# 1nc

## offs

**1**

**Interpretation: Intellectual property on medicine only refers to patents.**

**Oxfam** [Oxfam is a British founded confederation of 20 independent charitable organizations focusing on the alleviation of global poverty, founded in 1942 and led by Oxfam International. It is a major nonprofit group with an extensive collection of operations, “Intellectual property and access to medicine”, No Date, [https://www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/]//pranav](https://www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/%5d//pranav)

* Independently – becomes an alt cause to plan solvency

**Intellectual property (IP) has different forms; in the case of access to medicines, we are talking about patents.** Patents are a public policy instrument aimed at stimulating innovation. **By providing a monopoly through a patent—which gives inventors an economic advantage—governments seek to provide an incentive for R&D. At the same time, the public benefits from technological advancement.**

**Violation: Data exclusivity is IP on data from clinical trials, not on the medicine itself and is distinct from patent protection.**

**1AC Thrasher ’21** [Rachel, received a JD and a master’s degree in international relations, both from Boston University. She works on policy issues related to trade and investment agreements, trade law and development, economic relations between developing countries, and multilateral environmental agreements. She is the co-editor, alongside former Pardee Center Director Adil Najam, of a Pardee-sponsored book titled The Future of South-South Economic Relations. She teaches a course on trade and development at the Pardee School of Global Studies and continues to research areas of trade and investment agreements and their impact on development policy as part of the Global Economic Governance Initiative at Boston University, “Chart of the Week: How Data Exclusivity Laws Impact Drug Prices”, 05-21-2021, https://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data-exclusivity-laws-impact-drug-prices/]//pranav

**Data exclusivity is a form of intellectual property protection that applies specifically to data from pharmaceutical clinical trials.** While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years, depending on the specific law. **Data exclusivity operates independently of patent protection and can block generic manufacturers from gaining marketing approval even if the patent has expired or the original pharmaceutical product does not qualify for patent protection.**

#### [1] limits – their interp explodes the topic to intellectual property protections on things other than medicine – that includes food, music, clinical trials trademarks, and more, all with distinct scenarios and no unified neg ground which makes pre-round prep impossible, killing clash. That controls the internal link to education – only terminal impact in debate and fairness – only thing under the judge’s jurisdiction.

#### [2] Precision – not defending the text of the resolution justifies the affirmative doing away with random words in the resolution which a] means they’re not within the topic which is a voter for jurisdiction since you can only vote affirmative on the resolution and this debate never should have happened, b] they’re unpredictable and impossible to engage in so we always lose

#### Drop the debater – a] deter future abuse and b] set better norms for debate.

#### Competing interps –

#### [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm

#### [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs –

#### a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument

#### b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices

**2**

**The meta-ethic is practical reason—**

**[1] Inescapability— I can question why to follow or the validity of an ethical theory, which concedes the authority of reason as if I question reason, I use reason to question. Outweighs on validity—any other truth risks falsity Reality may be fake, our experiences may be arbitrary, and experience may be descriptive not normative, but questioning the validity of reason requires reason, conceding its validity. Any other ethic begs the question of why, meaning it’s arbitrary and nonbinding**

**[2] Action theory— Only reason can explain why we take transitional action to an overall end. For example, setting the end of tea provides me a reason to unify the necessary actions to produce tea, like getting a pot, filling it with water, etc. Any other explanation fails since it can’t give meaning to why we take transitioning action – freezing action. 2 Impacts—**

**[a] That’s a side constraint on the AC—ethics is a guide to action so it must appeal to a structure of action.**

**[b] Bindingness—reason is intrinsic to actions since only it can provide value to transitioning action, which justifies universality**

**That justifies universality—**

**If we are all reasoners, we must all be able to determine if an action is good. An action that maximizes my freedom at the cost of others then would have to be recognized as good by everyone, but that leads to a contradiction where everyone takes other’s freedoms to maximize theirs, making it impossible to reach my end**

**Thus, the standard is respecting a system of inner and outer freedom**

**Now Negate:**

**Possession of a medical innovation is a form of intelligible possession – the redistribution of a patented product with the affirmative harms economic gain, violating freedom.**

**Frederick 07 [Rauscher, Frederick, 7-24-2007, "Kant’s Social and Political Philosophy (Stanford Encyclopedia of Philosophy)," No Publication,** [**https://plato.stanford.edu/entries/kant-social-political/#ProConRig**](https://plato.stanford.edu/entries/kant-social-political/#ProConRig)**] // WW DL**

The “Doctrine of Right” begins with a discussion of property, showing the importance of this right for the implementation of the innate right to freedom. Property is defined as that “with which I am so connected that another’s use of it without my consent would wrong me” (6:245). In one sense, if I am holding an object such as an apple, and another snatches it from my hand, I have been wronged because in taking the object from my physical possession, the other harms me (Kant does not specify whether this harm is because one’s current use of the apple is terminated or because one’s body is affected, but the latter fits the argument better). Kant calls this “physical” or “sensible” possession. It is not a sufficient sense of possession to count as rightful possession of an object. Rightful possession must be possession of an object so that another’s use of the object without my consent harms me even when I am not physically affected and not currently using the object. If someone plucks an apple from my tree, no matter where I am and no matter whether I am even aware of the loss I am prevented from using that apple. Kant calls this “intelligible possession”.

His proof that there must be this intelligible possession and not merely physical possession turns on the application of human choice (6:246). An object of choice is one that some human has the capacity to use as means for various ends or purposes. Rightful possession would be the right to make use of such an object. Suppose that for some particular object, no one has rightful possession. This would mean that a usable object would be beyond possible use. Kant grants that such a condition does not contradict the principle of right because it is compatible with everyone’s freedom in accordance with universal law. But putting an object beyond rightful use when humans have the capacity to use it would “annihilate” the object in a practical respect, treat it as nothing. Kant claims that this is problematic because in a practical respect an object is considered merely as an object of possible choice. This consideration of the mere form alone, the object simply as an object of choice, cannot contain any prohibition of use for an object, for any such prohibition would be freedom limiting itself for no reason. Thus in a practical respect an object cannot be treated as nothing, and so the object must be considered as at least potentially in rightful possession of some human being or other. So all objects within human capacity for use must be subject to rightful or intelligible possession.

Intelligible possession, then, is required by right in order for free beings to be able to realize their freedom by using objects for their freely chosen purposes. This conclusion entails the existence of private property but not any particular distribution of private property. All objects must be considered as potential property of some human being or other. Now if one human being is to have intelligible possession of a particular object, all other human beings must refrain from using that object. Such a one-sided relation would violate the universality of external right. Kant further worries that any unilateral declaration by one person that an object belongs to that person alone would infringe on the freedom of others. The only way that intelligible possession is possible without violating the principle of right is if there is an agreement that puts all under an obligation to recognize each other’s intelligible possessions. Each person must acknowledge an obligation to refrain from using objects that belong to another. Since no individual will can rightfully make and enforce such a law obligating everyone to respect others’ property, this mutual obligation is possible only in accordance with a “collective general (common) and powerful will”, in other words, only in a civil condition. The state itself obligates all citizens to respect the property of other citizens. The state functions as an objective, disinterested institution that resolves disputes about individual property and enforces compliance with those determinations. Without a state to enforce these property rights, they are impossible.

**Reducing IP law uses people as a means to an end violating their freedom.**

**Kornyo, 14** (Emmanuel Kornyo, 9-11-2014, accessed on 8-14-2021, Journals.library.columbia, "Patent Protection and the Global Access to Essential Pharmaceuticals during Patent Infringements under TRIPS| Voices in Bioethics", https://journals.library.columbia.edu/index.php/bioethics/article/view/6467)WWPP

When I think of a categorical imperative I know at once what it contains. For, since the imperative contains, beyond the law, only the necessity that the maxim be in conformity with this law, while the law contains no condition to which it would be limited, nothing is left with which the maxim of action is to conform but the universality of a law as such ... There is, therefore, only a single categorical imperative and it is this: act only in accordance with thatmaxim through which you can at the same time will that it become a universal law.[xiv] In addition, the principle of deontology imposes an obligation on all people to never use another human being as a means to attain an end. In other words, the end does not justify the means. Hence, in dire humanitarian crises such as the HIV case, by breaking the patent, the government of these countries “used” the intellectual property of these patents to attain their own local or national needs. One cannot use the larger interest of the population to the exclusion of the investors or patent holders who have rights as well.[xv

**3**

**Biden PC is key to getting Manchin & Sinema on board and he won’t give up – it’s *try or die* & the margin of error is *literally* 0.**

**Strauss 10/13** [Daniel, Staff Writer @ The New Republic, “Has the Time Come for Biden to Knock Some Heads on Capitol Hill?”, 10-13-2021, https://newrepublic.com/article/163982/biden-reconciliation-cost-democrats]//pranav

At the same time, though, **the White House has moved to a different phase of negotiations**. **Susan Rice, the director of the White House’s Domestic Policy Council, has become more visible in negotiations on the Hill, oftentimes spotted going in and out of meetings with White House National Economic Council director Brian Deese**. Rice, according to multiple administration officials, **has been involved in the reconciliation package talks for months, and lawmakers have looked to her as one of the point people within the administration on topics that fall under the DPC’s purview: Health care, childcare, housing.** Deese and Rice have been “tag teaming” those meetings, one administration official said. “It’s just that as the negotiations have come to a head, she’s become a little more visible,” the official added. But veterans of past major Democratic policy battles warn about the limits of a White House that throws up its hands and says enough is enough. The White House has already gone out to the states, looking to rally support among the broader public by having Biden himself stump in key congressional districts. **He has also used the power of the Oval Office to try to win over lawmakers like Sinema and Manchin.** “Having dealt with situations like this, there is a point where the administration really doesn’t have a lot of leverage,” said former Democratic Senate Majority Leader Tom Daschle. “They can use the media. They can use the president’s Oval Office presence to bring people down and persuade as much as they can, but ultimately there isn’t a lot of leverage, and when you’re at 50–50 and almost 50–50 in the House, every person is in a position to veto a particular proposal.” But Daschle said, so far, **the White House has played its hand well in the negotiations**. “**I think the administration has played it about right. They’ve got to give the leaders enough flexibility,**” Daschle said. Phil Schiliro, who served as the White House director of legislative affairs during Barack Obama’s presidency, **stressed that right now the White House is in the common-ground phase of negotiating with lawmakers. “It really is [about] trying to find the opportunities to reach common ground, and that’s just a process**,” Schiliro said. Still, increasingly, Democrats are having to face picking one of two choices: spending less or including fewer programs in a domestic policy package they hoped just about every Democrat running in 2022 could run on. “Here, I don’t know that there’s any magic to any number, as much as there’s getting the policies right,” Schiliro said. Publicly, the White House is trying to exude calm. Its latest deadline for moving a package forward is still a few weeks away. White House press secretary Jen Psaki told reporters Tuesday that Biden’s role, right now, as he remains very involved in negotiations, is “to find common ground so that we can move forward with an agenda that the American people demand we pass.” Privately, though, **the White House and Washington Democrats in general know they’re fast approaching a different deadline—the moment when someone is going to have to come out and say whether to shrink the overall spending and duration of the package or include fewer programs**. That is the only way for Democrats to win over the members they need to pass anything at all. The only Democrat with the necessary stature and the ear of the people who matter most to make that call is the president. Biden was the one who promised to unite as much of Congress as possible behind as large a domestic policy agenda as anyone in Washington had ever seen. Now he has to cut it.

**Pharma hates the plan – they want longer data exclusivity which independently incentivizes development of “biosimilars”.**

**Park ’16** [Caroline, studied metabolic syndrome at the Cowan Laboratory of the Harvard Stem Cell Institute. As a Herchel Smith Fellow in 2016, she focused on the effects of maternal malnutrition on fetal development, “Data Exclusivity: What is it and why does it matter?”, 01-20-2016, https://www.senseandsustainability.net/2016/01/20/data-exclusivity-what-is-it-and-why-does-it-matter/]//pranav

Given the profitability of biologics, **there is strong incentive for companies to develop “biosimilars,” which are the generic versions of the original drugs**. Biosimilars must undergo the same rigorous FDA approval process before they can be sold, which means that they need to be proven in clinical trials to be safe and efficacious. **Companies can sell biosimilars at much lower cost if they can rely on the data generated from clinical trials submitted by the maker of the original biologic, since the two compounds will be extremely similar in chemical make-up**. Unsurprisingly, in recent history, **the original maker has tended to fight tooth and nail to keep that data confidential for as long as possible, thus keeping the competition at bay and extending monopoly power.** Data exclusivity – which arises from this exact scenario – is entirely separate from patent protection – a patent is generally granted very early in the drug development process, when the initial discovery is made. Under TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights), which is administered by the WTO, a potential drug has 20 years of enforceable patent protection. For some drugs, the 20-year shelf life is not long enough, since the process of discovery, production, and FDA approval does not always run on a smooth and straightforward timeline. That said, 20 years is still a significant amount of protection – in developing nations, which have special TRIPS flexibilities under the Doha Declaration, there is no patent protection at all. **In the situation where a compound is covered by data exclusivity but not by a patent, a company can create a knock-off generic based on the original compound’s chemical properties**. **And nothing legally bars that company from generating its own data to eventually market the generic drug.** The lack of legal barriers, however, is meaningless, because the financial barrier is essentially insurmountable. No company will go through the effort of replicating a full three-pronged clinical trial process for a drug that is already on the market. Though price secrecy is ubiquitous in the pharmaceutical industry, it is well-known that the bulk of production cost comes from the clinical trials. A highly-cited Tufts study on pharmaceutical data in 2003 suggests that the average total development cost of a new drug is US$800 million, of which 60% is incurred through clinical trials. As of 2014, the Tufts Center for the Study of Drug Development has updated that cost to $2.6 billion, which is the number that PhRMA (Pharmaceutical Research and Manufacturers of America) likes to cite. These figures, however, are still being hotly debated, with some experts claiming that the cost is inflated. Nevertheless, **given high up-front costs, with substantially smaller marginal costs, one can see why PhRMA is pushing for longer data exclusivity periods globally.** For every one blockbuster drug (like Gilead’s hep C treatment), there are thousands of failures that never see the light of day. Pharmaceutical companies argue that without extensive patent and data exclusivity rights, there is no incentive for companies to engage in risky and expensive innovation, where there are considerable sunk costs spread over a 10-15 year drug development timeframe. Opponents of extended data exclusivity laws – among them the Public Citizen and Médecins Sans Frontières – are quick to point out that pharmaceutical companies already make huge profits and do not need more protection in the market.

**They lash out against infra and use COVID clout to kill it – they have public support, and a win now postpones reform indefinitely which turns case**

**Fuchs et al. 09/02** [Hailey Fuchsattended Yale University and was an inaugural Bradlee Fellow for The Washington Post, where she reported on national politics**,** Alice Ollstein is a health care reporter for POLITICO Pro, covering the Capitol Hill beat. Prior to joining POLITICO, she covered federal policy and politics for Talking Points Memo, Megan Wilson is a health care and influence reporter at POLITICO, “Drug industry banks on its Covid clout to halt Dems’ push on prices”, 09-02-2021, https://www.politico.com/news/2021/09/02/drug-prices-democrats-lobbying-508127]//pranav

**As Democrats prepare a massive overhaul of prescription drug policy, major pharmaceutical companies are mounting a lobbying campaign against it, arguing that the effort could undermine a Covid fight likely to last far longer than originally expected.** In meetings with lawmakers, **lobbyists for the pharmaceutical industry have issued warnings about the reconciliation package now moving through both chambers of Congress that is set to include language allowing Medicare to negotiate the price of some drugs, which could generate billions of dollars in savings**. In those conversations, K Street insiders say, **lobbyists have explicitly mentioned that the fight against the coronavirus will almost certainly extend beyond the current surge of the Delta variant**. And they’re arguing that **now isn’t the time to hit the industry with new regulations or taxes, particularly in light of its successful efforts to swiftly develop vaccines for the virus**. “For years, politicians have been saying that the federal government can interfere in the price of medicines and patients won’t suffer any harm,” said Brian Newell, a spokesperson for the Pharmaceutical Research and Manufacturers of America, or PhRMA, in a statement. “**But in countries where this already happens, people experience fewer choices and less access to prescription medicines**. Patients know if something sounds too good to be true, then it usually is.” **The escalating warnings from the pharmaceutical industry are part of what is expected to be one of the more dramatic and expensive lobbying fights in recent memory**, and a heightened repeat of the industry’s pushback to actions by former President Donald Trump to target drug prices. The proposal now under consideration in Democrats’ reconciliation package could save the federal government hundreds of billions of dollars by leveraging its ability to purchase prescription drugs, according to a report from the Congressional Budget Office. Without those funds, Democrats won’t be able to pay for the rest of the health care agenda they’ve promised to voters, including expansions of Medicare, Medicaid and Obamacare. But the plan has political power as more than a revenue raiser. Party leaders — from President Joe Biden to Senate Budget Chair Bernie Sanders (I-Vt.) — are touting it as one of the most important components of the $3.5 trillion package, with the potential to lower out-of-pocket health spending for tens if not hundreds of millions of people. Outside advocates have also zeroed in on it as the most consequential policy fight on the horizon. “**This is the best chance that we have seen in a couple of decades to enact meaningful reforms to drug pricing policy in the United States that will lower the prices of prescription drugs, and it’s very clear that the drug companies are going all out to stop it**,” said David Mitchell, founder of Patients for Affordable Drugs. “This is Armageddon for pharma.” **Progressive Democrats and their outside allies believe they’re closer than they’ve been in decades to imposing some price controls, and worry that failure to do so this year will delay progress indefinitely given the possibility of the party losing one or more chambers of Congress in the 2022 midterms**. In April, the House passed a fairly aggressive version — H.R. 3 (117) — though a handful of moderate Democrats friendly to the industry have threatened to block it when it comes back to the floor for a vote later this fall. Leadership has largely shrugged off this threat, banking on the fact that the most vulnerable frontline Democrats are vocally in favor of the policy, while most of the dissenters sit in safe blue districts. The Senate is designing its own version, outlined by Sen. Ron Wyden (D-Ore.) in June, as a middle ground between HR3 and the more narrow, bipartisan bill he and Sen. Chuck Grassley (R-Iowa) put forward last Congress. A senior Senate Democratic aide confirmed to POLITICO that the bill is nearly complete and that they’re in the process of shopping it around to undecided senators to make sure it has enough support to move forward in the 50-50 upper chamber. “It makes sense to get buy-in before releasing it rather than releasing it with fingers crossed and then tweaking it once members complain,” the aide said. **But the reform push is coming at a time when the pharmaceutical industry is working hand-in-hand with government officials to combat the pandemic and enjoying a boost in public opinion as a result, even as drug costs continue to rise**. The companies claim that fundamental changes to their bottom line — in addition to the Medicare provision, the reconciliation bill will likely raise corporate tax rate significantly, as high as 28 percent (a jump of 7 percentage points) — will threaten its current investments in research and development at a historically critical juncture. With the final draft of the bill expected in the coming weeks, the Pharmaceutical Research and Manufacturers of America, the lobbying arm of the pharmaceutical industry, is taking its case public. The group has recently spent at least seven figures on ads pressuring Congress not to change Medicare drug policy.

**Big pharma always wins – independently kills aff solvency bc it causes the plan to be watered down so much that de facto monopolies can survive**

**Florko & Facher ‘19** [Nicholas Florko is a Stat News Washington correspondent and Lev Facher is Stat News health and life sciences writer, “How pharma, under attack from all sides, keeps winning in Washington”, 07-16-2019, Stat News, https://www.statnews.com/2019/07/16/pharma-still-winning/]//pranav

It does not seem to matter how angrily President Trump tweets, how pointedly House Speaker Nancy Pelosi lobs a critique, or how shrewdly health secretary Alex Azar drafts a regulatory change. **The pharmaceutical industry is still winning in Washington**. In the past month alone, **drug makers and the army of lobbyists they employ pressured a Republican senator not to push forward a bill that would have limited some of their intellectual property rights**, according to lobbyists and industry representatives. **They managed to water down another before it was added to a legislative package aimed at lowering health care costs**. **Lobbyists also convinced yet another GOP lawmaker — once bombastically opposed to the industry’s patent tactics — to publicly commit to softening his own legislation on the topic**, as STAT reported last month. Even off Capitol Hill, they found a way to block perhaps the Trump administration’s most substantial anti-industry accomplishment in the past two years: a rule that would have required drug companies to list their prices in television ads. To pick their way through the policy minefield, **drug makers have successfully deployed dozens of lobbyists and devoted record-breaking sums to their federal advocacy efforts.** But there is also a seemingly new strategy in play: industry CEOs have targeted their campaign donations this year on a pair of vulnerable Republican lawmakers — and then called on them not to upend the industry’s business model. In more than a dozen interviews by STAT with an array of industry employees, Capitol Hill staff, lobbyists, policy analysts, and advocates for lower drug prices, however, an unmistakable disconnect emerges. **Even though Washington has stepped up its rhetorical attacks on the industry, and focused its policymaking efforts on reining in high drug prices, the pharmaceutical industry’s time-honored lobbying and advocacy strategies have kept** both **lawmakers** and the Trump administration **from landing any of their prescription-drug punches**. **“Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers**,” Sen. Dick Durbin (D-Ill.) said in a statement to STAT. Durbin, who recently saw the industry successfully oppose his proposal to curtail some of the industry’s patent maneuvering, added that, “Pharma’s billions allow them to continue to rip off American families and taxpayers.” The industry doesn’t get all the credit; it has also benefited from a fractured Congress and discord between President Trump’s most senior health care advisers. PhRMA, the drug industry’s largest lobbying group here, declined to comment for this article. **But industry leaders have broadly argued against efforts to rein in the industry’s practices in terms of price hikes and patents, making the case that that could irreparably stifle medical innovation**. The battle is far from over, and industry representatives and lobbyists are quick to hypothesize that the worst, for them, is yet to come. They point to several ongoing legislative initiatives, including in the Senate Finance Committee, that could take more concerted direct aim at their pricing strategies in Medicare. They’re waiting, too, to see if House Democrats can cut a drug pricing deal with the White House to empower Medicare to negotiate at least some drug prices. **Another pending regulation, loathed by drug makers, might tie their pricing decisions in Medicare to an index of international prices**. They’ve also bemoaned the Trump administration’s decision last week to abandon a policy change that would have ended drug rebates — which, the pharmaceutical industry has said, could have given drug makers more space to lower their prices voluntarily. “We’re getting killed!” one pharma lobbyist told STAT. Of course, the Trump administration’s supposedly devastating decision to abandon that proposal simply maintains the status quo. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers.” n Valentine’s Day, Sen. Thom Tillis (R-N.C.) enjoyed a showering of love that is familiar in Washington: a flood of campaign contributions, many at the federal limit of $2,800 for a candidate or $5,000 for an affiliated political committee. One donation came from Pfizer’s CEO, Albert Bourla, who donated $5,000 to Tillis and another $10,000 to Sen. John Cornyn (R-Texas) and associated campaign committees. Another came from Kenneth Frazier, the top executive at Merck. The Tillis campaign committee eventually cashed checks from CEOs and other high-ranking executives at those companies as well as Amgen, Eli Lilly, Sanofi, and Bristol Myers-Squibb, plus two high-ranking officials at the advocacy group PhRMA. Six lobbyists at one firm that works with PhRMA, BGR, also combined to contribute $100,000 to a bevy of Republican lawmakers and the party’s campaign arms. Tillis raised an additional $64,500 from drug industry political action committees in the past quarter, according to disclosures released on Monday. A Pfizer spokeswoman declined to comment about Bourla’s contributions, and representatives for the other companies did not respond to STAT’s request for comment. Tills was one of few individual lawmakers — in many cases, the only one — to whom the executives had written personal checks during the current election cycle. While drug industry CEOs frequently contribute to political committees for congressional leadership, the breadth of executives who donated Tillis specifically is notable, particularly considering his outspoken role on pharmaceutical industry issues. While lobbyists pushed back on the notion that campaign contributions directly influence votes, the donations targeted so specifically to a particular candidate could be seen as a prime example of Washington’s system for rewarding loyalty and how industries protect their interests. The same PhRMA PAC that donated to Tillis has given generously in recent years: nearly $200,000 in the 2018 campaign cycle, roughly 58% of which was targeted toward Republicans. Drug industry PACs donated $10.3 million in total in that cycle, according to the Center for Responsive Politics. The figure two years before was even higher: a total of $12.2 million from industry-aligned PACs alone. **It is no accident that the pharmaceutical industry has maintained its reputation among the nation’s most powerful lobbies,** said Sheila Krumholz, the executive director of the Center for Responsive Politics, an organization that tracks political influence. “**Their access and influence goes beyond this Congress or even the administration**,” Krumholz said in an interview, adding that she “**was struggling to think of evidence” it had waned**. **Pharma has a reputation here for winning on policy** — often thanks to the lawmakers who are among the biggest recipients of the millions that drug corporations, employees, and the industry political arms donate each year. Even as the rhetoric has escalated, the industry has quietly worked to insulate itself from any major legislative changes. Take, for example, a recent about-face from Cornyn, the Texas Republican who took in some campaign cash alongside Tillis. As recently as February, Cornyn seemed to be positioning himself as a rare Republican figurehead for anti-pharma congressional wrath. At a widely publicized hearing before the Senate Finance Committee, he went head-to-head with AbbVie CEO Richard Gonzalez, pressing him to explain why the company had filed more than 100 patents on its blockbuster arthritis drug Humira. Cornyn introduced legislation soon after the skirmish to crack down on patent “thicketing,” a term for a drug company tactic to accumulate tens, if not hundreds, of patents to shield a drug from potential generic competition. Pharma sprung into action. They recruited congressional allies, including Tillis, to pressure Cornyn to significantly rework the bill, and they succeeded. The version of the bill that eventually cleared the Senate Judiciary Committee was stripped of language that would have empowered the Federal Trade Commission to go after patent thicketing. Instead, the bill limited how many patents a drug maker could assert in a patent lawsuit. The new version of the bill lost “a lot of teeth” and “solves a narrower problem in a narrow way,” advocates told STAT when the change was first introduced. It is far from the only example of the industry’s aggressive interventions to water down legislation. “In lots of ways they’re like the [National Rifle Association], **because they have an incredible power to squash out any negative opinion, nor to feel any of the ill effects of those things,”** said Pallavi Damani Kumar, an American University crisis communications professor who once worked in media relations for drug manufacturers. “It just speaks to how incredibly savvy they are.” Pharmaceutical industry lobbyists also successfully fought to keep another anti-drug industry patent proposal from Sen. Bill Cassidy (R-La.) and Dick Durbin (D-Ill.) out of a bipartisan drug pricing package moving through the Senate HELP Committee. **The legislation would have allowed the FDA to approve cheaper versions of drugs, even when the more expensive product was protected by certain patents**. Cassidy’s proposal never even made it into the HELP package. As the lobbyist who bemoaned the withdrawal of the rebate rule put it, Cassidy “simmered down” in the face of industry pressure. In recent weeks, the industry had targeted Cassidy in particular, in recent weeks, for fear he would break with many of his GOP colleagues to support a cap on some price hikes for drugs purchased under Medicare, a proposal so far pushed only by Democrats. “Sen. Cassidy doesn’t care what lobbyists think — he is going to do what’s best for patients,” said Ty Bofferding, a Cassidy spokesman. “Sen. Cassidy fought for the committee to include the REMEDY Act in the package, despite strong opposition from the pharmaceutical industry.” The committee eventually included half the bill’s provisions, he added, as well as four other pieces of legislation meant to prevent the industry from taking advantage of the patent system. The drug industry also notched a win by watering down another proposal in that package from Sen. Susan Collins (R-Maine) that would have blocked drug makers from suing over patents they didn’t disclose to the FDA. The version of the bill that actually made it into the package doesn’t block drug makers from suing, but instead directs the FDA to create a public list of companies that fail to disclose their patents. “This change is a big win for drug makers,” Michael Carrier, a Rutgers University professor and expert on patent gaming, told STAT. “**Shaming is something drug makers don’t seem worried about**.” Matthew Lane, the executive director of the Coalition Against Patent Abuse, likewise added that the altered bill “doesn’t seem to be doing much anymore.” Not all of the pharma-endorsed changes, however, are self-serving. Patent experts and federal regulators too had raised concerns with some of the bill being proposed. Cornyn’s patent bill was particularly controversial. “These provisions encourage ‘fishing expeditions’ by zealous bureaucrats, politically motivated by the popularity of efforts to reduce drug prices and garner the political benefits of being seen to be pursuing these ends,” Kevin Noonan, a patent lawyer at McDonnell Boehnen Hulbert & Berghoff wrote in a recent blog post, referring to the original Cornyn bill. Drug-pricing advocates said lobbyists have even managed to convince lawmakers to introduce some legislation they say has explicitly favored the drug industry, including intellectual property-focused legislation that would allow drug makers to patent human genes. That particular bill would “undo the bipartisan effort underway to fix pharma’s exploitation of the patent system,” said the Coalition Against Patent Abuse. And they were far from the only group raising concerns. The American Civil Liberties Union and more than 150 other groups wrote to lawmakers last month opposing the bill. Pharma’s list of policy victories goes on: Drug companies and allied patient groups forced the Trump administration to back off a proposal to make relatively minor changes to Medicare’s so-called protected classes policy. Currently, Medicare is required to cover all drugs for certain conditions, including depression and HIV. The Trump administration proposed in November that private Medicare plans should be able to remove certain drugs in those classes from their formularies, if the drugs were just new formulations of a cheaper, older version of the same drug, or when a drug spiked in price. But drug industry opposition helped convince the administration to spike that effort. A week ago, the industry struck its biggest blow yet. Three of the country’s largest pharmaceutical companies —Amgen, Eli Lilly, and Merck — prevailed in a lawsuit to strike down a Trump administration requirement that they disclose list prices in television advertisements. **The lack of congressional action — despite the Democratic enthusiasm and bipartisan appetite — is still further evidence of industry’s ability to stave off defeat. As the dozens of Democrats running for president ramp up their anti-pharma rhetoric**, both Trump and progressives have begun to fret that **Washington’s efforts have proven to be all bark and no bite**. With two weeks remaining before the August recess and an escalating 2020 campaign, some advocates fear that the window for bold action is closing quickly. “It’s appalling that we are six months into this Congress and we haven’t seen meaningful legislation passed on American’s number one issue for this congress,” said Peter Maybarduk, who leads drug-pricing initiatives for the advocacy group Public Citizen. “Congress needs to get its act together.”

**Infra’s k2 stopping existential climate change – warming is incremental and every change in temperature is vital**

**Higgins 8/16** [Trevor, Senior Director, Domestic Climate and Energy, “Budget Reconciliation Is the Key to Stopping Climate Change”, 08-16-2021, https://www.americanprogress.org/issues/green/news/2021/08/16/502681/budget-reconciliation-key-stopping-climate-change/]//pranav

The United States is **suffering** acutely from the chaotic changes in climate that scientists now directly attribute to the burning of fossil fuels and other human activity. **The drought, fires, extreme heat, and floods that have already killed hundreds this summer across the continent and around the world are a tragedy—and a warning of worsening instability yet to come**. However, this week, the **Senate initiated an extraordinary legislative response that would set the world on a different path**. **Enacting the full scope of President Joe Biden’s Build Back Better agenda would put the American economy to work leading a global transition to clean energy and stabilizing the climate.** A look at what’s coming next through the budget reconciliation process reveals a ray of hope that is easy to miss amid the fitful negotiations of recent months: **At long last, Congress is on the verge of major legislation that would build a more equitable, just, and inclusive clean energy economy. This is our shot to stop climate change. Building a clean energy future must start now Until the global economy stops polluting the air and instead starts to draw down the emissions of years past, the world will continue to heat up, blundering past perilous tipping points that threaten irreversible and catastrophic consequences. Stemming the extent of warming at 1.5 degrees Celsius rather 2 degrees or worse will reduce the risk of crossing such tipping points or otherwise exceeding the adaptive capacity of human society. Every degree matters.** Stabilizing global warming at 1.5 degrees Celsius starts with cutting annual greenhouse gas emissions in the United States to half of peak levels by 2030. This isn’t about temporary offsets or incremental gains in efficiency—it’s about the rapid adoption of scalable solutions that will work throughout the world to eliminate global net emissions by 2050 and sustain net-negative emissions thereafter. Building this better future will tackle climate change, deliver on environmental justice, and create good jobs. It will give us a shot to stop the planet from continuously warming. It will alleviate the concentrated burdens of fossil fuel pollution, which are concentrated in systemically disadvantaged, often majority Black and brown communities. It will empower American workers to compete in the global clean energy economy of the 21st century. There is no time to lose in the work of building a clean energy future.

**4**

**Biotech industry strong now – new innovation and R&D coming**

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

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

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

What about SPACs?

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

Fundamentals continue strong

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

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

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

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

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

More innovation on the horizon

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

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

**Reductions in Data Exclusivity stifle biopharmaceutical innovation**

**Chakrabarti 14** [ Gargi Chakrabarti is an Associate Professor at the Faculty of Law at National Law University, Jodhpur. September 2014 “Need of Data Exclusivity: Impact on Access to Medicine” http://nopr.niscair.res.in/bitstream/123456789/29506/1/JIPR%2019%285%29%20325-336.pdf]//aaditg

Economic Rationale behind Data Exclusivity In order to demonstrate a drug's efficacy and safety for its intended therapeutic use, it is necessary for the originator of the drug to conduct extensive testing on animals and humans in pre-clinical and clinical trials as well as toxicology, manufacturing feasibility and other scientific studies. **The results of these tests and studies**, which **are proprietary,** are contained in a registration dossier that is submitted to governmental prices of these DE protected medicines were up to 800% higher than in neighbouring Egypt. (2) A 2010 study by the Centre for Policy Analysis fon Trade and Health determined that once Guatemala enacted DE, prices of some medicine rose as much as 846% - even though just a ‘handful of them were under patent protection.\*! (3) Data exclusivity raises the price of medicines ‘even when no patent exists. For example, in the US, the price of colchicine, a treatment used mainly for gout, rose more than 5,000% after DE law was enacted.” Colchicine hes been in use for authorities to obtain marketing approval for the drug. ‘The generation of this confidential registration data involves a substantial amount of time and expense for the originator. **For example, \_ research-based pharmaceutical companies in the United States invested USS 21.8 billion in R&D in 1998, a 10% increase over 1997 (ref. 43). With 40% of this R&D expenditures going to pre-clinical functions and 30% towards completing the Phase I, Il, and III clinical trials required by the FDA, 70% of all R&D expenditure in the United States are targeted towards gaining regulatory approval.** A new drug costs, on an average, US$ 500 million and requires as long as 15 years to develop taking into account pre-clinical and Clinical trial phases. Only three out of ten drugs introduced in the United States from 1980 ~ 1984 had returns higher than their average after-tax R&D costs. **Comprehensive drug testing in the clinical trial stage alone can cost USS 150 million or more for a single medication and only 10% - 20% of drugs ever clear the full set of pre-clinical and clinical trials.”** In stark contrast, a manufacturer of a generic alternative, if itis not required to generate its own test data to gain marketing approval, needs to invest only USS | million to launch a competitor drug, as long as it can demonstrate bioequivalency. When the latter applicant receives the benefit of the data generated by the originator without any investment on its part, the originator is placed at a significant commercial disadvantage. Such a situation undermines the investment potential existing even in countries with strong and effective patent protection, since the results of the originator’s tests are immediately | available to competitors at no cost. In addition, the | burden is placed entirely on the originator to pursue any patent rights; under the data protection scenario, a | product is only considered for marketing approval | once the period of data protection has passed. Given | the imbalance between the cost to the originator in gaining marketing approval for its drug and the copier’s cost of coming on to the market, the research-based industry would have a reduced incentive, without such protection, to engage in the important R&D activities that will ultimately benefit patients through the availability of new and innovative drug therapies. The incentive for developing new drug therapies that is provided by a period of data exclusivity is especially critical when the new drug therapy is not patentable. The registrations of data are provided to the authorities in confidence and are not meant to be referred to by third parties. **If these data were immediately available to third parties, there would be no incentive for a ‘company to generate these data in the first instance,** unless the investment in terms of both time and costs were protected by other means. In many instances, a patent will cover the pharmaceutical product at issue. However, more and more compounds which are not patent protected (for whatever reason) are being developed and thus data exclusivity in some instances is the only available intellectual property right. It is important that governments protect the confidentiality of these data against its unauthorized use or disclosure in order to protect the proprietary interests of scientists and others and to maintain the economic incentives for further pharmaceutical research and development. However, because of a concem for avoiding repetitive tests and trials on animals and humans, governments have sought to limit the originator’s proprietary data rights. Therefore, the USA and the EU have acknowledged the right of data protection for a certain fixed period of time. After the period has expired, reference to the data is permitted by generic companies. This compromise is viewed as protecting the investment of the originator, while at the same time preventing unnecessary repetitive tests and trials. Arguably, if a country had no data protection law at all, then the data submitted as part of a registration should never be permitted to be referred to by a generic company. The period of data exclusivity is not fixed by the TRIPS Agreement. Earlier drafts of the TRIPS Agreement provided a minimum five year period of protection. However, this specific minimum time frame ‘was removed from the final version and was expected to be sufficient to protect the originator’s investment. **‘Thus, the generation of the data necessary for the original marketing approval requires a substantial investment of time, expertise, resources and money.** The originators of the drug must be given an opportunity — and the incentive — to recoup the enormous costs involved in generating such data before a competitor is permitted to rely on those data for the approval of the generic altemative.

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror – turns case**

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

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

**COVID incentivizes engineered bioterror- extinction**

**Walsh, 20** -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: **New tech**nology like **gene editing** and **DNA synthesis** has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, **engineered pandemics** are widely considered the **biggest existential risk facing humanity**.

That's in part because a pathogen could be **engineered** in a lab **for maximum contagiousness and virulence**, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The **democratization of biotech**nology could unleash a **wave of** creativity and **innovation**, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus,

**5**

**CP Text – The Member Nations of the World Trade Organization should increase production of the gene editing technology CRIPSR – Cas.**

**Solves their amr impact**

**MBS 19** [The Microbiology Society (previously the Society for General Microbiology) is a learned society based in the United Kingdom with a worldwide membership based in universities, industry, hospitals, research institutes and schools. “CRISPR-CAS COULD HOLD THE SOLUTION TO AMR” 3-7-2019 <https://microbiologysociety.org/news/society-news/crispr-cas-could-hold-the-solution-to-amr.html>] // aaditg

New research carried out at the University of Exeter has **found a novel way to tackle the growing issue of antimicrobial resistance (AMR) using the gene editing technology CRISPR-Cas. Many of the genes that code for AMR are found on accessory genetic elements such as plasmids**. Plasmids are rings of DNA that can spread easily between bacteria and replicate. Plasmids are not part of the bacteria’s DNA, but can distribute traits like AMR between cells. Researchers have engineered a plasmid to specifically target the resistance gene for Gentamicin, a broad-spectrum antibiotic used for a wide range of bacterial infections. When the plasmid identifies the gene for Gentamicin, it cuts out the DNA, removing the resistance and making the cell susceptible to the antibiotic. When using this new technique, the researchers found that **they could lower resistance levels by 33% compared with a control treatment** using a plasmid engineered in the same way, but without specifically targeting the Gentamicin-resistance gene. The researchers are able to cut out the genes for resistance by using CRISPR-Cas; a gene editing technology that allows for DNA to be altered by cutting it in a desired location. It is based on the antiviral CRISPR-Cas (Cas9) defence system that bacteria use against viruses. Scientists engineer a synthetic Cas9 enzyme and pair it with guide RNA which tells the Cas9 where to cut the DNA, allowing genes to be removed and if desired, replaced with new genes. David Sünderhauf, researcher at the University of Exeter said, “We’re facing a huge challenge with AMR in the coming years, and it is important to investigate different approaches to solve this problem.” AMR develops when pathogenic bacteria evolve resistance to an antibiotic - as these bacteria have a significant evolutionary advantage over others in their species, they survive, reproduce, and the genes for AMR spread. Over-use of antibiotics in the farming industry, not using antibiotics correctly, such as using them for viral infections or not finishing the course of antibiotics, allows resistance to spread even **faster**. Exacerbating the issue further is bacteria’s ability to transfer genes horizontally, where genetic material is passed between individuals without the need to reproduce. This process is done with plasmids, and can occur between species, leading to the development of AMR in a wide range of bacteria. While still in the early stages of research, this new approach to tackling AMR has huge potential, David Sünderhauf said; “Once fully developed we could use this approach to keep our current antibiotics working by removing resistance genes from clinical pathogens or from the environment.” David Sünderhauf will present his findings at the 2019 Microbiology Society Annual Conference. His poster, ‘AMR gene removal by conjugative delivery of CRISPR-Cas9’, will be available to view from Wednesday 10 April to Thursday 11 April in Hall 1D.

## case

**Framework**

**[1]Problem of induction—I predict based on past experiences, but there’s no justification for why those past experiences are true besides they worked in the past, which is based on experiences and is circular**

**[3]Gvosdev – a) this card is a a bunch of claims w out a warrant why cpnsequences overdetermine intentions b) intetions =/= rhetoric vs action**

**[4]enoch [a] You don’t will ends, you will an action, action theory disproves this to be possible, there’s an infinite number of smaller consequences from every action and they can’t even be verified because of the problem of induction ..**

**5. Bostrom – [A] fallacy of origin- life is important but not the center of an ethical theory just as having oxygen is good for me to debate doesn’t mean it should be the starting point for an ethical theory.**

### Advantage

**No offense – only the RESULTS of the data are private NOT the method which means pharma companies can j conduct similar studies which sovles your impacts**

**Arbitrary af – no reason why arbitrayily changing data exclusivity to a diff number does anything**

**Low prices independently cause AMR.**

**Babu and Suma 6** Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)//Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.

**There’s no relation between data exclusivity and high prices – Canada and Japan prove**

Philip **Stevens 15** [Director of the Geneva Network, a research and advocacy organization working on international health, trade, and intellectual property issues. Will Increasing the Term of Data Exclusivity for Biologic Drugs in the TPP Reduce Access to Medicines?, Center for Intellectual Property x Innovation Policy (8-6-2015) https://cip2.gmu.edu/2015/08/06/will-increasing-the-term-of-data-exclusivity-for-biologic-drugs-in-the-tpp-reduce-access-to-medicines/]//anop

Like several TPP countries, the governments of **Canada and Japan have national health insurance systems, and cover most health care costs, including medicines.** Unlike other TPP countries, **Canada and Japan have in the past decade adopted substantially longer terms of RDP.** Their experiences, captured in the data provided below, show that **expenditures on medicines did not change appreciably from previous trends**. In **2006 Canada changed its regulations in a way that effectively increased their RDP term from 0 years to 8 years**. As shown in Figure 1 ( based on 2014 OECD data ), **pharmaceutical spending as a percentage of total health spending has actually decreased since then.** As indicated in Figure 2 below, over the same period (2005-2011) pharmaceutical expenditure as a percentage of GDP (blue bars) remained relatively stable after RDP was increased in Canada in 2006, whereas overall health spending as a percentage of GDP in Canada has gradually increased (red bars). **Similarly, Japan increased data protection in 2007 from 6 to 8 years (effectively 9 yearsiv). As indicated by Figure 3, fluctuations in expenditures after that time have been in line with growth in health care spending as a percentage of GDP. In fact, in 2010 pharmaceutical spending decreased in a year where health care spending increased. Figure 4 shows that the gradual increases in pharmaceutical expenditure as a percentage of GDP in Japan between 2005 and 2010 (blue bars) was in line with the overall increase in health spending as a percentage of GDP in Japan over the same period (red bars). The past experiences of Canada and Japan described above indicate that increases in RDP terms do not result in meaningful increases in health care expenditures or expenditures on medicines relative to overall health care spending. There could be many explanations for this result, ranging from changes in procurement policies, to increases in the number of medicines whose patent terms have expired**. The evidence presented above, however, suggests that those concerned about access to medicines and the financial sustainability of public healthcare systems should focus their attention on policies other than Regulatory Data Protection

**Data exclusivity is key to foreign investment**

Jack **Ellis 17** [Jack Ellis is a journalist and editor who has written extensively on technology, investment, and innovation-related issues and a Contributor at Geneva Network.. Why regulatory data protection matters for medicines, Geneva Network (July 11, 2017) https://geneva-network.com/research/regulatory-data-protection-matters-medicines/]//anop

Israel has long been lauded as the ‘Start-up Nation’. But for many years, the country was curiously conspicuous by its lack of a significant R&D base in pharmaceuticals and biotechnology. Back in 2010, Israel’s Chief Scientist, Dr Eli Opper, had pinpointed biotech as a key area for future growth. His office had pushed through the establishment on several life sciences-focused incubators and was working to set up a biotech investment fund in an effort to attract investment in the nascent sector. But Opper was frustrated by the low level of interest in these incentives. **When he attended the BIO2010 US-Israel Dialogue later that year, one theme became apparent in all of his conversations with the companies and investors that he wanted to bring to Israel: the country’s IP protection system was proving a turn-off. Israel had failed to implement long-promised IP reforms; but even while Opper came face-to-face with the indictments of the country’s IP policy, it was already working towards significant improvements. Over the following five years, Israel undertook a deep and wide-ranging reform of its IP system, including the institution of RDP for chemical drugs of up to six years. Since then, there has been a boom in investment in the life science sector: in 2010, foreign capital accounted for around $56 million, or 17%, of all investment in Israeli life sciences companies. Fast forward to 2014, and foreign investment made up the majority (59%), at $469 million of a total $801 million.**

**Multiple alt causes to high drug prices and limited access**

**Kilberg et al 16 (William J. Kilberg is the most senior partner in the Labor and Employment Law Practice Group at Gibson, Dunn & Crutcher LLP. He has served on the firm’s Executive Committee, five-member Management Committee, and as Partner-in-Charge of the Washington office. He has argued many significant matters before eight United States Courts of Appeals and the United States Supreme Court., James A. Paretti, Jr. is an experienced management-side employment and labor relations attorney with in-depth political and policy knowledge of labor, pension, healthcare and employment law, regulations and legislation. Jim is well versed in all aspects of legislative and political processes with demonstrated knowledge in the substance of federal labor and employment policy. He has over two decades of experience working with federal legislators and policymakers, including former Speaker of the U.S. House of Representatives, Chairmen of the U.S. House Committee on Education and the Workforce, and senior level administration officials., Marisa Maleck focuses on litigation, regulatory matters and public policy, with a focus on consumer products. As a former senior counsel at a bio-tech company and in private practice, Marisa has substantial experience with and is skilled in providing creative solutions in the face of uncertainty. Marisa represents clients in a variety of matters with a focus on FDA-regulated products like food, beverages, pharmaceuticals, medical devices, wellness products, cosmetics, tobacco and cannabis. As a former senior counsel at an FDA-regulated biotech company and as a former partner in King & Spalding’s Litigation and Global Disputes practice group, she handled hundreds of suits in a multi-district litigation, multiple agency inquiries, an FTC lawsuit and 10+ state Attorney Generals actions. ), “The United Nations' Misguided Approach to Healthcare Access”, 9-6-16, The Federalist Society,** [**https://fedsoc.org/commentary/fedsoc-blog/the-united-nations-misguided-approach-to-healthcare-access**](https://fedsoc.org/commentary/fedsoc-blog/the-united-nations-misguided-approach-to-healthcare-access) **NT**

The Panel Is Poised To Ignore Real Access Problems The Panel’s misguided focus on patents has led the U.S. State Department to encourage the Panel to abandon its “narrow mandate” and instead focus on actual obstacles that stand in the way of persons obtaining life-saving drugs. Echoing the WHO, the State Department has pointed to four main reasons that the developing world lacks access to healthcare: (1) an inability to select and use medicines rationally; (2) unaffordable drug prices; (3) unreliable health and supply systems; and (4) inadequate financing. **None of these barriers are directly related to patents**. First, irrational drug use is a serious barrier to access. The WHO defines “irrational use” as any use that is not “appropriate to [patients’] clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” Two recent studies conducted in Africa illustrate this problem. One study conducted at Kapiri Mposhi District Hospital in Central province, Zambia found a high prevalence of irrational drug use. Fifty percent of 680 patient records surveyed showed some form of inappropriate drug use. And a study in Sudan found that 73% of participants reported to have acquired and used medication without a prescription at least a month prior to the study. Second, there is no doubt that affordability is a barrier to access. But patent protections are not to blame. In fact, patents do not protect the vast majority of essential medicines, which the WHO defines as “those drugs that satisfy the health care needs of the majority of the population.” 350 of these 375 “essential medicines” are available in generic versions and are thus sold at a much lower price point. Moreover, data shows that patent-holding companies do not frequently make use of patent laws in developing countries, even where they could. Moreover, **patent rights do not explain the high cost of drugs in the developing world.** The WHO itself points out that **taxes, tariffs** and other government policies play a significant role in keeping drug prices high in emerging markets. And, in fact, reports have concluded that excessive tariffs and taxes on imported medicines **may inflate the cost of medicines by up to one-third.** When combined with taxes on medicines, government-imposed levies account for an additional 55% in India; 40% in Sierra Leone; 34% in Nigeria; and 29% in Bangladesh. In any event, contrary to the Panel’s suggestion, patent protections ultimately help keep the costs of drugs low. To be sure, patented drug prices will often decline only after a patent expires. But the decline in price after patent expiration is not evidence that the drug manufacturer charged too much for the product. To the contrary, the decline in price of a formerly patented medicine is consistent with an efficient market. Patents expire after a certain period of time fixed by law. As economists have explained, during this period, prices will reflect both the costs of production and the company’s research and development costs. The exclusivity period that the patent creates attracts investment, which enables the innovator company to recoup its research and development costs. Once the patent expires, other companies may create generics that are priced lower. But these lower costs reflect the fact that copycat companies only need to recoup production costs, not research and development. In other words, a patent’s provision of an opportunity for an innovator company to recover costs enables it to produce the medicine in the first place. And the patent’s eventual expiration allows for robust competition that drives prices down. Third, as many experts point out, structural and economic barriers are a significant barrier to access to medicine in the developing world. Poor infrastructure and weak healthcare systems plague third-world countries. Several countries’ medical centers are located in remote areas that may only be reached through impassable roads. Also, many drugs and vaccines must be stored at certain temperatures. But many developing countries lack reliable electricity and sanitary facilities to enable proper storage. In India, for example, a quality-control study followed a series of vaccine vials through the supply-chain delivery process. The study found that 76 percent of the vaccines could not be used because they were stored in substandard storage facilities. Fourth, experts also acknowledge that developing countries tend to underinvest in health. In 2001, for example, African leaders met in Abuja, Nigeria, and pledged to allocate 15 percent of their national budgets to health. The 2015 DATA Report found, however, that between 2011 and 2013, just eight of the 47 countries for which there was data available spent 15 percent or more on health: Uganda, Rwanda, Malawi, Swaziland, Nigeria, Ethiopia, Liberia, and Togo. Twenty countries did not reach even the 10 percent level. If anything, patent protections could incentivize further investment in health in these countries. \* \* \* The UN has a real opportunity to address the critical issue of healthcare access. As it stands now, however, it seems poised to do more damage than good.

**Data Exclusivity is good for innovation**

**Goldman et al 11** [Dana P. Goldman, PhD and Darius N. Lakdawalla, PhD Schaeffer Center for Health Policy and Economics University of Southern California 3335 S. Figueroa St., Unit A Los Angeles, CA 90007 Jesse D. Malkin, PhD Precision Health Economics 11100 Santa Monica Blvd. Suite 500 Los Angeles, CA 90025 John Romley, PhD Schaeffer Center for Health Policy and Economics University of Southern California 3335 S. Figueroa St., Unit A Los Angeles, CA 90007 Tomas Philipson, PhD Irving B. Harris Graduate School of Public Policy Studies University of Chicago 1155 East 60th Street Chicago, IL 60637, Suite 112 Jan 2011 “The Benefits From Giving Makers Of Conventional `Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334e>] //aaditg

Although some have questioned whether profits drive innovation, **empirical evidence strongly supports this relationship**. The Orphan Drug Act of 1983, which provides pharmaceutical companies with incentives to develop drugs for treating rare diseases or conditions for which there are small patient populations, was followed by a sharp increase in the number of drugs approved for this market.4 **Higher profits from vaccines have been associated with a significant increase in the number of clinical trials to develop new vaccines.**5 There is also evidence that manufacturers have delayed new drug launches rather than accept a lower anticipated price.6 Daron Acemoglu and Joshua Linn7 concluded that a 1 percent increase in the potential market size for a drug class leads to a 3–4 percent growth in the entry of new drugs.7 To our knowledge, this is the only study that estimates this relationship for the entire drug market. As Darius Lakdawalla and colleagues observe,8 the relationship identified by Acemoglu and Linn presumes that increases in the number or share of the aged population (60+ years old) driven by past baby booms or busts also increase innovation in drug classes targeted toward the aged. Moreover, it presumes that pharmaceutical innovation does not drive historical trends such as baby booms of busts; there is no evidence that contradicts this presumption. Applying this relationship between market size and innovation to average sales within a drug class, **innovators produce one additional drug for every additional $97.5 million of annual potential revenue.** Because the cost of a new conventional drug is estimated to be $800 million,9 innovators require a 12 percent annual return on their investment—within accepted boundaries for the return on capital in the drug industry. In this paper we analyze the effect of a longer period of data exclusivity for conventional drugs on both current and future generations. We do not consider the effects of a change in the data exclusivity period for biologics. We focus on a twelve-year duration because, as noted above, this is data exclusivity period recently approved by Congress for biologics. As such, it serves as a natural benchmark for extended data exclusivity for conventional drugs. We address three specific policy questions: How would extending the initial five years of data exclusivity for new conventional drugs in the United States affect innovation? How would a longer period of data exclusivity affect the health of current and future generations? What is the dollar value of a longer period of data exclusivity to US society? Go to: STUDY DATA AND METHODS Our analysis has two main components. First, we estimated the effect of a longer period of data exclusivity on revenues to pharmaceutical companies. We used retrospective data from the drugs@FDA database10 and the FDA Electronic Orange Book11 of approved drug products to construct a representative profile of protection from generic competition during a drug's life cycle. Second, we feed that result into our global pharmaceutical policy model8 to determine the effect of increased pharmaceutical revenues on drug innovation and consumers' longevity. The model is a set of dynamic interactions that link present health and innovation to their future values. For example, next year's health status depends on today's health, on the drug treatments that are available, and on a set of random health “shocks” that vary with an individuals' own risk-factors such as age, health behaviors, and current disease conditions. An example of a shock would be exposure to an infection. Following Joseph Lipscomb and colleagues,12 we assume a real (inflation-adjusted) “social” discount rate of 3 percent in our baseline analysis. This discount rate captures the manner in which society discounts benefits in the future compared to benefits today. It is distinct from companies' cost of capital – the amount of interest they need to pay to borrow money – which is typically higher than 3 percent.9 For our baseline analysis, we assume an innovation elasticity of 3.0, meaning that a 1 percent increase in expected drug revenue leads to a 3 percent increase in the number of drugs approved within the class each year. This assumption is slightly conservative and understates changes in innovation, longevity, and welfare, relative to the findings of Acemoglu and Linn.7 Increased innovation in turn affects population health. The global pharmaceutical policy model uses the health benefits documented in the clinical literature as a result of recent drugs for seven major conditions (heart disease, hypertension, diabetes, cancer, lung disease, stroke and mental illness). The model also accounts for the increased likelihood of treatment associated with drug innovation. As innovation expands because of greater data exclusivity, the life expectancy of older Americans improves; this improvement results mainly from the increased likelihood of treatment, not the health benefits of new drugs. With longer life expectancy, the population of potential drug users grows, further increasing revenues and stimulating innovation over time. We model innovation and health through 2060. The monetary value of increased longevity, that is, the amount consumers are willing to pay for longer life spans, has long been a subject of debate. An analysis by Richard Hirth and colleagues of attitudes and behavior related to mortality risk showed that the median value of a life-year ranges from $110,200 to $505,400 (in 2004 US dollars).13 Research by Kip Viscusi and Joseph Aldy implies that the value of a life-year ranges from $150,000 to $360,000.8,14 In our baseline analysis, we assign a monetary value for increased longevity of $200,000 per life-year, though in sensitivity analyses we consider a range of values for this and other parameters. Additional details about our methods, data, and assumptions are provided in a technical appendix.15 Limitations Simulations of this sort have certain limitations. Because laws, regulations, science, and medicine are likely to change in unforeseen ways, the retrospective data we relied on may not characterize the future. Some plausible changes, for example, an increase in the number of successful challenges to patent validity,1 may cause us to understate the effects of longer data exclusivity. Other changes such as government price controls, which would reduce potential profits available to drug companies, may cause us to overstate effects. Still other changes, such as advances or setbacks in science and medicine that are impossible to anticipate, could lead to either understated or overstated effects. We do not model behavioral responses to a longer period of data exclusivity due to the technical complexity and lack of good evidence. For example, a generic drug company might attempt to bypass lengthier data exclusivity periods in the United States by conducting clinical trials of a generic version of an already-approved drug. If drug developers believe that generic manufacturers would behave in this way, our results overstate the long-term effects of longer data exclusivity. We do not model non-mortality benefits, for example, treatments for mental health conditions, pain, and rheumatoid arthritis. Such benefits account for much of the value of many drugs, yet there was insufficient evidence on the non-mortality benefits of new drugs. If these benefits are important, our estimates of the benefits of longer data exclusivity are conservative. Finally, we do not calculate the potential benefits of a data exclusivity period shorter than the current Hatch-Waxman provisions. Go to: STUDY RESULTS **Applying our findings about increased revenues over a drug's life cycle, we found that extending data exclusivity to twelve years would increase lifetime drug revenues by 5.0 percent on average.** Exhibit 1 explains how we reached this result. The exhibit shows the proportion of conventional drugs that had protection against generic competition under existing law—arising from either patents or data exclusivity—and the proportion of such drugs that would have had protection if data exclusivity had lasted twelve years. The drugs in our sample began facing generic competition eight years after launch. With a twelve-year period of data exclusivity, by contrast, all the drugs would have faced no generic competition for at least twelve years after launch. We also determined that **expanding data exclusivity to twelve years would result in 228 extra drug approvals between 2020 and 2060, relative to the number of approvals that we project under the current Hatch-Waxman data exclusivity provisions.** We lay out these data in Exhibit 2, which illustrates the impact of increasing the period of data exclusivity to twelve years on the number of conventional drug approvals in the United States. An external file that holds a picture, illustration, etc. Object name is nihms-512043-f0002.jpg EXHIBIT 2 Effect Of A Twelve of a twelve-year period of data exclusivity On Number Of Conventional Drug Approvals In The United States

**Thrasher ev**

**A] card is abt import prices not drug prices writ large**

**B] the ev asserts ipr keeps prices high w out explaining why**

**\**

**Brierly**

**[a] alt causes – stuff like health insurance and copyas is what dicates access to non adehenrence not data exclsuvity.**

**[b] these medicines are not abt the speciality medicine which proves its not reliant on de cuz its abt ppl not being pay for generics either**

**Farrah**

**[b] this card does not hv an ext warrant lmao**

**[c] incentives through patents to solve amrs checks the eadv cuz it j means tech would be created**

**Hotez**

**[a] this card is not abt the plan at all – it j says countries should talk not reduce ipp**

**Kickbush**

**[a c/a**

**[b] this card is abt brazil’s foreign affairs and ministry of health taking to each other – none of it is csua;**

**Zarocostas**

**[a] ev says better access to drugs is good but doesn’t warrant medical diplomacy spreaing accessibility**