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### Advantage – Cannabis

#### The current WTO patent system is locking in global cannabis monopolies.

Kellner 21 “Mitigating the Effects of Intellectual Property Colonialism on Budding Cannabis Markets” Hughie Kellner [Hughie Kellner came from the small farm town of Uvalde, Texas and received a bachelor’s degree in Physics from the University of Texas at Austin. Upon graduation from the Indiana University Maurer School of Law, Hughie will deploy his physics degree while prosecuting patents in the Frankfurt am Main, Germany office of Leydig, Voit, & Mayer. After Hughie’s first year at Maurer, he worked for a law firm in Thailand as a Stewart Fellow.] Indiana Journal of Global Legal Studies Vol. 28 #1 (Winter 2021) <https://www.repository.law.indiana.edu/ijgls/vol28/iss1/9/> SM

B. How the Patent Has Become a Tool for Globalization

The trade-offs have been deemed beneficial by most of the international community, judging by the WTO’s TRIPS Agreement, whereby any signatory must institute a patent system to their national order.57 This requirement was seen to advance the benefits that intellectual property brings to markets and provide assurance for companies who depend upon intellectual property (for our purposes, patents) that they will be protected.58 Thus, investment and commercial activity can now more easily flow into countries where before the lack of protection rendered prospective costs of business prohibitive.59

The TRIPS Agreement imposed strong, uniform requirements upon signatory countries that went a long way towards its goal of globalization, and unlike most international treaties, required enforcement mechanisms with teeth.60 The most relevant requirement here is that the member patent office examining the patent may not discriminate “as to the place of invention, the field of technology and whether products are imported or locally produced.”61 This requirement allows great freedom to engage in business within member countries, and prevents a patent office from giving any advantage to its own citizens that it would not give to a foreigner, unless allowed under other treaties.62 Further, if a patent is secured in the relevant country, a business does not need to set up a subsidiary within that country to obtain protection.63

To assist actors whose businesses cross international borders, the PCT was enacted by the World Intellectual Property Organization (WIPO) to reduce barriers when seeking protection for inventions.64 The PCT, while a treaty in name, acts more like an organization; as the WIPO describes the PCT:

The Patent Cooperation Treaty (PCT) assists applicants in seeking patent protection internationally for their inventions, helps patent Offices with their patent granting decisions, and facilitates public access to a wealth of technical information relating to those inventions. By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in a very large number of countries.65

Importantly, filing an application to the PCT does not grant a patent international reach; the inventor must file a patent application and await approval in each jurisdiction they wish to pursue, and patents are still enforceable only in the countries where they are obtained.66 Rather, filing your invention to the PCT, and denoting the countries where you seek patent protection, means that the PCT will provide information on the timeframe and likelihood of a patent being granted in that jurisdiction, along with certain assistance that varies based on the jurisdiction sought.67

C. How Companies Can Utilize Patents Internationally

Both the TRIPS Agreement and the PCT reduce barriers to transferring business across national boundaries by easing the transference of the intellectual property needed. The PCT acts merely as a helping hand and information collection tool, while the TRIPS Agreement acts to ensure that intellectual property will operate largely the same from jurisdiction to jurisdiction and, importantly, will be protected with uniform minimum standards. Without commenting on the desirability of this uniform treatment throughout varying economies, it has never been easier for businesses to use their intellectual property to enter international markets.68 In fact, under the TRIPS Agreement and PCT, companies can file a patent in a country where they have no connections,69 acquire a patent, and simply license the technology to (or bring infringement suits against) companies in the member country without needing to ever establish a presence.70

Notably, the PCT and many countries’ patent systems require you to file your patent application within a restricted timeframe after it is first disclosed.71 Thus, this transportation of patent rights must be loosely simultaneous throughout jurisdictions. However, the fact still remains that sophisticated actors who utilize the protections of the TRIPS Agreement can now acquire a monopoly to practice an invention in any country that is a signatory to the TRIPS Agreement or PCT. This usually reaches far short of global domination since companies generally file only in jurisdictions where they expect the benefit of using the patent to outweigh the cost of applying for one.72 However, if the inventor files a patent in every country that has a viable market for that invention, especially if only a few markets exist, the inventor could create an economic climate close to a global monopoly.

#### Thailand proves – the world is trending towards legalization but big pharma patents lock in cannabis monopolies and crowd out local growth.

Kellner 21 “Mitigating the Effects of Intellectual Property Colonialism on Budding Cannabis Markets” Hughie Kellner [Hughie Kellner came from the small farm town of Uvalde, Texas and received a bachelor’s degree in Physics from the University of Texas at Austin. Upon graduation from the Indiana University Maurer School of Law, Hughie will deploy his physics degree while prosecuting patents in the Frankfurt am Main, Germany office of Leydig, Voit, & Mayer. After Hughie’s first year at Maurer, he worked for a law firm in Thailand as a Stewart Fellow.] Indiana Journal of Global Legal Studies Vol. 28 #1 (Winter 2021) <https://www.repository.law.indiana.edu/ijgls/vol28/iss1/9/> SM

The reason the Thai public was so concerned over the cannabis patents filed by Otsuka and GW is that they represented the floor falling out from beneath them. The patents claimed both cannabinoid oil itself and a process for extracting the cannabinoid oil from the cannabis plant, which, based on the way they sought protection, was very likely not patentable anyway.88 However, if either Otsuka or GW received a patent, that patent would be an incredibly powerful tool in clearing competition in the upcoming market. Members of the Thai public saw their newly granted cannabis industry about to be swallowed up and taken from them by a foreign pharmaceutical company before they even had a chance to venture into it themselves.

This more than questionable “emergency order,” which temporarily blocked the possible grant of patents to Otsuka or GW, paid lip service to the allowances under the TRIPS Agreement,89 but in reality discriminated based on the applicant’s nationality. The goal of the order was to avoid a scenario of foreign monopolization that could pop up in any market that is a signatory to the TRIPS Agreement and institutes some form of commercialization of cannabis. GW and Otsuka Pharmaceuticals did not do anything illegal; they had the right to apply for protection of their intellectual property and did so. The Thai government acted on legally questionable grounds,90 but had a just reason to do so: attempting to avoid the exportation of an upstart cannabis market that would provide a lucrative cash crop to a highly agrarian Thai population.91

The scenario of recreational cannabis markets being promptly secured by foreign interests grows more and more likely as cannabis companies grow larger and more countries look to liberalize cannabis laws.92 As of right now, Canada’s recreational cannabis market, the only recreational cannabis market open to privatization,93 supports the largest cannabis companies in the world with vast amounts of capital, competition, and the best incentives to research and develop products better than and before their competitors.94

The logic of the feared scenario is as follows: if there exists a jurisdiction that establishes a market that produces entities who innovate more than any other jurisdiction, then that jurisdiction will be state of the art by definition. When another jurisdiction opens up a market, until that market supports entities who are innovating on their own and at a level that surpasses or escapes the prior jurisdiction, all entities will either operate below state of the art or at the same level as the prior, more advanced jurisdiction. With that innovation comes the possibility for patent protection. As discussed in Part II, a patent is only enforceable in the jurisdiction (usually country) it is acquired in. However, with the binding rules of the WTO TRIPS Agreement and the helping hand of the PCT, a patent in one country can easily become a patent in another country. If a patent is acquired by the most innovative entities and exported to the less innovative jurisdiction, entities in the less innovative jurisdiction must pay to use that patent if they wish to operate at the state of the art or, alternatively, stop their business. Therefore, the monopoly of one jurisdiction can be imposed upon another jurisdiction, suppressing actors in the less advanced jurisdiction simply because the first jurisdiction got a head start.95 This fear was present at the time the TRIPS Agreement was signed and is still present today:

[S]ome analysts interpret the growing concern of industrialized nations with intellectual property rights as an attempt to control the diffusion of new technologies . . . to freeze the existing international division of labor by way of the control of technology transfers . . . . [I]t is important to recognize that for a [lesser developed] country a reform designed to increase intellectual property rights protection will tend to generate a welfare loss at its initial stages. Because [lesser developed countries] are typically net importers of technology, a usual consequence of a more strict regime of intellectual property laws would be an increase in royalty payments to foreigners.96

As this plays out in today’s evolving cannabis industry, if someone is going to make advancements in the cannabis industry, most of those advancements will be from the Canadian actors before Thai actors, due to the head start and the stronger expected return on innovation in the Canadian recreational market. The Canadian actors’ innovations would be merely the product of the regulatory policies of their respective jurisdiction being amenable to innovation, and then importing those innovations into a jurisdiction that had not previously been amenable to innovation. Accordingly, the Canadian Patent Office has seen the effects of the innovative incentives: the Canadian market has produced and processed many patent applications.97

Further, even if Thailand prohibited any foreign actor from producing, importing, exporting, selling, or engaging with the Thai cannabis industry in any meaningful way, a foreign company could still force itself into the industry with the patent rights and structures available to it under the TRIPS Agreement.98 Without ever having a physical presence, business can be generated by filing a patent and forcing others to license the use of the patent or face an infringement lawsuit.99 Even if an action is not infringing, a patent could be used to threaten a lawsuit upon a new business 100 (every business in the Thai market will be new) that likely would not possess the resources to defend a patent lawsuit (one of the most expensive types of lawsuits)101 and would be forced to submit to a licensing arrangement or close its doors.102

This is so only because Canada decided to violate the terms of the UN Single Convention.103 Thus, Canada was able to safely internalize every first-mover benefit available because the other 184 countries party to the Single Convention, and all other G7 countries, would still be prevented from establishing a recreational cannabis market. Canada may not have had any malicious motives; after all, it did ensure that its regulatory scheme governed international trade as mandated by the Single Convention,104 and thus attempted to keep any acts that violate that treaty from causing other nations to violate it. This seems like the intention of a good neighbor who knows they have broken the rules, but the best intentions in the world do not alone alter the operation or availability of other global legal structures.

A solution needs to be found whereby local actors, who did not have a chance to innovate, are given an opportunity to establish themselves so they can innovate while foreign business and investment is also allowed to participate in the market, bringing their advantage of experience rather than legal monopoly. In the following section, I argue that a solution, unique to the cannabis market, can be found by imposing a small and circumscribed amendment to the TRIPS Agreement, as a resolution to the Canadian recusal from the UN Single Convention.

#### Big pharma leverages cannabis patents to block out competition and secure monopoly – decks medical marijuana access

Barnett 20 Hailey A. Barnett [J.D. candidate 2020, Tulane University Law School; B.A. 2017, Communication, cum laude, Texas A&M University.], "High Risk, High Reward: Patent Law's Effects on the Medical Marijuana Industry," Tulane Journal of Technology and Intellectual Property 22 (2020): 125-164 <https://heinonline.org/HOL/LandingPage?handle=hein.journals/tuljtip22&div=8&id=&page=> SM

B. Cannabis Patents and Pharmaceutical Companies

Patent protection is a key component of the United States legal system. On principle, we should compensate and reward those who have rightfully invented something, as well as incentivize and stimulate further innovation. The marijuana industry has been historically composed of people who believe in the cause, the plant, and the health benefits it brings. Yet, many of the field's "new players" are getting involved with a specific 89 business purpose in mind. Cannabis patents are one way to normalize and bring the industry to the mainstream, but the winners in the patent system are often those who are first and have the most money.'90

It's no secret why everyone wants a piece of the marijuana industry pie: according to an April 2018 report by Grand View Research, Inc., the global legal marijuana market is projected to be worth $146.4 billion by 025.'9' The report additionally found that in 2016, medical marijuana emerged as the largest segment of the industry and is estimated to be valued at $100.03 billion by 2025.192

One way to obtain a monetary stake in the medical marijuana market is to use the patent process to acquire ownership over a particular strain and its seeds.' 93 This limited monopoly ensures that the patent holder "is the only one who can make or sell the product, or license other people to do so."'94 However, there are so many unanswered questions that surround IP protection of a federally illegal substance, it is unclear if the patents will be upheld.'9 5 If cannabis patents are upheld in federal courts, it is possible that a handful of companies could be in a position to demand licensing fees from the rest of the industry.1 96

This incentive is particularly appealing to major multinational pharmaceutical companies (Big Pharma) and is already being capitalized on today. For example, pharmaceutical firms are already seven of the top ten cannabis patent holders in Canada.' 97 These patents, filed prior to the country's full legalization of marijuana, would have been difficult to enforce prior to legalization.' 9 8 However, after Canada legalized marijuana on October 17, 2018, the patents became fully enforceable and gave the companies a key strategic advantage over non-patent holders in the ever- increasingly competitive market.' 99 The biggest concern is that Big Pharma companies will harness their powerful lobbies and seemingly bottomless payrolls to engage in patent blitzes. In other words, they will try to enlarge their patent portfolios and subsequent ownership of marijuana strains and their ancillary byproducts, such as oils, to marginalize competitors.

In the United States, the FDA plays a crucial role in approving and 201 regulating medications for public use. Big Pharma requires the FDA's approval to bring their products to the public market, and it's no secret that Big Pharma's influence on the agency has accrued over many decades and billions of dollars spent.2 0 2 The current FDA Commissioner Scott Gottlieb recently slammed Big Pharma and accused drugmakers of using "gaming tactics" to stall the introduction of generic versions of biologic drugs, "a move that cost the U.S. healthcare system billions of dollars last year. "203 One of these tactics is to engage in patent blitzes, or evergreening, right before a drug's patent protection (and subsequent market exclusivity 20 4 period) expires. "In the pharmaceutical trade, when brand-name companies patent 'new inventions' that are really just slight modifications of old drugs, it's called 'evergreening. "'205 Evergreening occurs because once a drugmaker's patent on a particular drug expires, the door is open for other producers to bring generic versions of the drug to market.206 Patents in patent blitzes are often granted for even the most trivial improvements and innovations related to existing drugs.207 The purpose of evergreening is two-fold: first, to extend the commercial dominance of brand-name drugs, and second, to tie up producers of the generic drugs in 2 08 costly, time-consuming litigation. Evergreening prevents a generic drug's market entry and further extends Big Pharma's monopolies.2 09

A prime example of recent evergreening is when Mylan hiked the price of its life-saving epinephrine injectable drug, EpiPen, by more than 400%.210 After Teva Pharmaceuticals gained approval from the FDA for the first generic version of EpiPen, Mylan sued them for patent infringement, although epinephrine alone was already a generic drug.2 1 Mylan settled and kept "Teva off the EpiPen market until 2015."212 Much like AbbVie's battle with AmGen over a generic version of the former's costly biologic drug Humira, Big Pharma's inclination to place company profits over the needs and desires of patients could continue with cannabis strain patents. 2 13 This will ultimately affect cost and access to medical marijuana products.

Thanks to shifting public opinion and state legalization, a growing number of cannabis patent applications have been filed with the USPTO and it is very likely they will be granted. Although marijuana remains illegal at the federal level, the premature filings signal hope that sometime in the near future, the federal government will reconsider its stance on cannabis, and make medical and recreational marijuana use legal from sea to shining sea.215

Companies with a large numb1er of cannabis strain patents, such as BioTech, could become an even bigger national player in the field of cannabis strain patents as they acquire more market share. Overall, if Big Pharma obtains exclusive rights to use, produce, and sell particular cannabis strains, together with their large influence over the FDA and other government regulatory bodies, they can control public access and maintain already robust profit margins.217

Not surprisingly, Big Pharma is not the only industry chasing profits from marijuana IP rights. Smaller breeders, including scientists who alter the plant for medicinal purposes, worry that large bioagricultural companies like Monsanto and Syngenta will hoard cannabis-based patents and deploy their massive economic power to position themselves as another dominant force in the market.218 in short, an open and accessible marketplace for cannabis products, especially for medicinal use, depends on tracking the patent activity of wealthy, powerful entities to ensure smaller entities are not marginalized.219

#### Monopolies kill cannabis biodiversity which throttles medical marijuana advances and industry innovation.

Barnett 20 Hailey A. Barnett [J.D. candidate 2020, Tulane University Law School; B.A. 2017, Communication, cum laude, Texas A&M University.], "High Risk, High Reward: Patent Law's Effects on the Medical Marijuana Industry," Tulane Journal of Technology and Intellectual Property 22 (2020): 125-164 <https://heinonline.org/HOL/LandingPage?handle=hein.journals/tuljtip22&div=8&id=&page=> SM

A. Biodiversity Implications for Cannabis Strain Patents

Biodiversity, or biological diversity, is an ongoing controversy in the marijuana patent industry. Like comprehensive research on the benefits and drawbacks of medical marijuana, "empirical analysis on biodiversity in the patent system is limited."2 2 2 Biodiversity is a broad term but is generally defined as "biological diversity in an environment as indicated by numbers of different species of plants and animals." 23 Increasingly, however, countries and companies are asserting IP rights in native flora, 224 impacting global biodiversity.

"Historical documents from around the world, some dating as far back as 2900 B.C., tell us that cannabis has lived alongside humans for thousands of years, cultivated for food, fiber, and fodder, as well as for religious and medicinal purposes." 2 5 The fear is that without a wide variety of cannabis strains available for breeding and growing, production and processing of the plant will inevitably consolidate into the hands of large conglomerates.22 6

The United States and Thailand are signatories to the Convention on Biological Diversity (Biodiversity Convention), a multilateral treaty committed to sustainable development. The Biodiversity Convention's goals include "conserving biological diversity, promoting the sustainable use of its components, and the fair use and equitable sharing of benefits from biological resources."228 The Biodiversity Convention requires signatories to enforce regulations on plant patent applications and mandates that new patent applications include the plant's genetic resources and evidence of local use if they seek to patent the plant in a certain country. This is the chief reason behind the Biodiversity Sustainable Agriculture Food Sovereignty Action Thailand's (Biothai) call for careful scrutiny of recently filed foreign cannabis patents in the country, as discussed in greater detail in the next Section.

Since medical marijuana is now legal for use and manufacture in Thailand, the mere implication that fabled Thai marijuana strains, such as "Northern Lights," could be available on the global market has generated 23 much buzz. 1 Like Cuban cigars or French champagne, Thai marijuana is known for its potency and quality.232 Thailand's marijuana is apure sativa landrace strain, meaning it is a local strain of cannabis that has adapted to Thailand's native environment and conditions over time. Environment plays a key role in the THC, CBD, and terpene quality and quantity and is part of what makes landrace strains so unique. For example, the marijuana plants and seeds that are indigenous to the tropical jungles of Thailand are bred to preserve their naturally occurring high THC levels.235

As more cannabis strain patents are granted worldwide, it is possible that growers will be increasingly dependent on seed makers that hold patents on certain types of seeds and methods used to produce them. As a result, growers will be subject to agreements and royalties and will be charged licensing fees for use of the seeds. A healthy number and variety 236 of available cultivars are vital for advancing cannabis legalization and the industry’s continued growth. From an agricultural perspective, the patent system encourages a consolidation and reduction of variety in order to enhance and maximize profits. This can be seen in today's staple crops, such as com, soy, and wheat, where fewer cultivars exist than they did decades ago.23 9 Other crops globally consumed today, such as fruits 240 and vegetables, are likely grown from patented varieties or cultivars. As a result, agricultural biodiversity has diminished due to the introduction and consolidation of genetically modified, patented varieties, and it is highly likely the cannabis industry could see a similar fate.24 1

Cannabis biodiversity will be threatened if there are fewer available cultivars and, thus, fewer strain options.2 42 Fewer available strains could also lead to limited consumer experiences and patient treatment options. This notion, coupled with already limited clinical and scientific research, could significantly throttle advances in medical marijuana availability and use.2 43 The corporatization of the industry, thanks to patent law, could see smaller growers and businesses merging into giant conglomerates, with 2 the profits being held in the hands of a very few. 4 In short, the "winners" of the cannabis patent wars will dominate the industry post-prohibition.2 45

Some argue that expanding strain patents could have the opposite effect and allow researchers and physicians to "correctly identifty], dos[e], and perhaps even personalize prescriptions for particular strains in the future" to treat specific ailments.24 6 Patents are a hallmark of innovation, and with wide access to more and better cannabis strains, there could be innovation advances in the industry as a whole.2 47 However, the reality is that cannabis patents are likely to be held by large corporations, given what we have seen before with the United States government and the FDA's involvement.24 8

Both medical marijuana patients and recreational marijuana users are strain-driven. While the current cannabis landscape is rich with hundreds of different varieties, strain patents could lead to a "locked genetic landscape where innovation becomes rare and costly."2 4 9 Further, a monopoly on the local strains of one country could have disastrous effects on that country's biodiversity and its rights to that biodiversity.2 50

#### Monopolies kill market growth and disincentivize innovation.

Gunelius 20 “How Big Business, Monopolies and Stacked Licenses Impact the Marijuana Industry,” February 7, 2020, Originally published 3/4/17, Susan Gunelius is President & CEO of KeySplash Creative, Inc. <https://www.cannabiz.media/blog/how-big-business-monopolies-and-stacked-licenses-impact-the-marijuana-industry> SM

However, the continued growth and development of big businesses with deep pockets in the cannabis industry has many people worried that the result of continued mergers and acquisitions will be monopolies, lower quality products, and a shift of revenues away from mom and pop businesses in local communities to out-of-state (or out of country) corporations.

The Start of Monopolies and Oligopolies in the Cannabis Industry

Monopolies and oligopolies are already developing in the cannabis industry — not just in terms of big businesses usurping smaller businesses but also in terms of state regulations that allow vertical integration, which leads to markets dominated by one or a few players that control the cultivation, processing, and sale of cannabis products.

To clarify, all but two states (Louisiana and Washington) with active medical or recreational cannabis programs allow or require vertical integration of the cannabis supply chain. Cannabiz Media defines the related cannabis license structures as follows:

Fully stacked licenses: A single licensed business can or is required to handle all operations from seed to sale in a fully vertically integrated structure.

Partially stacked licenses: A single licensed business can or is required to handle more than one operation but not all operations from seed to sale.

Unstacked licenses: Different businesses handle different operations across the supply chain from seed to sale.

For example, in Minnesota, the state’s medical marijuana program requires full vertical integration with only one type of license – the Medical Cannabis Manufacturer license. Currently, only two of these licenses are allowed in the state to grow, process, and sell (at four dispensaries each) cannabis.

Other states, like Colorado and Oregon, have ceased to award additional licenses to some cannabis businesses in the past thereby creating oligopolies. In California, oligopolies are forming in a different way. Regulations passed leading up to opening the state’s adult-use market in 2018 allowed large businesses to exploit a loophole and obtain as many cultivator licenses as they could afford.

Across the country, smaller cannabis businesses are struggling to compete with other bigger cannabis companies. In Maryland, large out-of-state companies (including several well-known cannabis companies that are publicly traded on the Canadian Securities Exchange) have been quietly taking control of multiple marijuana dispensaries through management agreements or acquisition plans that circumvent the state’s regulations limiting ownership to one dispensary.

The concern about monopolies and oligopolies in the cannabis industry was in the Florida news extensively throughout 2019 when a Florida court ruled that the state’s required vertical integration was unconstitutional.

The Future of Marijuana and Big Business

Bottom line, whenever every business that wants to be in an industry cannot enter the market, competition will not flourish. The result is the same whether businesses are shut out due to state regulations or because big businesses have deeper pockets and force smaller players to leave. Either way, the result is the same. Fewer players equals less competition which usually leads to higher prices and limited market growth.

As Sean Williams of The Motley Fool warned back in 2017, “The culprit for the substantial drop in marijuana prices appears to be big businesses infiltrating the industry and flooding the market with product. As with any industry, if big business can push the little guy out, they’ll have considerably more liberties down the road to raise their prices back up and capture a juicier margin, along with greater market share.”

Only free competition ensures fair prices and market growth over the long-term as well as ongoing innovation and product accessibility.

#### Medical marijuana is key to resolving opioid pain reliever prescriptions – biggest internal link to addiction and overuse

Blake 20 [Dwight K Blake, Founder of American Marijuana, 15 years of experience in mental health counseling and addiction treatment.] “Medical marijuana reduces opioid prescribing rate,” American Marijuana, March 24, 2020, <https://americanmarijuana.org/medical-marijuana-solution-to-opioid-epidemic/> [note: charts/images omitted] TG

Medical Marijuana as A Painkiller

Marijuana contains many Cannabinoids including CBD or Cannabidiol and THC or Tetrahydrocannabinol. But contrary to the latter, topical CBD, particularly [CBD oil](https://americanmarijuana.org/best-cbd-oil/), manages and reduces pain, inflammation, discomfort, and a variety of other health conditions.

As of 2020, medical marijuana is legal in over 20 states in the USA since it was first decriminalized in Nevada in 2001. But in 2017, it was found that chronic pain was the most common qualification condition among patients who are licensed to use marijuana medically, accounting for almost 62% of nearly 1 million medical cannabis patients (representing an average of 33% to 73% each year from 1999 to 2016).

Opioid Crisis

Opioid is a group of chemically similar drugs containing prescription pain relievers and heroin. A good example of these includes hydrocodone (Vicodin®), oxycodone (OxyContin®), and morphine. This is what makes it one of the main contributing factors to the opioid crisis. According to [SAMHSA](https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf), approximately over in 2018, 10 million people aged 12 or older in 2018 have misused opioids. About 9.4 million of those have misused pain relievers exclusively while the remaining 506,000 have misused pain relievers and heroin use in the previous year. On a similar note, a little over 300,000 people have also misused heroin exclusively out of the 800,000 people who misused heroin in 2017.

From 1999 to 2017, it was found that there were about [400,000 people who died from overdoses](https://www.cdc.gov/drugoverdose/data/analysis.html) of any, prescription, and illicit opioids.

Medical Marijuana: A Potential Opioid Crisis Solution

So how exactly is medical marijuana a potential solution to the opioid crisis?

Here’s where things get really interesting…

Our Study

We’ve selected 19 states where medical marijuana is legal then compared the opioid prescribing rate 1 year before and after medical marijuana was legalized in the state. Here is what we found:

Out of the 19 states, 15 have shown a fall of opioid prescribing rate 1 year after legalization of medical marijuana, and only 4 have increased in usage, namely: New Jersey, New Mexico, Michigan, and Arizona.

Interestingly, the state with the highest fall of opioid prescribing rate among the 19 states was Ohio, from an average opioid prescribing rate of 82.7 down to 63.5, totaling 19.2 decreased prescribing rate after marijuana legalization.

The state with the second-highest fall of opioid prescribing rate was Pennsylvania, from an average opioid prescribing rate of 75.5 down to 57.7, a total of 17.8 decreased prescribing rate after marijuana legalization.

New Mexico and New Jersey had the least number of increase in opioid prescribing rate of the 4 mentioned states, with only 2.4 and 1.6 increase in usage after marijuana legalization, respectively.

Here is the full data of our study:

Data source: <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>, National Drug Use & Health Subtance Abuse; Mental Health Administration

To support our point of view, let’s compare this to similar studies:

Other studies

In an article published on [Harvard Health Publishing](https://www.health.harvard.edu/blog/access-to-medical-marijuana-reduces-opioid-prescriptions-2018050914509), M.D Peter Grinspoon has shown “access to medical marijuana can reduce opioid consumption”.​

A [study](https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2677000?redirect=true) conducted by Hefei Wen, Ph.D and Jason M. Hockenberry, Ph.D as of May 2018 showed that from 2011 to 2016, adult-use marijuana laws and medical marijuana laws were associated with lower opioid prescribing rates for Medicaid enrollees: 6.38% and 5.88% lower, respectively, compared with states without medical cannabis laws.

In October 2014, Marcus A. Bachhuber, Brendan Saloner, Ph.D, Chinazo O. Cunningham, MD, MS, and Colleen L. Barry, Ph.D, MPP also conducted a study to determine [the association between the presence of state medical cannabis laws and opioid analgesic overdose mortality](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1898878). The report concluded: Between 1999 to 2010, states with medical cannabis laws (Alaska, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Rhode Island, and Vermont) had a 24.8% lower mean annual opioid overdose mortality rate compared with states without medical cannabis laws. Although they still claim “further investigation is required to determine how medical cannabis laws may interact with policies aimed at preventing opioid analgesic overdose.”

It has to be noted that fewer annual drug doses were also being prescribed per physician in the U.S from 2010-2013:

In the given period, there were 1,826 fewer doses of drugs per year per physician treating pain than in states without medical marijuana laws. Moreover, there were 562 and 541 fewer annual doses of drugs per year per physician to treat anxiety and nausea, respectively.

In summary, 78% of the states (where medical marijuana is legal) have shown an average reduction rate of opioid consumption by 5.21.

#### The opioid crisis risks massively destructive terrorism – synthetic opioids can be weaponized and spread

Morell 17 (Michael Morell, the former Acting Director and Deputy Director of the Central Intelligence Agency, is one of our nation's leading national security professionals, with extensive experience in intelligence and foreign policy. During his 33-year career at CIA, Michael served as Deputy Director for over three years, served twice as Acting Director, served for two years as the Director of Intelligence, the Agency's top analyst, and for two years as Executive Director, the CIA's top administrator.)(“The Opioid Crisis Becomes a National Security Threat”, July 26, 2017, https://www.thecipherbrief.com/column\_article/opioid-crisis-becomes-national-security-threat)

On October 23, 2002, dozens of armed Chechen terrorists seized a Moscow theater and took some 850 people hostage. Because of the layout of the theater, the number of extremists, and the large amount of explosives in their possession, a SWAT-type raid was out of the question.

When two of the hostages were murdered almost three days into the crisis, the Russian government chose to pump an incapacitating agent into the theater via the air vents. But the agent was too toxic, and while all the extremists were killed, so too were some 130 of the hostages. The Russians have never publicly identified the particular chemical agent used, but it is widely believed to have been carfentanil.

Fast forward to June 2016, when authorities in Vancouver, Canada seized one kilogram of carfentanil. The agent was sent via mail from China to an address in Canada, and it was hidden in a package that was declared on a customs form to be printer accessories. It was the largest seizure of carfentanil to date.

Carfentanil, a synthetic opioid, is highly toxic. The drug is 10,000 times stronger than morphine and 5,000 times more potent than heroin. Only 20 micrograms, roughly the size of a grain of salt, can be fatal. The seizure in Vancouver was enough to kill 50 million people – every man, women, and child in Canada.

Carfentanil was developed in the 1970s as a tranquilizer for large animals – elephants and hippos. Dr. Rob Hilsenroth, the executive director of the American Association of Zoo Veterinarians said last year that carfentanil is so powerful that zoo officials wear protective gear “just a little bit short of a hazmat suit” when sedating animals because even one drop in a person’s eye or nose can be fatal.

The extreme lethality of carfentanil has led most countries to classify it as a chemical weapon. It is banned from the battlefield under the Chemical Weapons Convention. Andrew Weber, President Barack Obama’s Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Program, said it plainly and simply last year: “It’s a weapon.”

So, what is a chemical weapon doing on the streets of Canada – and the U.S.? Over the past year, drug dealers have learned that they can cut carfentanil into the heroin they sell to increase the “high” and to increase profits, as heroin is 15 times more expensive than carfentanil. In a public warning last fall, the Drug Enforcement Administration said “carfentanil is surfacing in more and more communities” and that it “has been linked to a significant number of overdose deaths in various parts of the country.”

The drug is largely produced in China by thousands of small chemical firms and shipped either through Mexico and Canada to the United States or directly through the mail system, often after an order is placed online. It is also produced by drug cartels in Mexico (with key ingredients imported from China). China, working with the United States, is now regulating carfentanil production and export, but the large number of producers there means the problem has only been reduced, not resolved.

There are signs that the production of carfentanil could be moving here as well, particularly after the Chinese government’s crack down. Some of equipment used to make carfentanil in China has been found in the United States. And the key ingredient to fentanyl – a less potent cousin of carfentanil – has also been discovered in the U.S., suggesting that fentanyl is being manufactured here. In May, federal agents in Massachusetts seized 50 kilograms of a key chemical used to make fentanyl.

The public discussion about – and the government focus on – carfentanil is all about the dangerous role it plays in the contemporary drug epidemic – with good reason. Drug overdoses, with a growing number caused by carfentanil, are now the leading cause of death from injury in the United States, surpassing motor vehicle accidents, suicides, and homicides. Some police and paramedics have themselves overdosed after coming into contact with carfentanil.

But the drug also constitutes a significant threat to national security. It is a weapon of mass destruction.

Indeed, carfentanil is the perfect terrorist weapon. It is readily available in large quantities. It comes in several forms – including tablets, powder, and spray. It can be absorbed through the skin or through inhalation. It acts quickly. And, it is deadly. Peter Ostrovsky, a senior official of the Immigration and Customs Service, said last fall, “Could it be weaponized? Yeah, it could be weaponized.” In short, a single terrorist attack using carfentanil could kill thousands of Americans.

And, there has been little focus on the drug as a terrorist weapon. In the Director of National Intelligence’s 2017 Worldwide Threat hearings, the issue of synthetic opioids was treated as part of the international drug problem, not as a terrorism risk. No one from either the Obama or Trump administrations has spoken publicly about the threat. The same is true for Congress. There has been little to no work by think tanks or the media on the terrorism risks.

This needs to change. There needs to be an NSC-directed policy and strategy on getting our arms around the national security risks of carfentanil – including increasing the focus of the Intelligence Community as well as the law enforcement and homeland security communities. There needs to be a focus by Congress, in part, to oversee the work of the Executive Branch. There needs to be work done at the state and local level that is integrated with what is happening at the federal level. There is a great deal to do.

Both al Qaeda and ISIS have said they are interested in acquiring weapons of mass destruction and that they would use them if they acquired them. Osama bin Laden called it a religious duty to do so. ISIS has used chemical weapons on the battlefield in Iraq and Syria. And now such a weapon is easily available to them. It would be a terrible tragedy if foreign terrorists were to use the consequences of our own domestic drug problem against us – particularly when it is so easy to see what might be coming.

#### Developments and attacks are coming now – spurs inter-state wars AND non-state actors which ensure escalation – taboo eroded, empirics prove, tech and motive are here

Henryde Quetteville et al 18. Special Correspondent @Telegraph, Technology. Former foreign correspondent in France, the Balkans and the Middle East., citing James Giordano, professor of neurology, chief of the Neuroethics Studies Program, and co-director of the O’Neill-Pellegrino Program in Brain Science and Global Health Law and Policy at Georgetown University Medical Center. He is an member of the Defense Advanced Research Projects Agency’s panel on neuroethics, legal, and social issues, and serves as a senior science advisory fellow to the Joint Staff at the Pentagon. His latest book is Neurotechnology in National Security and Defense: Practical Considerations, Neuroethical Concerns (CRC Press), citing Gavin Williamson, UK Secretary of Defense, citing Aimen Dean, also known as Ramzi is a Bahrainian man who was a founding member of al-Qaeda. In 1998, he joined the Secret Intelligence Service and became an MI6 spy, citing Hamish de Bretton-Gordon, a chemical weapons expert and chief operating officer of SecureBio Limited. He was formerly a British Army officer for 23 years and commanding officer of the UK's CBRN Regiment and NATO's Rapid Reaction CBRN Battalion, August 3, 2018, “The rise of biological and chemical weapons After Salisbury, how ready is the UK?”, <https://www.telegraph.co.uk/news/rise-of-biological-chemical-weapons/>. Rez

With nerve agents having been deployed in Syria, Malaysia and Salisbury, the 100 year taboo on the use of chemical weapons is in danger of collapse. The stakes could not be higher as gene-editing technologies put a new generation of bio-weapons within reach of almost anyone.

The small town of Melksham, in rural Wiltshire, is an unlikely location for one of the world’s largest producers of gas masks. Yet there, next to Farmers’ Roundabout, is a warehouse containing a production line that can turn out a quarter of a million masks a year. Models include the FM54, a sinister-looking bit of kit used by the SAS. This is Avon Protection, originally founded in the late 19th century as a tyre factory but which, come the First World War, spotted a new market for its rubber presses.

Today, business is booming. Orders are flooding in from the US military and the MoD. A contract is up for grabs from Canada’s army. India is keen. ‘All this CW has been good for us,’ says an executive. By CW he means chemical warfare. And it’s true. On Avon’s factory floor, permeated by the distinctive smell of its essential raw material, blue and yellow presses relentlessly inject molten rubber into dense matt-metal moulds. Every four minutes a new mask emerges, ready to be trimmed and equipped with tubes, visors and filters. Amid the beauty of Melksham’s peaceful surroundings, these blank-eyed robo-humanoid visors, worthy of Darth Vader, are the starkest possible reminder that 100 years after we thought we had said goodbye to all that, a new age of poison weapons is upon us.

It is an era in which a series of unprecedented plots and attacks – from England to Australia – has projected this darkest of the arts of war far from the traditional battlefield. They have seen an airport departure lounge and a medieval cathedral city in the West Country laced with the deadliest toxic chemicals, **upsetting a diplomatic and military status quo established in the wreckage of the First World War, and blowing away one of armed conflict’s weightiest taboos** like a breeze dispersing clouds of mustard gas over the trenches of the Western Front. Worse, some fear that with emerging threats from DIY bioweapons, **this may just be the beginning.**

The new age of weapons of mass destruction (WMD) has been decades in the making. As Aimen Dean, MI6’s mole in al-Qaeda, recounts in his new book Nine Lives, Osama bin Laden’s terror group plotted to smear deadly chemicals on the door handles of luxury cars in Britain in the late 1990s. After 9/11, Dean delivered intelligence that Abu Khabab, an al-Qaeda weapons engineer, had managed to develop a viable poison-gas device destined for New York’s subway system. The plot never came to fruition.

Terrorists continue to fantasise about striking fear into civilian populations with chemical and biological weapons. Last August, intelligence agencies in Australia intercepted an Isil plot that allegedly would have involved the release of toxic hydrogen sulphide gas. And just last month, German authorities arrested Seif Allah Hammami, a 29-year-old Tunisian who had apparently managed to manufacture significant quantities of ricin, a bioweapon first developed by the US during the First World War.

But it is **in Syria that the century-old toxic taboo has truly been blown away**. Since 2012, chlorine and sarin gas have repeatedly been dropped from the jets and helicopters of the Assad regime, as well as fired in warheads attached to artillery rockets. **Isil too has deployed gas in Syria** – both in contravention of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare – known in short as the Geneva Protocol – which was first signed in 1925.

The Protocol was an attempt to ensure that the horrors of the Great War were never repeated, yet in Syria today, just as on the Western Front then, chemical munitions have targeted networks of trenches housing enemy fighters. Bashar al-Assad spent four year besieging Aleppo with conventional weapons. When, in December 2016, he started using chemicals instead, the city fell in just over two weeks. Little matter that all too often they hit civilians too, as shown by heartbreaking images of choking, gagging, foaming men, women and children broadcast around the world. Ghouta in 2013 remains the deadliest single attack, almost unimaginable in scale. The final death toll has never been pinned down, but the US administration estimates almost 1,500 were killed. Hundreds more have died in over three dozen subsequent attacks in Syria that the world knows of.

Having been unleashed anew in Syria in 2012, it was only five years before these weapons were deployed – in February 2017 – in an exclusively civilian arena. The scene was the budget-airline terminal at Kuala Lumpur airport. Just as sarin is many times more toxic than chlorine, so VX is many times more toxic than sarin. And it was VX that was used to assassinate Kim Jong-nam, exiled half-brother of the North Korean dictator Kim Jong-un, when two women smeared the agent on his body in what they claim to have thought was a prank. Currently on trial, they could face the death penalty if their story is not believed.

But even that brazen attack was as nothing to what unfolded in Salisbury on 4 March this year, when the Russian military officer turned British spy Sergei Skripal and his daugher Yulia were found unconscious on a bench. Skripal was a victim of Novichok, a nerve agent that is perhaps 1,000 times more toxic than sarin. **Invisible and deadly, it brought a menace** to Britain’s streets that **most of us never imagined we would have to consider – let alone experience**. And that shock only deepened when, earlier this month, and out of the blue, Charlie Rowley, 45, and Dawn Sturgess (who died last weekend), 44, also fell victim to Novichok in Amesbury, just down the road from Salisbury.

On top of the attacks in Syria and the killing of Kim Jong-nam, the targeting of the Skripals and its protracted consequences made a devastating conclusion inescapable: a century after Wilfred Owen wrote of ‘Gas, gas’ and of the victim ‘yelling out and stumbling And flound’ring like a man in fire or lime’, the use of chemical weapons had become normal again.

It is easy to see why. **Toxic chemicals are the perfect weapon for our fake news world, where everything is disputable, objective truth malleable or elusive, blame and attribution hard to pin** down. Take the Skripal attack: afterwards Russia’s propaganda machine went into overdrive, peddling countless claims and counterclaims of its own: that the British state was itself responsible; that Yulia and her father were sedated and poisoned. Spinning this web of ambiguity was all the easier because of the absence of any international body empowered to attribute responsibility for attacks. The independent Organisation for the Prohibition of Chemical Weapons (OPCW) identified the Novichok in Salisbury, but pointing to its source was not within its remit. Moscow’s media trumpeted its failure to do so as exculpation anyway.

**For a former superpower like Russia, chemical weapons offer an alluring asymmetry too**, helping to level the playing field against the better-financed, better-equipped militaries of NATO. ‘We’re in a position now where we’re going into a new Cold War,’ says Hamish de Bretton-Gordon, former commander of the British Army’s Joint Chemical, Biological, Radiological and Nuclear Regiment (CBRN), which, ironically, was disbanded in 2011, a year before WMD were first deployed in Syria. ‘While we overmatch Russia in most areas, in chemical weapons their offensive capability more than overmatches us. If Russia did decide broadly to hit us with this stuff, we’d be found wanting.’

**Novichok**, which de Bretton-Gordon describes as **‘the world’s blue riband nerve agent’, was developed** in Shikhany, a town on the Volga that houses a military research establishment. Experts estimate that **Russia has perhaps a few tons of it, enough ‘to carry out assassinations but not to wage war’**. Still, only tiny doses are needed to block a crucial enzyme – acetylcholinesterase – which breaks down the neurotransmitter acetylcholine. When that happens, large branches of the nervous system become overexcited and ultimately shut down.

‘The first thing that happens is bowel and bladder incontinence,’ says Stefano Costanzi, associate professor in the department of chemistry at American University in Washington, DC, and an expert in the effects of chemical weapons. ‘Eventually that is followed by the collapse of the nervous system, with death typically resulting from respiratory failure and seizures.’ **How long that takes depends on exposure and dose. It can be minutes.**

Dr Stephen Jukes, intensive care consultant at Salisbury District Hospital, where the Skripals were treated (and where Rowley and Sturgess were taken), has described trying ‘all our therapies’ to keep Sergei and Yulia alive. Due to an astonishing coincidence, two doctors on duty had just returned from a course at Porton Down, Britain’s world-leading equivalent to Shikhany, when the pair were brought in. Recognising what looked like symptoms of nerve-agent poisoning, they made sure to include diazepam and atropine in their battery of treatments – the drugs compensate for some of the effects of acetylcholinesterase blockage – and plunged the Skripals into an artificial coma to prevent brain damage.

Then it was a question of waiting. ‘It is key to keep the victims alive long enough for their bodies naturally to restore their ability to break down acetylcholine,’ says Costanzi. Dr Jukes says that hospital staff did indeed wait, but more in hope than expectation. ‘When we first realised this was a nerve agent, we were expecting them not to survive,’ he told the BBC. His colleague Dr Duncan Murray attributed the fact that the Skripals did pull through to ‘very good, generic, basic critical care’. But simple good fortune, like the fact that Porton Down is just down the road from Salisbury, played a big part too. ‘There are only 10 or so countries in the world that could have possibly responded to the Skripal attack,’ one British official told me. ‘And even then we were very lucky.’

Soldiers march across Kim Il Sung Square, **North Korea**. The country **is known to hold stocks of VX nerve agent as well as long range nuclear missiles**

Lucky, and stretched to the absolute limit. Lorna Wilkinson, nursing director at the hospital, has said that when policeman Nick Bailey was also admitted with symptoms of poisoning similar to the Skripals’ ‘there was a real concern as to how big this could get’. She and fellow medical staff worried that **it could become ‘all-consuming and involve many casualties’.** According to de Bretton-Gordon, even containing the attack as it was required the deployment of ‘every bit of this country’s military establishment’. So could Britain cope with a bigger attack?

Responsibility for responding to major disasters in Britain lies with the Civil Contingencies Secretariat (CCS) in the Cabinet Office, which liaises with intelligence agencies and the Office for Security and Counter Terrorism (OSCT) at the Home Office to draw up the National Risk Register Of Civil Emergencies (NRR) – a list of 80 or so critical threats to the country, from flooding to a collapse of the national grid to cyber attacks. The NRR distinguishes between natural hazards or accidents, and malicious attacks, and even produces a table ranking these threats by their impact severity and likelihood, both on a scale of 1 to 5. The table makes it easy to see, for example, that the natural disaster the CCS is most worried about is a pandemic flu outbreak, which is given a 5 impact rating, and a 4 for its relative likelihood of occurring in the next five years.

When it comes to malicious acts, **chemical**, biological, radiological and nuclear (CBRN) **attacks are deemed the most severe threat to this country**. ‘Larger-scale incidents could include… much greater numbers of casualties and widespread, long-term impacts of a magnitude above all others,’ the cheery document suggests.

As one British diplomatic source puts it, ‘We assumed that the use of chemical weapons by states had drawn to an end. But their repeated use in Syria ate away at that. Then the sheer recklessness of the Skripal attack shocked not just us but a lot of our allies around the world.’ **And it’s not just states. Aimen Dean has called Salisbury a ‘big neon advertisement’ to jihadists about the potency of chemical attacks.**

British efforts to reverse this normalisation of WMD have included participating with the US and France in air strikes in Syria in April, aimed at redrawing some Obama-era ‘red lines’ that were blurred by six years of unpunished chemical attacks by the Assad regime. At the same time Gavin Williamson, the Defence Secretary, has pledged £48 million to build a new chemical weapons defence centre at Porton Down, and elements of de Bretton-Gordon’s disbanded CBRN regiment are being reconstituted. Quietly, this summer, the British Government has also pursued a high-stakes diplomatic gambit to ensure chemical attacks are no longer easy to get away with, by granting the OPCW powers to attribute blame for chemical attacks. Russia has repeatedly blocked such moves, but last month a special session of OPCW member states was convened and despite Russian pressure, 106 members turned up and 82 voted in favour of granting the OPCW powers ‘to identify the perpetrators of the use of chemical weapons’ – initially in Syria alone but then, so Britain hopes, around the world. ‘The taboo against the use of these weapons is breaking down and today the OPCW has not just the power to say the chemical weapons have been used, but can also point the finger at whoever did it,’ the then Foreign Secretary Boris Johnson said afterwards.

If the worst came to the worst, however, and a major attack did unfold, Britain would fall back on the Reserve National Stock, a chain of warehouses filled with antidotes and drugs for use in the event of a catastrophic WMD event. It was established in the 1970s after the eradication of smallpox, when dumps of the smallpox vaccine were maintained just in case the disease re-emerged. In 1995, after sarin terror attacks on the Tokyo subway launched by the Aum Shinrikyo cult, nerve-gas antidotes were added. Following 9/11, countermeasures for anthrax were also included; then, in 2003, the nerve agent response was upgraded with better drugs and personal-protection gear. Critical chemical- and biological- weapon treatments are strategically positioned around the country, with the aim of getting essential supplies to almost any affected location within five hours.

The kind of items in the stock is made clear in an NHS England document, identified with the bland ‘Gateway Reference Number 03088’. ‘1. Nerve agent antidote pod to treat 90 people. 2. Obidoxime further treatment for nerve agent poisoning. 3. Dicobalt edetate pod for treatment of cyanide poisoning in 90 people. 4. Botulinum antitoxin... Antibiotic pods (oral ciprofloxacin) to treat 250 adults for 10 days… with post-exposure prophylaxis for anthrax, plague or tularaemia…’

You get the picture.

The Reserve National Stock is kept under review, to ensure it contains the right kit and drugs to meet current threats. But that also begs a question: will it be able to respond to threats in the future? For no sooner have WMD resurfaced than the nature of the threat they pose is changing.

Today, for example, biological **pathogens can be modified to ‘improve’ their lethality using gene-editing techniques such as Crispr-Cas9.** Because of their ease of use, these techniques – more usually lauded for their medical applications – have been described by James Clapper, America’s national intelligence director until last year, as weapons of mass destruction, as **they do not require a vastly sophisticated lab**. ‘It makes it easy for individuals to operate outside a formal institutional setting,’ says James Giordano, professor of neurology and biochemistry at the Pellegrino Center for Clinical Bioethics of Georgetown University Medical Center in Washington, DC. ‘Crispr lends itself to biohacking.’

**Biohacking sounds subversive, but in fact is merely the name given to the growing trend for DIY bioengineering**, carried out by amateurs with no malicious intent, usually on entirely benign organisms, such as yeast.

Take a turn off the stalls of Shepherds Bush Market in west London, for example, and you will come across 45 purple and pink shipping containers. This is Open Cell, where biotech innovators can rent access to lab equipment like a thermal cycler (to reproduce DNA) for a few hundred pounds a month. Open Cell has the relaxed campus feel common to many collaborative working spaces of which entrepreneurs are fond. Except here, budding young companies are working on encouraging flies to do the pollinating work of bees, say, or exploiting potato waste to make chipboard-like material. It is a sign of London’s thriving biotech start-up scene. But it is also a sign of how biotech is breaking out of the state- or university-run lab. ‘That is exactly our passion,’ says Open Cell’s co-founder, biotechnologist Thomas Meany. He makes plain that security is a top concern, pointing to CCTV on site and constant threat assessments, as well as vetting of potential tenants. ‘We work with organisms you might find in your tummy or on your skin,’ he says. ‘We don’t use anything that could be potentially hazardous.’

Nevertheless, Open Cell is part of what Giordano calls ‘an increasingly global independent DIY movement’ in biotech. ‘It is not a Wild West of biohacking cowboys,’ he says. ‘But the ubiquity of these techniques now means people may drift outside the norm of a community through a “let’s see what happens” spirit. They may not be operating with controls to see something bad coming then mitigate it if it happens. Then of course other groups may simply not care – they want to see if they can do something a bit disruptive. They might say, “Let see if we can build something that will make people sick.”’

Such people, Giordano says, **could find themselves the tools of states looking to sow chaos but not take any blame**. ‘They could create bio-agents that are not even categorised by the biological weapons convention because they are new. You could take something common like E.coli and make it more pathogenic.’

He points to the case last year of two academics at the University of Alberta in Canada who ordered segments of horsepox DNA – related to smallpox – off the internet, and put them together so they became infectious. What particularly shocked peers was that the pair then published their work – effectively unveiling a deadly recipe. ‘You shake your head and wonder how it happened,’ says Giordano. ‘Before gene editing, of course, that’s not such a problem. But now putting out these types of recipes creates real problems because they will be read outside institutions where regulations are very stringent. I am very concerned about the external community. This is new territory. It needs to be surveillable and enforceable.’

Or as Clapper put it in his Worldwide Threat Assessment of the US Intelligence Community: ‘Given the broad distribution, low cost, and accelerated pace of development of this [gene-editing] technology, its deliberate or unintentional misuse might lead to far-reaching economic and national security implications.’

What people like Clapper fear is a genetically modified pox threat outpacing efforts to contain it, creating a pandemic which **could kill not thousands but, in the doomsday scenario, millions**. Last year Bill Gates said a bioweapon strike represented a bigger than nuclear attack, and put the potential death toll at 30 million. The economic fallout would also be catastrophic. This is hard to calculate, but in a paper some 20 years ago the Center for Disease Control in America tried to estimate the cost of containing an anthrax-based bioterror attack. The total? $26.2 billion per 100,000 persons exposed.

#### Nuke war causes extinction – Ice Age, famines, and war won’t stay limited

Edwards 17 [Paul N. Edwards, CISAC’s William J. Perry Fellow in International Security at Stanford’s Freeman Spogli Institute for International Studies. Being interviewed by EarthSky. How nuclear war would affect Earth’s climate. September 8, 2017. earthsky.org/human-world/how-nuclear-war-would-affect-earths-climate] Note, we are only reading parts of the interview that are directly from Paul Edwards -- MMG

In the nuclear conversation, what are we not talking about that we should be?

We are not talking enough about the climatic effects of nuclear war. The “nuclear winter” theory of the mid-1980s played a significant role in the arms reductions of that period. But with the collapse of the Soviet Union and the reduction of U.S. and Russian nuclear arsenals, this aspect of nuclear war has faded from view. That’s not good. In the mid-2000s, climate scientists such as Alan Robock (Rutgers) took another look at nuclear winter theory. This time around, they used much-improved and much more detailed climate models than those available 20 years earlier. They also tested the potential effects of smaller nuclear exchanges. The result: an exchange involving just 50 nuclear weapons — the kind of thing we might see in an India-Pakistan war, for example — could loft 5 billion kilograms of smoke, soot and dust high into the stratosphere. That’s enough to cool the entire planet by about 2 degrees Fahrenheit (1.25 degrees Celsius) — about where we were during the Little Ice Age of the 17th century. Growing seasons could be shortened enough to create really significant food shortages. So the climatic effects of even a relatively small nuclear war would be planet-wide. What about a larger-scale conflict? A U.S.-Russia war currently seems unlikely, but if it were to occur, hundreds or even thousands of nuclear weapons might be launched. The climatic consequences would be catastrophic: global average temperatures would drop as much as 12 degrees Fahrenheit (7 degrees Celsius) for up to several years — temperatures last seen during the great ice ages. Meanwhile, smoke and dust circulating in the stratosphere would darken the atmosphere enough to inhibit photosynthesis, causing disastrous crop failures, widespread famine and massive ecological disruption. The effect would be similar to that of the giant meteor believed to be responsible for the extinction of the dinosaurs. This time, we would be the dinosaurs. Many people are concerned about North Korea’s advancing missile capabilities. Is nuclear war likely in your opinion? At this writing, I think we are closer to a nuclear war than we have been since the early 1960s. In the North Korea case, both Kim Jong-un and President Trump are bullies inclined to escalate confrontations. President Trump lacks impulse control, and there are precious few checks on his ability to initiate a nuclear strike. We have to hope that our generals, both inside and outside the White House, can rein him in. North Korea would most certainly “lose” a nuclear war with the United States. But many millions would die, including hundreds of thousands of Americans currently living in South Korea and Japan (probable North Korean targets). Such vast damage would be wrought in Korea, Japan and Pacific island territories (such as Guam) that any “victory” wouldn’t deserve the name. Not only would that region be left with horrible suffering amongst the survivors; it would also immediately face famine and rampant disease. Radioactive fallout from such a war would spread around the world, including to the U.S. It has been more than 70 years since the last time a nuclear bomb was used in warfare. What would be the effects on the environment and on human health today? To my knowledge, most of the changes in nuclear weapons technology since the 1950s have focused on making them smaller and lighter, and making delivery systems more accurate, rather than on changing their effects on the environment or on human health. So-called “battlefield” weapons with lower explosive yields are part of some arsenals now — but it’s quite unlikely that any exchange between two nuclear powers would stay limited to these smaller, less destructive bombs.

#### Chemical WMDs cause extinction – one incident is enough

Gander 18, Kashmira. Citing the Global Catastrophic Risks Foundation’s Global Challenges Annual Report, edited by Martin Rees, UK Astronomer Royal, and Co-founder, Cambridge Centre for the Study of Existential Risk, and whose section on chemical warfare was reviewed by Angela Kane, Senior Fellow at the Vienna Centre for Disarmament and Non-Proliferation, visiting Professor at Sciences Po Paris, and former High Representative for Disarmament Affairs at the United Nations. 10-31-2018. "Experts reveal the nine most likely ways the world will end." Newsweek. <https://www.newsweek.com/how-will-world-end-experts-reveal-9-most-likely-ways-humans-will-be-wiped-out-1194616>. Rez.

Humanity being annihilated by chemical weapons or the molten lava of a supervolcano may sound like the plots of Hollywood disaster movies, but they are in fact among the very real ways mankind could be wiped out according to research. The Global Challenges Foundation—an organization which aims to reduce the global issues which we all face—highlighted the most probable scenarios to finish off the human race in its annual Global Catastrophic Risks report. To compile the document, researchers assessed scientific papers and consulted academics. Martin Rees, the U.K.’s Astronomer Royal, and co-founder of the Cambridge Center for the Study of Existential Risk, warned in the report that while most of us are worried about familiar risks like air crashes “we’re in denial about some emergent threats—the potential downsides of fast-developing new technologies and the risk of crossing environmental 'tipping points.' "These may seem improbable, but in our interconnected world, their consequences could cascade globally, causing such devastation that even one such incident would be too many," said Rees. The likelihood that nuclear war could break out is higher than it was a decade ago, the experts warned. In the wake of the Hiroshima bombing which killed up to 150,000 people in the immediate aftermath, “the world has lived in the shadow of a war unlike any other in history,” they said. Weapons with the highest yield have the power to obliterate 80 to 90 percent of lifeforms, including humans, in a 1-4 kilometer radius. With around 7,000 warheads each, the U.S and Russia have the biggest arsenals, with the U.K., France, China, India, Pakistan, North Korea and Israel confirmed or believed to possess some form of nuclear device. A nuclear war could not only wipe out lives and cities, and leave behind the threat of radioactive disease, but the resulting fallout could trigger a mini ice-age. Biological and chemical warfare GettyImages-672115 A member of the German Chemical Corps, a part of the German military that specializes in anti-nuclear, chemical and biological weapons operations, holds up a rapid tester whose two red lines indicate a positive result for chemical contamination during a demonstration at battalion headquarters November 19, 2001 in Sonthofen, Germany. The Global Challenges Foundations highlighted chemical warfare as a potential threat to human existence. SEAN GALLUP/GETTY IMAGES Compared with other traditional means of attack, biological and chemical weapons are relatively cheap to make. And technological advances in genetic engineering and synthetic biology make it easier than ever to alter micro-organisms in potentially dangerous ways. If these tiny living things were ever to be released out of a controlled laboratory, by mistake or nefariously, it could “cause a pandemic of unprecedented proportions," the report stated.

#### Plan – the member nations of the World Trade Organization ought to delay patent enforcement for cannabis.

Kellner 21 “Mitigating the Effects of Intellectual Property Colonialism on Budding Cannabis Markets” Hughie Kellner [Hughie Kellner came from the small farm town of Uvalde, Texas and received a bachelor’s degree in Physics from the University of Texas at Austin. Upon graduation from the Indiana University Maurer School of Law, Hughie will deploy his physics degree while prosecuting patents in the Frankfurt am Main, Germany office of Leydig, Voit, & Mayer. After Hughie’s first year at Maurer, he worked for a law firm in Thailand as a Stewart Fellow.] Indiana Journal of Global Legal Studies Vol. 28 #1 (Winter 2021) <https://www.repository.law.indiana.edu/ijgls/vol28/iss1/9/> SM

* Includes enforcement and duration

A simple solution to the problem is this: if a nation, or jurisdiction, provides for some new use of cannabis, be it medicinal, recreational, or scientific, the legislation or decision doing so should be accompanied by a law stating that patents may not be enforced as they relate to the subject matter legalized (cannabis strains, methods for ingesting/using, etc.) for some determinate amount of time, after which, patents may be acquired.105 This, at first glance, may seem to some patent attorneys to be a drastic solution as opposed to, for example, compulsory licensing106 or some other means that does not abscond with the rights demanded by international agreements. In support of my proposal, I will first explain why banning enforcement for a certain period yet keeping patent acquisition is desired, rather than banning patent acquisition altogether, as a means of highlighting the benefits that will accrue from the proposed change. Second, I will argue that imposing patent enforcement during the beginning stages of a jurisdiction’s cannabis market development is difficult to justify, as the incentives that patent enforcement are supposed to bring about already exist in great strength, leaving little for the patent sacrifice to provide.

\*\*Footnote 105: There are many aspects of this solution that this note will not address. One of those aspects is the exact duration. All that is addressed is that duration should be less than the full term of a patent for reasons advanced herein. Further, it is assumed that the exact suitable duration is better adjusted to the economic capabilities of the relevant jurisdiction than uniformly imposed. Another aspect is how the solution should be implemented. This effect, of a patent being filed but not yet enforceable for a significant portion of its term of protection, is not uncommon in the pharmaceutical world where a drug may take ten to fifteen, even eighteen years to get approved, and is only enforceable for the remainder of the twenty years since it was filed, leaving possibly two years to do. Therefore, the solution proposed may occur on its own in some medicinal cannabis markets that have long drug patent examination periods, such as Thailand, specifically. That is why the solution proposed does not come with a specified form of implementation; the same goal may be achieved through controlling varying means and portions of the patent application process.

#### The plan solves by reigning in monopolies without killing innovation.

Kellner 21 “Mitigating the Effects of Intellectual Property Colonialism on Budding Cannabis Markets” Hughie Kellner [Hughie Kellner came from the small farm town of Uvalde, Texas and received a bachelor’s degree in Physics from the University of Texas at Austin. Upon graduation from the Indiana University Maurer School of Law, Hughie will deploy his physics degree while prosecuting patents in the Frankfurt am Main, Germany office of Leydig, Voit, & Mayer. After Hughie’s first year at Maurer, he worked for a law firm in Thailand as a Stewart Fellow.] Indiana Journal of Global Legal Studies Vol. 28 #1 (Winter 2021) <https://www.repository.law.indiana.edu/ijgls/vol28/iss1/9/> SM

Patents may still be sought and possibly even acquired if the government so chooses. In this way, examiners will not introduce a new subject matter eligibility analysis changing the fundamental scheme of patentability. Rather, examiners will process the patent as normal, under conditions that actors within the patent system understand, reducing frustration with changing subject matter eligibility rules that are already ambiguous.107 Further, if the promulgating body determines that the window invalidating patent enforcement should be shorter than the patent term would last, there is a benefit for all actors involved. The reasoning supporting a patent enforcement ban rather than a patent acquisition ban rests on five principles.

First, the entity filing the patent will still receive monopoly protection for its invention, albeit with a shorter window than usual. Thus, the incentive to file a patent and disclose the invention to the public still exists, and in a lucrative market such as that for cannabis, a smaller window of monopoly can be compensated by the higher value of that window, which could bring the perceived benefit from a patent back to usual levels.108

Second, if the invention is conceived during the enforcement ban, patent acquisition would allow inventions to be processed just as patents. By allowing patent processing before and after the ban, the legal regime will reduce administrative costs and increase legal certainty.109 By comparison, a system where patent acquisition is prohibited until after the ban would only result in a complex scheme whereby prior use, prior art, and other novelty requirements are handled.

Third, if actors are utilizing technology under such currently unenforceable but soon-to-be enforceable patents, they will have clear notice when they must cease such infringing action, and either close their doors or develop a compliant way of doing business. Thus, actors in the market can establish themselves and then innovate their own means of carrying out business or license it from those who do. This is the exact action patents are meant to incentivize, innovating new solutions to problems, even if the problem here is merely a legal one.110

Fourth, after the cannabis market sustains established actors, the cannabis market may find that the benefits of promoting more actors in the market111—the purpose of barring patent enforcement—are once again outweighed by the value of the incentives that the patent system provides.112 Setting a time period for when patent enforcement will return ensures that the market is not devoid of the incentives once the initial “green rush”113 wears off.

Fifth, this solution bans foreign monopolies, not foreign participation. This solution does not inhibit foreign companies from moving their business to local markets if the legal regime allows.114 With the ability to move their intellectual property portfolio, foreign companies can still acquire a trademark and operate their business plan, benefitting from the experience acquired in the prior years of operation. Foreign participants, just like domestic participants, cannot monopolize their innovations, and are thus placed on an equal footing.

### Framing

#### Synthetic a posteriori moral naturalism is the basis of ethics:

#### A] The normative supervenes on the natural – natural facts like whether brains develop to permit rationality or subjectivity determine whether non naturalist moral facts can be premised on things like capacity for reason

**Lutz and Lenman 18.** Lutz, Matthew and Lenman, James, "Moral Naturalism", The Stanford Encyclopedia of Philosophy (Fall 2018 Edition), Edward N. Zalta (ed.), URL = <https://plato.stanford.edu/archives/fall2018/entries/naturalism-moral/>. //Massa

The first argument against normative non-naturalism concerns normative supervenience. **The normative supervenes on the natural; in all** metaphysically **possible worlds in which the natural facts are the same as** they are in **the actual world, the moral facts are the same** as well. **This** claim **has been called the “least controversial thesis in metaethics”** (Rosen forthcoming); **it is very widely accepted.** But it is also a striking fact that stands in need of some explanation. **For naturalists**, such an explanation is easy to provide: **the moral facts just are natural facts, so when we consider worlds that are naturally the same** as the actual world, **we will ipso facto be considering worlds that are morally the same** as the actual world. But for the non-naturalist, no such explanation seems available. In fact, **it seems** to be in principle **impossible for a non-naturalist to explain how the moral supervenes on the natural.** And if the non-naturalist can offer no explanation of this phenomenon that demands explanation, this is a heavy mark against non-naturalism (McPherson 2012).

#### Next, phenomenal introspection can bridge the gap from experiential natural facts to moral truths and necessitates hedonism. When I observe a lemon’s yellowness shifting my visual fields from darker to lighter shades, I can introspect on that experience and identify brightness as an intrinsic property of seeing a lemon. Similarly, when I feel pleasure, I can introspect on the shift in hedonic tones and identify that goodness is an intrinsic property of the pleasure that was increased.

#### This connection between pain and pleasure and phenomenal conceptions of intrinsic value and disvalue is irrefutable – everything else regresses – robust neuroscience proves.

Blum et al. 18 Kenneth Blum, 1Department of Psychiatry, Boonshoft School of Medicine, Dayton VA Medical Center, Wright State University, Dayton, OH, USA 2Department of Psychiatry, McKnight Brain Institute, University of Florida College of Medicine, Gainesville, FL, USA 3Department of Psychiatry and Behavioral Sciences, Keck Medicine University of Southern California, Los Angeles, CA, USA 4Division of Applied Clinical Research & Education, Dominion Diagnostics, LLC, North Kingstown, RI, USA 5Department of Precision Medicine, Geneus Health LLC, San Antonio, TX, USA 6Department of Addiction Research & Therapy, Nupathways Inc., Innsbrook, MO, USA 7Department of Clinical Neurology, Path Foundation, New York, NY, USA 8Division of Neuroscience-Based Addiction Therapy, The Shores Treatment & Recovery Center, Port Saint Lucie, FL, USA 9Institute of Psychology, Eötvös Loránd University, Budapest, Hungary 10Division of Addiction Research, Dominion Diagnostics, LLC. North Kingston, RI, USA 11Victory Nutrition International, Lederach, PA., USA 12National Human Genome Center at Howard University, Washington, DC., USA, Marjorie Gondré-Lewis, 12National Human Genome Center at Howard University, Washington, DC., USA 13Departments of Anatomy and Psychiatry, Howard University College of Medicine, Washington, DC US, Bruce Steinberg, 4Division of Applied Clinical Research & Education, Dominion Diagnostics, LLC, North Kingstown, RI, USA, Igor Elman, 15Department Psychiatry, Cooper University School of Medicine, Camden, NJ, USA, David Baron, 3Department of Psychiatry and Behavioral Sciences, Keck Medicine University of Southern California, Los Angeles, CA, USA, Edward J Modestino, 14Department of Psychology, Curry College, Milton, MA, USA, Rajendra D Badgaiyan, 15Department Psychiatry, Cooper University School of Medicine, Camden, NJ, USA, Mark S Gold 16Department of Psychiatry, Washington University, St. Louis, MO, USA, “Our evolved unique pleasure circuit makes humans different from apes: Reconsideration of data derived from animal studies”, U.S. Department of Veterans Affairs, 28 February 2018, accessed: 19 August 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6446569/>, R.S.

**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.

#### Thus, the standard is consistency with hedonic act utilitarianism. Prefer –

#### 1] Actor specificity –

#### A] Aggregation – every policy benefits some and harms others, which also means side constraints freeze action.

#### B] No intent-foresight distinction for governments – deliberating over an action requires analysis of foreseen consequences which could be prevented which makes them intrinsic to state action

#### C] Governments aren’t singular rational agents which makes theories about individuals irrelevant – only consequentialism solves by analyzing ends divorced from an actor

#### 2] No act-omission distinction – governments are culpable for omissions cuz their purpose is to protect the constituency – otherwise they would have no obligation to make murder illegal. Actor spec o/w – different agents have different ethical standings that affect their obligations and considerations.