# 1NC

### 1

#### Interpretation: “medicines” is a generic bare plural. The aff may not defend WTO member nations reducing intellectual property protections for a subset of medicines.

#### The upward entailment test and adverb test determine the genericity of a bare plural

Leslie and Lerner 16 [Sarah-Jane Leslie, Ph.D., Princeton, 2007. Dean of the Graduate School and Class of 1943 Professor of Philosophy. Served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. Adam Lerner, PhD Philosophy, Postgraduate Research Associate, Princeton 2018. From 2018, Assistant Professor/Faculty Fellow in the Center for Bioethics at New York University. Member of the [Princeton Social Neuroscience Lab](http://psnlab.princeton.edu/).] “Generic Generalizations.” Stanford Encyclopedia of Philosophy. April 24, 2016. <https://plato.stanford.edu/entries/generics/> TG

1. Generics and Logical Form

In English, generics can be expressed using a variety of syntactic forms: bare plurals (e.g., “tigers are striped”), indefinite singulars (e.g., “a tiger is striped”), and definite singulars (“the tiger is striped”). However, none of these syntactic forms is dedicated to expressing generic claims; each can also be used to express existential and/or specific claims. Further, some generics express what appear to be generalizations over individuals (e.g., “tigers are striped”), while others appear to predicate properties directly of the kind (e.g., “dodos are extinct”). These facts and others give rise to a number of questions concerning the logical forms of generic statements.

1.1 Isolating the Generic Interpretation

Consider the following pairs of sentences:

(1)a.Tigers are striped.

b.Tigers are on the front lawn.

(2)a.A tiger is striped.

b.A tiger is on the front lawn.

(3)a.The tiger is striped.

b.The tiger is on the front lawn.

The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers: a group of tigers in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), some individual tiger in ([2b](https://plato.stanford.edu/entries/generics/#ex2b)), and some unique salient or familiar tiger in ([3b](https://plato.stanford.edu/entries/generics/#ex3b))—a beloved pet, perhaps. In the first sentences, however, we are saying something general. There is/are no particular tiger or tigers that we are talking about.

The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

There are some tests that are helpful in distinguishing these two readings. For example, the existential interpretation is upward entailing, meaning that the statement will always remain true if we replace the subject term with a more inclusive term. Consider our examples above. In ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), we can replace “tiger” with “animal” salva veritate, but in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) we cannot. If “tigers are on the lawn” is true, then “animals are on the lawn” must be true. However, “tigers are striped” is true, yet “animals are striped” is false. ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) does not entail that animals are striped, but ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) entails that animals are on the front lawn (Lawler 1973; Laca 1990; Krifka et al. 1995).

Another test concerns whether we can insert an adverb of quantification with minimal change of meaning (Krifka et al. 1995). For example, inserting “usually” in the sentences in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) (e.g., “tigers are usually striped”) produces only a small change in meaning, while inserting “usually” in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) dramatically alters the meaning of the sentence (e.g., “tigers are usually on the front lawn”). (For generics such as “mosquitoes carry malaria”, the adverb “sometimes” is perhaps better used than “usually” to mark off the generic reading.)

#### It applies to “medicines” – 1] upward entailment test – “reduce intellectual property protections for medicines” doesn’t entail reducing protections for aids, because it doesn’t prove that we should derestrict other beneficial tech

#### **Violation – they only defend medicines used for women’s health**

#### Vote neg:

#### 1] Limits – you can pick anything from COVID vaccines to HIV/AIDS to random biotech to insulin treatments and there’s no universal disad since each one has a different function and implication for health, tech, and relations – explodes neg prep and leads to random medicine of the week affs which makes cutting stable neg links impossible. Limits key to reciprocal engagement since they create a caselist for neg prep.

#### 2] TVA – read the aff as an advantage to a whole rez aff. Also proves no drop out

#### No RVIs – a) illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance, b) norming – I can’t concede the counterinterp if I realize I’m wrong which forces me to argue for bad norms

#### Precision o/w – anything else justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

### 3

#### CP: The member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over whether to reduce intellectual property protections for women’s health. Member nations should support the proposal and adopt the results of consultation.

Solves the aff –

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation boosts strong leadership, authority, and cohesion among member states – key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

#### Ought means should

Merriam Webster n.d. – Merriam Webster’s Learner’s Dictionary, “ought”, <http://www.learnersdictionary.com/definition/ought>  
ought /ˈɑːt/ verb  
Learner's definition of OUGHT [modal verb] 1 ◊ Ought is almost always followed by to and the infinitive form of a verb. The phrase ought to has the same meaning as should and is used in the same ways, but it is less common and somewhat more formal. The negative forms ought not and oughtn't are often used without a following to. — used to indicate what is expected They ought to be here by now. You ought to be able to read this book. There ought to be a gas station on the way. 2 — used to say or suggest what should be done You ought to get some rest. That leak ought to be fixed. You ought to do your homework.

#### Should means must and is immediate

Summers 94 (Justice – Oklahoma Supreme Court, “Kelsey v. Dollarsaver Food Warehouse of Durant”, 1994 OK 123, 11-8, http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13)

¶4 The legal question to be resolved by the court is whether the word "should"[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13) in the May 18 order connotes futurity or may be deemed a ruling in praesenti.[14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn14) The answer to this query is not to be divined from rules of grammar;[15](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn15) it must be governed by the age-old practice culture of legal professionals and its immemorial language usage. To determine if the omission (from the critical May 18 entry) of the turgid phrase, "and the same hereby is", (1) makes it an in futuro ruling - i.e., an expression of what the judge will or would do at a later stage - or (2) constitutes an in in praesenti resolution of a disputed law issue, the trial judge's intent must be garnered from the four corners of the entire record.[16](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn16) [CONTINUES – TO FOOTNOTE] [13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn13) "*Should*" not only is used as a "present indicative" synonymous with *ought* but also is the past tense of "shall" with various shades of meaning not always easy to analyze. See 57 C.J. Shall § 9, Judgments § 121 (1932). O. JESPERSEN, GROWTH AND STRUCTURE OF THE ENGLISH LANGUAGE (1984); St. Louis & S.F.R. Co. v. Brown, 45 Okl. 143, 144 P. 1075, 1080-81 (1914). For a more detailed explanation, see the Partridge quotation infra note 15. Certain contexts mandate a construction of the term "should" as more than merely indicating preference or desirability. Brown, supra at 1080-81 (jury instructions stating that jurors "should" reduce the amount of damages in proportion to the amount of contributory negligence of the plaintiff was held to imply an *obligation* *and to be more than advisory*); Carrigan v. California Horse Racing Board, 60 Wash. App. 79, [802 P.2d 813](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=802&box2=P.2D&box3=813) (1990) (one of the Rules of Appellate Procedure requiring that a party "should devote a section of the brief to the request for the fee or expenses" was interpreted to mean that a party is under an *obligation* to include the requested segment); State v. Rack, 318 S.W.2d 211, 215 (Mo. 1958) ("should" would mean the same as "shall" or "must" when used in an instruction to the jury which tells the triers they "should disregard false testimony"). [14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn14) In praesenti means literally "at the present time." BLACK'S LAW DICTIONARY 792 (6th Ed. 1990). In legal parlance the phrase denotes that which in law is presently or immediately effective, as opposed to something that will or would become effective in the future *[in futurol*]. See Van Wyck v. Knevals, [106 U.S. 360](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=106&box2=U.S.&box3=360), 365, 1 S.Ct. 336, 337, 27 L.Ed. 201 (1882).

#### 1AR theory is skewed towards the aff – a) the 2NR must cover substance and over-cover theory, since they get the collapse and persuasive spin advantage of the 3min 2AR, b) their responses to my counter interp will be new, which means 1AR theory necessitates intervention. Implications – a) reject 1AR theory since it can’t be a legitimate check for abuse, b) drop the arg to minimize the chance the round is decided unfairly, c) use reasonability with a bar of defense or the aff always wins since the 2AR can line by line the whole 2NR without winning real abuse

### 4

#### CP: The member nations of the World Trade Organization should

#### reduce intellectual property protections for non-orphan drug women’s health.

#### should organize an international effort to purchase women’s health medicines and distribute it equitably at no cost on a needs basis by declaring it a human right.

#### Only exclusive patent protection rights paired with incentives can rare diseases that won’t be treated under natural market incentives.

Henry Grabowski 2, Patents, Innovation and Access to New Pharmaceuticals, *Journal of International Economic Law*, Volume 5, Issue 4, December 2002, Pages 849–860, <https://doi.org/10.1093/jiel/5.4.849>

* defined in a subsequent law as diseases or medical conditions which affect fewer than 200,000 patients

In 1983, Congress passed the Orphan Drug Act, which provided a variety of incentives to undertake R&D on orphan drug indications (defined in a subsequent law as diseases or medical conditions which affect fewer than 200,000 patients).37 The economic incentives included in the Act involved R&D tax credits, a clinical research grants programme, accelerated reviews at the FDA, and a guaranteed market exclusivity period of 7 years from the date of FDA approval (this was separate from any normal patent protection that might also apply to these products). Funding for R&D has also been provided by various non-profit foundations focused on particular rare illnesses. The effect of these incentives on the development of new orphan drugs has been impressive. In the period between 1983 and 1999, more than 200 drugs and biologicals for rare diseases have been introduced.38 This represents more than a 12-fold annual increase compared to the decade prior to the enactment of the law, when fewer than 10 such products came to the market for the entire 10-year period. In a recent paper, Professor Frank Lichtenberg has shown that the Act has had a favourable effect on mortality from rare illnesses. While the number of deaths from rare diseases had been increasing faster than those from other diseases in the 5-year period prior to 1983, the number of deaths from rare diseases declined, both in absolute terms and relative to other deaths, in the post-1983 period.39 To attack the ‘orphan disease’ problem confronting third world countries for diseases like malaria and leprosy, one needs an international counterpart to the US Orphan Drug Act. From a scientific standpoint, it is an auspicious time to proceed with such a programme, given the recent advances in genom- ics which enhance the possibility of developing significant new vaccines and therapies for infectious diseases prevalent in less affluent countries. As in the case of the Orphan Drug Act, a multifaceted approach is necessary including R&D subsidies to firms with promising new technologies. These could be funded through government as well as non-profit charitable entities and public-private partnerships. Given the low-income base of third world mar- kets, success of these programmes might well hinge upon guarantees to pur- chase amounts of economically sustainable products that are successfully developed. The purchase agreements could be tied to up-front commitments from the firms on the product’s price within third-world markets. Michael Kremer has characterized R&D incentive programmes based on purchase guarantees as ‘pull’ programmes and analyzed how they could be designed in the context of new vaccines for third-world diseases.40 A variety of risk- and reward-sharing arrangements between pharmaceutical firms and funding sponsors could be envisioned. The objectives would be to provide incentives for new R&D programmes for diseases in developing countries. For example, under the Gates Foundation-sponsored International AIDS Vaccine Initiative (IAVI), firms have received grants to partially sup- port development of AIDS vaccines targeted to African strains of the disease. The firms retain international patent rights to the technology, but have agreed to supply any approved vaccines developed from this programme at a small margin over cost to developing countries. Such terms can be particularly attractive to earlier stage biotech firms seeking funding for proof of principle for a new technology with multiple applications. Similarly, the Global Alli- ance for TB Drug Development has recently announced a memorandum of understanding with Chiron for the development of a new TB drug for which no royalties would be due on sales in less-developed countries.41 In summary, the success of the US Orphan Drug Act in stimulating R&D investment and innovation for diseases with low expected market potential provides a useful model for the orphan disease problem confronting less indus- trialized countries. While the characteristics of particular programmes may differ significantly from those employed in the case of the US Orphan Drug Act, the basic principle of public and private risk sharing within the context of a system of market incentives would appear to be a fruitful guiding principle.

#### It competes - LPCN 1107 or PTB is a designated orphan drug engineered to reduce pain and prevent preterm birth in women with a history of preterm birth – generates offense under the aff’s framing.

Lipocine 15 Lipocine Investor Room, 6-2-2015, "Lipocine Receives FDA Orphan Drug Designation for LPCN 1107, an Oral Product Candidate for the Prevention of Preterm Birth," <https://ir.lipocine.com/Lipocine-Receives-FDA-Orphan-Drug-Designation-for-LPCN-1107-an-Oral-Product-Candidate-for-the-Prevention-of-Preterm-Birth> mvp

SALT LAKE CITY, June 2, 2015 (GLOBE NEWSWIRE) -- [Lipocine Inc.](http://www.globenewswire.com/newsroom/ctr?d=10137027&l=1&a=Lipocine%20Inc.&u=http%3A%2F%2Fwww.lipocine.com%2F) (Nasdaq:LPCN), a specialty pharmaceutical company, today announced the U.S. Food and Drug Administration ("FDA") has granted orphan drug designation to LPCN 1107, the company's oral hydroxyprogesterone caproate ("HPC") product candidate, a potential treatment for the prevention of preterm birth ("PTB"). There are approximately 180,000 pregnancies annually in the United States in women with a prior history of at least one preterm birth.  Lipocine previously announced positive Phase 1b top-line results with LPCN 1107 in pregnant women.

"We are pleased to receive orphan designation for LPCN 1107, as PTB represents a significant unmet medical need and we believe that LPCN 1107 has the potential to be the first oral product of the only approved drug for this significant opportunity," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine Inc. "We expect to announce our clinical development plan for the program in the near future."

The orphan drug designation is based on a plausible hypothesis that LPCN 1107 may be clinically superior to the same drug that is already approved for the same orphan indication. In order to obtain orphan drug exclusivity upon approval, LPCN 1107 will need to demonstrate that it is clinically superior to this already approved drug.

The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.

Orphan designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing. A marketing application for a prescription drug product that has received orphan designation is not subject to a prescription drug user fee unless the application includes an indication for other than the rare disease or condition for which the drug was designated.

About LPCN 1107

LPCN 1107 has the potential to become the first oral HPC product for the prevention of preterm birth in women with a prior history of at least one preterm birth. Potential benefits of our oral product candidate relative to current injectable products include the elimination of pain and site reactions associated with weekly injections, elimination of weekly doctor visits or visits from the nurse, and elimination of interference/disruption of personal, family or professional activities associated with weekly visits.

#### Solves the aff – their solvency advocate is super vague and just says access needs to increase.

**1AC Mike 2**: Mike, Jennifer H. [School of Law, American University of Nigeria, Yola, Nigeria, Nigeria] “Access to essential medicines to guarantee women's rights to health: The pharmaceutical patents connection” *Wiley Online Library,* 2020. <https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12161> JP

The sum total of the arguments and analysis indicates that human rights relate to health and that access to medicines is germane to the enjoyment of the right to health as well as the right to life. **In this manner, human rights provide the basis to argue for the alleviation of problems inhibiting women's access to healthcare**. This rights approach to the issue of accessing medicine is relevant because it provides a guiding standard for national policies, laws and programmes to achieve the goal of fulfilling, protecting, respecting and generally securing their right to health. **To secure women's right to health and ensure that they can fully enjoy their human rights, it is submitted that there is a need to promote their access to affordable medicines. The article highlighted the concern that the patent protection of pharmaceuticals could result in high prices or stifle incremental innovation which could have the effect of impeding the availability of and women's access to affordable drugs for serious medical needs. In this event, one of the ways in which the state can meet its obligation, as to the right to health is to make sure that pharmaceutical patents do not constitute an obstruction to the enjoyment of the rights of women to adequate healthcare.** The foregoing discussion also argued that pharmaceutical companies and patent owners can have a human right to health responsibility within the sphere of their business operations. This responsibility would pertain to the pricing of their drugs, testing and clinical trials, R&D, provision of safe and good quality medicines and the duty to ensure that their practices do not constitute an obstacle, especially to women's enjoyment of human rights and their right to medicines. Notwithstanding the obligations of pharmaceutical companies to the right to access medicines, states are ultimately the duty bearers accountable for the guarantees, and prevention of the violations of the rights to access medicines. It is their duty to monitor and also ensure that pharmaceutical firms do not impede the enjoyment of the right to health. In closing, the argument based on human rights principles is a consideration of women's health needs in regulations and policies to fulfil their demands of healthcare. **Ultimately, if women's access to medicines is to be enhanced, the state must provide medicines and also guarantee the sustainable availability and accessibility of drugs through every avenue.**

### 5

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

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

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

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

What about SPACs?

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

Fundamentals continue strong

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

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

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

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

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

More innovation on the horizon

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

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

#### Even small exceptions that contravene TRIPS spill over by creating anti-IP precedent and momentum.

Balasubramanyam 14 “Battles Over Patents: Is India Changing The Rules Of The Game?” 02/18/2014 Ranjitha Balasubramanyam [Germany-based journalist and humanitarian researcher with over two decades of journalistic experience, working mainly for European broadcasters] <https://www.ip-watch.org/2014/02/18/battles-over-patents-is-india-changing-the-rules-of-the-game/> SM

While admitting that the impact would be “marginal,” Bayer said in a written response to Intellectual Property Watch that it was the prospect of a “spillover” they are worried about and that spillovers “are a general threat for the whole industry.” “Economically, there is no massive impact so far but this could change if more products are involved,” Bayer said, adding that if countries like India are regarded as a “role model” for other countries, “IP protection could be diluted in several jurisdictions.” That may well prove a watershed moment and therefore cause for serious concern for the big research-based pharmaceutical companies. The trend toward reform is already evident by moves in South Africa to overhaul the country’s patent laws in an attempt to address concerns over the cost of drugs. Moreover, middle income states like India, China, South Africa and Brazil have the potential to evolve into highly profitable markets for big pharmaceutical concerns, as the market continues to grow in those countries. Given the prospect for future revenues, Malpani said: “The companies are concerned about the precedent this is setting where in the long term they want to prevent these countries from using these measures to protect public health.”

#### A thriving and innovating biopharmaceutical sector is key to prevent future pandemics and bioterror.

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

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

#### Bioterror coming now and causes extinction – the tech exists and overcomes their impact defense

**Millett & Snyder-Beattie ‘17** [(Piers Millett: Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford. Andrew Snyder-Beattie: M.S., Director of Research, Future of Humanity Institute, University of Oxford.) " Existential Risk and Cost-Effective Biosecurity," Health Security, 15(4), 08-01-2017, https://www.liebertpub.com/doi/full/10.1089/hs.2017.0028] TDI

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

### Case

#### Framework – the role of the ballot is to determine whether the plan is a good idea through evaluation of consequences.

#### 1] Don’t let them weigh the sum total of their impact—they only get to weigh the unique amount solved by the affirmative. Filter the debate through scope of solvency—there’s no impact to root cause if they don’t solve it

#### 2] No performative or methodological offense, only offense from the plan—reject it cuz it explodes predictable limits, spiking out of neg ground making any discussion qualitatively worse

#### 3] Our impacts matter

#### A] Focus on large scale catastrophes is good and they outweigh – appeals to social costs, moral rules, and securitization play into cognitive biases and flawed risk calculus – 2020 is living proof

Weber 20 (ELKE U. WEBER is Gerhard R. Andlinger Professor in Energy and the Environment and Professor of Psychology and Public Affairs at Princeton University.), November-December 2020 Issue, "Heads in the Sand," Foreign Affairs, <https://www.foreignaffairs.com/articles/2020-10-13/heads-sand> mvp

We are living in a time of crisis. From the immediate challenge of the COVID-19 pandemic to the looming existential threat of climate change, the world is grappling with massive global dangers—to say nothing of countless problems within countries, such as inequality, cyberattacks, unemployment, systemic racism, and obesity. In any given crisis, the right response is often clear. Wear a mask and keep away from other people. Burn less fossil fuel. Redistribute income. Protect digital infrastructure. The answers are out there. What’s lacking are governments that can translate them into actual policy. As a result, the crises continue. The death toll from the pandemic skyrockets, and the world makes dangerously slow progress on climate change, and so on.

It’s no secret how governments should react in times of crisis. First, they need to be nimble. Nimble means moving quickly, because problems often grow at exponential rates: a contagious virus, for example, or greenhouse gas emissions. That makes early action crucial and procrastination disastrous. Nimble also means adaptive. Policymakers need to continuously adjust their responses to crises as they learn from their own experience and from the work of scientists. Second, governments need to act wisely. That means incorporating the full range of scientific knowledge available about the problem at hand. It means embracing uncertainty, rather than willfully ignoring it. And it means thinking in terms of a long time horizon, rather than merely until the next election. But so often, policymakers are anything but nimble and wise. They are slow, inflexible, uninformed, overconfident, and myopic.

Why is everyone doing so badly? Part of the explanation lies in the inherent qualities of crises. Crises typically require navigating between risks. In the COVID-19 pandemic, policymakers want to save lives and jobs. With climate change, they seek a balance between avoiding extreme weather and allowing economic growth. Such tradeoffs are hard as it is, and they are further complicated by the fact that costs and benefits are not evenly distributed among stakeholders, making conflict a seemingly unavoidable part of any policy choice. Vested interests attempt to forestall needed action, using their money to influence decision-makers and the media. To make matters worse, policymakers must pay sustained attention to multiple issues and multiple constituencies over time. They must accept large amounts of uncertainty. Often, then, the easiest response is to stick with the status quo. But that can be a singularly dangerous response to many new hazards. After all, with the pandemic, business as usual would mean no social distancing. With climate change, it would mean continuing to burn fossil fuels.

But the explanation for humanity’s woeful response to crises goes beyond politics and incentives. To truly understand the failure to act, one must turn to human psychology. It is there that one can grasp the full impediments to proper decision-making—the cognitive biases, emotional reactions, and suboptimal shortcuts that hold policymakers back—and the tools to overcome them.

AVOIDING THE UNCOMFORTABLE

People are singularly bad at predicting and preparing for catastrophes. Many of these events are “black swans,” rare and unpredictable occurrences that most people find difficult to imagine, seemingly falling into the realm of science fiction. Others are “gray rhinos,” large and not uncommon threats that are still neglected until they stare you in the face (such as a coronavirus outbreak). Then there are “invisible gorillas,” threats in full view that should be noticed but aren’t—so named for a psychological experiment in which subjects watching a clip of a basketball game were so fixated on the players that they missed a person in a gorilla costume walking through the frame. Even professional forecasters, including security analysts, have a poor track record when it comes to accurately anticipating events. The COVID-19 crisis, in which a dystopic science-fiction narrative came to life and took everyone by surprise, serves as a cautionary tale about humans’ inability to foresee important events.

Not only do humans fail to anticipate crises; they also fail to respond rationally to them. At best, people display “bounded rationality,” the idea that instead of carefully considering their options and making perfectly rational decisions that optimize their preferences, humans in the real world act quickly and imperfectly, limited as they are by time and cognitive capacity. Add in the stress generated by crises, and their performance gets even worse.

Because humans don’t have enough time, information, or processing power to deliberate rationally, they have evolved easier ways of making decisions. They rely on their emotions, which serve as an early warning system of sorts: alerting people that they are in a positive context that can be explored and exploited or in a negative context where fight or flight is the appropriate response. They also rely on rules. To simplify decision-making, they might follow standard operating procedures or abide by some sort of moral code. They might decide to imitate the action taken by other people whom they trust or admire. They might follow what they perceive to be widespread norms. Out of habit, they might continue to do what they have been doing unless there is overwhelming evidence against it.

Not only do humans fail to anticipate crises; they also fail to respond rationally to them.

Humans evolved these shortcuts because they require little effort and work well in a broad range of situations. Without access to a real-time map of prey in different hunting grounds, for example, a prehistoric hunter might have resorted to a simple rule of thumb: look for animals where his fellow tribesmen found them yesterday. But in times of crisis, emotions and rules are not always helpful drivers of decision-making. High stakes, uncertainty, tradeoffs, and conflict—all elicit negative emotions, which can impede wise responses. Uncertainty is scary, as it signals an inability to predict what will happen, and what cannot be predicted might be deadly. The vast majority of people are already risk averse under normal circumstances. Under stress, they become even more so, and they retreat to the familiar comfort of the status quo. From gun laws to fossil fuel subsidies, once a piece of legislation is in place, it is hard to dislodge it, even when cost-benefit analysis argues for change.

#### B] We access their role of the ballot—extinction by any process would cause massive suffering and obviously affects women. Proves even if they win their framing, extinction is still a tiebreaker – we’re not abstraction/inconsistent w their framing if we win our scenario

#### C] Anything other than probability \* magnitude is arbitrary and ethically irresponsible because it would justify a 100% chance of resolving a small amount of current suffering outweighs a 99% chance of preventing extinction, which is ethically disastrous and proves magnitude has to matter