# **1**

## **OFF**

#### **Despite challenges, pharmaceutical R&D shows signs of growth.**

Terry and Lesser 21. [Colin is a Partner in our Life Sciences practice. He has been with Deloitte since 2011 working in the US firm, until 2014 when he moved to the UK practice. Colin’s client advisory work in the Life Sciences sector ranges across strategy and operations focused on the R&D function including operating model development and implementation as well as post-merger integration (PMI). These engagements have been serving client Boards and their senior leadership teams in R&D, Commercial and Supply Chain. Neil is a principal with Deloitte Consulting LLP in the Life Sciences strategy practice and a leader in the Research & Development strategy practice. He joined Deloitte in 1998 and works with life sciences executives creating and implementing strategies that drive productivity, efficiency, and value. He leads strategy, operating model design, productivity improvement, and large transformation initiatives within R&D and Regulatory Affairs. Neil is a frequent writer and speaker on R&D productivity.] May 2021. Deloitte. “Seeds of Change: Measuring the return from pharmaceutical innovation 2020.” Accessed 19 September 2021. <<https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-measuring-the-return-from-pharmaceutical-innovation-2021.pdf#page=6>> //MHES

IRR – Internal Rate of Return

Breakthrough advances in science and technology continue to fuel innovation in the biopharmaceutical (biopharma) industry and shape health care. However, though biopharma R&D is under mounting pressure, this year's analysis is showing a potential for growth with our cohort seeing small improvements in returns on pharmaceutical innovation. Nevertheless, peak sales remain at much lower levels than in 2013, despite a small uptick this year, and R&D costs continue to increase. Costs are increasing due to the growing complexity of development and longer cycle times. There is a pressing need to optimise processes and fundamentally change the drug development paradigm through use of digital and transformative approaches. COVID-19 has spurred on these changes and the industry is well-positioned to build on the momentum and look optimistically for a future with higher returns on pharmaceutical innovation. Since 2010, our series of reports on Measuring the return from pharmaceutical innovation have provided insights into the state of biopharma R&D, by projecting the internal rate of return (IRR) on investment that 12 large-cap biopharma companies might expect to achieve from their late stage pipelines. In 2015, we added an extension cohort of four more specialised companies and backtracked their R&D investments to 2013. Over time, our analysis has shown that both cohorts have seen large declines in their expected returns, and there has been convergence in the performance of the original and extension cohorts. Moreover, for the first time since our research began, a company in the original cohort acquired an extension cohort company. For these reasons, and for the purpose of this and future reports, we have combined the original and extension cohorts to create a combined cohort of 15 companies. However, since this is a transition report, we also provide a comparative analysis of the performance of the separate cohorts. It should be noted that our analysis period was from May 2019 to April 2020 and, therefore, this report's pipeline of late-stage assets does not fully reflect the COVID-19 vaccines and therapies that have since emerged. Measuring the return from pharmaceutical innovation For the first time since 2014, the average IRR has had an uptick from the previous year, showing signs of a potential reversal in the declining trend. In 2020, the projected internal rate of return (IRR) for the combined cohort was 2.5 per cent, 0.9 percentage points higher than in 2019 but 3.9 percentage points lower than in 2013. The range between top and bottom performers narrowed from 2019 and was the third-lowest since 2013. While ten of the 15 biopharma companies in the combined cohort improved their average IRR from 2019, all but one are below the industry cost of capital. The projected IRR for the original cohort in 2020 was 1.7 per cent - an increase of 1 percentage point from 2019, but a decrease of 3.1 percentage points since 2013. The three company extension cohort, in contrast, had a projected IRR of 6.6 per cent in 2020, up from 5.2 per cent in 2019 but well below the 17.4 per cent achieved in 2013.

#### High risk nature of pharmaceutical R&D means patents are necessary to attract investments.

**Grabowski et al 15.** [Henry G. Grabowski is a professor of economics at Duke University, in Durham, North Carolina.

Joseph A. DiMasi is director of economic analysis at the Tufts Center for the Study of Drug Development, Tufts University, in Boston, Massachusetts. Genia Long is a senior advisor at the Analysis Group, in Boston, Massachusetts.] February 2015. Health Affairs, vol. 34, no. 2. “The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation.” Accessed 16 September 2021. <<https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047>> //MHES  
The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.  Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6  As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.  Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.  New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.  Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.  Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13

#### **Fiscal incentives key to preparedness against emerging threats—bioterror, antimicrobial resistance, and new infectious diseases.**

Marjanovic PhD and Feijao PhD 20. [Sonja Marjanovic directs RAND Europe’s portfolio of research in the field of healthcare innovation, industry and policy. Her work provides decisionmakers with evidence and insights to support innovation and improvement in healthcare systems, and to support the translation of innovation into societal benefits for healthcare services and population health. Carolina Feijao is an analyst working in the areas of science and emerging technology at RAND Europe. Previously, she worked for Frontiers, an Open Access scientific publisher, where she led the launch of and managed three peer-reviewed journals: Sustainable Food Systems, Forests and Global Change and Sustainable Cities. She gained experience in policy making through a placement at DEFRA and she has been a research associate for GenPol, a Cambridge-based think tank focusing on gender equality issues. She also participated in the Management of Technology & Innovation Programme at Cambridge Judge Business School and carried out consulting projects ranging from market entry strategies for a plant breeding company to pitching a business proposal on innovative wound dressing products.] 2020. RAND Corporation. “Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement.” Accessed 19 September 2021. <https://www.rand.org/content/dam/rand/pubs/perspectives/PEA400/PEA407-1/RAND\_PEA407-1.pdf> //MHES

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. The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate industry efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would qualify as an immediate crisis (e.g. growing risks of antimicrobial resistance to some infectious pathogens). However, such diseases and issues are recognised as global threats that could become crises in the future.13 The emerging threats raise important policy questions about how government and the pharmaceutical industry can work together to ensure that pharmaceutical industry innovation is incentivised sustainably and at scale. This is important to help mitigate against current and emerging threats becoming crises further down the line. At present, there are no clear and specific criteria to determine when a disease can trigger the types of healthcare-innovation-related policy actions that have been deployed in response to the COVID-19 crisis. For example, this applies to criteria for securing financial resources for innovation-related activities, reforming regulation to accelerate trials and regulatory approval processes, and securing reimbursement mechanisms that help enable industry engagement and the search for rapid solutions. The WHO guidance on what constitutes a pandemic phase does provide guidance on national policy response options, but not specifically as they relate to healthcare innovation activity.14 There are also questions as to whether such policy initiatives and incentives should only be applied in crisis situations, or also as part of proactive government and industry efforts to innovate in the areas of public health threats in order to prevent future global calamities. A crisis and ‘emergency mode’ response may be inevitable for some diseases, but more can be done to mitigate against the need for such a response – especially in cases where emerging threats and their consequences can be foreseen and are known to be a risk. We need to anticipate and act now in terms of how we plan and incentivise better for the future, and how we distinguish between different types of infectious disease threats and phases in framing incentives and regulation. Innovative financial instruments must be integral to any sustainable and scalable approach to incentivising pharmaceutical innovation for tackling emerging threats to public health from infectious diseases The pharmaceutical industry has a responsibility to both its shareholders and to society at large. Incentivising the pharmaceutical industry to innovate solely on the grounds of being a socially responsible sector is unlikely to lead to a sustainable and scalable approach for innovating in response to emerging infectious disease threats. There are also potential challenges to the types of innovation (i.e. how radical or incremental) a reliance on incentives rooted solely in a social responsibility argument can lead to. Donating existing compounds for testing is important, but it is different to at-scale, industry-wide intensive investment in R&D geared at developing highly innovative diagnostics, medicines and vaccines. Even in the case of COVID-19, there are significant differences in the scale of innovative activity that focuses on repurposing existing products and technologies – for example, through testing existing antiviral compounds for potential therapeutic value – and more radically innovative R&D efforts aimed at developing something that acts on the COVID-19 virus in fundamentally novel ways.

#### Bioengineered diseases cause extinction.

Millett/Snyder-Beattie 17 [Piers Millet is a Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie previously spent five years at the Future of Humanity Institute (University of Oxford), where he worked as a program manager and later as Director of Research, developing programs across the institute including those in biosecurity and systemic risk. Prior to that, he was a researcher at a personalized medicine startup. He holds a PhD/DPhil in Zoology from the University of Oxford and is an alumnus of the Johns Hopkins Emerging Leaders in Biosecurity Initiative, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out **entirely.** Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population). In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21

#### AMR is an existential threat, it’s nonlinear, and has an invisible tipping point

Silverman ’16 (Rachel Silverman – MPhil with Distinction in Public Health @ the University of Cambridge, Senior Policy Analyst and Assistant Director of Global Health Policy @ the Center for Global Development, focusing on global health financing and incentive structures, “Confronting Antimicrobial Resistance: Can We Get to Collective Action?” 19 April 2016, https://www.cgdev.org/blog/confronting-antimicrobial-resistance-can-we-get-collective-action)

Antimicrobial resistance is already causing huge harm – and the worst is yet to come. To open the panel, Dr. Chan issued a serious warning about the size and scope of the AMR threat: “everyone will be affected if we do not address this problem.” AMR is already responsible for an estimated 700,000 global deaths each year, 50,000 of which take place in the US and Europe. Extensively drug-resistant (XDR) tuberculosis—cases where the most effective first- and second-line drugs are rendered useless—infected an estimated 47,000 people worldwide in 2014, only one ‘last-line’ antimicrobial is available to reliably treat gonorrhea, and few new antimicrobial drugs are in the development pipeline. According to the latest review, AMR could cause 10 million deaths each year by 2050, with knock-on effects draining many trillions from the global economy. Summers suggested that AMR and potential pandemics, alongside climate change and nuclear proliferation, represent the top three existential threats to life on earth as we know it. And as Dr. Chan explained, the worst-case scenario implies the end of modern medicine as we know it. Even worse, Summers suggested that AMR seems like a “quintessential non-linear phenomenon, and therefore more dangerous.” Year by year the effects are small and mostly invisible. But at some point in the future they could suddenly become catastrophic, like a “levee that doesn’t hold and unleashes a flood.” Dr. Chan concurred that “the tipping point is not predictable because…microbes are invisible. We don’t even know when they’re going to make the switch” to become resistant to existing drugs. Antimicrobial efficacy is a global public good threatened by serious market failures.

# 2

## OFF

#### **Counterplan Text:** Member nations of the World Trade Organization ought to declare the COVID-19 pandemic a national emergency and issue compulsory licenses for relevant medicines.

#### **The counterplan is the fastest and most effective way to increase accessibility of medicines in developing nations.**

Min 14. [Chang-Sik Min] 2014. Georgetown University Law Center. “Compulsory Licensing of Pharmaceutical Patents in Developing Countries.” Accessed 21 September 2021. <https://repository.library.georgetown.edu/bitstream/handle/10822/1047832/Chang-sik%20Min%20dissertation\_opt.pdf?sequence=8&isAllowed=y> //MHES

While granting and enforcing patent rights has been strengthened in developing countries according to the patent protection requirements of the TRIPS Agreement, more developing countries have become interested in compulsory licensing as a measure to increase access to patented medicines, especially when generic versions are available at much lower prices in other countries.71 Why is compulsory licensing more attractive to the governments of developing countries than other proposals? There may be several reasons for this growing interest. First of all, the effect of compulsory licensing on the price of patented medicines is fast and effective, provided that cheaper generic medicines are available in other countries.72 The government of a developing country can reduce the price of a patented medicine significantly by granting a compulsory license because such a license will allow the manufacture or import of generic medicines in that country. Market competition is one of the most powerful measures that can reduce drug prices. Second, a real and immediate possibility of compulsory licensing can encourage patent owners to reduce their drug prices or to operate drug donation programs voluntarily for the residents of developing countries because they may want to avoid the compulsory licensing of their medicines.73 Lastly, compulsory licensing can be a good policy for the governments of developing countries which want to protect their infant industries until those industries grow up because compulsory licensing may allow follow-on innovations and local manufacturing of generic medicines.74 This strategy has also been used by some developed countries, such as Canada. The development of the Canadian pharmaceutical industry was accelerated by the Canadian government’s extensive use of compulsory licensing before the country signed up for the North American Free Trade Agreement (NAFTA). This strategy was also once proposed to boost the development of domestic industries (which were premature) in the U.S. It was, in fact, specifically proposed to construct laws that would encourage foreign owners of U.S. patents (who would want to avoid compulsory licensing) to grant domestic manufacturers licenses to manufacture and sell products using their patented inventions to avoid compulsory licensing.75 Developing countries’ interest in compulsory licensing as a measure to increase access to patented medicines has grown rapidly, as disease patterns in rich and poor countries converge, as patent protection in developing countries becomes stronger, and as infectious disease emergencies increase and become more severe. As disease patterns of developed and developing countries are getting similar to each other, the chance that the residents of developing countries would need the same drugs sold in developed countries under patent protection has increased. However, the governments of developing countries have little resources to purchase these medicines at high price points under patent monopolies. Under these circumstances, compulsory licensing can be a good option for them to increase access to these medicines within their limited budget. The need for compulsory licenses will also increase as patent protection becomes stronger in developing countries. As developed countries try to include stronger intellectual property provisions that cover pharmaceutical products (“TRIPS-plus provisions”) in their regional or bilateral free trade agreements with developing countries, the governments of these developing countries may have nothing but compulsory licensing left to increase access to patented medicines. Lastly, increased risk of infectious disease emergencies across multiple countries is making both developed and developing countries interested in compulsory licensing. Under these public health emergencies, conflicts may occur even between the governments of developed countries and patent owners because they are required to prioritize public health protection over patent protection, as illustrated in Canada and the U.S.’s responses to the avian flu outbreak.76 If vaccines or medicines are available but are highly-priced and limited in quantity because they are patented, then compulsory licensing can be a good measure to reduce the price and increase the quantity of these vaccines or medicines to be distributed to citizens.77

#### **Only compulsory licensing strikes the right balance between maintaining IP protection and ensuring access.**

Bacchus 20. [James Bacchus is a member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland.] 16 December 2020. CATO Institute. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines.” Accessed 23 September 2021. <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines> //re-cut MHES

As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”7 But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.8 After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”9 In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.10 In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.11 Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance struck by the members of the WTO between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies. Does a Novel Virus Present Novel Issues? Now comes the COVID-19 crisis. In the debate over the proposed COVID-19 waiver, mostly we have heard the usual arguments, all of them reminiscent of the HIV/AIDS debate. The pharmaceutical companies in the global vaccine chase have been quick to express their opposition to the proposed waiver of IP rights for the pandemic’s duration. They have warned that allowing their COVID-19 vaccines to be copied without their permission through recourse to compulsory licensing “would undermine innovation and raise the risk of unsafe viruses.”12 The reaction of most nongovernmental health organizations and other global advocacy groups to these arguments is summed up in the Access Campaign’s response: “Since the start of the pandemic, pharmaceutical companies have continued with their ‘business‐​as‐​usual’ approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19.”13 What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines. In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least‐​developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”14 India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case‐​by‐​case and product‐​by‐​product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”15 But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market. Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need. At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”16 This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.17 To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs? With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19 As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

# **3**

## OFF

**Counterplan text: The member nations of the World Trade Organization ought to:**

* **Create a task force for the specific purpose of punishing the production of counterfeit medicine**
* **Build a world-wide database to collect information on terrorist operations**
* **Adopt a treaty defining counterfeit medicine and criminalizing its production.**

#### The counterplan is most effective in garnering international support and cutting off terrorist funding.

**Cannon 15.** [Douglas T. Cannon Experienced attorney with a demonstrated history negotiating and drafting real estate, finance, and corporate transactions.] 2015. Case Western Journal of International Law, vol. 47, issue 1, pp. 343-375. “War Through Pharmaceuticals: How Terrorist Organizations Are Turning to Counterfeit Medicine to Fund Their Illicit Activity” Accessed 10 August 2021.

<https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1022&context=jil> // MHES

 The issue of counterfeit medicine has surpassed the ability to contain, and yields an immensely profitable result for terrorists.179 Terror organizations have eclipsed the age of narcotic smuggling, and traditional financing, and have transcended in to an era of sophisticated counterfeit medicine trafficking to gain an advantage over authorities and groups looking to obstruct them.180 The WHO estimates counterfeit medicine has surpassed a $75 billion industry, in which some is directed towards terror organizations bank accounts.181 While the international community has known about this problem for some time, an effective solution – until now – has yet to be proposed, or enacted. When countries on their own cannot enact change, it should be the responsibility of the internationally community to act, in concert, and provide what the singular country cannot.  In proposing, and evaluating a solution, this Note examined the actions of two groups – Hizballah, and the Real IRA – and exposed the lesser known counterfeit medicine production that they have previously and, in some cases, continue to employ to raise their funds. Next, an analysis of the complex issue of terror financing was explored. In examining how terrorist organizations fundraise, several methods are employed to raise funds that traditionally, were much easier to procure.182 Of the most common, charities are no longer the easiest method for terror organizations to traffic illicit money into for their activity.183 In the last decade, nearly $200 million in terrorist funds were seized or frozen, and the U.S., in concert with 36 other countries, organized the Financial Action Task Force on Money Laundering (“FATF”) to further combat terrorist organizations from laundering their criminal gains. 184 Countries such as the United States, have attempted to take action via domestic agencies such as the FDA, FBI, and the JTTF. While their effort should be commended, this effort fails to actively disrupt an activity that has the possibility to kill millions.185 In the international community, little has been done – once again – to proactively seek or disrupt these production facilities.186 While white papers have been written, and missions have been waged against online retailers and at Customs offices, a systematic failure to be proactive has led to the rise of an industry that has been condoned by religious zealots and their leaders for use only on Western infidels, and non-Shiite believers.187 The only way to truly neutralize terrorist organizations from producing counterfeit medicine, and thus funding their illicit activity, is a proactive taskforce melded with a world-wide, constantly updated database, and an international treaty providing countries and their courts with the authority to strike, seize, and sentence infringing individuals for their offenses. A properly produced a task-force should be molded after the IAPF in that it should consist of special forces soldiers, trained in asymmetric warfare and advanced combat techniques.188 The accompanying database should be modeled after the UNESCO Art databases for both ease of use, and effectiveness.189 Allowing governmental agencies, international organizations, and nongovernmental agencies to upload their findings to the database, provides the task-force instant feedback on the location, terrorist organization, and magnitude of their operation. IMPACT, through their WHO mandate shall be responsible for operating and ensuring proper connectivity with Interpol and their servers. In furthering the global knowledge of counterfeit medicine and specific drugs’ whereabouts, Customs officials should produce an Import Alert on all items from countries known to harbor production facilities for counterfeit medicine.190 Finally, to assist the international community in prosecuting these terrorists, a Treaty should be adopted, which both sets out the elements of the crime for producing counterfeit medicine, and also defines what counterfeit medicine is.191 Effectively setting forth these four principles, this Note proposes a solution, which should both garner the support of the international community, and frustrate the uncivilized attacks of terrorist organizations by disrupting their financing regimes.

#### A vaccine waiver greenlights counterfeit medicine – independently turns Case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### Bioterror poses an existential threat—mitigating risk is priority number one.

**Green 14.** [Brian Patrick Green @ Markkula Center for Applied Ethics and School of Engineering, Santa Clara University, California, USA] 2014. Workshop on the Research Agendas in the Societal Aspects of Synthetic Biology . “Little Prevention, Less Cure: Synthetic Biology, Existential Risk, and Ethics.” Accessed 25 September 2021. < https://cns.asu.edu/sites/default/files/greenp\_synbiopaper\_2014.pdf> //MHES

The biosecurity, biosafety, bioweapon, and biodefense risks of synthetic biology are enormous and have been discussed in some detail (e.g. Petro et al., 2003, Lemon and Relman et al., 2006). Such risks may include everything up to the destruction of most of life on Earth. These worstcase scenarios should not be discounted, because there are not only individual cults and terrorist groups that would be happy to perform such heinous acts, but also possibly entire states, such as North Korea. Historically, many states have been involved in bioweapon research and production, and as the power of biotechnology is democratized we should also expect non-state actors to become involved, as indeed some already have (e.g. the Rajneeshees in 1984, the 2001 Anthrax attacker, etc.). This raises the question of global catastrophic and existential risks. The philosopher Nick Bostrom has described global catastrophic risks as risks which threaten massive global disaster and existential risks as risks which threaten human extinction (Bostrom, 2002). Synthetic biology presents such risks, especially if permitted as a DIY hobby that anyone, including terrorists, could pick up. Because synbio permits such significant changes to living organisms, we should not expect to be able to prepare for all the various diverse and unpredictable bioweapons that could be produced by a fully democratized DIY synbio milieu. Indeed, we cannot even effectively deal with the natural biological problems that nature throws at us now. The philosopher Hans Jonas has argued that the first and most important rule of ethics, his “imperative of responsibility,” is that humankind must exist in the future (Jonas, 1984). One is not allowed to play a “va banque” game with humanity. Therefore anything that puts humanity at risk ought to be carefully controlled or eliminated, if possible. There are many risky things that we cannot control, but synthetic biology need not be one of them. Recalling the “risk equation” (risk = harm x probability), Michael Davis has argued that for any unacceptable harm with a non-zero probability the risk is too high (Davis, 2012). Human extinction should qualify as an unacceptable harm; therefore, since DIY synbio permits a certain non-zero probability of that harm, it presents an unacceptable risk that ought not be permitted. As we enter the risk terrain of DIY synbio, we – or at least some of us – are deciding that we are willing to risk everything on the possible finite goods synbio might give to us. Reasonable gamblers should not risk everything, including their own lives, on a finite win. Given the dangers presented by synbio and the ethical rule that humans ought to exist in the future (which we ought hardly to need, as self-interest would hopefully suffice), we need a strong governance and policy response to this threat. The current Presidential Commission for the Study of Bioethics Issues response of “prudent vigilance” is insufficient. “Prudent vigilance” would have been an odd solution to the dangers of nuclear power, for example. Synthetic biology permits the creation of destructive capacities worse than nuclear weapons and at much less difficultly. Adaptation to and mitigation of these risks will likely need to be, therefore, even more significant than the changes to the world that occurred due to the advent of nuclear weapons. Perhaps it is only because the power of nuclear weapons was made clear on Hiroshima and Nagasaki that nuclear technology has been controlled as well as it has. In lacking examples of the destructive power of synbio, our collective imaginations seem to fail. How can we respond to this failure of the imagination? We need to present these ideas to the public as best we can. Mitigation of and adaptation to the risks of synbio should be a top priority. This will require policy responses which include governance over scientific research and technological development. When people try to make nuclear reactors at home (as has happened more than once), the public and the government should be concerned. Reactors are peaceful uses for nuclear power, but they still do not belong in people’s homes. Likewise, when someone tries to do synthetic biology “at home,” the public and the government should be concerned. Glowing plants are not weapons, but the same methods which produce them could produce much worse things. No finite benefit can justify the risk of human extinction, but what of the risks of smaller accidents or attacks that might kill “only” millions of people? Can any benefit justify that level of risk? I would think not, but this is a question for the public to decide, not for academics, scientists, engineers, DIY inventors, or any one group. This is a question of the common good, and so the decision makers should be everyone. Synthetic biology needs intense scrutiny, public discussion, democratic process, and limitations and enforcement to prevent unacceptable scenarios, so that we produce the best possible future with these technologies and not the worst.