in these temporary monopolies: the number of patents granted annually has¶ skyrocketed roughly fivefold since the early 1980s. One unfortunate result has been the rise of “non-practicing entities,” better known as patent trolls: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. As a result, a law that is supposed to encourage innovation has turned into a¶ legal minefield for many would-be innovators. In the pharmaceutical industry, firms have abused the law by piling up patents for trivial, therapeutically irrelevant “innovations” that allow them to¶ extend their monopolies and keep raising prices long beyond the statutorily contemplated 20 years.¶ Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that¶ conflates “intellectual property” with actual property rights over physical objects. Enveloped in that fog, they regard any attempts to put limits on patent monopolies as attacks on private property and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. A well-designed patent system, in which benefits are maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions, and direct government support.¶ Public Health Emergencies and Direct Government Support¶ For pandemics and other public health emergencies, patents’ mix of costs and benefits is misaligned with what is needed for an effective policy response**. The basic patent bargain**, even when well struck, **is to pay for more innovation down the roa**d with slower diffusion of innovation today. In the context of a pandemic, that bargain is a bad one and should be rejected entirely. Here the imperative is to accelerate the diffusion of vaccines and other treatments, not slow it down. Giving drug companies the power to hold things up by blocking competitors and raising prices pushes in the completely wrong direction. What approach to encouraging innovation should we take instead? How do we incentivize drug makers to undertake the hefty R&D costs to develop new vaccines without giving them exclusive rights over their production and sale? **The most effective approach during a public health crisis is direct government support: public funding of R&D, advance purchase commitments** by the government **to buy large numbers of doses at set prices, and other, related payouts.** And when we pay drug makers, **we should not hesitate to pay generously**, even extravagantly**: we want to offer** drug companies **big profits so** that **they prioritize this work above everything else, and so that they are** ready and **eager to come to the rescue again the next time there’s a crisis.** It was direct support via Operation Warp Speed that made possible the astonishingly rapid development of COVID-19 vaccines and then facilitated a relatively rapid rollout of vaccine distribution (relative, that is, to most of the rest of the world). And it’s worth noting that a major reason for the faster rollout here and in the United Kingdom compared to the European Union was the latter’s misguided penny-pinching. The EU bargained hard with firms to keep vaccine prices low, and as a result their citizens ended up in the back of the queue as various supply line kinks were being ironed out. This is particularly ironic since the Pfizer-BioNTech vaccine was developed in Germany. As this fact underscores**, the chief advantage of direct support** isn’t to “get tough” with drug firms and keep a lid on their profits. Instead, it **is to accelerate the end of the public health emergency by making sure drug makers profit** handsomely **from doing the right thing.** Patent law and direct support should be seen not as either-or alternatives but as complements that apply different incentives to different circumstances and time horizons**. Patent law provides a decentralized system for encouraging innovation. The government doesn’t presume to tell the industry which new drugs are needed**; it simply incentivizes the development of whatever new drugs that pharmaceutical firms can come up with by offering them a temporary monopoly. It is important to note that patent law’s incentives offer no commercial guarantees. Yes, you can block other competitors for a number of years, but that still doesn’t ensure enough consumer demand for the new product to make it profitable. The situation is different in a pandemic. Here the government knows exactly what it wants to incentivize: the creation of vaccines to prevent the spread of a specific virus and other drugs to treat that virus. Under these circumstances, the decentralized approach isn’t good enough. There is no time to sit back and let drug makers take the initiative on their own timeline. Instead, the government needs to be more involved to incentivize specific innovations now. As recompense for letting it call the shots (pardon the pun), the government sweetens the deal for drug companies by insulating them from commercial risk. **If pharmaceutical firms develop effective vaccines and therapies, the government will buy large, predetermined quantities at prices set high enough to guarantee a healthy return.** For the pharmaceutical industry, it is useful to conceive of **patent law** as the default regime for innovation promotion. It **improves pharmaceutical companies’ incentives to develop new drugs while leaving them free to decide which new drugs to pursu**e – and also leaving them to bear all commercial risk. In a pandemic or other emergency, however, it is appropriate to shift to the direct support regime, in which the government focuses efforts on one disease. In this regime, it is important to note, the government provides qualitatively superior incentives to those offered under patent law. Not only does it offer public funding to cover the up-front costs of drug development, but it also provides advance purchase commitments that guarantee a healthy return. It should therefore be clear that the pharmaceutical industry has no legitimate basis for objecting to a TRIPS waiver. Since, because of the public health crisis, drug makers now qualify for the superior benefits of direct government support, they no longer need the default benefits of patent support. Arguments that a TRIPS waiver would deprive drug makers of the incentives they need to keep developing new drugs, when they are presently receiving the most favorable incentives available, can be dismissed as the worst sort of special pleading. That said, it is a serious mistake to try to cast the current crisis as a morality play in which drug makers wear the black hats and the choice at hand is between private profits and public health. We would have no chance of beating this virus without the formidable organizational capabilities of the pharmaceutical industry, and providing the appropriate incentives is essential to ensure that the industry plays its necessary and vital role. It is misguided to lament that private companies are profiting in the current crisis: those profits are a drop in the bucket compared to the staggering cost of this pandemic in lives and economic damage. What matters isn’t the existence or size of the profits, but how they are earned. We have good reason to want drug makers to profit from vaccinating the world: the comparative price is minuscule, and the incentive effects are a vital safeguard of public health in the event of future crises. What we want to avoid at all costs is putting drug makers in the position where drug companies can profit from standing in the way of rapid global vaccination. That is why intellectual property rights need to be taken out of the equation. Vaccinating the world in any kind of reasonable time frame will require large-scale technology transfer to drug firms in other countries and rapid expansion of their production capacity. And looking beyond the current pandemic to the longer term, we need ample, redundant global vaccine production capacity that is widely distributed around the planet. To achieve these goals as rapidly as possible will require the active cooperation of the U.S. pharmaceutical industry, which is why the direct support model now needs to be extended. What is needed now is an Operation Warp Speed for the world, in which we make it worth current vaccine producers’ while to share their know-how broadly and ramp up global capacity. Here again, we must recognize that the choice isn’t between people on the one hand and profits on the other. Rather, the key to good pandemic response policy is ensuring that incentives are structured so that drug company profit-seeking and global public health are well aligned. That means opting out of the default, decentralized patent bargain in favor of generous but well-focused direct government support.

#### CP answers their Gostin card because it enables domestic manufacturing

### 2

#### The pharma industry is strong now but patents are key for continued economic growth. Batell and PhRMA 14:

Batell and PhRMA {Battelle is the world’s largest nonprofit independent research and development organization, providing innovative solutions to the world’s most pressing needs through its four global businesses: Laboratory Management, National Security, Energy, Environment and Material Sciences, and Health and Life Sciences. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.}, 14 – “The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It,” http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf//marlborough-wr//

Compared to other capital-intensive, advanced manufacturing industries in the U.S., the biopharmaceutical industry is a leader in R&D investment, IP generation, venture capital investment, and R&D employment. Policies and infrastructure that helped foster these innovative activities have allowed the U.S. to seize global leadership in biopharmaceutical R&D over the past 30 years. However, as this report details, other countries are seeking to compete with the U.S. by borrowing and building upon some of these pro-innovation policies to improve their own operating environment and become more favorable to biopharmaceutical companies making decisions about where to locate their R&D and manufacturing activities. A unique contribution of this report was the inclusion of the perspective of senior-level strategic planning executives of biopharmaceutical companies regarding what policy areas they see as most likely to impact the favorability of the U.S. business operating environment. The executives cited the following factors as having the most impact on the favorability of the operating environment and hence, potential growth of the innovative biopharmaceutical industry in the U.S.: • Coverage and payment policies that support and encourage medical innovation • A well-functioning, science-based regulatory system • Strong IP protection and enforcement in the U.S. and abroad The top sub-attribute identified as driving future biopharmaceutical industry growth in the U.S. cited by executives was a domestic IP system that provides adequate patent rights and data protection. Collectively, these factors underscore the need to reduce uncertainties and ensure adequate incentives for the lengthy, costly, and risky R&D investments necessary to develop new treatments needed by patients and society to address our most costly and challenging diseases. With more than 300,000 jobs at stake between the two scenarios, the continued growth and leadership of the U.S. innovative biopharmaceutical industry cannot be taken for granted. Continued innovation is fundamental to U.S. economic well-being and the nation’s ability to compete effectively in a globalized economy and to take advantage of the expected growth in demand for new medicines around the world. Just as other countries have drawn lessons from the growth of the U.S. biopharmaceutical sector, the U.S. needs to assess how it can improve the environment for innovation and continue to boost job creation by increasing R&D investment, fostering a robust talent pool, enhancing economic growth and sustainability, and continuing to bring new medicines to patients.

#### COVID has kept patents and innovation strong, but continued protection is key to innovation by incentivizing quick biomedical research – it’s also crucial to preventing counterfeit medicines, economic collapse, and fatal diseases, which independently turns case. Macdole and Ezell 4-29:

Jaci Mcdole and Stephen Ezell {Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation (ITIF). She focuses on IP and its correlations to global innovation and trade. McDole holds a double BA in Music Business and Radio-Television with a minor in Marketing, an MS in Education, and a JD with a specialization in intellectual property (Southern Illinois University Carbondale). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she co-founded to study and further robust global IP policies. Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He comes to ITIF from Peer Insight, an innovation research and consulting firm he cofounded in 2003 to study the practice of innovation in service industries. At Peer Insight, Ezell led the Global Service Innovation Consortium, published multiple research papers on service innovation, and researched national service innovation policies being implemented by governments worldwide. Prior to forming Peer Insight, Ezell worked in the New Service Development group at the NASDAQ Stock Market, where he spearheaded the creation of the NASDAQ Market Intelligence Desk and the NASDAQ Corporate Services Network, services for NASDAQ-listed corporations. Previously, Ezell cofounded two successful innovation ventures, the high-tech services firm Brivo Systems and Lynx Capital, a boutique investment bank. Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown’s Landegger International Business Diplomacy program.}, 21 - ("Ten Ways Ip Has Enabled Innovations That Have Helped Sustain The World Through The Pandemic," Information Technology & Innovation Foundation, 4-29-2021, https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through)//marlborough-wr/

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future. The case studies are: Bharat Biotech: Covaxin Gilead: Remdesivir LumiraDX: SARS-COV-2 Antigen POC Test Teal Bio: Teal Bio Respirator XE Ingeniería Médica: CápsulaXE Surgical Theater: Precision VR Tombot: Jennie Starship Technologies: Autonomous Delivery Robots Triax Technologies: Proximity Trace Zoom: Video Conferencing As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future. THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5 To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7 In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12 To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13 THE IMPORTANCE OF INTELLECTUAL PROPERTY TO INNOVATION Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the reality is all IP-protected innovations are at risk if these rights are ignored, or vitiated. Certain arguments have shown a desire for the term “COVID-19 innovations” to include everything from vaccines, therapeutics, diagnostics, and PPE to biotechnology, AI-related data, and educational materials.14 This could potentially open the floodgates to invalidate IP protection on many of the innovations highlighted in this report. However, much of the current discussion concerning IP focuses almost entirely on litigation fears or R&D incentives. Although R&D is an important aspect of IP, as previously mentioned, these discussions ignore the fact that IP protection can be—and often is—used for other purposes, including generating initial capital to create a company and begin manufacturing and, more importantly, using licensing agreements and IP to track the supply chain and ensure quality control of products. This report highlights but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non-regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17 Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22 Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP-related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products. By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc. Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID-19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation. There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike.31 First, stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives.32 Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.33 There’s also evidence suggesting that developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines.34 And fifth, strong IP boosts exports, including in developing countries.35 Research shows a positive correlation between stronger IP protection and exports from developing countries as well as faster growth rates of certain industries.36 The following case studies illustrate these benefits of IP and how they’ve enabled innovative solutions to help global society navigate the COVID-19 pandemic.

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences 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 con-text**.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 compe-tition 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 pharmaceu-tical 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 sec-tor.2 It is therefore unsurprising that we are seeing indus-try-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 com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als 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 accel-erate 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 rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure 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 com-bination product that is being tested for therapeutic poten-tial 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**, **bioterror-ism** 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 imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious 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 contribu-tions 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 innova-tion conditions.

#### Bioterror causes extinction---quick innovation key

Farmer 17 (“Bioterrorism could kill more people than nuclear war, Bill Gates to warn world leaders” http://www.telegraph.co.uk/news/2017/02/17/biological-terrorism-could-kill-people-nuclear-attacks-bill/)

Bioterrorists could one day kill hundreds of millions of people in an attack more deadly than nuclear war, Bill Gates will warn world leaders. Rapid advances in genetic engineering have opened the door for small terrorism groups to tailor and easily turn biological viruses into weapons. A resulting disease pandemic is currently one of the most deadly threats faced by the world, he believes, yet governments are complacent about the scale of the risk. Speaking ahead of an address to the Munich Security Conference, the richest man in the world said that while governments are concerned with the proliferation of nuclear and chemical weapons, they are overlooking the threat of biological warfare. Mr Gates, whose charitable foundationis funding research into quickly spotting outbreaks and speeding up vaccine production, said the defence and security establishment “have not been following biology and I’m here to bring them a little bit of bad news”. Mr Gates will today (Saturday) tell an audience of international leaders and senior officers that the world’s next deadly pandemic “could originate on the computer screen of a terrorist”. He told the Telegraph: “Natural epidemics can be extremely large. Intentionally caused epidemics, bioterrorism, would be the largest of all. “With nuclear weapons, you’d think you would probably stop after killing 100million. Smallpox won’t stop. Because the population is naïve, and there are no real preparations. That, if it got out and spread, would be a larger number.” He said developments in genetic engineering were proceeding at a “mind-blowing rate”. Biological warfare ambitions once limited to a handful of nation states are now open to small groups with limited resources and skills. He said: “They make it much easier for a non-state person. It doesn’t take much biology expertise nowadays to assemble a smallpox virus. Biology is making it way easier to create these things.” The increasingly common use of gene editing technology would make it difficult to spot any potential terrorist conspiracy. Technologies which have made it easy to read DNA sequences and tinker with them to rewrite or tweak genes have many legitimate uses. He said: “It’s not like when someone says, ‘Hey I’d like some Plutonium’ and you start saying ‘Hmmm.. I wonder why he wants Plutonium?’” Mr Gates said the potential death toll from a disease outbreak could be higher than other threats such as climate change or nuclear war. He said: “This is like earthquakes, you should think in order of magnitudes. If you can kill 10 people that’s a one, 100 people that’s a two... Bioterrorism is the thing that can give you not just sixes, but sevens, eights and nines. “With nuclear war, once you have got a six, or a seven, or eight, you’d think it would probably stop. [With bioterrorism] it’s just unbounded if you are not there to stop the spread of it.” By tailoring the genes of a virus, it would be possible to manipulate its ability to spread and its ability to harm people. Mr Gates said one of the most potentially deadly outbreaks could involve the humble flu virus. It would be relatively easy to engineer a new flu strain combining qualities from varieties that spread like wildfire with varieties that were deadly. The last time that happened naturally was the 1918 Spanish Influenza pandemic, which went on to kill more than 50 million people – or nearly three times the death toll from the First World War. By comparison, the recent Ebola outbreak in West Africa which killed just over 11,000 was “a Richter Scale three, it’s a nothing,” he said. But despite the potential, the founder of Microsoft said that world leaders and their militaries could not see beyond the more recognised risks. He said: “Should the world be serious about this? It is somewhat serious about normal classic warfare and nuclear warfare, but today it is not very serious about bio-defence or natural epidemics.” He went on: “They do tend to say ‘How easy is it to get fissile material and how accurate are the plans out on the internet for dirty bombs, plutonium bombs and hydrogen bombs?’ “They have some people that do that. What I am suggesting is that the number of people that look at bio-defence is worth increasing.” Whether naturally occurring, or deliberately started, it is almost certain that a highly lethal global pandemic will occur within our lifetimes, he believes. But the good news for those contemplating the potential damage is that the same biotechnology can prevent epidemics spreading out of control. Mr Gates will say in his speech that most of the things needed to protect against a naturally occurring pandemic are the same things needed to prepare for an intentional biological attack. Nations must amass an arsenal of new weapons to fight such a disease outbreak, including vaccines, drugs and diagnostic techniques. Being able to develop a vaccine as soon as possible against a new outbreak is particularly important and could save huge numbers of lives, scientists working at his foundation believe.

### 3

#### The Aff’s portrayal of a world with reduced IP protections as an “information commons” where health inequality is solved by deregulation perpetuates the neoliberal myth of increased competition ensuring a perfect market **Kapczynski 14** [(Amy, a Professor of Law at Yale Law School, Faculty Co-Director of the Global Health Justice Partnership, and Faculty Co-Director of the Collaboration for Research Integrity and Transparency. She is also Faculty Co-Director of the Law and Political Economy Project and cofounder of the Law and Political Economy blog. Her areas of research include information policy, intellectual property law, international law, and global health.) “INTELLECTUAL PROPERTY’S LEVIATHAN” Duke Law, Law & Contemporary problems, 2014. <https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=4710&context=lcp>] BC

Over the last decade or so, a powerful set of critiques has emerged to contest the dominant account just sketched out as well as the contemporary state of IP law.12 These arguments have come from many directions, some even arising from scholars who previously were champions of the dominant account.13 The most prominent and potent line of theoretical critique in the legal literature has come in the guise of arguments for free culture and the “information commons” and has been most influentially articulated by Lawrence Lessig and Yochai Benkler.14 Both have stressed the problems with expansive exclusive rights regimes in information and have also sketched a set of actually existing alternatives to market-based exclusionary forms of information and cultural production. Lessig has written a series of influential books that have made him a “rock star of the information age,”15 particularly for young Internet and free-culture activists. He has argued powerfully, for example, that existing copyright law is in deep conflict with the radical new possibilities for creativity in the digital age. As he points out, when a mother posting a video of her toddler dancing to a Prince song on YouTube is threatened with a $150,000 fine for copyright infringement, something has gone seriously awry.16 Lessig also contends that copyright law today is too long, too expansive, and instantiates a “permission culture” that is antithetical to free expression in the age of the remix.17 As he puts it, “the Internet has unleashed an extraordinary possibility for many to participate in the process of building and cultivating a culture that reaches far beyond local boundaries,” creating the possibility of markets that “include a much wider and more diverse range of creators,” if not stifled by incumbents who use IP law to “protect themselves against this competition.”18 Benkler’s work has also been extraordinarily formative in the field, particularly for his insights into the multiplicity of modes of information production. As he has stressed, the conventional justification for IP does not account for the many successful and longstanding modes of market nonexclusionary information production.19 For example, attorneys write articles to attract clients, software developers sell services customizing free and opensource software for individual clients, and bands give music away for free to increase revenues from touring or merchandise.20 More pathbreaking still is Benkler’s account of the importance of “commons-based peer production,” a form of socially motivated and cooperative production exemplified by the volunteer network that maintains Wikipedia or the groups of coders who create open-source software products such as the Linux operating system.21 In the digital networked age, as Benkler describes, the tools of information production are very broadly distributed, “creating new opportunities for how we make and exchange information, knowledge, and culture.”22 These changes have increased the relative role in our information economy of nonproprietary production and facilitate “new forms of production [that] are based neither in the state nor in the market.”23 Because commons-based peer production is not hierarchically organized and is motivated by social dynamics and concerns, it also offers new possibilities for human development, human freedom, a more critical approach to culture, and more democratic forms of political participation.24 This line of critique has been profoundly generative and has helped launch an important new conceptualization of the commons as a paradigm. That paradigm, as a recent book puts it, “helps us ‘get outside’ of the dominant discourse of the market economy and helps us represent different, more wholesome ways of being.”25 Proponents of the commons concept draw upon contemporary articulations of successful commons-based resource management by Elinor Ostrom and her followers.26 They do mobilize retellings of the political and economic history of the commons in land in Europe before enclosure,27 and recent evidence from psychology and behavioral economics that suggests that humans have deep tendencies toward cooperation and reciprocation.28 They argue that A key revelation of the commons way of thinking is that we humans are not in fact isolated, atomistic individuals. We are not amoebas with no human agency except hedonistic “utility preferences” expressed in the marketplace. No: We are commoners—creative, distinctive individuals inscribed within larger wholes. We may have unattractive human traits fueled by individual fears and ego, but we are also creatures entirely capable of self-organization and cooperation; with a concern for fairness and social justice; and willing to make sacrifices for the larger good and future generations.29 This stands, of course, as a powerful rebuke to the neoliberal imaginary, which “constructs and interpellates individuals as . . . rational, calculating creatures whose moral autonomy is measured by their capacity for ‘self-care’— the ability to provide for their own needs and service their own ambitions.”30 III Given this radical—and, in my view, critically important—attempt to rethink the subject at the core of neoliberal accounts, it is all the more striking that proponents of the commons often appear to adopt a neoliberal image of the state. For example, the introduction to a recently edited volume that gathers writings on the commons from seventy-three authors in thirty countries (entitled, tellingly, The Wealth of the Commons: A World Beyond Market and State) has this to say: The presumption that the state can and will intervene to represent the interests of citizens is no longer credible. Unable to govern for the long term, captured by commercial interests and hobbled by stodgy bureaucratic structures in an age of nimble electronic networks, the state is arguably incapable of meeting the needs of citizens as a whole.31 The commons, they suggest, is a concept that seeks not only to liberate us from predatory and dysfunctional markets, but also from predatory and dysfunctional states. Something immediately seems incongruous here. If people are inherently cooperative reciprocators, why are states irredeemably corrupt? After all, as Harold Demsetz famously wrote in his 1967 attack on Arrow’s optimism about state production of information, “[g]overnment is a group of people.”32 Lessig, one of the progenitors of the language of the commons in the informational domain, often leads with a similar view of the state: [I]f the twentieth century taught us one lesson, it is the dominance of private over state ordering. Markets work better than Tammany Hall in deciding who should get what, when. Or as Nobel Prize-winning economist Ronald Coase put it, whatever problems there are with the market, the problems with government are more profound.33 Lessig reveals his own sense of the power of this conception of the state when he seeks to tar IP law with the same brush; we should rebel against current IP law, he suggests, because we should “limit the government’s role in choosing the future of creativity.”34 Benkler is more measured but admits as well to viewing the state as “a relatively suspect actor.”35 We should worry, he suggests, that direct governmental intervention “leads to centralization in the hands of government agencies and powerful political lobbies,”36 a view that echoes the neoliberal account described above. It should perhaps not surprise us that leading critics of neoliberal information policy embrace a neoliberal conception of the state. After all, neoliberalism is not merely an ideology, but also a set of policy prescriptions that may have helped to call forth the state that it has described. As David Harvey puts it, “[t]he neoliberal fear that special-interest groups would pervert and subvert the state is nowhere better realized than in Washington, where armies of corporate lobbyists . . . effectively dictate legislation to match their special interests.”37 There are, it must be said, few areas of law that better exemplify this problem than IP law. For example, Jessica Litman has documented the astonishing process through which the 1976 Copyright Act was drafted, in which Congress delegated most of the drafting to interest groups that were forced to negotiate with one another.38 Other scholars have offered similarly startling accounts of the genesis of the most important IP treaty today, the TradeRelated Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS came into force in 1996, revolutionizing international IP law by both imposing new standards and by rendering them enforceable through the WTO’s disputeresolution system, which authorizes trade retaliation to enforce its judgments. Most countries in the world are members of TRIPS, and the Agreement introduced, for developing countries in particular, substantial new obligations, such as the obligation to grant patents on medicines and food-related inventions. Several excellent histories of the treaty have been written, documenting its beginnings as a brash idea proposed by “twelve chief executive officers (representing pharmaceutical, entertainment, and software industries).”39 As Susan Sell has described, the TRIPS Agreement was a triumph of industry organizing. Through TRIPS, Industry revealed its power to identify and define a trade problem, devise a solution, and reduce it to a concrete proposal that could be sold to governments. These private sector actors succeeded in getting most of what they wanted from a global IP agreement, which now has the status of public international law.

#### Attempts to reform the WTO are neoliberal attempts to sustain the US regime of accumulation – the contradictions of neoliberalism are why credibility is low, not IP protection

Bachand 20 [(Remi, Professor of International Law, Département des sciences juridiques, member of the Centre d’études sur le droit international et la mondialisation (CÉDIM), Université du Québec à Montréal, Canada) “What’s Behind the WTO Crisis? A Marxist Analysis” The European Journal of International Law, 8/12/2020. https://academic.oup.com/ejil/article-abstract/31/3/857/5920920?redirectedFrom=fulltext] BC

To offer our own explanation, we must recall two aspects of our theoretical framework. The first is Robert Cox’s claim113 that the function of international organizations is to ensure the creation and reproduction of hegemony. To be more accurate, they serve, if we follow his argument, to defend and to expand the ‘mode of production’ (we elected to substitute this term for the concept of ‘regime of accumulation’ that appears to be more appropriate for our means) of the dominant social classes of the dominant state. Joining this idea with the école de la régulation and social structure of accumulation theory writing114 according to which a regime of accumulation needs some regulation institutions to help resolve its contradictions (and ensure profits and capital accumulation to dominant social classes), we can conclude that the Geneva organization’s function in the US hegemonic order is to make sure that neoliberalism works well enough to provide a satisfying rate of profit for US capitalists. Going in that direction, Kristen Hopewell shows that the WTO’s creation participated in a shift in global governance from ‘embedded liberalism’ to neoliberalism115 and was slated to be an important part of that governance. Using the conceptual framework developed earlier, we can infer that the WTO was thus given a regulation function that was to ensure the operationalization of counteracting factors to the fall of the rate of profit for US capitalists. Now, as we have seen, the US rate of profit has been extremely unstable in the last two decades and Chinese expansion (and that of other ‘emerging countries’) allows one to predict that the situation could easily worsen in the future. Consequently, it should come as no surprise that the crisis that has been striking neoliberalism for the last 20 years may also result in a crisis of the organizations that are supposed to manage its contradictions, especially the WTO. Concretely, this organization seems unable to fulfil its regulatory function anymore, which is to ensure US capitalists a good rate of profit and opportunities to operationalize enough counteracting factors to negate its fall. To go further, we now need to return to Stephen Gill’s claim that the function of an international organization is to limit political and economic possibilities. It is to exclude, in other words, options that are incompatible with the social order promoted by the hegemon from what is possible and achievable.116 Effectively, the WTO was created to play such a role. Indeed, promoting liberalization of goods and services, protecting (notably intellectual) property rights and attacking subsidies (in non-agriculture sectors), just to give a few examples, all serve to severely reduce state interventions into the economy and to circumscribe or at least to strongly impede the turn towards an alternative model to neoliberalism

#### Neoliberalism rips apart communal bonds to maintain the illusion that structural inequalities are individual problems – the impact is systemic victim-blaming, poverty, and violence.

Smith 12 [(Candace, author for Societpages, cites Bruno Amable, Associate Professor of Economics at Paris School of Economics) “Neoliberalism and Individualism: Ego Leads to Interpersonal Violence?” Sociology Lens is the associated site for Sociology Compass, Wiley-Blackwell’s review journal on all fields sociological] AT

There appears to be a link between neoliberalism, individualism, and violence. In reference to the association between neoliberalism and individualism, consider neoliberalism’s insistence that we do not need society since we are all solely responsible for our personal well-being (Peters 2001; Brown 2003). From a criminological standpoint, it is not hard to understand how this focus on the individual can lead to violence. According to Hirschi’s (1969) social control theory, for instance, broken or weak social bonds free a person to engage in deviancy. Since, according to this theory, individuals are naturally self-interested, they can use the opportunity of individualization to overcome the restraining powers of society. Bearing in mind neoliberalism’s tendency to value the individual over society, it could be argued that this ideology is hazardous as it acts to tear apart important social bonds and to thereby contribute to the occurrence of ego-driven crimes, including violent interpersonal crimes. Such a thought suggests that as neoliberalism becomes more prominent in a country, it can be expected that individualism and, as a result, interpersonal violence within that country will increase. When it comes to individualization, this idea is one of the fundamental aspects of neoliberalism. In fact, Bauman (2000:34) argues that in neoliberal states “individualization is a fate, not a choice.” As Amable (2011) explains, neoliberals have realized that in order for their ideology to be successful, a state’s populace must internalize the belief that individuals are only to be rewarded based on their personal effort. With such an ego-driven focus, Scharff (2011) explains that the process of individualization engenders a climate where structural inequalities are converted into individual problems.

#### The alt is to reject the aff in favor of a critique that cultivates educated hope - evaluate the aff and alt on the level of ideological commitments – these policies won’t happen which takes out consequentialism good offense – BUT until we unlearn the assumption that getting government out of the way will let markets flourish and solve all our problems, we'll never be able to engage in robust, communitarian policymaking that truly centers human need and our obligations to others. Wilson 17:

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New Stories for New Worlds As we will see in our mapping of the neoliberal conjuncture, competition's totalizing yet tenuous power over our everyday lives is rooted in what Keating calls “status quo stories”—those stories that get told in popular culture, and that we often tell ourselves, which cement our relationship to our present conjuncture and our investment in the world as we currently know it. She explains: Generally spoken with great certainty, these and similar comments (commands, really) reflect unthinking affirmation of the existing reality and a stubborn, equally unthinking resistance to change. Because we believe that our status-quo stories represent accurate factual statements about ourselves, other people, and the world, we view them as permanent, unchanging facts. This belief in the status-quo's permanence becomes self-fulfilling: We do not try to make change because change is impossible to make. “It's always been that way,” we tell ourselves, “so why waste our energy trying to change things?” “People are just like that-it's human nature, so plan accordingly and alter your expectations! There's no point in trying to change human nature!" Status-quo stories trap us in our current circumstances and conditions; they limit our imaginations because they prevent us from envisioning alternate possibilities.10 Status-quo stories double down on reality, making it seem like those socially constructed forces impinging on us are natural rather than historical, political, and subject to change. “Status-quo stories have a numbing effect,” Keating writes. “When we organize our lives around such stories or in other ways use them as ethical roadmaps or guides, they prevent us from extending our imaginations and exploring additional possibilities."11 One of my students aptly described neoliberal culture as a “status-quo storytelling machine.” To keep us living in competition, neoliberalism generates a host of status-quo stories about the naturalness and inevitability of self-enclosed individualism. Indeed, we might say that self-enclosed individualism operates as the foundational status quo story of neoliberal culture, where competition has become synonymous with all of life. Self-enclosed individualism keeps us not only divided from one another, but also actively pitted against each other. We are stuck in an oppositional consciousness that refuses to acknowledge our social interconnections, even though, as our shared anxieties suggest, we've never had more in common than right now! No matter where we are or what we're doing, neoliberal culture encourages us to see each other through a competitive lens that makes the transformation of our social world, and ourselves, impossible. We become incapable of acknowledging how our fortunes and fates are entwined with those of others who are living very different realities. We become callous and hardened to the suffering of others. We see suffering and death everywhere, and while this might register as bad or wrong or upsetting, we nonetheless stay stuck within the horizons of our own self-enclosed bubbles. The devastating powers of status-quo stories are clear in so many of the conversations we have on college campuses about power, privilege, and difference. In fact, I started teaching courses on neoliberal culture to help my students understand the broader histories and contexts that were impinging on these conversations and making them so fraught, and ultimately so unproductive. Time and time again, in open community forums and classroom discussions of systemic inequalities, I watched students voice painful personal experiences only to get nowhere. Indeed, when asked to consider various forms of privilege, many of my white, male students get defensive. The idea that they haven't earned their place through their own decisions and hard work, but rather benefited from inherited wealth and opportunity, means that they are not good people from the perspective of neoliberalism. Talking about issues of privilege threatens to diminish their sense of self and individual value, so they recoil from conversations that ask them to see their place within broader legacies of settler colonialism, patriarchy, and capitalism. Accordingly, they hold on tight to status-quo stories of self-enclosed individualism to protect themselves, doubling down on their privilege to secure their status in a competitive world. However, it is important to see that status-quo stories of self- enclosed individualism also inform my students from historically oppressed and marginalized groups. These students suffer daily: they live in an environment that professes to celebrate “diversity,” while, in the context of their own lives, they are reminded again and again just how much they don't belong or matter. Not surprisingly, they demand “safe spaces” and protection for themselves and their peers, and they often draw hard lines between allies and enemies. Here too though, we see neoliberal stories at work. What matters for my students, and rightly so, is the way that “microaggressions”—those daily, mundane experiences of discrimination that accumulate over time-diminish their own capacities for flourishing as self-enclosed individuals. My point here is not to suggest that privileged students and marginalized students are the same because they are both invested in a version of self-enclosed individualism. Rather, my point is they share a situation; despite their different and unequal social positions, they have similar feelings-of defensiveness and a fear of failure—and status-quo stories in common. These commonalities do not imply evenness or equality, but rather interconnection, that is, a shared conjuncture. It is the recognition of this conjunctural interconnection that can thread our lives together and open up possibilities for more egalitarian futures. However, living in competition and the oppositional consciousness it demands obscure these commonalities and the interconnections that could bring students into new relations with one another. As a result, we stay caught up in the world as we know it. We stay stuck in competition, even though we all are yearning for different worlds. We desperately need new stories, stories that offer us different pathways to each other. As Keating puts it, we need stories that help us move from “me” to “we” consciousness.12 However, this book is not going to write these new stories for you. Rather, the goal of this book is to provide you with the resources for writing these new stories in and through your own lives. The Work of Critique Ultimately, writing new stories will require a new sense of yourself and your world, as well as what is possible, and realizing this new sense will require, first and foremost, cultivating a deeply critical orientation toward the world as we currently know and experience it. This critical orientation dislodges the sense of inevitability of neoliberalism, self-enclosed individualism, and living in competition; it knows that things don't have to be this way and, thus, senses the possibilities for resistance and transformation that are everywhere. It is so crucial to understand that this critical orientation is not simply about saying that aspects of neoliberal culture are “bad” or "wrong.” Rather, the work of critique is about seeing the flows of power and ways of thinking that make the neoliberal conjuncture possible and hold it together. Critique is therefore a mode of knowing—a form of everyday intellectual work—that is aimed at exposing the myriad workings of power and its status-quo stories. As Michel Foucault explains, “A critique is not a matter of saying that things are not right as they are. It is a matter of pointing out on what kinds of assumptions, what kinds of familiar, unchallenged, unconsidered modes of thought the practices that we accept rest.”13 To clarify Foucault's idea, let's think back to the student discussions of power and privilege discussed above. The work of critique is not simply about pointing out privilege, although this is, of course, vital work. The work of critique goes beyond pointing out what's wrong and seeks to unravel the socially constructed conjuncture in which these problems emerge and get negotiated. For only then can we step outside of the competitive, oppositional consciousness of neoliberal culture and begin to imagine a radically different future built on equality and shared security. This work of dislodging the inevitability of our conjuncture and its status-quo stories is hard but vital intellectual work that requires not only critique of our social world, but also transformation of ourselves. Indeed, truly critical work is always profoundly disruptive of our own identities and knowledges. This work can be immensely painful, as it strips away the certainty and comfort provided by status-quo stories. This work can also be, and should be, immensely joyful and life-giving, as it enables us to free ourselves from the status-quo stories and devastating limitations they put on our lives, imaginations, and social relationships. This mix of pain and joy at the heart of critical work comes from the way that critique asks us to “lose confidence” in our world. As feminist theorist Sara Ahmed writes, Losing confidence: it can be a feeling of something gradually going away from you, being eroded. You sense the erosion. You might stumble, hesitate, falter; things might gradually unravel so you end up holding onto the barest of threads. It might be an experience in the present that throws things up, throws you off balance.... When you lose confidence it can feel like you are losing yourself: like you have gone into hiding from yourself.4 Losing confidence in your world is thus a form of existential crisis —you are disoriented; your world is shattered. At the same time, losing confidence in status-quo stories means gaining confidence for resistance and transformation. We become bolder, less anxious, more optimistic, capable of social interconnection, political intervention, and acting on and from a place of commonality. This is real freedom. Critique is ultimately about unlearning our world so that we might reconstruct it anew. Losing confidence in neoliberal culture means being able to say no to it in the conduct of our daily lives. In these capacities for resistance, we gain confidence that another world might actually be better, worth opening ourselves up to, worth fighting for. We begin to cultivate what Henry Giroux calls educated hope. Educated hope is not “a romanticized and empty” version of hope; rather, it is a form of hope enabled by critique that “taps into our deepest experiences and longing for a life of dignity with others, a life in which it becomes possible to imagine a future that does not mimic the present.” With educated hope, our sense of who we are and of what might be possible shifts in profound ways. This is when those new worlds we are longing for open up. What’s to Come Each of the chapters that follow offer a variety of intellectual tools for mapping the neoliberal conjuncture. Taken together, they are designed to produce a holistic and thick understanding of neoliberalism and its myriad powers to shape our identities, sensibilities, social worlds, and political horizons. Having a thick understanding of neoliberalism means that you feel in your bones that there is nothing natural or inevitable about neoliberalism and its status-quo stories. It means that you understand that neoliberalism is the outcome of a range of contingent historical processes that have consequences across social, political, economic, and cultural fields. In other words, by the end of our journey, you'll know how our neoliberal conjuncture has been, and continues to be, constructed. You'll also, therefore, be able to sense the other worlds on the horizon that are just waiting to be constructed, so long as, together, we can develop the resources, capacities, and stories of interconnection for bringing them into being. More specifically, the book is divided into two sections. The first section, titled “Critical Foundations,” focuses on cultivating a broad, critical orientation toward neoliberal culture. The first chapter charts the rise of neoliberal hegemony through four historical phases. The goal is to illustrate exactly how competition came to be the driving cultural force in our everyday lives. As we will see, there is nothing natural or inevitable about neoliberalism. It was a political and class-based project to remake capitalism and liberal democracy that was conceived, organized for, and eventually won. In the second chapter, we delve into the world of neoliberal theory and its critical consequences. Here we'll explore exactly what neoliberal thinkers believe about the state, markets, and human actors, and what distinguishes neoliberalism from earlier schools of liberal thought. We'll also interrogate what I call the four Ds—disposability, dispossession, disimagination, and de- democratization—which, taken together, enable us to clearly see and articulate what is so devastating about the rise of neoliberalism. The third chapter examines the cultural powers specific to neoliberalism. Neoliberalism advances through culture, specifically through the promotion of an enterprise culture that works to impose competition as a norm across all arenas of social life. In order to see and specify how neoliberalism works through culture, we take contemporary education as a case study and unpack the entangled cultural powers of neoliberal governmentality, affect, and ideology. The second section is titled “Neoliberal Culture.” In these chapters, we explore the worlds of neoliberal labor, affect, and politics respectively, tracing what happens when our everyday lives as workers, individuals, and citizens become organized around living in competition. The fourth chapter examines how neoliberalism turns everyday life into a “hustle,” where all the contexts of daily life become animated by the demands of neoliberal labor. At stake here are the ways in which we are all hustling to get by, yet we stay radically divided from one another along lines of gender, race, and class thanks to the norm of self- enterprise. The next chapter hones in on what it feels like to inhabit enterprise culture by exploring neoliberal affect and the care of the self. As we already know, living in competition breeds widespread anxiety, not to mention depression and illness, making self-care an ongoing, pressing problem of everyday life. While neoliberal culture offers us plenty of tools for self-care that ultimately keep us stuck in our self-enclosed individualism, this chapter also considers how self-care might be a site for resistance and political intervention. The final chapter focuses on neoliberal politics, tracing what happens to citizenship and social action in our contemporary conjuncture. As we'll see, neoliberalism privatizes our political horizons by remaking democracy into a market competition for visibility and equality. Throughout this mapping of the neoliberal conjuncture, we will engage in a mode of critical work that will, hopefully, enable you to unlearn neoliberalism and thus begin to write new stories about our conjuncture—including both our commonalities and differences—and the alternative worlds we are yearning for. Indeed, our critical work will only matter to the extent that it opens up our individual and collective horizons to a future beyond living in competition.

# EUL – CASE

### LbL

#### A2 Light:

#### Their card proves the Innovation DA - because 90% of drugs aren’t working, companies need a lot of upfront capital to break even

#### Ignores the investment link – if large returns aren’t possible, nobody’s going to give the capital

#### Marketing crucial to profits, which still links

#### A2 Gostin

#### Compensation only true in the United States

#### Waiving IP doesn’t constitute a government taking– ie companies can’t trademark racist logos, but they aren’t compensated for those logos – the clause won’t apply to a regulatory waiver like this

### Adv

#### Plan flaw – they only waive intellectual property as long as it’s unlicensed – WHO say the EUL is a “procedure for assessing and listing unlicensed vaccines” – either this means a) this means that as soon as it gets approved, the patent is no longer waived or b) governments won’t go through the approval process which both risks public safety and increases vaccine hesitancy

#### Alt causes – without tech transfer, no solvency for data exclusivity, copyrights, and industrial design. Zaitchik 4-22:

Alexander Zaitchik { Alexander Zaitchik is a freelance journalist living in New Orleans. His next book, Owning the Sun: A People’s History of Monopoly Medicine, from Aspirin to Covid-19, will be published by Counterpoint in 2022.}, 21 - ("Moderna’s Pledge Not to Enforce the Patents on Their COVID-19 Vaccine Is Worthless," No Publication, 4-22-2021, https://jacobinmag.com/2021/04/moderna-patents-covid-19-vaccine)//marlborough-wr/

The company was safe in its assumption that scrutiny would stop there, and the public impression would remain that of a sacrifice to help end the pandemic. But this impression is false, and not just because Moderna’s legal claims on [technologies developed with government money](https://jacobinmag.com/2020/12/socialism-vaccine-capitalism-distribution) is provisional in the first place. Moderna’s patent pledge was an empty gesture for another reason quite apart from its long-standing junior partnership with the National Institutes of Health (NIH). Their entire ploy was premised on outdated public perceptions about how intellectual property works in the twenty-first century. Modern Patents on Biomedicines Almost Never Contain the Information Needed to Mass Produce Them The patent is a form of intellectual property, not a synonym. As inherited shorthand for knowledge monopolies, “patent” is a throwback, a progressively old-fashioned catchall reference that obscures more than it explains, like calling the supercomputer in your pocket a telephone. Understanding why requires revisiting the patent’s origins as a social contract. Emerging in Renaissance Italy, the first patents functioned as royal permission slips; having one meant you could benefit exclusively from a technology, process, or trade. This privilege was half of a limited-term bargain with the sovereign: in exchange for the monopoly, the recipient of the patent agreed to introduce a new and productive form of knowledge into the realm, to be diffused when the patent expired. As technological invention grew more complex, patents required more detailed information to serve as effective notes of collateral: to get the monopoly privilege, inventors had to reveal and submit all of their knowledge — sometimes called “trade secrets” — to the state. Until 1880, the US Patent and Trademark Office required applicants to submit miniature, three-dimensional models, along with blueprints, instructions, and diagrams containing everything that someone “skilled in the art” would need to reproduce the invention. When the monopoly term expired, the secrets were spilled into the public domain and, it was hoped, made productive at lower, newly competitive prices. In 2021, that social contract is as quaint as the miniature riverboat buoyancy device a young Abraham Lincoln [submitted for patent](https://en.wikipedia.org/wiki/Abraham_Lincoln%27s_patent) consideration in 1849. Emerging in Renaissance Italy, the first patents functioned as royal permission slips. In high technology fields like biomedicine, modern patent applications rarely contain the knowledge required to manufacture the invention. This is by political design, the result of an industry push to change the rules under an obliging Reagan administration and that era’s Democratic Congress. Four decades later, the patent game is one of deterring reproduction, even and especially by those most “skilled in the art.” Key aspects of an invention and its practice are systematically shielded, often indefinitely, by a layered intellectual property barricade involving patents, copyright, and “undisclosed information,” a broad, opaque and relatively new category of intellectual property (IP) that contains three subcategories vital to making things like vaccines: know-how, trade secrets, and data. It is within these categories, not in the publicly filed patent, that the most valuable secrets are kept. Industry-oriented legal theorists and intellectual property law professionals sometimes call undisclosed information “the padlock on the patent.” Rare is the new technology without these padlocks to secure a corporation’s crown jewels beyond reach — before, during, and after the term of the legal monopoly. According to the US Defend Trade Secrets Act of 2016 (DTSA), which together with the Uniform Trade Secrets Act of 1985 (UTSA) has been integrated into the global intellectual property regime enforced by the World Trade Organization (WTO), anything a company deems valuable can be shielded by an undisclosed information claim, including all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically or in writing. This list begins to explain why Moderna was happy to exchange its patents for a good news cycle. The most important information safely lay elsewhere. Pharma and biotechs trying to establish and protect monopolies can hide just about anything under “undisclosed information,” including technical designs and specs, process and quality control procedures, best production methods, instruction manuals, and trial data. Moderna was happy to exchange its patents for a good news cycle. The most important information safely lay elsewhere. Unlike patents, claims on “undisclosed information” have no legal term limit. By enjoying infinite life, the category voids the original patent bargain not once, but twice: it allows companies to withhold necessary information from the public domain, which then serves to block competition and extend the granted monopoly beyond the agreed terms. In the age of undisclosed information, applicants are no longer required to provide governments with meaningful collateral in exchange for the benefits of government-protected monopolies. Instead, they can provide partial maps to technologies they have no intention of revealing in full — fragments designed to frustrate, obfuscate, and occlude, providing knowledge that’s necessary but not sufficient to actually make the thing. The New Intellectual Property Regime Has Other Ways of Protecting Their Valuable Secrets

1. **IPR is key to stopping counterfeits – EUL designation isn’t a guarantee of quality**

**Kilbride 2020** [Patrick, vice president of International Intellectual Property for the Global Intellectual Property Center at the U.S. Chamber of Commerce, IP Watchdog, "Calls for WTO to Suspend IP Rights for Vaccine Innovation Would Jeopardize Incredible Progress" December 9, https://www.ipwatchdog.com/2020/12/09/calls-wto-suspend-ip-rights-vaccine-innovation-jeopardize-incredible-progress/id=128085/

Finally: A safe, legitimate marketplace. Patents facilitate a market for innovative medicines, throughout the development stage, as well as in commercialization. Licensing arrangements facilitate the types of collaborations that have proven so successful in 2020; they also ensure that third-party manufacturers are making, using, and selling COVID-19 solutions safely and ethically. Without it, counterfeiters and other bad actors could put shoddy, unreliable, and downright dangerous dupes on the market, all the while marketing them as legitimate products. It’s literally a matter of life and death: Thousands, if not millions, of people die each year at the hands of counterfeit drugs.

1. **Turns case – increased vaccine hesitancy means you’ll never solve, even if the vaccine was included on the EUL**

**Baschuk 2021** [Bryce, reporter for Bloomberg News, "Covid-19 pandemic: WTO holiday from vaccine talks draws calls for action" July 26, https://www.business-standard.com/article/current-affairs/covid-19-pandemic-wto-holiday-from-vaccine-talks-draws-calls-for-action-121072601721\_1.html

Specifically, opponents to the waiver say it would create a chaotic patchwork of laws, unravel existing industry partnerships, lead to a supply crunch for scarce vaccine inputs and inject even more uncertainty into already complex arrangements.¶ There’s also the possibility that an IP waiver could result in the production of counterfeit and substandard medicines, which could increase vaccine hesitancy that’s already pervasive in even the world’s wealthiest nations.

#### Pharma innovation key to stop emerging diseases – basic ‘essential medicines’ aren’t

Marjanovic & Feijao, 20 [Sonja Marjanovic, directs RAND Europe’s portfolio of research in the field of healthcare innovation, industry and policy, previously led RAND Europe's institutional partnership with The Healthcare Improvement Studies Institute at Cambridge University, member of the Cambridge Centre for Health Services Research and is an expert advisor on innovation to the NHS England and NHS Improvement cancer programme; Caroline Feijao, analyst working in the areas of science and emerging technology at RAND Europe, Ph.D. in biochemistry from the University of Cambridge, May 2020, RAND, “Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement,” <https://www.rand.org/content/dam/rand/pubs/perspectives/PEA400/PEA407-1/RAND_PEA407-1.pdf>]

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.

#### Medical innovation is key to address future pandemics---extinction.

Engelhardt 8 (H. Tristram, doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine, “Innovation and the Pharmaceutical Industry: Critical Reflections on the Virtues of Profit,” <https://www.amazon.com/Innovation-Pharmaceutical-Industry-Reflections-Conflicts/dp/0980209447>) (Taiwan)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of profit is one of the most effective ways not only to acquire resources but productively to direct human energies in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

#### No solvo - Pharma companies have no incentive to ensure drugs are distributed and used properly.

**Hollis & Pogge ’08 -** Aidan Hollis [Associate Professor of Economics, the University of Calgary] and Thomas Pogge [Leitner Professor of Philosophy and International Affairs, Yale University], “The Health Impact Fund Making New Medicines Accessible for All,” *Incentives for Global Health* (2008

As highlighted throughout this book, one main barrier to access to available drugs is price. When manufacturers’ prices are lower, then the prices consumers are charged through both public and private distribution systems will also be lower. Affordable manufacturers’ prices are therefore crucial to improved access. But manufacturers’ prices are not the sole determinant of the cost to the consumer. Import duties, port clearage charges, inspection fees, pharmacy board fees, central and regional government taxes, storage and transportation costs, and wholesale and retail markups add substantially to the manufacturers’ price.1 These supplementary costs are not always passed on to the consumer in their entirety, since the state or the nonprofi t sector may provide subsidies to consumers. But in this case the financial burdens placed on the state or the nonprofi t sector are increased by high prices. Even where supplementary costs are only partially passed on to consumers, they can significantly aff ect the aff ordability of essential medicines. Price, while crucial, is not the only determinant of access. In many low-income countries, weak health infrastructure signifi cantly limits the extent to which essential drugs are accessible. For example, Ministries of Health are often reluctant to distribute drugs to hospitals and health clinics if they believe these facilities lack the trained and motivated medical staff or the physical assets needed to ensure that the drugs are properly stored, prescribed and dispensed.2 Alternatively, a **Ministry of Health**’sadministrative systems **may be** such that it is **not able to manage** the **efficient distribution of** the **drugs** that are available to it**, resulting in shortages, particularly in less accessible parts of the country. Weaknesses in transportation** systems **and drug management** practices can also **result in spoilage**, thereby compromising the quality of available drugs.3 On the demand side, weak infrastructure oft en imposes significant costs and time burdens on poor people in need of health treatment. For example, **patients may have long distances to travel, and in many countries,** “informal payments” or **bribes are required** to obtain access to subsidized medicines (Lewis, 2007). The second main element of the last mile problem is the failure to use correctly the drugs to which patients do have access. The **WHO estimates that worldwide 50 percent of all medicines are** prescribed, **dispensed**, or sold **incorrectly, and that about half of all patients do not take medicines as directed** (WHO 2004b, 75). **This** incorrect use **exacts a huge toll in** increased **morbidity and mortality,** in addition to the toll exacted by lack of access. Estimates suggest that between 60 and 90 percent of household health expenditure in developing countries is on medicines (DFID 2006, 1). **Poor prescribing and dispensing practices, and weak adherence** by patients **to treatment requirements, means that** much of this **spending brings little in the way of health benefits**. It can actually be harmful, increasing the likelihood that certain diseases will develop resistance to the drugs that are used to treat them.5 These problems occur not only in developing, but also developed countries. Common types of incorrect medicine use include (WHO 2004b, 76): • use of too many types of medicines per patient (polypharmacy); • prescription of antimicrobials in inadequate dosage or for inadequate periods or the prescription of antibiotics for non-bacterial infections (the WHO estimates that around two-thirds of all antibiotics worldwide are sold without prescription); • use of injections where oral formulations would be better, increasing the transmission of hepatitis, HIV/AIDS and other blood-borne diseases; • failure to prescribe in accordance with clinical guidelines (survey data show that between 1990 and 2004 only around 40 percent of primary care level patients in Africa, Asia, and Latin America were treated in accordance with clinical guidelines for a number of common conditions, with no improvement over this period; WHO 2006c, 2); and • inappropriate self-medication, oft en of prescription-only drugs. A key cause of incorrect use is the lack of suitably qualifi ed medical personnel available to developing country health systems. Recent fi gures show that the number of health workers per 1,000 people was only 2.3 in Africa and 4.3 in South & East Asia, compared to 18.9 and 24.8 in Europe and the Americas respectively.6 Moreover, many developing-country health workers are poorly trained and paid and are not given adequate administrative support. This in turn contributes to low morale and a high incidence of absenteeism. This problem is especially acute in rural and remote areas. **Health facilities** that **are understaffed** or staffed **by inadequately trained** or motivated **workers** are very poorly placed to meet the requirements of rational drug use (Das, Hammer, and Leonard 2008). The WHO estimates that 57 countries suffer critical shortfalls of doctors, nurses, and midwives that prevent these countries from meeting even the most basic standards of health care (WHO 2006d, 5, 11–12). This human-resource crisis is complicated by the fact that in many low-income countries **staff salaries take up an inordinately large share of the** health **budget, leaving insufficient funds for** non-staff requirements such as **vaccines,** essential **drugs, diagnostic tools and infrastructure maintenance**. Public sector health payrolls are oft en poorly administered, and phenomena such as so-called ghost workers (people who are on payrolls but do not provide the relevant services) result in significant inefficiencies. Resource-constrained countries are confronted with the need to reduce the share of the wage bill in their health budgets while increasing the number and quality of health professionals, particularly in poorer areas. In many cases, greater efficiency in the use of existing resources, while necessary, will not be sufficient to remedy these problems entirely. There is no escaping the need for significantly larger amounts of resources to be made available to developing country health sectors.7 While public sector and not-for-profit private providers are key parts of the health sector in most low-income countries, the for-profit private sector— particularly in the form of private drug outlets—is often the first point of call for large parts of the populations of these countries when they fall sick. In Cambodia, for example, it is estimated that more than 70 percent of the population first approach private drug sellers when they fall sick, and that 75 percent of legal antimalarials are sold through the private sector. In Senegal, four private wholesalers linked to pharmacies and chemists represent nearly 65 percent of all sales of antimalarials (Institute of Medicine 2004, 40–41).8 Worldwide, **an increasing share of health care is being delivered through the private sector** (WHO 2006c, 4). Especially in low-income countries, governments often regulate private-sector drug outlets poorly. Even where suitable regulations and licensing procedures exist, **the supervisory and enforcement support needed to ensure compliance is often lacking.** Coupled with poor training of staff in private drug outlets, these regulatory, supervisory and enforcement shortcomings result in poor diagnosis and dispensing practices, and subsequently in the sale of unnecessary or contra-indicated drugs or incomplete courses of medication. This wastes resources, compromises successful treatment, and can lead to adverse patient reactions and the development of drug-resistant disease forms. **The incentives that private sellers have to maximize sales regardless of clinical requirements add to the likelihood of incorrect use.** These incentives are present not only in the private sector, but apply where the prescribing and dispensing functions are combined, as is sometimes the case in some public health facilities in low-income countries. Th is point notwithstanding, survey data available to the WHO show that, in developing and transition countries, the use of medicines is signifi - cantly worse in the private than in the public sector (WHO 2006c, 4).9 Even where **drugs** are correctly prescribed, they **are often sold in inappropriate packaging, with inadequate instructions** for patient use,or both. Th is creates serious problems when patients are illiterate or ill-informed about the implications of not taking medication as directed. Th is is particularly problematic with respect to medicines whose partial completion is oft en suffi cient to relieve symptoms. The result is a serious problem with patient adherence to the requirements of their drug treatment. Drug prices are also a factor in lack of patient adherence to treatment regimens. Poor patients may purchase insufficient amounts of the medicine, in an attempt to economize. A 2006 WHO report suggests that, unless effective action is taken, the problem of incorrect drug use is likely to get worse. This is so for two reasons. First, an increasing share of health care worldwide is being provided through the private sector. In developing countries and countries in transition to a market economy, provision through the private sector is likely to result in a higher incidence of incorrect drug use than provision through the public sector, which is important given the prominence of private drug sellers as a first point of call. Second, **many large-scale initiatives to treat diseases** of major public health importance, such as malaria, HIV/ AIDS, and tuberculosis, concentrate primarily on access and **give insufficient attention to the problem** of irrational use (WHO 2006c, 4). Irrational use also occurs in developed countries. As Avorn (2004) notes, there is a paucity of reliable clinical trials comparing the risks and benefits of different medicines, and at the same time, pharmaceutical companies’ marketing muscle sometimes leads to poor prescribing choices by clinicians.

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

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

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