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## 1

Ought = Should  
Cambridge Dictionary, NO DATE, "Ought to," Cambridge, <https://dictionary.cambridge.org/us/grammar/british-grammar/modals-and-modality/ought-to> KD

Ought to and should are similar in meaning. Should is more common than ought to.Ought to is more formal than should:There ought to be more street lights here. (means the same as There should be more street lights here.)  
I really ought to walk my dog more. He’s so fat. (means the same as I really should walk my dog more. He’s so fat.)

**Should means the debate is only about government policy. They violate—they a general principle and a method to rebel against capitalism. Counterplans and pics must negate because they prove that the aff is an unethical policy.**

#### For reference --- Thus, I affirm “The member nations of the World Trade Organization ought to reduce intellectual property protection on medicines” as a general principle and method to rebel against the reactionary and commodifying forces of capitalism – counterplans and pics don’t negate because they don’t disprove the general principle of the aff

Ericson 3 (Jon M., Dean Emeritus of the College of Liberal Arts – California Polytechnic U., et al., The Debater’s Guide, Third Edition, p. 4)   
   
The Proposition of Policy: Urging Future Action In policy propositions, each topic contains certain key elements, although they have slightly different functions from comparable elements of value-oriented propositions. 1. An agent doing the acting ---“The United States” in “The United States should adopt a policy of free trade.” Like the object of evaluation in a proposition of value, the agent is the subject of the sentence. 2. The verb should—the first part of a verb phrase that urges action. 3. An action verb to follow should in the should-verb combination. For example, should adopt here means to put a program or policy into action though governmental means. 4. A specification of directions or a limitation of the action desired. The phrase free trade, for example, gives direction and limits to the topic, which would, for example, eliminate consideration of increasing tariffs, discussing diplomatic recognition, or discussing interstate commerce. Propositions of policy deal with future action. Nothing has yet occurred. The entire debate is about whether something ought to occur. What you agree to do, then, when you accept the affirmative side in such a debate is to offer sufficient and compelling reasons for an audience to perform the future action that you propose.

#### Automatically negate if they don’t read a counter-definition—that would imply that there’s no resolutional basis for their advocacy. This justifies ex post facto topic adjustment which kills fairness because there’s no predictable basis for anything they expect us to debate.

#### Limits DA—there are an unlimited amount of methods they can defend—Black Lives Matter, Native movements, the long history of anti-capitalism activism in the 80s, et cetera. There are so many of these and each of them have their own nuances; they require in-depth engagement. It’s impossible for the neg to effectively do this because they’re not based in the resolution! This outweighs (a) fairness: both sides should have an equal chance of wininng, otherwise debates are impossible to consistently adjudicate (b) violence: unprepared debaters are more likely to read offensive positions because they haven’t dedicated time to doing the reading (c) real world movements: a stasis point for clash incentivizes debaters to have sophisticated research practices and flexible advocacy skills which makes or breaks problem-solving, resource use, and coalition building. These are necessary for effective movements to resist co-option. That link turns all the education arguments in their framing section.

#### Framing solves their offense—they can criticize the status quo, and also argue that systemic impacts are more important—we’ll engage with this on the case. They just can’t defend anything extraneous to the topic.

#### Drop the debater – a. Dropping the argument is the same as drop the debater since it gets rid of the aff advocacy and b. serves as a deterrence

#### Competing interps –

#### a. Reasonability leads to a race to the bottom since people will constantly toe the line and read increasingly abusive arguments

#### Reasonability is arbitrary since we don’t know what is “reasonable,” inviting judge intervention or random unjustified thresholds

#### No RVIs

#### The aff shouldn’t win for being Topical – they have the burden for doing so because they can pick the 1ac

#### Chills Topicality –discourages debaters from running theory to check abuse and good T debaters will run abusive positions to bait T and win the round.

1. Forces theory – RVI’s center the debate on theory since substance has zero utility, so each speech has an incentive to go solely for theory, which destroys all substantive education

## DA

#### Biotech is the new frontier; America is ahead but China is dangerously close

Gupta 6/11 [Gaurav Gupta, Biotech Investor, Founder of Ascendant BioCapital, a life science investment firm based in New York. Previously, Gaurav worked at OrbiMed Advisors, and served as a resident in neurological surgery at Columbia University Medical Center. He has co-authored over a dozen articles in peer-reviewed journals, filed a patent on a device for use in spine surgery, and edited a book on the technical and ethical implications of using tissue engineered products in the operating room. Dr. Gupta obtained his M.D. from the Stanford University School of Medicine, where he was a Paul and Daisy Soros Fellow, and B.S. and M.S.E. in biomedical engineering from Johns Hopkins University, where he was a Charles R. Westgate Scholar.) “As Washington Ties Pharma’s Hands, China Is Leaping Ahead” Barron’s Magazine: Commentary, China., 6/11/2021] RM

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. In the last few years, [47% of all new medicines](https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf) were invented by U.S. biopharma companies, with [homegrown startups](https://www.cbo.gov/publication/57126) driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market.

An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical “firsts” for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting innovation.

The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while “Made in America” is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy.

From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from [$1 billion to over $200 billion](https://www.bloomberg.com/news/articles/2021-03-01/xi-mobilizes-china-for-tech-revolution-to-cut-dependence-on-west). China saw over [$28 billion](https://www.bioworld.com/articles/506978-china-sees-five-year-highs-in-life-sciences-investments-and-partnering) invested in its life sciences sector in 2020, double the previous year’s amount. Returns on China’s investment are already arriving. The FDA approved a drug developed in China for the first time ever in 2019. While China’s innovation capacity currently remains behind America’s, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast.

In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans’ access to cutting-edge therapies.

The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and the U.S. risks these technologies being mastered by Chinese companies.

It is widely held that allowing China to gain an asymmetric edge in critical technologies such as AI or quantum computing could destabilize the geopolitical balance of power. The same is true of biotechnology. Chinese scientists were the first to edit the genomes of human embryos, in [contravention](https://www.sciencemag.org/news/2019/12/chinese-scientist-who-produced-genetically-altered-babies-sentenced-3-years-jail) of international standards, and the U.S. national security community believes China is [pushing ahead](https://www.nbcnews.com/politics/national-security/china-has-done-human-testing-create-biologically-enhanced-super-soldiers-n1249914) with experimental concepts for biological and cognitive enhancement of soldiers and civilians. American policy should be focused on protecting, rather than undermining, the global dominance of our biotechnology industry.

#### The plan recapitulates IP to China, destroying competitive advantages

WSJ 5/6 [Wall Street Journal Editorial Board, WSJ Opinion Philosophy: “We speak for free markets and free people, the principles, if you will, marked in the watershed year of 1776 by Thomas Jefferson's Declaration of Independence and Adam Smith's “Wealth of Nations.” So over the past century and into the next, the Journal stands for free trade and sound money; against confiscatory taxation and the ukases of kings and other collectivists; and for individual autonomy against dictators, bullies and even the tempers of momentary majorities.” Edited by Paul A. Gigot and Daniel Henninger, “Biden’s Vaccine IP Debacle: His patent heist is a blow to the Covid fight and U.S. biotech.” The WSJ Opinion: Review and Outlook, May 6, 2021] RM

We’ve already criticized President Biden’s bewildering decision Wednesday to endorse a patent waiver for Covid vaccines and therapies. But upon more reflection this may be the single worst presidential economic decision since Nixon’s wage-and-price controls.

In one fell swoop he has destroyed tens of billions of dollars in U.S. intellectual property, set a destructive precedent that will reduce pharmaceutical investment, and surrendered America’s advantage in biotech, a key growth industry of the future. Handed an American triumph of innovation and a great soft-power opportunity, Mr. Biden throws it all away.

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India and South Africa have been pushing to suspend patents at the World Trade Organization for months. They claim that waiving IP protections for Covid vaccines and therapies is necessary to expand global access, but their motivation is patently self-interested.

Both are large producers of generic drugs, though they have less expertise and capacity to make complex biologics like mRNA vaccines. They want to force Western pharmaceutical companies to hand over IP free of charge so they can produce and export vaccines and therapies for profit. Their strategy has been to shame Western leaders into surrendering with the help of Democrats in the U.S.

But suspending IP isn’t necessary to expand supply and will impede safe vaccine production. The global vaccine supply is already increasing rapidly thanks to licensing agreements the vaccine makers have made with manufacturers around the world.

Pfizer and BioNTech this week said they aimed to deliver three billion doses this year, up from last summer’s 1.2 billion estimate. Moderna increased its supply forecast for this year to between 800 million and a billion from 600 million. AstraZeneca says it has built a supply network with 25 manufacturing organizations in 15 countries to produce three billion doses this year.

AstraZeneca and Novavax have leaned heavily on manufacturers in India to produce billions of doses reserved for lower-income countries. But India has restricted vaccine exports to supply its own population. IP simply isn’t restraining vaccine production.

Busting patents also won’t speed up production, since it would take months for these countries to set up new facilities. Competition will increase for scarce ingredients, and less efficient manufacturers with little expertise would make it harder for licensed partners to produce vaccines.

There’s also the problem of safety. Johnson & Johnson has experienced quality problems at an Emergent plant making its vaccines, and that’s in Baltimore. Imagine the potential problems with unlicensed producers in, say, Malaysia or Brazil. If vaccines made there have complications, confidence in licensed vaccines could plummet too. And who would Pfizer and Moderna sue to get their reputations back?

The economic self-damage is also hard to fathom. The U.S. currently has a competitive advantage in biotech and biologics manufacturing, which could be a growing export industry. Waiving IP protections for Covid vaccines and medicines will give away America’s crown pharmaceutical jewels and make the U.S. and world more reliant on India and China for pharmaceuticals.

Moderna has been working on mRNA vaccines for a decade. Covid represents its first success. Ditto for Novavax, which has been at it for three decades. Small biotech companies in the U.S. have been studying how to create vaccines using nasal sprays, pills and patches.

Thanks to Mr. Biden, all this could become the property of foreign governments. Licensing agreements allow developers to share their IP while maintaining quality control. Breaking patents and forcing tech transfers will enable China and low-income countries to manufacture U.S. biotech products on their own.

China’s current crop of vaccines are far less effective than those in the West, but soon Beijing might be able to purvey Pfizer knock-offs. The U.S. has spent years deploring China’s theft of American IP, and now the Biden Administration may voluntarily let China could reap profits from decades of American innovation.

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Instead of handing over American IP to the world, Mr. Biden could negotiate bilateral vaccine agreements and export excess U.S. supply. If Mr. Biden wants to increase global supply safely, the U.S. could spend more to help the companies produce more for export. Then the jobs would go to Americans. We thought this was the point of the production deal Mr. Biden negotiated between J&J and Merck.

Alas, this President seems to be paying more attention these days to Elizabeth Warren, Bernie Sanders, Alexandria Ocasio-Cortez and Nancy Pelosi. They think vaccines and new drugs can be conjured by government as a public good with no incentive for risk-taking or profit. This really is destructive socialism.

Mr. Biden ought to listen to Angela Merkel. Pfizer’s partner BioNTech is a German firm, and the German Chancellor said Thursday that she opposes the WTO heist: “The protection of intellectual property is a source of innovation and it must remain so in the future.”

At least IP is safe in Germany. Mr. Biden has sent a signal around the world that nobody’s intellectual property is safe in America.

#### China biotech heg causes a laundry list of impacts

Moore 19 Scott Moore - Director of the Penn Global China Program at the University of Pennsylvania, Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S. Department of State, Giorgio Ruffolo Post-Doctoral Research Fellow with the Belfer Center for Science and International Affairs at Harvard University, Truman, Fulbright, and Rhodes Scholar., Foreign Policy, "China's Genetic Experiments Are Pushing Ethical Limits", NOVEMBER 8, 2019, 2:53 PM, https://foreignpolicy.com/2019/11/08/cloning-crispr-he-jiankui-china-biotech-boom-could-transform-lives-destroy-them/ - BD

When James Clapper, the U.S. director of national intelligence at the time, appeared before Congress in early January 2016 for an annual briefing of threats to the United States, he didn’t lack for material. Just a few weeks earlier, North Korea had tested a nuclear device, and Russia had begun deploying cruise missiles that appeared to violate a crucial arms-control agreement. But to the surprise of many experts, Clapper devoted a good chunk of his time to describing a much more exotic threat: biomedical research. Specifically, Clapper warned, “Research in genome editing conducted by countries with different regulatory or ethical standards than those of Western countries probably increases the risk of the creation of potentially harmful biological agents or products.”

Clapper’s statement didn’t explicitly mention China—but it didn’t need to. As his testimony went on to make clear, while in the 20th century the United States and Soviet Union held the keys to preventing planetary catastrophe, in the 21st the principal players are the United States and China. And while in a previous age keeping Pandora’s box closed meant preventing nuclear war, today it’s about preventing biotech dangers.

In just the past few years, the development of inexpensive gene-editing techniques has democratized biomedical research, producing a biotech bonanza in places such as China and creating a whole new category of security threats in the process, from the use of genetic information to persecute dissidents and minority groups to the development of sophisticated bioweapons.

When it comes to the United States, China, and technology, artificial intelligence tends to grab most of the attention. But policymakers need to come to grips with the even bigger threat of biotechnology—and soon. Fortunately, though, shared concerns about China’s role in biotechnology also provide a rare chance for meaningful and productive engagement in shaping the rules of a new world.

China’s starring role in preventing the 21st century’s biotech perils stems from its skyrocketing investment in biomedical research. Historically, Western countries, and especially the United States, have been the epicenter of research in the life sciences. The United States alone accounted for some 45 percent of biotech and medical patents filed in the 14-year period ending in 2013. But now, thanks to heavy state-backed investment, China is catching up. Economic plans instituted in 2015 call for the biotechnology sector to account for more than 4 percent of China’s total GDP by 2020, and estimates suggest that as of 2018, central, provincial, and local governments had already invested over $100 billion in the life sciences. Chinese venture capital and private equity investment in the life sciences, meanwhile, totaled some $45 billion just from 2015 to 2017.

China has also invested considerable effort in competing with countries like the United States for biotech talent. Of some 7,000 researchers recruited under the Thousand Talents Plan since 2008, more than 1,400 specialized in the life sciences. A leading American geneticist, Harris Lewin, has warned that the United States is “starting to fall behind … the Chinese, who have always been good collaborators, [are] now taking the lead.”

For the United States and other Western countries, China’s growing role in biomedical research is raising plenty of concern. Several Chinese researchers have shown a willingness to ignore ethical and regulatory constraints on genetic research. In 2018, He Jiankui became a poster child for scientific irresponsibility when he announced he had edited the genes of two twins in utero without following basic safety protocols. He reportedly dismissed them as guidelines, not laws.

Yet the reaction at home was not what He had hoped for. His research had been made possible by the relatively lax standards of Chinese universities, even as he had kept the true nature of it secret from many involved – while discussing it with a small group of Western bioethicists and scientists, who stressed their disapproval. It’s not uncommon in China to break the rules and be lauded for the results anyway, whatever the field. For He, though, the vast international attention that came after the story broke cost him his career and possibly his freedom. Chinese media rushed to stress official disapproval of the experiments. Even the overt purpose of the editing – to ensure that the babies, born to HIV+ mothers, enjoyed protection against the virus – turned out to be scientifically weak.

As China’s biotech sector grows, so too do fears that Chinese researchers like He will be more willing to push the limits of both science and ethics than those in the United States. Earlier this year, Chinese researchers recorded another mind-bending milestone when they implanted human genes linked to intelligence into monkey embryos—and then said that the monkeys performed better on memory tests.

The dominance of the party-state in China raises serious concerns around biotechnology, especially because it carries increasingly ethnonationalist tone. When in 2018 Chinese researchers created the world’s first primate clones, for example, they dubbed them Zhong Zhong and Hua Hua, from the term zhonghua meaning “The Chinese Nation”—an oddly jingoistic moniker for a pair of monkeys. Chinese government policies often blur the line between eugenics and education, lumped together as improving the “quality” (suzhi) of the population, which received another stamp of official endorsement following the recent Fourth Plenum. These programs are carried out through the country’s huge so-called family planning bureaucracy—originally established to enforce the one-child policy.

Moreover, Beijing is increasingly extending its formidable social control apparatus into the realm of genetics. While there are considerable restrictions on private firms sharing biomedical data, largely because of an ugly history of popular discrimination against hepatitis carriers, the government has no such restrictions. A New York Times report earlier this year suggested, for example, that Chinese authorities had assembled a vast trove of genetic data on Chinese citizens without their consent, with the Uighur minority group having been specifically targeted.

Beijing’s brand of bio-nationalism also directly threatens the United States. U.S. officials have been warning universities and research institutions that the biotech sector is a focal point for Chinese industrial espionage activities in the United States. And this past August, a senior Defense Department official warned Congress that China’s growing role in pharmaceutical manufacturing could allow it to disrupt deliveries of critical battlefield medicines, or potentially even alter them to harm U.S. forces

Yet the biggest risks posed by biotech, for China, the United States, and other countries, pertain to nonstate actors. A critical feature of modern biotech, in contrast to technology like nuclear weapons, is that it’s cheap and easy to develop. A technique known as CRISPR, which the Chinese researcher He used in his illicit gene-editing work, makes it practical for just about anyone to manipulate the genomes of just about any organism they can lay their hands on. CRISPR makes it much simpler to skirt ethical restrictions and terrifyingly straightforward for terrorist groups to develop fearsome biological weapons.

Researchers have already shown it’s possible to reconstruct the smallpox virus, which was eradicated in the real world in the 1970s, for as little as $200,000 using DNA fragments you can order online. If a terrorist or rogue state were to successfully do so, virtually no one alive would have any resistance to the virus—and most stockpiles of the vaccine were destroyed long ago. There is an organization, the International Gene Synthesis Consortium, that tries to screen suspicious orders for DNA fragments that might be used to build such bioweapons. And while most of the world’s major DNA synthesis firms belong to the consortium, membership is completely voluntary, and there’s also a thriving and entirely unregulated black market—much of it based in China.

All of this means that biosecurity standards in places like China matter more than ever. After all, if a major bioweapon were to be unleashed, it’s unlikely that any major, globally integrated country could escape unharmed. Fortunately, there are growing signs China is open to better regulation of its biotech sector. In February, the Chinese government announced that “high risk” biomedical research would be overseen by the State Council, China’s equivalent of the cabinet—a sign of the concern with which Beijing views incidents like the He Jiankui CRISPR scandal. In a further sign of this concern, in August, the Chinese Communist Party announced the creation of a new committee to advise top leaders on research ethics.

Government worry is matched by growing public concern within China. Opposition to genetically modified organisms is arguably stronger in China than in the West, and health concerns top the list of public issues. Rumors and panics largely center around health issues, especially after a series of vaccination scandals. That means that the government has to walk unusually carefully and offers plenty of scope to build ethical concerns into both law and practice.

There are plenty of issues for U.S.-China cooperation on biotechnology and biosecurity to address. Given China’s role in the He Jiankui scandal, meanwhile, it would make sense to partner with the United States and other countries as part of a new World Health Organization effort to set international guidelines for the use of CRISPR. Another promising area of U.S.-China cooperation, especially in the research community, relates to so-called gene drives, the process of editing genomes and then spreading them through an entire population in just a few generations. Using gene drives to prevent select mosquito species from reproducing, for example, might finally banish the world of debilitating, widespread diseases such as malaria and Zika, while endangered species might be engineered to survive climate change.

Microsoft founder Bill Gates once observed that “The world hasn’t had that many technologies that are both promising and dangerous. … We had nuclear weapons and nuclear energy.” But thanks in large part to the efforts of biomedical researchers in the United States and China, biotechnology is opening a similar Pandora’s box. And while the world has so far avoided nuclear war or conflict, it’s done so largely though efforts by governments, aided by the fact that nuclear technology is extremely difficult and expensive to master.

The new wave of synthetic biology is exactly the opposite: It’s cheap to use and employ. For that very reason, while the U.S., Chinese, and other governments will be critical to dealing with the threat of new technologies, the discussions can’t be limited to nation-states. They’ll also have to gather together individual researchers, institutions, companies, and organizations like the International Gene Synthesis Consortium. When it comes to the risks posed by emerging technologies, Beijing, like Washington, will have to face the limits of its ability to solve the problem on its own.

#### China will leapfrog the US through biotech primacy

Cumbers 20 [John Cumbers, “I am the founder and CEO of SynBioBeta, the leading community of innovators, investors, engineers, and thinkers who share a passion for using synthetic biology to build a better, more sustainable universe. I publish the weekly SynBioBeta Digest, host the SynBioBeta Podcast, and wrote “What’s Your Biostrategy?”, the first book to anticipate how synthetic biology is going to disrupt virtually every industry in the world. I also founded BetaSpace, a space settlement innovation network and community of visionaries, technologists, and investors accelerating the industries needed to sustain human life here and off-planet. I’ve been involved with multiple startups, I am an operating partner and investor at the hard tech investment fund Data Collective, and I'm a former bioengineer at NASA. I earned my PhD in Molecular Biology, Cell Biology, and Biochemistry from Brown University and am originally from the UK.”) “China’s Plan To Beat The U.S. In The Trillion-Dollar Global Bioeconomy” Forbes, 2/3/2020] RM

The report, entitled “Safeguarding the Bioeconomy,” looks at how research and innovation in the life sciences is driving rapid growth in agriculture, biomedical science, information science and computing, energy, and other sectors of the U.S. economy. This economic activity—collectively referred to as the bioeconomy—presents many opportunities to create jobs, improve the quality of life, and continue to drive the U.S. economy as a whole.

The report says that while the U.S. has been a leader in advancements in the biological sciences, other countries are actively investing in and expanding their capabilities in this area—and the U.S.’s lead is beginning to slip.

Four reasons everyone should care about the U.S. bioeconomy

It might be easy for some to dismiss the report out of hand as a bunch of alarmist professors lobbying for more research money. But when you consider all the ways that biotechnology powers the economy and impacts our daily lives, it becomes clear that this is about something more:

The economy: at $1 trillion in value, the U.S. bioeconomy represents hundreds of thousands of quality, high-paying jobs for Americans.

Health & medicine: innovators in the bioeconomy are making next-generation therapies for cancer and diabetes, tackling emerging diseases like Coronavirus, and even increasing human longevity.

Food & farming: biotechnology is not only making agriculture more sustainable, it’s also bringing to market new and improved crops that are more nutritious, more affordable, and more delicious.

The environment: humanity’s health and well-being depend on our ability to stop and reverse climate change, and we can’t do it without biological solutions that treat carbon not as a waste product, but as the starting point for chemicals and materials that today use petroleum.

Considering all this, it doesn’t seem like an overstatement when the report authors say that U.S. competitiveness in the bioeconomy is key to maintaining the economic health and security of the country.

The very real risks to the U.S. bioeconomy

There are many things that can go wrong, causing the U.S. to lose its current edge in the global bioeconomy. Some of these are economic risks, and others present serious national security risks. All of them are related to a failure of our government to act now. Here’s a sampling of the risks to U.S. leadership at the frontiers of tech and bio:

Insufficient government R&D investment. Money for basic research and development builds the foundations of the bioeconomy. We learn, achieve new results, and create new applications. Investments that help develop enabling tools, technologies, and standards have the potential to maintain the U.S. bioeconomy competitive in a global bioeconomy.

Ineffective or inefficient regulations. Regulatory uncertainty stifles creative new approaches that may have unknown paths, long delays, or that might be prohibited by later changes.

Inadequate workforce. The U.S.’s K-12 education system may not prepare students to study STEM subjects at the university and postgraduate level, hindering the quality of workers. A skilled workforce gives U.S. companies the best talent to choose from, and it also encourages international firms to establish research and production facilities here.

Ineffective or inefficient intellectual property protections. Uncertainty over what is patentable could discourage innovators who are considering whether and how to bring their innovations to market. Patent eligibility is also important to venture capitalists and private equity investors when considering whether to invest in biotechnology companies.

Cybersecurity. As biological engineering depends more and more on massive datasets, the emerging bioeconomy now exists at the intersection of information science and biotechnological science. The bioeconomy’s growing reliance on software, networking, and computer hardware tools yields the same cyber vulnerabilities present in any other sector, including hacking, sabotage, breached privacy, or theft of intellectual property.

Biosafety and biosecurity risks. The tools of today’s bioeconomy are enabling new capabilities that can generate concerns regarding traditional biothreats. These can include the accidental or intentional creation or release of dangerous or lethal pathogens. Such biothreats can harm humans, animals, plants, agriculture, the environment, and materials.

Risks from climate change. Food and feed crops, biofuels crops, and crops used with bio-based fermentation products are susceptible to temperature and water stresses, as well as insects and pathogens that migrate with changing weather patterns.

China: the biotech elephant in the room

I’ve written previously written how the Chinese government is already making substantial investments in its bioeconomy. Here are three scary statistics, courtesy of Greg B. Scott of the ChinaBio Group:

China is out-investing the U.S. China’s private investors poured $14.4 billion into its bioeconomy in 2019. That compares to the United States’ more meager investment of $10.4 billion.

China is building a bigger bioeconomy workforce. China graduates about 8-10 million students each year. In the U.S., that number is closer to 400,000. Many Chinese students graduating from U.S. institutions stay here, but they are increasingly returning home to start highly innovative companies.

China is investing in itself. Historically, China has invested heavily in foreign companies, tech, and debt. Now we’re seeing an uptick in China-to-China investments—the country no longer needs to look abroad to find plenty of good biotech opportunities.

Chinese investments have led to centers of excellence in the regional technology hub of Shenzhen, including the Institute of Synthetic Biology at the Shenzhen Institute of Advanced Sciences (SIAT) and BGI Genomics. Shenzhen will compete for technological and economic leadership with U.S. regional biotech powerhouses such as San Francisco/Silicon Valley and Boston/Cambridge in the years to come.

Many of China’s long-standing challenges—environment, food, water, waste management, and rapid innovation to retain its global manufacturing competitiveness—are areas where synthetic biology is seen as a key technology for the future. In other words, synthetic biology is not just an academic pursuit for China. Rather, its leaders are thinking proactively about how biological engineering can be used to address the country’s strategic national interests—while U.S. leadership stands idly by.

What do we do?

So what can U.S. policymakers do to protect the U.S. bioeconomy and ensure continued technological and economic leadership in biology for the next twenty years?

Straight from the top. China has made clear its ambition to become a global tech superpower, with President Xi Jinping calling science and technology one of the main battlefronts of the economy. The U.S. administration needs to step up its game, too. President Trump recently declared January 2020 to be National Biotechnology Month, citing “boundless possibilities for economic growth, national security, healthcare, manufacturing, and agriculture.” That’s the right sentiment—now we need real action.

New legislation. Late last year, the U.S. House of Representatives passed the Engineering Biology Research and Development Act of 2019, which would direct the Office of Science and Technology Policy (OSTP) to implement a national research strategy for engineering biology. The explicit goal: maintain U.S. science, technology, and economic leadership in synthetic biology. The bill now resides in the Senate and awaits committee action. Legislative leadership is now needed to give this bill the appropriations necessary to give it real teeth, and then put it squarely on the President’s desk.

Investing for returns. The Human Genome Project is said to have returned $141 for every dollar invested by taxpayers. While “Big Science” yields tremendous benefits for everyone, it doesn’t happen without federal funding. In 2019, politically courageous Republicans and Democrats came together to produce a 2020 final spending bill that is kind to science, in essence ignoring President Trump’s proposed cuts and instead giving increases to each of the NIH, NSF, NASA, and DOE’s Office of Science. But the U.S. isn’t even in the top ten for R&D spending as a percentage of GDP, while China continues to close in on the U.S., meaning that the U.S. is no longer the uncontested global leader in science.

Leading the global bioeconomy: Have some courage

There are many things the U.S. could do to protect the American bioeconomy. But above all else, policymakers need to come together and demonstrate the kind of courage and vision needed to be a world leader. Science and technology know no partisan lines. Everybody wants healthy lives, clean water, and good jobs. Federal initiative and assistance are needed to bring these benefits to everyone living in the U.S..

Today, the American synthetic biology industry may be unprepared for the global competition it will face, lacking initiative and leadership at the highest levels of government. But this could change quickly. If a country like the U.S. makes engineering biology a national priority, anything is possible in the new bioeconomy.

#### Heg solves arms races, land grabs, rogue states, and great power war

Brands 18 [Hal, Henry Kissinger Distinguished Professor at Johns Hopkins University's School of Advanced International Studies and a senior fellow at the Center for Strategic and Budgetary Assessments." American Grand Strategy in the Age of Trump." Page 129-133]

Since World War II, the United States has had a military second to none. Since the Cold War, America has committed to having overwhelming military primacy. The idea, as George W. Bush declared in 2002, that America must possess “strengths beyond challenge” has featured in every major U.S. strategy document for a quarter century; it has also been reflected in concrete terms.6

From the early 1990s, for example, the United States consistently accounted for around 35 to 45 percent of world defense spending and maintained peerless global power-projection capabilities.7 Perhaps more important, U.S. primacy was also unrivaled in key overseas strategic regions—Europe, East Asia, the Middle East. From thrashing Saddam Hussein’s million-man Iraqi military during Operation Desert Storm, to deploying—with impunity—two carrier strike groups off Taiwan during the China-Taiwan crisis of 1995– 96, Washington has been able to project military power superior to anything a regional rival could employ even on its own geopolitical doorstep.

This military dominance has constituted the hard-power backbone of an ambitious global strategy. After the Cold War, U.S. policymakers committed to averting a return to the unstable multipolarity of earlier eras, and to perpetuating the more favorable unipolar order. They committed to building on the successes of the postwar era by further advancing liberal political values and an open international economy, and to suppressing international scourges such as rogue states, nuclear proliferation, and catastrophic terrorism. And because they recognized that military force remained the ultima ratio regum, they understood the centrality of military preponderance.

Washington would need the military power necessary to underwrite worldwide alliance commitments. It would have to preserve substantial overmatch versus any potential great-power rival. It must be able to answer the sharpest challenges to the international system, such as Saddam’s invasion of Kuwait in 1990 or jihadist extremism after 9/11. Finally, because prevailing global norms generally reflect hard-power realities, America would need the superiority to assure that its own values remained ascendant. It was impolitic to say that U.S. strategy and the international order required “strengths beyond challenge,” but it was not at all inaccurate.

American primacy, moreover, was eminently affordable. At the height of the Cold War, the United States spent over 12 percent of GDP on defense. Since the mid-1990s, the number has usually been between 3 and 4 percent.8 In a historically favorable international environment, Washington could enjoy primacy—and its geopolitical fruits—on the cheap.

Yet U.S. strategy also heeded, at least until recently, the fact that there was a limit to how cheaply that primacy could be had. The American military did shrink significantly during the 1990s, but U.S. officials understood that if Washington cut back too far, its primacy would erode to a point where it ceased to deliver its geopolitical benefits. Alliances would lose credibility; the stability of key regions would be eroded; rivals would be emboldened; international crises would go unaddressed. American primacy was thus like a reasonably priced insurance policy. It required nontrivial expenditures, but protected against far costlier outcomes.9 Washington paid its insurance premiums for two decades after the Cold War. But more recently American primacy and strategic solvency have been imperiled.

THE DARKENING HORIZON For most of the post–Cold War era, the international system was— by historical standards—remarkably benign. Dangers existed, and as the terrorist attacks of September 11, 2001, demonstrated, they could manifest with horrific effect. But for two decades after the Soviet collapse, the world was characterized by remarkably low levels of great-power competition, high levels of security in key theaters such as Europe and East Asia, and the comparative weakness of those “rogue” actors—Iran, Iraq, North Korea, al-Qaeda—who most aggressively challenged American power. During the 1990s, some observers even spoke of a “strategic pause,” the idea being that the end of the Cold War had afforded the United States a respite from normal levels of geopolitical danger and competition. Now, however, the strategic horizon is darkening, due to four factors.

First, great-power military competition is back. The world’s two leading authoritarian powers—China and Russia—are seeking regional hegemony, contesting global norms such as nonaggression and freedom of navigation, and developing the military punch to underwrite these ambitions. Notwithstanding severe economic and demographic problems, Russia has conducted a major military modernization emphasizing nuclear weapons, high-end conventional capabilities, and rapid-deployment and special operations forces— and utilized many of these capabilities in conflicts in Ukraine and Syria.10 China, meanwhile, has carried out a buildup of historic proportions, with constant-dollar defense outlays rising from US$26 billion in 1995 to US$226 billion in 2016.11 Ominously, these expenditures have funded development of power-projection and antiaccess/area denial (A2/AD) tools necessary to threaten China’s neighbors and complicate U.S. intervention on their behalf. Washington has grown accustomed to having a generational military lead; Russian and Chinese modernization efforts are now creating a far more competitive environment.

## CP

#### CP Text: The member nations of the World Trade Organization ought to restrict intellectual property protections for [medicines] for only one period of 20 years and require the public disclosure of the medicine.

**Feldman 19** [(Robin Feldman is professor of law and director of the Institute for Innovation Law at UC Hastings College of the Law in San Francisco and author of [“Drugs, Money, and Secret Handshakes”](https://www.cambridge.org/us/academic/subjects/law/us-law/drugs-money-and-secret-handshakes-unstoppable-growth-prescription-drug-prices?format=HB)) “‘One-and-done’ for new drugs could cut patent thickets and boost generic competition”, Stat News, 2/11/19] kzheng

Some experts believe the U.S. can rein in drug process with [value-based pricing](https://www.statnews.com/pharmalot/2017/06/01/drug-prices-outcomes-health-plans/), which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for [dismantling pharmacy benefit managers](https://www.statnews.com/2018/08/23/pbms-rebates-drug-purchasing/). Still others want large groups like Medicare [to negotiate with drug companies](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Manufactured%20Crisis-How%20Better%20Negotiation%20Could%20Save%20Billions%20for%20Medicare%20and%20America's%20Seniors.pdf) for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, [“Drugs, Money, and Secret Handshakes,”](https://www.cambridge.org/us/academic/subjects/law/us-law/drugs-money-and-secret-handshakes-unstoppable-growth-prescription-drug-prices?format=HB) the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem.

Drug companies have brought great innovations to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price.

But that’s not happening. Instead, drug companies build massive patent walls around their products, extending the protection over and over again. Some modern drugs have an avalanche of U.S. patents, with expiration dates staggered across time. For example, the rheumatoid arthritis drug [Humira](https://www.statnews.com/pharmalot/2018/11/07/abbvie-biosimilars-humira-patents/) is protected by [more than 100 patents](https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-1539687603). Walls like that are insurmountable.

Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, [more than three-quarters](https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsy022/5232981) of the drugs associated with new patents were not new ones coming on the market but existing ones. In other words, we are mostly churning and recycling.

Particularly troubling, new patents can be obtained on minor tweaks such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit.

[Related:](https://www.statnews.com/2019/02/05/biosimilars-biologics-explainer-video/)

[WATCH: What is a biosimilar, exactly?](https://www.statnews.com/2019/02/05/biosimilars-biologics-explainer-video/)

I believe that one period of protection should be enough. We should make the legal changes necessary to prevent companies from building patent walls and piling up mountains of rights. This could be accomplished by a “one-and-done” approach for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug.

Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit.

The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but not all of the above and more.

Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained.

Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through legislative changes to the FDA’s drug approval system, and would apply to patents granted going forward.

[Related:](https://www.statnews.com/2018/11/14/humira-abbvie-amgen-enbrel-price-hikes-biosimilars/)

[Extraordinary tactics, perverse incentives: Makers of top-selling drugs hike prices in lockstep, and patients bear the cost](https://www.statnews.com/2018/11/14/humira-abbvie-amgen-enbrel-price-hikes-biosimilars/)

One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing [patent obviousness](https://www.law.cornell.edu/wex/nonobviousness) doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented.

Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls.

Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results.

If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

## Case

### 1NC—AT: Commodification

#### The counter-standard is minimizing suffering.

#### All of their impacts implicitly rely on util. Their cards comment on particular ways we should think about death, but they still agree that pain is bad and that more pain is worse than less pain. Death forceloses the ability to live any life, which is the best metric because value to life is subjective. Any non-utilitarian framework is necessarily commodifying because it decides arbitrarily what is valuable, which is paternalistic; only util views all humans with equal ontological worth.

#### Group their education offense— they don’t solve; huge alt causes to debaters subjectivity—education, families, religion, etc. One ballot won’t change anything!

#### Any plausible moral theory must prioritize extinction.

Pummer 15 [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

#### Making impactful contributions demands causal policy relevance AND methodological pluralism -- that is the only way to draw accurate contextual conclusions and prevent violent, imprecise reification.

Michael C. Desch 19. Packey J. Dee Professor of International Relations at Notre Dame and founding director of the Notre Dame International Security Center, former Professor and Director of the Patterson School of Diplomacy and International Commerce at the University of Kentucky, #gocats. 2019. “Conclusions, Responses to Objections, and Scholarly Recommendations.” Cult of the Irrelevant: The Waning Influence of Social Science on National Security, Princeton University Press.

I want to reiterate that I am not arguing that scholarship that is formal or quantitative is by definition irrelevant. Indeed, one can point to examples of both that are. When applied to economic issues, the discipline of economics has managed to be both highly “scientific” and, at times, quite relevant, though for both good and ill. Likewise, there are examples of highly quantitative political science that policymakers have found useful.1 Finally, there is much nonquantitative scholarship, particularly but not exclusively in the humanities that, is jargon laden and otherwise inaccessible to a wider audience, including government policymakers.2 This is by no means an anti-social science methods screed, just a reminder of the tensions between rigor and relevance that need to managed rather than assumed away. Nor is this in any way a brief against theory. Former State Department official Roger Hilsman reminded us that everyone, including policymakers, uses theory. Paraphrasing John Maynard Keynes, he concluded that “it seems obvious that all thinking involves notions of how and why things happen. Even the ‘practical’ man who despises theory has a number of assumptions and expectations which lead him to believe that when certain things are done, certain results follow.. . .It is this ‘theory’ that helps a problem solver select from the mass of facts surrounding him those which he hopes are relevant.”3 Given that, I fully associate myself with Hans Morgenthau’s balanced view that “theory without verification is metaphysics, but empiricism without theory is aimless.”4 Since policymakers implicitly use theory in analyzing situations and assessing their alternatives, such theories should be stated explicitly and analyzed systematically, which is a comparative advantage of the scholars. Instead, what I offer is simply a critique of the increasing tendency of many social scientists to embrace methods and models for their own sake rather than because they can help us answer substantively important questions. This inclination is in part the result of the otherwise normal and productive workings of science, but is also reinforced by less positive factors such as organizational self-interest and intellectual culture. As a result of the latter, many political scientists have committed themselves to particular social science methods not so much because they believe they will illuminate real-world policy problems but because they serve a vested interest in disciplinary autonomy and dovetail with a particular image (mathematized and model-based) of what a “science” of politics should look like. In other words, the professionalization of social science is the root of the enduring relevance question. This tendency to equate rigor with technique imposes costs on the rest of society as well as the discipline, especially when it excludes a more balanced approach to rigor and relevance of the sort that characterized the subfield of security studies in the past. On the former, as diplomat George Kennan rightly observed, policymakers need academic expertise because they have to make decisions about issues and areas of the world “about which they cannot be expert and learned.”5 They depend on the academy for the raw data—whether quantitative or historical—that they use in decision making. They also rely on the social sciences for the theories they use to analyze and make sense of this data. The problem with relying exclusively on in-house government research to make up for the lack of policy-relevant academic research is that it is often of low quality. The role of the “independent policy analyst” is essential for three reasons: 6 He or she can challenge basic policy assumptions. As RAND’s Hans Spier put it, they can undertake “research which does not necessarily take the mission of the military for granted and admits the possibility U.S. may be wrong”7 And academic social scientists are particularly well suited to this role by virtue of the fact that they both conduct research and also teach future policymakers. Academics have some other advantages over policymakers. They have the time to develop greater depth of knowledge on issues and regions than most policymakers can. The institution of tenure also gives them, at least in theory, the freedom to explore controversial issues and take unpopular stands. And while peer review can homogenize and narrow scholarship, it also plays an indisputably positive role in advancing it. Finally, university-based scholars have less of a vested interest in certain policies and programs than do policymakers, though of course that is not to deny that they have their own institutional interests and biases.9 I am not suggesting, of course, that scholars would make better policy than bureaucrats and elected officials. They lack inside knowledge, have little actual power, and are often politically out of step with the rest of American society.10 They also come to policy issues with a markedly different intellectual orientation than policymakers.11 Rather, my point is simply that our democratic political system depends on the successful functioning of the marketplace of ideas and checks and balances in which individuals and groups with various strengths and weaknesses and offsetting biases participate in the larger policy debate, thereby compensating for each other’s limitations.12 We run into trouble when we lack one of these perspectives in policy debates. Indeed, there are instances—the war in Vietnam and the recent Iraq War—in which had the majority consensus of scholars in academia influenced policy, the country’s national interest would have been better served. As the flawed Iraq War debate demonstrates, our nation’s marketplace of ideas is bankrupt, particularly in national security affairs.13 Of course, our political problems run much deeper than just the Beltway/Ivory Tower gap, but closing it would represent an important step in the country’s intellectual recapitalization. This nation’s universities need to reclaim their place as one of society’s main sources of independent ideas about the problems that it faces.14 Less widely recognized, and perhaps more controversial given the prevailing sentiments in the Academy for a sharp distinction between “science” and “policy,” is my contention that the growing gap is ultimately bad for the generation of new knowledge. There are at least two reasons why greater attention to policy relevance produces better scholarship. First, it leads to more realistic theorizing. As John Kenneth Galbraith warned his economics colleagues nearly forty years ago, “No arrangement for the perpetuation of thought is secure if that thought does not make contact with the problems that it is presumed to solve.”15 Second, a focus on manipulatable variables makes it more likely that they are testable because the analyst can ensure variation on them. Also, the hyperspecialization of knowledge today makes it difficult for even scholars in related disciplines to understand each other, much less the general public. Such intellectual fragmentation makes the application of scholarly knowledge to policymaking extremely difficult. Therefore, a deeper and more regular engagement between the Ivory Tower and the Beltway will be mutually beneficial for both sides.16 Ultimately, even the most sophisticated social science will be judged by what it tells us about things that affect the lives of large numbers of people and which policymakers therefore seek to influence and control.17 The recurrent congressional debates about National Science Foundation funding for political science highlight the direct costs to the discipline of not being able to justify itself in terms of broader impact on the rest of society. Harkening back to the debate about the Mansfield Amendment, an article in Science cautioned that “to the extent that the research community disdains work on major national missions or behaves self-servingly in mission-oriented work, anti-intellectualism will increase its influence on the fate of American science.”18 Also, public and philanthropic community support for investment in academia generally reflects the belief that it will produce work that will speak to problems of broader importance. When the academy fails on that score, it can undermine that support.19 Political science’s subfield of international security studies can plausibly claim to save large amounts of money and even lives and so its increasing marginalization is a self-inflicted wound on the discipline. Response to Objections There are at least eight reasonable, though ultimately unpersuasive, objections to my argument that we should consider. First, some point to the influence of the Democratic Peace Theory (DPT) on the Clinton, George W. Bush, and Obama administrations as evidence that one of the most scientific of social science theories in international relations was both useful and influential among policymakers.20 The argument that democracies are unlikely to go to war with each other gained currency among social scientists based on statistical analysis of every major interstate war since 1815. In the words of Rutgers political scientist Jack Levy, the Democratic Peace Theory is “as close as anything we have to an empirical law in international relations.”21 Two scholars argued that the theory became relevant outside of the academy precisely “because of the law-like status of a particular empirical finding.”22 Others hold it up as a model of how basic research in political science can contribute to policymakers.23 It is not clear, though, that the influence of the DPT on recent U.S. foreign policy was due to its unassailable social scientific standing. While former Defense Department official and Ohio State political scientist Joseph Kruzel conceded that DPT “had substantial impact on public policy,” he attributed its attractiveness to policymakers to its simplicity rather than its social scientific rigor.24 It clearly identifies America’s enemies (nondemocratic states) and prescribed a simple response to them (make them democratic). It is also likely that the much less methodologically sophisticated articulation of the theory in the work of Michael Doyle was far more influential.25 And the process by which DPT entered the Clinton White House did not involve sophisticated social science. Rather, the key administration proponent of the democratic peace was National Security Advisor (and former college professor) Anthony Lake.26 It is clear, however, that to the extent that Lake was drawing support for the democratic peace from academic sources, it was not from statistically based research, but rather from the qualitative work of scholars like Harvard’s Samuel Huntington.27 The results of a survey of senior national security policymakers found that more than half of those familiar with the methodologically sophisticated democratic peace theory reported not being influenced by it in their government work.28 Finally, one could argue that U.S. policymakers have embraced the democratic peace because of its compatibility with our political culture rather than its scientific standing.29 A second, and in some ways, flip side of the first critique, is that the relevance problem with contemporary security studies is the result of the subfield’s domination by realism, and particularly its most abstruse and theoretical manifestation, neorealism.30 Critics point particularly to neorealist arguments that tout the virtues of nuclear proliferation as examples of theoretically elegant but politically unacceptable social science.31 Despite its respectability among scholars, neorealist proliferation optimism has reportedly had little influence on actual policy.32 While that particular policy issue may not have been influenced by realist thinking, as this book has shown realists have remained committed to policy relevance at times when the rest of the discipline has eschewed it. And they have more often been on the right side of policy debates as well.33 A third potential challenge to my argument is that many social scientists believe that they should avoid offering policy recommendations in favoring of focusing on basic research tasks such as identifying empirical regularities and offering generalizations to explain them.34 As Dartmouth political scientist Kalman Silvert warned, “It is not the legitimate role of the social scientist as scholar to advocate specific courses of governmental action or to act as implementer of government decisions.”35 Another rationale is that doing so is unnecessary given that the applied implications of basic research tend to trickle down by themselves.36 Policy engagement—particularly offering explicit policy recommendations—is both unwise and unnecessary in the view of many social scientists. Neither of these views, however, are shared by policymakers. Most believe that in addition to providing basic research findings, “scientists must explicitly define the linkage, whether immediate or remote, of the knowledge acquired or being acquired, to specific operational problems and continually assess the import of such knowledge to solution of the problems.”37 Nor are current and former policymakers sanguine about the trickle-down (or bubble-up in which senior policymakers get the results of scholarly work through their methodologically savvy staffs) process. As John K. Plank of the Brookings Institution, a former DoD official, recollected, “There is presumably a process whereby the research product is filtered up to [senior policymakers], but in point of fact very little of operational usefulness is transmitted.”38 Fourth, some political scientists believe that there are now so many new outlets for scholars to engage in the policy debate, it is both easier for them to do so and also unnecessary for them to concern themselves with doing so in their scholarship.39 Academics can now publish basic research in scholarly venues and then disseminate its applied implications through the new media. George Washington political scientist and blogger Marc Lynch effused that with the rise of the new media “this is in most ways a golden age for policy-relevant public spheres.”40 Indeed, many see the proliferation of new media outlets as the answer to political science’s perennial problem: its diminished public profile.41 The assumption here is that political scientists are simply not communicating their results effectively. There are three problems with these arguments: Until recently, we had no idea whether blogs and other new media reached policymakers. As one optimist conceded, we have “no solid statistics” on our impact.42 But we do now and it suggests that blogs and other new media are in fact not an important source of information for policymakers and therefore are unlikely to effectively convey the implications of basic research to policymakers, the media, or the general public.43 Moreover, even if a few blogs get some attention, many others do not, simply making more noise in an already cacophonous marketplace of ideas.44 And suggesting that the failure of communication argument misses the mark, Social Science Research Council president Craig Calhoun noted that scholarly “engagement with public constituencies must move beyond a dissemination model” that assumes that “pure research” will naturally triclde down, even with better communication.45 In other words, it is not the medium that matters as much as the message. And the message must be made more intelligible and useful to policymakers and the general public. Finally, there is systematic evidence that academic bloggers and scholars who utilize other new media venues receive little professional credit for them in the critical areas of promotion and tenure.46 In short, despite the explosive growth of new media outlets, professional incentives still do not encourage scholars to use them. A fifth conceivable objection is that advanced social science techniques and basic research will eventually become more useful to policymakers as they (or at least their staffs) become more sophisticated in their understanding of them. One optimist, for example, noted that most graduate public policy schools now include one or two required courses in economics and social science methods in their curricula. As these increasingly methodologically savvy young bureaucrats become senior policymakers, so this argument goes, they will be more adept at using them and more appreciative of their policy relevance.47 However, this argument assumes that training in advanced research techniques is a recent development. Policy schools, however, have long had methods courses as part of their required curriculum. Even prior to this, many national security policymakers came out of academic Ph.D. programs in which they were exposed to the latest innovations in social science methodology. It also ignores that the security studies subfield played a leading role in developing many of these sophisticated social science techniques, particularly at RAND in the 1950s.48 An example of the reverse flow of ideas from the policy world to the Academy was the “unquestionably” leading role that RAND mathematicians and other social scientists played in the development of game theory, a mathematical framework for strategizing under uncertainty.49 Despite early enthusiasm, many at RAND concluded that game theory had an Achilles Heel in its application to national security policy: how to assign the numerical values that were to be plugged into its formulas. That was not a trivial limitation, which led Hitch to confess that “for our purposes, Game Theory has been quite disappointing.”50 It also assumes that today’s aspiring policymakers come away from these methods courses with an unqualified appreciation of their usefulness. My experience after ten years in teaching in such schools, and familiarity with the evaluations students give these courses, leaves me skeptical. They often do not see the usefulness of such courses and suspect they are being forced to take them for academic, not professional, reasons.51 Other colleagues at professional schools share this impression.52 Finally, an earlier survey of current and former national security policymakers reveals that the more highly educated the policymaker, the greater the skepticism about their utility.53 This is consistent with the argument that familiarity with advanced techniques instills greater appreciation not only for their promise but also their limits. Even proponents of modern social science methods in international relations concede that “the emerging science of international relations has a long way to go before it can be of direct use to policy makers.”54 It is hard to find much evidence that the most sophisticated approaches to international relations are of much direct use to policymakers, and there are ample reasons for caution about how much of the discipline’s “basic” research is really trickling down to indirectly influence policymakers. Sixth, some point to the post-9 /11 resurgence of interest among younger social scientists as a harbinger of another renaissance of interest in policy relevance. Others suggest that changes in the nature of the “new paradigm of knowledge production,” which is “socially distributed, application-oriented, trans-disciplinary, and subject to multiple accountabilities” constitute grounds for optimism about a broader return to relevance among the social sciences.55 To be sure, there are reasons for optimism on this score but also for continuing caution. As we have seen, previous periods of optimism about answering the relevance question have given way to disappointment. Moreover, many scholars have claimed to be policy relevant even though policymakers did not find them so.56 As one CIA analyst warned, “Social scientists commonly define policy-relevant research far more broadly than the foreign policy community does.”57 A seventh potential criticism of my argument is there are other forms of “relevance” beyond just influencing government policymakers by offering policy recommendations to which scholars should aspire.58 Especially in a democratic political system, a scholar’s vocation for politics can also involve educating students and informing the wider public about pressing issues of policy. Moreover, an engaged scholar could serve with nongovernmental and private organizations rather than just through government service. While there is no doubt that policy influence is broader than just affecting government policy, that is ultimately the goal of the enterprise, either directly through policymakers or indirectly through the media or the public. Moreover, it is the clearest and most demanding standard of relevance available. So if we want to understand when and how social science matters to policymakers that is the most important, if not the only, aspect of it to consider.59 Finally, many political scientists share Daniel Drezner’s view that economics has solved the relevance question in being both rigorous and relevant. 60 The logical implication of such a belief is that the rest of social sciences should follow that discipline’s lead in terms of its approach and methodology. This economics envy is based on a misapprehension that academic trends in economics have not also created a relevance problem. For example, a recent review of research at the World Bank by leading academic economists raised questions about how much of the scholarship of bank analysts that was written for publication in academic journals was of any use to the bank.61 Their answer was not much. They blamed intellectual trends in the discipline because it encouraged research that was “too academic, too focused toward the previously existing academic agenda, and too directed towards technical rather than pressing policy issues.”62 Behind this economics envy lies an even deeper inferiority complex visa- vis the natural sciences. Many social scientists believe that the physical sciences have two advantages over the “softer” social sciences: more reliable data and a consensus on how to analyze it. Quantifiable data, in this view, is more persuasive, because it is clearer and less subject to dispute.63 This view of the superiority of the physical over the social sciences is widespread, with many of the former reveling in their preeminence and some of the latter manifesting two classic symptoms of an inferiority complex: resentment or reflexive emulation. Neither of these responses is healthy. It is simply not true that expressing propositions mathematically ensures that they are clearer and more transparent than conveying them in English. Economist Paul Romer admitted that “with enough math, an author can be confident that most readers will never figure out where FWUTV [facts with unknown truth values] is buried. A discussant or referee cannot say that an identification assumption is not credible if they cannot figure out what it is and are too embarrassed to ask.”64 On the latter, one would think that the 2008 Great Recession, in which the misguided belief that quantitative models of the economy could be used to guide investment decisions on the grounds they could reveal “the truth” about what drives the market, would temper confidence that such scientific approaches could ensure effective policy.65 In a much discussed essay in the New York Times Magazine, Princeton economist Paul Krugman concluded that “the economics profession went astray because economists, as a group, mistook beauty, clad in impressive-looking mathematics, for truth.. . . The central cause of the profession’s failure was the desire for an all-encompassing, intellectually elegant approach that also gave economists a chance to show off their mathematical prowess.”66 It is not even clear that natural scientists have been most influential when they have employed their most rigorous and mathematically sophisticated approaches, at least in the national security realm. Indeed, there is more evidence that they have been most influential when they have offered practical solutions to real-world problems. These solutions have often come from scientifically uncertain and incomplete data.67 These are the hallmarks of much of the best of qualitative social science. Social scientists also ought to take heart that they not only can make an important contribution using their own distinct approaches, but also that in some instances they might even be superior to those of the physical scientists. For example, many of the nuclear scientists involved in the Manhattan Project soon came to regret their role in the escalating nuclear arms race of the Cold War. Reflecting a collective sense of guilt, chemist and peace activist Linus Pauling got almost nine thousand scientists to sign a January 1958 petition to end nuclear testing as first step toward universal disarmament.68 Talcing an equally impractical tack, Hungarian physicist Leo Szilard wrote to Franldin Delano Roosevelt’s science adviser Vannevar Bush in January 1944, “This weapon is so powerful that there can be no peace if it is simultaneously in the possession of any two powers unless these two powers are bound by an indissoluble political union.”69 While not all of the atomic scientists harbored doubts—recall the famous debates between Robert Oppenheimer and Edward Teller—the majority became advocates of international control of nuclear weapons, a policy that in retrospect was politically unrealistic. In comparing the assessments and policy recommendations of the physical scientists in the Golden Age, with those of social scientists like Jacob Viner, Bernard Brodie, and William T. R Fox, it is hard to avoid the conclusion that the latter’s views of the nuclear problem (that the genie of nuclear weapons could not be stuffed back in the bottle), and their recommendations for dealing with that situation (nuclear deterrence), were far more “realistic” than those of the nuclear “one world” physical scientists. What Is to Be Done? There are, of course, some nuts-and-bolts issues that scholars should be mindful of if they want to participate in the broader policy debate. Since policymakers have short attention spans given the number and breadth of issues they have to deal with, scholarly efforts to engage them need to be brief in conveying their ideas.70 This explains why Op/Eds are particularly influential and why so many are optimistic that blogs could play a similar role. Moreover, policymakers find much current scholarly work—from across the methodological spectrum—inaccessible. The common sentiment animating their views is that scholars should cut the jargon. Policymakers don’t want scholars to write in Greek or French, but rather just plain English.71 There are also some much bigger issues undergirding the relevance question.72 To begin with, political science needs to rethink how it balances scholarly rigor with practical application. There is a middle ground between policy analysis and journalism, on one side, and scholastic irrelevance on the other.73 The best approach to balancing scholarly rigor with continuing policy relevance is methodological pluralism, which includes a commitment to using not any particular method (or all of them) but rather just the approach most appropriate for the question at hand. But methodological pluralism, by itself, is not sufficient. The latest trend in political science requiring the simultaneous use of multiple methods could, ironically, prove to be even more limiting of policy relevance. Indeed, given the need to employ all of these methods simultaneously, it is potentially even more constraining in terms of the problems it can address because it has to be limited to those which can be quantified, modeled, and studied in depth at the same time.74 Therefore, reinforcing methodological pluralism must also be a commitment to problem-, rather than method-, driven research agendas. It is only the combination of these two principles that will ensure that policy-relevant security studies can not only survive, but thrive, in political science.75 Scholars also need to think carefully about the role of theory in policyrelevant security studies scholarship. While there is no doubt that theory is important to policymakers, scholars need to be aware that as with many other things, too much of it can be a bad thing. In particular, the effort to cram the rich complexity of the social world into universal models can do intellectual violence to the phenomenon under study as well as produce suboptimal policy. Paul Nitze, then the director of the Secretary of State’s Policy Planning Staff, readily conceded policymakers’ need for theory but also noted that “there is the opposing consideration .. . that [theoretical] oversimplification presents great dangers.”76 Albert Wohlstetter advocated a balanced approach to theory, noting that the key to his success throughout his career “was the practical experience I had in working with engineers. I worked with them from two sides, so to speak, as someone who had been concerned with very abstract theory more basic than that familiar to design engineers, but on the other hand, I was also concerned with production, and therefore generally trying to get them to do things more practical than they wanted to do.”77 Theory is a powerful tool of statecraft, but when scholars embrace universal models they also risk irrelevance or worse. Likewise, the transmission belts conveying scholarly findings to the policy world must be repaired. Kennan envisioned the State Department’s Policy Planning Staff in the late 1940s serving this function, and in some respects it continues to do so to this day.78 However, there are limits to how effectively a part of the bureaucracy can serve as an honest research broker. A plethora of think tanks in Washington are also supposed to translate knowledge into action, though the trend in recent years has been toward the establishment of overtly political and advocacy organizations, rather than nonpartisan, translational research centers.79 Reinventing the role of think tanks as bridges between the Ivory Tower and the beltway is long overdue. While nonacademic transmission belts can mediate between the Ivory Tower and the Beltway, they are no substitute for the scholars who produce knowledge to themselves serve as their own translators of it into policy. To be sure, scholars should not stop writing scholarly books and monographs utilizing the most sophisticated techniques of their discipline, if appropriate. In addition to doing these things, scholars should address pressing real world problems, not just chase after disciplinary fads. No one is in a better position to highlight the policy implications of a given piece of research than the individual who conducted it. Academic social scientists, if they want to be heard by senior policymakers, and heard correctly, need to be their own policy “transmission belts.”80 The role of the Democratic Peace Theory in the recent Iraq war demonstrates the problems with scholars not specifying the concrete policy implications of their research.81 Drawing on DPT, some officials in the George W. Bush administration justified the invasion of Iraq as part of a larger strategy to bring peace to the region by spreading democracy.82 Democratic Peace proponent Bruce Russett objected to this conclusion after the fact though his voice had been largely mute in the run up to the war.83 Had he and other democracy scholars participated more actively in the prewar debate, this rationale may have been less credible. Academics also need to develop a more nuanced appreciation of the various influences on policy. Many, even in democratic political systems, tend to have an unrealistically “technocratic” attitude toward policymaking. 84 They often underestimate the role of politics in government decision making. Scholars must therefore understand that the policymaking process is inherently political and that without such an appreciation of the political considerations associated with any policy choice, even a good one may not be implemented.85

### 1NC—Case

#### Huge alt causes to commodification—massive military spending by the DoD, intense military cultures in schools, arms sales/military aid campaigns, neoliberal institutions—their evidence include commodity fetishization from ALL forms of IP law.

### 1NC – Counterfeiting

#### Patents are key to adequate regulation and testing of drugs -- AFF leads to rampant counterfeiting and unsafe medication, which threatens public health, kills most vulnerable patients, and causes narcotic/human trafficking to surge. Especially true now due to public desperation over COVID, rise in e-commerce, and expansion of substandard medicine manufacturers targeting critical life-saving drugs

IPKey 21 (IP Key – Run by EUIPO and the European Commission to provide news coverage and scientific knowledge concerning intellectual property rights, “Intellectual Property and Keeping Medicines Safe”, https://ipkey.eu/en/south-east-asia/news/intellectual-property-and-keeping-medicines-safe, 2 February 2021, EmmieeM)

If you are what you eat, and bad diets lead to bad health, imagine what unsafe medicines can do.

We ask today, why the provenance of vaccines has attracted so much attention when the origin of medicines we take, in some cases, every day and without even thinking, is not questioned at all? How do we know we can trust medicines readily available on the market from seemingly legitimate sources? Where does intellectual property (IP) come into all of this and why is a proper IP application and registration process important?

The global race to develop vaccines to fight the spread of COVID-19 has understandably captured the attention of the public worldwide. People of all generations and with little or no expertise in clinical trials have followed the process keenly, wishing and willing together that science can provide the answer to stopping the pandemic so what was called ‘normal’ life can return. This public interest has also rightly scrutinised the testing that is designed to make sure that these vaccines are safe and this same focus is thankfully putting medicines under the spotlight more broadly.

When we talk about medicines, they are universally understood to mean a drug or other preparation for the treatment or prevention of a disease or illness. In essence, they serve to keep us feeling healthy, or make us feel better. But what about when they achieve the exact opposite, when they are in fact harmful, or even fatal? The cause is usually because of fake and counterfeit medicines. This is because something they both have in common is the lack of rigorous inspections by public authorities that seek to guarantee the safety of medicines for widespread use.

What’s more, the proliferation of both kinds of these illegal medicines is worsened by a critical fact. Previously, they used to mainly be related to ‘lifestyle’ medicines, but now, even innovative or critical life-saving medicines, such as medicines that tackle cardiovascular diseases, are being increasingly created and are entering the market without official IP application and registration processes.

But if they are both illegal and both cause harm, what’s the difference between fake and counterfeit medicines? Fake medicines pass themselves off as real, authorised medicines but they may actually contain ingredients that are of low quality or in the wrong dosage. Since they have not passed through the necessary evaluation of quality, safety and efficacy as required by authorisation procedures, they can be a major health threat. Counterfeit medicines, in contrast, are those medicines that do not comply with intellectual and industrial property rights, such as registered trade marks or patent rights. But it is important to stress, this is not just an IP issue. In the vast majority of cases (90%) they can also be harmful to a patient’s health, according to a study recently released by the European Union Intellectual Property Office (EUIPO) and the Organisation for Economic Cooperation and Development (OECD) on ‘Trade in Counterfeit Pharmaceutical Products’. The World Health Organization (WHO) also shared in the 2017 report, ‘WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products’, that the estimated number of children who may die from pneumonia each year after consuming counterfeit medicines is between 72 000 and 169 000.

But counterfeit medicines are not just a public health concern. Innovation and creativity are the cornerstones of modern economies and counterfeit medicines siphon off revenue that should justly have been earned by the rightful owners of the medicines that counterfeit medicines seek to imitate. Not just legal pharmaceutical companies are hurt. The public lose out on better and more effective medicines because less revenue can be dedicated to further research and development.

Worryingly, experience shows that these products are finding their way into the legal supply chains more easily than ever, meaning the sale of counterfeit medicines is not limited to illegal trading channels, such as illegal retailers or online sales. Instead, innocent consumers and desperate patients with life-threatening conditions can unwittingly purchase them and be completely ignorant of the potentially harmful side effects.

But the problem does not stop there, either. As highlighted by the United Nations Office on Drugs and Crime report, organised crime is often behind the production of counterfeit medicines, meaning their profits can be used to fuel other illicit trades of, for example, narcotics or even human trafficking practices that help perpetuate more violent crimes, including kidnappings and extortion.

This process has been aided in part by the boom in e-commerce. Technological advancements and the growing tendency to buy online, especially during the pandemic, have made regulation more difficult and helped increase the prevalence of counterfeit goods. These conditions create the perfect environment for non-regulated sellers and, rather than big shipments, the European Commission’s report on the EU customs enforcement of intellectual property rights indicates that courier and postal traffic accounted for 84% of all detentions of counterfeit goods generally in the EU.

But citizens can play a part in combating counterfeit medicines. Basic steps such as checking the origin of products or looking for stamps of authorities help, as does greater awareness of their existence. We must come together to fight them because counterfeit medicines have existed in the market now for a long time, and without sufficient awareness, consumption of these substances can lead to unexpected symptoms, permanent disabilities, and even loss of life.