## NC

### Framework

**We agree with the value of Morality.**

**However, we feel that the proper criterion for this debate is minimizing suffering, as no coherent theory of justice or morality can deny that suffering is morally bad. Therefore, if we regard everyone’s pain as morally equal, we are obligated to minimize the amount of suffering people experience.**

**Evaluating the debate through the ethical framework of utilitarianism is better than through minimizing structural violence as this framework allows us to weigh the validity of all types of arguments. Because utilitarianism intrinsically evaluates minimizing suffering, both minimizing structural violence and minimizing life threatening and devastating impacts can be valued. This makes the debate space more inclusive of all arguments and allows us to evaluate impacts with huge consequences that would be unjustly ignored if we solely evaluated impacts through structural violence.**

**Moreover, maximizing utility is the only way to affirm equal and unconditional human dignity.**

**Cummiskey ’90 -** David Cummiskey. [Associate Philosophy Professor at Bates College].Kantian Consequentialism. Ethics, Vol. 100, No. 3. 1990. http://www.jstor.org/stable/2381810.

We must not obscure the issue by characterizing this type of case as the sacrifice of individuals for some abstract “social entity.” It is not a question of some persons having to bear the cost for some elusive “overall social good.” Instead, the question is whether some persons must bear the inescapable cost for the sake of other persons. Robert Nozick, for example, argues that “to use a person in this way does not sufficiently respect and take account of the fact that he is a separate person, that his is the only life he has.” But why is this not equally true of all those whom we do not save through our failure to act? **By emphasizing solely the one who must bear the cost if we act, we fail to** sufficiently **respect** and take account of **the many other separate persons**, **each with only one life, who will bear the cost of our inaction.** In such a situation, what would a conscientious Kantian agent, an agent motivated by the unconditional value of rational beings, choose? A morally good agent recognizes that the basis of all particular duties is the principle that “rational nature exists as an end in itself” (GMM 429). Rational nature as such is the supreme objective end of all conduct. **If one** truly **believes** that **all rational beings have** an **equal value**, then **the** rational **solution** to such a dilemma **involves maximally promoting the lives and liberties of as many** rational beings **as possible** (chapter 5). In order to avoid this conclusion, the non-consequentialist Kantian needs to justify agent-centered constraints. As we saw in chapter 1, however, even most Kantian deontologists recognize that agent-centered constraints require a non- value-based rationale. But we have seen that Kant’s normative theory is based on an unconditionally valuable end. How can a concern for the value of rational beings lead to a refusal to sacrifice rational beings even when this would prevent other more extensive losses of rational beings? **If the moral law is based on the value of rational beings and their ends, then what is the rationale for prohibiting a moral agent from maximally promoting these two tiers of value? If I sacrifice some for the sake of others, I do not use them arbitrarily, and I do not deny the unconditional value of rational beings. Persons may have “dignity**, **that** is, an unconditional and incomparable worth” that **transcends** any **market value** (GMM 436), **but persons also have a fundamental equality that dictates that some must sometimes give way for the sake of others** (chapters 5 and 7). The concept of the end-in-itself does not support the view that we may never force another to bear some cost in order to benefit others. If one focuses on the equal value of all rational beings, then equal consideration suggests that one may have to sacrifice some to save many.

### Health Impact Fund

#### There are better ways to solve the problem than waving IP rights.

#### The Health Impact Fund would guarantee patent rights and increase profits, while also equalizing the cost of medicines

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) AT

We propose the Health Impact Fund as the most sensible solution that comprehensively addresses the problems. Financed by governments, the HIF would offer patentees the option to forgo monopoly pricing in exchange for a reward based on the global health impact of their new medicine. By registering a patented medicine with the HIF, a company would agree to sell it globally at cost. In exchange, the company would receive, for a fixed time, payments based on the product’s assessed global health impact. The arrangement would be optional and it wouldn’t diminish patent rights.¶ The HIF has the potential to be an institution that benefits everyone: patients, rich and poor alike, along with their caregivers; pharmaceutical companies and their shareholders; and taxpayers.¶ HOW THE HEALTH IMPACT FUND WORKS FOR PATIENTS¶ The HIF increases the incentives to invest in developing medicines that have high health impact. It directs research toward the medicines that can do the most good. It can also reward the development of new products, and the discovery of new uses for existing products, which the patent system alone can’t stimulate because of inadequate protection from imitation. All patients, rich and poor, would benefit from refocusing the innovation and marketing priorities of pharmaceutical companies toward health impact.¶ Any new medicines and new uses of existing medicines registered for health impact rewards would be available everywhere at marginal cost from the start. Many patients – especially in poor countries, but increasingly in wealthy ones too – are unable to afford the best treatment because it is too expensive. Even if fully insured, patients oft en lack access to medicines because their insurer deems them too expensive to reimburse. The HIF simply and directly solves this problem for registered drugs by setting their prices at marginal cost.¶ HOW THE HEALTH IMPACT FUND WORKS FOR PHARMACEUTICAL COMPANIES¶ Most proposals for increasing access to medicines would reduce the profits of pharmaceutical companies and hence their ability to fund research. The HIF, however, leaves the existing options of pharmaceutical firms untouched. It merely gives them the opportunity to make additional profits by developing new high-impact medicines that would be unprofitable or less profitable under monopoly pricing. Selling such registered medicines at cost, firms won’t be forced to defend a policy of charging high prices to poor people and they won’t be pressured to make charitable donations. With HIF-registered medicines they can instead “do well by doing good”: bring real benefit to patients in a profitable way. Research scientists of these firms will be encouraged to focus on addressing the most important diseases, not merely those that can support high prices.¶ HOW THE HEALTH IMPACT FUND WORKS FOR TAXPAYERS¶ The HIF will be supported mainly by governments, which are supported by the taxes they collect. Taxpayers want value for their money, and the HIF provides exactly that. Because the HIF is a more efficient way of incentivizing the pharmaceutical R&D we all want, total expenditures on medicines need not increase. However, if they do, the reason is that new medicines that would not have existed without the HIF are being developed. The HIF mechanism is designed to ensure that taxpayers always obtain value for money in the sense that any product regis-tered with the HIF will have a lower cost for a given amount of health impact than products outside the HIF. Taxpayers may also benefit from a reduction in risks of pandemics and other health problems that easily cross national borders

#### If we eliminate IP protections, we cannot use a health impact fund. If there is no IP, then generic companies can manufacture medicines, getting a share of the funds. This would undermine the purpose of the health impact fund, because it is no longer compensating innovation. There are better ways to solve the problem than waving IP rights

### Innovation DA

#### 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 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.

who advises drugmakers. “Other than that, this is largely symbolic.”

#### 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---early response 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.

## Case

### Innovation

#### Link Turn – Cross apply Macdole and Ezell. Monetary incentives increase innovation. Making medicines is already risky, and expensive. Without monetary incentives, drug companies have little reason to continue manufacturing and researching medicines.

#### Solvency – The plan doesn’t solve structural violence because medicines are innovated for wealthy countries, where money can be made. Their own evidence says this.

#### HIF solves for innovation directed at poorer countries because it rewards high impact innovation

### Accessibility

#### No solvency – The Last Mile Problem.

**In the squo, pharmaceutical 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

#### HIF solves because it mandates medicines be sold at cost meaning that medicines will be much less expensive

#### HIF solves because it allows for pharma companies to be incentivized based on largest health impact. This means that they have to manufacture and distribute medicines sufficiently in order to get the benefit of the HIF.

## AT HIV/AIDS

#### No solvency—there are already generic versions of HIV/AIDS drugs. Kapczynski 19

Amy Kapczynski [professor of law at Yale Law School, faculty co-director of the Global Health Justice Partnership, and co-founder of the Law and Political Economy Blog], 19 - ("The Right to Medicines in an Age of Neoliberalism," Humanity Journal, 4-26-2019, http://humanityjournal.org/issue10-1/the-right-to-medicines-in-an-age-of-neoliberalism/)//ML

Why are these newer medicines so astronomically costly? Not because they are costly to make, but because producers enjoy monopoly rights. For example, a new breakthrough treatment for hepatitis C can be made for as little as $170, but the company holding the key patents priced it at $84,000 in the United States.85 This is, in fact, one of the core insights that fueled the access to medicines campaign: HIV medicines that were being sold for $10,000 to $15,000 a year (and that must be taken for life) could be sold for as little as $100 in the absence of monopoly.86 The treatment of millions of people with HIV in the global South has been, in fact, predicated on the use of cheaper, high-quality generic medicines, often imported from India or made locally.¶