# Food Innovation DA



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#### Biotech is strong now – hiring rates prove

Data Journalism Team, 22, (Data Journalism Team, The data journalism team works across GlobalData's media portfolio, providing data driven analysis from the company's proprietary datasets., 3-21-2022, Pharmaceutical Technology, North America is seeing a hiring boom in pharmaceutical industry big data roles, https://www.pharmaceutical-technology.com/analysis/north-america-is-seeing-a-hiring-boom-in-pharmaceutical-industry-big-data-roles/, 7-2-2022) SCade

North America extended its dominance for big data hiring among pharmaceutical industry companies in the three months ending January. The number of roles in North America made up 64% of total big data jobs – up from 59.7% in the same quarter last year. That was followed by Asia-Pacific, which saw a -0.9 year-on-year percentage point change in big data roles. The figures are compiled by GlobalData, who track the number of new job postings from key companies in various sectors over time. Using textual analysis, these job advertisements are then classified thematically. GlobalData's thematic approach to sector activity seeks to group key company information by topic to see which companies are best placed to weather the disruptions coming to their industries. These key themes, which include big data, are chosen to cover "any issue that keeps a CEO awake at night". By tracking them across job advertisements it allows us to see which companies are leading the way on specific issues and which are dragging their heels - and importantly where the market is expanding and contracting. Which countries are seeing the most growth for big data job ads in the pharmaceutical industry? The fastest growing country was the United States, which saw 57.6% of all big data job adverts in the three months ending January 2021, increasing to 61.4% in the three months ending January this year. That was followed by India (up 1.9 percentage points), Canada (0.5), and the United Kingdom (-0.199999999999999). The top country for big data roles in the pharmaceutical industry is the United States which saw 61.4% of all roles advertised in the three months ending January.

#### gene editing is key to innovation

Claire O’Connell, 11-14-2019, Claire O'Connell is a contributor to The Irish Times who writes about health, science and innovation "Why gene editing is decade’s most significant innovation", Irish Times, https://www.irishtimes.com/business/innovation/why-gene-editing-is-decade-s-most-significant-innovation-1.4080666, 6-28-2022, //ms

gene editing (like the other innovations) has been in the works for a while, the last seven years have seen major developments in our ability to specifically edit DNA in living cells. It is not without controversy. Recent claims that human embryos in China had been genetically edited and had resulted in twin babies prompted widespread condemnation from scientists, as well as discussions about safety and ethics and calls for effective regulation. But as a technology, the ability to alter a gene in a living cell offers many potential benefits, including treating inherited diseases, understanding what specific genes do, generating more resilient crops and even detecting species in the environment. "The field is amazing," says Jane Farrar, a professor of genetics at Trinity College Dublin. "I have had some very late nights updating my lecture slides for undergraduates, because so much in gene technology is happening so quickly." Gene editing – which directly changes the “letters” of the genome – is becoming more of a feature of gene therapy, notes Farrar, but it is the new kid on the block. “The ability to edit specific genes in living cells is relatively new,” she says. “That means many forms of gene therapy that have by now reached the clinic or are under late-stage development don’t use these new gene-editing techniques. They deliver the gene into the cell, rather than correcting or editing the DNA,” she notes. Farrar was one of the pioneers of gene therapy research in Ireland in the 1980s and 1990s, when the patient-led charity Fighting Blindness supported work to find the genetic changes linked to inherited forms of vision loss. “The eye is really an ideal place for gene therapy,” she explains. “It is accessible, it can tolerate the viruses used to deliver genes and you have a natural control – if you put the gene therapy in one eye you can compare it to the other over time.” Rare eye disease Farrar, Prof Pete Humphries and colleagues identified gene changes involved in a rare eye disease called retinitis pigmentosa, and developed a system to "rescue" the gene function by suppressing the mutant gene and delivering a new gene into the cell. The technology was acquired by Spark Therapeutics in 2016. In 2017, the FDA in the USA approved a different Spark therapy, Luxturna, which replaces the function of gene changes associated with progressive sight loss. It was the first gene therapy of its kind to be approved in the US. “In general, there’s a huge amount of commercial interest in new gene therapies,” says Farrar. “Plenty more are in the works, not just for inherited eye diseases but also for rare diseases that affect how cells break down cellular components to recycle them, conditions that damage the mitochondria [which act as “batteries” in cells] and spinal and central nervous system disorders, among others.” She believes that gene editing will become more common in gene therapy approaches in the coming years, particularly as we work out how to do it safely and effectively. “With gene editing, there is the potential risk of ‘off-targets’, where editing a target gene could bring about unintentional changes in the genome or cell function, so some researchers are looking for ‘safe harbours’ in DNA,” she explains. “These are stretches of DNA where in principle you could add different genes targeting different disorders, while avoiding negative off-target effects.” The availability of gene editing in recent years also means that scientists can now use it as a research tool to target specific stretches of DNA relatively easily, according to Prof Breandan Kennedy, a senior lecturer at University College Dublin. Probably the best known gene-editing technology is CRISPR-Cas9, which was made commercially available in 2012. A little like having a sat-nav and a scissors, CRISPR-Cas systems allows you target a specific sequence of DNA “letters” in a living cell, then cut the sequence at that point. ‘Very powerful’ “By doing this, we can inactivate a specific gene, and this gives us a lot of information about what that gene normally does,” says Kennedy, whose work at UCD school of biomolecular and biomedical science uses gene editing technology on microscopic worms, zebrafish and human cells in the lab. “By inactivating specific genes, which we can do much more quickly and easily now with CRISPR-Cas systems, our group has been able to identify genes that are important for vision, for eye development and for blood vessels in the eye to grow and work properly. We are also using the approach to validate in the lab whether particular DNA change in patients are involved in inherited eye disease. Ten years ago if you said such a technology would be widespread, people would have laughed, but now labs around the world can do this. It’s very powerful.” Plant science, too, is reaping the rewards of being able to target specific stretches of DNA in living cells. "What is possible now is what was impossible five years ago," says Dr Ewen Mullins, head of the crop science department at Teagasc, Oak Park. “The holy grail for plant breeding is to be able to control the activity of a single gene, or several linked genes, and now gene editing allows us to do that,” he says. “And crucially, we are not necessarily adding a gene in from another species. With CRISPR-Cas systems, we can edit the genes already in the plant.” This could help to make crop plants more resilient in the face of droughts, fluctuating temperatures and agents of disease, notes Mullins: “These are becoming issues for farmers in Ireland and other parts of the world now, and in the face of climate change we need to reduce those susceptibilities where we can into the future.” Identifying species Gene-editing technology can even help us to identify what species are living in a particular environment, as Dr Anne Parle-McDermott from Dublin City University is finding out. "We are looking at the different species of salmon that live in rivers and aquaculture, but we are doing that by analysing the DNA they shed, also known as environmental or e-DNA," she explains. "We can take a sample of water, then we add CRISPR to find unique stretches of DNA that tell us about the species it came from. The associated Cas protein then cuts a reporter DNA and we can detect that cutting activity, so we know that stretch of DNA is present in the sample. It gives us a whole new way of knowing what DNA is present in the environment." Dr Ciaran Seoighe, deputy director general at Science Foundation Ireland, is impressed that gene technology won the reader vote for the innovation of the decade. "CRISPR-Cas9 is a case of a discovery turned into an innovation," he says. "Decades ago, researchers were discovering that bacteria had this system of being able to find and cut DNA in viruses and so stop them attacking, and the innovation was to take that and use it to specifically edit genes ourselves. It was a case of finding something interesting and then doing something different with it. Now it provides a tool for researchers to work on more personalised approaches to medicine." Farrar is also impressed by the winning vote. “I think the readers are very insightful,” she says. “Gene technology has matured in the last decade, and thanks to gene-editing technology we can also now get far more understanding about disease. This is really a story of fundamental biology enabling a new technology. Without that curiosity, we might not have these exciting innovations now.”

#### The biotech industry solves for food shortages brought on by climate change via innovation

Elsevier, 14, (Elsevier, 2014, Elsevier, The agrochemicals industry takes on climate change https://www.elsevier.com/?a=196459, 6-25-2021) SCade

Food Shortage Fears Frustratingly, climate change threatens to damage and lessen the planet’s food supply at a time when we need more food than ever. The worldwide population continues to explode, meaning that it’s not just about protecting the current supply, but also being prepared to grow it substantially to meet an ever-greater global demand. The United Nations has declared that food production must double by 2050 in order to feed the burgeoning population, one billion of whom are already suffering from hunger. This is a concern that is raised again and again among those working in agrochemicals, who feel a great responsibility to see their industry meet this vital need. Biotech to the Rescue “I’m a big believer in biotech and the doors that it can open,” says Madden, who was working at Asgrow (a seed company owned by Monsanto) when the first biotechnology products were introduced in the 1990s. “Humanity is dependent on crop breeding in combination with biotechnology to keep up with climate change.” Advances in biotechnology have made it possible to genetically modify crops with traits that make them resistant to pests and diseases. This not only helps farmers fight off problems that may result from climate change, but it also means that they contribute less to it themselves. Why? When farmers get better yields, they need less land to grow on – therefore slowing deforestation and the greenhouse gas emissions that come with it. And there is so much more that biotech could do to actively fight climate change. In a piece in The Berkeley Blog, author David Zilberman suggests that one such innovation could be to make GM soybean crops with improved digestibility, so that the cattle eating them release fewer greenhouse gases. Researchers are working on biotechnology that could solve any number of problems related to climate change, but it can be a long and arduous process of trial and error, as they attempt to find effective solutions. GM crops that are resistant to drought, for example, would be a godsend for farmers, but Madden explains that though “drought tolerance has been worked on for quite a while, early gene products have been somewhat disappointing to companies based on what is offered and achieved. ”He points out that regional differences in rainfall and soil type, as well as climate shifts, can complicate matters.

#### Food price increases causes scarcity and war over the remaining food and land

Ore Koren, 16, (Ore Koren, Ore Koren is a PhD candidate at the University of Minnesota and a Jennings Randolph Fellow at the United States Institute of Peace., 11-23-2016, Washington Post, Food scarcity causes conflicts — but so can food abundance. Here’s why., https://www.washingtonpost.com/news/monkey-cage/wp/2016/11/23/food-scarcity-causes-conflicts-but-so-does-food-abundance-heres-why/, 6-28-2021) SCade

For a new U.S. administration facing global security challenges, the relationship between food security — what the World Bank defines as “access to enough food for an active, healthy life” — and armed conflict deserves serious consideration. As new research shows, even an abundance of food resources can cause conflict. Recent studies theorize that in Syria, where an estimated 250,000 to 400,000 people have died since 2011, the drought that preceded the civil war played a significant role in fueling political tensions. Increases in food prices caused by drought were also a factor in the 2011 Arab Spring uprisings in Tunisia, Jordan, Yemen and Egypt. The fact that prolonged food shortages can lead to drastic, violent behavior is becoming increasingly evident. The relationship between food and war is both complex and multidimensional, though. The links between food scarcity and war Warmer countries are more war-prone — that’s what researchers studying the relationships between environmental factors and civil war argue. As global temperatures increase, prolonged heat waves reduce crop yields. The impact is strongest in tropical regions, which are more likely to experience the harshest effects of global warming. Lower crop yields increase the competition for remaining crops. And rising prices mean that many people cannot afford to buy food to compensate for resources lost because of climatic shifts. In countries that lack a social “safety net,” the only alternative in many cases is to obtain food through stealing, looting and — frequently — fighting over fertile land. Anecdotal evidence from eastern Africa and the Middle East, at least, supports this theory. Attempts to measure the linkages between climate change and armed conflict, however, have yielded mixed results, with some studies at least partly reaffirming these connections and others debunking them. Some regions adapt to climate conditions better than others Studies of the “Green Revolution” movement of the 1960s suggest that regions such as Asia were far more successful than Africa at adopting drought-resistant crops, which improved food security and helped offset the risk of war. Similar efforts in sub-Saharan Africa and the Middle East were weak and generally unsuccessful until the late 1980s. These efforts met with limited success because of the types of grain available and other socioeconomic complexities, which left these regions food insecure. Had Syria successfully adopted drought-resistant crops, for instance, the social unrest of 2011 might have taken a different, less-violent course. As researchers continue to debate how climate change and its effects on global food stocks will impact food security in future decades, short-term environmental “shocks” such as droughts or floods have become more frequent in many parts of the world and are a potentially salient cause of armed conflict. These environmental disturbances can lead to sharp price increases that, in turn, can cause another well-established tradition: the food riot, when civilians take to the streets to protest high food prices. Low-income countries are particularly susceptible because high food prices in these situations have an especially destabilizing effect. In these countries, high food prices expose the government’s lack of ability to shield consumers. They also create opportunities for civilians to mobilize against the regime. Even in locations where food is sourced locally, drought-induced shocks may incite violence against civilians when rebel groups seek to appropriate local food supplies. My research documents this happening not only in the Syrian conflict but also in India and Thailand during a 2004 drought. Riots, protests and massacres are among the types of unrest that can lead to civil war — and all can be linked to food conflicts.

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### DA turns case

#### Tech and national response key to fight bioterror

Stockholm International Peace Research Institute, 19, (Stockholm International Peace Research Institute, 3-27-2019, 8-16-2021, World Economic Forum, < https://www.weforum.org/agenda/2019/03/how-emerging-technologies-increase-the-threat-from-biological-weapons/ > Blucas

The main conclusion is that, while new developments in these three emerging technologies could have an enabling effect in different steps of the development and use of biological weapons, the existing governance frameworks are ill-equipped to comprehensively address these risks. To improve the ability to govern the convergence of biotechnology with other emerging technologies, concrete steps could be taken by national governments, regional organizations such as the European Union (EU) and international institutions, and by academia, the private sector and the DIY community. National governments should more systematically assess technological developments, map domestic stakeholders, make use of parliamentary assessment mechanisms, increase resources for relevant authorities, and strengthen research on the detection, prevention, response and attribution of biological incidents. The EU should enhance engagement with the biotechnology industry and biosafety associations in the context of dual-use risks. The BTWC regime should reform some of its elements, including its working practices and stakeholder engagement, and create a BTWC Scientific Advisory Board. It could also raise the issue of convergence on its agenda and better address the potential for misuse of commercial biotechnology and emerging technologies. Academic institutions should introduce obligatory courses on ethics, law and biosafety in all natural science curriculums, encourage work on interdisciplinary technology assessments and further strengthen the collaboration between national academies of sciences, particularly on addressing risks resulting from technological convergence. The private sector should continuously strengthen its self-governance and compliance standards. The DIY community could organize workshop series on biosecurity for community laboratories and strengthen international efforts to foster responsible science and biosecurity awareness.

### 2NC---Biotech Links

#### Big pharma is partnering with germline developers now---the aff puts a stop to that innovation

[Annalee Armstrong](https://www.fiercebiotech.com/person/annalee-armstrong-0), Apr 5, 2022, Annalee Armstrong is a senior editor for Fierce Biotech. Prior to joining Fierce in April 2021, Annalee was an associate editor for S&P Global Market Intelligence’s healthcare news team. Before that, she was the EPA reporter covering climate and energy policy on the Hill in Washington, D.C. Annalee got her start in journalism at daily newspapers across Western Canada chasing sled dogs and other stories. In her free time, Annalee enjoys yoga, camping and exploring the Blue Ridge Mountains from her home base in Charlottesville, Virginia. "Big Pharma partnerships, record $22.7B investment raise profile of regenerative medicine in 2021", https://www.fiercebiotech.com/biotech/big-pharma-partnerships-record-investment-raise-profile-regenerative-medicine-2021, 7-3-2022, //ms

Regenerative medicine couldn't stop making news in 2021. The year was marked by Intellia's [first results in humans](https://www.fiercebiotech.com/biotech/first-human-trial-results-intellia-shows-world-gene-editing-has-arrived) for gene editing, massive Big Pharma partnerships and record investment of $22.7 billion. This past year saw six new cell, gene and tissue-based therapies approved, according to an [annual report](https://www.fiercebiotech.com/biotech/regenerative-medicine-nearing-a-banner-year-14-1b-cash-infusion-regulatory-milestones-and-a) from the Alliance for Regenerative Medicine (ARM). Meanwhile, CAR-T therapies put up the data to justify moving up a line in cancer treatment, and venture capital went all-in on the field. Some major milestones for the field are yet to come in 2022, ARM said. About nine therapies are awaiting FDA nods, and another seven are before EU regulators. They include Gamida Cell’s cell therapy omidubicel and BioMarin’s ValRox for hemophilia A. For 2023, two sickle cell disease treatments, bluebird bio’s gene therapy [bb1111](https://www.fiercebiotech.com/biotech/bluebird-bio-to-restart-sickle-cell-gene-therapy-trials-as-fda-lifts-clinical-hold) and CRISPR Tx and Vertex Pharmaceuticals’ [CTX001](https://www.fiercebiotech.com/biotech/crispr-vertex-show-crispr-cas9-gene-editing-therapy-works-more-patients), will be considered in the U.S. Pharmaceutical drug developers continue to realize the strong therapeutic potential of highly potent active pharmaceutical ingredients (HPAPIs). This is particularly true for therapeutic areas such as oncology, where highly potent drugs are becoming more commonplace. Download this Executive Summary to learn more about Catalent's approach on safe handling procedures and effective formulation strategy. There was much debate over delivery mechanisms for gene therapies, which ARM said weighed down the field in 2021. But the group, an advocacy organization with more than 425 members, is optimistic that the field is making progress in finding new ways to optimize the leading mechanism, adeno-associated viruses. ARM also noted that the FDA has indicated it will not impose a universal dose cap on AAV-based gene therapies. AAVs were used in 145, or 46% of all gene therapy clinical trials. Other mechanisms included lentivirus, which had 24 clinical trials, or 8%, and adenovirus, with 22, or 7% of trials. Gene editing had 41 trials underway this past year, with one-third in phase 1 and the rest in phase 2. About 80% of these use [CRISPR technology](https://www.fiercebiotech.com/biotech/crispr-patent-dispute-not-over-yet-charpentier-universities-appeal). That includes Intellia’s transthyretin amyloidosis treatment that had a much buzzed about readout in summer 2021. The company rolled out [some more data](https://www.fiercebiotech.com/biotech/intellias-crispr-therapy-durability-attr-amyloidosis-dose-clinical-trial) from the study in February that showed a dose-dependent response and began to answer the durability question associated with gene editing. More than half of all gene editing trials are in cancer. 2021 also saw the first gene editing therapy in a more common disease, when CRISPR Tx and ViaCyte launched a study in Type 1 diabetes. As for investment, gene therapy and cell-based companies nabbed the majority of funds at $10.2 billion and $10.1 billion, respectively. Cell therapy followed with $2 billion and tissue engineering biotechs garnered $341 million. The majority of the cash came from venture capital, which contributed $9.8 billion—a 75% increase over the year before. IPOs helped companies raise $4.8 billion, an increase of 30%. There’s been a rush of Big Pharma partnerships across biotech, and these deals helped raise $2.3 billion through upfront payments in 2021, a 23% increase year over year. ARM noted the $900 million upfront payment Vertex offered to CRISPR Tx to work on CTX001 and AbbVie’s $370 million check for [REGENXBIO](https://www.fiercebiotech.com/biotech/abbvie-bets-370m-pivotal-eye-disease-gene-therapy-puts-up-1-4b-biobucks) for an eye disease gene therapy. Cancer is easily the busiest indication for regenerative medicine, with a whopping 1,246 trials underway right now across oncology, or 52% of all studies in the field globally. The sector has long been working on hematological cancers, which saw 685 trials, or 55%. But ARM noted a shift over the past year toward solid tumors, which climbed to 561, or 45% of trials. Gastrointestinal cancers were the leading indication here, with 130 trials, or 23% of all solid tumor trials underway, followed by brain and spinal cord cancers with 71 or 13%. CAR-T therapies also moved up a treatment line this past year, with both Gilead Sciences and Bristol Myers Squibb reporting data showing their therapies performed well against second-line standard of care in relapsed or refractory large B cell lymphoma.

#### The marriage of big pharma and biotech is k2 innovation---but the aff seeks to act as a homewrecker

Joseph Pategou, 3-19-2019, Joseph Pategou is a consultant with the management consulting firm Wavestone, specialized in the pharmaceutical industry. He has published more than 20 articles and completed a Master of Sciences in International Strategy and Influence, as well as a master’s in chemistry and life sciences. "The Marriage of Big Pharma and Biotech", Drug Discovery and Development, https://www.drugdiscoverytrends.com/the-marriage-of-big-pharma-and-biotech/, 7-3-2022, //ms

In 2017, the worldwide pharmaceutical market reached 1 trillion Euro, an increase of 6.7 percent over 2016. This market is expected to continue to growth at 4 percent CAGR and exceed 1.1 trillion euros by 2020. Four main growth drivers are behind this evolution, which occurred in spite of bad and challenging market conditions—growing health spending in emerging countries, drug price increases in some key markets, growing demand for generics in a context of high patent expiries, and innovative drugs and new treatments, especially in the field of oncology, which accounted for 27 percent of active global R&D pipelines in 2017, ahead of neurology and virology. For decades, pharmaceutical companies have been bringing innovative drugs to market for the benefit of the patients and the society. However, this process is not straightforward. The average time for a new drug to reach the market is between eight and 12 years. On average, from 10,000 compounds at the discovery phase, only one is approved and reaches the market. With more than 14 percent of its revenues allocated to R&D, the pharmaceutical industry is a leading contender in terms of R&D spending. From 2007 to 2016, the industry invested more than $1.3 trillion in R&D and forecasts predict an annual investment of $204 billion by 2024, with the U.S. leading the pack. This huge investment in R&D is necessary for pharmaceutical companies to launch new drugs, to sustain growth and profit. However, in recent years declining productivity has become a concern for pharmaceutical companies. R&D returns declined to 2 percent in 2018, down from 10 percent in 2010, with figures showing a steady decline. Moreover, during the past decades, the average drug development costs has been multiplied by more than 13, from 160 million euros in 1970 to 2.3 billion in 2010. This evolution is due to many factors, such as higher technical, regulatory and economic constraints, but also the search of innovative drugs by companies facing competition. For many experts, this situation raises questions on the capacity of the industry to innovate and to create growth in the future. Furthermore, 160 drugs lost patents in recent years, and this number is expected to reach more than 40 between 2017 and 2020. The new landscape opens the door to generic and biosimilar drugs and creates more opportunity for more competition, between existing players and new ones. New business models This situation has a big impact on the big pharmaceutical blockbuster business model, which is based on top selling drugs that generated over 1 billion USD in annual sales. Large pharmaceutical companies are changing and adapting their capabilities by focusing on external growth, more precisely mergers and acquisitions (M&A), to increase R&D capabilities and boost portfolio with biotech companies as preferred targets. In the past 10 years, merger and acquisition activities have significantly increased, with a high in 2015 when the total value reached more than 345 billion USD. 2019 started with the same strength, a mega merger between Bristol-Myers Squibb and Celgene of 95 billion USD (including debt recovery)—an astronomical amount which confirms the growing interest in biotech. Beyond M&A, partnerships with biotech companies are also appealing to big pharmaceutical companies. We have observed an increase in partnerships between biotech companies and pharmaceutical companies as a way to feed their pipeline and minimize risks and costs. For example, through a strategic partnership, Genentech and AbbVie developed Venclexta, an oncology drug. It is jointly commercialized by Genentech in the United States and commercialized by AbbVie outside of the United States. Big pharmaceutical companies are looking at biotech companies for many reasons. First, biotechnology companies clearly dominate new drug pipelines. Secondly, they are characterized by a very specific know-how and high value-added research involving patented technologies. They participate strongly in therapeutic innovation and are structures of interest for large pharmaceutical companies. Finally, biotech companies can bring more efficiency and responsiveness through licensing agreements to pharmaceutical companies. Put all together, biotech startups can help pharmaceutical companies to strengthen and revitalize portfolios in a challenging landscape where innovation is key. At the same time large companies bring financial support and expertise to put drugs on the market through enhancement of clinical development, market access and regulatory affairs. This strategic shift by large pharmaceutical companies toward biotech through M&A and partnering is bearing fruit. During the past 10 years, the number of new molecular entities has increased steadily. In 2018, the European Medicines Agency (EMA) had approved 84 (vs 94 in 2017) new drugs with 42 (vs 35 in 2017) of these being new active substances. At the same time, the U S Food and Drug Administration (FDA) had approved 59 novel drugs and biologics in 2018 (vs 46 in 2017). Moreover, biotechnology drugs are contributing to sales at a large scale. For EvaluatePharma, these products will represent 31 percent of the market in 2024 in comparison to 25 percent in 2017. This heavy role played by biotech companies is more visible when the top 100 products sales are put in the spotlight; biotech drugs are predicted to account for 52 percent of sales in 2024 (vs 49 percent in 2017). Based on this forecast, the dependency of the industry on biotech is clear. In this landscape, Roche has a leading position build through continued investment, the acquisition of Genentech, a biotechnology pioneer, in 2009 for $46.8 billion or Ignyta, a biotech in oncology, for $ 1.7 billion in 2017 in order to foster the company’s position in oncology. A new strategic roadmap Biotechnology companies can be a strategic pillar to help pharmaceutical giants redesign themselves. In the past decades, many groups have been defining a new strategic roadmap from diversification strategy to focus on core areas. In the case of Sanofi, the company is remaining on a diversification strategy, but started since 2016 restructuring a plan and discarded non-strategic activities. Sanofi sold its animal health business (Merial) and withdrew from some of its generic business by selling its subsidiary Zentiva, which manufactures generic drugs for the European market. In order to position itself on the strategic areas of oncology, immunology and multiple sclerosis, Sanofi have been using external growth strategy. Between 2017 and 2018, Sanofi bought three biotechnology companies, which allow it to reinforce its presence in the specialty medicine landscape. The first was Protein Sciences in 2017 for $750 million, through the acquisition of the biotech, Sanofi Pasteur, the vaccines global business unit of Sanofi. This adds a promising product, based on recombinant proteins, to its influenza vaccine portfolio. The second acquisition is Ablynx, a Belgian biotech company for $4.8 billion. Ablynx is engaged in the development of nanobodies, proprietary therapeutic proteins based on single-domain antibody fragments, which combine the advantages of conventional antibody drugs with some of the features of small-molecule drugs. Ablynx has more than 45 proprietary and partnered programs in development in various therapeutic areas, including inflammation, hematology, immuno-oncology, oncology and respiratory disease. Finally, Sanofi purchased Bioverativ for $11.6 billion, a U.S. biotech company focusing on therapies for hemophilia and other rare blood disorders. This acquisition should have two upsides or benefits—it helps Sanofi build a leading hemophilia portfolio and strengthens Sanofi’s portfolio in specialty care. The decline in R&D productivity, the increase in costs of drugs, the tough competition between existing and new players, and expertise of biotech companies has created an undeniable and undisputable incentive for a marriage between big pharma and biotech companies. Even if, the path to success is not guaranteed, the opportunity need to be taken for a brighter and exciting future for patients, large pharma players and in the end, creation of shareholder value.

#### Gene Editing is K2 Innovation

Sinha 22**.** (Sinha, [Rohit,  Head of Cryptography at Swirlds Labs.] [ARK2] "A CRISPR Framework for Emerging Biotechnology Applications: A Proposal to Separate Science from Politics." *J. Health & Biomedical L.* 18 (2022): 142. bin/get\_pdf.cgi?handle=hein.journals/jhbio18&section=11. shARK)

Nevertheless, because genetic engineering of humans has a place in the biotech industry, the infuence of leading scientists must still vie with the influence of business. Companies built on the very foundation of genome editing tools are being funded 22 Royal Road by wealthy investors and intrinsically propelled by eager scientists who wish to expand the horizons of genetic engineering. In April 2015, the market for biotechnology companies utilizing the CRISPR/Cas9 system within the human health sector was estimated to be $46 billion (van Erp et al. 88). The main interests of these markets include “gene-therapy, cell-therapy, immunotherapy, fast and efcient development of transgenic research animals, drug discovery, as well as target validation and screening” (88). At least 14 diferent companies have been identified in furthering these interests—not including the accessory companies like Twist Bioscience that actually synthesize DNA sequences for CRISPR/Cas9 targeting. Many of these companies have predicted the advancements of genetic engineering in human cells and have been accruing capital since before human applications of CRISPR/Cas9 have even been published. Similar to how business has dominated the pharmaceutical industry, its influence is closing in on the newly established market of genetic engineering. The looming threat of business’s influence on genetic engineering industries presents further complexity for the establishment regulation. Since the biotech industry is in its infancy, critically relevant healthcare and business policies have not yet been set. For example, in terms of novel drug discovery, the pharmaceutical industry requires rigorous conditions to be met before drug approval (Eisenberg 477-491). Furthermore, high demands for new therapies have resulted in noncompliance to existing standards. In his book, Corporate Crime in the Pharmaceutical Industry, John Braithwaite—an expert on business regulation and a distinguished professor at Australian National University—writes about issues such as these. Braithwaite states, “The pharmaceutical industry has a worse record of international bribery and corruption than any other industry, a history of fraud in the safety testing of drugs, and a disturbing record of criminal negligence in the unsafe manufacture of drugs” (5-6). Criminal behavior in an industry responsible for the health of human beings is reprehensible. The pharmaceutical industry parallels genetic engineering of human beings in how they both affect human health. Since health concerns cannot deter criminal behavior in the pharmaceutical industry, it is possible a similar trend will be observed in the human health sector of the biotech industry. Moreover, infringement of business may not always be illegal even if it is inherently wrong. Recall when Mylan, the manufacturer of the EpiPen—a treatment necessary to save lives—risked many lives in raising the price of the emergency treatment to $600 in order to maximize proft during a lag in FDA approval for alternative, generic forms ("O'Toole Calls on FDA to Approve Generic EpiPens to Combat Mylan's Monopoly on Market"). Dr. James Baker, the CEO and chief medical ofcer of the advocacy group Food Allergy and Research Education, reluctantly reports, “Is Mylan doing anything illegal? No, it's taking advantage of all these things to take the market and basically push it to an extreme” (qtd. in Lupkin). Problems like these mirror future expectations for the market of genetic engineering. Once businesses have leverage in a particular market, it is their goal to maximize proft, even if it is at the expense of others’ lives. An economist from Indiana University and Ameritech Chair of Economic Development, David B. Audretsch, suggests: To generate a successful regional cluster, the existence of world class scientific talent is a necessary condition. However, it is not a sufficient condition. The ancillary or complementary factors must also be available to translate this knowledge into a commercialized product. The complementary factors include the presence of venture capital and other forms of finance, the existence of an entrepreneurial culture, and transparent and minimal regulations fostering the start-up and growth processes. (3) Since science sparked the market of genetic engineering, businesses now have the capacity to continue without the impediment of harsh, legal restrictions. Also, since gene-editing technology is democratizing the practice of genetic engineering, it will only require a degree of training for basic procedures to be accomplished. In conclusion, the open market or “laissez faire” 24 Royal Road approach to business in America conflicts with any progress made to reduce democratization of CRISPR.

#### A Germline ban would disrupt innovation in the pharma industry

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Given the broad scope and scale of this growing threat, the United States should take a series of actions to mitigate the risks, without unduly stunting the growth of the biotechnology field. To date, bioterrorist attacks have been low-risk, high-impact events. While they have been extremely rare, their frequency will only increase as will their ramifications. However, overregulating the spread of biotechnological tools could stunt innovation and the profound potential of this increasingly important sector. Furthermore, existing methods of preventing bioterrorism may no longer be effective. The government could previously monitor the purchase of expensive and dangerous biotechnology tools and the laboratories that owned them in large quantities. This is no longer possible to the same degree when such tools are increasingly cheap, widespread, and usable in a garage. The FBI is currently attempting to address this risk by building relationships with the iGEM community and with life scientists so that they can report suspicious behavior. These efforts should continue, but are wildly insufficient, since some bioterrorists may have minimal contact with the larger community of biologists and biology hobbyists. The release of a bioweapon by a terrorist, if left unchecked, could spread throughout the globe, just as a naturally occurring pandemic would. Thus, one major step that the United States should take is to establish improved responses to disease outbreaks, particularly learning from COVID-19. This should include building a larger stockpile of PPE and establishing a set of clear step-by-step actions to be taken in the event of an attack. Building resilience in this fashion will not prevent bioterrorism, but it will mitigate its effects, and may slightly disincentivize utilizing bioweapons to cause terror. Beyond this, the United States should secure its laboratories and the data within, as terrorists could leverage that knowledge to build bioweapons. For example, new technology allows pathogens to be synthesized from the data describing their genetic sequences. In a recent controversial study, scientists published a methodology that would allow horsepox virus, a virus very similar to one that causes smallpox, to be synthesized. This research was conducted with a noble goal: understanding how the horsepox virus could be used as a potential treatment for cancer. However, it had significant dual-use implications. Research like this should not be banned outright, but the United States should establish norms to evaluate whether it is worth the risk before such research is conducted, and then ensure that it is conducted and the results published in the most secure ways. Replicability is an important part of science, but the general public should not be able to replicate the most dangerous experiments. Where building resilience would reduce the impact of a bioterror incident, restricting access to dual-use methodologies will reduce the likelihood of one occurring in the first place. Finally, enforcing domestic standards is not enough. Pathogens spread across borders, and the spillover effects of even a targeted bioterrorist attack could kill many unintended victims. Thus, the United States must work with other countries to protect against the bioterrorist threat, monitor the emergence of new viruses and bacteria that could be leveraged for a bioweapon, limit access to the most dangerous pathogens (and data associated with those), and build global response networks in the event of an attack. Importantly, this collaboration should emphasize working with allies, but should also include adversaries: if China or Russia remain unregulated, an attack within their borders would still affect the United States and its allies. Emerging biotechnology will result in new medicines and medical techniques, a greater understanding of how pathogens function and spread (and thus a better understanding of how to combat them), a healthier populace, innovative new capabilities that could transform daily life, and greater engagement with the biological sciences. While ensuring that these benefits are maintained, the United States and its allies and partners must take logical steps to protect themselves from the worst-case scenarios. The risk of bioterrorism is growing, and the United States must be prepared to face the future.

#### Big pharma and biotech partnerships are necessary to maintain innovation in drugs and medicine

NoëL Brown, 10-5-2021, "RBC Capital Markets", https://www.rbccm.com/en/gib/biopharma/episode/biotech-and-big-pharma-blueprint-for-successful-partnership, 7-3-2022, //ms

Strategic partnerships have long been an important contributor to how drugs are discovered. For decades, big pharma companies have been forming alliances with smaller biotech innovators to increase R&D productivity. From the biotech’s perspective pharma expands the geographical reach of a drug and aids in better managing late-stage development and commercialization costs. Greg Wiederrecht, Ph.D., Managing Director in the Global Healthcare Investment Banking Group at RBC Capital Markets, is no stranger to the importance of these deals. Before moving to the banking world in 2015, Wiederrecht was the Vice President and Head of External Scientific Affairs (ESA) at Merck, where his group of 85 physicians and scientists was responsible for the identification and scientific assessment of all licensing, collaboration, partnership, and acquisition opportunities for Merck worldwide. Wiederrecht’s experience gives him a unique perspective on why partnerships are vital for both biotech and big pharma companies. A question of scale “It’s impossible for large pharma companies to work in every single sub-therapeutic area out there,” explains Wiederrecht. “In today's markets, the vast majority of approved drugs are associated with some type of licensing partnership or acquisition component. Even the largest companies can only work on so many targets at once, whereas there are hundreds of thousands of researchers in academia and biotechs out there who can specialize in vastly more diseases and afflictions. If one of them makes a discovery that satisfies an unmet medical need, then large pharma can form some type of strategic partnership or collaboration to provide a jump start on their competitors.” The path to innovation So, what exactly does a strategic partnership entail? According to Wiederrecht, partnerships can take many forms. “It can be something as minor as a feasibility study on a potential partner's asset, or something more significant like a research collaboration, patent license, development commercialization agreement, or even an acquisition. In fact, many acquisitions begin with a collaboration that went so well the pharma wants to acquire the entire biotech. We've certainly seen some examples of that recently.” Evaluating potential Clearly, big pharma is dependent on collaborative alliances. But from a biotech perspective, when is a strategic partnership the best path forward? “Strategic partnerships can be essential to a biotech for several reasons. A biotech may have a patent position on a novel target. However, it may not have the volume of chemists and preclinical development experts that a big pharma can muster to get through what we call the ‘zone of chaos’ in drug development, which largely involves solving toxicity issues that can lead to unwanted surprises in clinical development.” “Also, if a biotech is working on a project in a large-scale indication that afflicts hundreds of thousands of people, the clinical trial costs may be too much for them to endure”, continues Wiederrecht. “Commercialization – particularly for those larger indications – is something big pharma excels in. They have established infrastructures in most countries around the world to sell the product.”

#### It is imperative to maintain the symbiotic relationship of biotech and pharma

Robin Robinson, 1-1-2020, “Small Pharma Driving Big Pharma Innovation”, PharmaVoice, https://www.pharmavoice.com/news/2020-01-pharma-innovation/612330/, 7-3-2022, //ms

“The future R&D model will leverage the synergy that develops between those small companies, the grassroots innovators, and the remaining big pharma companies,” Mr. Munos, who is also a fellow at FasterCures, a Center of the Milken Institute, says. “There will still be challenges that will require scale to be overcome. Small entrepreneurial companies can do quite a lot, but they won’t be able to completely replace the capabilities of their big pharma counterparts.” Mr. Davé predicts that small, innovative companies will continue to “do what they do best” in terms of science and be funded by large capital coming from the large pharma. Not only do big pharma companies have deep pockets but they also have the salesforces and the marketing muscle to get new drugs out to the masses. “It’s a very nice dynamic for the future and I see this model continuing to grow and get stronger and stronger,” he says. Large pharma companies will never lose the marketing and sales muscle they have to drive the product to the marketplace, and that works well for the small biotech companies. “The relationship that we have now is very symbiotic and it’s advantageous when everyone continues to work in their own individual ecosystems,” Mr. Davé says. He provides a real-life example of how this new symbiotic relationship and the ecosystem works. In the rare disease space, a small biotech company was developing a biologic that would treat only 700 people worldwide. The science was solid but getting funding was a struggle. “There weren’t a lot of people lining up to support a product that was going to have only 700 customers in the world,” Mr. Davé says. “And the price tag for development is the same whether developing a rare disease drug or a traditional hypertensive drug.” Enter a large pharma partner operating in the oncology space. The pharma company was interested because the rare disease being addressed was a precursor to cancer, and the large pharma company saw funding the innovation as an opportunity. With that funding relationship came access to the biotech’s voucher that can be used to accelerate the timeline of any drug in the pipeline, which would prove very valuable to the large pharma partner. Mr. Davé says the infusion of money from the large pharma company allowed the small biotech to produce a solution for 700 patients in the world and keep the price tag of the drug to a respectable level where it is still affordable and able to be reimbursed. Over time, the budding relationships between large and small pharma may evolve to the point of a new business and R&D model across the entire industry. “We have started to witness a shift in the balance of power over the past decade, with a burst of innovation from the early-stage and emerging biotech companies,” says Naheed Kurji, CEO, Cyclica. “As the market landscape for drug discovery evolves, early-stage biotechs are increasingly entering the spotlight with a combination of subject-matter expertise in the science and the benefits of a lean organization conducive to rapid innovation.” “The industry has become more open-minded about its business model, and more companies are getting bolder and starting to implement new ways of doing business,” Mr. Munos says. “The pharmaceutical industry used to be built on proprietary knowledge, tools, science, and data. This has changed.” Innovation is now being energized by countless “mad scientists,” as Mr. Munos calls them, who work out of academia, incubators, or virtual companies. “They add up to a giant grassroots innovation movement that operates on a shoestring,” he says. “Together, they explore emerging biology, and are quick to embark on translation when they spot an opportunity. It used to be that a biotech startup would need $50 million to get going because it had to recreate all the functions of a big company — HR, legal, and everything else. Today, companies don’t need this type of infrastructure. They can turn to crowdsourcing platforms, like scientist.com, for example. So, if you’re a chemist you focus on chemistry and procure everything else from the crowdsourcing platform when you need it. This flexibility has changed the dynamics of innovation. Startups now have the opportunity to grow without adding scale. This is a pretty valuable feature.” Crowdsourcing a Startup “The crowdsourcing model is remarkable because it used to be that if someone wanted to start up a company, he or she needed to excel in everything, because the expertise was needed inside the company; procuring resources wasn’t very easy and the market was not transparent or efficient,” Mr. Munos says. “Today, if a company wants somebody to design a trial, clone a peptide, do a toxicology study, or synthesize one gram of a molecule, it can be easily resourced. All someone has to do is send an email to a crowd-sourcing platform and say, ‘Hey, I need that. Can you help?’” There are several factors that have inspired and validated this model, effectively changing the pipeline in which medicines are brought to market. First, the patent cliff, as well as a significant decrease in new R&D returns, and the lack of discovery of more blockbuster drugs, to name a few. All of these factors led to big pharma looking toward smaller biopharma companies to develop innovations that it could not. “Early-stage biotech companies are seizing the opportunity to grab their share of the market, with recent data from IQVIA suggesting that emerging biotech companies now account for more than 70% of the total R&D pipeline, up from 52% in 2003,” Mr. Kurji says. “Emerging and innovative biotechs will continue to decentralize the drug discovery pipeline and develop breakthrough treatments that offer greater benefits beyond incremental improvements and reshape the way medicines are discovered and brought to market.” Funding Gets Easier This emerging paradigm makes it easier for small or emerging companies to get funding, whereas before it was one of their biggest hurdles. When small biotechnology companies had to rely on venture capital only, funding was difficult. If the VC-driven environment lost confidence in the biotechnology space or if fund managers lost confidence in certain medical innovations then the money stopped flowing in. “Now, there is another player that has come to the table and that is large pharma, which has very deep pockets,” Mr. Davé says. “So, when a VC will not fund an innovative company or innovative product, these companies have at least another suitor that can fill that gap — big pharma.” According to Mr. Kurji, large pharmaceutical companies are definitely supporting the creation, early-seed financing, and later-stage investment in biotech companies through their venture arms, but he also sees the venture capital ecosystem warming up to small pharma. “There has been considerable interest in the small pharma and biotech industry, which has certainly captured the attention of VCs,” he says. “StartUp Health in its Q3 insights reports that there has been a considerable increase in both the funding amount and deal counts in the healthcare and pharma space. In 2010, there was $1.1 billion with 152 deal counts, which is in stark comparison to the $10.4 billion and 556 deals by Q3 of 2019, with the largest amount of funding focused on earlier stage healthcare companies.” Not only has there been an increase in the number of deals and funding, there has also been an increase in the pool of investors supporting smaller biotechs and healthcare companies, with 1,061 unique investors participating in the industry, compared with 299 in 2012. A large proportion of these investors are based in the United States, and most venture investments are focused around companies in Silicon Valley and Boston. There also has been recent growth in the Asian markets, particularly in China. “As the market evolves, we will see a greater decentralization of resources as big pharma, non-profit organizations, and venture capital firms seek further innovation opportunities,” Mr. Kurji says. Pharma Spinoffs Spur Innovation In addition to funding innovation from outside sources, sometimes large pharmaceutical companies create their own spinoffs to discover and develop innovative products as an independent arm of the larger business. This model may operate differently from an independent startup, but there are many advantages over the cumbersome R&D model of big pharma. “There are a number of pharma spinoffs that have emerged over the past decade,” Mr. Kurji says. “These spinoff companies typically take programs that have been discontinued or slowed down within the larger pharma company’s operations, and progress those programs independently with the appropriate rights and licenses. Cerevel is a great example, which spun out of Pfizer and is funded by Bain Capital. Cerevel is pursuing neurodegenerative disease, a therapeutic area that Pfizer recently divested its internal efforts.” According to a company release, Pfizer is contributing a portfolio of precommercial neuroscience assets to Cerevel, which includes three clinical-stage compounds and several preclinical compounds designed to target a broad range of CNS disorders, including Parkinson’s, Alzheimer’s, epilepsy, schizophrenia, and addiction. Funds affiliated with Bain Capital Private Equity and Bain Capital Life Sciences have committed $350 million with the ability to provide additional capital should it be needed in the future. Bain Capital and Pfizer will support Cerevel in building a dedicated team of CNS scientists and life-sciences executives with extensive experience in clinical development of potential therapies for patients who have neurological and neuropsychological diseases. “Unquestionably, pharma spinoffs operate differently from independent startups in two critical ways,” Mr. Kurji adds. “One, from the ideation of a pharma spinoff, there is a clear objective and strategy, and a visibility back to the pharma company, and two, the venture arms of a big pharma company are key as they financially support the ideation and creation of new companies that are strategically aligned to the pharma company’s mandates.” While the hurdles that independent startups face are much higher than those of pharma spinoffs, there are advantages to being independent, he says. “An independent startup has more freedom to operate and try new things and pivot along the journey,” Mr. Kurji says. Mr. Davé says the incubator concept within large pharma started gaining ground about three years ago. “Large pharma companies started to create their own incubators and attract talent to those incubators,” he says. “I’ve seen many cases where top scientists from the academic space have shifted over to large pharma incubators where they’re still doing the same thing but the opportunities to advance their science and technology are better, because of the infrastructure that a large pharma company can provide.” Many large pharma companies have started to move in this direction, realizing that it was a way to thrive and prepare for the transformation that is taking place in the industry. “I’d say half of the top 12 pharma companies have a pretty good understanding of what’s going on,” Mr. Munos says. “They started long ago to prepare themselves for the transformation that is taking place. For instance, I remember when I first met Dr. Stoffels 10 years ago he would tell anyone who cared to listen that the model was broken and needed changing.” Not surprisingly, years later, Dr. Stoffels was instrumental in developing JLABS at J&J, which now comprises 12 pharma incubators which are mentored but not funded by J&J, according to Mr. Munos. “This allows JLABS to explore emerging biology in 400 directions, something that could never be done within the company because it would raise its risk profile to unacceptable levels,” he says. “But the purpose is to unleash innovation and it is working great guns.” Mr. Munos also notes that Novartis, AstraZeneca, Bayer, Takeda, Boehringer Ingelheim, and Merck KGaA have retooled themselves in ways that have re-energized innovation. The round up in his own words: “Novartis has gone through various iterations or versions of its innovation model. This was one of the first companies to return to scientists the freedom to innovate and the company has become one of the most prolific innovators, with 20 drugs approved in the last 10 years. AstraZeneca had a difficult transition, but its new drug output is rejoining the company to the leading innovators. Interestingly the mid-size companies such as Bayer, Takeda, Boehringer Ingelheim, Merck KGaA, seemed to have felt the heat a little sooner than their larger peers. But they all came to the realization that they needed to act in order to thrive in the new environment and they came up with new innovation models that have been remarkable. Takeda is a prime example of what we’re discussing because it used to be a rather staid company. Likewise, Boehringer Ingelheim came up with its own approach after realizing that much of the high-value innovation comes from outside. So it created a “research-beyond-borders” model that aims at harnessing new innovation ripples before they become waves. And its leadership has been pretty savvy at doing this. And Merck KGaA has taken multiple initiatives to basically implement open source R&D within its corporate structure. “All this is taking place as we speak and it is changing the dynamics of research by boosting new drug approvals while harnessing the shoestring economics of startups,” Mr. Munos continues. “Basically, this is opening pathways to overcome the pricing and affordability challenges that companies have been facing. It is putting the industry back on a sustainable course.” “When large pharma companies started to turn their attention to smaller biotech and emerging companies, innovation finally had a stage and an opportunity to be accelerated,” Mr. Davé says. “While we’re not producing $1 billion drugs, we are producing many more drugs that are providing solutions to a wider range of patients who were ignored or unattended to from a therapeutic perspective. Large pharma’s shift in focus away from billion-dollar drugs to more innovative drugs has proved beneficial to patients.” With more companies and people engaging in innovation, there will be more ideas, more hypotheses, and more drug candidates that make it to the clinic. Scientific breakthroughs are quickly followed by the creation of multiple well-funded startup companies to exploit the new opportunities. “This wasn’t the case 10 years ago, but now it’s become routine,” Mr. Munos says. “The reality is that if innovation is getting cheaper, we’re going to see more of it, and that’s exactly what is happening.” Mr. Munos adds this as a “very exciting time” in the industry and there are many reasons to be optimistic about the future of the pharmaceutical industry. He anticipates that entrepreneur scientists and small companies will have a much easier route to achieving their goals than they have in the past. “There will be a lot of turbulence in the near term, but in another five to 10 years or so, the industry will be on much better footing,” Mr. Munos says.(PV)

#### CRISPR goes beyond germline---but banning it stops innovation

By Michael A. Stramiello, Published in Landslide, Vol. 10, No. 3, January/February 2018, by the American Bar Association, "CRISPR: The New Frontier of Biotechnology Innovation ", No Publication, https://www.americanbar.org/groups/intellectual\_property\_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/, 7-3-2022, //ms

Since 2012, CRISPR has become the genome-editing platform of choice for life scientists around the world, largely due to its simplicity, efficiency, and low cost. Often described as “molecular scissors,” CRISPR systems typically have two fundamental components: a strand of guide RNA (gRNA) and a CRISPR-associated endonuclease (e.g., Cas9). Together, they form a search-and-snip complex in which the gRNA takes on a hairpin shape. While one end of that hairpin dangles free to interact with nearby DNA, the other lugs along its endonuclease counterpart. As the complex encounters DNA, it bumps into short sequences (protospacer adjacent motifs), using them as footholds to quickly unzip the double helix and check for a gRNA-DNA match. Upon finding one, the complex undergoes a conformational change that causes its Cas9 component to cut the target DNA. (Put differently, gRNA searches and Cas9 snips.) Otherwise, the complex lets go and continues to hunt. CRISPR’s search-and-snip functionality is especially useful in the presence of natural repair enzymes that lurk near DNA, looking for and patching up breaks. By delivering beneficial DNA fragments to the vicinity of sequences that are targeted and cut, scientists can leverage those repair enzymes to rewrite the genome. In light of this capacity to rapidly create specific mutations, CRISPR has been hailed as “an unprecedented tool” for identifying the genetic basis of disease and reprogramming cellular behavior.[2](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "2) CRISPR’s beauty lies also in its versatility, which does not stop with genome editing. Researchers have developed alternative, “broken scissors” techniques that focus on delivering molecular cargo rather than cutting. That cargo might serve a simple role, like latching onto a gene and blocking transcription, or it might do more, like inducing gene expression in response to external stimuli (e.g., light or chemicals). CRISPR can also be used to target RNA (which is continuously produced from DNA), greatly reducing any risk of permanent mistakes. From what we have seen so far, CRISPR has stunning potential to change the future of medicine—some even speculate that “in the not-too-distant future it will cure genetic disease.”[3](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "3) Still, hurdles remain. For example, scientists have voiced concerns about possible problems with immunogenicity,[4](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "4) unintended mutations,[5](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "5) and genetic variation across patients.[6](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "6) As those concerns are addressed, enthusiasm has mounted over preclinical studies (i.e., studies conducted in animals), which suggest that CRISPR may be used to cure muscular dystrophy, Huntington’s disease, hemophilia, and many other genetic diseases, as well as to eliminate antibiotic-resistant bacteria and viruses (e.g., HIV and PERV, the latter of which has long frustrated developments in xenotransplantation). Given those promising results, researchers around the globe are cautiously pressing ahead and have at least 20 clinical trials in the works.[7](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "7) Enthusiasm for CRISPR has also gained steam in other industries. In agriculture, for example, hopes are high that CRISPR will pave the way to hardier livestock and crops (e.g., tuberculosis-resistant cows and canker-resistant oranges). In fact, you might have already seen CRISPR’d, browning-resistant mushrooms at your local grocery.[8](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "8) CRISPR has also begun to make its mark on industrial biotechnology. For instance, one company recently began using CRISPR to make hydrogen peroxide for a new line of cleaning wipes, praising the technique as not just environmentally friendly, but also “cheaper and more efficient” than chemical syntheses.[9](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "9) Others have made strides toward modifying small organisms such as algae and E. coli into tiny biofuel factories. This broad range of applications sets the stage for wide-ranging and rapid advancements over the coming decades. In fact, recent estimates peg the revenue potential from CRISPR/Cas9 tools at $25–$30 billion by 2030.[10](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "10) The IP Landscape Despite its promise, CRISPR remains hampered by a complex, uncertain IP landscape. In the United States, two key players are locked in an epic battle over how to divvy up foundational patent rights (i.e., those not focused on a specific gene or use), and there may be more to come. Meanwhile, storm clouds are gathering overseas, with foreign patent offices signaling that they may go in different directions. To further complicate domestic matters, some commentators have begun to call for government intervention in licensing. And while early discussion of patent pools brings hope, their viability is another open question. Finally, the FDA may be gearing up for announcements on how it will regulate CRISPR innovations in human therapeutics. Though true clarity in the CRISPR patent landscape is years away, important developments are on the horizon in 2018. CRISPR Battle Lines Life sciences patent attorneys might remember 2017 as the year they finally took notice of CRISPR. At the center of their attention was the US Patent and Trademark Office’s (USPTO’s) Patent Trial and Appeal Board (PTAB), which in February 2017 surprised many by terminating a closely watched patent interference[11](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "11) between the University of California (UC, with collaborators University of Vienna and Emmanuelle Charpentier[12](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "12)) and the Broad Institute (Broad, with collaborators Harvard and MIT). Central to that dispute, which the USPTO initiated at UC’s request, is the question of which team first invented the claimed applications of CRISPR/Cas9 systems in eukaryotic environments (e.g., human cells). For example, UC argues that its application describes CRISPR/Cas9 systems and how they can be used for gene editing in any environment.[13](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "13) Broad counters that, among other things, a person of ordinary skill in the art would have had no reasonable expectation that such systems could be successfully applied to eukaryotic cells, as claimed in its own application and patents.[14](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "14) Ultimately, the PTAB was persuaded by Broad’s arguments and found that neither party’s claims, if considered to be prior art, would have rendered the opposing claims anticipated or obvious,[15](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "15) meaning there was no “interference in fact,” a threshold requirement rooted in 37 C.F.R. § 41.203(a). The PTAB therefore terminated the proceeding. That the PTAB did not cancel or finally refuse any claims, however, has not stopped some commentators from speculating that the patent landscape will ultimately play out with UC and Broad owning CRISPR rights in prokaryotes and eukaryotes, respectively.[16](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "16) The countervailing view, set out in layperson’s terms by one of UC’s named inventors, boils down to this: “the Broad Institute’s patent is for green tennis balls but the patent [UC] will have is for all tennis balls.”[17](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "17) In any event, UC appealed to the US Court of Appeals for the Federal Circuit,[18](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "18) which will likely hear oral arguments in April or May of 2018. As the UC-Broad interference winds down, CRISPR watchers should not lose sight of the USPTO, where more challenges may wait in the wings. For example, at least one ex parte reexamination against a foundational patent owned by Broad has already been granted (and suspended until the interference concludes). There is also a looming threat of additional interferences, as mentioned in recent USPTO communications[19](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "19) and acknowledged in the pre-IPO disclosures of all three CRISPR-centric biotechnology companies publicly traded in the United States (i.e., CRISPR Therapeutics AG, Editas Medicine Inc., and Intellia Therapeutics Inc.). Potential dark horses identified in those filings include: (1) Rockefeller University, a joint applicant on certain Broad applications; (2) ToolGen Inc., whose suggestions of interference against Broad are still pending; and (3) Vilnius University, which has its own US patent for use of CRISPR/Cas9 systems and is party to a cross-licensing agreement with one of UC’s licensees. Other entities may also come out of the woodwork with freedom-to-operate strategies that challenge key patents via inter partes review or post-grant review. Additional CRISPR disputes will happen overseas in 2018—and if patent grants are any indicator, foreign agencies might not simply follow the USPTO’s lead. The European Patent Office’s (EPO’s) Opposition Division (OD) will kick things off on January 16, when it hears oral arguments in oppositions lodged against a foundational patent owned by Broad. Among other things, challengers have attacked the purported novelty of Broad’s claims, a determination that may hinge on whether Broad validly claimed priority to two of its early applications. If it did not, at least seven of Broad’s other opposed patents may be vulnerable too. The OD has already issued a preliminary opinion indicating that it expects the oppositions to succeed.[20](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "20) While that opinion is nonbinding, European analysts have stressed that it is usually “very difficult” to sway the OD from its preliminary views.[21](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "21) In any event, Broad will not be the only foundational patent holder fighting to keep its rights alive across the pond in 2018, as the EPO has also granted noteworthy patent rights to UC, Sigma-Aldrich, and Cellectis, thus opening nine-month windows for would-be challengers to file post-grant oppositions. The fight over UC’s patent, which controversially covers use of CRISPR in both prokaryotes and eukaryotes, may be especially heated. It has already withstood over a half dozen third-party observations (including some filed by Broad),[22](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "22) and at least two groups have now filed post-grant oppositions.[23](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "23) China, home to the world’s second-busiest CRISPR patent landscape (after the United States), may host similar turf wars in 2018. UC and Broad, among many others, are already on the scene and may be drawing up battle plans. While Broad’s applications remain pending, China’s State Intellectual Property Office announced in June its intention to grant UC a patent covering CRISPR/Cas9 methods and compositions for applications in any environment. One of UC’s key licensees in human therapeutics praised the decision as “further global recognition that [UC and its collaborators] are the pioneers in the application of CRISPR/Cas9 in all cell types.”[24](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "24) Not missing a beat, Broad issued an ominous reminder that “[i]n China, patents are subject to invalidation proceedings after they are issued.”[25](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "25) Agency Invasion CRISPR tangles in the United States have already sparked calls for government intervention per the Bayh-Dole Act of 1980. This law generally allows recipients of federal funds to license the fruits of their labor, providing commercialization opportunities that fuel innovation and public access to technologies made possible by taxpayer dollars. A more controversial aspect of Bayh-Dole, however, provides federal agencies with “march-in rights.” Under specific circumstances, those rights—which have never been exercised[26](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "26)—confer on the executive branch the power to compel “nonexclusive, partially exclusive, or exclusive license[s]” to “responsible applicant[s].”[27](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "27) Other commentators have more generally advocated for “updating Bayh-Dole’s pro-commercialization safeguards,” apparently out of concern “that courts [will] let overly broad patent rights emerge.”[28](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "28) Their critics, however, ponder how agencies would properly determine whether patents are “overly broad,”[29](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "29) also pointing out a placid statement from the federal government’s premier funder of medical research, the National Institutes of Health (NIH): While we have not received any inquiries or complaints about lack of access to the CRISPR-CAS9 technology for research or commercial development from those who are in a position to use the technology, we continue to monitor access and use of the CRISPR technology that was funded by NIH with respect to public access and compliance with NIH principles and policies. At this time, we do not believe that a new NIH policy to address the licensing of CRISPR patented technology is necessary.[30](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "30) In arriving at that conclusion, the NIH considered and reported no violation of its long-standing “Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.” Among other things, those recommendations discourage exclusive licensing, “except in cases where the licensee undertakes to make the research tool widely available to researchers through unrestricted sale, or [where] the licensor retains rights to make the research tool widely available.”[31](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "31) Patent Pool: Oasis or Mirage? As CRISPR marches on, there may be an elegant solution for making it widely available without government intervention in licensing: patent pools. These joint licensing platforms enable owners to combine their IP rights into bundles that are made accessible, nonexclusively, to a broad range of users via a single transaction with predictable terms. As a result, licensors and licensees can concentrate on innovation and commercial development, respectively, while minimizing transaction costs and litigation risk.[32](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "32) This model was popularized in the 1990s, when the consumer electronics industry adopted it to facilitate deployment of the MPEG-2 digital video standard, which has yielded about $5 trillion in worldwide product sales since 1997.[33](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "33) A key coordinator of that effort, MPEG LA LLC, now invites CRISPR/Cas9 patent holders to participate in their own pool. MPEG LA has been gauging interest from CRISPR rights holders since at least April 2017.[34](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "34) Broad and Rockefeller University announced that they had submitted nearly two dozen “key CRISPR-Cas9 patents,”[35](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "35) from 10 families, “for evaluation of eligibility to participate in discussions facilitated by MPEG LA regarding creation of a CRISPR Joint Licensing Platform.”[36](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "36) UC reportedly has no plans to follow suit, citing potential conflicts with its existing licenses.[37](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "37) The effect that pooling would have on such arrangements may remain unclear until contributors finalize pool terms, which could take years. Early efforts might focus on pooling foundational patents, and there has also been speculation about specialized pools geared toward particular CRISPR applications (e.g., agriculture and industrial biotechnology).[38](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "38) Pooling may prove to be more of a challenge with respect to human therapeutics, a field where rights holders typically expect exclusivity as a reward for their enormous investment in rigorous clinical trials. Toward the Clinic In June 2017, an FDA senior policy advisor announced that the agency has begun building the capacity to regulate treatments that use CRISPR/Cas9 technologies.[39](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "39) Hammering out the details will take time, but related approvals, market exclusivities, and patent scuffles may be governed by the Biologics Price Competition and Innovation Act (BPCIA). Though gene therapies are not expressly included in the BPCIA’s definition of “biological product[s],”[40](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "40) the FDA has made clear that marketing of “genetic material to modify or manipulate the expression of a gene product or to alter the biological properties of living cells for therapeutic use” requires an approved biologics license application.[41](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "41) As regulatory channels take shape, do-it-yourself CRISPR kits have already become available for purchase, pitched with a warning that they are “not injectable or meant for direct human use.”[42](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "42) The CEO founder of one such vendor recently made headlines by publicly injecting a CRISPR concoction after announcing: “This will modify my muscle genes to give me bigger muscles.”[43](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "43) The FDA quickly responded with a statement expressing its “concern[] about the safety risks” of such products and noting that their sale “is against the law.”[44](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/" \l "44) It said nothing, though, of whether or how it would enforce that law. Either way, heavily invested patent owners may see traditional infringement litigation as a means to shield their nascent technologies from bad press as they wind their way toward the market. Conclusion All things considered, 2018 is poised to be another defining year for the CRISPR patent landscape. While the interference saga between UC and Broad may be nearing an end, it might be replaced by a similarly important ex parte reexamination and perhaps more interferences. Tremors may be felt overseas too, with high-profile opposition proceedings set to begin at the EPO and additional post-grant battles looming in Europe and possibly China. Adding to that uncertainty are (1) the possibility of government intervention in licensing, and (2) lingering questions about patent pooling efforts, which have been successful in other contexts and could dramatically simplify CRISPR licensing. Finally, the FDA may soon issue guidelines for human therapeutics, which could either fuel or dampen enthusiasm for CRISPR-based medicine. While many of these questions (and others) will likely remain at the end of 2018, what happens between now and then may fundamentally shape the evolution of what many consider to be one of the most important scientific discoveries of the twenty-first century.

#### Medical Innovation is ONLY Accessible Through Germline Edits

Sinha 22. (Sinha, [Rohit, Head of Cryptography at Swirlds Labs.] [ARK1] "A CRISPR Framework for Emerging Biotechnology Applications: A Proposal to Separate Science from Politics." *J. Health & Biomedical L.* 18 (2022): 142. https://heinonline.org/hol-cgi-bin/get\_pdf.cgi?handle=hein.journals/jhbio18&section=11. shARK)

The democratization of the CRISPR/Cas9 system paired with its fallibility may threaten the safety of society. Researchers Doudna and Charpentier recognize that there are errors associated with CRISPR/Cas9, although many other research scientists have declared that it is the quickest and most efficient of common genome-editing tools such as zinc-finger nucleases (ZFNs) and transcription activator-like effector nucleases (TALENs) (1081). The maximum efficiency for genetic engineering in humans, depending on target genes, is approximately 80%, which is higher than observed with other genome editing tools. However, the efficiency is still not high enough. Dr. Emily Leproust, an expert in synthetic biology and CEO of Twist Bioscience, states, “Critical to genome editing are precision and 100% guide representation. Precision (brought about by sequence accuracy of the guides) and effective guide representation are possible only through highly uniform synthesis” (34). CRISPR is also cheaper and easier to assemble than other gene editing tools; and its mechanisms are universal to organisms within all three domains of life (Doudna and Charpentier 1078). Some laboratory procedures using CRISPR/Cas9 techniques are reported to cost as little as $30 (Ledford 21). Its unprecedented affordability and ease of use incited what seemed instant discoveries in the field of genetic engineering. Alternatively, the fact that CRISPR/Cas9 is quick, easy, and affordable may also be the reason for serious mistakes because the system 20 Royal Road lacks the precision necessary for any real-world applications.

#### Innovation Occurs in Areas Without Bans

Yaeger 18 (Yaeger, Brianna. "When Innovation Exceeds Technological Capacity: A Moral Evaluation of CRISPR/Cas9’s Role in Genetic Engineering Research." (2018).<https://utampa.dspacedirect.org/bitstream/handle/20.500.11868/407/Yaeger_RoyalRoad_2_2018_A.pdf?sequence=1>. shARK.)

Incredibly, no one has disputed effective jurisdiction over the experimental use of the CRISPR system. Although officials have enacted countrywide bans in 40 nations, these restrictions are globally insignificant because the most progressive research in the human genetic engineering occurs in countries that lack any official ban—such as the United States and China (König 502-506). At present, valid concerns for genetic engineering with gene-editing tools such as CRISPR/Cas9 involve its democratization combined with its fallibility. The risks associated with these issues can manifest at any point in the near future, because legal interventions have yet to be made. In addition, the increasing use of CRISPR/Cas9 calls for legal intervention for the sake of impending issues, such as healthcare inequality and inevitably inspired nonmedical applications. The imminent problems contingent on CRISPR/Cas9’s popular use are anticipated to be palpable in the near future unless regulations are instituted for their effective prevention. This paper discusses some of the situational issues that the world is bound to deal with moving forward with the global democratization of CRISPR/Cas9.

### 2NC---Biotech IL

#### Bans impact Bio Techs ability to solve numerous impacts – GMO Crops Prove

Chui, Evers, & Zheng 20**. Chui**, Michael (Global Institute Partner at McKinsey and Comp. Leads research on the impact of information technologies and innovation on business, the economy, and society) Matthias **Evers** (is a senior partner in McKinsey’s Hamburg office and co-leads the firm’s global research and development work in the pharmaceutical and medical products practice., **and** Alice **Zheng**( s a consultant in the Silicon Valley office of McKinsey and Comp.). "How the bio revolution could transform the competitive landscape." *McKinsey Quarterly* 7 **(2020).** https://economicas.unsa.edu.ar/afinan/informacion\_general/lecturas\_recomendadas/lecturas/mckinsey\_how\_eng.pdf.shARK)

The rate at which biological opportunities enter the market will fluctuate sharply in response to regulatory pressures. Regional variations of regulation can have significant impact on the potential to scale and commercialize biological technologies.Companies will need to sharpen their capabilities for engaging with national and supranational agencies. Public opinion and perception can lead to regulation changes and are therefore vital factors in how the Bio Revolution proceeds. We have seen this pattern before, with the regulation of the first wave of genetically modified crops. The United States took a permissive regulatory stance, Europe put in place a near-total ban, and China recently came out somewhere in the middle by banning the farming of genetically modified crops but not the import of selected varieties of harvested genetically modified crops. Beyond general sentiment, trust is a critical factor. People must have a degree of trust in companies that propose to sequence and analyze a person’s genome, edit children’s genes, or connect to a brain–machine interface. Within consumer markets alone, as the mining of personal genetic data increases, businesses will need to understand the trade-offs between advancing commercial opportunities and protecting public and social welfare.14 For example, the data-sharing practices of some direct-to-consumer genetic-testing companies with pharma companies and app developers have been called into question by consumers and media, revealing just how precious trust is—and how easy it is to damage it with just a few poorly handled mistakes.

### 2NC---Biotech Impacts

#### The biochemical industry is k2 solve COVID-19 and all existential crisis

Steve Hedrick, 20, (Steve Hedrick, Steve Hedrick is the chairman &amp; CEO of MATRIC, a strategic research and development partner in the chemical, energy and environmental industries, as well as the advanced software space. MATRIC’s headquarters is in South Charleston., 4-17-2020, Charleston Gazette-Mail, Steve Hedrick: Innovation key to defeating pandemic (Opinion), https://www.wvgazettemail.com/opinion/op\_ed\_commentaries/steve-hedrick-innovation-key-to-defeating-pandemic-opinion/article\_9a5cf118-f9b4-5e2b-976a-7a0bb1f959d2.html, 6-24-2021) SCade

We’ve been forced to identify the difference between wants and needs for ourselves and others around us. We’ve realized what real needs are, such as life-saving tools and resources for front-line workers to help combat the coronavirus. From ventilators to surgical gowns to N95-equivalent masks to even hand sanitizer. There was and continues to be a need and demand for these items. Being a critical part of producing everyday essentials for people isn’t new to the chemical industry. Touching 96% of all manufactured goods, the chemical industry was deemed “essential critical infrastructure” by the U.S. Department of Homeland Security. Companies and leaders are stepping up to be part of the solution, donating money and supplies. Even more impressive is the companies finding ways to think and operate differently, to be a part of the solution in ways they never thought they would have to. Using critical-thinking skills in a different manner, they’ve developed new ways to continue operations, be it remotely or otherwise in some cases, to get the job done in the face of adversity. This demand — the need — to produce goods for a greater cause has induced wonderful innovation. It’s innovation at its finest. Innovation — thinking in new and different ways. Developing new processes. Identifying new products or services. Acting differently based on new inputs. Adapting a supply chain. Finding a way to be a part of the solution. The innovation occurring in the science, technology and manufacturing industries is for the good of all, and it’s inspiring to experience. It is occurring at a pace that, in recent years, has been stymied by lack of resources, possibly the lack of a true rallying need or by a thought process that was not driven to move with decisive speed and effect. The chemical and discreet manufacturing sectors, working in unison for a common purpose, are delivering needed goods they do not normally make, and they’re doing so at a staggering pace. Companies such as Dow are manufacturing much-needed hand sanitizer for emergency responders in a safe and environmentally sound manner by repurposing reaction trains that were never intended to manufacture this product. Companies like Eagle Manufacturing, part of the Justrite Safety Group, are working day and night to help deliver much-needed personal protective equipment in the form of masks to our National Guard. This is something they’ve never made before. And I’ve seen parts for face shields and masks being produced on 3D printers, something that would not have even been possible just a few short years ago. There are millions of other people and thousands of other companies making change happen to help us win against this unprecedented global crisis. And I am proud of the people who work at MATRIC, everyone from our most senior leaders to our newest hire. They refuse to stop asking the question, “How can we help?” Innovation matters to — and for — us all. Innovation in all its forms allows critical thinkers to make change, to deliver on need for mankind and to help us win. And let there be no doubt, our industry, our society, will do what we must do. We will win.

#### Stable U.S. ag key to prevent great power wars—multiple hotspots

Castellaw 17 (John – 36-year veteran of the U.S. Marine Corps and the Founder and CEO of Farmspace Systems LLC, “Opinion: Food Security Strategy Is Essential to Our National Security,” 5/1/17, https://www.agri-pulse.com/articles/9203-opinion-food-security-strategy-is-essential-to-our-national-security)

The United States faces many threats to our National Security. These threats include continuing wars with extremist elements such as ISIS and potential wars with rogue state North Korea or regional nuclear power Iran. The heated economic and diplomatic competition with Russia and a surging China could spiral out of control. Concurrently, we face threats to our future security posed by growing civil strife, famine, and refugee and migration challenges which create incubators for extremist and anti-American government factions. Our response cannot be one dimensional but instead must be a nuanced and comprehensive National Security Strategy combining all elements of National Power including a Food Security Strategy. An American Food Security Strategy is an imperative factor in reducing the multiple threats impacting our National wellbeing. Recent history has shown that reliable food supplies and stable prices produce more stable and secure countries. Conversely, food insecurity, particularly in poorer countries, can lead to instability, unrest, and violence. Food insecurity drives mass migration around the world from the Middle East, to Africa, to Southeast Asia, destabilizing neighboring populations, generating conflicts, and threatening our own security by disrupting our economic, military, and diplomatic relationships. Food system shocks from extreme food-price volatility can be correlated with protests and riots. Food price related protests toppled governments in Haiti and Madagascar in 2007 and 2008. In 2010 and in 2011, food prices and grievances related to food policy were one of the major drivers of the Arab Spring uprisings. Repeatedly, history has taught us that a strong agricultural sector is an unquestionable requirement for inclusive and sustainable growth, broad-based development progress, and long-term stability. The impact can be remarkable and far reaching. Rising income, in addition to reducing the opportunities for an upsurge in extremism, leads to changes in diet, producing demand for more diverse and nutritious foods provided, in many cases, from American farmers and ranchers. Emerging markets currently purchase 20 percent of U.S. agriculture exports and that figure is expected to grow as populations boom. Moving early to ensure stability in strategically significant regions requires long term planning and a disciplined, thoughtful strategy. To combat current threats and work to prevent future ones, our national leadership must employ the entire spectrum of our power including diplomatic, economic, and cultural elements. The best means to prevent future chaos and the resulting instability is positive engagement addressing the causes of instability before it occurs. This is not rocket science. We know where the instability is most likely to occur. The world population will grow by 2.5 billion people by 2050. Unfortunately, this massive population boom is projected to occur primarily in the most fragile and food insecure countries. This alarming math is not just about total numbers. Projections show that the greatest increase is in the age groups most vulnerable to extremism. There are currently 200 million people in Africa between the ages of 15 and 24, with that number expected to double in the next 30 years. Already, 60% of the unemployed in Africa are young people. Too often these situations deteriorate into shooting wars requiring the deployment of our military forces. We should be continually mindful that the price we pay for committing military forces is measured in our most precious national resource, the blood of those who serve. For those who live in rural America, this has a disproportionate impact. Fully 40% of those who serve in our military come from the farms, ranches, and non-urban communities that make up only 16% of our population. Actions taken now to increase agricultural sector jobs can provide economic opportunity and stability for those unemployed youths while helping to feed people. A recent report by the Chicago Council on Global Affairs identifies agriculture development as the core essential for providing greater food security, economic growth, and population well-being. Our active support for food security, including agriculture development, has helped stabilize key regions over the past 60 years. A robust food security strategy, as a part of our overall security strategy, can mitigate the growth of terrorism, build important relationships, and support continued American economic and agricultural prosperity while materially contributing to our Nation’s and the world’s security.

# AFF ANSWERS

### 2AC---BioPharma UQ

#### BioPharma is already prepared to deal with a regulatory environment from the FTC and Congress – current labor and supply shortages coupled with geopolitical tensions created tensions in the sector

Glenn Hunzinger and Roel Van Den Akker, June 2022, (Glenn Hunzinger and Roel Van Den Akker, Glenn is a Partner, Pharmaceutical and Life Sciences Consulting Solutions Leader, PwC US, Roel is Partner, PwC US., June 2022, PwC, Pharmaceutical life sciences: Deals 2022 midyear outlook, https://www.pwc.com/us/en/industries/health-industries/library/pharma-life-sciences-deals-outlook.html, 7-5-2022) SCade

All of the stars are aligned for there to be a flurry of deals activity across all areas of the sector despite the slow start to the year so far. Many large pharma players are flush with cash (particularly those that have COVID-19 treatments in their arsenal), biotech valuations have been normalizing after years of a boom market and the 2025 patent cliff is rapidly approaching, all making for a strong deal environment. Given the broader labor changes, supply shortages and constantly changing supply chain strategies and operations, the focus on quality can be challenging to sustain. Yet the downside can have massive impacts on businesses, including the potential inability to manufacture products. The long litany of macroeconomic and regulatory headwinds has CEOs looking for transactions that are easily integrated and will get cash off their balance sheet as inflationary pressures mount. Pharmaceutical & life sciences deals outlook Increased scrutiny from the US Federal Trade Commission (FTC) around larger deals could mean that 2022 will be a year of bolt-on transactions in the $5 to $15 billion range as pharma companies take multiple shots on goal in order to make up for revenues lost to generic competition in the remainder of the decade. However, don’t rule out the potential for larger deals ⁠— consolidation is good for the health ecosystem and drives broader efficiency. Expect to see big pharma picking up earlier stage companies to try and fill the pipeline gaps that are likely to start in 2024. While market conditions suggest bargain prices for biotech are possible, recent transactions indicate that pharma companies are still paying significantly above current trading prices (ranging from approximately 50 to 100% of current trading), but below the peak valuations of recent memory. In the first few months of the year, semi-annualized deal value was down 58% from the same period last year, with companies investing just $61.7 billion so far. Only 137 deals were announced during that time, compared to 204 in the year-prior period. Talk of drug pricing regulations continues in Washington as Congress bats around a pared down version of the Build Back Better plan. Expect some of that tension to ease in the fall if a new Congress takes on a different agenda. Other areas of the sector like medical devices face similar headwinds from regulators, and continue to deal with a greater impact from semiconductor shortages. Even though semi-annualized deal value in the medical device space is down 85% from the same period the prior year, expect these companies to remain focused on M&A as the subsector searches for alternative forms of revenue ⁠— particularly from new consumer-centric technologies. Macroeconomic headwinds and geopolitical tensions have created volatility in spending at CDMOs and CROs, limiting their willingness to deploy capital as the uncertainty persists.

#### The Pharma subsector isn’t doing any better – but their main profits are drugs

Glenn Hunzinger and Roel Van Den Akker, June 2022, (Glenn Hunzinger and Roel Van Den Akker, Glenn is a Partner, Pharmaceutical and Life Sciences Consulting Solutions Leader, PwC US, Roel is Partner, PwC US., June 2022, PwC, Pharmaceutical life sciences: Deals 2022 midyear outlook, https://www.pwc.com/us/en/industries/health-industries/library/pharma-life-sciences-deals-outlook.html, 7-5-2022) SCade

Pharma

Deal activity in the pharma space is down by 30% on a semi-annualized basis. Yet, deal values have dropped about 50% in that time period, reflecting pharma’s appetite for smaller deals around a single asset or bolt-on deals, as the industry attempts to stay below the radar of regulators at the FTC. Like most other sectors, pharma continues to experience labor shortages, supply chain snags and higher input costs ⁠— particularly around packaging ⁠— due to inflationary pressures. In an effort to stay nimble in a rapidly changing environment, pharma companies are re-examining capital allocation strategies, as well as considering alternative options for their supply chains. Even as uncertainty persists, expect pharma to focus on inorganic growth ahead of some of the world’s largest drugs going off patent later this decade.

#### Biotech peaked and is coming down now – HARD

Glenn Hunzinger and Roel Van Den Akker, June 2022, (Glenn Hunzinger and Roel Van Den Akker, Glenn is a Partner, Pharmaceutical and Life Sciences Consulting Solutions Leader, PwC US, Roel is Partner, PwC US., June 2022, PwC, Pharmaceutical life sciences: Deals 2022 midyear outlook, https://www.pwc.com/us/en/industries/health-industries/library/pharma-life-sciences-deals-outlook.html, 7-5-2022) SCade

Biotech

The XBI biotechnology index hit a peak in January 2021, outpacing the S&P 500, but has been on the decline since with more than 60 biotechs announcing layoffs in 2022 so far and several announcing they are closing their doors for good. There were 104 biotech IPOs in 2021 that raised nearly $15 billion in funds, while 2022 has seen only 14 IPOs raising less than $2 billion collectively. While biotech executives have been slow to accept lower valuations, Pfizer’s recently announced acquisition of Biohaven and GlaxoSmithKline’s announced deals with Sierra Oncology and Affinivax suggest more companies are willing to explore alternative means of financing as capital becomes harder to come by.

#### Biopharma is doing poorly now – Congress and rapidly changing regulatory environment – the aff is a drop in the bucket

Investors Business Daily, 22, (Investor'S Business Daily, 7-1-2022, Investor's Business Daily, Biotech Stocks To Watch: Track The Latest News On Pharmaceutical Stocks And Drug Companies, https://www.investors.com/news/technology/biotech-and-pharma-industry-and-stock-news-merk-bristol-myers-amgn-gilead/, 7-5-2022) SCade

One minute Dow Jones industrial average component Merck (MRK) might be doing battle with fellow drugmaker Bristol Myers Squibb (BMY) over drugs that can ward off cancer. The next, biotech giants like Amgen (AMGN) and Sanofi (SNY) are tussling in court over the fate of cholesterol-busting drugs. Meanwhile, a company like Gilead Sciences (GILD) might be raked over the coals in Congress for charging $1,000 a day to treat hepatitis. It's a brave — and contentious — new world for pharmaceutical and biotechnology companies. It's a realm where science is trying to develop landmark medicines that cure cancer. Think Novocure (NVCR), hepatitis and other life-threatening illnesses. All the while it does a delicate dance with Wall Street and regulators — balancing public health issues with the demands of shareholders. Investors will find it tricky to navigate the sector, as companies can rise and fall at the drop of a hat.

#### The merge of biotech and big pharma hurts innovation

Tracy Staton, Aug 30, 2016 10, Tracy Staton is the editor of FiercePharma and FiercePharmaMarketing. She has been a freelance writer for 8 years. Before that, she served as editor of the Dallas Business Journal, editor of Texas Business magazine, and a senior editor at American Way, the inflight magazine of American Airlines. She is based in Vermont and can be reached at tracy@fiercemarkets.com, or find her on LinkedIn."It's official: Pharma mergers hurt innovation, and not only for the dealmakers", Fierce Pharma, https://www.fiercepharma.com/pharma/it-s-official-pharma-mergers-hurt-innovation-and-not-only-for-dealmakers, 7-4-2022, //ms

Pharma mergers might boost short-term profits. But long-term value? Think again, because everyone knows that big mergers hurt innovation. That’s the claim, at least, repeated by critics every time a major pharma combo hits the news. Problem is, those complaints tend to be based on anecdotal evidence, from scientists who’ve seen their work hit the slough of despond as one big R&D operation integrated with another. But now, the Harvard Business Review has some [empirical](https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge) [evidence](https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge). Two researchers from the Institute for Competition Economics in Germany set out to address drug mergers from an antitrust perspective. All well and good for competition watchdogs to look at overlaps in companies’ marketed products and pipelines, they figured. What about the drugs that might have The researchers analyzed 65 pharma deals, comparing the participating companies before and after they combined. They also analyzed companies that were developing drugs in similar therapeutic areas, but hadn’t merged. “Our results very clearly show that R&D and patenting within the merged entity decline substantially after a merger, compared to the same activity in both companies beforehand,” the authors, Justus Haucap and Joel Stiebale, wrote in the HBR. That’s to be expected, the authors posit, because merger-minded companies often target rivals with similar pipeline assets, to gain strength in particular drug markets. But here’s what else the authors found: “On average, patenting and R&D expenditures of non-merging competitors also fell--by more than 20%--within four years after a merger. Therefore, pharmaceutical mergers seem to substantially reduce innovation activities in the relevant market as a whole." Haucap and Stiebale’s [paper](https://ideas.repec.org/p/zbw/dicedp/218.html) includes patent counts and R&D spending numbers, and they conclude that “innovation output” by the merged company decreases, on average, by more than 30%. Among the merged company’s competitors, output declined by 7%, on average, they found. The men’s research “is the first to show that there are follow-on effects across the industry,” [wrote](http://blogs.sciencemag.org/pipeline/archives/2016/08/24/drug-mergers-hurt-in-every-direction-save-one) Derek Lowe at In The Pipeline, which has sliced and diced pharma M&A for years. “Inside the merged companies, there’s a great deal of disruption, as many readers here can testify,” Lowe wrote. “But across the industry as a whole, things get less competitive the fewer players there are and the fewer the approaches being tried.” As for the business effects? Profitability increased post-merger, for the merged companies and for their competitors, too. For the merged company, the profits may depend on cost cuts; in integrating, the post-merger company “decreases its scale” compared to the two merger partners, pre-acquisition. For “non-merging rivals,” profits tended to grow on increased sales. “What we have, then, is probably a perverse incentive--companies can improve their numbers by doing mergers and acquisitions, but that very activity hurts their long-term prospects and those of the entire industry,” Lowe observes. McKinsey & Co. analysts [emphasized](http://www.fiercepharma.com/m-a/thumbs-up-or-down-on-megamergers-depends-on-your-point-of-view) the “shareholder value” effects of megamergers in a 2014 study, and they found that, reductively speaking, the deals worked. Lowe picked apart that research, as did ex-Pfizer R&D chief John LaMattina, who wrote up his own [rebuttal](http://www.forbes.com/sites/johnlamattina/2014/02/24/mckinseys-view-that-pharma-megamergers-work-is-short-sighted/?partner=yahootix) in Forbes, enumerating the many ways repeated megamergers sap the life out of research, as focus and energy go into logistical decisions, layoff worries, and the like--and away from science.\

#### Trends prove that the chemical industry’s fate is sealed

Ge Digital, 2021, (Ge Digital, 2021, General Electric, The Future of the Chemical Industry, https://www.ge.com/digital/blog/future-chemical-industry, 6-25-2021) SCade

Four chemical industry trends to watch There are four broad trends currently defining the chemical industry, each affecting a different element of business, from operations through production and compliance.

Mergers and acquisitions: The last couple of years saw notable consolidation in the form of multiple mergers and acquisitions. A result of slow overall industry growth and a desire to consolidate resources and capabilities in the areas with the most promising growth, M&A is also being driven by growing pressure to gather the resources needed for digital transformation. Mega mergers are radically altering the top of the industry­­–a fact that has not escaped the attention of farmers, legislators, and regulatory bodies.

A new regulatory environment: Governments and regulatory bodies around the world are overhauling chemical regulations for the first time in decades. Both environmental and industry groups note that these changes could signal a kind of détente between the chemical industry and its watchdogs over the next few years. In other parts of the world, however, the relationship between the industry, activist groups, and regulatory bodies remains more acrimonious.

Investment: After decades of taking a back seat to emerging markets, North America saw a significant wave of investments in new multi-billion-dollar production facilities from a number of chemical manufacturers. Factors involved in this growth include the considerable size and strength of the regional market, and favorable political and regulatory environments in American states with significant chemical production segments.

Digital transformation: Rising demand and growing competition have increased the pressure on all chemical manufacturers to adopt advanced technologies and transform their operations and structures. Improved efficiencies, safety, and reliability can be realized through implementation of advanced technology–all of which can reduce costs for the manufacturer. These transformations are also enabling new business models that could bring chemical manufacturers closer to their suppliers, their direct customers, and even their end customers.

### 2AC---BioPharma Link D

#### still can use CRISPR for other editing and advances.

Gregory E. Kaebnick is a research scholar at The Hastings Center and the editor of theHastings Center Report. A Moratorium on Gene Editing? March 27 2015 https://www.thehastingscenter.org/a-moratorium-on-gene-editing/

CRISPR/Cas9 can be turned to many other uses than editing the human germline, however. One of the most extraordinary is the possibility of using it in “gene drives” that could be make genetic modifications to sexually reproducing populations of microorganisms, animals, or plants. Sexually reproducing organisms have two sets of gene—one from each parent. A gene drive is a set of genes that, if it is inserted into one set, will get itself copied to the appropriate location on the other set, replacing any competing genes and also ensuring that all of the organism’s offspring receive the drive. Within those offspring, the drive will again replace any competing genes, ensuring that all of the next generation receives the gene. If a species reproduces rapidly, it might be possible to quickly alter the whole species. Mosquitoes could be altered so that they can no longer transmit malaria or dengue, for example.

#### no link- ban doesn’t apply to research uses or somatic editing.

Lander, et.al. 2019 Eric S. Lander , Françoise Baylis , Feng Zhang , Emmanuelle Charpentier , Paul Berg , Catherine Bourgain , Bärbel Friedrich , J. Keith Joung , Jinsong Li , David Liu , Luigi Naldini , Jing-Bao Nie , Renzong Qiu , Bettina Schoene-Seifert , Feng Shao , Sharon Terry , Wensheng Wei & Ernst-Ludwig Winnacker 13 March 2019 Adopt a moratorium on heritable genome editing https://www.nature.com/articles/d41586-019-00726-5

To be clear, our proposed moratorium does not apply to germline editing for research uses, provided that these studies do not involve the transfer of an embryo to a person’s uterus. It also does not apply to genome editing in human somatic (non-reproductive) cells to treat diseases, for which patients can provide informed consent and the DNA modifications are not heritable.

### 2AC---BioPharma IL Defense

#### BioPharma bad – high profits are a result of price gouging drugs and tax credits. Innovation doesn’t happen in big pharma now.

Abbey Meller and Hauwa Ahmed, 8-30-2019, Abbey Meller is an organizing associate for Democracy and Government at the Center for American Progress. Hauwa Ahmed is a research assistant for Democracy and Government at the Center. "How Big Pharma Reaps Profits While Hurting Everyday Americans", Center for American Progress, https://www.americanprogress.org/article/big-pharma-reaps-profits-hurting-everyday-americans/, 7-3-2022, //ms

It’s no secret that the Trump administration has fostered a culture of corruption in which special interests and big donors advance their interests at the expense of everyday people. Perhaps no policy area exemplifies this corruption more than the issue of drug pricing. President Trump has long promised to stand up to the pharmaceutical industry and lower prescription drug prices, but he has avoided taking serious action to drive down prices while at the same time filling top spots in his administration with industry insiders. This administration’s culture of corruption, which continues a decadeslong practice of political pandering to the pharmaceutical industry, carries a real cost; Americans spent $535 billion1 on prescription drugs in 2018, an increase of 50 percent since 2010. These price increases far surpass inflation, with Big Pharma increasing prices on its most-prescribed medications by anywhere from 40 percent to 71 percent from 2011 to 2015.2 Moreover, pharmaceutical companies receive substantial U.S. government assistance in the form of publicly funded basic research and tax breaks, yet they continue to charge exorbitant prices for medications. But the issue goes beyond cost. In America, more than 1 million individuals suffer from Type 1 diabetes3, a condition where the body cannot make insulin, which is essential for getting glucose (also known as blood sugar) into cells from the bloodstream. Without insulin, glucose accumulates in the bloodstream4, causing dangerously high blood sugar levels. Among all Americans suffering from diabetes, at least 1 in 45 have said that they engaged in insulin rationing—a tactic of using less insulin than is needed in order to make the doses last longer—as a direct result of the skyrocketing price of the drug. A vial of insulin, which is the only life-sustaining option for Type 1 diabetics, retails at around $300.6 A 2018 study commissioned by the Congressional Diabetes Caucus found that the price of insulin has doubled since 20127; in the 10 years prior, the price of insulin nearly tripled. Despite the dangers of insulin rationing, which can lead to diabetic ketoacidosis, a fatal condition, many Americans have no other choice. That was the case for Antroinette8, whose daughter was rationing insulin due to the high cost and died at the age of 22 as a result. Insulin facts Access to insulin for patients with Type 1 diabetes is a matter of life or death.9 While insulin has existed since the1920s10, the price since then has skyrocketed, especially in recent years. Prices for insulin increased by 197 percent between 2002 and 2013, from $4.34 per milliliter to $12.92 per milliliter.11 There are three insulin manufacturers serving the United States: Eli Lilly and Co., Novo Nordisk A/S, and Sanofi SA. Eli Lillyannounced12 in March 2019 that it would begin selling a generic version of its Humalog insulin at half the price. The medication, known as lispro, will cost $137.35 per vial. To compare pricing, a 2018 study13 estimated that the cost of making a year’s worth of insulin for one patient ranges from $78 to $133. Ahead of its hearing on drug pricing in February 2019, the U.S. Senate Committee on Finance sent aletter14 to Eli Lilly asking why insulin is priced so astonishingly high. A vial of NovoLog, one type of insulin, costs15 anywhere from $14 to $300 in the United States but only $48 in Singapore, $14 in India, $6 in Austria, and $0 in Italy. American taxpayers fund basic research Billions of taxpayer dollars go into the creation and marketing16 of new drugs. The Los Angeles Times reports that, “Since the 1930s, the National Institutes of Health has invested close to $90017 billion in the basic and applied research that formed both the pharmaceutical and biotechnology sectors.” Despite taxpayers’ crucial investment, U.S. consumers are increasingly paying more for their prescription drugs. A 2018 study18 on the National Institute of Health’s (NIH) financial contributions to new drug approvals found that the agency “contributed to published research associated with every one of the 210 new drugs approved by the Food and Drug Administration from 2010–2016.” More than $100 billion in NIH funding went toward research that contributed directly or indirectly to the 210 drugs approved during that six-year period. The NIH Research Project Grant (R01)19—which supports health-related research—was by far the most common kind of grant used to fund the science that supported the new drugs. In all, NIH gave out nearly 118,00020 R01 grants related to those drugs from 2010 to 2016. Federal perks for Big Pharma add up Pharmaceutical companies also benefit from research and development tax credits. The federal R&D tax credit was first introduced in 1981 to encourage private sector investment in pioneering research.21 This tax credit is available to businesses that attempt to develop new, improved, or technologically advanced products or trade processes.22 In 2015, former President Barack Obama signed into law the Protecting Americans from Tax Hikes Act23, which made these tax credits permanent and extended them to small businesses and startup companies. Pharmaceutical industries also receive a tax deduction for their marketing and advertising expenses. According to a report in the Journal of the American Medical Association, “From 1997 through 2016, medical marketing expanded substantially, and spending increased from $17.7 to $29.9 billion,24 with direct-to-consumer advertising for prescription drugs and health services accounting for the most rapid growth, and pharmaceutical marketing to health professionals accounting for most promotional spending.” The report also found that from 1997 through 2016, “the number of advertisements … increased from 79,000 (including 72,000 television commercials) in 1997 to 4.6 million (663,000 television25 commercials) in 2016.” Big Pharma’s drug pricing maximizes profits Despite these taxpayer subsidies, prescription drug prices are nonetheless increasing at an alarming rate. In 2019, price increases from drug manufacturers affected more than 3,40026 drugs. For example, Allergan, a major pharmaceutical manufacturer, raised prices on 51 drugs, just more than half its portfolio. Some medications that Allergan manufactures saw a 9.5 percent jump in cost, while others saw a 4.9 percent increase in cost.27 Teva Pharmaceutical Industries Ltd., the largest generic drug manufacturer in the world, increased its drug prices by more than 9 percent.28 These sharp increases in price occur as companies continue to report millions of dollars in revenue. In 2018, Allergan reported $15.8 million29 in revenue, while Teva Pharmaceuticals reported $18.8 million30 in revenue. Pharmaceutical companies’ profit margins receive significant bumps when they launch new drugs, specifically specialty drugs, used to treat life-threatening conditions. These drugs often cost more than most Americans can afford. Pharmaceutical companies have stated that the prices are high because the drugs are difficult to manufacture. In 2013, for example, industry giant Gilead Sciences launched Sovaldi, a hepatitis C drug, at $1,000 per pill31, or $84,00032 per treatment, which could last 12 to 24 weeks.33 After an 18-month investigation into the company’s pricing, the Senate Finance Committee concluded that Gilead had pursued a marketing and pricing strategy designed to “maximize revenue with little concern for access or affordability.”34 Drug companies also benefit from patents, which give them monopoly power for their on-patent products. These patents ensure that prices remain high by reducing competition. Drug patents last for 20 years after the filing date. Pharmaceutical companies have also employed tactics such as evergreening and thicketing to prolong a drug’s exclusivity. When evergreening, pharmaceutical companies make certain modifications to a drug such as changing its35 chemical composition slightly or making an external change as minor as adding a stripe to a pill36 in order to preserve their patents. A 2018 study in the Journal of Law and the Biosciences found that 78 percent37 of new drug patents awarded in the past decade went to drugs that already existed. Seventy percent 38 of the nearly 100 bestselling drugs extended their exclusivity protections at least once, and 50 percent extended their patents more than once. The second tactic—thicketing—involves flooding the U.S. Patent and Trademark Office and the courts with excessive patents and applications to make it difficult for competing firms to secure patents. These tactics help preserve pharmaceutical companies’ monopolies and ensure that drug prices remain uncompetitive and thus less affordable for everyday Americans. While consumers continue to pay the price of this market manipulation, a Government Accountability Office (GAO) report on the pharmaceutical industry found that these unfair practices are significantly enriching manufacturers. As the report stated, “Among the largest 25 companies, annual average profit margin fluctuated between 15 and 20 percent.”39 The GAO contextualizes these profits by comparing the pharmaceutical industry’s profits with those of its counterparts, stating that “the annual average profit margin across non-drug companies among the largest 500 globally fluctuated between 4 and 9 percent.” In 2018 alone, the CEOs of major pharmaceutical companies Allergan, Johnson & Johnson, and Pfizer Inc. made a total of $90 million.40 Meanwhile, according to a CBS News report, Americans spent $535 billion41 on prescription drugs in 2018—an increase of 50 percent since 2010.42 As pharmaceutical industry profits increase43, everyday Americans—whose tax dollars play a critical role in funding the research and development of these medications—are not receiving anything close to a fair return on their investment. A recent Pew Charitable Trusts study found that Americans spent $65.8 billion44 out of pocket in 2016 for retail prescription drugs, up from $59.5 billion in 2012. The high cost of prescription drugs is a significant driver of medical debt45 because Americans are increasingly reliant on medication to manage long-term chronic conditions.46 Additionally, the high cost of prescription drugs has forced many Americans to take drastic measures, including foregoing taking their medications as prescribed or traveling abroad in order to save on medications. A 2019 Centers for Disease Control and Prevention study found that 11.4 percent47 of adults aged 18 to 64 did not take their prescription drugs as prescribed in order to reduce how much they spent on their medications. And, as NPR recently reported, “The U.S government estimates that close to 1 million48 Americans in California alone go to Mexico annually for health care, including to buy prescription drugs.” In May 2019, a group of Americans49 living with Type 1 diabetes traveled to Canada to purchase insulin and call on the U.S. government to regulate the cost of lifesaving drugs. The costs associated with traveling abroad make it logistically and financially impractical for most Americans. Further, traveling abroad presents certain health risks given that some countries have lax drug certification standards compared with FDA standards. President Trump’s broken promises on drug pricing In an interview with Time magazine ahead of being chosen as its Person of the Year in 2016, Trump said, “I’m going to bring down drug prices. I don’t like what’s happened with drug prices.”50 He promised to bring Americans’ drug spending down to $0 by negotiating drug prices.51 Trump made grandiose promises on drug pricing but almost three years later has only managed to deliver a handful of half-measures, illustrating his administration’s lack of commitment to lowering drug prices. One of Trump’s proposals from his so-called presidential blueprint52 included eliminating some rebates paid by drug companies53 that hide the true cost of drugs. However, the Congressional Budget Office estimated that the measure would actually increase federal spending on Medicare and Medicaid by $177 billion.54 The Trump administration also announced a regulation that would require TV ads for drugs to include the list price.55 Some experts believe this policy will be ineffective56 at making pharmaceutical companies lower list prices or end price hikes for drugs and will only confuse or mislead consumers rather than help them.57 These half-measures, combined with Trump surrounding himself with high-level Big Pharma officials, clearly communicates that the administration is not on track to lower drug costs for Americans. Congress has done little to address the problem of high drug prices. Instead, many members continue to enjoy cozy relationships with the pharmaceutical industry. The industry spent more than $62 million in the 2016 congressional elections—the most it has ever spent on political campaigns.58 The massive influx of campaign cash benefited members of both parties, including those that sit on committees with jurisdiction over drug pricing.59 Big Pharma’s investment has paid off as recently as July 2019, when the Senate Finance Committee failed to pass an amendment on the Prescription Drug Pricing Reduction Act of 2019, which would have allowed Medicare to negotiate drug prices with manufacturers.60 Medicare’s ability to negotiate on drug prices, which is currently prohibited by law, “would provide the leverage needed to lower drug costs.”61 Despite his promise to be tough on Big Pharma, President Trump has proven to be a friend to the industry. Big Pharma officials have filled at least 1662 current or former positions in the Trump administration, and many of Trump’s top health advisers have been industry insiders or close to the pharmaceutical companies. Trump’s first secretary of health and human services, former Rep. Tom Price (R-GA), was a longtime friend of the industry63 in Congress, where he not only pushed Big Pharma’s agenda but also benefited from it financially.64 Price, who drew scrutiny for more than $300,000 in health care stock trades, was eventually forced to resign in 201765 as a result of his illicit use of private jets on the taxpayers’ dime. In 2017, Trump nominated Joe Grogan66 to a top position at the U.S. Office of Management and Budget. Grogan spent five years as a lobbyist for Gilead—the pharmaceutical company that is infamous for its sky-high prices on a cure for hepatitis C.67 Since joining the administration, Grogan has led drug-pricing proposals and participated in Trump’s Drug Pricing and Innovation Working Group.”68 However, the working group has proposed pharma-friendly measures such as implementing monopoly rights outside of the United States, speeding up approval from the FDA for new drugs, and eliminating price cuts for hospitals in impoverished areas. President Trump chose to replace Price with Alex Azar, the former president of Eli Lilly—one of the companies that is working to keep drug prices high while everyday Americans suffer—to oversee his efforts to address drug pricing as secretary of health and human services. In 2018, pharmaceutical companies spent more than $283 million in lobbying dollars69, with Eli Lilly spending just less than $6.8 million in 2018.70 While Azar, Trump’s chief health adviser, was president of Eli Lilly, the company drastically increased insulin prices. Eli Lilly is currently defending itself against a class-action lawsuit71 accusing the company of colluding with pharmacy benefit managers—individuals who negotiate drug pricing and availability with drug companies for the government and other insurance plans—to increase prices. Big Pharma and pharmacy benefit managers have been playing a blame game72 while lawmakers—who have held several hearings in the U.S. House of Representatives73 and the U.S. Senate74—try to find the source of America’s drug pricing problem. Given the sway that Big Pharma has with the administration, the industry has no plans to reduce prescription drug prices or reverse past price gouging. For his part, President Trump tried but failed to pass the American Health Care Act of 2017, which would have hurt millions of Americans while benefiting the pharmaceutical industry, among others. However, he was successful in signing into law a new tax bill that lowered the corporate tax rate by 14 percent, allowing pharmaceutical companies, including those with ties to the Trump administration, to save a total of $76 billion.75 After the tax law was enacted, Eli Lilly received a tax cut of nearly $4.5 billion on offshore profits.76 Instead of using these tax savings to lower drug prices, big pharmaceutical companies such as Eli Lilly together used $45 billion of their total tax savings77 to benefit shareholders via stock buyback programs. After President Trump helped Eli Lilly save billions, Azar, the company’s top executive, was confirmed to head the U.S. Department of Health and Human Services78 at the beginning of the following year. Conclusion Although the Trump administration keeps promising to lower drug prices, drug costs continue to climb as Americans suffer and pharmaceutical companies profit and their CEOs line their pockets. The government-funded research and major tax benefits that these pharmaceutical companies enjoy help them stay profitable. Meanwhile, they continue to hike up the costs of drugs, particularly life-sustaining drugs such as insulin. Big Pharma can play this game indefinitely, benefiting from this culture of corruption, using allies in the administration and in Congress to grow their profit margins while everyday people suffer. But there are steps lawmakers can take to reduce the influence of special interests, including Big Pharma.79 For example, lobbyists are currently allowed to fundraise for candidates for federal office—and many of them provide far more financial support beyond the $2,800 per candidate limit by hosting fundraising events and bundling contributions. Banning lobbyists from fundraising80 for candidates would reduce special-interest influence over the legislative process. Another way to limit corrupting conflicts of interest is to ban members of Congress from accepting campaign donations from entities under the jurisdiction of the committees on which the serve. It is understood that conflicts can easily arise from committee contributions, which explains why 88 percent of voters support this prohibition.81 Additionally, Washington’s infamous revolving door between private industry and government must be closed. Proposals to do so include a lifetime lobbying ban on members of Congress and a five-year lobbying ban on senior congressional staffers.82 As Americans are caught trying to decide whether to pay for rent or medicine, pharmaceutical companies continue to reap government benefits. Reducing drug prices and the costs that everyday people must pay is not possible without fixing the broken system in Washington.

### 2AC---Food Defense

#### No food wars

Vestby et al. 18 – Jonas, Doctoral Researcher at the Peace Research Institute Oslo, Ida Rudolfsen, doctoral researcher at the Department of Peace and Conflict Research at Uppsala University and PRIO, and Halvard Buhaug, Research Professor at the Peace Research Institute Oslo (PRIO); Professor of Political Science at the Norwegian University of Science and Technology (NTNU); and Associate Editor of the Journal of Peace Research and Political Geography. “Does hunger cause conflict?”, <https://blogs.prio.org/ClimateAndConflict/2018/05/does-hunger-cause-conflict/>, 05-18-2018

It is perhaps surprising, then, that there is **little scholarly merit** in the notion that a short-term reduction in access to **food increases the probability that conflict** will break out. This is because to start or participate in violent conflict requires people to have both the means and the will. Most people on the **brink of starvation are not in the position to resort to violence**, whether against the government or other social groups. In fact, the urban middle classes tend to be the most likely to protest against rises in food prices, since they often have the best opportunities, the most energy, and the best skills to coordinate and participate in protests.

Accordingly, there is a **widespread misapprehension** that social unrest in periods of high food prices relates primarily to food shortages. In reality, the sources of discontent are considerably **more complex** – linked to **political structures**, **land** ownership, **corruption**, the desire for **democratic reforms** and general **economic problems** – where the price of food is seen in the context of general increases in the cost of living. Research has shown that while the international media have a tendency to seek simple resource-related explanations – such as drought or famine – for conflicts in the Global South, debates in the local media are permeated by more complex political relationships.

#### Worst case, fast government response stops collapse.

OECD ’21 [October 19; OECD, “Keep calm and carry on feeding: Agriculture and food policy responses to the COVID-19 crisis,” <https://www.oecd.org/coronavirus/policy-responses/keep-calm-and-carry-on-feeding-agriculture-and-food-policy-responses-to-the-covid-19-crisis-db1bf302/>;]

Despite significant disruption to the agriculture and food supply chains, particularly in the first half of 2020, most sector shocks were absorbed rapidly, with trade and markets recovering during the year. Average gross farm receipts for OECD and emerging economies actually increased in 2020, and the sector was the best performing or least affected economically in several countries. At the same time, restricting measures impacted the food security of many low income or unemployed consumers.

This relative economic resilience of the agriculture and food sector was largely due to sector specific policy measures undertaken by governments in response to the COVID-19 pandemic and associated restrictions. Many governments moved swiftly to keep agricultural supply chains functioning, including by designating agriculture and food as an essential sector and by ensuring international co-operation to limit trade disruptions.

An estimated 776 unique policy response measures were adopted by governments of 54 OECD and emerging economies in 2020. These measures were widely diverse, highlighting the breadth and responsiveness of public actions to address the impact of the crisis. Close to 20% of the total were urgent measures, adopted in order to contain the pandemic while keeping food and agriculture supply chains working. Just under 70% of measures took the form of temporary relief, seeking to contain the impact of the crisis on agriculture and food sector actors, and should be phased out as the crisis recedes. Most of the remaining measures (10%) were “no regrets” policies with the potential to improve the long-term resilience of the agro-food sector, and which have the potential to be scaled up further. At the same time, 11% of measures had the potential to distort markets or be harmful to the environment.

A first assessment of budgetary expenditures in response to the COVID-19 crisis suggests that a minimum of USD 157 billion was earmarked in funding or offered in financing means to the sector in 2020, including USD 75 billion in OECD countries and USD 82 billion in emerging economies. Actual disbursements have so far been lower, partly reflecting the overall resilience of agriculture to the COVID-19 shock, and the fact that recovery packages in several countries include multi-year investments.

#### --Ukraine thumps

Welsh 02-26 – Caitlin, Director, Global Food Security Program. “Putin’s War of Choice Threatens Food Security Worldwide”, Center for Strategic and International Studies, <https://www.csis.org/analysis/putins-war-choice-threatens-food-security-worldwide>, 02-26-2022

The blood on Putin’s hands is not only from Ukraine and Russia, but from countries around the world that rely on imports for their food security. The consequences of Putin’s war will play out in regions already experiencing acute food insecurity and in food-importing countries that are most vulnerable to supply shocks and price increases. Buried in today’s headlines, an underreported reality is that global food insecurity is already at a 10-year high. Prior to Russia’s invasion of Ukraine, the follow-on effects of the pandemic—lost jobs and wages, supply chain disruptions, food price volatility—pushed the number of food-insecure people to record levels. This spike in food insecurity happened despite ample global food stocks and record-low fuel prices. Russia’s invasion has put global stocks of grains and oilseeds into question and caused energy prices to soar, throwing fuel onto the fire and risking pushing food insecurity skyward. Shocks to global agriculture markets can reverberate worldwide. In 2007 and 2008, decreases in production from major producers—Australia, Myanmar, Russia, and others—led to price increases and riots from Haiti to Cote d'Ivoire to nearly 40 other countries. Today, decreases in the global stocks of wheat and other grains and oilseeds from Ukraine and Russia could exacerbate ongoing crises in Afghanistan, Syria, Ethiopia, and other hotspots and aggravate instability in Egypt, Lebanon, and Syria. Among Ukraine’s major wheat buyers, almost half already experience acute food insecurity; particularly vulnerable to a decrease in Russian wheat supply are its purchasers across Asia and Africa.

#### Increased food production is bad – more likely to cause conflict

Ore Koren, 16, (Ore Koren, Ore Koren is a PhD candidate at the University of Minnesota and a Jennings Randolph Fellow at the United States Institute of Peace., 11-23-2016, Washington Post, Food scarcity causes conflicts — but so can food abundance. Here’s why., https://www.washingtonpost.com/news/monkey-cage/wp/2016/11/23/food-scarcity-causes-conflicts-but-so-does-food-abundance-heres-why/, 6-28-2021) SCade

How can an abundance of food lead to war? Food scarcity, however, is only one aspect of food security. Whether people have easy access to food resources is also important. So even in countries where plenty of food is available, a large share of the population might still go hungry. As Nobel Laureate Amartya Sen notes, “Starvation is the characteristic of some people not having enough food to eat. It is not the characteristic of there being not enough food to eat.” Grievances over food and the necessity to secure access to food resources can motivate marginalized groups to participate in rebellions and wars. A number of scholars are researching how inequitable access to food affects violence within the state. As Ben Bagozzi and I show in a recent paper, armed actors worldwide are motivated to fight over local food resources. Here’s why these conflicts tend to happen in regions with more food crops, not less. For rebel groups, securing — and controlling — food resources is vital for the insurgency to advance. And when the government is slow or unable to supply combat rations, state forces also may be forced to extract food supplies from the local population, So scarce food resources in a region locked in conflict act as both fuel and reward for hungry combatants. Access to more local food resources, especially in the case of rebel groups, can also be used to attract recruits, as happened in Sierra Leone and Somalia. Regions where wheat and barley are grown are also an important source of support for the Islamic State in Iraq and Syria. The focus on how the demand for food resources influences armed conflict complements the research done on the effects of food scarcity. It also explains why agricultural areas see more violence. In these regions, individuals live largely on locally grown food. If the government’s safety nets are mismanaged or weak, those who control access to food can more easily recruit individuals and operate for a longer period of time. And this also explains why there is an uptick in violence during times of more rainfall — for instance, in sub-Saharan Africa. By providing armed groups with an added motivation to fight as well as the ability to expand their numbers and strength, local food security can therefore shape global conflict patterns.