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#### The standard is maximizing expected well being. Prefer –

#### 1] Only pleasure and pain are intrinsically valuable – all other frameworks collapse.

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]

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.

#### 2] The public nature of policy-making necessitates consequentialism.

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The central point of conflict is that the first concern of those responsible for public policy is, and ought to be, the consequences of their actions for public policy and the persons that those policies affect. This is not to say that they should not be concerned with the moral evaluation of those consequences-they should; nor that they must be moral consequentialists in the evaluation of the policy, and in turn human, consequences of their actions-whether some form of consequentialism is an adequate moral theory is another matter. But it is to say that persons who directly participate in the formation of public policy would be irresponsible if they did not focus their concern on how their actions will affect policy and how that policy will in turn affect people. The virtues of academic research and scholarship that consist in an unconstrained search for truth, whatever the consequences, reflect not only the different goals of scholarly work but also the fact that the effects of the scholarly endeavor on the public are less direct, and are mediated more by other institutions and events, than are those of the public policy process. It is in part the very impotence in terms of major, direct effects on people's lives of most academic scholarship that makes it morally acceptable not to worry much about the social consequences of that scholarship. When philosophers move into the policy domain, they must shift their primary commitment from knowledge and truth to the policy consequences of what they do. And if they are not prepared to do this, why did they enter the policy domain? What are they doing there?

#### 3] Weighability – only consequentialism can explain the ethical difference in breaking a promise to take someone to the hospital and breaking a promise to take someone to lunch

#### 4] Intuitions outweigh – they’re a necessary side constraint on all ethics – philosophy follows intuitions not the other way around

#### Consequences can be used to judge actions before they occur via predictions

#### There are infinite stemming consequences, but a few of them we can guarantee are 99.999% likely and effect the most people. When I drop a glass, it will break and probably injure my lower body

#### Probability theory is by definition deductive not inductive – we can extrapolate based on trends we don’t only look at what has already happened.

#### Probability doesn’t assume causation – and correlation is enough to act 90% of the time

#### Off case plans do not flow aff – an alternative and exclusive course of action disproves a general principle because it is actively worse than another scenario

#### Actions can be singular and indivisible – fiat makes the time spent to pass the plan functionally 0 and forces us to consider only what happens after passage

#### Reading Koorsgaard “to benefit small schools” is the most backwards thing I’ve ever heard – most circuit debate is policy and there are stock positions that allow the lone wolf type to exist, not to mention just getting prep from the wiki and generics from the open ev project

#### Consequentialism is universalizable, while absolute defense of rights fail

Nielsen, Kai [Ph.D. at Duke University Emeritus of philosophy at the University of Calgary. Before moving to Canada, Nielsen taught at New York University (NYU). He specializes in metaphilosophy, ethics, and social and political philosophy.. ]. "Against moral conservativism." Ethics 82.3 (1972): 219-231.

Alan Donagan, arguing rather as Anscombe argues, maintains that "to use any innocent man ill for the sake of some public good is directly to degrade him to being a mere means" and to do this is of course to violate a principle essential to morality, that is, that human beings should never merely be treated as means but should be treated as ends in them selves (as persons worthy of respect)." But, as my above remarks show, it need not be the case, and in the above situation it is not the case, that in killing such an innocent man we are treating him merely as a means. The action is universalizable, all alternative actions which would save his life are duly considered, the blasting out is done only as a last and desperate resort with the minimum of harshness and indifference to his suffering and the like. It indeed sounds ironical to talk this way, given what is done to him. But if such a terrible situation were to arise, there would always be more or less humane ways of going about one's grim task. And in acting in the more humane ways toward the fat man, as we do what we must do and would have done to ourselves were the roles reversed, we show a respect for his person.12 In so treating the fat man-not just to further the public good but to prevent the certain death of a whole group of people (that is to pre vent an even greater evil than his being killed in this way)-the claims of justice are not overidden either, for each individual involved, if he is reasoning correctly, should realize that if he were so stuck rather than the fat man, he should in such situations be blasted out. Thus, there is no question of being unfair. Surely we must choose between evils here, but is there anything more reasonable, more morally appropriate, than choosing the lesser evil when doing or allowing some evil cannot be avoided? That is, where there is no avoiding both and where our actions can determine whether a greater or lesser evil obtains, should we not plainly always opt for the lesser evil? And is it not obviously a greater evil that all those other innocent people should suffer and die than that the fat man should suffer and die? Blowing up the fat man is indeed monstrous. But letting him remain stuck while the whole group drowns is still more monstrous. The consequentialist is on strong moral ground here, and, if his reflective moral convictions do not square either with certain unre hearsed or with certain reflective particular moral convictions of human beings, so much the worse for such commonsense moral convictions. One could even usefully and relevantly adapt here-though for a quite different purpose-an argument of Donagan's. Consequentialism of the kind I have been arguing for provides so persuasive "a theoretical basis for common morality that when it contradicts some moral intuition, it is natural to suspect that intuition, not theory, is corrupt."13 Given the comprehensiveness, plausibility, and overall rationality of consequential ism, it is not unreasonable to override even a deeply felt moral convic tion if it does not square with such a theory, though, if it made no sense or overrode the bulk of or even a great many of our considered moral convictions, that would be another matter indeed.

#### Consequentialism is apriori in the relevant sense, but a stronger account apriori is wrong.

Nielsen, Kai [Ph.D. at Duke University Emeritus of philosophy at the University of Calgary. Before moving to Canada, Nielsen taught at New York University (NYU). He specializes in metaphilosophy, ethics, and social and political philosophy.. ]. "Against moral conservativism." Ethics 82.3 (1972): 219-231.

We should not take such a short way with consequentialists, for what is true in Donagan's claim about moral theory's being a priori will not refute or even render implausible consequentialism, and what would undermine it in such a claim about the a priori nature of moral theory and presumably moral claims is not true. To say that moral theory is a priori is probably correct if that means that categorical moral claims-fundamental moral statements-can not be deduced from empirical statements or nonmoral theological state ments, such that it is a contradiction to assert the empirical and/or non moral theologcial statements and deny the categorical moral claims or vice versa.10 In that fundamental sense, it is reasonable and, I believe, justifiable to maintain that moral theory is autonomous and a priori. It is also a priori in the sense that moral statements are not themselves a kind of empirical statement. That is, if I assert 'One ought never to tor ture any sentient creature' or 'One ought never to kill an innocent man,' I am not trying to predict or describe what people do or are likely to do but am asserting what they are to do. It is also true that, if a moral statement is true, it holds for all possible worlds in which situations of exactly the sort characterized in the statement obtain. If it is true for one, it is true for all. You cannot consistently say that A ought to do B in situation Y and deny that someone exactly like A in a situation exactly like Y ought to do B. In these ways, moral claims and indeed moral theory are a priori. But it is also evident that none of these ways will touch the conse quentialist or utilitarian arguments. After all, the consequentialist need not be, and typically has not been, an ethical naturalist-he need not think moral claims are derivable from factual claims or that moral claims are a subspecies of empirical statement and he could accept-indeed, he must accept-what is an important truism anyway, that you cannot con sistently say that A ought to do B in situation Y and deny that someone exactly like A in a situation exactly like Y ought to do B. But he could and should deny that moral claims are a priori in the sense that rational men must or even will make them without regard for the context, the situation, in which they are made. We say people ought not to drive way over the speed limit, or speed on icy roads, or throw knives at each other. But, if human beings had a kind of metallic exoskeleton and would not be hurt, disfigured, or seriously inconvenienced by knives sticking in them or by automobile crashes, we would not-so evidently at least have good grounds for saying such speeding or knife throwing is wrong. It would not be so obvious that it was unreasonable and immoral to do these things if these conditions obtained. In the very way we choose to describe the situation when we make ethical remarks, it is important in making this choice that we know what the world is like and what human beings are like. Our understanding of the situation, our understanding of human nature and motivation can not but effect our structuring of the moral case. The consequentialist is saying that, as the world goes, there are good grounds for holding that judicial killings are morally intolerable, though he would have to admit that if the world (including human beings) were very different, such killings could be something that ought to be done. But, in holding this, he is not committed to denying the universalizability of moral judg ments, for, where he would reverse or qualify the moral judgment, the situation must be different. He is only committed to claiming that, where the situation is the same or relevantly similar and the persons are rele vantly similar, they must, if they are to act morally, do the same thing. However, he is claiming both (1) that, as things stand, judicial killing of the innocent is always wrong and (2) that it is an irrational moral judgment to assert of reasonably determinate actions (e.g., killing an innocent man) that they are unjustifiable and morally unacceptable in all possible worlds, whatever the situation and whatever the consequences.

#### Ethics come from contingent assumptions- apriori impossible-

Rawls 99 John Rawls, “A Theory of Justice, Revised Edition,” Some Remarks about Moral Theory, Harvard University Press, 1999

I wish to stress that in its initial stages at least a theory of justice is precisely that, namely, a theory. It is a theory of the moral sentiments (to recall an eighteenth century title) setting out the principles governing our moral powers, or, more specifically, our sense of justice. There is a definite if limited class of facts against which conjectured principles can be checked, namely, our considered judgments in reflective equilibrium. A theory of justice is subject to the same rules of method as other theories. Definitions and analyses of meaning do not have a special place: definition is but one device used in setting up the general structure of theory. Once the whole framework is worked out, definitions have no distinct status and stand or fall with the theory itself. In any case, it is obviously impossible to develop a substantive theory of justice founded solely on truths of logic and definition. The analysis of moral concepts and the a priori, however traditionally understood, is too slender a basis. Moral theory must be free to use contingent assumptions and general facts as it pleases. There is no other way to give an account of our considered judgments in reflective equilibrium. This is the conception of the subject adopted by most classical British writers through Sidgwick. I see no reason to depart from it.26 Moreover, if we can find an accurate account of our moral conceptions, then questions of meaning and justification may prove much easier to answer. Indeed some of them may no longer be real questions at all. Note, for example, the extraordinary deepening of our understanding of the meaning and justification of statements in logic and mathematics made possible by developments since Frege and Cantor. A knowledge of the fundamental structures of logic and set theory and their relation to mathe- matics has transformed the philosophy of these subjects in a way that conceptual analysis and linguistic investigations never could. One has only to observe the effect of the division of theories into those which are decidable and complete, undecidable yet complete, and neither complete nor decidable. The problem of meaning and truth in logic and mathematics is profoundly altered by the discovery of logical systems illustrating these concepts. Once the substantive content of moral conceptions is better understood, a similar transformation may occur. It is possible that convincing answers to questions of the meaning and justification of moral judgments can be found in no other way.

#### Util is axiomatic - all value stems from experienced wellbeing.

Harris 10. Sam, CEO Project Reason; PHD UCLA Neuroscience; BA Stanford Philosophy.  The Moral Landscape: How Science Can Determine Human Values.”

I believe that we will increasingly understand good and evil, right and wrong, in scientific terms, because moral concerns translate into facts about how our thoughts and behaviors affect the well-being of conscious creatures like ourselves. If there are facts to be known about the well-being of such creatures—and there are—then there must be right and wrong answers to moral questions. Students of philosophy will notice that this commits me to some form of moral realism (viz. moral claims can really be true or false) and some form of consequentialism (viz. the rightness of an act depends on how it impacts the well-being of conscious creatures). While moral realism and consequentialism have both come under pressure in philosophical circles, they have the virtue of corresponding to many of our intuitions about how the world works. Here is my (consequentialist) starting point: all questions of value (right and wrong, good and evil, etc.) depend upon the possibility of experiencing such value. Without potential consequences at the level of experience—happiness, suffering, joy, despair, etc. —all talk of value is empty. Therefore, to say that an act is morally necessary, or evil, or blameless, is to make (tacit) claims about its consequences in the lives of conscious creatures (whether actual or potential).I am unaware of any interesting exception to this rule. Needless to say, if one is worried about pleasing God or His angels, this assumes that such invisible entities are conscious (in some sense) and cognizant of human behavior. It also generally assumes that it is possible to suffer their wrath or enjoy their approval, either in this world or the world to come. Even within religion, therefore, consequences and conscious states remain the foundation of all values.

### Comp Worlds – Fairness

#### Evaluate the debate as the desirability of the plan vs a competitive policy option.

#### A. Truth testing forces us into extremist philosophical stances that no one actually defends. This makes research meaningless and divorces our discussions from how they take place in academia.

#### B. Reciprocity – truth testing justifies multiple NIBS like skep and a prioris which gives them a 2:1 advantage

#### C. And even if they win truth testing, our offense links and they beg the question of the framework. We prove the resolution false that we are obligated to keep pb to prevent terrorism

#### D. Topics generate their meaning through context specific debates. Truth testing allows the neg to recycle the same generic NC’s without engaging the topic, which kills the entire point of debate and gives them infinite prep against our aff.

## 1

#### Interp: Reduce means permanent reduction – it’s distinct from “suspend”

Reynolds 59 – Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959, lexis)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway.  [\*\*\*13]  The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency.

#### Violation – they fiat a temporary waiver of medicines for covid

#### 1. Ground – allows affs to put infinite conditions in the plan – makes it impossible to be neg. aff doesn’t specify the timeframe for how long a waiver will be, which allows them to skirt neg offense

#### 2. Precision – if the condition in the plan is not met, IPP for medicines are not being reduced – means they don’t affirm

#### Paradigm Issues –

#### 1. Fairness first – debate is a game, and it’s the only way to determine the better debater

#### 2. Topicality is Drop the Debater – it’s a fundamental baseline for clash, best way to set norms

#### 3. Use Competing Interps –

#### Race to the top

#### Reasonability is arbitrary and invites judge intervention

#### 4. No RVI’s –

#### Chilling effect on T and theory

#### Encourages baiting

#### Illogical – you don’t win for being fair

#### 5. T before theory – less time to set norms, 1NC abuse was necessary to check 1AC abuse

## 2

#### A. Uniqueness- Pharma profits are up from COVID vaccines, patent waivers threaten this

Buchholz 5-17-21

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales took a nosedive on the news of Biden’s reversal. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the short term, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 vaccines in the long term. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

#### B. Link- IP Protections are vital to innovation and economic growth-reject myopic moralizing about human rights

Bacchus, JD, 20

(James, adjunct scholar at the Cato Institute, a professor of global affairs at the University of Central Florida, An Unnecessary Proposal A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines <https://www.cato.org/sites/cato.org/files/2020-12/FTB_78.pdf>, 12-16)

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for . . . profitability in decision-making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”16 This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.17 To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs? With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long-standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long-term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know-how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas-based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19 As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights.”21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### C. Impact- Pharmaceutical profits are key to innovation against emerging disease threats – the impact is extinction

Engelhardt 8 – PhD, MD, Professor of Philosophy @ Rice

(Hugo, “Innovation and the Pharmaceutical Industry: Critical Reflections on the Virtues of Profit,” EBrary)

Many are suspicious of, or indeed jealous of, the good fortune of oth-ers. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceu-tical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge.¶ Profit in the market for the pharmaceutical and medical-device¶ industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of profit is one of the most effective ways not only to acquire resources but productively to direct human energies in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

#### D. Emerging diseases and bioterrorism are comparatively the largest impact – pharmaceutical industry key

Milne 4 – Formerly a practicing veterinarian in New Jersey and Maryland, Dr. Milne attended Johns Hopkins University in 1987-88 where he earned a master's degree in public health with a concentration in epidemiology. For six years, he worked for the New Jersey Department of Health in risk assessment as well as legislative and regulatory review, and finally served as Emergency Response Coordinator. Dr. Milne joined Tufts University's Center for the Study of Drug Development in 1998 as a Senior Research Fellow, after graduation from law school. His research interests include the evaluation of regulatory initiatives affecting the pharmaceutical and biotechnology industries, and incentive programs for the development of new medicines for neglected diseases of the developing world. Dr. Milne is currently Assistant Director at the Center and a member of the bar in New Hampshire

(Christopher, “Racing the Globalization of Infectious Diseases: Lessons from the Tortoise and the Hare,” 11 New Eng. J. Int'l & Comp. L. 1)

Although we have faced planet-killing events such as nuclear brinkmanship during the Cold War and mega-meteors colliding with earth in pre-history, the most imminent threat is one we face everyday from the globalization of infectious diseases. Leading authorities in government, medical institutions, and schools of public health have been ringing the warning bell for over a decade about the major threats to global public health. 2Link to the text of the note Threats such as infectious diseases in the developing world, drug resistant bacteria, and the problem of multiple HIV strains, remain unaddressed. The public health community lacks answers to key scientific questions for an AIDS vaccine, and needs to press harder on research for a tuberculosis (TB) vaccine, a process which could take twenty to fifty years. 3Link to the text of the note Experts believe that the threat warning level has risen from orange to red, comparing the circumstances favoring a pandemic today to the "Perfect Storm," due to the continuing increase of worldwide antimicrobial resistance, diminished U.S. capacity to recognize and respond to microbial threats, and the likelihood of intentional releases of biological agents.¶ The sources of this public health challenge derive from a panoply of emerging and re-emerging natural plagues, thirty of which have been recognized just in the last few decades with thirteen occurring in North America. 4Link to the text of the note According to Anthony Fauci, Director of the National Institutes [3] of Allergies and Infectious Diseases (NIAID), emerging diseases are defined as ones that have not been previously recognized, such as acquired immunodeficiency syndrome (AIDS) or severe acute respiratory syndrome (SARS). Comparatively, re-emerging disease has usually been in existence for a long time but has changed location, as did the West Nile Virus. Dr. Fauci considers bioterrorism to be a part of the continuum of emerging and re-emerging diseases, and points out that when it comes to bioterror: "The Worst Bioterrorist May be Nature Itself." 5Link to the text of the note¶ Infectious diseases with the potential to be global killers come in two basic forms: the "slow epidemic," taking months or years to reach pandemic status, with an insidious onset and long latency, that resists treatment - the archetypical example being AIDS, 6Link to the text of the note and the "fast epidemic," rapidly spreading from country to country, typically aerosol-borne, with fairly quick onset, and high mortality and morbidity - most recently manifested in pandemic SARS. 7Link to the text of the note Both forms have potential uses as bioweapons, although most of the counter-terror attention focuses on the SARS-like diseases.¶ Part II of this article will discuss the scenarios for a global pandemic presented by SARS, AIDS, or bioweaponized incarnations - what they have done, what they could do, and why it is so hard to stop them. Part III will describe the scope of the public health problem, particularly the globalization factors that serve as enablers of the pandemic potential of these diseases, as well as a host of ill-defined "x" factors that have served to further complicate the dynamics of dealing with these global killers. Part IV will consider solutions to the problem by discussing what we have versus what we need. Part V will present recommendations for how government, pharmaceutical and biotechnology industries, as well as international non-governmental organizations can be part of the solution. Lastly, Part VI provides a conclusion.¶ "Ring around the rosie, pocket full of posies,¶ Ashes, ashes - we all fall down!" - According to legend, a children's rhyme dating from the time of the plague in medieval Europe.¶ II. Scenes from a Plague¶ SARS has been compared to the bubonic plague of the Middle Ages, but the Black Death was not a "fast epidemic" due to the limitations of its [4] mode of transmission, as well as the modes of medieval transportation. While SARS is somewhat comparable to flu epidemics of the last century and to the putative bioterror agents of today, AIDS has the dubious distinction of being closer to the experience of the Black Death. However, unlike that ancient pandemic, which was more limited temporally and geographically, AIDS is embarking upon what, Dr. Peter Piot, executive director of UNAIDS, refers to as a "true globalization phase." 8Link to the text of the note¶ A. Black Death Redux¶ The superlatives used to describe the public health impact of AIDS never seem to be exhausted. One commentator noted that AIDS will soon exceed the death toll of the Bubonic Plague, making it the most "numerically lethal pandemic" the world has ever known. 9Link to the text of the note The World Health Organization (WHO) refers to it more prosaically, but with similar notoriety, as the "toughest health assignment the world has ever faced." 10Link to the text of the note Even after twenty years, AIDS is still something of a medical and scientific conundrum. Diversity of the virus increases with duration of infection, further complicating drug treatment. 11Link to the text of the note Vaccine development is similarly complicated due to existence of ten major genetic types or clades of HIV-1, each with a distinct geographical spread. 12Link to the text of the note¶ What we do know is that AIDS is caused by an infection with the human immunodeficiency virus (HIV), transmitted through unprotected sex, sharing hypodermic needles, transfusions of contaminated blood, or from mother to child during pregnancy, labor, delivery, or breast-feeding. The virus attacks the immune system by infecting white blood cells, known as CD4+ cells, making it difficult for the body to fight off infections. AIDS itself is considered the final stage of HIV disease. 13Link to the text of the note Without treatment, HIV will progress to full-blown AIDS within nine to eleven years, and is usually fatal within two years after that point. 14Link to the text of the note The AIDS/HIV toll is [5] approaching forty million infected, with fourteen thousand new infections daily and ninety-five percent of new infections occurring in the developing world. 15Link to the text of the note¶ What we do not know is just how soon and how much of an impact AIDS will have. In sub-Saharan Africa, only an estimated ten percent of the predicted illness and death has occurred; the full impact on people, communities, and economies is still to come. 16Link to the text of the note Nonetheless, one forecast is that seventy million will die of AIDS by 2020, mostly in Africa and Asia. 17Link to the text of the note Besides its own death-dealing impact, AIDS exacerbates the morbidity and mortality of other "slow epidemics" like malaria and tuberculosis, and drains resources that would otherwise be dedicated to their treatment. 18Link to the text of the note By 2010, a report by the Central Intelligence Agency (CIA) states that five countries - Nigeria, Ethiopia, Russia, India, and China - will suffer a total of fifty to seventy-five million cases of HIV/AIDS. 19Link to the text of the note¶ For a preview of the AIDS wasteland that faces us without a serious course change, consider the devastation wrought by AIDS on Botswana. Before the AIDS epidemic reached Botswana in the early 1990s, per-capita income had risen tenfold over the previous thirty years, primary school enrollment had doubled, and infant mortality had decreased almost threefold. A decade after AIDS swept over the land, thirty percent of the country's economic growth was erased and the number of years each citizen is expected to contribute to the economy has been reduced from fifteen-to-thirty productive years to just five. Moreover, one-fifth of Botswana's children will soon be AIDS orphans. 20Link to the text of the note Botswana now has the lowest life expectancy of any country in the world at 30.8 years of age, which is about three times less than the highest life expectancy of 83.5 years in the European nation of Andorra. 21Link to the text of the note At the current pace, close to [6] fifty percent of the world's population could live in countries gripped by the AIDS pandemic by the end of the decade.¶ B. Cold Virus on Steroids¶ The official acronym for severe acute respiratory syndrome is SARS-CoV, which derives from the fact that it is a coronavirus, the same family of viruses that cause the common cold. However, SARS acts more like a cold virus pumped up on anabolic steroids. According to statistics, the recent outbreak of SARS was both debilitating and deadly: eleven percent of its victims died; sixty percent required hospitalization; twenty to thirty percent needed treatment in intensive care units with intubations; six to twenty percent suffered respiratory sequelae; and thirty to sixty percent experienced post-traumatic stress. 22Link to the text of the note Ultimately, the SARS pandemic led to ten billion dollars in economic losses. 23Link to the text of the note¶ The SARS incubation period is typically six days, but can range anywhere from two to twenty days. SARS is more environmentally stable than other respiratory viruses. However, unlike most respiratory viruses the role of seasonality is unknown, noting that most respiratory viruses are winter creatures. SARS is primarily transmitted by respiratory droplets or fomites (i.e., inanimate objects or substances that transfer an infectious agent), in health care and hospital settings, but also by contaminated sewage. Old age and co-existing illness are contributory factors to SARS, but children tend to contract a more mild form of the illness. SARS is believed to be of an animal origin, but unlike most other species jumpers, SARS has also become efficient at human-to-human transmission. 24Link to the text of the note¶ Although we are still learning from the SARS pandemic, some lessons are clear: animal pathogens pose major risks; a problem in a remote area can become a world problem within weeks; molecular virology can identify and sequence genetic structures of new pathogens within weeks; the epidemiological tracks of a disease can be followed even in remote areas; basic infection control measures work well; and the phenomena of the superspreader (i.e., an infected person responsible for a disproportionate number of transmissions), airborne transmission, and heightened risk to health care workers (i.e., twenty-one percent of SARS infections were in health care workers 25Link to the text of the note) complicate control efforts. 26Link to the text of the note Another lesson is that [7] humans can be the worst enemy regarding transmission. Four SARS outbreaks occurred within one year in Singapore, Taipei, and Beijing from laboratory accidents. 27Link to the text of the note The loose ends that dangle perilously from the tail of the SARS epidemic caused one SARS researcher to remark ominously: "this is not the end of the story… ." 28Link to the text of the note¶ C. Black Wind of Death¶ A warning on a radical Islamic fundamentalist website stated that a "Black Wind of Death" would soon be visited upon the enemies of Islam. Some believe that this statement refers to the use of a bioweapon. A conservative estimate of the number of naturally occurring potential bioterror agents is about seventy to eighty, but the possibilities for genetically engineered pathogens are practically limitless. In fact, the pioneers of the Soviet bioweapons program were able to refine the "binary inoculary," in which treatment of the first microbe would set off infection with a more deadly second microbe. The combinations were limitless, but the results were always the same - the ultimate nightmare. For example, if a person contracts a dreaded disease, such as the plague, and is treated with tetracycline, the treatment may unleash a second disease lying dormant, such as Ebola, for which there is no cure.¶ The question remains: How much lethal know-how is out there? In the 1980s, the Soviets' bioweapons industry employed about sixty thousand people, half of whom were scientists. In the past thirty years, critical masses of two to three thousand new pathogens have appeared; some developing from nature and some designed in the lab, but not always as bioweapons. Fully mapping and understanding the complex interactions of hosts and pathogens for the known biological entities that could be weaponized would take decades. 29Link to the text of the note D.A. Henderson, senior advisor for the Center for Biosecurity at the University of Pittsburgh, framed this problem: "Like it or not, I'm afraid the threat is with us forever." 30Link to the text of the note¶ [8] "Globalization, after all, is fundamentally about market expansion, the rise of new political, social, and cultural movements, and changes in the state and institutions." - Hitchner, Tufts University¶ III. Scope¶ For better or worse, globalization is also about public health. The scope of the public health challenge faced today must now be considered within the context of other globalization factors. Just as addressing the problems of globalization, public health must also be taken into account. This is especially true for infectious diseases, as West Nile virus, monkey pox, SARS, avian flu, and antibiotic-resistant bugs are only the beginning. According to one expert, "the new normal" has become a public health problem uniquely created by globalization. 31Link to the text of the note¶ A. The Global Village: A Good Place to Raise Deadly Offspring¶ 1. The Urbanization Triplets: Crowding, Poverty, and Destruction of Habitat¶ Certain sequelae of globalization have been identified as facilitating the spread of global infectious diseases. Urbanization, which is defined as rapid population growth in the cities, especially in tropical and subtropical areas in less developed countries, results in large populations coming into closer contact with one another, increasing the probability of infectious diseases. Urbanization is also characterized by poverty and poor sanitation. 32Link to the text of the note Poverty is considered both a cause and an effect of widespread disease. For instance, poverty often results in malnutrition, which in turn weakens the population's ability to fight off diseases, such as malaria. Malaria can cause the deaths of up to half of a million children per year in sub-Saharan Africa alone, resulting in a loss of one percent of the region's GNP. 33Link to the text of the note Urbanization and poverty also contribute to overcrowding in hospitals and health care facilities, which then leads to a struggle with sterilization and isolation procedures. Cross-contamination through blood and instruments occurs more readily. Due to the favorable environment, microbes increase in number and become more diverse through mutations. If a virulent "bug" pops up, it has a good chance of becoming established quickly.¶ Urbanized areas are often large population centers and are served by [9] modern transportation routes. Once an individual becomes infected, they are only a plane ride away from anywhere in the world. 34Link to the text of the note Urbanization also causes destruction of natural habitats, resulting in the release of previously unknown infectious diseases. Many such diseases have been unleashed by the increased human contact with animal reservoirs, due to altered land-use patterns and changing movement of animal and human populations. 35Link to the text of the note In fact, many of the thirty or so new pathogens recognized in the past three decades originated in animals. 36Link to the text of the note¶ 2. The "T-way" of Global Plague¶ Through the pathways provided by the "3Ts" of globalization - travel, trade, and tourism - humans have inadvertently paved the way for pandemics. Two million people travel internationally everyday, 37Link to the text of the note with approximately five hundred million traveling by commercial airlines every year, 38Link to the text of the note and millions of tons of food, hazardous materials, and waste in transport daily. 39Link to the text of the note With international travel increasing by fifty percent each decade, the prospects of containing new outbreaks of disease are diminishing. 40Link to the text of the note We are no longer protected by formerly formidable natural barriers like oceans, and even less so by artificial barriers, such as political borders.¶ B. The "X" Factors: The Known, the Unknown, and the Unknowable¶ The factors discussed are complex and their impacts are still under study, but to some degree, they are "known" factors that are quantifiable in the calculus of planning for the future. There are also a number of biological, environmental, socioeconomic, cultural, legal, and political factors that continue to crop up in unpredictable manners. Some were previously unknown but have been factored into the problem equation. Others seem to be so random in occurrence and incalculable as to outcomes [10] that the ultimate impacts remain "unknowable."¶ 1. Microbial Resistance¶ Resistant strains to antibiotics developed within a few years of the discovery of antibiotics some fifty years ago. However, according to the United States Food and Drug Administration (FDA), the difference now is that resistance is no longer an isolated problem, especially in hospitals. 41Link to the text of the note For example, in the United States, about seventy percent of bacteria causing infections in hospitals are resistant to at least one of the most common drugs used to treat them. 42Link to the text of the note In the United Kingdom, the infection rate for methicillin-resistant Staphylococcus aureus, a common hospital contaminant, has risen six-hundred percent over the last ten years. 43Link to the text of the note The WHO warned that due to the overuse of antibiotics in rich countries and the under use in poor countries, drug resistance is a worldwide problem. The result is wasting of billions of dollars that could have been better spent on research and development (R&D) for infectious disease treatments over the last few years. 44Link to the text of the note¶ Antibiotics are not the only medicines with resistance problems. The main drugs used to combat AIDS, the so-called anti-retrovirals (ARVs), are also a source of concern. A recent study showed that ten percent of all newly infected patients in Europe 45Link to the text of the note are infected with drug-resistant strains. In San Francisco, the rate is twenty-seven percent. 46Link to the text of the note According to a recent survey of infectious disease specialists in the U.S., only forty-one percent of patients are able to be treated with the most commonly used ARV regimen, while another forty-five percent are on back-up regimens. For fourteen percent of infected patients, treatment with ARVs has all but failed. 47Link to the text of the note¶ [11] Experts agree that resistance is also a problem in the developing world, 48Link to the text of the note further complicated by factors such as counterfeit drugs, irregular access to treatments, environmental degradation, inconsistent compliance, and diversion of drugs to the black market. 49Link to the text of the note¶ 2. Sociocultural¶ None of the problems associated with the globalization of infectious diseases seem to be confined to one part of the world. For instance, half of reported polio cases worldwide occurred in Nigeria, due to disruption of vaccination efforts. This interruption stemmed from a rumor that the United States government was clandestinely implementing population control by adding contraceptives to the vaccine. 50Link to the text of the note In the U.S., a surgeon recently reported that a several-year-long effort to convince a hospital staff to regularly use a sixty percent alcohol gel for hand disinfection was almost thwarted by a rumor that the gel would reduce fertility. 51Link to the text of the note¶ Actions taken by the general public are often at cross-purposes with actions taken to protect the public health. One of the most crucial problems involved with tackling AIDS in the developing world is the extreme fear and social stigma associated with the disease. These sentiments are exemplified by violence and abuse against woman in Africa 52Link to the text of the note and discrimination against HIV patients by their own families and hospitals in India. 53Link to the text of the note In the U.S., the population is so risk-averse that the construction of three Biosafety Level Four labs in California, Texas, and Massachusetts are being vigorously disputed by residents. 54Link to the text of the note¶ [12] ¶ 3. Legal¶ The criminal element always seems to find a way to further complicate an already complicated situation, which is not dissimilar to opportunistic infections. Up to ten percent of the world's drug supply is counterfeit, and may be perhaps as high as fifty percent in many developing countries. 55Link to the text of the note Diversion of medicines to the black market is most common in certain parts of the developing world, but occurs universally. Serostim, a growth hormone prescribed to fight wasting syndrome in AIDS patients, has found an underground recreational use as a bodybuilding drug in the United States. The drug costs about eighty thousand dollars for a year's supply, often paid for by Medicaid, but on the black market, it can fetch two thousand dollars for a week's supply. 56Link to the text of the note Even a new disease, such as SARS, did not take long to develop a criminal element. In May 2002, the FDA issued a special alert regarding internet marketing of bogus SARS prevention products. 57Link to the text of the note¶ In addition to violations of the law, tensions exist within the law as well. The needs of bioscience and the concerns for biosecurity are often adverse. The regulations for "select agents" are so confusing that one researcher was reportedly arrested simply because he traversed a room where a select agent was stored. 58Link to the text of the note Such incidents are one reason why an international group of scientists seeks to keep SARS off the select agents list, arguing [13] that restrictions would stifle research and hurt public health efforts. 59Link to the text of the note However, other experts acknowledge that the transfer of knowledge among scientists is often a leaky process, and scientists may become unwitting accomplices to global bioterror. 60ALink to the text of the note careful balance must be struck between freedom in research endeavors and controls designed to prevent the misuse of material and knowledge. 61Link to the text of the note¶ Conflicts of law also exist between public health and privacy. Due to the evolving nature of the newly implemented medical privacy regulations under the Health Insurance Portability and Accountability Act (HIPAA), 62Link to the text of the note state health officials believe themselves to be limited in releasing information regarding deaths from the flu or other reportable diseases, due to new legal protections afforded to patients. However, HIPAA contains a public health exception, and most officials argue that releasing certain information is required by state public health laws to provide information about risk factors that the public should be aware of. 63Link to the text of the note¶ The United States Security and Exchange Commission (SEC) has become embroiled in this problem as well. SEC regulations are an issue, not only due to antitrust laws prohibiting collaboration on countermeasures by "competing" companies, 64Link to the text of the note but also due to accounting regulations that determine when a company can recognize revenue from a stockpile. Under the current scheme, the United States Department of Health and Human Services (HHS) plans to purchase vaccines, but have companies store them until needed to avoid additional cost and logistical problems for HHS. Problems then arise under current SEC regulations, as entities may not declare revenue from undelivered products. 65Link to the text of the note¶ [14] ¶ 4. The Ultimate "X" Factor¶ Global infectious disease, bioterror, and national security are becoming strange bedfellows. The HHS Secretary announced in the fall of 2003 that grants totaling 350 million dollars over five years would be made available for the establishment of eight Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCEs), stating: "These new grants add to this effort and will not only better prepare us for a bioterrorism attack, but will also enhance our ability to deal with any public health crisis, such as SARS… ." 66Link to the text of the note Concern regarding the public health crisis precipitated by SARS was believed to have caused some "holdouts" waffling on support of Bioshield to come on board. 67Link to the text of the note The President of the Association of State and Territorial Health Officials believes that the infusion of dollars into bioterrorism awareness has helped to improve the public health system capacity to deal with health emergencies in general. 68Link to the text of the note¶ Internationally, the Security Council of the United Nations (UN) discussed a health issue for the first time as a threat to world stability: HIV/AIDS in Africa. 69Link to the text of the note The African, Caribbean, and Pacific Ocean sectors of the World Trade Organization (WTO) petitioned the WTO's Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) to find a solution to the deadlock over access to affordable drugs, as the outbreak of diseases such as SARS had made it "a matter of urgency." 70Link to the text of the note The deadlock was broken. In a report by the United States National Intelligence Council, experts emphasized the worldwide threat presented by infectious disease to military capacity, socioeconomic development, international trade and travel, and global stability. 71Link to the text of the note¶ [15] However, common goals can sometimes result in competition instead of cooperation when time, money, and resources are limited. The media reported that National Institute of Health (NIH) studies on AIDS, TB, malaria, and other infectious diseases would be shortened in length due to a White House mandate shifting funding to development of an anthrax vaccine. 72Link to the text of the note While the NIAID budget grew twenty-fold from 1980 to 2004, the increase was mainly due to efforts to combat changing priorities of life-threatening infectious diseases, such as AIDS in the 1990s and bioterror in the 2000s. 73Link to the text of the note In fact, the NIAID budget allotment for AIDS R&D has flat lined for 2002 through 2005, while the biodefense budget went up from $ 200 million in 2002 to $ 1.6 billion slated for 2005. 74Link to the text of the note In a survey of nearly four hundred scientists, forty-six percent felt that government spending on bioterror R&D diverts monies from more important investigative work. 75Link to the text of the note Internationally, in January 2002, the WHO's Executive Board stated that it was focusing attention on the health effects of poverty, but also needed to devote attention to preparations for "newer threats such as the deliberate use of anthrax and smallpox agents." 76Link to the text of the note¶ C. The World as a Marketplace, Health Care as a Business¶ Due to the globalization of infectious diseases, the distinction between national and international public health programs have as little relevance as political borders. 77Link to the text of the note However, this also implies that public health counter-measures must be considered within the context of market realities driving globalization. There is a strengthening current within the international public health community to consider access to health care as a universal human right shared by rich and poor alike. 78Link to the text of the note However, one must inquire: Where does the money for health research come from? Independent [16] foundations and charities contribute only about four percent of the billions spent globally each year on health research. 79Link to the text of the note Regarding medicine, a sizeable amount of the funding for basic research comes from governments, but the lion's share of the funding for applied research that turns concepts brewing in test-tubes on lab benches into bottles for injection on clinic shelves comes from private industry. In particular, these are the major pharmaceutical companies, also known as "big pharma." 80Link to the text of the note¶ They don't call it big pharma for nothing! The industry's financial might and resources are impressive. When the list of the world's one hundred largest public companies by market value is released each year, close to one-fifth are pharmaceutical companies. Monsanto, a life-science multinational corporation, has a R&D budget more than twice the R&D budget of the entire worldwide network of public sector tropical medicines research institutes. 81Link to the text of the note¶ These resources must be brought to bear if the global community is to make any headway against the globalization of infectious diseases. However, this is where the economic and political realities of globalization are actualized. According to previous work on providing incentives to industry to conduct R&D for neglected parasitic and infectious diseases in the developing world, five disincentives must be addressed: lack of interest on the part of big pharma; an unfavorable cost/risk ratio for big pharma; the fact that only impoverished markets exist for the products of such R&D; the difficulty of directing capacity in the Northern hemisphere to address the needs of the South; and the realities of the vaccine market. 82Link to the text of the note

## 3

#### CP Text: The member nations of the World Trade Organization ought to buy medicines and distribute it for free as per Adler et al and Operation Warp Speed.

#### Solves COVID without reducing IP protections- OWS proves. Time frame is now and the CP is totally feasible and can be conducted through coordination from the WTO and its member nations

Adler et al. 8-4-21 [David Adler is author of the monograph The New Economics of Liquidity and Financial Frictions, coeditor of the forthcoming anthology The Productivity Puzzle, and an adviser on industrial strategy at the Common Good Foundation (UK). Reda Cherif is a Senior Economist at the International Monetary Fund (IMF). He joined the IMF in 2008 and worked in several departments on fiscal issues and macroeconomic analysis of emerging and developing countries. His research focuses on development economics, natural resources, fiscal policy, and growth and innovation. Reda holds a PhD in economics from the University of Chicago. Fuad Hasanov is a Senior Economist at the International Monetary Fund (IMF) and an Adjunct Professor of Economics at Georgetown University. Before joining the IMF, Fuad was an Assistant Professor of Economics at Oakland University in Rochester, Michigan in 2004-2007. Fuad received a PhD in economics from the University of Texas at Austin. “How to deliver 10 billion COVID-19 vaccines at Warp Speed.” World Economic Forum. August 4, 2021. <https://www.weforum.org/agenda/2021/08/how-to-deliver-10-billion-covid-19-vaccines-at-warp-speed/>] HW Alex Lee

The US government's **Operation Warp Speed** (OWS) initiative **showed how successful public/private collaboration can be in rolling out a mass vaccination programme.** It provides a blueprint for how to build supply, regulate and distribute COVID-19 vaccines on a global scale. This kind of approach would focus on building capacity, supporting production in emerging or developing countries and encouraging rapid testing while vaccine production is underway. Operation Warp Speed (OWS), the US government initiative to accelerate the development, trials and production of COVID-19 vaccines, has been a **spectacular success. It showed that the state could work effectively with private firms to promote innovation and provide a powerful weapon against the virus.** It consisted of early and massive funding of R&D and investment in production of various vaccine candidates, as well as coordinating the value chain and addressing all regulatory and logistical hurdles. The result: several vaccines available within a year and widespread vaccination in most advanced countries. OWS showed that the state could effectively work with private firms to promote innovation and provide a powerful weapon against the virus. —Reda Cherif & Fuad Hasanov, IMF; David Adler, The Common Good Foundation (UK) However, **the pandemic** is far from over. It **is still raging in the developing world.** The official global death toll has passed 4 million people while The Economist has estimated 7-13 million excess deaths, most of which are outside advanced countries. New, more contagious variants are also affecting a younger population, implying that many poorer countries may not be protected by the youth of their populations anymore. **An OWS for the World is needed.** Given the many uncertainties and risks about vaccine production and supply, regulation, distribution, and virus variants, the market will most likely fail to provide the necessary volume of vaccines. This will lead to long delays in reaching global herd immunity. **OWS represents a blueprint of effective industrial policy in action. Speed is of the essence in the face of a pandemic** While the development of a vaccine has been an amazing feat, vaccination campaigns in many parts of the world have been dismal. By mid-June, about a billion people globally have had at least one dose of a vaccine (with more than 2.3 billion doses administered), and most of them reside in advanced countries. Africa has so far inoculated less than 30 million people, little more than 2% of its population. The US, in comparison, has vaccinated more than 170 million people, more than half of its population. The G7 leaders have committed to provide 1 billion vaccine doses by end-2022. The US has pledged to buy a total of 500 million doses from BioNTech/Pfizer to provide to poor countries by mid-2022 (with 200 million doses by end-2021). Although these initiatives show that the race against time to vaccinate the world has started, many campaigners argue **these commitments fall short of what is needed to end the pandemic as fast as possible. To vaccinate the world, another 10 billion doses are urgently required.** Waiting until end-2022 would still wreak havoc on many parts of the world. Delivering 10 billion vaccines in a year A recent IMF proposal to end the pandemic within a year called for donations of extra doses, financing of vaccines for poor countries, and investments to increase vaccine manufacturing capacity by 1 billion doses by early 2022. Moreover, many downside risks considered in the proposal, such as export restrictions and supply chain bottlenecks, have already materialized. The EU and others have called for scaling up and diversification of production as a result. This kind of risk-based approach calls for further global action along the lines of OWS to ensure the delivery of 10 billion doses within a year, accounting for extra capacity and redundancy. This would involve **three main steps**: Purchasing the required capacity from key vaccine manufacturers directly - essentially building capacity, if necessary - to send the needed doses to other countries; Facilitating building or expanding vaccine production in emerging and developing countries, including through partnerships such as that of Senegal’s Institut Pasteur and a Belgian biotech firm; and Producing and distributing rapid tests for widespread testing while vaccines are on the way. Building capacity, facilitating collaboration and rapid testing Creating extra production capacity to produce hundreds of millions of doses a month within a year is **feasible and would cost a fraction** of advanced countries’ foreign aid budget. Producing 8 billion doses of mRNA vaccines would cost between $10 billion (BioNTech/Pfizer) and $25 billion (Moderna) and could be done within a year, according to recent research from Imperial College London. Procurement alone is likely to take longer than desired. Buying or building capacity is what OWS did, and is what economists such as Nobel laureate Michael Kremer have advocated. Coordinating all stakeholders and clearing bottlenecks would be key to the success of OWS for the World. It could be done by the US Biomedical Advanced Research and Development Authority (BARDA), in coordination with an EU or UK vaccine taskforce and WHO, or **any other global task force**. As we argue in the context of industrial policy against pandemics and OWS as a model, this task force needs to set up relevant objectives, clear resulting hurdles - whether in supply chain, distribution, or communication - and coordinate across government agencies, manufacturers, and in this case, global users. The EU vaccine task force has already mapped, tracked, and cleared bottlenecks. It retrofitted a German dengue vaccine bottling factory for Johnson & Johnson’s vaccine, for example. At the same time, advanced countries need to help others build their own production facilities and supply chains to manufacture vaccines and rapid tests. Indeed, this would create a more resilient vaccine production system globally, mitigating against uncertainties and risks when providing booster shots and other vaccines in the future for developing countries. Since vaccine production may take longer, producing rapid tests, which could be easier and faster, is a hedge against delays in vaccine production. Finally, while awaiting vaccines, many countries need to conduct universal or widespread testing to prevent outbreaks. Creating extra production capacity to produce hundreds of millions of doses a month within a year is feasible and would cost a fraction of advanced countries’ foreign aid budget. —Reda Cherif & Fuad Hasanov, IMF; David Adler, The Common Good Foundation (UK) Last year, we argued that testing would end the pandemic within a few months, but only a few countries experimented with it. Rapid worldwide vaccination could do the same. Reducing the length of the pandemic, even by days, **would save lives and is worth the investment. It is not too late to act.**

## Case

#### Covid-19 is being brought under control now—vaccination efforts, immunity, etc

Byjillian **Kramer,** 8-06-20**21**,

"How will the pandemic end? The science of past outbreaks offers clues.," Science, <https://www.nationalgeographic.com/science/article/how-will-the-pandemic-end-the-science-of-past-outbreaks-offers-clues>

When the worldwide spread of a disease is brought under control in a localized area, it’s no longer a pandemic but an epidemic, according to the WHO. If COVID-19 persists globally at what the WHO judges to be “expected or normal levels,” the organization will then re-designate the disease “endemic.” At that stage, SARS-CoV-2 will become a circulating virus that’s “less consequential as we build immunity,” says [Saad Omer](https://medicine.yale.edu/yigh/profile/saad_omer/), an epidemiologist and director of the Yale Institute for Global Health. ([Read more about how we’ll live with COVID-19 as an endemic disease](https://www.nationalgeographic.com/science/article/covid-19-will-likely-be-with-us-forever-heres-how-well-live-with-it).) Only [two diseases](https://asm.org/Articles/2020/March/Disease-Eradication-What-Does-It-Take-to-Wipe-out) in recorded history that affect humans or other animals have ever been eradicated: smallpox, a life-threatening disease for people that covers bodies in painful blisters, and rinderpest, a viral malady that infected and killed cattle. In both instances, intensive global vaccination campaigns brought new infections to a halt. The [last confirmed case of rinderpest](https://www.theguardian.com/science/2010/oct/14/rinderpest-virus-eradicated) was detected in Kenya in 2001, while the [last known smallpox case](https://www.cdc.gov/smallpox/history/history.html) occurred in the U.K. in 1978. [Joshua Epstein](https://publichealth.nyu.edu/faculty/joshua-epstein), professor of epidemiology in the New York University School of Global Public Health and founding director of its Agent-Based Modeling Laboratory, argues that eradication is so rare that the word should be wiped from our disease vocabulary. Diseases “retreat to their animal reservoirs, or they mutate at low levels,” he says. “But they don’t typically literally disappear from the global biome.” There is no one definition of what the end of a pandemic means. RACHAEL PILTCH-LOEBHARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH Most causes of past pandemics are still with us today. More than [3,000 people caught the bacteria that cause both bubonic and pneumonic plague](https://www.who.int/en/news-room/fact-sheets/detail/plague) between 2010 and 2015, according to the WHO. And the virus behind the 1918 flu pandemic that ravaged the globe, killing at least 50 million people, ultimately morphed into less lethal variants, with its [descendants becoming strains of the seasonal flu](https://www.nejm.org/doi/full/10.1056/nejmp0904819). As with the 1918 flu, it’s likely the SARS-CoV-2 virus will continue to mutate, and the human immune system would eventually adapt to fend it off without shots—but not before many people fell ill and died. “Developing immunity the hard way is not a solution that we should be aspiring to,” Omer says. Finding ways to slow the spread of a disease and manage its effects is by far the safer path, experts say. Today, for instance, pest control and advanced hygiene keep the plague at bay, while any new cases can be treated with antibiotics. For other diseases, such as the flu, vaccines can also make a difference. The available COVID-19 vaccines are highly safe and effective, which means getting enough people vaccinated can end this pandemic faster and with lower mortality than natural infections alone. Why we need vaccines for all WHO Director Tedros Adhanom Ghebreyesus last week reinstated a goal of vaccinating at least 10 percent of every nation’s population by September, with the loftier goal of reaching 40 percent global inoculation by year’s end and 70 percent by mid-2022.

#### Tech transfer is key and not included under IP

Smith 05/05

(Laura Smith-Spark; Newsdesk Editor, CNN Digital; (05-05-21) Rich nations urged to share vaccine knowledge while WTO debates waiving patents; CNN; <https://www.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html>; CKD)

Thomas Bollyky, director of the Global Health Program at the Council on Foreign Relations, told CNN on Friday that what's really needed to scale up global manufacturing of vaccines is technology transfer. "It's not just a matter of intellectual property. It's also the transfer of know-how," he said. "I don't think there's clear evidence that a waiver of an intellectual property is going to be the best way for that technology transfer to occur." Waiving patents will not work in the same way for vaccines as it has for drugs, Bollyky said. For HIV drugs, for example, manufacturers were more or less able to reverse engineer them without much help from the original developer. "It's very different for vaccines, where it's really a biological process as much as a product. It's hard to scale up manufacturing in this process for the original company, let alone another manufacturer trying to figure this out without assistance," he said. "It requires a lot of knowledge that's not part of the IP." The deal between AstraZeneca and the Serum Institute of India is a successful example of such technology transfer, Bollyky said, where the licensing of IP happened voluntarily. "The question is what can we do to facilitate more deals like the one between AstraZeneca and the Serum Institute of India to have this transfer," he said. Michael Head, senior research fellow in global health at the University of Southampton, in England, told CNN that increasing regional manufacturing capacity, particularly in the global south, was key -- and should be a focus between pandemics. "Sharing intellectual property during the pandemic is something that should happen but that doesn't resolve the issues," he said. "Manufacturing vaccines is hard. It's hard to rapidly set up a new site with all the equipment, infrastructure, all the vaccine ingredients, with suitable staff to produce a large number of high quality vaccine products." Philanthropist Bill Gates, a major supporter of [global Covid-19 vaccine equity](https://www.cnn.com/2021/02/05/world/covax-explainer-intl/index.html) through the Bill & Melinda Gates Foundation, also [told Sky News](https://news.sky.com/story/covid-19-bill-gates-hopeful-world-completely-back-to-normal-by-end-of-2022-and-vaccine-sharing-to-ramp-up-12285840) last month that he did not believe overriding IP rules was the answer. "There's only so many vaccine factories in the world and people are very serious about the safety of vaccines," he said. "The thing that's holding things back in this case is not intellectual property. There's not, like, some idle vaccine factory with regulatory approval that makes magically safe vaccines. You've got to do the trials on these things and every manufacturing process has to be looked at in a very careful way.

#### During pandemics means no solvency – acting with a condition like “during pandemics” means the action is not universalizeable to outside of pandemics and means no offense even if they win fw

#### Consider the pharma DA a huge “private property” / IP IS contingent with free market DA even under koorsgaard – we just extended that to consequences as well as morality so no matter who wins fw we get lots of offense

#### IP is universalizeable – says only make what you make, not that making is inherently not allowed – their understanding is clearly flawed

#### Aff doesn’t attack all of the root causes of disease spread

Brant & Burns 7-29-21 [Jennifer Brant, CEO and Founder of Innovation Insights, and Thaddeus Burns, Head of Life Science Government & Public Affairs at Merck and served in senior positions at the US Department of Commerce and the White House Office of the US Trade Representative, served as a member of the National Academy of Sciences Committee charged with preparing a report on the science and technology capabilities of the U.S. Department of State. “Trade restrictions are delaying the COVID response. The WTO must act.” July 29, 2021. <https://www.weforum.org/agenda/2021/07/wto-members-must-launch-new-work-to-reinforce-the-covid-response-in-november/>] AL

The COVID-19 pandemic hit at a time when bio-manufacturing was undergoing a process of democratization. Technological progress had enabled growing capacity in many countries including Brazil, Indonesia, South Africa, Tunisia, Argentina, and Egypt. By 2020, the business model for bio-manufacturing had fundamentally changed and it was becoming the norm for companies to distribute research, development and manufacturing across geographies and work with partners. As recently as 15 years ago, building a facility to produce biologics such as monoclonal antibodies or vaccines could require an investment of as much as €500m, and it would take up to 3 years to bring that facility online. New manufacturing technologies have made it cheaper and easier to build new facilities and to scale up existing ones. Today, an investment of €20m can get a bio-manufacturing plant up and running. Such changes are part of the reason the global community was able to launch production of new COVID-19 vaccines so quickly. The urgency of COVID-19 accelerated further innovations in bio-manufacturing equipment and processes, and compressed production time in a way that will have positive impacts in the future. But the pandemic also revealed major weaknesses in global value chains. It was difficult for manufacturers to keep up with the sudden surge for demand for raw materials and equipment, as many new research and development and manufacturing partnerships rapidly took off. To extend capacity, new employees, intensive training and collaboration, and more infrastructure were needed. The global community was faced with the reality that facilities cannot be built everywhere in an instant, and that there are bottlenecks in the supply chain. Government action in some cases made things worse. Some countries enacted export restrictions on COVID-related products, which made it extremely difficult to run a global supply chain. Another difficult issue has been the tariffs applied on biologics and the products needed for their manufacture. Eighteen months into the pandemic, biologics manufacturers are still trying to cope with a range of challenges. There is still surging demand for equipment and raw materials. In some cases, they have expanded manufacturing capacity to produce more equipment such as filters and bioreactors. This continues to require time and significant investments.