## Advantage

#### IP undermines competition and keeps medicine prices high.

MSF ’17 – Médecins Sans Frontières [Doctors Without Borders - Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters.], “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines,” September, 2017. Accessed Aug. 12, 2021. <<https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>> AT

Intellectual property undermines competition and keeps prices high¶ As MSF has seen repeatedly for medical products critical to our operations, competition among multiple manufacturers is a proven way to reduce prices and increase access. Without competition, single suppliers can set prices high, and limited supply options leave vulnerabilities, including dependence on a sole manufacturer’s ability to maintain consistent supply. The effects of IP monopolies like patents on competition and supply for pharmaceutical products are well documented.11,12,13 Yet, as increasingly recognised, and discussed in more detail within this document, patent-based monopolies can also be a barrier in the field of vaccine production and have posed challenges to vaccine development for decades.¶ Traditional narrative of technology transfers and lack of consideration of patent barriers ¶ Prior experiences of developing vaccines for diphtheria, whole-cell pertussis, polio, measles, mumps, influenza, rubella, and yellow fever in World Bank-classified low- and middle-income countries had suggested that patents do not play a major role in modifying the behaviour of vaccine manufacturers. Historically, these vaccines have been developed using conventional egg-based and cell culture-based methods generally not protected by patents. In these cases, the process of manufacturing and key ‘know how’\* was considered a barrier to entry for new competitors.14¶ When looking at the manufacturing experiences of some older vaccines, this perception is an oversimplification. The development of the hepatitis B vaccine, for example, dating back nearly half a century, faced patent barriers resulting in monopolies and high prices.15 The two manufacturers of recombinant hepatitis B vaccines, Merck and SmithKline Beecham, needed licences to more than 90 patents from universities, public institutes and private companies to produce their vaccines. Despite the contributions of publicly funded R&D, product prices at introduction were as high as $40 per dose for this 3-dose regimen (equivalent to more than $87 per dose in real terms in 2016).¶ Patents are increasingly an issue for development of newer vaccines¶ Patent activity in the field of vaccine development and manufacturing has been increasingly recognised as problematic over the past 15 years, according to manufacturers interviewed for this report. International organisations with vaccines expertise such as WHO and Gavi, the Vaccine Alliance, have similarly noted that patent thickets are an increasing concern for vaccines.16¶ For medical products such as PCV and HPV vaccines, patent barriers can slow the development process, increase costs, increase uncertainty and deter or even block other manufacturers considering entering the market.17 A recent analysis by Chandrasekharan et al. found 106 Patent Cooperation Treaty (PCT) applications “potentially relevant to the manufacturing of pneumococcal vaccines”† and 93 patents applications “relevant to the manufacturing of HPV vaccines.”18¶ The patent applications and discussions with manufacturers indicate that broad monopolies are being pursued for these vaccines, through tactics such as using overly general language in patent claims concerning the scope of the inventions. According to national criteria, many of these patents or applications could be challenged or rejected due to their weak technical merits. With patents sought for PCV and HPV vaccine technology in major and emerging markets, like Brazil, China, Europe, India, and the US, governments and other stakeholders seeking to encourage competition and access to affordable vaccines must consider how to mitigate the constraints that pending and granted patents in developing countries place on the ability of potential competitor vaccine manufacturers to develop or sell competitor vaccines.¶ Patents undermine competition throughout PCV and HPV vaccine manufacturing and beyond¶ Patents can act as barriers throughout vaccine development, manufacturing and administration processes. PCV and HPV vaccine products are protected by a series of patents and patent applications, covering all aspects including starting materials, composition, process technologies, and methods of using vaccines, including age groups, vaccine presentations and schedules. Potential competitor vaccine manufacturers considering entering the market may face patent challenges “in any step of the development process starting from preclinical R&D, to scale up, formulation and licensure in the markets of choice, and hence may alter their decision pathways… at each step.”19¶ The typical strategy for a vaccine manufacturer seeking a patent monopoly is to use broad, non-specific claim language to define what they claim is the invention. Many of those patents and applications do not merit patent protection according to national laws, and many are used mainly to maximise the scope of monopoly.¶ Starting materials¶ Starting materials patents cover the inputs/initial ingredients for making a vaccine, including various chemical reagents, host cells, vectors, and DNA and/or RNA sequences of various types. These inputs are highly likely to be required for vaccine production. If the rights to use these materials in vaccine manufacturing are not obtained by a company, it may be very difficult to ‘design around’ the need for these materials. These materials have often been patented years ago and they may now be in the public domain, as is the case for PCV and HPV vaccines.¶ Several patent applications were filed on HPV vaccine starting materials from the mid-1990s. For instance, Merck filed a patent application on the basic HPV DNA,20 covering the most common antigen types HPV 16 and HPV 18. The application attempts to protect recombinant DNA sequences encoding the important antigenic proteins of papillomavirus and purified virus-like particles comprised of the recombinant proteins. It also tries to cover the methods of making and using the recombinant proteins. Merck additionally filed a patent application seeking monopoly protection over virus-like particles containing HPV 18.21 Where granted as claimed, these patents could block anyone who plans to develop alternative HPV vaccines during the patent term. These two Merck applications, where granted, should have started to expire around the world beginning in 2015-2016.¶ A number of newer patent applications since the 2000s on HPV vaccines are also related to starting materials. It is a common practice to file such ‘second-generation’ applications to seek additional commercial advantages. For instance, GSK filed a patent application22 claiming modified DNA sequences of HPV which provide enhanced levels of expressed antigen. This patent would expire in 2023 where granted. Another example is a GSK patent application23 related to cross-reactivity, where HPV 16 and HPV 18-containing constructs can be used in a vaccine that protects against other HPV antigens besides 16 and 18. The detailed effects of these newer patent applications on follow-on development of alternative HPV vaccines require further analysis.¶ Vaccine composition¶ Vaccine composition patents typically seek to cover the resulting combination of immunologically important parts of the vaccine, plus associated materials, such as adjuvants, buffers and preservatives. These types of patents can potentially have strong blocking effects.¶ One of the key patents that Pfizer is seeking for its PCV13 product relates to the vaccine’s composition.24 See more details on this PCV13 patent application and why it represents an unwarranted obstacle to pricelowering competition for PCV in the PCV13 patent opposition case study.¶ There are numerous other examples of vaccine composition patents and these may also warrant further analysis for the effects they may have on competition. For example, Pfizer, GSK and other companies have further filed a series of patent applications claiming different aspects of PCV compositions including those covering up to 20 and 26 valent PCV vaccines.25¶ Process technologies¶ Patents related to vaccine process technologies grant monopolies on the way a vaccine is manufactured. The specific manufacturing methods depend on the type of vaccine. Many different patents and patent applications have been identified that cover or attempt to cover various aspects of vaccine process technologies. ¶ For example, basic conjugation technology needed for PCV manufacturing is patent protected in at least six countries.26 This patent is broad and non-specific, blocking competitors from using a general process for combining several vaccine elements (a polysaccharide, e.g., derived from a Pneumococcus, activated with a specific organic compound and then joined to a carrier protein) to obtain a conjugated immunogenic product. These patents have already begun to expire as of 2016. Until expiry, a vaccine manufacturer wanting to offer a more affordable PCV is required to address this barrier in countries where the patent has been filed or granted.¶ Some other examples of patents filed by different applicants claiming different process technologies related to PCV production may also warrant further analysis to assess their potential impact on competition for PCV vaccines.27¶ Methods of using vaccines¶ ‘Methods of use’ patents seek a monopoly on the way a product is used, for example how a vaccine is administered to children. Depending on the specific claim language, this can include patents on various vial presentations, dose regimens, populations or age groups covered, other elements related to the presentation and packaging of the vaccine itself, or the use of the vaccine in people.¶ These patents are highly problematic because they may undermine the ability of Ministries of Health and clinicians to practise medicine and immunise children in the most appropriate way, free from any potential patent infringement risks. Additionally, these patents may also make potential competitors liable if their product labels and package inserts include information on dosage regimens or methods of use that are under the scope of the concerned patents. This can be the case even if more affordable competitor vaccine products themselves do not infringe on an originator’s patents on a given vaccine.¶ One example of this is a GSK patent application28, which essentially seeks a monopoly on administering PCV after a child has received tetanus and/or diphtheria vaccines.\* This ‘preimmunisation’ claim term is particularly broad; many national immunisation programmes could have a national vaccination protocol through which a child may receive tetanus or diphtheria vaccines before getting PCV.¶ If granted, this patent may have a strong blocking effect on the use of any alternative PCV in national immunisation schedules. GSK has applied for this PCV patent in Great Britain (withdrawn in 2011), Brazil, Eurasian Patent Organisation and Morocco.29 The application was also filed, but subsequently withdrawn, in various other jurisdictions, including Australia, Canada, China, Germany and the European Patent Office, South Korea, and abandoned in India, following pre-grant opposition.30 It has already been granted in South Africa.31¶ Patents related to age groups¶ Patent claims can also cover specific age groups to which the vaccine can be administered. If granted, these patents can restrict competition by blocking other manufacturers from selling vaccines for administration to the specified (and likely necessary) age groups. For example, the European Patent Office granted a patent32 to GSK for a method of using a ‘two dose’ HPV16/18 vaccine.33 The patent application includes a patent claim stating that the vaccine is formulated for administration ‘to a subject 14 years of age or below’.34 It indicates a monopoly on immunising people who are 14 years old or younger, which covers the full age range of girls recommended by WHO to receive HPV vaccines.35 This may well be a patent that blocks competition in Europe and prevents competitor manufacturers from offering more affordable versions of HPV vaccines that protect against these two critical strains of HPV. In its PCT application36, the initial claims of the equivalent patent are even broader, covering the use of the concerned method for females aged ‘25 years or under’, ‘9 to 25 years’, ‘9 to 14 years’, ‘15 to 19 years’ and ‘20 to 25 years’, thereby seeking to cover all possible vaccination schedules for the full ranges of ages for whom HPV vaccine would be most effective.¶ Patents related to vaccination schedule and presentation¶ Dose regimens are formalised schedules by which medicines or vaccines are administered, including the dose of the vaccine, the number of doses in a period of time and the time between doses. The patenting of these regimens, including for vaccines, effectively grants a patent holder a monopoly that inhibits the development of competitor products that may need to be administered in the same or a similar dosing regimen, and undermines the ability of medical professionals to prescribe the most medically sound regimens based on health needs.¶ For example, a GSK patent application on the HPV vaccine37 contains very broad claims. The technology in this GSK patent application covers both bivalent\* and quadrivalent† HPV vaccines and claims a process of administering a ‘two-dose regimen’ consisting of a first dose and a second dose, wherein both doses can be either bivalent or quadrivalent, covering all virus types causing cervical cancer. It is sufficiently broad to affect manufacturers who intend to move towards two-dose regimen administration for their bivalent or quadrivalent HPV products, while a two-dose schedule is currently recommended by WHO for HPV.38 This patent application has been issued in Europe39 for the ‘two-dose’ bivalent HPV vaccine, and the vaccine was approved for marketing by the European Commission in December 2013. Applications have also been filed in Australia, Canada, China, India, New Zealand, South Korea and the US. It has been withdrawn in the Philippines and refused in Ukraine.40¶ In other situations, broad claims in patent applications could also seek monopoly protection over the vial presentation and carry concerning implications for the launch of alternative versions of the vaccine by followon manufacturers. Vial presentation refers to the format of the vaccine, in terms of the number of doses, the volume and the weight contained within one unit of production. For example, it could refer to a single-dose pre-filled syringe, a 10-dose vial with 2 ml per dose, a 20-dose vial and so on.¶ Multi-dose vial presentations, where more than one dose of the vaccine is contained in a vial, are an advantage for developing country immunisation programmes because they decrease cold chain capacity requirements and ease vaccination programme logistics. Multi-dose vials, in general, also have a lower price per dose compared to single-dose vial and/or syringe formats. Pfizer filed a patent application concerning a multidose vial PCV13,41 which includes broad claims related to specific presentations, including pre-filled vaccine delivery devices (such as a syringe) as well as a vial container. If granted as claimed, it might effectively block the development and launching of alternative versions of multi-dose vial PCV13 and secure the market of using such presentations (multi-dose vials) for only Pfizer’s product. The monopoly associated with this patent could mean that public health programmes looking to switch to multi-dose vial PCV13 or a pre-filled ‘device,’ such as a pre-filled syringe, would either have to stay with a single dose vial format or have to use Pfizer’s version only. This patent has been granted in Australia, South Korea, the US and by the European Patent Office.42 An equivalent application has also been filed in China43 and India44, where the applications are pending examination.¶ Summary¶ There are many different aspects of vaccines that are being patented, in many cases undeservingly so per national laws. These patents pose significant barriers for other manufacturers to enter the market and contribute to a competitive environment that could help lower prices and increase access. Taken together, these patents indicate that throughout the vaccine development process and beyond, patents pose a threat to affordable vaccines by impeding, and possibly outright blocking price-lowering follow-on competition. In some cases, potential competitors have opportunities to address and overcome these barriers providing they have the time, resources, technical know-how and an accurate assessment of the vaccine patent landscape.

#### Millions, including many children, die from pneumonia and HPV, but low-income countries and families can’t afford the vaccines to prevent them.

MSF ’17 – Médecins Sans Frontières [Doctors Without Borders - Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters.], “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines,” September, 2017. Accessed Aug. 12, 2021. <<https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>> AT

Through our operations, MSF teams vaccinate thousands of vulnerable children each year against pneumonia, the number one killer of children under five years worldwide. MSF is also starting to provide vaccinations against human papillomavirus (HPV), a sexually transmitted infection that can lead to cervical cancer, one of the leading cancer killers of women in developing countries. The World Health Organization (WHO) recommends vaccination with the pneumococcal conjugate vaccine (PCV) for all children worldwide and HPV vaccination for girls worldwide. However, these vaccines are often unaffordable for developing countries. Millions of children around the world are left unprotected from pneumonia or HPV when Ministries of Health cannot afford to incorporate these vaccines into their national immunisation programmes.¶ Pneumonia¶ Globally, pneumonia kills nearly one million children every year.2 Children in crisis-affected contexts are particularly susceptible to pneumonia, and MSF medical teams often see its deadly effects in our health facilities. PCV can prevent many cases of pneumonia and is currently manufactured for children by just two companies: Pfizer and GlaxoSmithKline (GSK). Unfortunately, PCV is priced out of reach of many parents, governments and treatment providers, due in part to high prices caused by a lack of sufficient competition. Approximately one third of the world’s countries have not been able to introduce PCV because of its high price.3 Millions of vulnerable children living in countries such as Jordan, Thailand and the Philippines are left without affordable access to this life-saving vaccine. According to 2015 WHO/UNICEF estimates, 60% of the world’s infants (81.6 million) were not receiving PCV in 2015, either because they lived in one of 55 countries that had not yet introduced the vaccine, or they were not being reached by the routine immunisation services in their country.¶ MSF provides PCV through our work in countries such as Central African Republic, Ethiopia, Greece, South Sudan, Syria and Uganda, among others. From 2009 to 2014, MSF negotiated with Pfizer and GSK to obtain a sustainable, affordable price for PCV, exceptionally accepting a limited-term donation, with agreement from both Pfizer and GSK that they would work on longer-term solutions to improve affordability. In the absence of such a solution, MSF and other humanitarian organisations continued to struggle to purchase PCV at an affordable price. For example, in 2016 MSF paid 60 Euros (US$68.10) for one dose of the Pfizer product to vaccinate refugee children in Greece – 20 times more than the lowest PCV price offered by Pfizer and GSK. ¶ In 2015, faced with the impossibility of obtaining an affordable price, MSF launched a public campaign – A Fair Shot – calling on both companies to lower the price of PCV for humanitarian use and in all developing countries. Because of this pressure, in late 2016, both Pfizer and GSK finally agreed to extend their lowest global price to humanitarian organisations vaccinating in emergencies, but not to developing countries more broadly.4 Many governments, providers, and parents still struggle to afford PCV.¶ Human papillomavirus¶ The World Health Organization (WHO) estimates that more than one million women are living with cervical cancer worldwide, most often as a “consequence of a long-term infection with human papillomavirus (HPV).” WHO also notes that most cases occur in developing countries;5 in 2012, more than a quarter of a million women died from cervical cancer in developing countries.6¶ Two companies, GSK and Merck, manufacture vaccines that protect against two (GSK), four and nine (Merck) different types of HPV. Types 16 and 18 are associated with 71% of cases of cervical cancers and are present in all three vaccines.7 Despite the importance of this vaccine, by mid-2016, only 65 countries had introduced HPV vaccines.8 Prices for the vaccines range from $4.50 per dose at the lowest global price up to $193 per dose in the US private sector.9 In contrast, based on peer-reviewed manufacturing estimates, HPV vaccines could be manufactured for as little as $0.50 to $0.60 per dose.10¶ MSF provides cervical cancer screenings and HPV vaccines in some projects, for example in the Philippines, and is preparing to do so in Zimbabwe.

**Poverty and disease are mutually reinforcing, causing staggering suffering and injustice.**

**Hollis & Pogge ’08 -** Aidan Hollis [Associate Professor of Economics, the University of Calgary] and Thomas Pogge [Leitner Professor of Philosophy and International Affairs, Yale University], “The Health Impact Fund Making New Medicines Accessible for All,” *Incentives for Global Health* (2008) AT

In 2004, some 970 million people, around 15 percent of the world’s population, were living below the extreme poverty line of $1 a day (more strictly defi ned, $392.88 annually) in 1993 Purchasing Power Parity (PPP) terms (Chen and Ravallion 2007, 16579).3 Furthermore, those living below this very low poverty line fell on average around 28 percent below it. Th eir average annual purchasing power therefore corresponded to approximately $420 in the US in 2008 dollars.4¶ Th ese are the poorest of the poor. Th e World Bank also uses a somewhat less miserly poverty line, namely $2 dollar a day, or an annual amount of $785.76 PPP 1993. Th e Bank’s data show that around 40 percent of the world’s population, or over 2.5 billion people, lived in income poverty so defi ned in 2004,5 with this population falling on average 41 percent below this higher line.6 Individuals In this much larger group could buy, on average, about as much in 2004 as could be bought in the US in 2008 for $690.¶ The Effects of Global Income Poverty on Health¶ The effects of such extreme income poverty are foreseeable and extensively documented. It is estimated that around 13 percent of all human beings (830 million) are chronically undernourished, 17 percent (1.1 billion) lack access to safe water, and 41 percent (2.6 billion) lack access to basic sanitation (UNDP 2006, 174, 33). About 31 percent (2 billion) lack access to crucial drugs and 25 percent (1.6 billion) lack electricity (Fogarty n.d., IEA 2002). Some 780 million adults are illiterate (UNESCO 2006), and 14 percent of children aged between fi ve and 17 (218 million) are child laborers, more than half in hazardous work (ILO 2006, 6).¶ Worldwide, diseases related to poverty, including communicable, maternal, perinatal, and nutritionrelated diseases, comprise over 50 percent of the burden of disease in low-income countries, nearly ten times their relative burden in developed countries (WHO 2006b, 3). If the developed world had its proportional share of poverty-related deaths (onethird of all deaths), severe poverty would kill some 16,000 Americans and 26,000 citizens of the European Union each week.¶ The cycle of mutually reinforcing poverty and disease besetting low income countries, and particularly the poorer communities in these countries, could be broken by signifi cantly reducing severe poverty. But it is also possible to make substantial progress against the global burden of disease more directly by improving health care in developing countries.¶ Poverty does not merely render poor people more vulnerable to disease, but also makes it less likely that they can obtain medical treatment for the diseases they contract. This is because in poor countries medical care is rarely available for free, and poor people are typically unable to buy either the care needed by themselves or their families or the insurance policies that would guarantee them such care. The price of health care in poor countries therefore also plays a crucial role in explaining the catastrophic health situation among the global poor.

#### We have a duty to assist others when the tradeoff is morally insignificant. This simple precept is more compelling than arcane moral reasoning or tortured negative fantasizing about remote catastrophes. If you came across a drowning child, would you wade in to save them or contemplate the possibility that you might cause nuclear war?

Singer ’72 - Peter Singer [Prof. Bioethics at Princeton] “Famine, Affluence, and Morality” Philosophy and Public Affairs, vol. 1, no. 1 Spring 1972 AT

My next point is this: if it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it. By "without sacrificing anything of comparable moral importance" I mean without causing anything else comparably bad to happen, or doing something that is wrong in itself, or failing to promote some moral good, comparable in significance to the bad thing that we can prevent. This principle seems almost as uncontroversial as the last one. It requires us only to prevent what is bad, and to promote what is good, and it requires this of us only when we can do it without sacrificing anything that is, from the moral point of view, comparably important. I could even, as far as the application of my argument to the Bengal emergency is concerned, qualify the point so as to make it: if it is in our power to prevent something very bad from happening, without thereby sacrificing anything morally significant, we ought, morally, to do it. An application of this principle would be as follows: if I am walking past a shallow pond and see a child drowning in it, I ought to wade in and pull the child out. This will mean getting my clothes muddy, but this is insignificant, while the death of the child would presumably be a very bad thing. The uncontroversial appearance of the principle just stated is deceptive. If it were acted upon, even in its qualified form, our lives, our society, and our world would be fundamentally changed. For the principle takes, firstly, no account of proximity or distance. It makes no moral difference whether the person I can help is a neighbor's child ten yards from me or a Bengali whose name I shall never know, ten thousand miles away. Secondly, the principle makes no distinction between cases in which I am the only person who could possibly do anything and cases in which I am just one among millions in the same position.

## Solvency

#### The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines using the mechanisms described by MSF ’17:

MSF ’17 – Médecins Sans Frontières [Doctors Without Borders - Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters.], “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines,” September, 2017. Accessed Aug. 12, 2021. <<https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>> AT

Countries can take a variety of steps to promote competition in vaccine manufacturing and help mitigate the complex patent thickets that could block, delay or increase uncertainties around access to multiple sources of vaccines. Governments should adopt public health-oriented IP policies, making full use of TRIPS flexibilities in both substantive and procedural aspects of national patent laws. Countries should:

• Encourage and accelerate follow-on development and competition of vaccines and vaccine technologies through the introduction and use of broad Bolar exemptions. This will support an early start for research and clinical studies by follow-on manufacturers, and support independent follow-on research and development.

• Apply strict patentability criteria for vaccine and vaccine technologies in patent examination and judicial proceedings. Countries should closely scrutinise patent applications concerning common methods of treatment, dosage forms and claims concerning specific age groups. Countries should reject trivial changes to known vaccine technologies, or composition patent applications that merely present the assembly of more ingredients using a known technology.

• Implement robust pre- and post-grant opposition procedures in national patent law systems that allow greater public scrutiny and opportunities to challenge unmerited patent applications from an early stage. Procedures that allow third-party observation but lack a mandatory hearing requirement could be improved to provide better transparency and accountability to the public.

• Improve use of compulsory licencing. Governments should strengthen the mechanisms of issuing compulsory licences to facilitate the most expedited access to multiple sources of vaccines and to safeguard public health.

• Strengthen technical capacity to ensure patent examiners apply strict patentability criteria and screen out unmerited applications in a timely manner. This will provide clarity on the patent landscape concerning important vaccines and technologies.

• Increase transparency of patent office filings to enable third parties to better understand the IP landscape, especially through procedures to promote disclosure of non-proprietary biological qualifier names74 of vaccines. Prospective manufacturers will be able to make decisions more efficiently if they understand the IP landscape clearly. Government procurement decision making will also be improved by addressing the current information asymmetry.

• Make full use of LDCs’ exemption from mandatory patent protection to accelerate access to quality assured follow-on new vaccines and encourage competition to improve affordability of vaccines.

• Demand that international organisations like WHO, Gavi, the Pan American Health Organization (PAHO) and the United Nations Children’s Fund (UNICEF) improve technical support for countries to: identify legal barriers, use flexibilities under IP laws and improve transparency of patent information to facilitate follow-on development and foster robust competition for new vaccines.75

#### The neoliberal drive to privatization created the tragedy of the anti-commons, stifling innovation through excessive protection of ever more segmented intellectual property.

Heller & Eisenberg ’98 - Michael Heller [Prof. of Property Law, Columbia Law School] & Rebecca S. Eisenberg [Prof. of Patent Law, Michigan Law], “Can Patents Deter Innovation? The Anticommons in Biomedical Research,” SCIENCE, VOL. 280, P. 698, 1998 (1998). <<https://scholarship.law.columbia.edu/faculty_scholarship/1158>> AT

Since Hardin’s article appeared, biomedical research has been moving from a commons model toward a privatization model (4). Under the commons model, the federal government sponsored premarket or “upstream” research and encouraged broad dissemination of results in the public domain. Unpatented biomedical discoveries were freely incorporated in “downstream” products for diagnosing and treating disease. In 1980, in an effort to promote commercial development of new technologies, Congress began encouraging universities and other institutions to patent discoveries arising from federally supported research and development and to transfer their technology to the private sector (5). Supporters applaud the resulting increase in patent filings and private investment (6), whereas critics fear deterioration in the culture of upstream research (7). Building on Heller’s theory of anticommons property (3), this article identifies an unintended and paradoxical consequence of biomedical privatization: A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development.¶ The Tragedy of the Anticommons¶ Anticommons property can best be understood as the mirror image of commons property (3, 8). A resource is prone to overuse in a tragedy of the commons when too many owners each have a privilege to use a given resource and no one has a right to exclude another (9). By contrast, a resource is prone to underuse in a “tragedy of the anticommons” when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use. In theory, in a world of costless transactions, people could always avoid commons or anticommons tragedies by trading their rights (10). In practice, however, avoiding tragedy requires overcoming transaction costs, strategic behaviors, and cognitive biases of participants (11), with success more likely within close-knit communities than among hostile strangers (12– 14). Once an anticommons emerges, collecting rights into usable private property is often brutal and slow (15).¶ Privatization in postsocialist economies starkly illustrates how anticommons property can emerge and persist (3). One promise of the transition to a free market was that new entrepreneurs would fill stores that socialist rule had left bare. Yet after several years of reform, many privatized storefronts remained empty, while flimsy metal kiosks, stocked full of goods, mushroomed on the streets. Why did the new merchants not come in from the cold? One reason was that transition governments often failed to endow any individual with a bundle of rights that represents full ownership. Instead, fragmented rights were distributed to various socialist-era stakeholders, including private or quasi-private enterprises, workers’ collectives, privatization agencies, and local, regional, and federal governments. No one could set up shop without first collecting rights from each of the other owners.¶ Privatization of upstream biomedical research in the United States may create anticommons property that is less visible than empty storefronts but even more economically and socially costly. In this setting, privatization takes the form of intellectual property claims to the sorts of research results that, in an earlier era, would have been made freely available in the public domain. Responding to a shift in U.S. government policy (4) in the past two decades, research institutions such as the National Institutes of Health (NIH) and major universities have created technology transfer offices to patent and license their discoveries. At the same time, commercial biotechnology firms have emerged in research and development (R&D) niches somewhere between the proverbial “fundamental” research of academic laboratories and the targeted product development of pharmaceutical firms (7). Today, upstream research in the biomedical sciences is increasingly likely to be “private” in one or more senses of the term—supported by private funds, carried out in a private institution, or privately appropriated through patents, trade secrecy, or agreements that restrict the use of materials and data.¶ In biomedical research, as in postsocialist transition, privatization holds both promises and risks. Patents and other forms of intellectual property protection for upstream discoveries may fortify incentives to undertake risky research projects and could result in a more equitable distribution of profits across all stages of R&D. But privatization can go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research (16). Upstream patent rights, initially offered to help attract further private investment, are increasingly regarded as entitlements by those who do research with public funds. A researcher who may have felt entitled to coauthorship or a citation in an earlier era may now feel entitled to be a coinventor on a patent or to receive a royalty under a material transfer agreement. The result has been a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research. Researchers and their institutions may resent restrictions on access to the patented discoveries of others, yet nobody wants to be the last one left dedicating findings to the public domain.¶ The problem we identify is distinct from the routine underuse inherent in any wellfunctioning patent system. By conferring monopolies in discoveries, patents necessarily increase prices and restrict use—a cost society pays to motivate invention and disclosure. The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.

**The Aff challenges dehumanizing cultural frames that allow us to ignore human suffering. Recognition of common vulnerability is key to a politics that rejects violence, oppression, and indifference.**

**Butler ’04 -** Judith Butler [Prof. of Rhetoric and Comparative Literature, University of California at Berkeley], Precarious Life: The Powers of Mourning and Violence. New York: Verso (2006; First Published 2004). pp. 30-35 AT

Is there something to be gained from grieving, from tarrying with grief, from remaining exposed to its unbearability and not endeavoring to seek a resolution for grief through violence? Is there something to be gained in the political domain by maintaining grief as part of the framework within which we think our international ties? If we stay with the sense of loss, are we left feeling only passive and powerless, as some might fear? Or are we, rather, returned to a sense of human vulnerability, to our collective responsibility for the physical lives of one another? **Could** the experience of a **dislocation of First World safety** not **condition** the **insight into the radically inequitable ways that** corporeal **vulnerability is distributed globally?** To foreclose that vulnerability,to banish it, **to make ourselves secure at the expense of every other** human consideration **is to eradicate** one of the **most important resources from which we must** take our bearings and **find our way.¶** To grieve, and to make grief itself into a resource for politics, is not to be resigned to inaction, but it may be understood as the slow process by which we develop a point of identification with suffering itself. The disorientation of grief- “Who have I become?” or, indeed, “What is left of me?” “What is it in the Other that I have lost?” – posits the “I” in the mode of unknowingness.¶ But this can be a point of departure for a new understanding if the narcissistic preoccupation of melancholia can be moved into a consideration of the vulnerability of others. Then we might critically evaluate and oppose the conditions under which certain human lives are more vulnerable than others,and thus certain human lives are more grievable than others. From where **might a principle emerge by which we vow to protect others from the kinds of violence we have suffered,** if not **from an apprehension of a common human vulnerability?** I do not mean to deny that vulnerability is differentiated, that it is allocated differentially across the globe. I do not even mean to presume upon a common notion of the human, although to speak in its “name” is already (or perhaps only) to fathom its possibility.¶ I am referring to violence, vulnerability, and mourning, but there is a more general conception of the human with which I am trying to work here, one in which we are, from the start, given over to the other, one in which we are, from the start, even prior to individuation itself and, by virtue of bodily requirements, given over to some set of primary others: this conception means that we are vulnerable to those we are too young to know and to judge and, hence, vulnerable to violence; but also vulnerable to another range of touch, a range that includes the eradication of our being at the one end, and the physical support for our lives at the other.¶ Although I am insisting on referring to a common human vulnerability, one that emerges with life itself, I also insist that we cannot recover the source of this vulnerability: it precedes the formation of the “I.” This is a condition, a condition of being laid bare from the start and with which we cannot argue. I mean, that we can argue with it, but we are perhaps foolish, if not dangerous, when we do. I do not mean to suggest that the necessary support for a newborn is always there. Clearly, it is not, and for some this primary scene is a scene of abandonment or violence or starvation, that theirs are bodies given over to nothing, or to brutality, or to no sustenance.¶ We cannot understand vulnerability as a deprivation, however, unless we understand the need that is thwarted. Such infants still must be apprehended as given over, as given over to no one or to some insufficient support, or to an abandonment. It would be difficult, it not impossible, to understand how humans suffer from oppression without seeing how this primary condition is exploited and exploitable, thwarted and denied. The condition of primary **vulnerability**, of being given over to the touch of the other, even if there is no other there, and no support for our lives, **signifies a primary helplessness and need**, one **to which any society must attend.** Lives are supported and maintained differently, andthere are radically different ways in which human physical vulnerability is distributed across the globe. **Certain lives will be highly protected, and the abrogation of their** claims to **sanctity will** be sufficient to **mobilize the forces of war. Other lives** will not find such fast and furious support and **will not even qualify as “grievable.”¶** A hierarchy of grief could no doubt be enumerated. We have seen it already, in the genre of the obituary, where lives are quickly tidied up and summarized, humanized, usually married, or on the way to be, heterosexual, happy, monogamous. But this is just a sign of another differential relation to life, since we seldom, if ever, hear the names of the thousands of Palestinians who have died by the Israeli military with United States support, or any number of Afghan people, children and adults**. Do they have names, faces, personal histories, family, favorite hobbies, slogans by which they life?** What defense against the apprehension of loss is at work in the blithe way in which we accept deaths caused by military means with a shrug or with self-righteousness or with clear vindictiveness? To what extent have Arab peoples, predominantly practitioners of Islam, fallen outside the “human” as it has been naturalized in its “Western” mold by the contemporary workings of humanism? What are the cultural contours of the human at work here? How do our **cultural frames for thinking the human set limits on the kinds of losses we can avow** as loss**?** After all, if someone is lost, and that person is not someone, then what and where is the loss, and how does mourning take place?¶ This last is surely a question that lesbian, gay, and hi-studies have asked in relation to violence against sexual minorities; that transgendered people have asked as they are singled out for harassment and sometimes murder; that intersexed people have asked, whose formative years are so often marked by unwanted violence against their bodies in the name of a normative notion of the human, a normative notion of what the body of a human must be. This question is no doubt, as well, the basis of a profound affinity between movements centering on gender and sexuality and efforts to counter the normative human morphologies and capacities that condemn or efface those who are physically challenged. **It must** also **be part of** the affinity with **anti-racist struggles, given the racial differential that undergirds** the **culturally viable notions of the human**, ones that we see **acted out in** dramatic and **terrifying ways in the global arena** at the present time**.**¶ I am referring not only to humans not regarded as humans, and thus to a restrictive conception of the human that is based upon their exclusion. **It is** not a matter of a simple entry of the excluded into an established ontology, but **an insurrection at the level of ontology**, a critical opening up of the questions, What is real? **Whose lives are real?** How might reality be remade? Those who are unreal have, in a sense, already suffered the violence of derealization. What, then, is the relation between violence and those lives considered as "unreal"? Does violence effect that unreality? Does violence take place on the condition of that unreality?¶ If violence is done against those who are unreal, then, from the perspective of violence, it fails to injure or negate those lives since those lives are already negated. But they have a strange way of remaining animated and so must be negated again (and again). They cannot be mourned because they are always already lost or, rather, never "were," and they must be killed, since they seem to live on, stubbornly, in this state of deadness. Violence renews itself in the face of the apparent inexhaustibility of its object. The derealization of the "Other" means that it is neither alive nor dead, but interminably spectral. The infinite paranoia that imagines the war against terrorism as a war without end will be one that justifies itself endlessly in relation to the spectral infinity of its enemy, regardless of whether or not there are established grounds to suspect the continuing operation of terror cells with violent aims.¶ How do we understand this derealization? It is one thing to argue that first, **on the level of discourse, certain lives are not considered lives at all**, they cannot be humanized, that they fit no dominant frame for the human, and that **their dehumanization** occurs first, at this level, and that this level then **gives rise to** a physical **violence that** in some sense **delivers the message of dehumanization** that is **already at work in the culture.** It is another thing to say that discourse itself effects violence through omission. If 2oo,ooo Iraqi children were killed during the Gulf War and its aftermath/ do we have an image, a frame for any of those lives, singly or collectively? Is there a story we might find about those deaths in the media? **Are there names attached to those children?**¶ There are no obituaries for the war casualties that the United States inflicts, and there cannot be. If there were to be an obituary, there would have had to have been a life, a life worth noting, **a life worth valuing and preserving, a life that qualifies for recognition.** Although we might argue that it would be impractical to write obituaries for all those people, or for all people, I think we have to ask, again and again, how the obituary functions as the instrument by which grievability is publicly distributed. It is the means by which a life becomes, or fails to become, a publicly grievable life, an icon for national self-recognition, the means by which a life becomes noteworthy. As a result, we have to consider the obituary as an act of nation-building. The matter is not a simple one, for, if a life is not grievable, it is not quite a life; it does not qualify as a life and is not worth a note. It is already the unburied, if not the unburiable.¶ It is not simply, then, that there is a "discourse" of dehumanization that produces these effects, but rather that there is a limit to discourse that establishes the limits of human intelligibility. It is not just that a death is poorly marked, but that it is unmarkable. Such a death vanishes, not into explicit discourse, but in the ellipses by which public discourse proceeds. The queer lives that vanished on September I I were not publicly welcomed into the idea of national identity built in the obituary pages, and their closest relations were only belatedly and selectively (the marital norm holding sway once again) made eligible for benefits. But this should come as no surprise, when we think about how few deaths from AIDS were publicly grievable losses, and how, for instance, the extensive deaths now taking place in Africa are also, in the media, for the most part unmarkable and ungrievable.

**Underview 2**

**Their disads will surely be ridiculous.**

**(A) Ethics – WTO countries are complicit in hoarding lifesaving medicines from the world’s most vulnerable people. Apply a *VERY* high standard of proof to any rationalization of that policy.**

**(B) Compound Probability - Multiplied probabilities of long link chains have negligible net probabilities. This is the slippery slope fallacy.**

**(C) Causal Direction - They will say the fractional probability of a huge impact still has a large expected value, but it’s impossible to determine the direction of low-probability links. Does the butterfly flapping its wings cause the hurricane or prevent it? Disregard tiny-probability links because they don’t guide decision-making.**

**(D) Complexity – the DA presents a simplistic and deterministic narrative that fails to account for the myriad confounding factors that can disrupt or reverse the link chain of the DA. The most important of these is the probability that people will recognize the dangerous path they’re on and change course, e.g. leaders backing down during the Cuban Missile Crisis.**

**(E) Decision Gridlock – Every course of action or inaction has a negligible possibility of causing extinction. This makes it impossible**

**to prioritize averting existential risk over all else because such risk is unavoidable. We have no choice but to prioritize REALISTIC probabilities**

#### (F) Apocalyptic rhetoric is an independent voter – justifies violence, trades off with addressing real risks, and causes nihilism.

**Pinker ’18** - Steven Pinker [Johnston Professor of Psychology, Harvard U.], Enlightenment Now: The Case for Reason, Science, Humanism, and Progress. New York: Viking. (2018). pp. 291-292

At first glance one might think that the more thought we give to existential risks, the better. The stakes, quite literally, could not be higher. What harm could there be in getting people to think about these terrible risks? The worst that could happen is that we would take some precautions that turn out in retrospect to have been unnecessary.¶ But apocalyptic thinking has serious downsides. One is that false alarms to catastrophic risks can themselves be catastrophic. The nuclear arms race of the 1960s, for example, was set off by fears of a mythical “missile gap” with the Soviet Union.1 The 2003 invasion of Iraq was justified by the uncertain but catastrophic possibility that Saddam Hussein was developing nuclear weapons and planning to use them against the United States. (As George W. Bush put it, “We cannot wait for the final proof—the smoking gun—that could come in the form of a mushroom cloud.”) And as we shall see, one of the reasons the great powers refuse to take the common-sense pledge that they won’t be the first to use nuclear weapons is that they want to reserve the right to use them against other supposed existential threats such as bioterror and cyberattacks.2 Sowing fear about hypothetical disasters, far from safeguarding the future of humanity, can endanger it.¶ A second hazard of enumerating doomsday scenarios is that humanity has a finite budget of resources, brainpower, and anxiety. You can’t worry about everything. Some of the threats facing us, like climate change and nuclear war, are unmistakable, and will require immense effort and ingenuity to mitigate. Folding them into a list of exotic scenarios with minuscule or unknown probabilities can only dilute the sense of urgency. Recall that people are poor at assessing probabilities, especially small ones, and instead play out scenarios in their mind’s eye. If two scenarios are equally imaginable, they may be considered equally probable, and people will worry about the genuine hazard no more than about the science-fiction plotline. And the more ways people can imagine bad things happening, the higher their estimate that something bad *will* happen.¶ And that leads to the greatest danger of all: that people will think, as a recent New York Times article put it, “These grim facts should lead any reasonable person to conclude that humanity is screwed.”3 If humanity is screwed, why sacrifice anything to reduce potential risks? Why forgo the convenience of fossil fuels, or exhort governments to rethink their nuclear weapons policies? Eat, drink, and be merry, for tomorrow we die! A 2013 survey in four English-speaking countries showed that among the respondents who believe that our way of life will probably end in a century, a majority endorsed the statement “The world’s future looks grim so we have to focus on looking after ourselves and those we love.”4¶ Few writers on technological risk give much thought to the cumulative psychological effects of the drumbeat of doom. As Elin Kelsey, an environmental communicator, points out, “We have media ratings to protect children from sex or violence in movies, but we think nothing of inviting a scientist into a second grade classroom and telling the kids the planet is ruined. A quarter of (Australian) children are so troubled about the state of the world that they honestly believe it will come to an end before they get older.”5 According to recent polls, so do 15 percent of people worldwide, and between a quarter and a third of Americans.6 In The Progress Paradox, the journalist Gregg Easterbrook suggests that a major reason that Americans are not happier, despite their rising objective fortunes, is “collapse anxiety”: the fear that civilization may implode and there’s nothing anyone can do about it.

#### (G) Distrust low-probability predictions of catastrophe – subjectivity, cognitive bias, and history of failed predictions.

**Pinker ’18** - Steven Pinker [Johnston Professor of Psychology, Harvard U.], Enlightenment Now: The Case for Reason, Science, Humanism, and Progress. New York: Viking. (2018). pp. 292-295

Of course, people’s emotions are irrelevant if the risks are real. But risk assessments fall apart when they deal with highly improbable events in complex systems. Since we cannot replay history thousands of times and count the outcomes, a statement that some event will occur with a probability of .01 or .001 or .0001 or .00001 is essentially a readout of the assessor’s subjective confidence. This includes mathematical analyses in which scientists plot the distribution of events in the past (like wars or cyberattacks) and show they fall into a power-law distribution, one with “fat” or “thick” tails, in which extreme events are highly improbable but not astronomically improbable.7 The math is of little help in calibrating the risk, because the scattershot data along the tail of the distribution generally misbehave, deviating from a smooth curve and making estimation impossible. All we know is that very bad things can happen.¶ That takes us back to subjective readouts, which tend to be inflated by the Availability and Negativity biases and by the gravitas market (chapter 4).8 Those who sow fear about a dreadful prophecy may be seen as serious and responsible, while those who are measured are seen as complacent and naïve. Despair springs eternal. At least since the Hebrew prophets and the Book of Revelation, seers have warned their contemporaries about an imminent doomsday. Forecasts of End Times are a staple of psychics, mystics, televangelists, nut cults, founders of religions, and men pacing the sidewalk with sandwich boards saying “Repent!”9 The storyline that climaxes in harsh payback for technological hubris is an archetype of Western fiction, including Promethean fire, Pandora’s box, Icarus’s flight, Faust’s bargain, the Sorcerer’s Apprentice, Frankenstein’s monster, and, from Hollywood, more than 250 end-of-the-world flicks.10 As the engineer Eric Zencey has observed, “There is seduction in apocalyptic thinking. If one lives in the Last Days, one’s actions, one’s very life, take on historical meaning and no small measure of poignance.”11¶ Scientists and technologists are by no means immune. Remember the Y2K bug?12 In the 1990s, as the turn of the millennium drew near, computer scientists began to warn the world of an impending catastrophe. In the early decades of computing, when information was expensive, programmers often saved a couple of bytes by representing a year by its last two digits. They figured that by the time the year 2000 came around and the implicit “19” was no longer valid, the programs would be long obsolete. But complicated software is replaced slowly, and many old programs were still running on institutional mainframes and embedded in chips. When 12:00 A.M. on January 1, 2000, arrived and the digits rolled over, a program would think it was 1900 and would crash or go haywire (presumably because it would divide some number by the difference between what it thought was the current year and the year 1900, namely zero, though why a program would do this was never made clear). At that moment, bank balances would be wiped out, elevators would stop between floors, incubators in maternity wards would shut off, water pumps would freeze, planes would fall from the sky, nuclear power plants would melt down, and ICBMs would be launched from their silos.¶ And these were the hardheaded predictions from tech-savvy authorities (such as President Bill Clinton, who warned the nation, “I want to stress the urgency of the challenge. This is not one of the summer movies where you can close your eyes during the scary part”). Cultural pessimists saw the Y2K bug as comeuppance for enthralling our civilization to technology. Among religious thinkers, the numerological link to Christian millennialism was irresistible. The Reverend Jerry Falwell declared, “I believe that Y2K may be God’s instrument to shake this nation, humble this nation, awaken this nation and from this nation start revival that spreads the face of the earth before the Rapture of the Church.” A hundred billion dollars was spent worldwide on reprogramming software for Y2K Readiness, a challenge that was likened to replacing every bolt in every bridge in the world.¶ As a former assembly language programmer I was skeptical of the doomsday scenarios, and fortuitously I was in New Zealand, the first country to welcome the new millennium, at the fateful moment. Sure enough, at 12:00 A.M. on January 1, nothing happened (as I quickly reassured family members back home on a fully functioning telephone). The Y2K reprogrammers, like the elephant-repellent salesman, took credit for averting disaster, but many countries and small businesses had taken their chances without any Y2K preparation, and they had no problems either. Though some software needed updating (one program on my laptop displayed “January 1, 19100”), it turned out that very few programs, particularly those embedded in machines, had both contained the bug and performed furious arithmetic on the current year. The threat turned out to be barely more serious than the lettering on the sidewalk prophet’s sandwich board. The Great Y2K Panic does not mean that all warnings of potential catastrophes are false alarms, but it reminds us that we are vulnerable to techno-apocalyptic delusions.

#### (H) No infinite-risk analysis. Low-probability existential threats can’t be compared, and are so unlikely that a reasonable decision-maker can ignore them.

Dolley ’86 - Steven D. Dolley [University of Vermont], “APOCALYPSE WHEN?:Determining and Comparing Catastrophic Risks,” Fertile Ground : The Agriculture Debate (1986). AT

1. The impact is absolute. Any risk is enough.¶ Many disasters such as a nuclear war or total destruction of the Earth's ecosystem are likely infinite-magnitude harms, in that they would engender the extinction of humanity and most other forms of life. Any likelihood of such an infinite-magnitude harm creates an infinite risk, since infinity times anything greater than zero is infinity. Disarmament activist Johnathan Schell gave an eloquent summary of the "any risk" position, which sounds hauntingly familiar to those who have heard dozens of second negative rebuttals.¶ (T)he mere risk of extinction has a significance that is categorically different from, and immeasurably greater than, that of any other risk, and as we make our decisions we have to take that significance into account . . . . We have no right to place the possibility of this limitless, eternal defeat on the same footing as risks that we run in the ordinary conduct of our affairs in our particular transient moment of human history. To employ a mathematical analogy, we can say that although the risk of extinction may be fractional, the stake is, humanly speaking, infinite, and a fraction of infinity is still infinity. In other words, once we learn that a holocaust might lead to extinction we have no right to gamble, because if we lose, the game will be over, and neither we nor anyone else will ever get another chance. 5/¶ Mathematically this argument is valid, but it becomes difficult or impossible to apply in practice. First, it is a rare debate indeed where only one team is claiming to avoid an infinite-magnitude harm. This will be especially true on this year's agricultural policy topic. When both teams claim to avoid total catastrophe, the likelihood of occurrence must be sketched sharply enough that likelihood can be compared. After all, what can a judge do if either choice s/he is presented with carries infinite risk? Under such circumstances, why not just get drunk and wait for the mushroom clouds?¶ Second, the risk analyst must discern if any likelihood at all adheres to the infinite-magnitude harm. The logic of the "any risk" position itself requires this, since even infinity times zero equals zero. Quite frequently, scenarios for global destruction are so poorly documented, extended, or linked to the issue at hand that essentially no likelihood of occurrence exists. Certainly it would be cavalier and foolhardy to ignore apocalyptic threats, but it seems equally silly and futile to live our lives cowering in fear of a million imaginary Rube Goldberg-like disasters that have no chance of occurring. If I get up now, walk over to my cassette blaster and pop in a tape, there is an ephemeral chance of my being electrocuted even before Jerry and the boys begin to play "Sugaree." After all, my blaster is crackling with 120 volts of alternating current. Merely touching it could, if there were a short circuit, end my career as a forensic wise guy in one big blue flash. Nevertheless, I routinely discount that minimal-likelihood hazard. Its risk is so low as to be ignored. So, excuse me for a moment; the music has stopped.

#### (I) Hold extinction impacts to a high burden of proof. Even huge disasters don’t lead to extinction. Just calling something existential doesn’t make it so.

**Pinker ’18** - Steven Pinker [Johnston Professor of Psychology, Harvard U.], Enlightenment Now: The Case for Reason, Science, Humanism, and Progress. New York: Viking. (2018). pp. 305-306

For the techno-doomsters, though, tiny probabilities are no comfort. All it will take, they say, is for one hacker or terrorist or rogue state to get lucky, and it’s game over. That’s why the word threat is preceded with existential, giving the adjective its biggest workout since the heyday of Sartre and Camus. In 2001 the chairman of the Joint Chiefs of Staff warned that “the biggest existential threat out there is cyber” (prompting John Mueller to comment, “As opposed to small existential threats, presumably”).¶ This existentialism depends on a casual slide from nuisance to adversity to tragedy to disaster to annihilation. Suppose there was an episode of bioterror or bioterror that killed a million people. Suppose a hacker did manage to take down the Internet. Would the country literally cease to exist? Would civilization collapse? Would the human species go extinct? A little proportion, please—even Hiroshima continues to exist! The assumption is that modern people are so helpless that if the Internet ever went down, farmers would stand by and watch their crops rot while dazed city-dwellers starved. But disaster sociology (yes, there is such a field) has shown that people are highly resilient in the face of catastrophe.53 Far from looting, panicking, or sinking into paralysis, they spontaneously cooperate to restore order and improvise networks for distributing goods and services. Enrico Quarantelli noted that within minutes of the Hiroshima nuclear blast,¶ survivors engaged in search and rescue, helped one another in whatever ways they could, and withdrew in controlled flight from burning areas. Within a day, apart from the planning undertaken by the government and military organizations that partly survived, other groups partially restored electric power to some areas, a steel company with 20 percent of workers attending began operations again, employees of the 12 banks in Hiroshima assembled in the Hiroshima branch in the city and began making payments, and trolley lines leading into the city were completely cleared with partial traffic restored the following day.54¶ One reason that the death toll of World War II was so horrendous is that war planners on both sides adopted the strategy of bombing civilians until their societies collapsed—which they never did.55 And no, this resilience was not a relic of the homogeneous communities of yesteryear. Cosmopolitan 21st-century societies can cope with disasters, too, as we saw in the orderly evacuation of Lower Manhattan following the 9/11 attacks in the United States, and the absence of panic in Estonia in 2007 when the country was struck with a devastating denial-of-service cyberattack.56

**(J)Prioritize probability.**

**Kessler 08** (Oliver; April 2008; PhD in IR, professor of sociology at the University of Bielefeld, and professor of history and theory of IR at the Faculty of Arts; Alternatives, Vol. 33, “From Insecurity to Uncertainty: Risk and the Paradox of Security Politics” p. 211-232)

The problem of the second method is that it is very difficult to "calculate" politically unacceptable losses. If the risk of terrorism is defined in traditional terms by probability and potential loss, then the focus on dramatic terror attacks leads to the **marginalization of probabilities**. The reason is that even the highest degree of improbability **becomes irrelevant** as the measure of loss goes to infinity.^o The mathematical calculation of the risk of terrorism thus tends to overestimate and to dramatize the danger. This has consequences beyond the actual risk assessment for the formulation and execution of "risk policies": If one factor of the risk calculation approaches infinity (e.g., if a case of nuclear terrorism is envisaged), then there is no balanced measure for antiterrorist efforts, and **risk management as a rational endeavor breaks down**. Under the historical condition of bipolarity, the "ultimate" threat with nuclear weapons could be balanced by a similar counterthreat, and new equilibria could be achieved, albeit on higher levels of nuclear overkill. Under the new condition of uncertainty, no such rational balancing is possible since knowledge about actors, their motives and capabilities, is largely absent. The second form of security policy that emerges when the deterrence model collapses mirrors the "social probability" approach. It represents a **logic of catastrophe**. In contrast to risk management framed in line with logical probability theory, the logic of catastrophe does not attempt to provide means of absorbing uncertainty. Rather, it takes uncertainty as constitutive for the logic itself; uncertainty is a crucial precondition for catastrophes. In particular, catastrophes happen at once, without a warning, but with major implications for the world polity. In this category, we find the impact of meteorites. Mars attacks, the tsunami in South East Asia, and 9/11. To conceive of terrorism as catastrophe has consequences for the formulation of an adequate security policy. Since catastrophes hap-pen irrespectively of human activity or inactivity, **no political action** could possibly prevent them. Of course, there are precautions that can be taken, but the framing of terrorist attack as a catastrophe points to spatial and temporal characteristics that are beyond "rationality." Thus, political decision makers are exempted from the responsibility to provide security—as long as they at least try to preempt an attack. Interestingly enough, 9/11 was framed as catastrophe in various commissions dealing with the question of who was responsible and whether it could have been prevented. This makes clear that under the condition of uncertainty, there are no objective criteria that could serve as an anchor for measuring dangers and assessing the quality of political responses. For ex- ample, as much as one might object to certain measures by the US administration, it is almost impossible to "measure" the success of countermeasures. Of course, there might be a subjective assessment of specific shortcomings or failures, but there is no "common" currency to evaluate them. As a consequence, the framework of the security dilemma fails to capture the basic uncertainties. Pushing the door open for the security paradox, the main problem of security analysis then becomes the question how to integrate dangers in risk assessments and security policies about which simply nothing is known. In the mid 1990s, a Rand study entitled "New Challenges for Defense Planning" addressed this issue arguing that "most striking is the fact that we do not even know who or what will constitute the most serious future threat, "^i In order to cope with this challenge it would be essential, another Rand researcher wrote, to break free from the "tyranny" of plausible scenario planning. The decisive step would be to create "discontinuous scenarios ... in which there is **no plausible** audit **trail** or storyline from current events"52 These nonstandard scenarios were later called "wild cards" and became important in the current US strategic discourse. They justified the transformation from a threat-based toward a capability- based defense planning strategy.53 The problem with this kind of risk assessment is, however, that even the most **absurd scenarios** can gain plausibility. By constructing a **chain of potentialities**, improbable events are linked and brought into the realm of the possible, if not even the probable. "Although the likelihood of the scenario dwindles with each step, the residual impression is one of plausibility. "54 This so-called Othello effect has been effective in the dawn of the recent war in Iraq. The connection between Saddam Hussein and Al Qaeda that the US government tried to prove was disputed from the very beginning. False evidence was again and again presented and refuted, but this did not prevent the administration from presenting as the main rationale for war the improbable yet possible connection between Iraq and the terrorist network and the improbable yet possible proliferation of an improbable yet possible nuclear weapon into the hands of Bin Laden. As Donald Rumsfeld famously said: "**Absence of evidence is not evidence of absence**." This sentence indicates that under the condition of genuine uncertainty, different evidence criteria prevail than in situations where security problems can be assessed with relative certainty.

**(J) We can’t predict extinction impacts**

**Matheson 15** (Calum Matheson – This is his PhD dissertation at the University of North Carolina at Chapel Hill, “Desired Ground Zeros: Nuclear Imagination and the Death Drive”, https://cdr.lib.unc.edu/indexablecontent/uuid:4bbcb13b-0b5f-43a1-884c-fcd6e6411fd6, pgs. 77 – 86,)

Herman Kahn and Bernard Brodie, perhaps the most prominent American strategists of the early Cold War, tried to make nuclear war “thinkable” in the sense that they tried to explain how such a war might start and what options would exist for national leaders. At the same time, both acknowledged that the outcome of a full-scale nuclear war was indescribable. In Brodie’s words, to “make an intellectual prediction of the likelihood of war is one thing, to project oneself imaginatively and seriously into an expected war situation is quite another” (Ghamari-Tabrizi 149). The unwillingness or inability to think “seriously” about a nuclear war—in other words, to understand it instrumentally rather than through dislocating language of the sublime—was met by organizations like the RAND Corporation with an attempt to systematize nuclear strategy and develop the intellectual and technical means to actually fight and control a nuclear war. Before RAND exercised its power through the “Whiz Kids” of the Kennedy Administration, the Strategic Air Command’s “Sunday punch” nuclear plan, enshrined in SIOP-62, was an all-out nuclear attack on the USSR, Eastern Europe, and the People’s Republic of China. It might have killed 285 million people in the initial attack (Kaplan 269). Despite its intricate planning and detailed execution strategies, SIOP was immensely inflexible. Asked whether the U.S. had any options to attack without striking China, which might not even be a combatant in the war, General Thomas Power replied “Well yeh [sic], we could do that, but I hope nobody thinks of it because it would really screw up the plan” (Kaplan 270, emphasis in original). Starting in the 1960s, a set of war games of various complexity was developed to test a broader range of nuclear theories and attack options at RAND and elsewhere (Arbella 35). Games like them continue to be used for strategic military planning today (Raatz). Most of these games—or at least their results—are classified, as they became the basis for US nuclear plans. In politicomilitary games, a number of military officers, civilians, and generally mid- to lowranking government officials would play various roles as US and/or foreign. decisionmakers. Another group, “control,” would feed them information about the actions of countries or groups not played by the participants or about world events that might influence the context of their actions. In more limited military simulations, extant or proposed war plans would be evaluated by computer or human players to identify possible flaws and improvements. The games themselves **never had a guarantee of accuracy and were often quite obviously flawed**. In one Navy game, American aircraft carriers were declared to be unsinkable. In others, the Soviet Union was assumed to have no effective airpower. Because factors like air pressure, prevailing winds, defense effectiveness, early warning, and missile failure rate were largely random or incalculable, a “fudge factor” simply declared estimated success. Even their designers sometimes admitted that the games were inaccurate, unprovable, or simply wishful thinking (Ghamari-Tabrizi 8; Allen 78). Especially in the case of nuclear war, these games **cannot possibly be understood as accurate simulations of a real-world system,** because there is **no empirical data** on the compound effects of many near-simultaneous nuclear explosions and no data **on what factors cause states to cross the nuclear threshold** against other similarly-armed states, a fact that bedevils nuclear planning in general and always has (Kaplan 87). By the admission of many of those who create and play them, they are “social science fiction” with no tangible effect other than that they are entertaining (Ghamari-Tabrizi 160-1). Some contemporary **social science work supports this claim especially in the context of extinction-level events.** Human beings simply aren’t wired to think at such a scale, and they perform very poorly assessing probability and calculating magnitude (Yudkowsky). Others have suggested that warfare is a stochastic system that we could never identify laws for, no matter how diligent we might be, because its initial conditions are simply too complex a model and they do not conform to linear causality (Beyerchen; Buchanan 62). Indeed, military planners tended to be far less willing to predict the conduct and outcome of a conventional war—despite an enormous data set spanning thousands of years—than a nuclear war fought between two superpowers, an event that has never occurred in recorded history. Fred Iklé, former RAND strategists who was at times head of the Arms Control and Disarmament Agency and Undersecretary of Defense for Policy, criticized these semi-mathematical abstractions in harsh terms that deserve to be quoted at length: The prominence of the calculations continues because we know how to make them…we have tailored the problem to our capability to calculate. The seemingly rigorous models of nuclear deterrence are built on the rule: "What cannot be calculated, leave out’”…Such thoughts, especially those focusing on deterrence, lack real empirical referents or bases. No other field of human endeavor demands—absolutely compels—one to work out successful solutions without obtaining directly relevant experience, without experimenting. There can be no trial and error here, no real learning. Curiously, we are far more skeptical in accepting the calculations of traditional conventional military campaigns than the calculations of nuclear warfare. In fact, the more battle experience and information military analysts have, the more modest they become in predicting the course of conventional war. Such modesty is missing for nuclear war, where pretentious analyses and simplistic abstractions dominate and blot out the discrepancies existing between abstractions and possible reality—a reality that for so many reasons is hard even to imagine. (Iklé 246). Iklé is drawing attention to two unique aspects of nuclear war planning: first, that no empirical date (or at least very little) can be gathered for the species of war that planners concerned themselves with, and second, that unlike other military problems where little data exists, defense intellectuals were willing to display great confidence in untested (and untestable) theories. Despite this lack of empirical grounding, nuclear war simulations have been repeated again and again over the decades while nuclear doctrine has remained fundamentally the same (McKinzie et al. ix-xi). There has been some dispute in military circles about whether these exercises should be called simulations or games, with “simulations” becoming more popular by the 1980s (Allen 7). To call politico-military exercises “roleplaying games” conjures images of adolescent boys rolling dice and weaving fantasies about orcs and dragons. To call battle simulations “war games” might associate them with videogames produced for entertainment. Still, even military officers responsible for the creation of these artifacts had trouble distinguishing between game, model, and simulation and used them interchangeably. In his comprehensive history of U.S. wargaming, Thomas Allen writes that the three words “hover over imaginary battlefields like a mysterious, ever-shifting concept of the Trinity” (64, emphasis added). Berger, Boulay and Zisk, writing in the journal Simulation & Gaming acknowledge that “[d]efinitions of simulation are legion,” but center on representations of a system that allow users to model behavior (Berger et al. 416). Brewer and Shubik define games as a subset of simulation and simulation as a subset of modelling, the key defining feature of a game being the inclusion of human beings playing roles. Still, their extended attempt to define these terms results in the acronym MSG, grouping them all together (3-8). The difficulty in Brewer and Shubik’s definition is that all models and simulations require that human beings make decisions at least indirectly, at a minimum defining the independent variables and the parameters of the exercise. As a result, they all create some possibility for investment in the outcome. In common usage, the difference between simulations and models, on the one hand, and games, on the other appears to be a ludic dimension. Games are for play, with an agent making decisions within a set of prescribed rules to change the outcome, while simulations and models may simply represent the rules of a system. The least common denominator is that one rules-bound system—the game— stands in for another. Games, simulations, and models therefore have a metaphorical quality to them.10 In his work on videogames, Ian Bogost has identifies what he calls procedural rhetoric as “the practice of persuading through processes in general and computational processes in particular…a technique for making arguments with computational systems and for unpacking computational arguments others have created” (3). Whereas oral rhetoric attempts to persuade an audience to adopt a particular viewpoint through speech and written rhetoric does the same through writing, procedural rhetoric has its own unique goals and characteristics suited to the medium of games. Videogames create a digital process that simulates a real-world process, allowing the player to model something extant in the world of flesh, blood, steel and glass that exists outside of the game. Procedural rhetoric is the persuasive aspect of simulation. Bogost’s argument might be adapted to this understanding of metaphor. The replacement of the tenor (the thing represented) with the vehicle (the signifier standing in for it) makes an enthymematic argument that draws the audience to do the work of cathexis in connecting the two based on the shared principle that allows the substitution. This does not suggest that we read games as texts. Games require their players to invest in a specific way because they are called on to make choices that alter the outcome. Players identify with their characters in a powerful way: what is shared is not just a set of traits, but decisions over time that, to maintain the interest that keeps players playing, require at least some minimal attachment. One can identify deeply with Sauron, but no reading of Lord of the Rings can make him finally subjugate his haughty human and elven foes, let alone order the Scourging of the Shire and its disgustingly bourgeois hobbits when he still has a chance to succeed.11 This is the procedural element of Bogost’s theory: it is the procedure that links the system with its representation in the game, and the sense of control that binds us, something that differentiates this medium from others. One doesn’t have to decide that play matters and narrative doesn’t—it is the interaction between the two that channels the player’s investment in a game. In war games, attachments are formed even when a computerized Sam fights a computerized Ivan to test the SIOP and RSIOP.12 Allen’s book is full of examples of war game players becoming emotionally tied to their games, sometimes in perverse ways. Failing in a game that he was allowed to play, Allen himself described his team reacting with shock, real shock, not just a reaction to a bad break in a game. We were really feeling upset about what was happening in our imaginary world. ‘What is happening to our institutions?’ someone indignantly asked, as if real institutions were really going through what the situation paper had described. I had an unreasonable feeling of helplessness and failure. Some of us spoke softly to each other about having failed. (18). The prevalence of this reaction is confirmed in more recent scholarship by Paul Bracken