# 1NC

## 1

#### The meta-ethic is phenomenalism – induction first

Sayre-McCord 1 Geoffrey Sayre-McCord, Philosophy, University of North Carolina, Chapel Hill, "Mill's “Proof” Of The Principle of Utility: A More Than Half-Hearted Defense", Social Philosophy and Policy, 2001, accessed: 1 April 2020, https://www.cambridge.org/core/journals/social-philosophy-and-policy/article/mills-proof-of-the-principle-of-utility-a-more-than-halfhearted-defense/FDBE07CBE08D4E17523930BF8C7BBC32, R.S.

When it comes to visibility, no less than desirability, Mill explicitly denies that a "proof" in the "ordinary acceptation of the term" can be offered.25 As he notes, "To be incapable of proof by reasoning is com mon to all first principles; to the first premises of our knowledge, as well as to those of our conduct."26 Nonetheless, support -- that is, evidence, though not proof -- for the first premises of our knowledge is provided by "our senses, and our internal consciousness." Mill's suggestion is that, when it comes to the first principles of conduct, desire play the same epistemic role that the senses play, when it comes to the first principles of knowledge. To understand this role, it is important to distinguish the fact that someone is sensing something from what is sensed, which is a distinction mirrored in the contrast bet ween the fact that someone is desiring something and what is desired. In the case of our senses, the evidence we have for our judgments concerning sensible qualities traces back to what is sensed, to the content of our sense-experience. Likewise, Mill is suggesting, in the case of value, the evidence we have for our judgments concerning value traces back to what is desired, to the content of our desires. Ultimately, the grounds we have for holding the principles we do must, he thinks, be traced back to our experience, to our senses and desires. Yet the evidence we have is not that we are sensing or desiring something but what it is that is sensed or desired. When we are having sensations of red, when what we are looking at appears red to us, we have evidence (albeit overrideable and defeasible evidence) that the thing is red. Moreover, if things never looked red to us, we could never get evidence that things were red, and would indeed never have developed the concept of redness. Similarly, when we are desiring things, when what we are considering appears good to us, we have evidence (albeit overrideable and defeasible evidence) that the thing is good. Moreover, if we never desired things, we could never get evidence that things were good, and would indeed never have developed the concept of value. Recall that desire, for Mill, like taste, touch, sight, and smell, is a "passive sensibility." All of these, he holds, provide us with both the content that makes thought possible and the evidence we have for the conclusions that thought leads us to embrace. "Desiring a thing" and "thinking of it as desirable (unless for the sake of its consequences)" are treated by Mill as one an d the same, just as seeing a thing as red and thinking of it as red are one and the same. Accordingly, a person who desires x is a person who ipso facto sees x as desirable. Desiring something, for Mill, is a matter of seeing it under the guise of the good. This means that it is important, in the context of Mill's argument, that one not think of desires as mere preferences or as just any sort of motive. They constitute, according to Mill, a distinctive subclass of our motivational states, and are distinguished (at least in part) by t heir evaluative content. Thus, Mill is neither assuming nor arguing that something is good because we desire it; rather, he is depending on our desiring it as establishing that we see it as good. At the same time, while desiring something is a matter of seeing it as good, one could, on Mill's view, believe that something is good without desiring it, just as one can believe something is red without seeing it as red. While desire is supposed to be the fundamental source of our concept of, and evidence for, desirability, once the concept is in place there are contexts in which we will have reason to think it applies even when the corresponding sensible experience is lacking. Indeed, in Chapter IV, Mill is concerned not with generating a desire, but with justifying the belief that happiness is desirable, and the only thing desirable, as an end, and so concerned with defending the standard for determining what should be desired. Mill's aim is to take what people already, and he thinks inevitably, see as desirable and argue that those views commit them to the value of the general happiness (whet her or not their desires follow the deliverances of t heir reason). Those who, like Mill, desire the general happiness already hold the view that the general happiness is desirable. They accept the claim that Mill is trying to defend. As Mill knows, however, there are many who do not have this desire -- many who desire only their own happiness, and some who even desire that others suffer. These are the people he sets out to persuade, along with others who are more generous and benevolent, but who nonetheless do not see happiness as desirable, and the only thin g desirable, as an end. Mill's argument is directed at convincing t hem all -- whether their desires follow or not -- that they have grounds for, and are in fact already com mitted to, regarding the happiness of others as valuable as an end. Mill recognizes that whatever argument he might hope to offer will need to appeal to evaluative claims people already accept (since he takes to heart Hume's caution concerning inferring an 'ought' from an 'is'). The claim Mill thinks he can appeal to -- that one's own happiness is a good (i.e. desirable) -- is something licensed as available by people desiring their own happiness. Yet he is not supposing here that the fact that they desire their own happiness, or anything else, is proof that it is desirable, just as he would not suppose that the fact that someone sees something as red is proof that it is. Rather, he is supposing that if people desire their own happiness, or see something as red, one can rely on t hem having available, as a premise for further argument, the claim that their own happiness is desirable or that the thing is red (at least absent contrary evidence). As he puts it in the third paragraph, "If the end which the utilitarian doctrine proposes to itself were not, in theory and in practice, acknowledged to be an end nothing could ever convince any person that it was so." Thus, in appealing to the analogy bet ween judgments of sensible qualities and judgments of value, Mill is not trading on an ambiguity, nor does his argument here involve identifying being desirable with being desired or assuming that "desirable" means "desired." He is instead relying consistently on an empiricist account of concepts and their application -- on a view according to which we have the concepts, evidence, and knowledge we do only thanks to our having experiences of a certain sort. In the absence of the relevant experiences, he holds (with other empiricists), we would not only lack the required evidence for our judgments, we would lack the capacity to make the judgments in the first place. In the presence of the relevant experiences, though, we have both the concepts and the required evidence -- "not only all the proof which the case admits of, but all which it is possible to require."

#### The standard is maximizing expected wellbeing. Pleasure and pain are intrinsic value and disvalue – everything else regresses – robust neuroscience.

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**Pleasure** is not only one of the three primary reward functions but it also **defines reward.** As homeostasis explains the functions of only a limited number of rewards, the principal reason why particular stimuli, objects, events, situations, and activities are rewarding may be due to pleasure. This applies first of all to sex and to the primary homeostatic rewards of food and liquid and extends to money, taste, beauty, social encounters and nonmaterial, internally set, and intrinsic rewards. Pleasure, as the primary effect of rewards, drives the prime reward functions of learning, approach behavior, and decision making and provides the basis **for hedonic** theories of reward function. We are attracted by most rewards and exert intense efforts to obtain them, just because they are enjoyable [10]. Pleasure is a passive reaction that derives from the experience or prediction of reward and may lead to a long-lasting state of happiness. The word happiness is difficult to define. In fact, just obtaining physical pleasure may not be enough. One key to happiness involves a network of good friends. However, it is not obvious how the higher forms of satisfaction and pleasure are related to an ice cream cone, or to your team winning a sporting event. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure [14]. Pleasure as a hallmark of reward is sufficient for defining a reward, but it may not be necessary. A reward may generate positive learning and approach behavior simply because it contains substances that are essential for body function. When we are hungry, we may eat bad and unpleasant meals. A monkey who receives hundreds of small drops of water every morning in the laboratory is unlikely to feel a rush of pleasure every time it gets the 0.1 ml. Nevertheless, with these precautions in mind, we may define any stimulus, object, event, activity, or situation that has the potential to produce pleasure as a reward. In the context of reward deficiency or for disorders of addiction, homeostasis pursues pharmacological treatments: drugs to treat drug addiction, obesity, and other compulsive behaviors. The theory of allostasis suggests broader approaches - such as re-expanding the range of possible pleasures and providing opportunities to expend effort in their pursuit. [15]. It is noteworthy, the first animal studies eliciting approach behavior by electrical brain stimulation interpreted their findings as a discovery of the brain’s pleasure centers [16] which were later partly associated with midbrain dopamine neurons [17–19] despite the notorious difficulties of identifying emotions in animals. Evolutionary theories of pleasure: The love connection BO:D Charles Darwin and other biological scientists that have examined the biological evolution and its basic principles found various mechanisms that steer behavior and biological development. Besides their theory on natural selection, it was particularly the sexual selection process that gained significance in the latter context over the last century, especially when it comes to the question of what makes us “what we are,” i.e., human. However, the capacity to sexually select and evolve is not at all a human accomplishment alone or a sign of our uniqueness; yet, we humans, as it seems, are ingenious in fooling ourselves and others–when we are in love or desperately search for it. It is well established that modern biological theory conjectures that **organisms are** the **result of evolutionary competition.** In fact, Richard Dawkins stresses gene survival and propagation as the basic mechanism of life [20]. Only genes that lead to the fittest phenotype will make it. It is noteworthy that the phenotype is selected based on behavior that maximizes gene propagation. To do so, the phenotype must survive and generate offspring, and be better at it than its competitors. Thus, the ultimate, distal function of rewards is to increase evolutionary fitness by ensuring the survival of the organism and reproduction. It is agreed that learning, approach, economic decisions, and positive emotions are the proximal functions through which phenotypes obtain other necessary nutrients for survival, mating, and care for offspring. Behavioral reward functions have evolved to help individuals to survive and propagate their genes. Apparently, people need to live well and long enough to reproduce. Most would agree that homo-sapiens do so by ingesting the substances that make their bodies function properly. For this reason, foods and drinks are rewards. Additional rewards, including those used for economic exchanges, ensure sufficient palatable food and drink supply. Mating and gene propagation is supported by powerful sexual attraction. Additional properties, like body form, augment the chance to mate and nourish and defend offspring and are therefore also rewards. Care for offspring until they can reproduce themselves helps gene propagation and is rewarding; otherwise, many believe mating is useless. According to David E Comings, as any small edge will ultimately result in evolutionary advantage [21], additional reward mechanisms like novelty seeking and exploration widen the spectrum of available rewards and thus enhance the chance for survival, reproduction, and ultimate gene propagation. These functions may help us to obtain the benefits of distant rewards that are determined by our own interests and not immediately available in the environment. Thus the distal reward function in gene propagation and evolutionary fitness defines the proximal reward functions that we see in everyday behavior. That is why foods, drinks, mates, and offspring are rewarding. There have been theories linking pleasure as a required component of health benefits salutogenesis, (salugenesis). In essence, under these terms, pleasure is described as a state or feeling of happiness and satisfaction resulting from an experience that one enjoys. Regarding pleasure, it is a double-edged sword, on the one hand, it promotes positive feelings (like mindfulness) and even better cognition, possibly through the release of dopamine [22]. But on the other hand, pleasure simultaneously encourages addiction and other negative behaviors, i.e., motivational toxicity. It is a complex neurobiological phenomenon, relying on reward circuitry or limbic activity. It is important to realize that through the “Brain Reward Cascade” (BRC) endorphin and endogenous morphinergic mechanisms may play a role [23]. While natural rewards are essential for survival and appetitive motivation leading to beneficial biological behaviors like eating, sex, and reproduction, crucial social interactions seem to further facilitate the positive effects exerted by pleasurable experiences. Indeed, experimentation with addictive drugs is capable of directly acting on reward pathways and causing deterioration of these systems promoting hypodopaminergia [24]. Most would agree that pleasurable activities can stimulate personal growth and may help to induce healthy behavioral changes, including stress management [25]. The work of Esch and Stefano [26] concerning the link between compassion and love implicate the brain reward system, and pleasure induction suggests that social contact in general, i.e., love, attachment, and compassion, can be highly effective in stress reduction, survival, and overall health. Understanding the role of neurotransmission and pleasurable states both positive and negative have been adequately studied over many decades [26–37], but comparative anatomical and neurobiological function between animals and homo sapiens appear to be required and seem to be in an infancy stage. Finding happiness is different between apes and humans As stated earlier in this expert opinion one key to happiness involves a network of good friends [38]. However, it is not entirely clear exactly how the higher forms of satisfaction and pleasure are related to a sugar rush, winning a sports event or even sky diving, all of which augment dopamine release at the reward brain site. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure. Remarkably, there are pathways for ordinary liking and pleasure, which are limited in scope as described above in this commentary. However, there are **many brain regions**, often termed hot and cold spots, that significantly **modulate** (increase or decrease) our **pleasure or** even produce the opposite of pleasure— that is disgust and fear [39]. One specific region of the nucleus accumbens is organized like a computer keyboard, with particular stimulus triggers in rows— producing an increase and decrease of pleasure and disgust. Moreover, the cortex has unique roles in the cognitive evaluation of our feelings of pleasure [40]. Importantly, the interplay of these multiple triggers and the higher brain centers in the prefrontal cortex are very intricate and are just being uncovered. Desire and reward centers It is surprising that many different sources of pleasure activate the same circuits between the mesocorticolimbic regions (Figure 1). Reward and desire are two aspects pleasure induction and have a very widespread, large circuit. Some part of this circuit distinguishes between desire and dread. The so-called pleasure circuitry called “REWARD” involves a well-known dopamine pathway in the mesolimbic system that can influence both pleasure and motivation. In simplest terms, the well-established mesolimbic system is a dopamine circuit for reward. It starts in the ventral tegmental area (VTA) of the midbrain and travels to the nucleus accumbens (Figure 2). It is the cornerstone target to all addictions. The VTA is encompassed with neurons using glutamate, GABA, and dopamine. The nucleus accumbens (NAc) is located within the ventral striatum and is divided into two sub-regions—the motor and limbic regions associated with its core and shell, respectively. The NAc has spiny neurons that receive dopamine from the VTA and glutamate (a dopamine driver) from the hippocampus, amygdala and medial prefrontal cortex. Subsequently, the NAc projects GABA signals to an area termed the ventral pallidum (VP). The region is a relay station in the limbic loop of the basal ganglia, critical for motivation, behavior, emotions and the “Feel Good” response. This defined system of the brain is involved in all addictions –substance, and non –substance related. In 1995, our laboratory coined the term “Reward Deficiency Syndrome” (RDS) to describe genetic and epigenetic induced hypodopaminergia in the “Brain Reward Cascade” that contribute to addiction and compulsive behaviors [3,6,41]. Furthermore, ordinary “liking” of something, or pure pleasure, is represented by small regions mainly in the limbic system (old reptilian part of the brain). These may be part of larger neural circuits. In Latin, hedus is the term for “sweet”; and in Greek, hodone is the term for “pleasure.” Thus, the word Hedonic is now referring to various subcomponents of pleasure: some associated with purely sensory and others with more complex emotions involving morals, aesthetics, and social interactions. The capacity to have pleasure is part of being healthy and may even extend life, especially if linked to optimism as a dopaminergic response [42]. Psychiatric illness often includes symptoms of an abnormal inability to experience pleasure, referred to as anhedonia. A negative feeling state is called dysphoria, which can consist of many emotions such as pain, depression, anxiety, fear, and disgust. Previously many scientists used animal research to uncover the complex mechanisms of pleasure, liking, motivation and even emotions like panic and fear, as discussed above [43]. However, as a significant amount of related research about the specific brain regions of pleasure/reward circuitry has been derived from invasive studies of animals, these cannot be directly compared with subjective states experienced by humans. In an attempt to resolve the controversy regarding the causal contributions of mesolimbic dopamine systems to reward, we have previously evaluated the three-main competing explanatory categories: “liking,” “learning,” and “wanting” [3]. That is, dopamine may mediate (a) liking: the hedonic impact of reward, (b) learning: learned predictions about rewarding effects, or (c) wanting: the pursuit of rewards by attributing incentive salience to reward-related stimuli [44]. We have evaluated these hypotheses, especially as they relate to the RDS, and we find that the incentive salience or “wanting” hypothesis of dopaminergic functioning is supported by a majority of the scientific evidence. Various neuroimaging studies have shown that anticipated behaviors such as sex and gaming, delicious foods and drugs of abuse all affect brain regions associated with reward networks, and may not be unidirectional. Drugs of abuse enhance dopamine signaling which sensitizes mesolimbic brain mechanisms that apparently evolved explicitly to attribute incentive salience to various rewards [45]. Addictive substances are voluntarily self-administered, and they enhance (directly or indirectly) dopaminergic synaptic function in the NAc. This activation of the brain reward networks (producing the ecstatic “high” that users seek). Although these circuits were initially thought to encode a set point of hedonic tone, it is now being considered to be far more complicated in function, also encoding attention, reward expectancy, disconfirmation of reward expectancy, and incentive motivation [46]. The argument about addiction as a disease may be confused with a predisposition to substance and nonsubstance rewards relative to the extreme effect of drugs of abuse on brain neurochemistry. The former sets up an individual to be at high risk through both genetic polymorphisms in reward genes as well as harmful epigenetic insult. Some Psychologists, even with all the data, still infer that addiction is not a disease [47]. Elevated stress levels, together with polymorphisms (genetic variations) of various dopaminergic genes and the genes related to other neurotransmitters (and their genetic variants), and may have an additive effect on vulnerability to various addictions [48]. In this regard, Vanyukov, et al. [48] suggested based on review that whereas the gateway hypothesis does not specify mechanistic connections between “stages,” and does not extend to the risks for addictions the concept of common liability to addictions may be more parsimonious. The latter theory is grounded in genetic theory and supported by data identifying common sources of variation in the risk for specific addictions (e.g., RDS). This commonality has identifiable neurobiological substrate and plausible evolutionary explanations. Over many years the controversy of dopamine involvement in especially “pleasure” has led to confusion concerning separating motivation from actual pleasure (wanting versus liking) [49]. We take the position that animal studies cannot provide real clinical information as described by self-reports in humans. As mentioned earlier and in the abstract, on November 23rd, 2017, evidence for our concerns was discovered [50] In essence, although nonhuman primate brains are similar to our own, the disparity between other primates and those of human cognitive abilities tells us that surface similarity is not the whole story. Sousa et al. [50] small case found various differentially expressed genes, to associate with pleasure related systems. Furthermore, the dopaminergic interneurons located in the human neocortex were absent from the neocortex of nonhuman African apes. Such differences in neuronal transcriptional programs may underlie a variety of neurodevelopmental disorders. In simpler terms, the system controls the production of dopamine, a chemical messenger that plays a significant role in pleasure and rewards. The senior author, Dr. Nenad Sestan from Yale, stated: “Humans have evolved a dopamine system that is different than the one in chimpanzees.” This may explain why the behavior of humans is so unique from that of non-human primates, even though our brains are so surprisingly similar, Sestan said: “It might also shed light on why people are vulnerable to mental disorders such as autism (possibly even addiction).” Remarkably, this research finding emerged from an extensive, multicenter collaboration to compare the brains across several species. These researchers examined 247 specimens of neural tissue from six humans, five chimpanzees, and five macaque monkeys. Moreover, these investigators analyzed which genes were turned on or off in 16 regions of the brain. While the differences among species were subtle, **there was** a **remarkable contrast in** theneocortices, specifically in an area of the brain that is much more developed in humans than in chimpanzees. In fact, these researchers found that a gene called tyrosine hydroxylase (TH) for the enzyme, responsible for the production of dopamine, was expressed in the neocortex of humans, but not chimpanzees. As discussed earlier, dopamine is best known for its essential role within the brain’s reward system; the very system that responds to everything from sex, to gambling, to food, and to addictive drugs. However, dopamine also assists in regulating emotional responses, memory, and movement. Notably, abnormal dopamine levels have been linked to disorders including Parkinson’s, schizophrenia and spectrum disorders such as autism and addiction or RDS. Nora Volkow, the director of NIDA, pointed out that one alluring possibility is that the neurotransmitter dopamine plays a substantial role in humans’ ability to pursue various rewards that are perhaps months or even years away in the future. This same idea has been suggested by Dr. Robert Sapolsky, a professor of biology and neurology at Stanford University. Dr. Sapolsky cited evidence that dopamine levels rise dramatically in humans when we anticipate potential rewards that are uncertain and even far off in our futures, such as retirement or even the possible alterlife. This may explain what often motivates people to work for things that have no apparent short-term benefit [51]. In similar work, Volkow and Bale [52] proposed a model in which dopamine can favor NOW processes through phasic signaling in reward circuits or LATER processes through tonic signaling in control circuits. Specifically, they suggest that through its modulation of the orbitofrontal cortex, which processes salience attribution, dopamine also enables shilting from NOW to LATER, while its modulation of the insula, which processes interoceptive information, influences the probability of selecting NOW versus LATER actions based on an individual’s physiological state. This hypothesis further supports the concept that disruptions along these circuits contribute to diverse pathologies, including obesity and addiction or RDS.

#### Prefer:

#### 1] Bindingness-- I could put my hand on a hot stove and I’d automatically pull it back before a signal is sent to my brain-- Anything else fails to be morally binding because one could always ask “why not?”

#### 2] Actor spec—governments must use util because they don’t have intentions and are constantly dealing with tradeoffs—outweighs since different agents have different obligations

#### Actor Spec—Fixation on the motives of duty doesn’t make sense for governments.

Robert E. Goodin 95 [professor of government at the University of Essex, and professor of philosophy and social and political theory at Australian National University], “Utilitarianism as a Public Philosophy”, Cambridge Studies in Philosophy and Public Policy, May 1995, BE

The great advantage of utilitarianism as a guide to public conduct is that it avoids gratuitous sacrifices, it ensures as best we are able to ensure in the uncertain world of public policy-making that policies are sensitive to people’s interests or desires or preferences. The great failing of more deontological theories, applied to those realms, is that they fixate upon duties done for the sake of duty rather than for the sake of any good that is done by doing one's duty. Perhaps it is per- missible (perhaps it is even proper) for private individuals in the course of their personal affairs to fetishize duties done for their own sake. It would be a mistake for public officials to do likewise, not least because it is impossible. The fixation on motives makes absolutely no sense in the public realm, and might make precious little sense in the private one even, as Chapter 3 shows. The reason public action is required at all arises from the inability of uncoordinated individual action to achieve certain morally desir- able ends. Individuals are rightly excused from pursuing those ends. The inability is real; the excuses, perfectly valid. But libertarians are right in their diagnosis, wrong in their prescription. That is the mes- sage of Chapter 2. The same thing that makes those excuses valid at the individual level - the same thing that relieves individuals of re- sponsibility - makes it morally incumbent upon individuals to organ- ize themselves into collective units that are capable of acting where they as isolated individuals are not. When they organize themselves into these collective units, those collective deliberations inevitably take place under very different cir- cumstances, and their conclusions inevitably take very different forms. Individuals are morally required to operate in that collective manner, in certain crucial respects. But they are practically circumscribed in how they can operate, in their collective mode. And those special con- straints characterizing the public sphere of decision-making give rise to the special circumstances that make utilitarianism peculiarly apt for public policy-making, in ways set out more fully in Chapter 4. Gov- ernment house utilitarianism thus understood is, I would argue, a uniquely defensible public philosophy.”

#### 3] Only consequentialism explains degrees of wrongness—if I break a promise to meet up for lunch, that is not as bad as breaking a promise to take a dying person to the hospital. Only the consequences of breaking the promise explain why the second one is much worse than the first which is the most intuitive. That outweighs:

#### A] Parsimony – metaphysics relies on long chains of questionable claims that make conclusions less likely.

#### B] Hijacks – intuitions are inevitable since even every framework must take some unjustified assumption as a starting point.

#### 4] Use epistemic modesty for clash – disincentives debaters going all in for framework meaning we get the ideal balance between normative and applied philosophy

#### 5] Reject calc indicts and util triggers permissibility arguments:

#### A] Theory—they’re functionally NIBs that everyone knows are silly but skew the aff and move the debate away from the topic and actual philosophical debate, killing valuable education

#### B] Morally abhorrent – it would say we have no obligation to prevent genocide and that slavery was permissible which is morally abhorrent and makes debate unsafe

#### 5] Lexical pre-requisite: threats to bodily security preclude the ability for moral actors to effectively act upon other moral theories since they are in a constant state of crisis that inhibits the ideal moral conditions which other theories presuppose

#### 6] Topic lit: util ensures that we have a wide breadth of literature about the topic to read because contention level arguments are centered around current events and substantive. Outweighs because of accessibility – it might be difficult for debaters to access paywalled philosophical journals and to make sense of them, but general topic literature like news and op eds are easily accessible.

#### 8] Extinction first under any framework

#### A] Future lives -- trillions of future lives are lost. They are just as valuable as current ones – anything else says some lives are worth less than others which is genocidal rhetoric

#### B] Reversibility -- extinction forecloses future improvement; prefer -- if we’re unsure about which interpretation of the world is true, we should preserve it to figure things out.

## 2

#### Medical innovation is high now

Kenan 6-9, The Frank Hawkins Kenan Institute of Private Enterprise develops and promotes innovative, market-based solutions to vital economic issues. With the belief that private enterprise is the cornerstone of a prosperous and free society, the institute fosters the entrepreneurial spirit to stimulate economic prosperity and improve the lives of people in North Carolina, across the country and around the world. Kenan Institute, 6-9-21, “Turbocharging Healthcare Innovation” <https://kenaninstitute.unc.edu/kenan-insight/turbocharging-healthcare-innovation/> brett

As COVID-19 began to spread around the globe, companies and entrepreneurs stepped up to develop new technologies and redeploy existing technologies in their portfolio to tackle the disease and cope with the constraints it brought. The pandemic forced telemedicine into the mainstream and brought mRNA vaccine technology to the forefront. At the same time, new technologies such as CRISPR gene editing and artificial intelligence (AI) approaches have been finding their niche for speeding up drug discovery and development. Healthcare innovation was already on the fast train before the pandemic. Now, it’s been turbocharged. In this Kenan Insight, we explore why the 2021 Trends in Entrepreneurship Report names emerging technology in the healthcare industry as a key trend for entrepreneurship, along with some of the challenges that come with fast-moving technology advances. A trajectory of explosive growth The healthcare industry has experienced extraordinary growth over the past four decades. Big pharma is driving much of this boom, accounting for 10% of the U.S. economy’s overall R&D spending at the end of 2020.1 The medical device industry, expected to generate $54.5 billion over the next four years, is another important player.2 This growth is catching the attention of investors. In 2020, health tech startups raised approximately $14 billion in venture capital funding, nearly double that of 2019.3 CB Insights estimates there are now 51 healthcare unicorns, defined as startups valued at $1 billion or more. Health-tech venture funding reached record levels in 2020 Source: Deloitte analysis of Rock Health’s Digital Health Funding Database Innovation is a critical driver in the healthcare sector. Increasing rates of innovation can be seen in the sharp rise of U.S. patents granted for pharmaceuticals and medical devices in recent years. Between 2013 and 2019, more than 60,000 pharmaceutical patents and more than 125,000 medical device patents were granted.4 Today, there are more than 18,500 drugs at various stages of the development process worldwide.5 Maturing technologies The increasing numbers of patent applications, clinical trials and collaborations are leading indicators of a vibrant and growing biopharmaceutical ecosystem. However, the proliferation of innovation tools, rather than just innovative products, is what will allow the next generation of pharmaceutical drugs to be discovered more quickly and more efficiently, to provide more effective treatments and to target diseases that have so far evaded our collective intervention efforts. As scientists learn more about human genes and their connection to diseases, these insights can feed into tools that make drug R&D faster, less expensive and more precise. AI technology has matured to the point where it can now be used reliably to analyze huge amounts of data and solve extremely complex problems. This has made AI attractive to the pharmaceutical industry as a tool that can enable more efficient identification of new drugs and drug targets. In 2020, drug discovery was the focus area that received the most private AI investment, with more than $13.8 billion invested globally. This was 4.5 times higher than the total for 2019.6 CRISPR gene editing is another hot technology that is enabling the development of more innovative and accurate therapeutic strategies. This tool is making it easier to determine the genes and proteins that cause or prevent disease and thus to identify new targets for potential drugs. As of the second quarter of 2020, there were 724 active companies around the world focused on using or developing CRISPR technology and almost 50 clinical trials involving CRISPR.7 mRNA was certainly one of the brightest technology stars of 2020. After decades of research, mRNA proved to be the ideal solution for developing a highly effective COVID-19 vaccine at record speed. However, this is likely only the beginning of the story for mRNA. Therapies based on mRNA technology are being developed to treat malaria, cancer and multiple sclerosis and we’ll likely see more mRNA-based vaccines designed to fight a host of current and future infectious diseases. As of February 2021, CB Insights reports more than 520 ongoing clinical trials worldwide that were applying mRNA technology to more than 20 disease classes.8

#### The plan undermines the economic certainty provided by TRIPS---that disrupts innovation in every sector

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Public posturing aside, the Biden Administration surely knows that a TRIPS waiver for COVID-19 related IP will likely be futile. Scaling up production, as Klain alluded to, has proven to be the main challenge to manufacturing larger quantities of vaccine.[4] Waiving TRIPS would do nothing to address this constraint. Waiving TRIPS would instead encourage IP abuse and distort market forces and innovation. TRIPS Provisions The TRIPS agreement is an international trade agreement among all 164 members of the WTO. It is one of three founding and central components of the WTO, along with the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS). The purpose of the TRIPS agreement is to unify trade and provide increased certainty in international economic relations. Among other things, TRIPS specifically: Provides minimum IP protections and standards that apply to all WTO members; Outlines enforcement actions that countries can undertake to remedy violations of the above standards; and Establishes dispute settlement procedures to allow countries to negotiate an end to disagreements. TRIPS does, however, allow for compulsory licensing where in a public health emergency, a country may copy patented drugs without the permission of the original manufacturer with WTO approval. Proposal to Waive TRIPS The recent proposal submitted by India and South Africa and signed on by over 100 developing countries would waive four specific protections of COVID-19 vaccines and related medical products and services: Copyrights; Patents; Trademarks; and Undisclosed information procedures. The first three protections allow companies to prevent foreign companies from copying their products. They require the original company to disclose information about the product, however. Foreign companies are free to study the disclosed information of the patent but cannot copy it unless given a licensing agreement from the original company. Contrarily, companies can choose not to get patents for their products and instead keep their information secret. The fourth protection prevents the theft of trade secrets of foreign companies. While TRIPS has been waived previously, if approved, this would be the broadest waiver since the agreement’s enactment in 1995.[5] TRIPS and Manufacturing Capacity The primary justification for waiving TRIPS is that IP protections cause underutilized manufacturing capacity. By removing TRIPS, developing nations could copy patented drugs and use their own manufacturers to produce vaccines, thereby increasing access. This rationale, however, is flawed. Adar Poonawalla, CEO of the Serum Institute of India—currently the largest producer of COVID-19 vaccine doses in the world—has argued that access to IP is not limiting vaccine production, rather it is the time involved in scaling up manufacturing capacity.[6] It should also be noted that Moderna has already pledged not to enforce its own COVID-19 vaccine patents during the pandemic.[7] In addition, COVID-19 vaccines such as those produced by Pfizer and Moderna use emerging and very complex technologies and processes. These technologies and processes are essential to producing and increasing scale of COVID-19 vaccines. They are not published in patents but rather kept as trade secrets. The fourth protection mentioned above only prevents theft of trade secrets; it does not allow or disallow a company from keeping trade secrets. Waiving TRIPS therefore does nothing to speed up vaccine production even if there were excess manufacturing capacity, as manufacturers would not receive the essential trade secrets they would need. The issue at present is not underutilized manufacturing capacity, rather scaling up production has been the largest difficulty of vaccine manufacturing. It takes anywhere from 60 to 120 days to produce a single batch of vaccines. Even with manufacturing challenges, between 9.5 and 13.5 billion doses of COVID-19 vaccines are projected to be produced in 2021. Eleven billion doses would be sufficient to vaccinate 70 percent of the world population and reach heard immunity, assuming 2-dose vaccinations.[8] TRIPS and Compulsory Licensing Separate from a broad IP waiver, TRIPS includes a compulsory licensing process. Foreign manufacturers are free to ask a patentee for a voluntary licensing agreement to manufacture a product. This process can be long, however, and the patentee can ultimately refuse. When this happens, TRIPS allows the manufacturer through its national government to grant a compulsory license provided the manufacturer has first sought a voluntary licensing agreement. This compulsory license is issued by that national government to the manufacturer to produce a patented drug without the original patentee’s permission. Each compulsory license must apply to a specific product. It is important to note that TRIPS does not have a governing body which oversees this process. At the same time, if a country grants an internationally unpopular compulsory license, it will face economic, political, and retaliatory ramifications from other governments and private firms, so governments must weigh these costs. In addition, if a country declares a national emergency or other circumstances of extreme urgency, TRIPS allows a foreign manufacturer to immediately apply for a compulsory license, skipping the process to apply for a voluntary license. A TRIPS waiver, like the one suggested for COVID-19-related IP, is therefore entirely unnecessary—even if IP protections were an obstacle to vaccine access. In the case of COVID-19, compulsory licensing would not, however, address the real issues related to scaling manufacturing capacity. The Vagueness of the Proposed TRIPS Waiver Under the broad language of the proposed TRIPS waiver, any drugs that have use for patients with COVID-19, including those that predate the pandemic, could lose patent protection. Thus, a foreign company could produce a specific drug under the auspices of COVID-19 but sell it for another disease. Moreover, the foreign company would not have to provide any financial compensation to the company from whom they took the IP. The proposal’s language is so broad that other patented medical products beyond pharmaceutical drugs such as masks, non-pharmaceutical chemical compounds, and respirators would also be subject to the waiver. It is also noteworthy that the vaccines developed by Pfizer, Moderna, and Johnson & Johnson are not currently approved by the Indian government for use in India, due to regulatory obstacles related to localized clinical trials. Effectively then, India is pointing to IP protections as an obstacle to obtaining vaccines they have not even approved for use in their country.[9] At the same time, a concerted global effort is underway to ensure access to COVID-19 vaccines in all countries. The WHO, Gavi (previously the Global Alliance for Vaccines and Immunization), and the Coalition for Epidemic Preparedness Innovations have partnered to establish the COVAX initiative, designed specifically to distribute vaccines to the developing world. COVAX is projected to distribute at least 2 billion vaccines by the end of 2021.[10] Johnson & Johnson has further announced plans to distribute 500 million vaccines to developing nations starting in mid-2021, in addition to those it already allocated to other nations.[11] TRIPS and Innovation The TRIPS agreement and its IP protections were created to increase unity and certainty in the global economy. The economic certainty provided by IP protections preserve competitiveness and increase value—i.e., IP protections provide incentives to companies to create new and groundbreaking technologies. In terms of the COVID-19 pandemic, perhaps it is these incentives that encouraged companies to produce vaccines quickly and successfully. Without IP protections, companies could not reap the rewards of their efforts. Waiving TRIPS would weaken the market forces that encourage innovation. Combined with the broad language of the TRIPS waiver, the loss of innovation would happen in many industries and sectors of the global economy. Conclusion The proposal to waive TRIPS is based on the misperception that IP protections serve as barriers to COVID-19 vaccine production. In fact, the difficulty of scaling up production is the key challenge. Waiving TRIPS will do nothing to increase vaccine production, represents poor policy toward IP, and will create a whole new set of trade policy challenges. A better approach is to build upon current global vaccine partnerships while ensuring that companies can secure their supply chains. Such efforts would increase access to vaccines while avoiding the potentially widespread and long-term problems associated with waiving IP protections provided by TRIPS.

#### Innovation is an impact filter---it encompasses AND outweighs every existential threat.

Dylan Matthews 18. Co-founder of Vox, citing Nick Beckstead @ Rutgers University. 10-26-2018. "How to help people millions of years from now." Vox. <https://www.vox.com/future-perfect/2018/10/26/18023366/far-future-effective-altruism-existential-risk-doing-good> brett

If you care about improving human lives, you should overwhelmingly care about those quadrillions of lives rather than the comparatively small number of people alive today. The 7.6 billion people now living, after all, amount to less than 0.003 percent of the population that will live in the future. It’s reasonable to suggest that those quadrillions of future people have, accordingly, hundreds of thousands of times more moral weight than those of us living here today do. That’s the basic argument behind Nick Beckstead’s 2013 Rutgers philosophy dissertation, “On the overwhelming importance of shaping the far future.” It’s a glorious mindfuck of a thesis, not least because Beckstead shows very convincingly that this is a conclusion any plausible moral view would reach. It’s not just something that weird utilitarians have to deal with. And Beckstead, to his considerable credit, walks the walk on this. He works at the Open Philanthropy Project on grants relating to the far future and runs a charitable fund for donors who want to prioritize the far future. And arguments from him and others have turned “long-termism” into a very vibrant, important strand of the effective altruism community. But what does prioritizing the far future even mean? The most literal thing it could mean is preventing human extinction, to ensure that the species persists as long as possible. For the long-term-focused effective altruists I know, that typically means identifying concrete threats to humanity’s continued existence — like unfriendly artificial intelligence, or a pandemic, or global warming/out of control geoengineering — and engaging in activities to prevent that specific eventuality. But in a set of slides he made in 2013, Beckstead makes a compelling case that while that’s certainly part of what caring about the far future entails, approaches that address specific threats to humanity (which he calls “targeted” approaches to the far future) have to complement “broad” approaches, where instead of trying to predict what’s going to kill us all, you just generally try to keep civilization running as best it can, so that it is, as a whole, well-equipped to deal with potential extinction events in the future, not just in 2030 or 2040 but in 3500 or 95000 or even 37 million. In other words, caring about the far future doesn’t mean just paying attention to low-probability risks of total annihilation; it also means acting on pressing needs now. For example: We’re going to be better prepared to prevent extinction from AI or a supervirus or global warming if society as a whole makes a lot of scientific progress. And a significant bottleneck there is that the vast majority of humanity doesn’t get high-enough-quality education to engage in scientific research, if they want to, which reduces the odds that we have enough trained scientists to come up with the breakthroughs we need as a civilization to survive and thrive. So maybe one of the best things we can do for the far future is to improve school systems — here and now — to harness the group economist Raj Chetty calls “lost Einsteins” (potential innovators who are thwarted by poverty and inequality in rich countries) and, more importantly, the hundreds of millions of kids in developing countries dealing with even worse education systems than those in depressed communities in the rich world. What if living ethically for the far future means living ethically now? Beckstead mentions some other broad, or very broad, ideas (these are all his descriptions): Help make computers faster so that people everywhere can work more efficiently Change intellectual property law so that technological innovation can happen more quickly Advocate for open borders so that people from poorly governed countries can move to better-governed countries and be more productive Meta-research: improve incentives and norms in academic work to better advance human knowledge Improve education Advocate for political party X to make future people have values more like political party X ”If you look at these areas (economic growth and technological progress, access to information, individual capability, social coordination, motives) a lot of everyday good works contribute,” Beckstead writes. “An implication of this is that a lot of everyday good works are good from a broad perspective, even though hardly anyone thinks explicitly in terms of far future standards.” Look at those examples again: It’s just a list of what normal altruistically motivated people, not effective altruism folks, generally do. Charities in the US love talking about the lost opportunities for innovation that poverty creates. Lots of smart people who want to make a difference become scientists, or try to work as teachers or on improving education policy, and lord knows there are plenty of people who become political party operatives out of a conviction that the moral consequences of the party’s platform are good. All of which is to say: Maybe effective altruists aren’t that special, or at least maybe we don’t have access to that many specific and weird conclusions about how best to help the world. If the far future is what matters, and generally trying to make the world work better is among the best ways to help the far future, then effective altruism just becomes plain ol’ do-goodery.\*

#### Medical innovation is key to address future pandemics---extinction.

Engelhardt 8 (H. Tristram, doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine, “Innovation and the Pharmaceutical Industry: Critical Reflections on the Virtues of Profit,” <https://www.amazon.com/Innovation-Pharmaceutical-Industry-Reflections-Conflicts/dp/0980209447>) (Taiwan)

Many are suspicious of, or indeed jealous of, the good fortune of others. 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 pharmaceutical 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.

## Case

### COVID

#### The issue is lack of resources, not IPR.

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When the IP waiver concept was first proposed last October, Moderna agreed not to enforce its COVID-19 related patents during the pandemic. But despite Moderna’s voluntary waiver of its IP rights, no other company has stepped up to manufacture the Moderna vaccine. The most significant obstacle to COVID-19 vaccine supply is not just the IP rights that companies have obtained, or are pursuing, but rather the lack of raw materials and manufacturing facilities to produce the vaccines. Currently, there are shortages of raw materials and equipment used to make vaccines and biological products.

Unlike drug manufacturing, vaccine production processes are extremely complex and difficult to develop without support from current manufacturers. Additional manufacturers would need to have or acquire skilled expertise in mRNA technology and create or reconfigure manufacturing sites. Manufacturing vaccines requires additional processing steps and testing to assure quality and consistency. Manufacturing vaccines will also likely use the patented technology of other companies, who have not waived their IP rights. Investment in manufacturing is also an important piece of the solution. Whether existing companies can retool facilities and jump start manufacturing or new facilities need to be created through investment will be outcome determinative.

There is little doubt that the waiver proposals would at the very least up-end the existing incentives, including the prospect of future pharmaceutical innovation and development of products, that resulted in the rapid development and approval of COVID-19 vaccines. Moreover, the TRIPS waiver proposals may not have the desired effect of boosting COVID vaccine production and availability of mRNA vaccines. On the other hand, recent attempts at voluntary licensing and technology transfer agreements related to adenovirus vector technology have resulted in increased vaccine production and availability. A TRIPS waiver may not be as effective for more complex vaccine production.

Scaling up COVID-19 vaccine production is not a one-size-fits -all proposition. Ensuring equitable availability and delivery complicates the matter further.

### WTO

#### The plan creates a perception of uncertainty about WTO rules in times of crisis.

Clete Willems 8-5, J.D., Georgetown University Law Center, cum laude, 2008 B.S.Ch.E., University of Notre Dame, 2002. Official transcription from OnAir: Health Care. August 5, 2021. “Ep. 4: Onshoring Drug Manufacturing and TRIPS Waiver Part II” <https://www.akingump.com/a/web/fkezGqrYvu1TKfz4kpbUXb/33Qgf1/onair-health-care-ep04-clete-willems-jim-deyonker.pdf> brett

Clete Willems: I do think that there's value in the conversation, and if you look at the European proposal, actually, I think that's the way to go because what the Europeans are saying is let's not get rid of the WTO agreements in times of crisis. What they're saying is let's make sure that the provisions that are already embedded in those agreements on compulsory licensing actually work. I do think that that is a useful conversation. I don't want to get too philosophical on you all, but if you think about the trading system more generally and you think about the rules on international trade, they're supposed to work in all circumstances. They're not supposed to just work in the best of times. They're supposed to work in the worst of times. If you go down the path of India and South Africa and you say, "We're just going to get rid of the WTO rules during a pandemic," that doesn't make any sense. That's the law of the jungle.

#### That outweighs – their impact is specific to the willingness of WTO Members to follow trade rules – lifting them during crises sends the signal that trade rules are less important now.

#### Alternative causes to WTO legitimacy.

MCBride et al 6-14 James Mcbride, Andrew Chatzky, and Anshu Siripurapu 21, 6-14-2021, "What’s Next for the WTO?," Council on Foreign Relations, https://www.cfr.org/backgrounder/whats-next-wto, accessed 7/25/2021 EH

What are the alternatives to the WTO system? Even with Doha stalled, WTO talks have continued through what are known as plurilateral negotiations, or agreements among subsets of WTO members. Plurilateral deals are easier to negotiate, as they are narrower in focus and not all members are bound by their terms. At the 2015 Nairobi talks, for instance, fifty-three WTO members concluded an expansion of the Information Technology Agreement, or ITA, which reduces trade tariffs on a raft of IT products. The agreement means that more than 97 percent of all global IT trade is now covered by WTO rules. A major plurilateral agreement in progress is the Trade in Services Agreement (TiSA), under negotiation since 2013 [PDF] among twenty-three members, including the United States and European Union (EU) but excluding China. TiSA’s backers hope to use the talks to further the WTO’s liberalization of the global services trade, the rules for which haven’t been updated since 1995. In 2012, nineteen members agreed to update the Government Procurement Agreement (GPA), which seeks to further open government procurement markets. And in 2014, fourteen members, including the United States, China, the EU, and Japan, opened negotiations on a proposed Environmental Goods Agreement (EGA), which would liberalize trade in environmental products, such as wind turbines and solar panels. In 2019, a group of more than seventy countries, including those in the EGA negotiations, launched talks for an agreement on e-commerce, an increasingly important trade issue. Many countries have also turned to bilateral free trade agreements (FTAs) or larger regional ones. The Obama administration pushed for so-called megaregional deals, such as the Trans-Pacific Partnership (TPP) and the U.S.-EU Transatlantic Trade and Investment Partnership (TTIP). But Trump voiced deep skepticism about multilateralism, preferring to deal with trading partners on a bilateral basis. He withdrew from the TPP immediately upon taking office, and the remaining members completed the deal without the United States. As U.S. allies advanced FTAs without him, Trump pursued unilateral measures to confront China and other countries on trade, raising serious doubts about the future of the WTO.