**SO21 – DA – Innovation (1:05-1:15)**

**Pharma innovation is strong now – patent incentives are key to maintaining progress, Austin and Hayford 21:**

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At a Glance This report examines research and development (R&D) by the pharmaceutical industry. Spending on R&D and Its Results. **Spending on R&D and the introduction of new drugs have both increased in the past two decades.** In 2019, the **pharma**ceutical industry **spent $83 billion dollars on R&D.** Adjusted for inflation, **that** **amount is about 10 times what the industry spent per year in the 1980s**. Between 2010 and 2019, the number of **new drugs approved** for **sale increased by 60 percent** compared with the previous decade, with a peak of 59 new drugs approved in 2018. Factors Influencing R&D Spending. **The amount of money that drug companies devote to R&D is determined by** the amount of **revenue** they expect to earn from a new drug, the expected **cost** of developing that drug, **and** **policies** that influence the supply of and demand for drugs. The **expected** **lifetime global revenues of a new drug depends on the prices that companies expect to charge** for the drug in different markets around the world, the volume of sales they anticipate at those prices, and the likelihood the drug-development effort will succeed. **The expected cost** to develop a new drug—**including capital costs and expenditures on drugs that fail to reach the market**—**has been estimated to range from less than $1 billion to more than $2 billion**. The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand. Notes Research and Development in the Pharmaceutical Industry Summary Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered **policies** **that** would **lower** drug **prices** and reduce federal drug expenditures. Such policies would probably **reduce the industry’s incentive to develop new drugs**. In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. **The share of revenues that drug companies devote to R&D has also grown**: On **average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000**. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. What Factors Influence Spending for R&D? Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs. **Various considerations inform companies’ expectations** about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The **prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments**. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.** In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. **Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA**. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and **during that time the company does not receive a financial return on its investment in developing that drug.** The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatments of uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, **the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D.** Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, **spending on drug R&D increased by nearly 50 percent between 2015 and 2019**. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, **the trend is broadly representative of R&D spending by the industry as a whole**.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3

**Intellectual property protections are key to pharmaceutical innovation – laundry of list of studies – that solves access better, Ezeli and Cory 19:**

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INTELLECTUAL PROPERTY UNDERPINS INNOVATION AND GROWTH Intellectual property rights arrangements are well recognized, going back to the Middle Ages, as enabling innovators to earn the returns necessary to continue to innovate and promote the availability of leading-edge technologies. **Nobel laureate economist Douglas North**, one of the foremost scholars of economic history, **argues that the introduction of intellectual property rights had one of the most profound impacts on spurring economic growth in human history**. North points out that average global economic growth rates for about one and a half millennia prior to the Industrial Revolution were essentially zero. Eighteenth-century elites in England had practically the same per capita income as their counterparts in third-century Rome.21 North has shown that the inflection point toward greater economic growth was the widespread development of patent systems in the 19th century.22 Gregory Clark, in his seminal book, Farewell to Alms: A Brief Economic History of the World, reached a similar conclusion that the introduction of **IPRs was catalytic to turbo-charging global economic growth**.23 **Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks**. By raising the private rate of return closer to the social rate of return, in**tellectual property rights address the knowledge-asset incentive problem, allowing inventors to realize economic gain from their inventions, thereby catalyzing investment in knowledge creation.** If innovators know that most of the benefits from their innovations would go to others without compensation, **they would be much less likely and capable of engaging in future innovations**. In addition, as they capture a larger portion of the benefits of their innovative activity, **innovating companies obtain the resources to pursue the next generation of innovative activities.** **IP thus produces a number of positive benefits, including: 1) creating powerful incentives for domestic innovation; 2) inducing knowledge spillovers that help others to innovate; 3) ensuring** a country’s **companies can focus on operating productively and innovating**, instead of having to devote an undue amount of their time and resources to protecting their IP in an environment where it’s at risk; **4) promoting the international diffusion of technology, innovation, and knowhow; and 5) boosting a country’s levels of research and development, inbound foreign direct investment (FDI), and exports of goods and services**.24 Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks. The **evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike.** As the definitive 2010 OECD review of the effects of intellectual property rights protections on developing countries, “Policy Complements to the Strengthening of IPRs in Developing Countries” found, “The results point to a tendency for IPR reform to deliver positive economic results.”25 The OECD study found that **developing-country IPR reforms concerning patent protection have tended to deliver the most substantial results**, although the results for copyright reform and trademark reform are also positive and significant. But to have the greatest impact on economic growth, IPR reforms must occur concomitantly with other positive complements, particularly ones regarding inputs for innovative and productive processes and the ability to conduct business. These include policies that influence the macro-environment for firms as well as the availability of resources (e.g., related to education), a country’s legal and institutional conditions, and fiscal incentives.26 The evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike. The following section details the broad swath of academic literature reviewing the relationships between IPR strengthening and trade, FDI, and technology transfer; IPR reform and innovation and R&D; and IPR reform and exports and industry growth, revealing the benefits of stronger IPR protections for developed and developing countries alike. IPRs Strengthen Trade, FDI, and Technology Transfer A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Strengthening IPR protection has been shown to correlate with increased trade.27 For instance, Fink and Primo Braga found that IPR protection is positively associated with international trade flows, in particular of manufactured, non-fuel imports.28 Other studies have found a positive association between IPR protection and trade flows in high-technology products.29 Likewise, strengthening of IPR protection has also been connected with increased inflows of FDI. Cavazos Cepeda et al. found that a 1 percent increase in the protection of IPRs as measured by the Patent Rights Index (a measure of the strength of countries’ IPR regimes) is associated with a 2.8 percent increase in the inflow of FDI.30 Similarly, a 1 percent increase in trademark protection levels is associated with a 3.8 percent increase in incoming FDI; and a 1 percent increase in copyright protection yields a 6.8 percent increase in FDI.31 Moreover, the researchers identified a virtuous cycle between FDI and protection of IP, whereby improvements in the IPR environment are associated with improved economic performance—in particular with respect to FDI—and, in turn, further improvements in the IPR environment. Park and Lippoldt showed that stronger IPRs in developing countries are associated with an increase of technology-intensive FDI, while Awokuse and Yin provided a concrete example concerning the relationship of IPR protection in China to FDI inflows, concluding that IPR reforms in China have had a positive and significant effect on inbound FDI.32 There is also evidence that countries with similar levels of intellectual property protection trade more with one another.33 Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that weak IP rights reduce pharmaceutical investment.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41 A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that developing countries can entice technology transfer from the North by providing IPR protection for incoming products (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45 **IPRs Strengthen Innovation** Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that **counties with stronger IP protection have more creative outputs** (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), **even at varying levels of development**.46 **IPR reforms also introduce strong incentives for domestic innovation**. **Sherwood**, using case studies from 18 developing countries, **concluded that poor provision of intellectual property rights deters local innovation and risk-taking**.47 In contrast, **IPR reform has been associated with increased innovative activity, as measured by domestic patent filings**, albeit with some variation across countries and sectors.48 For example, **Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets**.49 **Park** **and Lippoldt also observed that** the provision of adequate protection for **IPRs can help to stimulate local innovation**, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, **local innovators are introduced to technologies** first **through** the technology transfer that takes place in an environment wherein **protection** of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.**52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts**. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that **R&D to GDP ratios are positively related to the strength of patent rights**, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56 BOX 1: INNOVATE FOR HEALTH: IP IS NOT THE PROBLEM, BUT PART OF THE SOLUTION **Many opponents of robust IPR rights view them as antithetical to the interests of developing countries in terms of access to medicines or the provision of national health care services**. Yet the reality is that **stronger IPR rights in developing nations actually unleash the power of developing-country innovators to contribute to solving health challenges both in their own nations and across the global economy**. First, opponents of IP fail to recognize **that intellectual property rights matter for health care innovation in emerging economies.** **A**n Information Technology and Innovation Foundation (ITIF) and George Mason University Center for Intellectual Property Protection **report**, “How Innovators Are Solving Global Health Challenges,” **provides 25 case studies that show innovators in developing countries relying on IP to invent and bring solutions to market**.57 The 25 case studies revealed a number of key themes, including that there is opportunity in adapting health care interventions for developing-country environments where resources and infrastructure are scarce, and that local innovation and **IP can contribute substantially toward providing both affordable and robust tests for diagnosing diseases and affordable interventions to meet basic needs in challenging environments.** Second, **opponents of IP tend to ignore broader systemic issues that contribute to poor health care outcomes in developing countries.** **While cost is a central factor for policymakers in all countries, given resource scarcity, these trade-offs are not unique to health**. **The greater the resource scarcity, the greater the need for innovation**. One of the biggest challenges policymakers and innovators in developing countries confront again and again is scarcity—in access to trained professionals, in transportation, and in other infrastructure. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.58 A 2014 World Health Organization study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.59 More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 citizens.60 The challenge is even more daunting when it comes to specialists. For instance, Cameroon has fewer than 50 cardiologists supporting a population of over 23 million citizens.61 And Ethiopia, a country of some 90 million residents, is served by a single radiation-treatment center located in the capital of Addis Ababa.62 In other instances, individuals lack access to essential medicines, with cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.63 Again, **the cost of medicines is far from the most serious problem in the provision of health care services in developing nations**. Indeed, **the vast majority of drugs—at least 95 percent—on the World Health Organization’s Essential Medicines list are off-patent, and thus potentially available in generic versions**.64 **The problem, in much larger part, stems from countries’ underdeveloped health systems and the fact that many people live in rural areas far from care.** **Stronger IP rights create an environment wherein entrepreneurs can innovate to meet health challenges in their own nations, the benefits thereof spilling over to benefit the entire international community.** IPRs Strengthen Exports and Industry Growth Academic research has also found that **stronger IPR protections support exports from developing countries and faster growth rates of certain industries.** Yang and Kuo argue that stronger IPR protection improves the export performance of firms benefitting from technology transfer. And in their research, Cavazos Cepeda et al. found that trademark protection has a statistically significant association in relation to the export turnover, sales, and total assets of firms studied. They also found a significant association between copyrights and export turnover. Moreover, they found “a positive influence of patent right protection on export turnover (e.g., sales) under certain specifications with respect to complementary policies.”65 In cross-country studies, researchers have found that stronger patent rights are associated with faster company growth in IP-intensive industries such as pharmaceuticals. In fact, during the early 1990s, a one-standard-deviation increase in patent rights was associated with an increase in firm growth of 0.69 percent (an advantage amounting to nearly one-fifth of the average industry growth rate of 3.7 percent).66 Consequences of Countries Not Enacting Robust IPR Protections and Enforcement **Nations** **that** have not implemented—or **do not enforce**—**robust intellectual property rights protections end up harming their economic development in at least three principle ways. First, they deter future innovative activity. Second, they discourage trade** and foreign direct investment, which only hurts their own consumers and businesses, by both limiting their choices and inhibiting their enterprises’ ability to access best-of-breed technologies that are vital to boosting domestic productivity. **Third, in countries with weak IP protections, firms are forced to invest undue amounts of resources in protection rather than invention**. Ironically, **developing countries’ own economic development opportunities** and intellectual property development potential **are inhibited by their own weak intellectual property protections.** For instance, the lack of effective protection for intellectual property rights in China has limited the introduction of advanced technology and innovation investments by foreign companies, thereby reducing potential benefits to local innovation capacity.67 As Cavazos Cepeda et al. found in a case study of IPR protections in that economy, “China has made progress in strengthening the protection of intellectual property over the past two decades, as attested to by indicators such as the Patent Rights Index…. However, uncertainty around the protection of intellectual property [remains] an important deterrent for foreign as well as domestic firms engaging in R&D-related activities.”68 Ironically, developing countries’ own economic development opportunities and intellectual property development potential are inhibited by their own weak intellectual property protections.

**Pharma Innovation prevents Extinction – checks new diseases.**

**Engelhardt 8**, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

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

## SO21 – DA – Biotech

**US dominance is secured in biotech now, but China’s closing the gap fast – that allows geopolitical and economic advantages**

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EXECUTIVE SUMMARY Even by the standards of emerging technologies, **biotechnology has the potential to utterly transform geopolitics, economics**, and society in the 21st century. Yet while the United States has long been the world leader in most segments of the global biotechnology sector, **China is fast becoming a significant player**. This brief assesses the implications of China’s changing role in biotechnology for the United States, which span national security, data security, and economic competitiveness. On current trends the United States is likely to remain the world leader in most biotechnology areas. **However, the gap between China and the U.S. is narrowing in the biotechnology sector,** and U.S. policymakers must boost public investment, liberalize immigration and foreign student visa policies, and enact regulatory reforms to ensure America remains competitive. At the same time, areas like vaccine development and regulation of emerging technologies like synthetic biology present rich opportunities for Sino-U.S. cooperation. INTRODUCTION Thanks to extensive government funding for biomedical research, an unparalleled ability to translate basic research into commercial products and applications, and strong intellectual property protections, the United States has been the dominant global player in developing and commercializing biotechnology for decades.1 This dominance is reflected in the fact that United States accounted for almost half of all biotechnology patents filed worldwide from 1999 to 2013.2 However, in the intervening years, and just as in the case of artificial intelligence and other emerging technologies, other nations, including South Korea and Singapore, have invested heavily in developing their biotechnology sectors and industries. These efforts pale, however, in comparison to those of China, and the sheer size and scale of the Chinese biotechnology industry pose a range of economic, security, and regulatory issues for American policymakers. The determination of China’s one-party state to become a leading player in biotechnology is reflected by the rapid growth in investment in the sector. Some estimates claim that collectively, **China’s** central, local, and provincial **governments have invested over $100 billion in life sciences** research and development. Regardless of the true figure, official encouragement has led to a torrid place of investment. In just the two-year period from 2015 to 2017, venture capital and private equity investment in the sector totaled some $45 billion.3 The value of commercial deals concluded in the fields of biology, medicine and medical machine technology, meanwhile increased from 25.8 billion renminbi (RMB), or $3.6 billion, in 2011 to over 75 billion RMB ($10.6 billion) in 2017.4 Annual research and development expenditures by Chinese pharmaceutical firms, the foundation of the biotechnology sector, rose from some 39 billion RMB in 2014 ($5.5 billion) to over 53 billion RMB (US$7.5 billion) by 2017. Expenditure on new product development among these firms, an important indicator of future growth potential, increased from just over 40 billion RMB ($5.6 billion) to almost 60 billion ($8.4 billion).5 By Western standards, some of these figures are still low. Swiss drugmaker Roche, the world leader in biotechnology research and development, spent some $11 billion in 2018 alone.6 As these figures suggest, the development of China’s biotechnology sector paints a nuanced picture for U.S. policymakers. On one hand, the sector’s rapid growth, and high-level commitment to continued investment, means that China will inevitably become an increasingly important player in the global biotechnology sector, **with implications for national security, economic competitiveness, and regulation**. An executive from In-Q-Tel, the U.S. government’s inhouse national security venture capital fund, warned Congress in a November 2019 hearing, for example, that China “intends to own the biorevolution… and they are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that.”7 The CEO of European drugmaker AstraZeneca has similarly opined that “Much of [China’s] innovation in the last three to four years has been ‘me too,’ but now on the horizon we can see firstin-class innovation.”8 Yet on the other hand, while China’s biotechnology sector will almost certainly continue to grow in scale, sophistication, and competitiveness, there is little reason to believe on current trends that the United States will lose its edge in the sector. Indeed, the biggest risk to the global competitiveness of the U.S. biotechnology industry likely comes from the prospect of declining public investment and reduced mobility for world-class researchers and industry professionals. Moreover, the COVID-19 crisis underscores both the importance of continued investment in biotechnology and the many challenges to promoting effective international cooperation on global health security. This brief first examines the key policies and actors in China’s biotechnology sector, then offers an assessment of the sector’s current capabilities and future trends, and finally further explores the implications of developments in Chinese biotechnology for U.S. policy.

**The aff’s waiving of IP doesn’t solve but it does give away sensitive national security information that allows China to lead ahead in biotech**

Josh **Rogin 4-8**. [(Washington Post Columnist covering National Security Issues.) “Opinion: The wrong way to fight vaccine nationalism” https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819\_story.html ] TDI // Recut NChu

Americans will not be safe from covid-19 until the entire world is safe. That basic truth shows why vaccine nationalism is not only immoral but also counterproductive. But the simplest solutions are rarely the correct ones, **and some countries are using the issue to advance their own strategic interests**. The Biden administration must reject the effort by some nations to turn our shared crisis into their opportunity. As the inequities of vaccine distribution worldwide grow, a group of more than 50 developing countries led by India and South Africa is pushing the World Trade Organization to dissolve all international intellectual property protections for pandemic-related products, which would include vaccine research patents, manufacturing designs and technological know-how. The Trump administration rejected the proposal to waive the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the pandemic when it was introduced in October. Now, hundreds of nongovernmental organizations and dozens of Democratic lawmakers are pushing the Biden administration to support the proposal. But many warn **the move would result in the United States handing over a generation of advanced research** — much of it funded by the U.S. taxpayer — **to** our country’s greatest competitors, above all **China**. In Congress, there’s justified frustration with the United States’ failure to respond to China’s robust vaccine diplomacy, in which Beijing has conditioned vaccine offers to pandemic-stricken countries on their ignoring security concerns over Chinese telecom companies or abandoning diplomatic recognition of Taiwan. There’s also a lot of anger at Big Pharma among progressives for profiting from the pandemic. “We are in a race against time, and unfortunately Big Pharma is standing in the way of speedily addressing this problem,” Rep. Jan Schakowsky (D-Ill.), who supports the effort to waive intellectual property protections, told me in an interview. “I think the real security issue is that while the United States balks in making sure that we help ourselves, that these adversaries will just jump right in.” Schakowsky argued that alternative measures for helping poor countries manufacture vaccines are simply not moving fast enough to save lives and that the United States has a duty to respond. House Speaker Nancy Pelosi (D-Calif.) personally conveyed her support for the waiver to President Biden, Schakowsky said. But Big Pharma is just one piece of the puzzle. Countries such as India and South Africa have been trying to weaken WTO intellectual property protections for decades. **The mRNA technology that underpins the Pfizer and Moderna vaccines was funded initially by the Defense Advanced Research Projects Agency and has national security implications.** Inside the Biden administration, the National Security Council has already convened several meetings on the issue. The waiver is supported by many global health officials in the White House and at the U.S. Agency for International Development, who believe the United States’ international reputation is suffering from its perceived “America First” vaccine strategy. On Wednesday, U.S. Trade Representative Katherine Tai spoke with WTO Director General Ngozi Okonjo-Iweala about the waiver issue. USTR is convening its own interagency meetings on the issue, which many see as a move to reassert its jurisdiction over WTO matters. If and when this does get to Biden’s desk, he will also hear from national security officials who believe that waiving TRIPS would result in the forced transfer of national security-sensitive technology to China, **a country that strives to dominate the biotechnology** ***field*** as part of its Made in China 2025 strategy. **Once countries such as China have this technology, they will apply their mercantilist industrial models to ensure their companies dominate these strategically important industries, potentially erasing thousands of U.S. jobs.** “We would be delivering a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense, when there are other ways of doing this,” said Mark Cohen, senior fellow at the University of California at Berkeley Law School. **A preferable approach would be to build more vaccine-manufacturing capacity** in the United States and then give those vaccines to countries in need, said Cohen. The U.S. pharmaceutical industry would surely benefit, but **that’s preferable to being dependent on other countries when the next pandemic hits.** “If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally,” Cohen said. What’s more, it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licensing agreements are already successfully facilitating cooperation between patent-holding vaccine-makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world. Vaccine equity is a real problem, but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. **That means helping the world and thinking about our strategic interests at the same time.**

**China will convert biotechnology gains to military advantages, undermining US primacy – specifically true in the context of vaccines**

Mercy A. **Kuo 2017** [(Executive Vice President at Pamir Consulting.) “The Great US-China Biotechnology and Artificial Intelligence Race” <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>] TDI // Recut NChu

Trans-Pacific View author Mercy Kuo regularly engages subject-matter experts, policy practitioners, and strategic thinkers across the globe for their diverse insights into the U.S. Asia policy. This conversation with Eleonore Pauwels – Director of Biology Collectives and Senior Program Associate, Science and Technology Innovation Program at the Wilson Center in Washington D.C. – is the 104th in “The Trans-Pacific View Insight Series.” Explain the motivation behind Chinese investment in U.S. genomics and artificial intelligence (AI). With large public and private investments inland and in the U.S., China plans to become the next AI-Genomics powerhouse, which indicates that these technologies will soon converge in China. China’s ambition is to lead the global market for precision medicine, **which necessitates acquiring strategic tech**nological and human capital in both genomics and AI. And the country excels at this game. A sharp blow in this U.S.-China competition happened in 2013 when BGI purchased Complete Genomics, in California, with the intent to build its own advanced genomic sequencing machines, therefore securing a technological knowhow mainly mastered by U.S. producers. There are significant economic incentives behind China’s heavy investment in the increasing convergence of AI and genomics. This golden combination will drive precision medicine to new heights by developing a more sophisticated understanding of how our genomes function, leading to precise, even personalized, cancer therapeutics and preventive diagnostics, such as liquid biopsies. By one estimate, the liquid biopsy market is expected to be worth $40 billion in 2017. Assess the implications of iCarbonX of Shenzhen’s decision to invest US$100 million in U.S.-company PatientsLikeMe relative to AI and genomic data collection. iCarbonX is a pioneer in AI software that learns to recognize useful relationships between large amounts of individuals’ biological, medical, behavioral and psychological data. Such a data-ecosystem will deliver insights into how an individual’s genome is mutating over time, and therefore critical information about this individual’s susceptibilities to rare, chronic and mental illnesses. In 2017, iCarbonX invested $100 million in PatientsLikeMe, getting a hold over data from the biggest online network of patients with rare and chronic diseases. If successful, this effort could turn into genetic gold, making iCarbonX one of the wealthiest healthcare companies in China and beyond. The risk factor is that iCarbonX is handling more than personal data, but potentially vulnerable data as the company uses a smartphone application, Meum, for customers to consult for health advice. Remember that the Chinese nascent genomics and AI industry relies on cloud computing for genomics data-storage and exchange, creating, in its wake, new vulnerabilities associated with any internet-based technology. This phenomenon has severe implications. How much consideration has been given to privacy and the evolving notion of personal data in this AI-powered health economy? And is our cyberinfrastructure ready to protect such trove of personal health data from hackers and industrial espionage? In this new race, will China and the U.S. have to constantly accelerate their rate of cyber and bio-innovation to be more resilient? Refining our models of genomics data protection will become a critical biosecurity issue. Why is Chinese access to U.S. genomic data a national security concern? **Genomics** and computing research **is inherently dual-use, therefore a strategic advantage in a nation’s security arsenal.** Using AI systems to understand how the functioning of our genomes impacts our health **is of strategic importance for biodefense.** This knowledge will lead to increasing developments at the forefront of medical countermeasures, **including vaccines**, antibiotics, and targeted treatments relying on virus-engineering and microbiome research. Applying deep learning to genomics data-sets could help geneticists learn how to use genome-editing (CRISPR) to efficiently engineer living systems, but also to treat and, even “optimize,” human health, **with potential applications in military enhancements**. A $15 million partnership between a U.S. company, Gingko Bioworks, and DARPA aims to genetically design new probiotics as a protection for soldiers against a variety of stomach bugs and illnesses. China could be using the same deep learning techniques on U.S. genomics data to better comprehend how to develop, patent and manufacture tailored cancer immunotherapies in high demand in the United States. Yet, what if Chinese efforts venture into understanding how to impact key genomics health determinants relevant to the U.S. population? **Gaining access to increasingly large U.S. genomic data-sets gives China a knowledge advantage into leading the next steps in bio-military research.** Could biomedical data be used to develop bioweapons? Explain. Personalized medicine advances mean that personalized bio-attacks are increasingly possible. The combination of AI with biomedical data and genome-editing technologies will help us predict genes most important to particular functions. Such insights will contribute to knowing how a particular disease occurs, how a newly-discovered virus has high transmissibility, but also why certain populations and individuals are more susceptible to it. Combining host susceptibility information with pathogenic targeted design, **malicious actors could engineer pathogens that are tailored to overcome the immune system or the microbiome of specific populations.**

**Maintenance of the US-led LIO is key to reduce a host of existential threats – establishes great-power peace.**

**Brands 18**. [(Hal Brands is a Henry Kissinger Distinguished Professor at Johns Hopkins University’s School of Advanced International Studies, Scholar at the American Enterprise Institute. “America’s Global Order Is Worth Fighting For, Bloomberg Opinion, Politics & Policy,” August 14, 2018, Bloomberg. <https://www.bloomberg.com/opinion/articles/2018-08-14/america-s-global-order-is-worth-fighting-for>] TDI // Recut NChu

The first argument is **easily disposed** of. Yes, the postwar world has been **thoroughly imperfect**, featuring nuclear arms races, genocides, widespread poverty and other scourges. But the world has **always been** imperfect, and by **any** meaningful **comparison**, the last **seven decades** have been a **veritable golden age**. The **liberal international** economic order has led to an **explosion** of **domestic** and **global prosperity**: According to World Bank data, both U.S. and global **per capita** income have increased **roughly three-fold** (in inflation-adjusted terms) since 1960, with U.S. gross domestic product increasing nearly six-fold. The U.S. **system** of alliances and forward military deployments has **contributed critically** to the **longest period** of **great-power peace** in modern history, and **the incidence of war** and conquest **more broadly** have dropped **dramatically**. The number of **democracies** in the world has **increased** from perhaps a dozen during World War II to well over 100 today; **respect for basic** human rights has also reached **impressive levels**. As a **bevy of scholarship** has shown, the policies that the U.S. has **pursued** and the **international order** it has built have contributed **enormously** and **directly** to these **outcomes**. If the **liberal international order** can’t be considered a **smashing success**, no **international order** could be. The second critique is also overstated. It is true that Washington, like all great powers throughout history, has been willing to bend the rules to get its way. It is hard to reconcile Cold War-era interventions in Guatemala, Chile and other countries with a professed solicitude for human rights and democracy; the Iraq War of 2003 is only one instance in which the U.S. brushed aside the concerns of international organizations such as the U.N. Security Council. Likewise, when the U.S. government determined that the Bretton Woods system of monetary relations no longer suited its interests in the 1970s, it terminated that scheme and insisted on creating a more favorable one. But again, the proper standard here is not sainthood but reality. And the U.S. has **generally** enlisted its power in the **service** of **universal values** such as **democracy** and **human rights**; it has, more often than not, promoted **a positive-sum** international system in which **like-minded** nations can be **secure** and **wealthy**. This goes back to the very beginning of the liberal order: Washington did not seek to hold its defeated adversaries in subjugation after World War II; it rebuilt Japan and western Germany into thriving, democratic allies that became fierce economic competitors to the U.S. The U.S. has taken this approach not simply because it wanted to do good in the world — powerful as this motivation is — but because of a hard-headed desire to do good for itself. In an interdependent global environment, American officials have long calculated, the U.S. cannot divorce its own well-being from that of the wider world. And in contrast to how other great powers — Imperial Japan, for instance, or the Soviet Union — ruled their spheres of influence, American behavior has been positively enlightened. It is this relatively benign behavior that has convinced so many countries to tolerate American leadership — and it is the emergence of a darker form of U.S. hegemony under the Trump administration that so profoundly worries them today. As for the third critique, the premise is right, but the **conclusion** can easily **go too far**. It is always **dangerous** to become **so enraptured** by past **achievements** that one **loses sight** of the **need for adaptation** in **the future**. This is particularly true today, because the strength of the liberal order is being tested from within and without, by issues ranging from unequal burden-sharing among American allies to the ambivalence of the American people themselves. There is **little evidence** to suggest, however, that either American power or **the liberal order** it supports have **eroded** so **dramatically** that **Washington**’s postwar project cannot be **sustained**. Quite the contrary — the U.S. is likely to remain the **world’s strongest power** for **decades to come**.

#### compulsory licensing exists, Fink 04

Fink, Carsten; Senior Economist, World Bank Institute, World Bank Office in Geneva; November 2004; "Intellectual Property and the WTO"; https://openknowledge.worldbank.org/handle/10986/25931, World Bank, Washington, Dc., accessed 7-22-2021; JPark

**Responding to concerns that the TRIPS patent rules could undermine access to medicines** in poor countries, **members** of the WTO **issued a Declaration** at the Ministerial Meeting **in Doha**, Qatar in 2001. In this Declaration, WTO **Members agreed that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.” It reaffirms the right of governments to use compulsory licenses to override the exclusive rights conferred by patents.** Moreover, for least-developed countries, it delayed the implementation of TRIPS with respect to pharmaceutical products until 2016 (with the possibility of further extensions). In the future, **granting a compulsory license to a local producer may emerge as an effective strategy to promote generic competition in developing countries that have the capacity to manufacture pharmaceuticals.** For example, well-developed pharmaceutical industries can be found in Brazil, China, India, or Thailand. Yet many other developing countries—especially the least developed countries in Africa—do not possess pharmaceutical manufacturing capabilities. These countries can effectively use the compulsory licensing option only if they are allowed to import generic drugs. Yet there was legal uncertainty in the original TRIPS Agreement whether such importation would be allowed if the drug is patented in the exporting country. The ‘Doha Declaration’ acknowledged the difficulties countries with insufficient or no manufacturing capacity face in effectively using the compulsory licensing mechanism and called for negotiations “… to find an expeditious solution to this problem.” After almost two years of negotiations, WTO Members decided in 2003 on a mechanism that creates a framework for the importation of generic drugs produced under a compulsory license. This mechanism includes several safeguards intended to minimize the risk that drugs destined for poor countries leak in to rich countries’ pharmaceutical markets. While the 2003 Decision still needs to be formally integrated into the TRIPS Agreement, several developing and developed country WTO members have initiated legislative changes that would allow for the export of generic drugs under terms consistent with the Decision.

**SO21 – DA – Infrastructure (2:00)**

**Biden’s infrastructure bill will pass through reconciliation but absolute Dem Unity is key.**

* Turns Structural Violence

**Pramuk and Franck 8-25** Jacob Pramuk and Thomas Franck 8-25-2021 "Here’s what happens next as Democrats try to pass Biden’s multitrillion-dollar economic plans" <https://www.cnbc.com/2021/08/25/what-happens-next-with-biden-infrastructure-budget-bills-in-congress.html> (Staff Reporter at CNBC)//Elmer

WASHINGTON — **House Democrats just patched up a party fracture** **to take a critical step forward with a mammoth economic agenda**. But the **path ahead could get trickier** as party leaders try to thread a legislative needle to pass more than $4 trillion in new spending. **In** the **coming weeks**, **Democrats** **aim to approve** a $1 trillion bipartisan **infrastructure** plan and up to $3.5 trillion in investments in social programs. Passing both **will require a heavy lift**, as leaders will need to **satisfy** **competing demands of centrists** wary of spending **and progressives** who want to reimagine government’s role in American households. The House is leaving Washington **until Sept. 20** after taking key steps toward pushing through the sprawling economic plans. The chamber on Tuesday approved a $3.5 trillion budget resolution and advanced the infrastructure bill, as House Speaker Nancy Pelosi, D-Calif., promised centrist Democrats to take up the bipartisan plan by Sept. 27. The Senate already passed the infrastructure legislation, so **a final House vote would send it to Biden’s desk for his** signature. Now that both chambers have passed the budget measure, **Democrats can move without Republicans** to push through their spending plan **via reconciliation**. Party leaders want committees to write their pieces of the bill by Sept. 15 before budget committees package them into one massive measure that can move through Congress. Committees could start marking up legislation in early September. Party leaders **face a challenge** in coming up with a bill that will satisfy centrists who want to trim back the $3.5 trillion price tag and progressives who consider it the minimum Congress should spend. As **one defection in the Senate** — **and four in the House** — **would sink legislation,** **Democrats have to satisfy a diverse range of views** to pass their agenda. “We write a bill with the Senate because it’s no use doing a bill that’s not going to pass the Senate, in the interest of getting things done,” Pelosi told reporters on Wednesday. Given the magnitude of the legislation, passing it quickly could prove difficult. To appease congressional progressives who have prioritized passage of the budget bill, Democrats could move to pass both proposals at about the same time. While Pelosi gave a Sept. 27 target date to approve the infrastructure plan, the commitment is not binding. Still, she noted Wednesday that Congress needs to pass the bill before surface transportation spending authorization expires Sept. 30. “We have long had an eye to having the infrastructure bill on the President’s desk by the October 1, the effective date of the legislation,” she wrote in a separate letter to Democrats on Wednesday. Democrats say the bills combined will provide a jolt to the economy and a lifeline for households. Supporters of the Democratic spending plan, including Pelosi and Senate Budget Committee Chair Bernie Sanders, I-Vt., have cast it as the biggest expansion of the U.S. social safety net in decades. “This is a truly historic opportunity to pass the **most transformative** and consequential **legislation for families** in a century, and will stand alongside the New Deal and Great Society as pillars of **economic security**,” Pelosi wrote to colleagues Wednesday. The plan would **expand Medicare**, **paid leave** and child care, extend enhanced household tax credits and encourage **green energy adoption**, **while hiking taxes on corporations and the wealthy**. Democrats hope to sell a wave of new support for families as they campaign to keep control of Congress in next year’s midterms. Those elections, though, have helped to generate staunch opposition on the other side of the aisle. The GOP has cited the trillions in new spending and the proposed reversal of some of its 2017 tax cuts in trying to take down the Democratic budget bill. Republicans and some Democrats have in recent weeks said that another $4.5 trillion in fiscal stimulus could not only boost economic growth but have the adverse effect of fueling inflation.

**Pharma backlashes to the Plan – they’re aggressive lobbyists and will do anything to preserve patent rights.**

* Turns Case – Waters down the Plan due to lobbying
* Optional Card – still thinking on if its necessary [note from Elmer]

**Huetteman 19** Emmarie Huetteman 2-26-2019 “Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash” <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/> (former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School)//Elmer

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public **outrage** **over** drug prices, the fact that **drugmakers** gave most **to** the **lawmakers working to change the patent system** belies how important securing **the exclusive right to market a drug, and keep competitors at bay, is to their bottom line**. “**Pharma will fight to the death to preserve patent rights**,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the **pharmaceutical industry** has **spent** about $**233 million per year on lobbying**, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the **Affordable Prescriptions for Patients Act,** which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to **prosecute** them: “**product-hopping**,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “**patent-thicketing**,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. **PhRMA opposed the bill.** **The next day, it gave Cornyn $1,000**. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The **pharmaceutical industry lobbied tooth and nail against it**,” she said. “And **when the bill finally came** out of committee, the strongest provisions — the **patent-thicketing provisions — had been stripped**.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

**They choose Infrastructure as backlash – they bill costs Pharma millions – lobbyists can derail the Agenda.**

**Brennan 8-2** Zachary Brennan 8-2-2021 "How the biopharma industry is helping to pay for the bipartisan infrastructure bill" <https://endpts.com/how-the-biopharma-industry-is-helping-to-pay-for-the-bipartisan-infrastructure-bill/> (Senior Editor at Endpoint News)//Elmer

Senators on Sunday finalized the text of **a massive, bipartisan infrastructure bill** that contains little **that might** **impact the biopharma industry** other than two ways the legislators are planning to pay for the $1.2 trillion deal. On the one hand, senators are **seeking to** further **delay** a **Trump-era Medicare** Part D **rule** **related to drug rebates**, this time until 2026. Senators claim the rule could end up saving about $49 billion (and that number increased this week to $51 billion), but the PBM industry has attacked it as it would remove rebates from a safe harbor that provides protection from federal anti-kickback laws. The **pharmaceutical industry**, however, is in favor of the rule and **opposes this latest delay** as it continues to point its finger at the PBM industry for the rising cost of out-of-pocket expenses. Debra DeShong, EVP of public affairs at PhRMA, said via email: Despite railing against high drug costs on the campaign trail, lawmakers are threatening to gut a rule that would provide patients meaningful relief at the pharmacy. If it is included in the infrastructure package, this proposal will provide health insurers and drug middlemen a windfall and turn Medicare into a piggybank to fund projects that have nothing to do with lowering out-of-pocket costs for medicines. This would be an unconscionable move that robs patients of the prescription drug savings they deserve to help fill potholes and fund other infrastructure projects. The **other provision** **in the infrastructure bill**, which is estimated to save about $3 billion, **would save money for Medicare** **on discarded medications** from large, single-use drug vials. **Manufacturers will be required to pay refunds** for such discarded drugs, and each manufacturer will be subject to periodic audits on the refunds issued. If manufacturers don’t comply, HHS can fine them the refund amount that they would have paid plus 25%. Drugs that will be excluded from these refund payments include radiopharmaceuticals or imaging agents, as well as those that require filtration during the drug preparation process. So do these two pay-fors mean that the pharma industry is getting off without any serious drug pricing reforms? Not quite, according to Alex Lawson, executive director of Social Security Works. Lawson told Endpoints News in an interview that he still fully expects major drug pricing reforms to make their way through Congress between now and the end of September as Sen. Ron Wyden (D-OR) refines his plan, part of an early fall spending package. Senate Majority Leader Chuck Schumer has promised both the infrastructure and spending package will pass before the Senate leaves for August recess. At the very least in terms of drug pricing provisions, expect to see a combination of the Wyden bill he co-wrote with Sen. Chuck Grassley (R-IA) last year, alongside further Medicare negotiations, Lawson said. “Talk is still optimistic,” Lawson said on the prospects of a drug pricing deal getting done, while noting that **pharmaceutical** company **lobbyists** are **swarming Capitol Hill** at the moment because of **not just drug pricing plans**, but **tax provisions** and the **TRIPS waiver** that the biopharma industry is worried about. “These are **challenges to their entire existence**, **so they’re willing to protect them at any cost**,” Lawson said, noting the target for drug pricing is about $500 billion in savings. As the House has jetted off to enjoy what might be an abbreviated summer recess, the Senate has just this week to get its work done, unless its recess is cut short too. “There’s a **real possibility** that **the whole thing blows up** and we get nothing on either side,” Lawson said.

**Democrat Senators in Big Pharma’s pocket derails the Plan.**

**Sirota 8-23** David Sirota 8-23-2021 "Dem Obstructionists Are Bankrolled By Pharma And Oil" <https://www.dailyposter.com/dem-obstructionists-are-bankrolled-by-pharma-and-oil/> (an American journalist, columnist at The Guardian, and editor for Jacobin. He is also a political commentator and radio host based in Denver. He is a nationally syndicated newspaper columnist, political spokesperson, and blogger)//Elmer

The **small group of conservative Democratic lawmakers** that has been **threatening to** help Republicans **halt** **Democrats’ budget package** have **raked in more than $3 million from donors in the pharmaceutical** and fossil fuel **industries** that could see reduced profits if the plan passes. As the House reconvenes today to tackle the budget reconciliation process, nine Democrats legislators have been promising to kill their party’s $3.5 trillion budget bill until Congress first passes a separate, smaller infrastructure spending measure, which has garnered some Republican support and which some environmental advocates say would exacerbate the climate crisis. Indeed, an ExxonMobil lobbyist was recently caught on tape saying the company had worked to strip climate measures out of the infrastructure bill. “**We will vote against a budget resolution** if the infrastructure package isn’t brought up first,” Democratic **Rep**. Josh **Gottheimer** **told** the Washington Post this weekend, **though** the American Prospect reported on Sunday that “**several**” of the **legislators** now **indicated they could back down**. **In the narrowly divided House**, **obstructionism from these** conservative Democrats **could decouple the infrastructure** and budget **measures** from one another. Many believe that would kill the latter by letting conservative Democrats in the Senate such as Kyrsten Sinema (D-Ariz.) and Joe Manchin (D-W.Va.) get the infrastructure bill they want without having to provide the votes necessary to enact the much larger and more progressive budget measure. “If we were to pass the bipartisan [infrastructure] bill first, then we lose leverage,” Democratic Rep. Ritchie Torres (NY) told the Wall Street Journal. Along with Gottheimer, the eight other Democrats who have threatened to obstruct the budget bill are Carolyn Bordeaux (Ga.), Ed Case (Hawaii), Jim Costa (Calif.), Henry Cuellar (Texas), Jared Golden (Maine), Vicente Gonzalez (Texas), Kurt Schrader (Ore.), and Filemon Vela (TX). The U.S. Chamber of Commerce — Washington’s most powerful corporate lobby group — has been airing digital ads thanking the nine Democrats for their maneuvers. Eight of the nine Democrats represent congressional districts won by President Joe Biden, who supports the reconciliation package. Big Pharma’s Big Allies The reconciliation bill is still being negotiated, and many Democratic lawmakers — including those in key swing districts — are pushing for it to include long-promised legislation to allow Medicare to use its enormous purchasing power to negotiate lower prices for prescription drugs. The **pharmaceutical industry** has **aggressively lobbied against the initiative**, which the Congressional Budget Office has estimated would save Medicare $345 billion in medicine costs. The nine House Democrats threatening to derail the reconciliation bill have raked in nearly $1.2 million from donors in the pharmaceutical and health products industries, according to data compiled by OpenSecrets. Among them are two of the Democratic Party’s **top recipients of health care industry money**: **Gottheimer** ($228,186) **and Schrader** ($614,830). Schrader’s third biggest career donor is Pfizer’s political action committee, and his former chief of staff is now a registered lobbyist for the Pharmaceutical Researchers and Manufacturers Association, the pharmaceutical industry’s main lobbying group. Both Gottheimer and Schrader signed a letter earlier this year slamming Democratic leaders’ legislation to lower prescription drug prices. Eight out of the nine Democrats threatening to kill the budget bill also declined to sponsor Democrats’ standalone legislation to let Medicare negotiate lower drug prices. In the Senate, Sinema’s renewed threat to vote down a final reconciliation bill came after she received $519,000 from donors in the pharmaceutical and health products industries.

**Infrastructure reform solves Existential Climate Change – it results in spill-over.**

**USA Today 7-20** 7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option" <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Elmer

**Not long ago**, **climate change** for many Americans **was** like **a distant bell**. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. **Top climate scientists** from around the world **warned of a "code red for humanity**" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to **intense heat waves and drought**, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost **certainly made worse and more intransigent by human-caused climate change**. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The **consequences of** what mankind has done to the atmo**sphere are now inescapable**. Periods of **extreme heat** are projected to **double** in the lower 48 states by 2100. **Heat deaths** are far **outpacing every other form of weather killer** in a 30-year average. A **persistent megadrought** in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say **warming oceans** are **fueling** ever **more powerful storms**, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. **Rising seas** from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global **temperature** has **risen** nearly **2 degrees** Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a **2.7**-degree increase. That's **enough** warming **to cause catastrophic climate changes**. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar **infrastructure bill** negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would **improve access** by the nation's power infrastructure **to renewable energy sources,** **cap millions of abandoned oil and gas wells spewing greenhouse gases**, **and harden structures against climate change**. It also **offers tax credits for** the **purchase of electric vehicles** and funds the construction of charging stations. (**The nation's largest source of climate pollution are gas-powered vehicles**.) Senate approval could come very soon. Much **more is needed** if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. **The vehicle** for these additional proposals **would be a second infrastructure bill**. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.