### 1

#### The standard is maximizing expected well-being, or hedonistic act utilitarianism.

#### 1] Neuroscience- pleasure and pain *are* intrinsic value and disvalue – everything else regresses.

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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** the **neocortices**, 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.

#### 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—takes out calc indicts since they are empirically denied.

#### Util is key to debates about IP.

Kar 19 [Mohit; Writer at the Original Position; “Utilitarianism in the Context of Intellectual Property,” The Original Position; 9/18/19; <https://originalpositionnluj.wordpress.com/2019/09/18/utilitarianism-in-the-context-of-intellectual-property/>] Justin

Jeremy Bentham is known as the founder of modern utilitarianism. He believed in production of the greatest possible quantity of happiness, on the part of those whose interest is in view. With regards to intellectual property, he had opined that inventors and authors should be given absolute privilege over their work, which would ensure they get remunerated duly for their work, thus leading to further creative actions being taken by them. In this article, the author will make an analysis of the utilitarian theory as proposed by Jeremy Bentham and its interplay with Intellectual Property.

According to utilitarians, the main purpose of property rights is the maximization of common well-being.[i] According to Jeremy Bentham, the common well-being here mentioned is the good for the greatest number of people in a population. He defined the principle of utility as carrying an object of production of maximum happiness in a given time in a particular society.[ii]

The wealth of a society consists of the cumulative wealth of each of its individual members. The most effective way to increase individual wealth is to leave the management of wealth to the individual himself, since – between the individual and the government – it is the individual who can best manage his own wealth. The society gains benefits because the increase in individual wealth is also the increase of collective wealth. Sharing this wealth is managed by the government, through taxes. Bentham argued that the value of outcome of a society is positive if the total quantity of pleasure gained by each individual under its influence is greater than the total quantity of pain.[iii] Thus, Bentham put stress on the happiness and wealth of individuals in a society.

Jeremy Bentham’s utilitarianism advocates the maximization of common well-being and the proper use of resources available. To show us a practical point of view, he criticized the kind of trade strategies where a country prevents the purchase of cheaper products from another country only to protect its market. In his opinion, to pay more for a product that can be manufactured elsewhere with the same quality standards only to favor the national industry is a waste of resources.[iv] Bentham believed that trade barriers to foreign imports cannot increase trade and commerce in a particular country.[v] He termed it as a necessary evil which would give rise to monopolies and lower the quality of production.[vi]

Transposing this theory to intellectual property rights, for the maximization of common welfare to be made, the legislators should strike a balance between, the monopoly of rights to stimulate creation and giving access to the population to inventions. Bentham defended the idea of ​​a limited period of protection for patents and he believed in the absolute privilege of the inventor, so that the latter can recover the amounts invested during the inventive process, while being paid for his creative activity.[vii] The right must also help the inventor since without any laws to protect him; any third party could copy his invention and thus enjoy his work without any compensation being granted. The logic to defend the monopoly stems from the fact that, without the latter, the inventor would not be encouraged to put his product or invention on the market. In this case, it would be the society that would have lost wealth which could have been added to the common well-being. In the name of enriching common well-being, Bentham stresses the importance of patents in a society and even argues that their concession should be a free service offered to inventors.[viii]

The contemporary version of this theory has been presented to us by William Landes and Richard Posner in two separate works, one on copyright and the other on trademark law.[ix] Economic analysis of intellectual property rights presented by these two authors demonstrates that the protection of intellectual property may be too expensive for society and it limits the use of products. If we extrapolate a little, this contemporary utilitarian vision can assert that the products by intellectuals should be easily copied since the copies of a product do not prevent the use of the same product by several people.

William Landes and Richard Posner consider the creative process as divided into two parts.[x] If we use a book as an example, its production is split between the part comprising author’s time and effort plus publishing costs, and the second part includes publication and distribution costs of the book. Generally, it is the first of these two elements that demands the most investment. The second will be more or less expensive, depending on the quantity of copies that will be produced. When the work is complete, its reproduction does not require any investment at the creative level. Hence, they stated that striking a correct balance between access and incentives is one of the central problems of copyright law.[xi] In this way, as already mentioned, the lack of remuneration of creators for the exploitation of their works may have as a consequence the diminution of the cultural wealth of a society, given that the creators will not have the desire to continue to create unless paid. It is important to note that the lack of protection conferred by copyright would not change this problem. In a society where copyright protection does not exist, a book could be easily copied without the act of copying being considered an offense. When the contemporary utilitarian vision is applied, it indicates that the benefits that they bring to a society are: It makes it easier for consumers to choose the product which has the qualities corresponding most to its needs. Since consumers already know the brand, they should not search among a whole range of products available on the market; It encourages producers to maintain good quality of their products, because consumers associate the product quality with the brand attached to it; It improves the language. Landes and Posner believe that the brands create new words that end up being incorporated in the lexicon of the language.[xii]

Suppose the utilitarian theory – that of Bentham, or Posner’ and Landes’ – would be applied to intellectual property as it stands today: the benefits that would be brought to society by this analysis would be the incentive for creativity, the optimization of production and the disappearance or diminution of similar inventions made by different individuals.

Among these three advantages, we can consider the incentive to creation as the most important. In this case, the monopoly guaranteed by intellectual property stimulates creation in a society and, especially with regard to patents; inventions will bring more happiness and pleasure to society in general. This justifying argument is in harmony with Bentham’s utilitarianism. The problem here is that no one really knows what kind of invention would bring more or less happiness or pleasure to the society. Moreover, the term “monopoly concession” for patents, trademarks and copyright is not based on any empirical or objective study and is rather random.

Optimization of production sees ownership monopolies intellectual property as a “service” to society since data from sale indicates the products for which the company has the most need. This approach could even justify increasing the period of protection of intellectual property products. The logic here is that the decrease in the protection period or even the removal of the protection would deprive the producers of information that enables them to optimize their production. Thereby, the withdrawal or diminution of protection could even be considered harmful to society. However, if we do not impose limitations to this theory, the result could be a disparity of investments in intellectual property over investments in other areas, such as education and health, as well as in general research activities.

CONCLUSION

Utilitarianism, as it stands today, is intimately linked to the information obtained from the use of intellectual property monopolies. The goal is to avoid duplication of production. The problem in this case is that in a society which values ​​and encourages the production of new patents and new technologies, the plethora of patents complicates the process. This finding is based on the fact that new inventions normally rely on existing patents and the production of a new patented product will require a large number of licenses before it can begin. As Richard Posner said in his blog: ‘Patents are a source of great social costs, and only occasionally of commensurate benefits. Most firms do not actually want patents; for those firms, the costs involved in obtaining licenses from patentees are not offset by the prospect of obtaining license fees on their own patents.’

#### Outweighs –

#### A] Most articles about IP are written through util – means other frameworks can never engage with core questions of the lit and decks predictability – equal topic lit means fair ground.

#### B] TJFs first – substance begs the question of a framework being good for debate – fairness is a gateway issue to deciding the winner and education is the reason schools fund debate.

#### 2) util is the baseline introduction to debate and the most accessible, other fw’s require coaches to learn which are expensive B. TJFs first – substance begs the question of a framework being good for debate, 2) fw debates are functionally topicality debates of the word ought so they have to be theoretically justified

#### Impact calc – extinction outweighs

#### A] Objectivity- body count is the most objective way to calculate impacts because comparing suffering is unethical

#### B] Uncertainty- if we’re unsure about which interpretation of the world is true, we should preserve the world to keep debating about it

### 2

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The aff crushes innovation in the pharma sector---incentivizes them to focus on non-important issues.

Glassman 21 [Amanda; 5/6/21; Executive vice president and a senior fellow at the Center for Global Development, a nonpartisan, nonprofit think tank in Washington and London; “*Big Pharma Is Not the Tobacco Industry*,” Barron, <https://www.barrons.com/articles/big-pharma-is-not-the-tobacco-industry-51620315693>] Justin

But here is the crux of the problem: The pharmaceutical industry is not the tobacco industry. They are not merchants of death. The companies are amoral and exist to make money, but their business is not fundamentally immoral. Big Pharma (mostly) develops and sells products that people need to survive and thrive. Their products improve health and welfare. Fights over access to medicines are possible because medicines exist in the first place—medicines that were usually developed by Big Pharma. And yes, the pharmaceutical industry benefits from public subsidy and publicly financed foundational research. But the companies also put their own capital at risk to develop new products, some of which offer enormous public benefits. In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen. But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita. It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize, preventable disease and deaths address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started. What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could? No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

#### Pharma Innovation prevents Extinction – checks new diseases.

Engelhardt 8, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (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)

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.

#### Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

### 3

#### Interpretation: affirmative debaters must delineate what intellectual property they reduce in the 1AC.

#### Four types of IP that are vastly different.

Ackerman 17 [Peter; Founder & CEO, Innovation Asset Group, Inc; “The 4 Main Types of Intellectual Property and Related Costs,” Decipher; 1/6/17; <https://www.innovation-asset.com/blog/the-4-main-types-of-intellectual-property-and-related-costs>] Justin

Intellectual property protection isn’t as simple as declaring ownership of a particular product or asset. In most countries, there are four primary types of intellectual property (IP) that can be legally protected: patents, trademarks, copyrights, and trade secrets. Each has their own attributes, requirements and costs.

Before narrowing your focus on which form of protection to use, know that these forms of protection are not mutually exclusive. Depending on what you’re doing, you might be able to use a “belt & suspenders” approach and apply multiple forms of protection, or one approach might be the most sensible. Read the descriptions below to get some of the basics.

Used to protect inventive ideas or processes – things that are new, useful and nonobvious - patents are what most often come to mind when thinking of IP protection. **Patents** are also used to protect newly engineered plant species or strains, as well.

Procedure For most companies, patents result from the following stages: Conceptualization Typically, innovation teams work to address a common problem facing their organization, industry, or the world at large when developing their idea. When they’ve arrived at a solution or concept, they’ll draw up plans and gather the resources necessary to make it a reality. Prototypes or drawings can be created to provide a more accurate description of the end product or process. Invention Disclosure An internal review process often occurs with every invention. The innovation team consists of internal counsel and an invention review panel of varying disciplines. The reviewers assess, rate, rank, score, and highlight potential flaws in the supporting documents and descriptions for the invention, which are then addressed by the inventor. These reviews can and often do take place multiple times for a single invention. Patent Application If the invention is deemed meritorious enough for the pursuit of patent protection, some organizations prepare their own provisional or nonprovisional patent applications. Others will farm this stage out. There may be more tweaks as an application is prepared, and then submission to the appropriate patent office and the prosecution stage begins (the back & forth with the government patent office). Typically it is outside counsel that manages this process and related docketing activities. Docketing is the overarching name for activities that include management of paperwork and meeting filing deadlines specified by the government patent office. Because the application process is often very complicated, patent offices highly recommend working with experienced patent attorneys to handle this process. Maintenance Once a patent is approved, it has a finite lifetime. Patent holders are responsible for maintaining and tracking the usage of their patents and paying the appropriate periodic government renewal fees. If a given technology or other patented asset is collecting dust, you might not want to renew it. Instead, you can try and sell, license or donate it. Conversely, if a patented asset is performing well through product sales or licensing activities and its life is getting shorter, you might think about innovating ahead and maintaining competitive momentum. Costs Costs will vary depending on the country or countries where you file an application, and can run into tens of thousands of dollars depending on the invention’s complexity, plus attorney fees. Maintenance fees over the lifetime of the patent can run into thousands more per patent, per country where patent rights have been granted. You have to keep your eyes on these costs.

Trademark

A trademark is unlike a patent in that it protects words, phrases, symbols, sounds, smells and color schemes. Trademarks are often considered assets that describe or otherwise identify the source of underlying products or services that a company provides, such as the MGM lion roar, the Home Depot orange color scheme, the Intel Inside logo, and so on.

Procedure Trademarks do not necessarily require government approval to be in effect; they can apply through abundant use in interstate commerce. Still, registration of a trademark affords far superior protection and is gained by filing an application with the proper government office. A trademark application requires the company or user to provide a clear description and representation of the mark and its uses in conjunction with associated products or services. As with patents, it’s a good idea to partner with outside counsel that specializes in trademark applications and/or search services so they can help ensure there is a clear path for your desired mark. Costs Trademarks are generally quite less expensive to obtain. According to the US Patent and Trademark Office, trademark registration currently costs between $225 and $325 for each class code you use per mark. Attorney and search fees are extra. There are also periodic (and relatively inexpensive) government maintenance fees for trademarks.

Copyrights do not protect ideas, but rather the manner in which ideas are expressed (“original works of authorship”) - written works, art, music, architectural drawings, or even programming code for software (most evident nowadays in video game entertainment). With certain exceptions, copyrights allow the owner of the protected materials to control reproduction, performance, new versioning or adaptations, public performance and distribution of the works. Procedure Copyrights in general attach when the original works become fixed in a tangible medium, but should be registered with the government copyright office for optimal protection in the form of damages, injunctions and confiscation. Copyright registration applications are much simpler than patents or trademarks, and typically can be obtained by the author alone. The US Copyright Office encourages use of their online application system, and requires a sample of the work to be protected and some background information about the author. Costs Depending on the type of work being protected, currently fees vary between $25-$100 in the US. The most frequent copyright registration sought is for one work by one author, and costs about $35.

Trade Secret

Trade secrets are proprietary procedures, systems, devices, formulas, strategies or other information that is confidential and exclusive to the company using them. They act as competitive advantages for the business. Procedure There actually isn’t a federally-regulated registration process for trade secrets. Instead, the onus is on the company in possession of the secret to take necessary precautions to maintain it as such. This is an ongoing, proactive process and can include clearly marking relevant documents as “Confidential,” implementing physical and data security measures, keeping logs of visitors and restricting access. The issuance of nondisclosure agreements or other documented assurances of secrecy can also be employed. One of the first defenses typically put up when you assert that someone misappropriated your trade secret is that you failed to adequately treat it as a trade secret. Costs Though there are no official registration costs, there are costs associated with taking appropriate precautions and security measures. You must weigh the competitive significance of your secrets against the cost of protecting them.

#### Violation:

#### Negate:

#### 1] Shiftiness- they can redefine what intellectual properties the 1ac defends in the 1ar which decks strategy and allows them to wriggle out of negative positions which strips the neg of specific IP DAs, IP PICs, and case answers. They will always win on specificity weighing.

#### CX can’t resolve this and is bad because A] Not flowed B] Skews 6 min of prep C] They can lie and no way to check D] Debaters can be shady.

#### 2] Real World- policy makers will always specify what the object of change is. That outweighs since debate has no value without portable application. It also means zero solvency since the WTO, absent spec, can circumvent aff’s policy since they can say they didn’t know what was affected.

#### This spec shell isn’t regressive- it literally determines what the affirmative implements and who it affects

### Case

## 1NC – Deleuze AC (Scarsdale KS)

### 1NC – Overview (Util)

#### Framing issue – we both have competing theories of experience – it’s a question of determining what’s ethical from that:

#### 1] Constantly changing desires and actions do not change our ONTOLOGICAL NATURE—there’s no internal link between the flux of desires and the flux of agency and we don’t blindly follow our desires – if I get angry I don’t attack someone.

#### 2] Bindingness:

#### A] Instability proves subjectivity is constantly changing which means ethics is impossible. Just saying “we are in flux” doesn’t prescribe obligations or tell us what to do in any circumstance – proves no explanatory power. Independently triggers skep: fluidity means you can act upon anything and we can’t condemn actions.

#### B] Biology- only our theory can inform experiences, like how we pull our hand from a stove even without prior experiences because of neurology. It also proves we have intrinsic values which disproves fluidity.

#### 3] It is metaphysically impossible for a subject to contain themselves to a good norm because the subject is always changing – only util informs what affect is good and bad.

#### 4] Although some instances desire would alter the subject, this does not affect their AGENCY as a whole. Certain negative or positive experiences contextualize how an agent pursues and formulates their desires.

### 1NC – affect

#### Affect

#### Just cause experience is good doesn’t mean that its intrinsicly valuable

#### There’s no metaethics to determine why experience is valuable in the first place

#### Active affect

#### Its defined by pleasure and pain

#### Static structures aren’t always bad- if someone likes their job why would 1NC – Ballot

#### ROB is to vote for the better debater. Only evaluating the consequences of the plan allows us to determine the practical impacts of politics and preserves the predictability that fosters engagement. Rigorous contestation and third and fourth-line testing are key to generate the self-reflexivity that creates ethical subjects.

### Adv

#### Aff fails---trade secrets remain secrets and existing logistical hubs fail.

Banri Ito 21 [(Professor of Economics, Aoyama Gakuin University; Fellow, RIETI), 8/8/21, Impacts of the vaccine intellectual property rights waiver on global supply, <https://voxeu.org/article/impacts-vaccine-intellectual-property-rights-waiver-global-supply>] Justin

Regarding waivers of vaccine patents, there have been some voluntary initiatives. On 8 October, soon after South Africa and India proposed a waiver of the TRIPS agreement on 2 October 2020, Moderna, a US pharmaceutical company, expressed its intention not to exercise its patent rights on its COVID-19 vaccine.1 Although Moderna reached an agreement with South Korean pharmaceutical company Samsung Biologics on consignment production of the vaccine on 22 May 2021, so far there have been very few confirmed cases of efforts to reproduce Moderna's vaccine or of licenses being granted to other companies.

With respect to the COVID-19 vaccines developed by Pfizer (jointly with BioNTech of Germany) and Moderna, it appears that the whole body of relevant technical knowledge has not necessarily been patented but that some of the technical knowledge remains undisclosed as trade secrets. Patenting is only one means of ensuring ‘appropriability’, which refers to a company's capacity to secure profits from its own technological innovation. While patent information may make it possible for outsiders to achieve development results similar to those achieved by the patented technology through a similar method without infringing the patent right, keeping the technology undisclosed as a trade secret or incorporating complex processes into it may be an effective means of ensuring appropriability. Pharmaceuticals can easily be counterfeited through ‘reverse engineering’, which refers to a process in which the active ingredients of a drug are identified as a result of deformulation. Therefore, as a general rule, it is considered important to exclude the risk of counterfeiting through patenting.

While it is not clear how much of the relevant technological knowledge remains unpatented, there are apparently some technical reasons for not obtaining full patent protection. The Pfizer and Moderna vaccines use advanced technology based on messenger RNA (mRNA), representing the first case of practical application of such technology. Although I, a non-expert in this field, will refrain from going into further detail, it is highly likely that those vaccines cannot easily be counterfeited as their production requires complex production processes and unique technology.

Patenting involves public disclosure of technical knowledge, providing information on how to reproduce patented inventions. It has the function of lowering technology trade costs by clarifying property rights on technical knowledge. If the technical knowledge necessary for manufacturing a certain product remains undisclosed as a trade secret, it may not be recorded in a written or other tangible form, and it may become necessary to pass down the technical information as cumulative implicit knowledge. As a result, technology transfer may become difficult.

Perhaps in view of that risk, in April 2021, the World Health Organization (WHO) established a COVID-19 vaccine technology transfer hub as a scheme to promote the sharing of mRNA-based technology. However, there are no media reports to date indicating that technical knowledge has been provided through this scheme.2