# NC

## 1

#### The California recall has given democrats optimal election strategy for the midterms to maximize gains – right-wing extremists winning primaries alienate moderates

Ronayne and Riccardi 9/15 (Kathleen Ronayne and Nicholas Riccardi; 9/15/21; AP News; *“Democrats see a midterm map in California recall success”*; accessed 9/19/21; <https://apnews.com/article/donald-trump-california-recall-california-campaigns-health-48a08f0362762dd53f8171c35c09f57b>; Kathleen Ronayne is a olitical reporter for The Associated Press with bylines from California to New Hampshire and swing states in between. Now covering the recall election of Gov. Gavin Newsom and California's influence on the national political debate; Nicholas is a political writer at the associated press) HB

Few Democrats were surprised to see Democratic Gov. Gavin Newsom swat down a Republican-driven recall campaign in bright-blue California. But they were pleased with how he did it. By making the race into a referendum on former President Donald Trump and his supporters’ “extreme” resistance to coronavirus precautions, Newsom offered a formula for survival that could translate to dozens of races in next year’s midterm elections, Democrats said. A healthy turnout, spurred by some late anxiety, showed Democrats remain eager to vote against the former president, even when he’s not on the ballot. California voters rejected the “Republican brand that is centered around insurrection and denying the pandemic,” said Rep. Sean Patrick Maloney, chairman of the Democratic Congressional Campaign Committee. Republicans said they saw nothing to worry about in the California results. Losing badly in a liberal stronghold isn’t much of a prediction of the party’s performance in battlegrounds like Florida or Georgia, they said. They argue they were saddled with a flawed candidate — talk radio host Larry Elder, the Republican frontrunner whom Democrats likened to a Trump clone in a state the former president lost by 30 percentage points and did little to appeal to moderate voters in swingy suburbs. But President Joe Biden and his party won’t have it as easy next year as Newsom did, said Ron Nehring, a former chairman of the California Republican Party who was harshly critical of Elder and worked for one of his rivals “Gavin Newsom had one opponent who he was able to define in the minds of enough swing voters,” he said. “No. 1, Biden himself is not going to be on the ballot and No. 2, he does not have a singular opponent.” On Wednesday, Biden embraced Newsom’s victory and his message. “This vote is a resounding win for the approach that he and I share to beating the pandemic: strong vaccine requirements, strong steps to reopen schools safely, and strong plans to distribute real medicines — not fake treatments — to help those who get sick,” Biden said in a statement. But there will be better test cases coming on how these messages play with voters. In November, voters in Virginia will choose between Democrat Terry McAuliffe, a former governor and longtime Democratic operative, and GOP businessman Glenn Youngkin. McAuliffe has been hammering Youngkin as too extreme for a state that has been growing more diverse, more suburban and more Democratic for years. California has similar demographic trends at play. In Orange County, long a GOP bastion, racial and ethnic diversity and the growing distaste higher-educated, wealthy voters have shown for Trump have opened the door to Democrats in the county — although the GOP won back two House seats there last year. The recall was failing in Orange County by 5 percentage points on Wednesday, although the vote count in California will go on for weeks and the final margins may change. Newsom and his Republican opponent John Cox essentially tied in the county in 2018. Even the incomplete the results buoyed Democrats. “We’re pretty excited about California, and it’s not because we thought we’re going to lose it — it’s because the margin is better than expected and it shows the Republican message is failing badly in swing districts,” Mahoney said. Still, it’s hard to draw too many conclusions from a single election in a state so liberal that Democrats held every statewide office even during Republican wave years of 2010 and 2014. “It’s like us boasting about beating a recall in Alabama,” quipped Matt Gorman, a former strategist with the National Republican Congressional Committee. Gorman said Democrats would only get so much mileage out of demonizing Republican nominees and trying to tie them to Trump. “Biden is the focus” of the midterms, Gorman said, noting how Republicans unsuccessfully tried to tie congressional Democrats to Nancy Pelosi in 2018, when she was only minority leader and didn’t control the House of Representatives. “It becomes less effective once they’re out of power.” “If inflation is high, gas prices are high and COVID is spiking, it’s going to be much harder” for Democrats to talk about Trump and Republican extremism in 2022, Gorman said. It will also be hard for Republicans not to talk about Trump. GOP primaries for Senate seats in Ohio, Georgia and Pennsylvania already are poised to be a competition for Trump’s base. House candidates have been clamoring for Trump’s endorsement. The former president hasn’t been shy about anointing favorites. Democrats are certain to use that against those candidates when they face a general election. “I think a sad reality of the modern GOP is that there are going to be a lot of Larry Elders on the ballot in 2022 because they’re going to win Republican primaries,” said Addisu Demissie, a Newsom campaign strategist. “When the alternative is extreme, you represent not just your base but the middle.”

#### The plan is politically unpopular – voters are divided which means that plans passage flips the major thin margins – vaccines proves

The Hill 5/4 (The Hill; 5/4/21; The Hill; *“Poll: Majority oppose proposal to temporarily waive intellectual property rights on COVID-19 vaccines”*; accessed 8/27/21; <https://thehill.com/hilltv/what-americas-thinking/551797-poll-majority-oppose-proposal-to-temporarily-waive-intellectual>) HB

A majority of voters oppose the proposal to temporarily waive intellectual property rights on COVID-19 vaccines, a new Hill-HarrisX poll finds. The survey comes as the Biden administration faces mounting pressure to support a proposal led by India and South Africa that would waive an international intellectual property agreement that protects pharmaceutical trade secrets. Backers of the move argue it would enable lower-income countries to manufacture the vaccines themselves while those opposed say it could make the vaccine less safe and damper production in existing locations. Fifty-seven percent of registered voters in the May 3-4 survey said they oppose the proposal to waive intellectual property rights on COVID-19 vaccines. By contrast, 43 percent of respondents said they support the proposal. Sixty-four percent of Republican voters along with 52 percent of both Democratic and independent voters said they oppose waiving the intellectual property rights of vaccines. "This is a complex issue with a remarkably sophisticated understanding by the public. The tension is as follows: On one hand you have the need to protect the intellectual property rights of the scientists and companies that brought about the fastest vaccine in history, and will likely need to produce new versions of the shot even faster to battle evolving strains," Dritan Nesho, chief researcher and CEO of HarrisX, told Hill.TV. "On the other hand there’s the need to save lives, reaching global heard immunity and providing access to the vaccine as broadly and equitably as as possible," Nesho continued. "Today a majority of 57 percent of U.S. voters would like to protect the intellectual property of vaccine makers, but as more and more people are vaccinated in advanced economies, voter pressure for broader and more equitable distribution will rise," Nesho added. "Already we see Democrats and independents here split on the issue of whether or not to waive IP rights to provide greater access to the vaccines." President Biden is expected to weigh in on the proposal at a World Trade Organization meeting on Wednesday. The most recent Hill-HarrisX poll was conducted online among 939 registered voters. It has a margin of error of 3.2 percentage points.

#### A Republican win in 2022 shuts out climate action for decades

Silverman 8/24 (Ellie Silverman; 8/24/21; The Washington Post; *“Climate activists fear this is the last chance to pass meaningful legislation”*; accessed 8/27/21; <https://www.washingtonpost.com/dc-md-va/2021/08/24/climate-biden-congress-protest/>; Ellie Silverman covers protest movements, activism and local news. At The Post, she has also covered local crime and courts. She has previously reported on retail, breaking news and general assignment stories for the Philadelphia Inquirer, her hometown paper. She graduated from the University of Maryland, where she reported for the Diamondback) HB

There is a rising frustration among many of those organizers, who say they helped turn out the vote in 2020 but are not seeing climate pledges translate into meaningful changes. They are worried that the opportunity to push through ambitious climate legislation will soon be gone — and that they may not have another chance. “He said he was the climate president,” Peltier — an Anishinaabe citizen of the Turtle Mountain Band of Chippewa and a member of the Indigenous environmental justice organization Honor the Earth — said outside the White House on Monday. “Now he doesn’t care.” Many climate activists have described an escalating sense of urgency to implement the sweeping changes needed to slow Earth’s warming, highlighted by the recent landmark report from the Intergovernmental Panel on Climate Change. U.N. Secretary General António Guterres called the report a “code red for humanity.” The pace of emissions shows the planet is on track to warm more than two degrees Celsius above preindustrial levels, which could trigger irreversible damage, according to the IPCC report. The Greenland ice sheet could collapse, and sea levels could rise more than six feet. There will be more of the climate-fed fires of this summer, deadly heat waves and devastating floods. Natalie Mebane read the IPCC report and thought of how much ground the climate movement in this country lost under President Donald Trump, whose administration allowed more pollution and weakened protections for wildlife. She worries Republicans will regain power in the 2022 midterms and thinks the slim window from now until then may be the final opportunity to see climate priorities passed through Congress. If not, it could be years before Democrats are in control — wasted time that Mebane fears could cause permanent devastation. “If the Democrats lose a single seat in the Senate, it’s over,” said Mebane, the associate director of U.S. policy for 350.org, an international climate group. “These years that we have right now is the last time that we can even make an impact and influence on climate change before it becomes runaway climate change that we have zero control over.” Biden has tackled greenhouse-gas emissions by proposing new federal goals and mandates to begin shifting the country toward electric cars, rejoined the Paris climate accord and revoked a federal permit for the Keystone XL oil pipeline. But activists point out Biden is still supporting Line 3, a tar-sands oil-pipeline expansion project that will be able to carry 760,000 barrels a day from Canada across northern Minnesota and into Wisconsin. They have called for him to revoke the permit, as he did with Keystone XL, and have protested for months, including on construction sites, chaining themselves to equipment and risking arrest. The White House did not respond to a request for comment. Earlier this month, the Senate approved the $1.2 trillion infrastructure bill with funding to tackle climate change, but many activists said the legislation has fallen short of dramatically addressing goals as lofty as this crisis demands. That does not mean Democrats should pass just any climate legislation, activists say — it has to include the right policies. Compromising on climate, they said, is not good enough. Though the bipartisan infrastructure bill apportions billions of dollars toward funding new public transit and electric-car charging stations, measures that are meant to cut climate-warming emissions, environmental organizations say it does not go far enough. They want to see legislation supporting Biden’s stated goal of replacing 100 percent of lead pipes and the replacement of all diesel school buses with clean electric ones. “It’s hard to square the scale of the problem with the solutions being discussed,” said Lukas Ross, program manager for the Climate and Energy Justice program at Friends of the Earth, another environmental group. “This is not the moment to bargain away the store in the name of passing anything.” Climate groups are focusing on the passage of a second bill through budget reconciliation, a process that would allow Democrats to pass more dramatic climate legislation without Republican support. Democrats in Congress are hoping to work in a clean-energy standard that would compel power providers to shift to wind, solar and other low-emission sources of energy to achieve 80 percent clean electricity by the end of the decade.

#### US climate action is key to world wide action

Beeler 19 (Carolyn Beeler; 9/18/19; PRI; *“Top US leadership is 'missing ingredient' in climate change action”*; accessed 8/27/21; <https://www.pri.org/stories/2019-09-18/top-us-leadership-missing-ingredient-climate-change-action>; Carolyn Beeler leads environment coverage for The World. She reports and edits stories focused on the people and places most impacted by climate change, and what they're doing to address it. She has reported from all seven continents and won national and regional awards for her breaking news and in-depth feature reporting. Before joining The World, Carolyn helped pilot the weekly health and science show, The Pulse, at WHYY in Philadelphia, and reported from Berlin for a year as a Robert Bosch Foundation fellow. She studied journalism at Northwestern University and got her start in radio as a Kroc fellow at NPR.) HB

World leaders will meet in New York next week for the United Nations Climate Summit, an event called by the Secretary-General to push for more and faster cuts to global greenhouse gas emissions. Notably missing at the summit: American leadership. Five years ago, a joint climate policy announcement from the US and China paved the way for the Paris climate accord to come to fruition after decades of failed attempts at an international climate pact. Then in June 2017, President Donald Trump announced that he would withdraw the US from the very same agreement his country had helped broker just a few years before. Under the rules of the accord, countries can announce the intention to leave, but must wait two years before being allowed to do so. Two years later, what impact has this policy whiplash had on the climate? Inside the US, that answer is relatively simple to quantify. Across the country, some 4,000 state and local governments, institutions and businesses have declared that, though the federal government intends to withdraw from the Paris climate agreement, they’re still on board with cutting emissions. One of those local governments is in Arlington, Massachusetts, where the town hall was illuminated green after Trump’s 2017 Paris withdrawal announcement. “We’ve come to the realization that if the federal government’s not going to do it, it’s going to fall to the local level,” said Adam Chapdelaine, Arlington’s town manager. “Somebody has to step up and be a leader.” Even before the Paris Agreement, the town has long worked to reduce its greenhouse gas emissions, from switching its street lights to LED bulbs to buying electric vehicles for its official fleet. Residents can opt-in to 100% renewable energy in their homes and the town is advocating for all-electric heating and cooling systems. Since the US federal government reversed its climate change policies, Arlington has gotten perhaps more ambitious: The town’s new high school is being designed to run on geothermal and solar energy and the whole town aims to go carbon-neutral by 2050. These state and local actions are being highlighted as “answering the global call to combat the climate crisis” by a coalition of sub-national actors formed by New York Mayor Michael Bloomberg and former California Gov. Jerry Brown. But these actions have only partly counteracted sweeping federal changes under the Trump administration. Trump has slashed regulations on emissions from power plants, air conditioners and refrigerators, and oil and gas drilling nationwide. He moved to revoke California’s ability to set its own strict vehicle emission rules on Wednesday, highlighting the limits of state-based action on climate change. So how does the emissions balance sheet tally up today, two years after the US backed away from the Paris agreement? Kate Larsen, a director at the independent research firm the Rhodium Group, said US carbon emissions are a few percentage points higher than they would have been if former President Barack Obama-era policies were in place. Projected forward five years, that gap will just grow. “Under the current set of Trump administration policies, the US is on track to achieve only about 14 to 17% emission reductions below 2005 levels in 2025,” Larsen said. That’s about half of the 26 to 28% emission reductions that the US promised in the climate accord. “[It's] a long way from the commitment that Obama reached in Paris,” Larsen said. Scientists say that to limit warming to 1.5 degrees Celsius and avoid the worst impacts of climate change, global emissions must be cut nearly in half by 2030. Inside the US, local action is partly, but not wholly, counteracting federal policies. The bigger question is how much global ambition to tackle the climate crisis will flag if the world’s largest historic emitter is no longer leading the push. Will countries, seeing the US doing less on climate change, do the same themselves? Under Obama, the US put its full diplomatic muscle into getting countries signed on to the Paris Agreement. “If you were a head of state from India, from China, or from anywhere and you were going to meet with the United States, you knew that you'd have to be prepared to speak about climate change and the Paris Agreement,” said Elan Strait, a former climate negotiator on the Paris Agreement who now works at the World Wildlife Foundation. By 2020, countries are requested to announce new carbon cuts as part of the Paris process. Those cuts have to be more ambitious if countries hope to meet the Paris Agreement goal of keeping warming “well below” 2 degrees Celsius and pursue efforts to limit warming to the scientist-recommended 1.5 degree Celsius. “I completely believe that the missing ingredient this time around is the United States leadership driving climate as a head-of-state agenda,” Strait said. Only when those 2020 climate pledges start rolling in will the international community start to see the full impact of the US climate policy reversal.

**Climate change causes extinction – ocean acidification, water and resource wars, econ collapse, and regional conflicts.**

Pachauri and Meyer 15 (Rajendra K. Pachauri Chairman of the IPCC, Leo Meyer Head, Technical Support Unit IPCC were the editors for this IPCC report, “Climate Change 2014 Synthesis Report” <http://epic.awi.de/37530/1/IPCC_AR5_SYR_Final.pdf> IPCC, 2014: Climate Change 2014: Synthesis Report. Contribution of Working Groups I, II and III to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change [Core Writing Team, R.K. Pachauri and L.A. Meyer (eds.)]. IPCC, Geneva, Switzerland, 151 pp)

SPM 2.3 Future risks and impacts caused by a changing climate Climate change will amplify existing risks and create new risks for natural and human systems. Risks are unevenly distributed and are generally greater for disadvantaged people and communities in countries at all levels of development. {2.3} Risk of climate-related impacts results from the interaction of climate-related hazards (including hazardous events and trends) with the vulnerability and exposure of human and natural systems, including their ability to adapt. Rising rates and magnitudes of warming and other changes in the climate system, accompanied by ocean acidification, increase the risk of severe, pervasive and in some cases irreversible detrimental impacts. Some risks are particularly relevant for individual regions (Figure SPM.8), while others are global. The overall risks of future climate change impacts can be reduced by limiting the rate and magnitude of climate change, including ocean acidification. The precise levels of climate change sufficient to trigger abrupt and irreversible change remain uncertain, but the risk associated with crossing such thresholds increases with rising temperature (medium confidence). For risk assessment, it is important to evaluate the widest possible range of impacts, including low-probability outcomes with large consequences. {1.5, 2.3, 2.4, 3.3, Box Introduction.1, Box 2.3, Box 2.4} A large fraction of species faces increased extinction risk due to climate change during and beyond the 21st century, especially as climate change interacts with other stressors (high confidence). Most plant species cannot naturally shift their geographical ranges sufficiently fast to keep up with current and high projected rates of climate change in most landscapes; most small mammals and freshwater molluscs will not be able to keep up at the rates projected under RCP4.5 and above in flat landscapes in this century (high confidence). Future risk is indicated to be high by the observation that natural global climate change at rates lower than current anthropogenic climate change caused significant ecosystem shifts and species extinctions during the past millions of years. Marine organisms will face progressively lower oxygen levels and high rates and magnitudes of ocean acidification (high confidence), with associated risks exacerbated by rising ocean temperature extremes (medium confidence). Coral reefs and polar ecosystems are highly vulnerable. Coastal systems and low-lying areas are at risk from sea level rise, which will continue for centuries even if the global mean temperature is stabilized (high confidence). {2.3, 2.4, Figure 2.5} Climate change is projected to undermine food security (Figure SPM.9). Due to projected climate change by the mid-21st century and beyond, global marine species redistribution and marine biodiversity reduction in sensitive regions will challenge the sustained provision of fisheries productivity and other ecosystem services (high confidence). For wheat, rice and maize in tropical and temperate regions, climate change without adaptation is projected to negatively impact production for local temperature increases of 2°C or more above late 20th century levels, although individual locations may benefit (medium confidence). Global temperature increases of ~4°C or more 13 above late 20th century levels, combined with increasing food demand, would pose large risks to food security globally(high confidence). Climate change is projected to reduce renewable surface water and groundwater resources in most dry subtropical regions (robust evidence, high agreement), intensifying competition for water among sectors (limited evidence, medium agreement). {2.3.1, 2.3.2} Until mid-century, projected climate change will impact human health mainly by exacerbating health problems that already exist (very high confidence). Throughout the 21st century, climate change is expected to lead to increases in ill-health in many regions and especially in developing countries with low income, as compared to a baseline without climate change (high confidence). By 2100 for RCP8.5, the combination of high temperature and humidity in some areas for parts of the year is expected to compromise common human activities, including growing food and working outdoors (high confidence). {2.3.2} In urban areas climate change is projected to increase risks for people, assets, economies and ecosystems, including risks from heat stress, storms and extreme precipitation, inland and coastal flooding, landslides, air pollution, drought, water scarcity, sea level rise and storm surges (very high confidence). These risks are amplified for those lacking essential infrastructure and services or living in exposed areas. {2.3.2} Rural areas are expected to experience major impacts on water availability and supply, food security, infrastructure and agricultural incomes, including shifts in the production areas of food and non-food crops around the world (high confidence). {2.3.2} Aggregate economic losses accelerate with increasing temperature (limited evidence, high agreement), but global economic impacts from climate change are currently difficult to estimate. From a poverty perspective, climate change impacts are projected to slow down economic growth, make poverty reduction more difficult, further erode food security and prolong existing and create new poverty traps, the latter particularly in urban areas and emerging hotspots of hunger (medium confidence). International dimensions such as trade and relations among states are also important for understanding the risks of climate change at regional scales. {2.3.2} Climate change is projected to increase displacement of people (medium evidence, high agreement). Populations that lack the resources for planned migration experience higher exposure to extreme weather events, particularly in developing countries with low income. Climate change can indirectlyincrease risks of violent conflicts by amplifying well-documented drivers of these conflicts such as poverty and economic shocks (medium confidence). {2.3.2} 2010 )

## 2

#### Counterplan Text: The member states of the World Trade Organization should institute a dormancy tax on intellectual property protections – it’s dispo with a condition of a perm.

#### The counterplan solves the aff – it imposes taxes on new patents which naturally reduces the number of patents as opposed to artificial maneuvers

Magliocca 7(Gerard Magliocca; 6/1/7; The Notre Dame Law Review; *“Blackberries and Barnyards: Patent Trolls and the Perils of Innovation”*; accessed 8/31/21; <https://scholarship.law.nd.edu/cgi/viewcontent.cgi?article=1308&context=ndlr>; Gerard Magliocca is an associate professor at the Indiana University School of Law; pages 1836-1837) HB

B. A Dormancy Tax If eliminating an entire patent class is too hard to stomach, then the focus should turn to administrative solutions. Improving patent quality by reforming the examination process can help matters, but the application process is not the only point where trolls are vulnerable.116 If there are too many dormant patents that can be used to snare the unwary, then one way that can be resolved is by taxing patents at a higher rate to increase the costs of engaging in opportunistic behavior. This proposal to raise the maintenance fees for patents builds on the existing system. To retain ownership of a patent, the rights holder must pay a $900 maintenance fee in the fourth year.1 17 In the eighth year, the fee goes to $2300, and in the twelfth year it jumps to $3800.118 Now imagine a scheme in which these fees are sharply increased and assessed more frequently. The cost of acquiring and holding patents would skyrocket. As a result, firms would have a strong incentive to either use their dormant patents or allow them to lapse and enter the public domain. This would starve trolls of their sustenance. Furthermore, opportunistic licensers that obtain patents with the intent of holding them back until others start using the same technology will pay dearly for their sandbagging. 19 A tax on patents would not eliminate opportunistic litigation, but it might go a long way toward bringing the problem under control. A significant objection to this proposal, of course, is that hiking the maintenance fees on patents raises the costs of innovation. This is certainly true, even though the cost of a patent application would not go up. 120 One response is that trolls already impose a tax on innovation, but one that is unpredictable and concentrated on a handful of unlucky victims. Changing the fee structure, by contrast, would spread this burden more evenly and rationally. Moreover, while a fee increase is not going to please the industries unaffected by trolls, they may be more likely to accept a reform that does not affect their patent rights and remedies as the current proposals do. This may be a case where we need to seek a "second-best" solution that accepts a suboptimal outcome because it can actually be implemented. Reforming the fee assessment in lieu of abolishing technology patents could be just what the doctor ordered in this respect. In sum, the failure of many thoughtful reforms during the nineteenth-century debate on patent sharks shows that a solution focused on altering substantive rights or remedies cannot succeed. Policymakers should instead direct their efforts at an outright repeal or at administrative solutions that reduce the number of dormant patents and their ability to disrupt settled expectations.

## 3

#### The COVID epidemic has exposed massive flaws in biosecurity, lack of public health compliance, anti-vaxxers, and PPE shortages have shown unique vulnerabilities – the US is specifically exposed

Lyon 21 (Regan Lyon; 7/1/21; Military Medicine, Volume 186, Issue7-8, July-August 2021, Pages 193-196; *“The COVID-19 Response Has Uncovered and Increased Our Vulnerability to Biological Warfare”*; accessed 8/13/21; <https://academic.oup.com/milmed/article/186/7-8/193/6135020>; Department of Defense Analysis at the Naval Postgraduate School) HB \*We do not endorse the ableist language of the card\*

INTRODUCTION Biological warfare has been an unlikely, but serious, concern for military operations and national security. The 2018 National Biodefense Strategy (NBS) articulated a collaborative plan to prevent, detect, and respond to biological threats to the USA.1 The NBS highlights recent, isolated outbreaks of Systemic Acute Respiratory Syndrome (SARS), Ebola, and Zika viruses as warnings to nation states and justification for enhanced biological threat responses. Although these events are not considered deliberate threats, clandestine bioweapon programs and terrorist groups seeking such programs are known to exist and capitalize on such natural outbreaks.1 The NBS’s emphasis on prevention and response drives the requirement to enhance biological weapon deterrence and defense strategies to avert the employment of biological weapons on U.S. civilians or military personnel.1 The public health crisis that ensued with SARS-associated coronavirus-2 (SARS-CoV-2) has highlighted our nation’s bioweapon vulnerabilities on the international stage and has the potential for disastrous effects on national security. Previous questions regarding how the USA would respond to a large biological outbreak (or biological weapon) have now been answered for potential adversaries across the world. The ambiguity of both our capabilities and weaknesses, which provided deterrence to adversarial employment of biological weapons before the pandemic, no longer exists. This article will provide an overview on biological weapons and the concepts of deterrence and defense in the context of bioterrorism. Then, it will analyze how the national personal protective equipment (PPE) shortage, public resistance to public health measures, the anti-vaccination movement, and USNS (United States Navy Ship) Comfort deployment to New York City have increased our vulnerability to bioterror attack by impacting our deterrence and defense measures. Finally, it will offer recommendations to restore our bioterrorism security after the detrimental effects from the events unfolding in the USA. BIOLOGICAL WEAPONS REGULATIONS, DETERRENCE, AND DEFENSE Even though biological warfare is considered a “weapon of mass destruction” and is prohibited by a treaty drafted by the 1972 United Nations Biological Weapons Convention (BWC), not all adversaries adhere to these standards. Terrorist groups and covert operations have utilized biological weapons for small operations because the actors, by nature, are either non-eligible to ratify the treaty or would not do so if they could. Although there have been no intentional large-scale attacks, especially by adversarial nation states, this is not guaranteed to be the case in the future.2 The BWC does not prohibit ratified nations from having pathogens or toxins for peaceful purposes, such as the development of vaccines. After the natural outbreak of smallpox and its subsequent eradication accomplished by the World Health Organization in 1980, less virulent poxviruses have continued to be used in a variety of laboratories for research and development of vaccines for a variety of diseases.3 The original, more deadly strain of smallpox has been retained at two facilities in Russia and Atlanta.4 Because smallpox’s virology makes it an ideal biological weapon, the samples in Atlanta and Russia offer defense through researching countermeasures should an attack occur and simultaneously provide a repository from which a biological weapon can be acquired. “Deterrence” and “defense” are two concepts which are typically described in terms of nuclear warfare, but they can also be applied to national security from a biological attack.5 Deterrence is the ability to prevent an adversary from taking some action during peacetime.5 For biological warfare deterrence, vaccines and preventative medicine measures prevent susceptibility to a microbe. For a largely vaccinated and/or health-conscious population, the costs of production, storage, and dissemination of a bioweapon greatly outweighs the rare chance of the target contracting the disease. New Zealand’s robust public health measures, citizen compliance, and continued efforts to sustain a caseload under 20 since April is a strong deterrent for biological attack.6 Defense mechanisms decrease the effectiveness of the attack, putting a high cost-to-benefit burden on the adversary.5 A defense measure for bioterrorism would be an adequate medical treatment response to casualties of the bioweapon, decreasing mortality and the overall effectiveness of the weapon. COVID-19 PANDEMIC ANALYSIS The novel SARS-CoV-2 has several characteristics of an ideal biological weapon, including high transmission rate, long incubation period, airborne transmission, and significant morbidity/mortality.7 In fact, early in the pandemic, suspicion was cast that the virus was being developed as a biological weapon by a laboratory in Wuhan, China.8 Although these allegations have been deemed conspiracy theories as a result of misinformation operations, the resulting pandemic and the panicked public share similarities to a bioterror attack. The events occurring within the USA during the coronavirus disease 2019 (COVID-19) pandemic create a global narrative on how we respond to a biological crisis. The 2018 NBS emphasized the continued threat of biological weapons to national security and identified the need to deter and defend against bioterrorism acts.1 This section will analyze events in the USA during the pandemic, how they bolstered or negated our current bioterrorism deterrence or defense strategies, and offer areas for improvement to restore our bioterror security. Personal Protective Equipment Shortage The 2018 NBS mandates having a robust mobilization of PPE for frontline healthcare workers and an adequate communication plan on preventative health measures for the general public in the event of an attack.1 The ability to provide sufficient quantities of PPE for medical personnel is a vital defense tactic as it increases the efficiency of the healthcare system to treat casualties in response to a biological outbreak. Having the ability to mobilize these resources to hospitals strengthens bioterror deterrence by demonstrating to a potential adversary that a bioterror attack would have a limited effect on a population given the healthcare preparedness. As conflicting information was published across multiple media platforms from January to March, panic spread that the virus was more dangerous than originally believed. Citizens flooded stores in town and online, buying “essential items” in preparation for a lockdown. Items such as masks, gloves, and sanitizers were out of stock everywhere, including healthcare supply chains. More importantly, citizens heard N95 masks could prevent contracting the virus, suddenly increasing N95 demand.9 Demand exceeded supply quickly, and healthcare workers began complaining of the nation-wide shortage of appropriate PPE required to care for infected patients.10 The inability to acquire necessary PPE supplies due to crippled supply chains and general public hoarding caused a ripple effect within the healthcare system. As a result, hospitals began to institute resource conservation measures, attempting to extend the life of supplies intended for one-time use. These PPE conservation measures, however, were interpreted by some healthcare workers as putting their lives in jeopardy and instigated lobbying and campaigning for government involvement. News reports flourished of disgruntled healthcare workers who were at risk of infection due to a lack of PPE. Such reports of general public hoarding, inadequate PPE logistical chains, and inappropriate PPE conservation measures by hospitals demonstrate the USA’s poor public health response. The NBS calls for an extensive mobilization of adequate PPE in response to a biological outbreak to decrease the pathogen spread, minimize its effects, and improve our resiliency.1 The capability to decrease the pathogen’s effects increases an attacker’s “sunk costs” should they choose to release a biological weapon. An impaired, or presumably impaired, capability adversely affects our defense strategy. In addition, the decrease in cost-to-risk ratio impairs our deterrence measures by showing worsened biological denial. The rapid healthcare PPE disappearance secondary to pandemic panic demonstrated a critical vulnerability in one of the most important defense strategies for a bioterror attack. To improve our defense capability, our healthcare workers must have an adequate supply of PPE, which can be mobilized expeditiously. Bioweapons have a high transmission rate and are easily disseminated, which make airborne and droplet transmission favorable. Public health experts should retrospectively analyze the types and amounts of PPE utilized in areas highly impacted by SARS-CoV-2. With these data, models can be created to make recommendations for phase-based mobilization of PPE and to determine the size of stockpile needed for immediate release. Government agencies need to establish agreements with PPE manufacturers to prioritize production in declared biological emergencies. Anti-Vaccination Movements Non-compliance with recommended public health and protective measures, including vaccines, also cripples our nation’s biodefense. Public health measures such as social distancing, aggressive sanitation, and mask mandates are examples of defense tactics for the COVID-19 pandemic. The individualistic U.S. culture fueled widespread non-compliance with these measures and has had significant effect on our ability to “flatten the curve” compared to other countries.11 The preference for “freedom…without interference from the state” is present in 58% of U.S. citizens, compared to 30-38% of European countries.11 The USA’s inability to uniformly employ these measures and decrease the virus spread compared to other countries signals to adversaries a weakness in our defense to decrease the effects of a biological outbreak. Furthermore, the speculation and conspiracy theories surrounding COVID-19 vaccines suggest an inevitable resistance to receiving the vaccine when available. Resistance to vaccinations is nothing new and caused challenges for vaccination against smallpox in the 19th-century U.K. epidemic.12 Then in 2019, the U.S. measles outbreak was amplified by anti-vaxxer campaigns.13 Since early in the COVID-19 pandemic, social media posts have warned that future coronavirus vaccines contain either tracking devices for the U.S. government or toxic chemicals.13,14 This unopposed and contagious anti-vax movement directly affects future biological deterrence because our adversaries know that the population will not be universally compliant with vaccination and will be susceptible to certain pathogens. Recent polls indicate that one-third of U.S. citizens,14 compared to 14% of U.K. citizens,12 would avoid receiving a SARS-CoV-2 vaccine, even if available and affordable. A poor vaccination rate increases a population’s disease susceptibility and decreases biological weapon deterrence by denial. The anti-vaccination movement has caught traction from massive information operations and propaganda on multiple media platforms. Since May 2020, anti-vaxxers have been propagating lies about the side effects of the coronavirus vaccine, but as of June, the Centers for Disease Control, which is responsible for vaccine education, had only a “plan” to counter such anti-vaccine campaigns.14 When the first vaccines were being administered to healthcare workers in the USA in December 2020, multiple social media efforts were started to promote the vaccine.15 Hashtags such as #vaxup, #IGotTheShot, #vaccineswork, and many more were used with social media posts of doctors, nurses, and other medical personnel receiving their vaccine.16 Some posts continued with threads of updates on any side effects encountered to quell public concerns. Information operations such as these may be more effective to counter the anti-vaccination propaganda than government-sponsored campaigns and require further research by public health officials.

#### Patents are the key to preventing bioweapon development – they prevent technology from being accessible to hostile state and non-state actors

Finlay 10 (Brian Finlay; Summer 2010; The Fletcher Forum of World Affairs, *“The Bioterror Pipeline: Big Pharma, Patent Expirations, and New Challenges to Global Security”*; accessed 8/13/21; Brian Finlay is a senior associate at the Stimson Center in Washington, DC, where he directs the Managing Across Boundaries Program. He has worked at the Brookings Institution, the Century Foundation, and Canadas Laboratory Center for Disease Control/Health Canada; pages 54-58; ask me for the pdf) HB

NEW CHALLENGES: THE BIOTECH REVOLUTION AND THE ROLE OF THE PRIVATE SECTOR Myriad private sector actors, ranging from single-employee enterprises to major multinational pharmaceutical giants dominate today's biopharmaceutical marketplace. Privately owned companies not only develop, produce, and operate the lion's share of biological industrial equipment, but carry out the greatest share of the scientific research and development for the relevant technologies, goods, and methods of application. University and other non-profit research is often commercially-funded, and many governments around the globe have built public-private partnerships, even in some of the most sensitive areas of biotechnology, to capitalize on cost reductions and innovation. According to a recent Ernest and Young study of the industry, today more than 80 percent of biotechnology firms-and, thus, the technologies they innovate-are in the hands of the private sector." In the United States, the industry's compound annual growth rate has historically hovered around 15 percent, yielding aggregate revenues of more than $70 billion in 2008.18 With fortunes to be made, unprecedented new applications to be discovered, and practically unlimited possibilities for growth, the biopharmaceutical industry has swelled dramatically over the past decade. It is estimated that the biotech sector supports about 3.2 million jobs across the U.S. economy-a little more than one job for every 100 Americans.' 9 In Europe, publicly traded biotech companies' revenues increased 17 percent in one year, from f9.6 billion in 2007 to £11.2 billion in 2008. And although the recent global financial crisis had a negative impact, the product pipelines of European industry are growing across all phases of clinical development.20 By virtually any measure, the United States and Europe remain unmatched global hubs for biotechnological investment and innovation. For national security analysts, this reality has long provided some measure of comfort. Although the system of security assurances mandated by technologically advanced (principally Western) governments is far from a panacea against biothreats, the absence of similarly robust legal barriers in many countries raises serious international security concerns. 2' For instance, although the United States, Canada, the United Kingdom, Germany, and Singapore have all introduced strict regulations on pathogenic agents that may be of interest to committed bioterrorists, most countries have not. Similarly, export controls and enforcement over many sensitive technologies are often extremely lax, particularly in countries of the Global South.22 And because terrorists and proliferant states may shop for pathogens and dual-use production technologies where controls are the weakest, this uneven patchwork of regulations leaves open a significant gap in global biosecurity standards.23 It was in this porous regulatory environment that President Obama released his National Strategy for Countering Biological Threats in November 2009. His plan cited both unparalleled innovations in the life sciences and imperfections in existing control regimes as the principle motivations for a new strategy that seeks to prevent biotechnology products from being used for harmful purposes.24 However, while the President's plan presented a more forward-leaning agenda to counter the rising risk of proliferation by explicitly leveraging public health in support of international security, at its root, the strategy extends the traditional state-centric approaches to a problem that is increasingly one of the private sector. A proper approach to the issue-and its solution set-must place industry at its epicenter. In short, the Obama strategy exemplifies the continued mismatch between governments' near singular focus on regulation of the industry on the one hand, and the elusive nature of privately-driven biotech innovation on the other. Beyond encouraging the industry to adopt more stringent security standards in the public interest, governments have generally proven bereft of innovative ideas that more directly link these measures to the private sector's enlightened self-interest. This mismatch is aggravated by the reality that the biotech and pharmaceutical community stands on the brink of yet another grand transformation that will render traditional control efforts, however effective they may have proven in the past, even more anachronistic. Over the course of the coming decade, the traditional drug development strategies employed so successfully by Western biopharmaceutical companies in the past will run headlong into two realities that will fundamentally alter biopharmaceuticals' business model: continued and rampant globalization of the life sciences and big pharma's patent expiration challenges. These forces will have profound implications on the future of drug development and the internationalization of intellectual property. Further, it threatens to open a new era of biological weapons proliferation by pushing bio-innovation into regions that are ill-prepared to manage the leakage of sensitive knowledge and equipment to those intent on developing biological weapons. Accelerating Globalization of the Life Sciences As globalization began to take firm root in the 1980s, virtually every industrial sector across the Western world sought to capitalize upon its underlying forces to promote efficiency and financial gain. Conceptions of tightly integrated firms whose product development was bound by national borders gave way to an internationalization of R&D, production, and supply chains. Expedited global trade, hastened by advances in everything from information to transportation technologies, allowed profit and efficiency to be maximized through outsourcing, off-shoring, supply-chaining, and other activities that drove intellectual and manufacturing capacity far beyond Western shores. The corresponding transfer of information, processes, and technology generated new local enterprises, including subsidiary operations that collaborated with or competed for global market share. This dynamic, in turn, created a virtuous cycle that accelerated the biotechnological competencies of these new markets. Soon, states that were seen to have lacked the indigenous expertise to perform complex R&D and manufacturing operations began to develop advanced, competitive industrial sectors.25 By the late 1990s, the spread of biotechnological knowledge and equipment allowed even more companies, universities, and research institutes around the world to benefit from advances in the life sciences. Today, developing countries nurture competitive industrial sectors that challenge traditional suppliers in Western Europe. According to the United Nations, many developing countries, including Argentina, Brazil, China, Cuba, Egypt, India, Mexico, and South Africa are already approaching the leading edge of biotechnological applications and have "significant" research capacity in the biosciences.26 In aggregate, this can only be seen as a significant boon to global development. As in the North, the developing South is putting these biotech capacities to work for peaceful purposes. Recent technological breakthroughs are indicative of this new geographic diversity of biological talent: the first vaccine against meningitis B was developed in Cuba; South Africa was the first country involved in HIV-C strain preventive treatment; India is the world's largest producer of the hepatitis B vaccine; and China was the first country to license gene therapy.27 Meanwhile, biotechnology is providing an infusion of high-skilled, stable, and lucrative jobs, and endowing struggling economies with critical growth and diversification. For the security conscious, however, the globalization of biotechnology has also expanded the locus of the bioproliferation challenge from technologically advanced countries of the North into far-flung places around the globe.28 Thus, even as humankind reaps the benefits of the biotech revolution, governments around the world are increasingly challenged by the confluence of rapidly advancing science and technology and by globalization itself. High technical hurdles to isolation and weaponization of dangerous pathogens once confined fears about the development and use of biological weapons to advanced industrial states. But now, the spread of dual-use biotechnologies means that a growing number of countries-and even terrorist groups-may gain access to the capacities necessary to develop a bioweapon.

#### Any reduction in bioweapons threat is key – 1ar impact defense doesn’t account for future technology developments that make them a existential threat

Millett and Snyder-Beattie 17 (Piers Millett and Andrew Snyder-Beattie; 2017; Health Security, Volume 15, Number 4; *“Existential Risk and Cost-Effective Biosecurity”*; accessed 8/13/21; <https://www.liebertpub.com/doi/pdf/10.1089/hs.2017.0028>; Piers Millett, PhD, is a Senior Research Fellow, and Andrew Snyder-Beattie, MS, is Director of Research; both at the University of Oxford, Future of Humanity Institute, Oxford, England.; page 378) HB

Why Uncertainty Is Not Cause for Reassurance Each of our estimates rely to some extent on guesswork and remain highly uncertain. Technological breakthroughs in areas such as diagnostics, vaccines, and therapeutics, as well as vastly improved surveillance, or even eventual space colonization, could reduce the chance of disease-related extinction by many orders of magnitude. Other breakthroughs such as highly distributed DNA synthesis or improved understanding of how to construct and modify diseases could increase or decrease the risks. Destabilizing political forces, the breakdown of the Biological Weapons Convention, or warfare between major world powers could vastly increase the amount of investment in bioweapons and create the incentives to actively use knowledge and biotechnology in destructive ways. Each of these factors suggests that our wide estimates could still be many orders of magnitude off from the true risk in this century. But uncertainty is not cause for reassurance. In instances where the probability of a catastrophe is thought to be extremely low (eg, human extinction from bioweapons), greater uncertainty around the estimates will typically imply greater risk of the catastrophe, as we have reduced confidence that the risk is actually at a low level.48 xxx Given that our conservative models are based on historical data, they fail to account for the primary source of future risk: technological development that could radically democratize the ability to build advanced bioweapons. If the cost and required expertise of developing bioweapons falls far enough, the world might enter a phase where offensive capabilities dominate defensive ones. Some scholars, such as Martin Rees, think that humanity has about a 50% chance of going extinct due in large part to such technologies.49 However, incorporating these intuitions and technological conjectures would mean relying on qualitative arguments that would be far more contentious than our conservative estimates. We therefore proceed to assess the cost-effectiveness on the basis of our conservative models, until superior models of the risk emerge.

#### Bioweapon usage causes extinction – increasing development of lethality and spread proves that the threat is increasing – action now to bolster infrastructure is key

Millett and Snyder-Beattie 17 (Piers Millett and Andrew Snyder-Beattie; 2017; Health Security, Volume 15, Number 4; *“Existential Risk and Cost-Effective Biosecurity”*; accessed 8/13/21; <https://www.liebertpub.com/doi/pdf/10.1089/hs.2017.0028>; Piers Millett, PhD, is a Senior Research Fellow, and Andrew Snyder-Beattie, MS, is Director of Research; both at the University of Oxford, Future of Humanity Institute, Oxford, England.; page 374) HB

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a long historical track record of state-run bioweapon research applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of staterun bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25The possibility of a war between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27 Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons for the express purpose of causing extinction.28 Environmental groups, such as the Gaia Liberation Front, have argued that ‘‘we can ensure Gaia’s survival only through the extinction of the Humans as a species. we now have the specific technology for doing the job. several different [genetically engineered] viruses could be released’’(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,32

## Case

#### 1] Extinction outweighs: A] Reversibility- it forecloses the alternative because we can’t improve society if we are all dead B] Structural violence- death causes suffering because people can’t get access to resources and basic necessities C] Objectivity- body count is the most objective way to calculate impacts because comparing suffering is unethical D] Uncertainty- if we’re unsure about which interpretation of the world is true, we should preserve the world to keep debating about it

### AT – Solvency

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>] Justin

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

### Contention 1

#### Can’t make enough vaccines vital components are too scarce

Tepper 4-10 James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

Vaccine-makers around the world face shortages of vital components including large plastic growbags, according to the head of the firm that is manufacturing a quarter of the UK’s jab supply. Stan Erck, the chief executive of Novavax – which makes the second vaccine to be grown and bottled entirely in Britain – told the Observer that the shortage of 2,000-litre bags in which the vaccine cells were grown was a significant hurdle for global supply. His warning came as bag manufacturers revealed that some pharmaceutical firms were waiting up to 12 months for the sterile single-use disposable plastic containers, which are used to make medicines of all kinds, including the Pfizer, Moderna and Novavax Covid-19 vaccines. But Erck and his British partners said they were confident they had enough suppliers to avoid disruption to the supply of Novavax. The vaccine is waiting for approval from the Medicines and Healthcare products Regulatory Agency (MHRA) but the first of 60 million doses ordered by the government are already in production in Teesside. The Fujifilm Diosynth Biotechnologies factory began growing the first cells for the Novavax vaccine in Billingham, County Durham this month and in a few weeks they will fill the bioreactor bag, ready to be transported to GlaxoSmithKline’s plant at Barnard Castle to be put into vials for distribution. “The first hurdle is showing it works and we don’t have that hurdle any more,” Erck said. But he added there were others still to overcome. “There’s the media that the cells have to grow in,” Erck said. “You grow them in these 2,000-litre bags, which are in short supply. Then you pour it out and you have to filter it, and the filters are in short supply. The little things count.” Novavax almost ran out of bags at one of its 20 factories earlier this year, but there had been no delays for the UK operation, according to Martin Meeson, global chief executive of Fujifilm Diosynth. “We started working on our part of the supply chain in summer last year,” he said. “We had to accelerate some of the investment here, but the commitment we made last summer to start manufacturing in February has been fulfilled.” Production of coronavirus vaccines is being ramped up. Production of coronavirus vaccines is being ramped up. Photograph: Christophe Archambault/AP Both Meeson and Erck said the UK’s vaccine taskforce had been helpful in sorting out supply issues so far, but other countries and other medical supplies might be affected. ABEC makes bioreactor bags at two plants in the US and two in Fermoy and Kells in Ireland, and delivered six 4,000-litre bags to the Serum Institute in India last year for its Covid vaccines. Brady Cole, vice-president of equipment solutions at ABEC, said: “We are hearing from our customer base of lead times that are pushing out to nine, 10, even 12 months to get bioreactor bags. We typically run out at 16 weeks to get a custom bioreactor bag out to a customer.” He said ABEC was still managing to fulfil orders at roughly that rate. “The bag manufacturing capacity can’t meet demand right now,” he added. “And on the component side, the tubes and the instruments and so forth that also go into the bag assembly – those lead times are also starting to get stretched as well. But the biggest problem we see is it really is just the ability to get bags in a reasonable amount of time.” ABEC expanded its factories last year and has now started making 6,000-litre bags, which are roughly the size of a minibus. Other firms including MilliporeSigma, part of German company Merck, have also been expanding their manufacturing facilities. American firm Thermo Fisher Scientific expects it will finish doubling its capacity this year. The US government has also blocked exports of bags, filters and other components so it can supply more Pfizer vaccines for Americans. Adar Poonawalla, the chief executive of the Serum Institute of India, said the restrictions were likely to cause serious bottlenecks. Novavax is hoping to avoid delays and “vaccine nationalism” by operating on four continents, with 20 facilities in nine countries. “One year ago, we had exactly zero manufacturing capacity,” Erck said. “We’re self-sufficient. The two main things we need to do are done in the UK. And in the EU we have plants in Spain and the Czech Republic and fill-and-finish in Germany and the Netherlands.” There was no need for vaccines to cross borders to fulfil contracts, he said. The Oxford/AstraZeneca vaccine was hit by a delay to a delivery of 5 million doses from India and a problem with a batch made in Britain, and the company has been dragged into a lengthy row between the UK and the EU over vaccine exports.

#### 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.

#### Extinction - generic defense doesn’t apply.

Srivatsa 17 Kadiyali Srivatsa 1-12-2017 “Superbug Pandemics and How to Prevent Them” <https://www.the-american-interest.com/2017/01/12/superbug-pandemics-and-how-to-prevent-them/> (doctor, inventor, and publisher. He worked in acute and intensive pediatric care in British hospitals)//Elmer

It is by now no secret that the human species is locked in a race of its own making with “superbugs.” Indeed, if popular science fiction is a measure of awareness, the theme has pervaded English-language literature from Michael Crichton’s 1969 Andromeda Strain all the way to Emily St. John Mandel’s 2014 Station Eleven and beyond. By a combination of massive inadvertence and what can only be called stupidity, we must now invent new and effective antibiotics faster than deadly bacteria evolve—and regrettably, they are rapidly doing so with our help. I do not exclude the possibility that bad actors might deliberately engineer deadly superbugs.1 But even if that does not happen, humanity faces an existential threat largely of its own making in the absence of malign intentions. As threats go, this one is entirely predictable. The concept of a “black swan,” Nassim Nicholas Taleb’s term for low-probability but high-impact events, has become widely known in recent years. Taleb did not invent the concept; he only gave it a catchy name to help mainly business executives who know little of statistics or probability. Many have embraced the “black swan” label the way children embrace holiday gifts, which are often bobbles of little value, except to them. But the threat of inadvertent pandemics is not a “black swan” because its probability is not low. If one likes catchy labels, it better fits the term “gray rhino,” which, explains Michele Wucker, is a high-probability, high-impact event that people manage to ignore anyway for a raft of social-psychological reasons.2 A pandemic is a quintessential gray rhino, for it is no longer a matter of if but of when it will challenge us—and of how prepared we are to deal with it when it happens. We have certainly been warned. The curse we have created was understood as a possibility from the very outset, when seventy years ago Sir Alexander Fleming, the discoverer of penicillin, predicted antibiotic resistance. When interviewed for a 2015 article, “The Most Predictable Disaster in the History of the Human Race, ” Bill Gates pointed out that one of the costliest disasters of the 20th century, worse even than World War I, was the Spanish Flu pandemic of 1918-19. As the author of the article, Ezra Klein, put it: “No one can say we weren’t warned. And warned. And warned. A pandemic disease is the most predictable catastrophe in the history of the human race, if only because it has happened to the human race so many, many times before.”3 Even with effective new medicines, if we can devise them, we must contain outbreaks of bacterial disease fast, lest they get out of control. In other words, we have a social-organizational challenge before us as well as a strictly medical one. That means getting sufficient amounts of medicine into the right hands and in the right places, but it also means educating people and enabling them to communicate with each other to prevent any outbreak from spreading widely. Responsible governments and cooperative organizations have options in that regard, but even individuals can contribute something. To that end, as a medical doctor I have created a computer app that promises to be useful in that regard—of which more in a moment. But first let us review the situation, for while it has become well known to many people, there is a general resistance to acknowledging the severity and imminence of the danger. What Are the Problems? Bacteria are among the oldest living things on the planet. They are masters of survival and can be found everywhere. Billions of them live on and in every one of us, many of them helping our bodies to run smoothly and stay healthy. Most bacteria that are not helpful to us are at least harmless, but some are not. They invade our cells, spread quickly, and cause havoc that we refer to generically as disease. Millions of people used to die every year as a result of bacterial infections, until we developed antibiotics. These wonder drugs revolutionized medicine, but one can have too much of a good thing. Doctors have used antibiotics recklessly, prescribing them for just about everything, and in the process helped to create strains of bacteria that are resistant to the medicines we have. We even give antibiotics to cattle that are not sick and use them to fatten chickens. Companies large and small still mindlessly market antimicrobial products for hands and home, claiming that they kill bacteria and viruses. They do more harm than good because the low concentrations of antimicrobials that these products contain tend to kill friendly bacteria (not viruses at all), and so clear the way for the mass multiplication of surviving unfriendly bacteria. Perhaps even worse, hospitals have deployed antimicrobial products on an industrial scale for a long time now, the result being a sharp rise in iatrogenic bacterial illnesses. Overuse of antibiotics and commercial products containing them has helped superbugs to evolve. We now increasingly face microorganisms that cannot be killed by antibiotics, antifungals, antivirals, or any other chemical weapon we throw at them. Pandemics are the major risk we run as a result, but it is not the only one. Overuse of antibiotics by doctors, homemakers, and hospital managers could mean that, in the not-too-distant future, something as simple as a minor cut could again become life-threatening if it becomes infected. Few non-medical professionals are aware that antibiotics are the foundation on which nearly all of modern medicine rests. Cancer therapy, organ transplants, surgeries minor and major, and even childbirth all rely on antibiotics to prevent infections. If infections become untreatable we stand to lose most of the medical advances we have made over the past fifty years. And the problem is already here. In the summer of 2011, a 43-year-old woman with complications from a lung transplant was transferred from a New York City hospital to the Clinical Center at the National Institutes of Health (NIH), in Bethesda, Maryland. She had a highly resistant superbug known as Klebsiella pneumoniae carbapenemase (KPC). The patient was treated and eventually discharged after doctors concluded that they had contained the infection. A few weeks later, a 34-year-old man with a tumor and no known link to the woman contracted KPC while at the hospital. During the course of the next few months, several more NIH patients presented with KPC. Doctors attacked the outbreak with combinations of antibiotics, including a supposedly powerful experimental drug. A separate intensive care unit for KPC patients was set up and robots disinfected empty rooms, but the infection still spread beyond the intensive care area. Several patients died and then suddenly all was silent on the KPC front, with doctors convinced they had seen the last of the dangerous bacterium. They couldn’t have been more mistaken. A year later, a young man with complications from a bone marrow transplant arrived at NIH. He became infected with KPC and died. This superbug is now present in hospitals in most, if not all U.S. states. This is not good. This past year an outbreak of CRE (carbapenem-resistant enterobacteriaceae) linked to contaminated medical equipment infected 11 patients and killed two in Los Angeles area hospitals. This family of bacteria has evolved resistance to all antibiotics, including the powerful carbapenem antibiotics that are often used as a last resort against serious infections. They are now so resilient that it is virtually impossible to remove them from medical tools such as catheters and breathing tubes placed into the body, even after cleaning. Then we have gonorrhea, chlamydia, and other sexually transmitted diseases that we cannot treat and that are spreading all over the world. Anyone who has sex can catch these infections, and because most people may not exhibit any symptoms they spread infections without anyone knowing about it. Sexually transmitted diseases used to be treatable with antibiotics, but in recent years we have witnessed the rise of multi-drug resistant STDs. Untreated gonorrhea can lead to infertility in men and women and blindness and other congenital defect in babies. As is well known, too, we have witnessed many cases of drug-resistant pneumonia. These problems have arisen in part because of simple mistakes healthcare professionals repeatedly make. Let me explain. Neither superbugs nor common bacterial infections produce any special symptoms indicative of their cause. Rashes, fevers, sneezing, runny noses, ear pain, diarrhea, vomiting, coughing, fatigue, and weakness are signs of common and minor illnesses as well as uncommonly deadly ones. Therefore, the major problem for clinicians is to identify a common symptom that may potentially be an early sign of a major infection that could result in an epidemic. We know that dangerous infections in any given geographical area do not start at the same time. They start with one victim and gradually spread. But that victim is only one among hundreds of patients a doctor will typically see, so many doctors will miss patients presenting with infections that are serious. They will probably identify diseases that kill fast, but slow-spreading infections such as skin infections that can lead to septicemia are rarely diagnosed early. In addition, I have seen doctors treating eczema with antibiotic cream, even though they know that bacteria are resistant to the majority of these drugs. This sort of action encourages simple infections to spread locally, because patients are therefore not instructed to take other, more useful precautions. On top of that, some people are frivolous about infections and assume doctors are exaggerating the threat. And some people are selfish. Once I was called to see a passenger during a flight who had symptoms consistent with infection. He boarded the plane with these symptoms, but began to feel much worse during the flight. I was scared, knowing how infections such as Ebola can spread. This made me think about a way to screen passengers before they board a flight. Airlines could refund a traveler’s ticket, or issue a replacement, in case of sickness—which is not the policy now. We currently have no method to block infectious travelers from boarding flights, and there are no changes in the incentive system to enable conscientious passengers to avoid losing their money if they responsibly miss a flight because of illness. Speaking of selfishness, I once saw a mother drop her daughter off at school with a serious bout of impetigo on her face. When I asked her why she had brought her daughter to school with a contagious infection, she said she could not spare the time to keep her at home or take her to the doctor. By allowing this child to contact other children, a simple infection can become a major threat. Fortunately, I could see the rash on the girl’s face, but other kids in schools may have rashes we cannot see. Incorrect diagnosis of skin problems and mistaken use of antibiotics to treat them is common all over the world, and so we are continually creating superbugs in our communities. Similarly, chest infections, sore throats, and illnesses diagnosed as colds that unnecessarily treated with antibiotics are also a major threat. By prescribing antibiotics for viral infections, we are not only helping bacteria develop resistance, but we are also polluting the environment when these drugs are passed in urine and feces. All of this helps resistant bacteria to spread in the community and become an epidemic. Ebola is very difficult to transmit because people who are contagious have visible and unusual symptoms. However, the emerging infections and pandemics of the future may not have visible symptoms, and they could break out in highly populous countries such as India and China that send thousands of travelers all over the world every day. When a person is infected with a contagious disease, he or she can expect to pass the illness on to an average of two people. This is called the “reproduction number.” Two is not that high a number as these things go; some diseases have far greater rates of infection. The SARS virus had a reproduction number of four. Measles has a reproduction number of 18. One person traveling as an airplane passenger and carrying an infection similar to Ebola can infect three to five people sitting nearby, ten if he or she walks to the toilet. The study that highlighted this was published in a medical journal a few years ago, but the airline industry has not implemented any changes or introduced screening to prevent the spread of infections by air travel passengers, a major vehicle for the rapid spread of disease. It is scary to think that nobody knows what will happen when the world faces a lethal disease we’re not used to, perhaps with a reproduction number of five or eight or even ten. What if it starts in a megacity? What if, unlike Ebola, it’s contagious before patients show obvious symptoms? Past experience isn’t comforting. In 2009, H1N1 flu spread around the world before we even knew it existed. The Questions Remains Why do seemingly intelligent people repeatedly do such collectively stupid things? How did we allow this to happen? The answer is disarmingly simple. It is because people are incentivized to prioritize short-term benefits over long-term considerations. It is what social scientists have called a “logic of collective action” problem. Everyone has his or her specialized niche interest: doctors their patients’ approval, business and airline executives their shareholders’ earnings, hospitals their reputations for best-practice hygienics, homemakers their obligation to keep their own families from illness. But no one owns the longer-term consequences for hundreds of millions of people who are irrelevant to satisfying these short-term concerns. Here is an example. At a recent Superbug Super Drug conference in London that I attended, scientists, health agencies, and pharmaceutical companies were vastly more concerned with investing millions of dollars in efforts to invent another antibiotic, claiming that this has to be the way forward. Money was the most pressing issue because, as everyone at the conference knew, for many years pharmaceutical companies have been pulling back from antibiotics research because they can’t see a profit in it. Development costs run into billions of dollars, yet there is no guarantee that any new drug will successfully fight infections. At the same conference Dr. Lloyd Czaplewski spoke about alternatives to antibiotics, in case we cannot come up with new ones fast enough to outrun superbug evolution. But he omitted mention of preventive strategies that use the internet or communication software to help reduce the spread of infections among families, communities, and countries. It is madness that we don’t have a concrete second-best alternative to new antibiotics, because we need them and we need them quickly. Of course, this is why we have governments, which have been known occasionally in the past as commonwealths. Governments are supposed to look out for the wider, common interests of society that niche-interested professionals take no responsibility for, and that includes public health. It is why nearly every nation’s government has an official who is analogous to the U.S. Surgeon General, and nearly every one has a public health service of some kind. Alas, national governments do not always function as they should. Several years ago physician and former Republican Senator Bill Frist submitted a proposal to the Senate for a U.S. Medical Expeditionary Corps. This would have been a specialized organization that could coordinate and execute rapid responses to global health emergencies such as Ebola. Nothing came of it, because Dr. Frist’s fellow politicians were either too shortsighted or too dimwitted to understand why it was a good idea. Or perhaps they simply realized that they could not benefit politically from supporting it. Plenty of mistakes continue to be made. In 2015, a particularly infectious form of bird flu ripped through 14 U.S. states, leading farmers to preventively slaughter nearly 40 million birds. The result of such callous and unnecessary acts is that, instead of exhausting themselves in the host population of birds, the viruses quickly find alternative hosts in which to survive, and could therefore easily mutate into a form that can infect humans. Earlier, during the 1980s, AIDS garnered more public attention because a handful of rich and famous people were infected, and because the campaign to eradicate it dovetailed with and boosted the political campaign on behalf of homosexual rights. Methicillin resistant Staphylococcus aureus (MRSA) in hospitals, by far the bigger threat at the time, was virtually ignored. Some doctors knew that MRSA would bring us to our knees and kill millions of people worldwide, but pharmaceutical companies and device and equipment manufacturers ignored these doctors and the thousands of patients dying in hospitals as a result of MRSA. They prioritized the wrong thing, and government did not correct the error. And that is partly how antibiotic-resistant infection went from an obscure hospital problem to an incipient global pandemic. Politics well outside the United States plays several other roles in the budding problem that we are confronting. Countries often will not admit they have a problem and request help because of the possible financial implications in terms of investment and travel. Guinea did not declare the Ebola epidemic early on and Chinese leaders, worried about trade and tourism, lied for months in 2002 about the presence of the SARS virus. In 2004, when avian influenza first surfaced in Thailand, officials there displayed a similar reluctance to release information. Hospitals in some countries, including India, are managed and often owned by doctors. They refuse to share information about existing infections and often categorically deny they have a problem. Reporting infections to public health authorities is not mandatory, and so hospitals that fail to say anything are not penalized. Even now, the WHO and the CDC do not have accurate and up-to-date information about the spread of E. coli or other infections, and part of the reason is that for-profit hospitals are reluctant to do anything to diminish their bottom line. Syria and Yemen are among those countries that are so weak and fragmented that they cannot effectively coordinate public healthcare. But their governments are also hostile to external organizations that offer relief. Part of the reason is xenophobia, but part is that this makes the government look bad. Relatedly, most poor-nation governments do not trust the efficacy of international institutions, and think that cooperating with them amounts to a re-importation of imperialism. They would rather their own people suffer and die than ask for needed help. That brings us to the level of international public health governance. Alas, sometimes poor-country governments estimate the efficacy of international institutions accurately. The WHO’s Ebola response in 2014-15 was a disaster. The organization was slow to declare a public health emergency even after public warnings from Médecins Sans Frontières, some of whose doctors had already died on the front line. The outbreak killed more than 28,000 people, far more than would have been the case had it been quickly identified. This isn’t just an issue of bureaucratic incompetence. The WHO is under-resourced for the problems it is meant to solve. Funding comes from voluntary donations, and there is no mechanism by which it can quickly scale up its efforts during an emergency. The result is that its response to the next major disease outbreak is likely to be as inadequate as were its responses to Ebola, H1N1, and SARS. Stakeholders admit that we need another mechanism, and most experts agree that the world needs some kind of emergency response team for dangerous diseases. But no one knows how to set one up amid the dysfunctional global governance structures that presently exist. Maybe they should turn to Bill Frist, whose basic concept was sound; if the U.S. government will not act, perhaps some other governments will, and use the UN system to do so. But as things stand, we lack a health equivalent of the military reserve. Neither government leaders nor doctors can mobilize a team of experts to contain infections. People who want to volunteer, whether for government or NGO efforts, are not paid and the rules, if any, are sketchy about what we do with them when they return from a mission. Are employers going to take them back? What are the quarantine rules? It is all completely ad hoc, meaning that humanity lacks the tools it needs to protect itself. And note, by the way, the contrast between how governments prepare for facing pandemics and how they prepare for making war. War is not more deadly to the human race than pandemics, but national defense against armed aggression is much better planned for than defense against threats to public health. There is a wealth of rules regarding it, too. Human beings study and plan for war, which kills people both deliberately and accidentally, but they do not invest comparable effort planning for pandemics, which are liable to kill orders of magnitude more people. To the mind of a medical doctor, this is strange. Creating Conditions for Infections to Spread Superbug infections spread for several interlocking reasons. Some are medical-epidemiological. Most of the infections of the past thirty years have started in one place and in one family. As already noted, they spread because many infectious diseases are highly contagious before the onset of symptoms, and because it is difficult to prevent patients who know they are sick from going to hospitals, work, and school, or from traveling further afield. But again, one reason for the problem is political, not medical. Many governments have no strategies in place to prevent pandemics because they are unwilling to tell their people how infections spread. They don’t want to worry people with such talk; it will make them, they fear, unpopular. So governments may have mountains of bureaucracy with great heaps of rules and regulations concerning public health, but they are generally unwilling to trust their own citizens to use common sense on their own behalf. This, too, seems very strange. Until now, no one has come forward to help us develop strategies to educate people how to identify and prevent the spread of infection to their families and communities. The majority of stakeholders have also been oblivious to the use of new technologies to help reduce the spread of these infections. There are some exceptions. In a fun blog post called Preparedness 101: Zombie Apocalypse, the CDC uses the threat of a zombie outbreak as a metaphor to encourage people to prepare for emergencies, including pandemics. It is well meaning and insightful, yet when my colleagues and I try to discuss ways of scaling up the CDC’s example with doctors and nurses, they shut down. Nobody plans for an actual crisis partly because it is too scary and hence paralyzing to think about. But it is also because it is not most health professionals’ job; it is not what they are trained and paid to do. It is always someone else’s job, except that it has turned out to be nobody’s job. Worse, the situation is not static. While we sit paralyzed, superbugs are evolving. Epidemiological models now predict how an algorithmic process of disease spread will move through the modern world. All urban centers around the entire globe can become infected within sixty days because we move around and cross borders much more than our ancestors did, thanks to air travel. A new pandemic could start crossing borders before we even know it exists. A flu-like disease could kill more than 33 million people in 250 days.3

### Contention 2

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

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

#### Strong IP protection are the only incentive for drug innovation.

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment**

#### EVEN IF INDIVIDUAL PATENTS DON’T FOSTER INNOVATION, THE COLLECTION OF THOSE PATENTS DRIVE INNOVATION

**Thomas 09** (John R. Thomas (Visiting Scholar, Congressional Research Studies), November 13, 2009, Patent “Evergreening”: Issues in Innovation and Competition, <https://ipmall.law.unh.edu/sites/default/files/hosted_resources/crs/R40917_091113.pdf>)

Patent law experts believe that these legal standards appropriately recognize that most technological progress occurs on an incremental basis. Attorney Ivar Kaardal explains that “most patents ... are granted for incremental, or even insignificant, technological advances.”66 Some observers believe that, on an individual or collective basis, patents on more marginal improvements may provide the public with valuable sources of technological information. As Jeanne C. Fromer, a member of the Fordham Law School faculty, states: while there are a rising number of patents for incremental technical advances, which individually might not be commercially or informationally valuable, the collectivity of incremental advances provides essential information for further innovation in many areas.... 67 Some commentators also believe the critique that many “evergreen” patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects.

### Contention 3

#### It’s extra T since paying for discoveries isn’t mentioned in the resolution – that’s a voter for limits since they could read anything attached to the aff which explodes neg research which is a voter for fairness bc debate is a game and requires fairness to function

#### None of their evidence is reverse causal saying that this result in bigger amounts of access or innovation, or helps decrease drug prices which is the biggest internal link that they have identified