### 1

#### Weed is a medicine and is used in medicine

WebMD 20 [WebMD Medical Reference, WebMD is an American corporation known primarily as an online publisher of news and information pertaining to human health and well-being. The site includes information pertaining to drugs. It is one of the top healthcare websites by unique visitors. It was founded in 1998 by internet entrepreneur Jeff Arnold., August 20, 2020, "Medical Marijuana FAQ,", WebMD LLC, https://www.webmd.com/a-to-z-guides/medical-marijuana-faq, 8-21-2021] //WHS MR

What is medical marijuana? Medical marijuana uses the marijuana plant or chemicals in it to treat diseases or conditions. It's basically the same product as recreational marijuana, but it's taken for medical purposes. The marijuana plant contains more than 100 different chemicals called cannabinoids. Each one has a different effect on the body. Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) are the main chemicals used in medicine. THC also produces the "high" people feel when they smoke marijuana or eat foods containing it. What is medical marijuana used for? Researchers are studying whether medical marijuana can help treat a number of conditions including: Alzheimer's disease Appetite loss Cancer Crohn's disease Diseases effecting the immune system like HIV/AIDS or Multiple Sclerosis (MS) Eating disorders such as anorexia Epilepsy Glaucoma Mental health conditions like schizophrenia and posttraumatic stress disorder (PTSD) Multiple sclerosis Muscle spasms Nausea Pain Seizures Wasting syndrome (cachexia) But it’s not yet proven to help many of these conditions, with a few exceptions, Bonn-Miller says. "The greatest amount of evidence for the therapeutic effects of cannabis relate to its ability to reduce chronic pain, nausea and vomiting due to chemotherapy, and spasticity [tight or stiff muscles] from MS," Bonn-Miller says. How does it help? Cannabinoids -- the active chemicals in medical marijuana -- are similar to chemicals the body makes that are involved in appetite, memory, movement, and pain. Limited research suggests cannabinoids might: Reduce anxiety Reduce inflammation and relieve pain Control nausea and vomiting caused by cancer chemotherapy Kill cancer cells and slow tumor growth Relax tight muscles in people with MS Stimulate appetite and improve weight gain in people with cancer and AIDS Can medical marijuana help with seizure disorders? Medical marijuana received a lot of attention a few years ago when parents said that a special form of the drug helped control seizures in their children. The FDA recently approved Epidiolex, which is made from CBD, as a therapy for people with very severe or hard-to-treat seizures. In studies, some people had a dramatic drop in seizures after taking this drug. Has the FDA approved medical marijuana? The cannabidiol Epidiolex was approved in 2018 for treating seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. In addition, the FDA has approved two man-made cannabinoid medicines -- dronabinol (Marinol, Syndros) and nabilone (Cesamet) -- to treat nausea and vomiting from chemotherapy. The cannabidiol Epidiolex was approved in 2018 for treating seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. How do you take it? To take medical marijuana, you can: Smoke it Inhale it through a device called a vaporizer that turns it into a mist Eat it -- for example, in a brownie or lollipop Apply it to your skin in a lotion, spray, oil, or cream Place a few drops of a liquid under your tongue How you take it is up to you. Each method works differently in your body. "If you smoke or vaporize cannabis, you feel the effects very quickly," Bonn-Miller says. "If you eat it, it takes significantly longer. It can take 1 to 2 hours to experience the effects from edible products."

#### The weed industry is growing, but needs investors to stay afloat – patents draw in investors and help companies expand

Roberts 20 [Chris Roberts, An award-winning investigative reporter and covered the legalization movement and the cannabis industry with a political economy lens for more than a decade. He launched northern California’s first cannabis-centric print vertical and founded San Francisco’s first dedicated drug-policy column. His work’s been featured in VICE, The Daily Beast, The Guardian, Deadspin, Observer, Curbed, Leafly News, High Times, SF Weekly, and many other places. He hold a master’s degree in politics from Columbia Journalism School, 5-28-2020, "Why Patent Cannabis? For Markets, Mostly.," Forbes, https://www.forbes.com/sites/chrisroberts/2020/05/28/why-patent-cannabis-for-markets-mostly/, 8-21-2021] //WHS MR

On May 20, Charlotte’s Web, the Colorado-based CBD giant and arguably one of the biggest names in legal cannabis, announced that the company was awarded its second federal patent on a cannabis plant. Unlike the company’s 2018 plant patent on a Farm Bill-compliant high-CBD hemp cultivar—which was the first hemp strain to receive federal intellectual property protection—US Patent No. 10,653,085 is a utility patent. This means, after satisfying a more rigorous process, including dropping off thousands of seeds at an official United States depository, Charlotte’s Web now claims as its intellectual property both the cultivar of hemp the company calls CW1AS1 as well as “methods” of plant production and cannabinoid extraction. Okay! But so what? Why patent a hemp strain—why patent two? What does it all mean? Does Charlotte’s Web now have legal claim to the entire CBD game?To the last question, no. And as for what this means, for normal people and cannabis consumers, very little. For patent attorneys or competitors of Charlotte’s Web in the CBD industry, it portends a little more, but just a little. At least for now, cannabis patents like this one aren’t really intended to defend intellectual property in court—which is where a patent has its most practical value. No, this patent is probably meant for the market. Patents like this exist mostly for companies to satisfy and woo investors, for whom a company’s ability to say “Look! I have a patent” might be the difference between signing a check, or not. And like all publicly traded cannabis companies, Charlotte’s Web has a lot of spooked and angry investors who need pleasing. Patents “generate interest in the company, and are something investors would look at,” said Jonathan Hyman, an attorney and partner at the Los Angeles office of Knobbe Martens. Whether Charlotte’s Web would enforce the patent, and how, “remains to be seen,” he added. Company officials were not available to discuss the matter. In a statement provided by Sylvia Tawse, the company’s director of communications, CEO Deanie Elsner said Charlotte’ Web “will continue to pursue patent protection for unique and novel hemp genetics developed by our horticulture division.” Whether that meant there are any pretenders the company plans to sue, she did not say. Though cannabis-related patent applications have been a thing since well before legalization and have tripled since 2015, as IP Watchdog noted, the mere phrase “cannabis patent” can still be triggering in cannabis circles. Patent talk can often lead to galaxy-brain thinking like the “Monsanto is supporting legalization in order to steal cannabis” or the “Philip Morris is buying up land in Humboldt County” conspiracy theories. In the case of Charlotte’s Web, the company’s already locked up what’s probably its most valuable asset: its name. Charlotte’s Web is named for Charlotte Figi, the sufferer of childhood epilepsy who enjoyed relief from her symptoms after taking an extract of high-CBD cannabis grown by the Stanley brothers (and who died earlier this month after contracting COVID-19). The world came to know Charlotte Figi and the Stanley brothers, seven photogenic Coloradans whose first names all begin with J, after they were prominently featured in a 2014 CNN special hosted by Sanjay Gupta. A very famous children’s book and a very famous and recognizable name, the company was sure lock down the name “Charlotte’s Web” with a trademark—one the company is currently defending in federal court, after a rival company dared market CBD products called Charlotte’s Web. That’s what patents are for in terms of the law. But markets are another matter—and it’s worth observing that the company went public after securing its first patent. Like almost all publicly traded companies in the cannabis sector, Charlotte’s Web is stuck in high-loss doldrums after hitting early peaks. For the past week, shares in Charlotte’s Web have been trading in the $7 to $9 range in the Toronto Stock Exchange. That’s a big gain from the $4.24 seen at the company’s mid-March nadir, but still far below last summer’s high-water mark of $28.21, set in August. Despite being sold in more than 11,000 stores, the company still lost $1.7 million in 2020—a hit smaller than other companies in the cannabis sector, but still in the red. Patenting hemp genetics and the processes to achieve them won’t be enough to rescue the rest of the company’s lost value. But if Charlotte’s Web wants to be a global CBD brand, with product in supermarkets and convenience stores all over the globe—and why wouldn’t it?—this means something. "Having this patent, that they can wave around and say, 'Hey, we've got coverage on it, and it's the best variety [of CBD rich hemp] that you're going to get,’ ” said Andrew Merickel, who holds a Phd in neuroscience and is also an attorney and partner at the San Francisco office of Knobbe Martens. “That’s pretty valuable.” How valuable? That’s all up to the logic of the market.

#### Cannabis is key to agricultural tech innovation – k2 long term sustainability and security

Yamazaki 17 Kevin Yamazaki (founder and CEO of [Sidebench](http://sidebench.com/), a leading digital product and venture studio that creates custom software and apps), 3-27-2017, "High Tech: How Marijuana Legalization Breeds Innovation," Observer, https://observer.com/2017/03/high-tech-how-marijuana-legalization-breeds-innovation/, SJBE

With the competition blazing and increased legalization on the horizon, we can expect to see the weed market become a hotbed for tech innovations. Forecasts indicate that revenue in the U.S. from medical marijuana alone will reach at least [$10.8 billion by 2018](http://fortune.com/2016/02/01/marijuana-sales-legal/). When states expand to allow recreational use, this number will surely increase. As investors become more comfortable deploying capital around cannabis, tech will revolutionize the marijuana ecosystem for producers, distributors, and consumers alike. The future of marijuana innovation Innovation has begun to outpace legalization as tech organizations make groundbreaking strides in researching and developing applications for marijuana. For example, [Kalytera](https://kalytera.co/) is exploring how cannabidiol — a non-psychoactive cannabinoid with a number of potential medical applications — can be used to target diseases such as obesity and osteoporosis. The findings of such research could transform how people cope with chronic illness and pain. Companies are also experimenting with improvements in [weed-growing processes](http://www.ibtimes.com/legal-marijuana-cultivation-driving-technology-revolution-industrial-agriculture-1925167). Cannabis is a finicky crop, so the ability to fine-tune growing processes could generate products far superior to today’s. Several organizations are devising smart, energy-efficient systems that automatically adjust growing environments according to changes in moisture, temperature, and sunlight. Meanwhile, data-capture technologies enable growers to identify optimal conditions for their plants, leading to larger and better-quality yields. The primary speed bump for the industry at this point is that marijuana is still classified as a Schedule I drug and is illegal at the federal level. Even if this factor doesn’t inhibit marijuana-centric technology innovation directly, it certainly has a strong indirect effect, as many potential financiers (and entrepreneurs) are scared away by either fear of prosecution or skepticism about the industry’s stability. That said, as more states allow for medical marijuana or legalize the drug entirely, the potential market size for marijuana-centric products expands as well. Perhaps more importantly, with some form of state legalization becoming the norm rather than the exception, there is a degree of safety in numbers. Assuming we see the trend of legalization for medical and recreational uses continue, production will inevitably become an even bigger business. Technology will play an increasing role in ensuring quality, consistency, and efficiency on the production side. We’re already seeing startups like [Cannafuse](http://cannafuse.com/) and [Teewinoit Life Sciences](https://tlscorp.com/) focusing on providing a tech-enabled scientific approach to the mass scientific production and distribution of cannabis. Advances in the irrigation systems, efficiency lamps, and data tracking processes used to grow marijuana may have far-reaching effects beyond the cannabis industry. Industrial farmers could adopt these techniques to increase their outputs and reduce energy expenses, while building managers can use them to lower energy loads from their properties. On the consumer side, the medical marijuana industry, in particular, will likely see an explosion of on-demand delivery services. Consumers are accustomed to using their smartphones to book cars, buy groceries, and mail packages. Why wouldn’t they receive their medical marijuana that way, too? Expect to see personalized services as well — think apps that recommend strains of marijuana on the basis of your preferences. Apps such as [MassRoots](https://massroots.com/) bring the social media aspect to what is, for many people, a social product by connecting weed enthusiasts to one another through news updates and other types of content. Even Microsoft is throwing its hat into the ring with [marijuana tracking software](http://www.businessinsider.com/microsoft-marijuana-tracking-software-2016-11) that ensures growers comply with their tax obligations and prevents legally grown pot from ending up on the black market. As the cannabis industry expands, the opportunities for growth are diverse and extensive. Tech-enabled companies will inevitably spur that growth, driving breakthroughs in medicine, crop development, and customer experiences. The momentum created by legalization will transform a once-taboo drug into a mainstream commodity, and the tech world stands to benefit enormously.

#### Food insecurity causes conflict and goes nuclear

FDI 12 FDI Team, 25 May 2012, “Food and Water Insecurity: International Conflict Triggers & Potential Conflict Points,” Future Directions International, <https://www.futuredirections.org.au/publication/international-conflict-triggers-and-potential-conflict-points-resulting-from-food-and-water-insecurity/>, SJBE

There is little dispute that conflict can lead to food and water crises. This paper will consider parts of the world, however, where food and water insecurity can be the cause of conflict and, at worst, result in war. While dealing predominately with food and water issues, the paper also recognises the nexus that exists between food and water and energy security. There is a growing appreciation that the conflicts in the next century will most likely be fought over a lack of resources. Yet, in a sense, this is not new. Researchers point to the French and Russian revolutions as conflicts induced by a lack of food. More recently, Germany’s World War Two efforts are said to have been inspired, at least in part, by its perceived need to gain access to more food. Yet the general sense among those that attended FDI’s recent workshops, was that the scale of the problem in the future could be significantly greater as a result of population pressures, changing weather, urbanisation, migration, loss of arable land and other farm inputs, and increased affluence in the developing world. In his book, Small Farmers Secure Food, Lindsay Falvey, a participant in FDI’s March 2012 workshop on the issue of food and conflict, clearly expresses the problem and why countries across the globe are starting to take note. . He writes (p.36), “…if people are hungry, especially in cities, the state is not stable – riots, violence, breakdown of law and order and migration result.” “Hunger feeds anarchy.” This view is also shared by Julian Cribb, who in his book, The Coming Famine, writes that if “large regions of the world run short of food, land or water in the decades that lie ahead, then wholesale, bloody wars are liable to follow.” He continues: “An increasingly credible scenario for World War 3 is not so much a confrontation of super powers and their allies, as a festering, self-perpetuating chain of resource conflicts.” He also says: “The wars of the 21st Century are less likely to be global conflicts with sharply defined sides and huge armies, than a scrappy mass of failed states, rebellions, civil strife, insurgencies, terrorism and genocides, sparked by bloody competition over dwindling resources.” As another workshop participant put it, people do not go to war to kill; they go to war over resources, either to protect or to gain the resources for themselves. Another observed that hunger results in passivity not conflict. Conflict is over resources, not because people are going hungry. A study by the International Peace Research Institute indicates that where food security is an issue, it is more likely to result in some form of conflict. Darfur, Rwanda, Eritrea and the Balkans experienced such wars. Governments, especially in developed countries, are increasingly aware of this phenomenon. The UK Ministry of Defence, the CIA, the US Center for Strategic and International Studies and the Oslo Peace Research Institute, all identify famine as a potential trigger for conflicts and possibly even nuclear war.

#### Extinction – nuke war fallout creates Ice Age and mass starvation

Steven Starr 15. “Nuclear War: An Unrecognized Mass Extinction Event Waiting To Happen.” Ratical. March 2015. <https://ratical.org/radiation/NuclearExtinction/StevenStarr022815.html> TG

A war fought with 21st century strategic nuclear weapons would be more than just a great catastrophe in human history. If we allow it to happen, such a war would be a mass extinction event that [ends human history](https://ratical.org/radiation/NuclearExtinction/StarrNuclearWinterOct09.pdf). There is a profound difference between extinction and “an unprecedented disaster,” or even “the end of civilization,” because even after such an immense catastrophe, human life would go on.

But extinction, by definition, is an event of utter finality, and a nuclear war that could cause human extinction should really be considered as the ultimate criminal act. It certainly would be the crime to end all crimes.

The world’s leading climatologists now tell us that nuclear war threatens our continued existence as a species. Their studies predict that a large nuclear war, especially one fought with strategic nuclear weapons, would create a post-war environment in which for many years it would be too cold and dark to even grow food. Their findings make it clear that not only humans, but most large animals and many other forms of complex life would likely vanish forever in a nuclear darkness of our own making.

The environmental consequences of nuclear war would attack the ecological support systems of life at every level. Radioactive fallout produced not only by nuclear bombs, but also by the destruction of nuclear power plants and their spent fuel pools, would poison the biosphere. Millions of tons of smoke would act to [destroy Earth’s protective ozone layer](https://www2.ucar.edu/atmosnews/just-published/3995/nuclear-war-and-ultraviolet-radiation) and block most sunlight from reaching Earth’s surface, creating Ice Age weather conditions that would last for decades.

Yet the political and military leaders who control nuclear weapons strictly avoid any direct public discussion of the consequences of nuclear war. They do so by arguing that nuclear weapons are not intended to be used, but only to deter.

Remarkably, the leaders of the Nuclear Weapon States have chosen to ignore the authoritative, long-standing scientific research done by the climatologists, research that predicts virtually any nuclear war, fought with even a fraction of the operational and deployed nuclear arsenals, will leave the Earth essentially uninhabitable.

### 2

#### Biotech industry strong now.

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

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

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

What about SPACs?

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

Fundamentals continue strong

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

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

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

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

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

More innovation on the horizon

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

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

#### IP protections are key to innovation – recouping startup costs and high risk of failure

Grabowski et al 15 [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] JL

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.

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

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

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

#### Disease causes extinction cross apply the aff evidence

### Case-- Hedge

#### Non U/q Heg is high now and will stay

**Babones, 15** [Salvatore Babones, 6-11-2015, accessed on 9-10-2021, The National Interest, "American Hegemony Is Here to Stay", https://nationalinterest.org/feature/american-hegemony-here-stay-13089] chsAK

America’s only global rival in the twentieth century was the Soviet Union. The Soviet Union never produced more than about half of America’s total national output. Its nominal allies in Eastern Europe were in fact restive occupied countries, as were many of its constituent republics. Its client states overseas were at best partners of convenience, and at worst expensive drains on its limited resources. The Soviet Union had the power to resist American hegemony, but not to displace it. It had the bomb and an impressive space program, but little else. When the Soviet Union finally disintegrated in 1991, American hegemony was complete. The United States sat at the top of the international system, facing no serious rivals for global leadership. This “unipolar moment” lasted a mere decade. September 11, 2001, signaled the emergence of a new kind of threat to global stability, and the ensuing rise of China and reemergence of Russia put paid to the era of unchallenged American leadership. Now, America’s internal politics have deadlocked and the U.S. government shrinks from playing the role of global policeman. In the second decade of the twenty-first century, American hegemony is widely perceived to be in terminal decline. Or so the story goes. In fact, reports of the passing of U.S. hegemony are greatly exaggerated. America’s costly wars in Iraq and Afghanistan were relatively minor affairs considered in long-term perspective. The strategic challenge posed by China has also been exaggerated. Together with its inner circle of unshakable English-speaking allies, the United States possesses near-total control of the world’s seas, skies, airwaves and cyberspace, while American universities, think tanks and journals dominate the world of ideas. Put aside all the alarmist punditry. American hegemony is now as firm as or firmer than it has ever been, and will remain so for a long time to come. THE MASSIVE federal deficit, negative credit-agency reports, repeated debt-ceiling crises and the 2013 government shutdown all created the impression that the U.S. government is bankrupt, or close to it. The U.S. economy imports half a trillion dollars a year more than it exports. Among the American population, poverty rates are high and ordinary workers’ wages have been stagnant (in real terms) for decades. Washington seems to be paralyzed by perpetual gridlock. On top of all this, strategic exhaustion after two costly wars in Afghanistan and Iraq has substantially degraded U.S. military capabilities. Then, at the very moment the military needed to regroup, rebuild and rearm, its budget was hit by sequestration. If economic power forms the long-term foundation for political and military power, it would seem that America is in terminal decline. But policy analysts tend to have short memories. Cycles of hegemony run in centuries, not decades (or seasons). When the United Kingdom finally defeated Napoleon at Waterloo in 1815, its national resources were completely exhausted. Britain’s public-debt-to-GDP ratio was over 250 percent, and early nineteenth-century governments lacked access to the full range of fiscal and financial tools that are available today. Yet the British Century was only just beginning. The Pax Britannica and the elevation of Queen Victoria to become empress of India were just around the corner.

#### Developing countries already have patent waivers – means we don’t need the aff to resolve

#### WTO 15

[Enrico Bonadio. “World’s Poorest Countries Allowed to Keep Copying Patent-Protected Drugs.” The Conversation, 24 Nov. 2015, theconversation.com/worlds-poorest-countries-allowed-to-keep-copying-patent-protected-drugs-50799. Accessed 5 Sept. 2021] Akaash

The World Trade Organisation has agreed to [extend a waiver](https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm) that allows poor countries to copy patented medicines. The waiver, which was due to expire in January 2016, has now been extended to 2033.

The countries that will benefit from the waiver are the **48 poorest nations**, classified by the United Nations as “Least Developed Countries” or LDCs, and include many African and some Asian countries. About half of the 900m population across these countries live on less than [US$1.25 a day](http://unohrlls.org/about-ldcs/facts-and-figures-2/).

All other countries, including developing countries such as India and China, are still bound by the WTO’s agreement on trade-related intellectual property rights (or TRIPS) with respect to drug patents.

#### Waivers don’t solve restrictive bilateral agreements that devolping countries are in

Bonadio 21 Enrico Bonadio, (Reader in Intellectual Property Law, City, University of London) and Dhanay M. Cadillo Chandler (Postdoctoral research fellow, University of Turku), 2/24/21, Intellectual property and COVID-19 medicines: why a WTO waiver may not be enough, The Conversation, <https://theconversation.com/intellectual-property-and-covid-19-medicines-why-a-wto-waiver-may-not-be-enough-155920>/SJKS

There are other barriers that the waiver wouldn’t address. One is that some developing countries have entered into bilateral agreements, especially with the US, the EU and other industrialised nations. These have limited the ability of generics producers to manufacture and distribute cheap medicines. One example is that this has limited the freedom to rely on parallel imports. These usually guarantee the importation of cheaper medicines purchased in countries where the drugs are sold at a lower price. Also, certain free trade agreements have introduced provisions which prevent national drug regulatory authorities from registering and allowing the sale of generics if the medicine is still patented. This is the so-called “[patent linkage](https://www.drugpatentwatch.com/blog/patent-linkage-resolving-infringement/)”. Among the countries that have signed these agreements are those who are part of the Comprehensive and [Progressive Agreement for Trans-Pacific Partnership](https://link.springer.com/article/10.1007/s40319-018-0758-3). They include Brunei, Chile, Malaysia, Mexico, Peru and Vietnam. Other trade and partnership agreements have also obliged certain developing countries to provide an absolute protection of clinical [test data](http://www.hjil.org/wp-content/uploads/Nsour-FINAL.pdf) submitted to regulatory agencies to demonstrate the quality, safety and efficacy of new medicines. This strong exclusivity stops the manufacturers of generics from using such data while applying for their own marketing authorisation. This inevitably slows down the availability of cheaper drugs. Countries like Morocco, Jordan, El Salvador, Guatemala, Honduras and Nicaragua do protect such data as a consequence of trade agreements concluded with the US.

### Case—Vaccine

#### Alleyne 20 evidence is about vaccines in general saving lives, not covid alone saving, but all the links are about covid

#### Overreliance on vaccines hurts overall pandemic response.

**Lovelace 21:** Lovelace, Berkeley [health-care reporter for CNBC, mainly covering pharmaceuticals and the Food and Drug Administration] "WHO says Covid vaccines aren’t ‘silver bullets’ and relying entirely on them has hurt nations," *CNBC,* January 13, 2021

The World Health Organization said Friday that [coronavirus](https://www.cnbc.com/2021/01/15/coronavirus-live-updates.html) vaccines aren’t “silver bullets” and **relyi**ng solely on them to fight the pandemic has hurt nations. Some countries in Europe, Africa and the Americas are seeing spikes in Covid-19 cases “because we are collectively not succeeding at breaking the chains of transmission at the community level or within households,” WHO Director-General Tedros Adhanom Ghebreyesus said during a news conference from the agency’s Geneva headquarters. With [global deaths reaching 2 million](https://www.cnbc.com/2021/01/15/coronavirus-live-updates.html) and new variants of the virus appearing in multiple countries, world leaders need to do all they can to curb infections “through tried and tested public health measures,” Tedros said. “There is only one way out of this storm and that is to share the tools we have and commit to using them together.” The [coronavirus](https://www.cnbc.com/coronavirus/) has infected more than 93.3 million people worldwide and killed at least 2 million since the pandemic began about a year ago, according to data compiled by Johns Hopkins University. The virus continues to accelerate in some regions, with nations reporting that their supply of oxygen for Covid-19 patients is running “dangerously low,” the WHO said. Some countries, including the U.S., have focused heavily on the use of vaccines to combat their outbreaks. While vaccines are a useful tool, they will not end the pandemic alone, Mike Ryan, executive director of the WHO’s health emergencies program, said at the news conference. “We warned in 2020 that if we were to rely entirely on vaccines as the only solution, we could lose the very controlled measures that we had at our disposal at the time. And I think to some extent that has come true,” Ryan said, adding the colder seasons and the recent holidays also may have also played a role in the spread of the virus. “A big portion of the transmission has occurred because we are reducing our physical distancing. ... We are not breaking the chains of transmission. The virus is exploiting our lack of tactical commitment,” he added. “We are not doing as well as we could.” Dr. Bruce Aylward, a senior advisor to the WHO’s director-general, echoed Ryan’s comments, saying, vaccines are not “silver bullets” “Things can get worse, numbers can go up,” he said. We have vaccines, yes. But we have limited supplies of vaccines that will be rolled out slowly across the world. And vaccines are not perfect. They don’t protect everyone against every situation.” In the U.S., the pace of vaccinations is going slower than officials had hoped. As of Friday at 6 a.m. ET, more than 31.1 million doses of vaccine had been distributed across the U.S., but just over 12.2 million shots have been administered, according to data compiled by the Centers for Disease Control and Prevention. Meanwhile, cases are rapidly growing, with the U.S. recording at least 238,800 new Covid-19 cases and at least 3,310 virus-related deaths each day, based on a seven-day average calculated by CNBC using Johns Hopkins data. On Thursday, President-elect Joe Biden [unveiled a sweeping plan](https://www.cnbc.com/2021/01/14/biden-unveils-sweeping-plan-to-combat-the-covid-pandemic-in-the-us.html) to combat the coronavirus pandemic in the United States. While his administration will invest billions in a vaccine campaign, it will also scale up testing, invest in new treatments and work to identify new strains, among other measures.

#### Independently the innovation DA turns this – it won’t help if the drugs we are sharing are bad drugs, as diseases get more complicated, we need better drugs.

#### IP laws are key to prevent the development and spread of counterfeit drugs.

**Mercurio 21:** Mercurio, Bryan [the Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law] “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review”, *Virginia Journal of International Law Online (Forthcoming 2021),* Feb 12, 2021

The protection of IP not only provides incentives to innovators to create, but also plays a crucial role in ensuring the safety of vaccines and helping to prevent the importation of fraudulent and dangerous goods. Unlike the typical pharmaceutical industry, the vaccine market is not a free and open market.69 Vaccines contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 70 Moreover, the manufacturing process for vaccines is much more complex as it requires the use of facilities and equipment with a high degree of specialization.71 The complexity of vaccine products implies that more time and regulatory requirements are needed in order to make or “copy” the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licenses, as this is the most responsible way to bring their technologies to the world and safeguard global health. In addition, as the COVID-19 pandemic continues there has been a noticeable increase in the circulation of fake medicines around the world. According to the International Criminal Police Organization (Interpol), **organized crime groups have been producing fake drugs and medical products and selling them for lucrative profits in developing countries.72 With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected**, according to the United Nations Office on Drugs and Crime (UNODC).73 Counterfeits of the legitimate products provide false promises of protection and could lead to disastrous consequences, including worsened illness and death for the individual and the retardation of herd immunity for the population at large. Effective and proactive IP procurement is essential and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. While important during normal times, IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, putting millions of human lives at risk and reducing trust in vaccines.

#### TURNS CASE – counterfeits cause major health crises – Niger proves.

**Williams & McKnight 14:** Williams, LaKeisha [Drug Information Specialist, Xavier University of Louisiana College of Pharmacy, New Orleans, Louisiana] McKnight, Ellen [PharmD Candidate, 2017, Xavier University of Louisiana College of Pharmacy, New Orleans, Louisian] “The Real Impact of Counterfeit Medications” June 19, 2014 AA

**Counterfeiting drugs is not only illegal, but it is also a major public health concern.** **Counterfeit drugs often contain the correct ingredients in incorrect quantities**; however, **they may also contain** either a wrong API—which may even be **toxic**—or no active **substance** at all.15 **Treatment with ineffective counterfeit drugs such as antibiotics can lead to the emergence of resistant organisms and may have a deleterious effect on a wide section of the population.** In extreme cases, **counterfeit drugs may even cause death**.3 **For example,** it has been estimated that between **60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit** vaccine containing only chloramphenicol, an antibiotic that is generally combined with another medication, which may have resulted in more than 100 fatal infections.17, 18 As a consequence of such damaging effects, **counterfeit drugs may erode public confidence in healthcare systems, healthcare professionals, the suppliers and sellers of genuine drugs, the pharmaceutical industry, and national drug regulatory authorities**.4

#### Quality Control DA: massive expansion of medicines leads to significantly worse medicines being manufactured since it costs more to develop good medicines this will lead to worse medicines being produced since they must be produced at a higher scale.

#### Turn: the aff reduces medicine access since elites within countries will make medicines contingent on factors like political allegiances i.e., you must be loyal to the US to get vaccines.

#### Turn: the aff decreases access to medicines because companies will produce fewer drugs if the know they can’t get as much economic rewards. Most companies only make money based of mass-producing one drug, but the aff takes that route away from them.