Negative case 1

I affirm the res

Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

Definitions for today's debate are

- Member nations: Any nations involved or in the World Trade organization, defined by wto.org
- World trade organization: The **World Trade Organization** (**WTO**) is the only global international organization dealing with the rules of trade between nations, defined by wto.org
- Ought: obligation, oxford
- Intellectual property protections: Intellectual Property Protection is **protection for inventions, literary and artistic works, symbols, names, and images created by the mind**. definition.com

b) aff quality—plan text disclosure discourages cheap shot affs. If the aff isn't inherent or easily defeated by 20 minutes of research, it should lose—this will answer the 1ar's claim about innovation—with 30 minutes of prep, there's still an incentive to find a new strategic, well justified aff, but no incentive to cut a horrible, incoherent aff that the neg can't check against the broader literature.

Schwartz "A Defense of Naïve Empiricism: It is Neither Self-Refuting Nor Dogmatic." Stephen P. Schwartz. Ithaca College. pp.1-14.

The empirical support for the fundamental principle of empiricism is diffuse but salient. Our common empirical *experience and* experimental *psychology offer evidence that humans do not have any capacity to garner knowledge except by empirical sources*. The fact is that we believe that *there is no source of knowledge*, information, or evidence *apart from observation*, empirical scientific investigations, and our sensory experience of the world, and we believe this on the basis of our empirical a posteriori experiences and our general empirical view of how things work. For example, we believe on empirical evidence that *humans are continuous with the rest of nature and* that *we rely* like other animals *on our senses to tell us how things are.* If humans are more successful than

other animals, it is not because we possess special non-experiential ways of knowing, but because we are better at cooperating, collating, and inferring. In particular *we do not have any capacity for substantive a priori knowledge. There is no known mechanism by which such knowledge would be made possible.* This is an empirical claim.

Biotech disad

Biotech DA

Medicinal Biotech investment high now

PwC 15 (PwC Research & Analysis, company that provides industry-focused assurance, tax, and advisory servicesBiotech holds strong amid record high investments, 2015, https://www.pwc.com/us/en/health-industries/publications/assets/lifesciencesmoneytreeq32015.pdf)
Life sciences venture capital investment The $2.9 billion investments in life sciences during the third quarter of 2015 was the highest investment in the sector since the start of the MoneyTree data series in 1995. The life sciences share of total venture funding increased from 17% during the second quarter of 2015, to 18% during the third quarter of 2015. The **Biotech**nology industry received the second largest amount of venture capital in the third quarter of 2015, with $2.1 billion going into 121 deals, an increase of 77% in deal value and 1% in deal volume, compared with the third quarter of 2014. The medical device industry also increased by 30% in terms of value, but deal volume declined by 12% for the third quarter of 2015, compared with the same quarter last year, capturing $821 million in 73 deals. We're on track for one of our largest biotech years we have had in quite a long time," said Greg Vlahos, Life Sciences Partner at PWC. Life sciences investment jumped to $2.9 billion in the third quarter of 2015, compared with the third quarter of 2014, during which $1.8 billion was invested. On a year-over-year basis, both biotechnology and medical devices investments jumped by 77% and 30% respectively in terms of value. When compared with the second quarter of 2015, funding declined by 0.5% for biotechnology, but increased 3% for medical devices. "The third quarter of 2015 shows there is continued interest in biotechnology and medical devices," said Vlahos. "With the strong exit markets for biotechnology set up for renewed interest in life sciences."

Patent Protections are independently key sustainability of biotech industry – aff collapses biotech investment

Gregory 18 – Adam Gregory, Associate Patent Attorney at Mewburn Ellis LLP, November 26th ("The Importance Of Patents To Biotech Start-Ups," Biotech Connection Singapore, Available online at https://www.biotechconnection-sg.org/the-importance-of-patents-to-biotech-start-ups/, Accessed 9-11-2020) LR
Why do patents matter to biotech start-ups? Early-stage biotech companies are often founded based on the exciting results of pre-clinical research relating to a new product or treatment. However, due to the need for refinement/development, as well as the extensive work required to demonstrate safety and efficacy in order to obtain regulatory approval, early-stage biotech companies are often a long way away from bringing a new drug or therapy to market. Unlike in many industries where a new company will have a product/service that can be readily commercialised to generate revenue, early stage biotech companies often find that they have a concept for a new product/treatment that could ultimately generate billions of dollars in sales annually, but have no obvious way to commercialise or finance the technology in the short-term. This problem is compounded by the very large amount of capital required to advance a new drug or therapy from the pre-clinical stage to treating patients in the clinic. The Tufts Center for the Study of Drug Development (CSDD) estimates that it now costs more than USD 2.5 billion to bring a new drug to market. The ability to attract investment is therefore critical for an early stage biotech company to thrive. In the absence of a tangible product, would-be investors will look at the potential futurecommercial revenue if the product or treatment makes it to market. The decision of whether or not to invest, and the scale of any investment, is based on how well the technologies that form the core of a company have been protected. This is where patents come in. As the actual and potential scope of commercial exclusivity is the basis for the value

proposition, investors look very closely at patent portfolios. Essentially, potential investors ask 'what can this company do that no other company can do without their permission?' Any serious investor will usually undertake thorough due diligence of the patent portfolio, looking not only the granted patents, but also at the pending patent applications, to understand what protection the companyalready has, and what they are seeking protection for. Patents can also be useful for generating revenue in the short-term. Patents and patent applications can be sold, or licensed to other parties that wish to use the invention. Licensing agreements can also form the basis of collaborations with other companies or research institutions, which can in turn lead to improvements to the technology. Having patent protection, or the opportunity to obtain patent protection, covering the core technology of the company, and being able to present a plan for generating future IP, can be key to the success of a biotech start-up.

Biotech innovation key to stop disease – turns all aff offense

Guilford-Blake 08 [(Roxanna Guilford-Blake is an award-winning writer with 20+ years' experience. Expertise in health, biotech, value-based care & more) "Preparedness for Pandemics and Biodefense" Biotechnology Innovation Organization, 2008] TDI

In the wake of the September 11 terrorist attacks, BIO surveyed the industry and found that many biotech companies were already working on defense projects or developing technologies useful for both conventional health care and for defense against biological, chemical and radiological/nuclear agents. Biotechnology companies are also developing novel approaches to prepare for a pandemic, including the development of new vaccines, antivirals and diagnostic and detection tools. Policy BIO has a long-standing policy of opposing the use of biotechnology to develop weapons of any sort that contain pathogens or toxins aimed at killing or injuring humans, crops or livestock. Appropriate uses of biotechnology include products and services to inoculate citizens against infectious agents that may be used in an attack, to detect biological, chemical or radiological/nuclear attacks, and to diagnose and treat those who may have been exposed to such attacks. A Strategic Asset Many U.S. biotechnology companies are actively developing medical countermeasure technologies. Some companies are working on defense-specific technologies under contracts with the federal government. Many more are working on technologies that can be used for conventional health care, pandemics and biological defense, such as antivirals, antibiotics, and diagnostic tools. Recognizing the important value that the biotechnology industry has in developing bioterror countermeasures, President Bush announced in January 2003 the Project BioShield initiative, which would fund new programs at the National Institutes of Health designed to spur countermeasure development. The Project Bioshield Act was signed into law in July 2004 and authorizes $5.6 billion in procurement funding for medical countermeasures against chemical, biological, radiological or nuclear attacks. Similarly, the President approved $3.3 billion in FY 2006 and an additional $2.3 billion in FY 2007 for the Department of Health and Human Services for development and procurement of medical countermeasures against a potential influenza pandemic. Biotechnology companies have products and platforms, including vaccines, therapeutics and diagnostics, that can be enlisted to prepare our nation for man-made and natural emergencies. In addition, drug-delivery technology can make urgently needed medications easier to administer on the battlefield or during a civilian crisis. Medications could even be stored in a soldier's backpack. VACCINES AGAINST WEAPONIZED PATHOGENS Vaccines of varying efficacy and convenience exist for anthrax, smallpox, plague and tularemia, and vaccines are in development for other infectious agents that may be used in biological assaults.The major challenges in vaccine technology are to develop vaccines against a variety of infectious agents (including new strains), to shorten the time needed to establish immunity (some vaccines require multiple boosters to be effective), to be able to produce them in large quantities, improve ease of administration, and make them even safer. Biotechnology companies are working to solve these problems with new vaccines based on improved delivery technologies and discoveries made through genetic research. Examples: Researchers are exploring new vaccine technologies, including vector technology to induce rapid protection. Applications include a third-generation anthrax vaccine. This strategy has the flexibility to address a number of different bioterrorism agents and may elicit a long-lasting immune response after a single oral dose. By manipulating an immunotoxin-hybrid molecule used to kill tumor cells in lymphoma patients, researchers have created a vaccine that has been shown to protect mice against ricin, an extremely potent toxin, without significant side effects. Agricultural biotechnology researchers are working on fruits and vegetables genetically modified to contain vaccines. Such foods could protect large populations in a very short period of time. MONOCLONAL ANTIBODIES Monoclonal antibodies can be used like antibiotics or antivirals, as a way to treat viral and bacterial infections; they can also be used to detect the presence of infectious agents or to clear bacterial toxins from the bloodstream. And, like vaccines, they can confer immunity against biological agents. Example: An antibody combination that attaches to anthrax toxin and clears it from the body is under study. The technology could be applied to other biowarfare threats, such as dengue fever, Ebola and Marburg viruses, and plague. DNA- OR RNA-BASED THERAPEUTICS Researchers are applying genomics and proteomics technologies

to discover weaknesses in viruses and bacteria that can be targeted with a new generation of antibiotics and antivirals. Such weaknesses include proteins or segments of RNA essential to an infectious organism's survival or replication. Projects are under way targeting both. RNAi, or RNA interference, is another exciting technology. RNAi technologies aim to "silence" targeted genes to prevent the manufacture of disease-causing proteins. RNAi could apply to a number of infectious diseases related to national preparedness. In a similar vein, the Defense Advanced Research Projects Agency (DARPA) has funded projects that entail rapid DNA analysis, followed by the rapid synthesis of drugs that can bind, or disable, segments of DNA crucial to an infectious organism's survival. Researchers have completed genome sequences for numerous infectious agents, including the bacteria that cause malaria, stomach ulcers and food poisoning, as well as organisms responsible for hospital-acquired infections, cholera, pneumonia and chlamydia, and for potential biowarfare agents, such as the organism responsible for bubonic plague (Yersinia pestis). BATTLEFIELD EPIDEMICS Under battlefield conditions, soldiers are vulnerable to naturally occurring infections such as influenza. The biotechnology industry is addressing such illnesses with vaccines (including some under development that could be taken orally), antivirals and antibiotics. DETECTION AND DIAGNOSIS As we saw in the anthrax scare of 2001, we need to be able to rapidly determine whether a person has been exposed to an infectious agent, and we also need capabilities for detecting these agents in the environment. Some devices have been developed already for these purposes, and others are in the pipeline.

Also Independently – Biotech industry survival is key to food security

Molly E. Brown 8 [NASA Goddard Space Flight Center Biospheric Sciences Branch] and Christopher C. Funk [University of California – Berkeley], “Food Security Under Climate Change”, NASA Publications, 1 Feb 2008, BE

Climate change impacts on farmers will vary by region, depending on their use of tech- nology. Technological sophistication determines a farm’s productivity far more than its climatic and agricultural endowments. Food insecurity, therefore, is not solely a product of “climatic determinism” and can be addressed by improvements in economic, political, and agricultural policies at local and global scales. In currently food-insecure regions, **farming** is typically conducted manually, using a hoe and planting stick with few inputs. The difference between the productivity of these farms and those using petroleum-based fertilizer and pesticides, biotechnology-enhanced plant varieties, and mechanization is extreme (5). Not only will climate change have a differen- tial effect on ecosystems in the tropics due to their already warmer climates, but also poor farmers in the tropics will be less able to cope with changes in climate because they have far fewer options in their agricultural system to begin with. These handicaps can be exacer- bated by macro-economic policies that create disincentives for agricultural development,¶ such as agricultural subsidies in the United States and Europe and poorly implemented cash transfer programs (6).¶ The study by Lobell et al. suggests that communities can cope with climate change, for example, by switching from producing corn to producing sorghum, whose lower water requirements and higher temperature tolerances are better suited to a warmer and drier climate. However, this adaptation mea- sure may be impossible to implement in many parts of the developing world. For example, it assumes markets for millet in regions where only maize is eaten, and technology and know-how about how to process and consume sorghum in maize zones. Communities may nevertheless be forced, as they are today, to consume what they produce regardless of cul- tural preferences.¶ Today, millions of hungry people subsist on what they produce. If climate change reduced production while populations increase, there is likely to be more hunger. However, it may still be possible to reduce world hunger through programs that feed the poor during crises and by investing in agricultural inputs such as fer- tilizer and improved varieties that can dramati- cally increase yields (2). Improved environ- mental monitoring and prediction systems can provide more effective early warnings, which may help governments to take action to pre- serve the thin agriculture production margins by which many make ends meet (7). Early warning systems involve extensive climate monitoring and prediction tools that could be used to enhance agricultural development pro- grams. Crop insurance programs that are trig- gered by remote sensing data products may ensure farmer’s livelihoods even in drought years. Investments in improved seeds and vari- etals and an augmented use of inorganic fertil- izer (2, 6) can increase yields. Improved local governance, reduced developed-world agricul-¶ tural subsidies, and more nuanced food aid policies that protect local markets could together produce rapid improvements in food access and availability, reducing hunger while providing for more people.

Food insecurity causes extinction

Cribb ‘10 [Julian, principal of JCA, fellow of the Australian Academy of Technological Sciences, “The Coming Famine: The¶ Global Food Crisis and What We Can Do to Avoid It”, pg 10]

The character of human conflict has also changed: since the early 1990S, more wars have been triggered by disputes over food, land, and water than over mere political or ethnic differences. This should not surprise US: people have fought over the means of survival for most of history.But in the abbreviated reports on the nightly media, and

even in the rarefied realms of government policy, the focus is almost invariably on the players—the warring national, ethnic, or religious factions—rather than on the play, the deeper subplots building the tensions that ignite conflict. Caught up in these are groups of ordinary, desperate people fearful that there is no longer sufficient food, land, and water to feed their children—and believing that they must fight 'the others" to secure them. At the same time, the number of refugees in the world doubled, many of them escaping from conflicts and famines precipitated by food and resource shortages. Governments in troubled regions tottered and fell. The coming famine is planetary because it involves both the immediate effects of hunger on directly affected populations in heavily populated regions of the world in the next forty years—and also the impacts of war, government failure, refugee crises, shortages, and food price spikes that will affect all human beings, no matter who they are or where they live. It is an emergency because unless it is solved, billions will experience great hardship, and not only in the poorer regions. Mike Murphy, one of the world's most progressive dairy farmers, with operations in Ireland, New Zealand, and North and South America, succinctly summed it all up: "Global warming gets all the publicity but the real imminent threat to the human race is starvation on a massive scale. Taking a 10—30 year view, I believe that food shortages, famine and huge social unrest are probably the greatest threat the human race has ever faced. I believe future food shortages are a far bigger world threat than global warming."2° The coming famine is also complex, because it is driven not by one or two, or even a half dozen, factors but rather by the confluence of many large and profoundly intractable causes that tend to amplify one another. This means that it cannot easily be remedied by "silver bullets" in the form of technology, subsidies, or single-country policy changes, because of the synergetic character of the things that power it.

Framing

1AC—Base

The standard is maximizing expected well being.

pleasure and pain are intrinsically valuable. People consistently regard pleasure and pain as good reasons for action, despite the fact that pleasure doesn't seem to be instrumentally valuable for anything.

Moen 16 [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo "An Argument for Hedonism" Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI

Let us start by observing, empirically, that **a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues.** This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have.** "Pleasure" and "pain" are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 **The special value statuses of pleasure and**

pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, **I might ask: "What for?" This is a reasonable question, for when you go to the convenience store you usually do so**, not merely for the sake of going to the convenience store, but **for the sake of achieving something further that you deem to be valuable.** You might answer, for example: "To buy soda." This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: "What is buying the soda good for?" This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: "Well, I want it for the pleasure of drinking it." **If I then proceed by asking "But what is the pleasure of drinking the soda good for?" the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.**3 As Aristotle observes**: "We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.**"4 Presumably, a similar story can be told in the case of pains, for if someone says "This is painful!" we never respond by asking: "And why is that a problem?" We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value.**

Moral uncertainty means preventing extinction should be our highest priority.

Bostrom 12 [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. "Existential Risk Prevention as Global Priority." Global Policy (2012)]

These reflections on **moral uncertainty suggest** an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might** well **be confused. We may not** now know — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet **be able to imagine the best ends** of our journey. **If we are** indeed profoundly **uncertain** about our ultimate aims, then we should recognize that **there is a great** option **value in preserving** — and ideally improving — **our ability to recognize value and** to **steer the future accordingly. Ensuring** that **there will be a future** version of **humanity** with great powers and a propensity to use them wisely **is** plausibly **the best way** available to us **to increase the probability that the future will contain** a lot of **value.** To do this, we must prevent any existential catastrophe.

Solvency

Vaccine waiver leads to ineffective vaccines

Crosby et al. 21 Daniel Crosby, Evan Diamond, Isabel Fernandez De La Cuesta, Jamieson Greer, Jeffrey Telep, Brian White; Crosby specializes in international trade, investment and matters related to public international law. Diamond is a partner on our Intellectual Property, Patent, Trademark and Copyright Litigation team.; 3-5-2021; "Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products"; https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/, JD Supra, accessed 7-21-2021

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented "trade secret" information and other critical "know-how," that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products. Under the present **TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are "in relation to prevention, containment or treatment of COVID-19." For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as "personal protective equipment" or components thereof, or in other measures arguably relating to COVID-19 "prevention" or "containment."** *At the same time, it is unclear how the proposed TRIPS waiver could provide the* ***technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences****. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so.*

Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other

Unsafe and ineffective vaccines would fuel vaccine hesitancy – spillover to other vaccines and turns case

Trogen et al 20 Trogen B, Oshinsky D, Caplan A. Adverse Consequences of Rushing a SARS-CoV-2 Vaccine: Implications for Public Trust. JAMA. 2020;323(24):2460–2461. doi:10.1001/jama.2020.8917 Brit Trogen is a pediatrics resident at Bellevue Hospital and NYU Langone in New York. David Oshinsky holds the Jack S. Blanton Chair in History at the University of Texas and is a Distinguished Scholar in Residence at New York University Arthur L. Caplan, is the Drs. William F. and Virginia Connolly Mitty Professor of Bioethics at New York University Langone Medical Center and the founding director of the Division of Medical Ethics.

As the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) pandemic persists across the US and the world, the spotlight on vaccine science has never been more intense. Researchers across the globe are working rapidly to produce a potential vaccine, and 7 candidates are already in clinical trials.[1] Operation Warp Speed, the vaccine development project announced by President Trump, has advocated for a vaccine to be made available in the US by the beginning of 2021.[1] But for scientists and physicians, the term “warp speed” should trigger concern. *Good science requires rigor, discipline, and deliberate caution.* ***Any medical therapy approved for public use in the absence of extensive safeguards has the potential to cause harm, not only for COVID-19 prevention efforts and vaccine recipients, but also for public trust in vaccination efforts worldwide. Long before coronavirus disease 2019 (COVID-19), vaccine hesitancy and refusal were increasing***.[2] In 2019, **the World Health Organization listed vaccine refusal as one of the top 10 global health threats.**[3] Pediatricians, in particular, frequently encounter resistance to childhood vaccinations, and as a result, outbreaks of measles and **other vaccine-preventable illnesses, such as pertussis and influenza, have increased in recent decades.**[4]**Much of the distrust of vaccines (and, by extension, the physicians and scientists who promote them) is driven by widespread misinformation from both online sources and skeptical communities.**[2,4] ***The belief that vaccines cause harmful adverse effects like autism has persisted despite carefully designed research studies that have refuted such claims.*** *When physicians promote vaccines, they do so knowing that the benefits far outweigh the minimal risks, and that each vaccine has been studied extensively to establish its safety profile. Yet vaccine opponents frequently*

accuse physicians and researchers of failing in this respect, citing financial or political interests as the motivation for promoting vaccines. **As the search for a SARS-CoV-2 vaccine accelerates, physicians and scientists who wish to maintain the public's trust must not promote a vaccine that has either bypassed established safety standards or is open to a serious charge of having done so. There is grim historical precedent for allowing expediency to rule vaccine development. In 1955, the inactivated polio vaccine developed by Jonas Salk was declared "safe, potent, and effective" following the largest public health experiment in the nation's history, involving more than a million schoolchildren.**[5] Within weeks, however, the **miracle vaccine intended to end the scourge of polio stood accused of causing it.** ***Years in development, the Salk vaccine had been rigorously tested in preparation for the massive trials. But the very success of these trials led to an understandable outcry for the immediate, but premature, public release of the vaccine.*** *Five pharmaceutical companies were given Salk's formula and left to produce the vaccine without significant oversight. As speed took precedence over caution, serious mistakes went unreported.*[5] *One company, Cutter Laboratories, distributed a vaccine so contaminated with live poliovirus that 70 000 children who received that vaccine developed muscle weakness, 164 were permanently paralyzed, and 10 died.*[6] Not surprisingly, that incident forced the federal government to directly intervene. The legacy of this event is a regulatory landscape in which vaccines undergo thousands of tests to ensure their safety and effectiveness.[6] Yet on rare occasions, this vital evidence-based process of vaccine development and testing has still been ignored. *In 1976, concerns about the emergence of a new swine flu strain reminiscent of the lethal 1918 version led President Gerald Ford to convene a panel that recommended a government-backed mass vaccination program.*[7] *Poorly conceived, the attempt to vaccinate the US population at breakneck speed failed in virtually every respect. Safety standards deteriorated as one manufacturer produced the incorrect strain. The vaccine tested poorly on children who, depending on the form of vaccine tested, either developed adverse reactions with high fevers and sore arms or did not mount an immune response at all.* ***Reports emerged that the vaccine appeared to cause Guillain-Barré syndrome in a very small number of cases, a finding that remains controversial, but added to the early momentum of the antivaccine movement.***[7] ***Once again, the pressure to rapidly distribute a vaccine undermined the scientific integrity of the process and damaged public trust***. COVID-19 has created intense concern and uncertainty in the US and throughout the world. There are immense public and political pressures to develop a new vaccine, a process that typically takes years, not months. But as history warns, these pressures must not supplant rigorous scientific practice. Proceeding stepwise through the phases of clinical trials is the ethical standard for investigations involving human research participants. **Adherence to the scientific method is the only way to safeguard against a SARS-CoV-2 vaccine that is ineffective,**

or worse, carries unacceptable adverse *effects. Failing to abide by standards of safety and scientific rigor during the COVID-19 crisis will fuel the argument that physicians and scientists cannot be trusted. Vaccination rates, which are declining due to widespread concern about visiting clinicians' offices, could further decrease*. The US could see resurgences of many vaccine-preventable illnesses, and inevitably, massive increases in avoidable deaths and irreversible outcomes. There are, however, reasons to hope that these scenarios will not come to pass. In response to past failures, vaccine development in the US is subject to increased regulatory oversight designed to protect against substandard practices. Technological advances permit the rapid communication of adverse events in clinical trials, and the understanding of the genetic factors influencing immunologic responses has increased. To proactively address safety concerns, these and other safeguards should be clearly communicated to the public during the vaccine development process. Both the public and the scientific community want an effective and safe intervention to prevent COVID-19. The morbidity, mortality, and societal and financial devastation that SARS-CoV-2 has caused throughout the world will have wide-reaching consequences for almost every aspect of life for years to come. Nothing should dampen the ardor of researchers worldwide in the aggressive search for effective treatments. In this unprecedented crisis, novel trial designs, such as those that include challenge studies, should be carefully considered.[8] But what cannot and must not be allowed is for desperation to result in the suspension of scientific principles and ethical research values. Physicians should not administer inadequately vetted vaccines; researchers should not endorse them without sufficient data. The scientific community has only one chance at winning public acceptance of a SARS-CoV-2 vaccine. The likelihood of achieving that goal will depend on convincing evidence of vaccine safety and efficacy.

5] Covid mutates too fast to contain South Africa and UK variants prove

David Ho 3/8 [David Ho, (David Da-i Ho is a Taiwanese-American AIDS researcher, physician, and virologist who has made a number of scientific contributions to the understanding and treatment of HIV infection.)]. "New Study of Coronavirus Variants Predicts Virus Evolving to Escape Current Vaccines, Treatments." Columbia University Irving Medical Center, 3-8-2021, Accessed 8-5-2021. https://www.cuimc.columbia.edu/news/new-study-coronavirus-variants-predicts-virus-evolving-escape-current-vaccines-treatments // duongie

A *new study of the U.K. and South Africa variants of SARS-CoV-2 predicts that current vaccines and certain monoclonal antibodies may be less effective at neutralizing these*

variants and that the new variants raise the specter that reinfections could be more likely. The study was published in Nature(link is external and opens in a new window) on **March 8, 2021. A preprint of the study was first posted to BioRxiv(link is external and opens in a new window) on January 26, 2021. The study's predictions are now *being borne out with the first reported results of the Novavax vaccine*, says the study's lead author David Ho, MD. The company reported(link is external and opens in a new window) on Jan. 28 that the *vaccine was nearly 90% effective in the company's U.K. trial, but only 49.4% effective in its South Africa trial, where most cases of COVID-19 are caused by the B.1.351 variant*. "Our study and the new clinical trial data show that the *virus is traveling in a direction that is causing it to escape from our current vaccines and therapies that are directed against the viral spike,"*** says Ho, the director of the Aaron Diamond AIDS Research Center and the Clyde'56 and Helen Wu Professor of Medicine at Columbia University Vagelos College of Physicians and Surgeons. ***"If the rampant spread of the virus continues and more critical mutations accumulate, then we may be condemned to chasing after the evolving SARS-CoV-2 continually, as we have long done for influenza virus*,"** Ho says. "Such considerations require that we stop virus transmission as quickly as is feasible, by redoubling our mitigation measures and by expediting vaccine rollout." After vaccination, the immune system responds and makes antibodies that can neutralize the virus. *Ho and his team found that antibodies in blood samples taken from people inoculated with the Moderna or Pfizer vaccine were **less effective at neutralizing the two variants**, B.1.1.7, which emerged last September in England, and B.1.351, which emerged from South Africa in late 2020*. Against the U.K. variant, *neutralization dropped by roughly 2-fold, but against the South Africa variant, neutralization dropped by 6.5- to 8.5-fold. "The approximately 2-fold loss of neutralizing activity against the U.K. variant is unlikely to have an adverse impact due to the large 'cushion' of residual neutralizing antibody activity,"* Ho says, "and we see that reflected in the Novavax results where the vaccine was 85.6% effective against the U.K. variant." Data from Ho's study about the loss in neutralizing activity against the South Africa variant are more worrisome. "*The drop in neutralizing activity against the South Africa variant is appreciable, and we're now seeing, based on the Novavax results, that this is causing a reduction in protective efficacy,*" Ho says. The new study did not examine the more recent variant found in Brazil (B.1.1.28) but given the similar spike mutations between the Brazil and South Africa variants, Ho says the Brazil variant should behave similarly to the South Africa variant. "We have to stop the virus from replicating and that means rolling out vaccine faster and sticking to our mitigation measures like masking and physical distancing. Stopping the spread of the virus will stop the development of further mutations," Ho says. The *study also found that certain monoclonal antibodies used now to treat COVID patients may not work against the South Africa variant. And based on results with plasma from COVID patients who were infected earlier in the*

pandemic, the B.1.351 variant from South Africa has the potential to cause reinfection. New study contains comprehensive analysis of variants The new study conducted an extensive analysis of mutations in the two SARS-CoV-2 variants compared to other recent studies, which have reported similar findings. The new study examined all mutations in the spike protein of the two variants. (Vaccines and monoclonal antibody treatments work by recognizing the SARS-CoV-2 spike protein.) The researchers created SARS-CoV-2 pseudoviruses (viruses that produce the coronavirus spike protein but cannot cause infection) with the eight mutations found in the U.K. variant and the nine mutations found in the South African variant. They then measured the sensitivity of these pseudoviruses to monoclonal antibodies developed to treat COVID patients, convalescent serum from patients who were infected earlier in the pandemic, and serum from patients who have been vaccinated with the Moderna or Pfizer vaccine. Implications for monoclonal antibody treatments The study measured the neutralizing activity of 18 different monoclonal antibodies—including the antibodies in two products authorized for use in the United States. Against the U.K. variant, most antibodies were still potent, although the neutralizing activity of two antibodies in development was modestly impaired. Against the South Africa variant, however, the neutralizing activity of four antibodies was completely or markedly abolished. Those antibodies include bamlanivimab (LY-CoV555, approved for use in the United States) that was completely inactive against the South Africa variant, and casirivimab, one of the two antibodies in an approved antibody cocktail (REGN-COV) that was 58-fold less effective at neutralizing the South Africa variant compared to the original virus. The second antibody in the cocktail, imdevimab, retained its neutralizing ability, as did the complete cocktail. **"Decisions of the use of these treatments will depend heavily on the local prevalence of the South Africa and Brazil variants," Ho says, "*highlighting the importance of viral genomic surveillance and proactive development of next-generation antibody therapeutics." Reinfection implications Serum from most patients who had recovered from COVID earlier in the pandemic had 11-fold less neutralizing activity against the South Africa variant and 4-fold less neutralizing activity against the U.K. variant. "The concern here is that reinfection might be more likely if one is confronted with these variants, particularly the South Africa one*," Ho says.**

Posner concludes that disease can cause extinction

Posner 5 – Posner, University of Chicago Law School senior lecturer, 2005 [Richard A., United States Court of Appeals Seventh Circuit Judge, "Catastrophe: the dozen most significant catastrophic risks and what we can do about them.(Excerpt)(Cover Story)," www.highbeam.com/doc/1G1-130930466.html]

The 1918-1919 flu pandemic is a reminder that nature may yet do us in. The disease agent was an unexpectedly lethal variant of the commonplace flu virus. Despite its lethality, it spread far and wide because most of its victims did not immediately fall seriously ill and die, so they were not isolated from the healthy population but instead circulated among the healthy, spreading the disease. (1) No one knows why the 1918-1919 pandemic was so lethal, although it may have been due to a combination of certain features of the virus's structure with the crowding of troops in the trenches and hospitals on the Western Front (where the pandemic appears to have originated near the end of World War D, facilitating the spread of the disease. (2) The possibility cannot be excluded that an even more lethal flu virus than that of the 1918-1919 pandemic will appear someday and kill many more people. There is still no cure for flu, and vaccines may be ineffective against a new mutant strain--and the flu virus is notable for its high rate of mutations. (3) Another great twentieth-century pandemic, AIDS, which has already killed more than 20 million people, (4) illustrates the importance to the spread of a disease of the length of the infectious incubation period. The longer a person is infected and infectious---yet either asymptomatic or insufficiently ill to be isolated from the healthy population--the farther the disease will spread before effective measures, such as quarantining, are taken. What has proved to be especially pernicious about AIDS is that its existence was not discovered until millions of people had been infected by and were transmitting the MDS virus (HIV), which has an average infectious incubation period of 10 years. Given the length of that period, the only thing that may have prevented MDS from wiping out the human race is that it is not highly infectious, as it would be if HIV were airborne rather than being transmissible only by being introduced into a victim's bloodstream. Even by unsafe sex it is "generally poorly transmitted. For example, the probability of transmission from a single anal receptive sexual contact with an infected partner is estimated at 1 in 100 to 1 in 500." (5) However, the length of HIV's infectious incubation period and the difficulty of transmission may be related; for, given that difficulty, were the virus unable to "hide" from its host's immune system for a considerable time, it would be detected and destroyed before it had a chance to replicate itself in another host. (6) AIDS illustrates the further point that despite the progress made by modern medicine in the diagnosis and treatment of diseases, developing a vaccine or cure for a new (or newly recognized or newly virulent) disease may be difficult, protracted, even impossible. Progress has been made in treating AIDS, but neither a cure nor a vaccine has yet been developed. And because the virus's mutation rate is high, the treatments may not work in the long run. (7) Rapidly mutating viruses are difficult to vaccinate against, which is why there is no vaccine for the common cold and why flu vaccines provide only limited protection. (8) Paradoxically, a treatment that is neither cure nor vaccine, but merely reduces the severity of a disease, may accelerate its spread by reducing the benefit from avoiding becoming infected. This

is an important consideration with respect to AIDS, which is spread mainly by voluntary intimate contact with infected people. Yet the fact that Homo sapiens has managed to survive every disease to assail it in the 200,000 years or so of its existence is a source of genuine comfort, at least if the focus is on extinction events. There have been enormously destructive plagues, such as the Black Death, smallpox, and now AIDS, but none has come close to destroying the entire human race. There is a biological reason. Natural selection favors germs of limited lethality; they are fitter in an evolutionary sense because their genes are more likely to be spread if the germs do not kill their hosts too quickly. The AIDS virus is an example of a lethal virus, wholly natural, that by lying dormant yet infectious in its host for years maximizes its spread. Yet there is no danger that AIDS will destroy the entire human race. The likelihood of a natural pandemic that would cause the extinction of the human race is probably even less today than in the past (except in prehistoric times, when people lived in small, scattered bands, which would have limited the spread of disease), despite wider human contacts that make it more difficult to localize an infectious disease. The reason is improvements in medical science. But the comfort is a small one.Pandemics can still impose enormous losses and resist prevention and cure: the lesson of the AIDS pandemic. And there is always a [first] time. That the human race has not yet been destroyed by germs created or made more lethal by modern science, as distinct from completely natural disease agents such as the flu and AIDS viruses, is even less reassuring. We haven't had these products long enough to be able to infer survivability from our experience with them. A recent study suggests that as immunity to smallpox declines because people am no longer being vaccinated against it, monkeypox may evolve into "a successful human pathogen," (9) yet one that vaccination against smallpox would provide at least some protection against; and even before the discovery of the smallpox vaccine, smallpox did not wipe out the human race. What is new is the possibility that science, bypassing evolution, will enable monkeypox to be "juiced up" through gene splicing into a far more lethal pathogen than smallpox ever was.