CONFRONTING THE STATUS QUO IN OPIOID ADDICTION TREATMENT: HOW THE REGULATORY ECOSYSTEM STIFLES INNOVATION

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Abstract:
In this paper, I discuss the regulatory ecosystem behind current opioid treatment systems which are primarily focused on a one size fits all harm reduction techniques where the goal is to primarily reduce deaths. I find that the relationship between treatment programs and the surrounding regulatory environment leaves much to be desired in terms of breakthrough innovations. The current incentives for treatment are not geared towards helping patients but rather the incentives are about maintaining the status quo and benefiting entrenched interest groups resulting in the tendentious promotions of suboptimal paradigms. The paper will use the fortress vs. frontier model to understand the status quo environment and discuss some innovations on the frontier and why frontier innovations must be encouraged.

Keywords: Opioid Addiction; perverse ecosystem; ASAM levels of care; Fortress vs. Frontier

JEL: I10, I11, I18, I19

1. INTRODUCTION

The increase in morbidity and mortality associated with opioid analgesics is a cause of alarm for those concerned about public health. The attempts to crack down on their use have resulted in people substituting street heroin as a cheaper

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alternative (Kolodny et al. 2015). Since 2013, the rise of fentanyl-related deaths has been dramatic, creating major concerns (Ciccarone 2019). The Centers for Disease Control and Prevention (CDC) sees the deaths by licit and illicit opioids as a top concern (CDC 2015). In the U.S., between 1999 and 2017, the opioid overdose death rates per 100,000 population (age-adjusted) has increased from 2.9 to 14.9 (a 414% increase).[1] The deaths are expected to grow mainly driven by illicit opioids instead of prescription opioid misuse (Chen et al. 2019). However, the drug-associated mortality could be double the numbers implied by drug-coded deaths (Glei and Preston 2020).

The total economic burden in 2013 due to prescription opioid overdose, abuse, and dependence in the U.S. was $78.5 billion. These include health care costs (33.2%), criminal justice costs (9.7%), lost productivity costs (26%), substance abuse treatment costs (3.6%), and fatal overdose costs (27.4%) (Florence et al. 2016). These costs could be divided into two broad categories: costs associated with opioid use (premature death and lost productivity) and costs associated with prohibition or treating opioid use as a medical condition. A report from the White House Council of Economic Advisers estimated the cost of the opioid crisis at $504 billion for 2015. The higher number was primarily caused by adding the "value of a statistical life" which captures a lot more than just lost earnings due to premature death, but also other valuable activities beyond work (2017).

There are an estimated 100 million civilian adults (about 1/3 of the population) who experience chronic pain which includes joint pain or arthritis (Gaskin and Richard 2011, 302, Quinones 2016, 189) creating a market for opioid pain relief products. The total economic cost to treat pain including direct (marginal cost of "medical care due to pain") and indirect costs (due to lower productivity) was estimated conservatively to be between $560 to

[1] https://www.kff.org/other/state-indicator/opioid-overdose-death-rates/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (accessed January 11, 2020).

$635 billion in 2010, which was much higher than other medical causes such as cardiovascular diseases ($309 billion) (Gaskin and Richard 2011, 313). However, these numbers were exaggerated, and the true numbers of affected individuals are closer to 25 million, yet, the 100 million number dominated the discourse (Lembke 2016).

The history describing the increase in drug overdose deaths is complex. Some scholars have attributed it to the 1980 letter to the editor in *The New England Journal of Medicine*, which stated that the risk of addiction is rare in patients treated with narcotics who have no history of addiction (Porter and Jick 1980)[2] and a 1986 paper found that opioid analgesics could be prescribed safely on a long-term basis as opiates were not inherently addictive. Further, that only certain types of people might become addicted as only two of their thirty-eight cancer patients developed addiction (Portenoy and Foley 1986).[3] Based on these two documents, along with the approval of OxyContin in 1995 by the FDA, and Purdue Pharma's (the maker of Oxycontin) role in advocating for pain treatment beyond cancer pain (Kolodny et al. 2015) resulted in the widespread use of opioids and its abuse not just of OxyContin but also hydrocodone containing drugs (Inciardi and Goode 2003).

Others have suggested that the abuse from prescribed opioids is not the primary driver of opioid overdose deaths. In fact, there has been a steady exponential increase in the overdose crisis since at least the late 1970s, long before OxyContin was developed (Jalal et al. 2020). Only a small percentage of those who are prescribed opioids develop an addiction to opioids and that addiction develops over many months of exposure (Volkow and McLellan 2016). While the prescription volume has dropped in recent years, the overdose rate continues to climb, driven by the non-legal market (e.g., fentanyl). This is because the crackdown on OxyContin has

[2] A note from the editors today states: "For reasons of public health, readers should be aware that this letter has been 'heavily and uncritically cited' as evidence that addiction is rare with opioid therapy." (http://www.nejm.org/doi/10.1056/NEJM198001103020221 accessed April 12, 2018).

[3] Portenoy later said his paper was based on "weak, weak, weak data," (Quinones 2016, 99).

resulted in individuals seeking pain relief in the underground market with drugs with unknown potency (Sullum 2020).

The increased use of opioids for pain, and the rising addiction to legal and illegal opiates, with the concurrent rise in deaths from an opioid overdose, has resulted in increased interest to solve the opioid addiction problem and has resulted in emergency declarations in numerous states and at the federal level.[4,5] However, the regulatory ecosystem of the current health care system is not geared towards finding solutions to the opioid addiction problem. Rather, the focus is on the status quo, which, while reducing harm, is not an optimal solution. I will, in this paper, look at how it is difficult to innovate amid this perverse ecosystem.

In section 2, I will look at the timeline of relevant history in addiction science and treatment that resulted in the suboptimal status quo for treating substance users. In section 3, I introduce the fortress vs. frontier model to understand the current regulatory ecosystem. In section 4, I will look at the architecture of care maintaining the fortress in treating opioid addiction. In section 5, I will look at some frontier innovations. Section 6 concludes.

2. TIMELINE OF RELEVANT HISTORY OF ADDICTION SCIENCE AND TREATMENT LEADING TO THE SUB OPTIMAL OUTCOMES

This section will look at relevant history leading to the suboptimal outcomes that we have today.

2.a. CONCEPTUAL DISARRAY-- NO CLEAR LINES OF THOUGHT

Historically, there were various theories/models of addiction. Having various theories and models indicates that entrepreneurs seek a solution through trial-and-error experimentation. As Hayek

[4] https://www.whitehouse.gov/opioids/ (accessed November 24, 2018).
[5] http://www.astho.org/StatePublicHealth/Emergency-Declarations-in-Eight-States-to-Address-the-Opioid-Epidemic/01-11-18/ (accessed November 24, 2018).

puts it, for progress, there must be a "maximum of opportunity for accidents to happen" (Hayek 1960). Distributed intelligence is the key to a multi-frontal attack on the problem of addiction.

One of the earliest is the moral model of addiction which sees addiction as a sin and addicts as depraved needing repentance and giving up their addiction. The legal model is where the harmful effects of addictive properties prompt legislative action to limit/control the distribution and possession of drugs. The disease/medical model saw addiction as a disease, and in the 18th century, the cure was seen as abstinence. While this view was unpopular during the era of the temperance movement, it became the dominant view after World War II and was adopted by groups such as the AA (Alcoholics Anonymous), AMA (American Medical Association), and many others. The pharmacological model saw the addict as the victim of the substance extraneous to the addict. Hence, the government was to protect its citizens by controlling alcohol and drugs (Rasmussen 2000).

There are numerous biological theories of addiction. The neurobehavioral theory of addiction gives a large role for genetic predispositions. The genetic theory focuses on the impact of heredity. The early psychological theories saw addiction as a symptom of mental illness and not a medical disease. However, today, addiction is seen as a medical disease by the American Psychological Association and the American Psychiatric Association and numerous sub-theories exist like social learning theory, stress management theory, etc. Sociocultural theories focus on cultural, environmental, familial factors that affect addiction (Rasmussen 2000).

Transcendental/spiritual theories of addiction are recognized by the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition. The 12-step recovery programs use spirituality as a key factor in overcoming addiction. Some theories, like the biopsychosocial model, incorporate more than one model and see addiction as biological, psychological, and sociocultural (Rasmussen 2000).

If there are no clear lines of thought, it would be ideal for policymakers to keep out of the debate by not picking a winner or

loser and imposing a one-size-fits-all solutions resulting in suboptimal outcomes. Most practitioners choose one model to guide their treatment, research, advocacy, and prevention strategies. With addiction seen as either a "behavior" or "mental illness" or "medical disease" or a "phenomenon" various methods/models were developed to deal with addiction.

2.b. DEFINITIONAL CAPTURE

However, even amid these multitudinous definitions, the primary definition of addiction today is that it is a "brain disease" (Satel and Lilienfeld 2014). One way to give preference to a model is to capture the institutions (government, insurance, etc.) so that they support your preferred treatment model. For example, the first White House advisor on drugs, Jerome Jaffe, when asked for advice by the Nixon Administration regarding treating addicts, suggested Methadone, although he was familiar with other options, like therapeutic communities and opioid antagonists like Cyclazocine and Naltrexone (1999a, 1976).

> We sat down and tried to think, If we had $50m or $75m, which at that time was a huge amount of money relative to what was being invested in treatment through the standard Federal channels, what would we do if we were going to expand treatment?...the idea that there ought to be a national strategy found its way into the report that I wrote…the major recommendation that we made were basically that there are an awful lot of people waiting for treatment with methadone and you just can't keep pretending that methadone is a small research project. The evidence looks compelling, you ought to approve methadone and expand treatment (1999a, 20f).

When the federal government gets involved in a new area, the program that it supports is tied to the first experts who are consulted. The experts, in turn, set up the architecture of care that

focuses on the areas and models they are involved in. This results in a path dependence problem that could easily lead to sub-optimal outcomes caused by expert direction. Further, interest groups will form to maintain the status quo resulting in the creation of cartels. Bureaucracies also develop routines and momentum, resulting in inertia and the inability to innovate during changing times. As Rourke states, "bureaucratic services generate constituencies that oppose their liquidation"(1984, 33) and hence maintain the status quo.

With Methadone being rushed for approval in 1974 via presidential order,[6] it was seen as a temporary solution till safer alternatives such as LAAM (a long-acting Methadone) and Naltrexone (an antagonist) were developed (Selbrede 2017).[7] Naltrexone was synthesized in 1965, and studies had shown that Naltrexone helps in eliminating drug cravings and "opioid-seeking" behavior and was safe to use (Leavitt 2002). However, once an inferior solution was hoisted on the nation as Opioid substitution therapy,[8] Methadone interest groups kept out LAAM[9] and Naltrexone from seeing the light of day. Similar lobbying was seen for Buprenorphine (1999b). More recently, methadone interest groups continue to lobby for maintaining restrictions on Buprenorphine (Knopf 2019, 2015). When Naltrexone and LAAM were finally approved in 1984 (with the passage of the Orphan Drug Act), Naltrexone came with a black box warning that it caused liver damage which took 30 years to get removed.[10] This warning essentially kept out Naltrexone from the market and any

[6] This was due to the soldiers returning from the Vietnam War.

[7] The Nixon administration had a plan to decommission methadone clinics in a few years till alternatives could be developed.

[8] This has been rebranded as MAT (Medication Assisted Treatment) and rebranded again as MAT (Medications for Addiction Treatment) https://www.asam.org/resources/definition-of-addiction (accessed November 1, 2019).

[9] LAAM requires only 3 visits per week to the clinic, reducing Methadone clinic profits which see patients daily. LAAM was eventually withdrawn due to side effects.

[10] Liver damage occurred only under high dosage, but it was reversible (2009).

serious further studies on its effectiveness were not completed. Further, Naltrexone was rejected as a treatment option because of poor compliance by patients, which was primarily due to the lack of proper psychosocial support (Rounsaville 1995). Further, when LAAM was finally approved by the FDA in 1993, numerous barriers related to public policy (e.g., regulations, reimbursement) and competition (e.g., pushback from methadone clinics) resulted in an unsuccessful launch (1997).

However, a major study tied to a work-release program in Nassau County (NY) prisons found that Naltrexone was completely effective opiate blocking agent "with no major side effects in 691 patients over a 10-year period" (Brahen et al. 1984). Those using Naltrexone were seen as trustworthy, and the treatment was seen as a bridge to living a productive "drug-free" life. This study was ignored, and Naltrexone was never seen as a potentially better alternative to Methadone to help those abusing substances. Numerous other studies have shown that Naltrexone helps in eliminating drug cravings and "opioid-seeking" behavior and was safe to use (Leavitt 2002), with one paper suggesting that the major side effect of naltrexone "is the prolongation of life" (Gold et al. 1982). Treatment was bifurcated for those abusing substances, with Methadone being used for people with lower opportunity cost, whereas Naltrexone was used for those with high opportunity cost, resulting in a much smaller market (e.g., doctors, pilots, business executives, etc.) (Menzies 2019, Srivastava and Gold 2018). One study has advocated for the use of extended-release Naltrexone for those in the criminal justice system to reduce the risk of recidivism and overdose (Koppel and Skolnick 2017).

2.c. UNIFIED FRAMEWORK YET NO CLEAR SCIENCE ON WHAT IS ADDICTION?

While there are many models of addiction, one of the main organizations in the addiction treatment industry, the American Society of Addiction Medicine (ASAM), was one of the prime movers in codifying the notion that addiction should be seen as an

incurable disease to provide a uniform framework. In 2011, a vague and unauthored definition of addiction appeared; however, the implication is that addiction is a brain disease. The short definition of addiction is:

> Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.
>
> Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death[11].

The more extended definition of addiction runs three pages long. Having such lengthy and opaque definitions result in unclear approaches to treating patients who are addicted to opioids resulting in poorly designed incentives and regulations to treat patients. The longer definition indicates a lack of clarity on what addiction is and a lack of clear science backing it up. While the definition is focused on the brain disease model, the scientific foundation is not clear. If the scientific foundation is not clear, then the structure built on top of it to help addicts is unlikely to deliver.

What is interesting is that before 2011, the overall perspective in ASAM was that addiction was a type of behavior and was generally pro sobriety in its outlook, the shift to the

[11] https://www.asam.org/resources/definition-of-addiction (accessed June 1, 2018).

chronic brain disorder definition was either due to neurosciences advances (Medicine 2011) or possibly due to pharma industry capture (Kishore 2018, Tannenbaum 2011). Further, NIDA, the National Institute on Drug Abuse, a federal government agency, saw addiction as a relapsing brain disease a few years before ASAM, helping cement this definition (Hammer et al. 2013). On September 15, 2019, ASAM came out strongly in favor of addiction as a brain disease model.[12]

2.d. ADDICTION AS A BRAIN DISEASE

Today, the primary definition of addiction is that it is a brain disease. As Jaffe (2007) states "It was a useful way for particular agencies to convince Congress to raise the budgets…[and] it has been very successful. The budget has grown. From that perspective, you can't argue with success. But it's a Faustian bargain. The price that one pays is that you don't see all the other factors that interact. You minimize all the other major factors that interact."

Further, over half of NIDA's research budget is given over to focusing on the issue of addiction as a brain disease via funding things like neuroimaging, neurobiological research, etc. NIDA, which funds almost all substance abuse research in the US, "sets the national agenda regarding which research gets funded and therefore the nature of the data produced and the kinds of topics that investigators propose"(Satel and Lilienfeld 2014, 4). Funding for prevention of addiction and other approaches to treatment is hence lacking and possibly more effective and cheaper solutions are ignored (Heather et al. 2018).

Having the brain disease model keeps you helpless and the only solution is MAT resulting in over-medicalizing and creating a whole host of side effects and the unlikelihood of a patient

[12] https://www.asam.org/resources/definition-of-addiction (accessed November 1, 2019).

achieving sobriety.[13] The brain disease model invites paternalism as patients are seen as incapable of making the right decisions for treatments. Since many quit addiction without treatment, and evidence exists that the social experience is important for recovery, this challenges the notion of addiction as a chronic relapsing brain disease as championed by NIDA (Heather et al. 2018, Bose 2021). A study that looked at soldiers from the general sample group in Vietnam found that 0.2% were addicted to narcotics prior to Vietnam, and in Vietnam, that number increases to 20%. Since Vietnam, the number drops back down to 0.7%. When soldiers returned to the US, the less stressful environment, family, and extended support helped people become de-addicted[14] (Robins, Helzer, and Davis 1975).

3. THE FORTRESS VS. FRONTIER MODEL

When there is a perverse ecosystem, then it becomes hard to innovate, to create better solutions. Why it is hard to innovate? Interest groups develop around the status quo to maintain the status quo. I will use the Fortress vs. Frontier Model to make sense of this.

A discussion on entrepreneurship must start with the work of Schumpeter who saw the entrepreneur as one whose innovations are a disruptive force of the status quo (Schumpeter [1934] 1947: 132). Schumpeter writes, "the function of the entrepreneur is to reform or revolutionize the pattern of production by exploiting an invention"((1942) 1976, 132). This creative destruction is similar

[13] There are benefits to MAT, for example, one is less likely to die, use emergency room services due to illicit drug use, etc., but is using a legal addictive drug the most beneficial and efficient outcome?

[14] Less access to drugs also played an important role. When Soviet soldiers returned home from Afghanistan, they continued using opiates in large numbers. This was primarily due to the easy availability of drugs from Afghanistan. (Adams 2006, Kamrany and Killian 1992, Astapenia 2013, Kadykalo 2015)

to the idea of disruptive innovations, where Bower and Christiensen suggest that innovations occur outside the industry mainstream (Bower and Christiensen 1995). Graboyes suggests that these disruptions occur on the "Frontier" of medicine (2014, 12). The Schumpeterian entrepreneur is motivated by a desire for profits and economic power.

Kirzner, on the other hand, emphasizes that the entrepreneur discovers new opportunities in the existing status quo. The entrepreneur is hence an equilibrating force "whose activity responds to the existing tensions and provides those corrections for which the unexploited opportunities have been crying out" (Kirzner 1973, 127). Due to uncertainty and ignorance, there is much opportunity to be exploited, thus earning profits for an alert entrepreneur. Kirzner (1994, 107) has described this alertness for him as a "generalized intentness upon noticing the useful opportunities that may be present within one's field of vision." Innovations within such a framework can be seen as "sustaining" innovation rather than "disruptive" innovation, they are brought about by insiders, and increase the costs (Christensen, Grossman, and Hwang 2009).

Graboyes suggests that the "Fortress" promotes sustaining innovation and helps existing players (2014, 12), where the world is regulated and engineered (Postrel 1998), and where innovators need to ask permission to innovate and create. In the fortress model, the entrepreneur does not revolutionize the status quo as entrepreneurs are only alert to existing opportunities within a regulated framework. In a sense, this approach has some commonalities with Kirzner's entrepreneur. However, there is a significant difference between Kirzner's entrepreneurs and the fortress model: the former exists only where there are no regulations stifling entrepreneurial discovery (Kirzner 1973), while the latter presupposes regulatory barriers to entry that favor and consolidate the position of firms, interest groups, and bureaucracies that are already active in the given market. When looking at the history of drug addiction, we see that it was

primarily driven by fortressinnovations where the methods have not changed over the years, but only the drugs used, e.g., Morphine to Methadone to Buprenorphine (White 1998). Fortress innovations are promoted by the state, as it is involved in the picking of winners and losers and thus creating path dependence. In a stifling regulatory ecosystem, fortress innovations are accommodated and tolerated, but frontier innovations are not encouraged.

The frontier encourages creative destruction with new products and methods, and in the process, destroys old industries. Whereas the fortress protects insiders from competition via the state and innovations come from within the existing industries at a higher cost (Graboyes 2014, 13). The frontier is a world of dynamism where "constant creation, discovery, and competition" occur (Postrel 1998), resulting in lower costs and better outcomes. The Schumpeterian entrepreneur generates economic growth, the Kirznerian entrepreneur brings the market to equilibrium, and entrepreneurial judgment brings about profit and loss (Foss and Klein 2012, 78).

4. STRUCTURE OF THE FORTRESS: DEFINED ARCHITECTURE FOR CARE MAKING INNOVATION DIFFICULT

The fortress is fortified to make innovation outside the fortress very difficult. With the first drug czar recommending Methadone as the best option to the federal government, what framework is needed to lock in the program resulting in suboptimal equilibriums? What should individuals, insurers, governments be willing to subscribe to deal with addiction?

4.a. ASAM LEVELS OF CARE & PUBLIC HEALTH REGULATIONS AND LICENSING

One way to ensure your method is locked in is to provide standards of care that allow for legislators and insurers to latch onto them whether they are effective or not.

One such system has been developed by the ASAM. ASAM has come up with five levels of care to deal with addiction treatment.[15] The ASAM standardized treatment matching tool allows clinicians to "systematically evaluate the severity of a patient's need for treatment along six dimensions, and then utilize a fixed combination rule to determine which of five levels of care a substance abusing patient will respond to with greatest success" (Turner et al. 1999, Rasmussen 2000).[16]

From these five levels of care, a whole architecture of care, rules, regulations, licensing requirements, etc., has been developed to deal with addiction which hinders innovation and prevents efficient outcomes resulting in cookie-cutter care. As ASAM is an assortment of groups with conflicting goals, e.g., AA focusing on sobriety and other groups focusing on addiction as a metabolic syndrome needing medication, their architecture of care is not optimal for patients. Further, the levels of care deal with substance use disorder, an all-encompassing term that includes, for example, alcohol and opioids, hence what is appropriate care for a person with alcohol use disorder may not be ideal for a person with opioid use disorder (Menzies 2020).

ASAM is a provider organization that guides addiction doctors, insurers, and public officials in the area of addiction. The ASAM levels of care are what insurance companies and public health systems have adopted when determining the care provided as well as reimbursement. ASAM is a private enterprise that cornered (monopolized) the market on who should get treatment and what the treatment is, and it has political pull. The state and federal governments and insurance companies have adopted the same criteria preventing innovation. Any innovation around these

[15] The five levels of care are early intervention (level 0.5, added later by ASAM), outpatient treatment, intensive outpatient/partial hospitalization, residential/ inpatient treatment, and medically managed intensive inpatient treatment. (Rasmussen 2000)

[16] https://www.asam.org/docs/publications/survey_of_state_use_of_ppc_nasadad-2006. pdf?Status=Master&sfvrsn=2

levels of care will typically not be reimbursed hence discouraging any sort of Schumpeterian type entrepreneurship, while deviation from the standards of care can risk the loss of licenses.

4.b. SNAKES & LADDERS: SLOTTING, LICENSING, CERTIFICATE OF NEED

This slotting of patients into different levels of care (per ASAM guidelines) results in suboptimal outcomes. It prevents physicians from following through in the treatment of the patient. For example, once the patient goes through, say, intensive outpatient care, once the process is completed, the physician has completed their duty and is paid. There is no follow-up, no quarterbacking, for the patient to see if the patient has truly given up opioids or has relapsed. In the meantime, if the patient is back on opiates, then the whole process starts over as the game of snakes and ladders. For each episode, the patient is "releveled" via ASAM levels of care, resulting in increased costs. Licensing results in practitioners who provide episodic care (e.g., inpatient care, or detox). Practitioners are in silos and unable to think and act outside of them, thereby limiting the physician's entrepreneurial experimentation in the health care industry.

All levels of care are time-limited. For any patient that needs more time in say intensive detox, the hospital might not get paid by insurance or the government. This is based on a general consensus or rules of the game (best practices). Further, licenses issued by public health agencies are given to different hospitals to deal with different levels of care, resulting in a patient needing to be treated at different locations with different teams. This is based on a certificate of need or determination of need regulations by public health agencies. These agencies might not license one hospital to have 3 or 4 different levels of care being in one place (Kishore 2018) for reasons such as curbing health care costs or minimizing duplicative services. Further, in rural areas, licensed

facilities offering the different ASAM levels of care might not exist, making appropriate slotting of patients for treatment unavailable. Further, if no beds are available, in say, a residential facility, one might be sent to an intensive outpatient facility instead, thus creating suboptimal care (Lawrence 2019).

Public health regulations both at the state level and federal-level[17] are on top of ASAM guidelines dealing with substance abuse in many states. The regulations can be onerous, incompatible, at cross purposes, and with different goals. For example, regulations for detox (inpatient vs. outpatient) vs. regulations for rehab are different. Only a few organizations are licensed to see addicted patients and they are usually licensed in one area of care, for example, for detox, or for halfway houses, or for methadone maintenance (all of these are determined by Certificate of need). This further strengthens these silos of care.[18]

In general, licenses are given based on certifications of need determined by the public health bureaucracy. However, additional hurdles include dealing with NIMBY (not in my backyard) activists in the local community that might resist having a halfway house or an Opioid treatment program in their neighborhood. These clashes could result in expensive litigation to resolve the matter.

Further, a patient might only be allowed one detox/lifetime due to regulations, and if that is used up, a relapsed patient might not be able to seek detox again without paying out of their pocket, and if they are unable, the only option might be Methadone maintenance which could be a sub-optimal outcome. Further, the scope of practice regulations are an additional barrier to effective treatment. For example, states with more restrictive scope-of-practice regulations for nurse practitioners prescribe less Buprenorphine (Nguyen et al. 2021).

[17] The federal-level regulations would be only for interstate issues; hence typically, they apply if Medicare and Medicaid federal dollars are involved.
[18] Regulations might restrict one from opening a detox center close to a school.

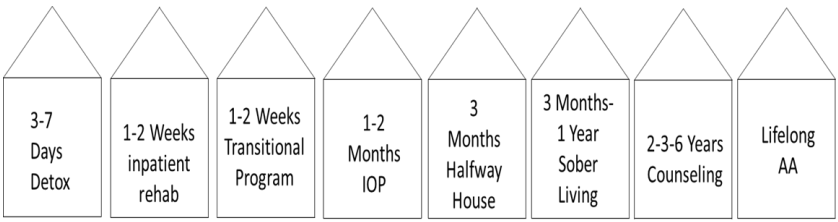

Figure 1: Silos of care to prevent relapse. The silos on the left are more expensive than the ones on the right.

Because of silos (see figure 1) and lack of resources, one could start in silo 1 (detox), and end up in silo 4 (IOP: Intensive Outpatient Care), and then end up in AA (silo 8) and this mismatch of care could be due to the lack of availability of beds or whatever the insurance contract allows. The silos are not linked. The patient goes into different silos trying to take care of themselves without a single physician being a quarterback. Shifting from one practice to another for different treatment and lacking continuity of care increases costs due to lower success rates and due to the lack of relationships and trust with providers. These silos prevent quarterbacking. Patients might have to direct care themselves by calling up insurance to see what insurance covers and for how many days. Does the patient know what is best for them (Kishore 2019)?

4.c. NO CLEARLY DEFINED BENCHMARKS FOR SUCCESS

One of the difficulties in addiction care is that there is no clear benchmark for success. Success is defined in many ways (Kishore 2018): 1) Completing the program (graduating) is considered a success. This is an artificial benchmark. 2) Continued engagement in treatment despite drug use is also seen as a success (i.e., retention within the treatment pool). 3) Self-reported sobriety where there is no verification is also considered a success. Validity is attributed by fiat to self-reporting, which is

then used as if it were a legitimate benchmark despite the absence of laboratory confirmation. 4) Sobriety based on direct observations by care providers and reports from collateral sources are used as a measure of success. The methodical use of detection testing is employed to confirm that the patient is not using drugs (e.g., urine toxicology tests). 5) Periodic-use scenarios, also known as chipping (Zinberg and Jacobson 1976) (where the addict is not using drugs on the weekdays but uses it on the weekends or for recreational purposes), are also considered acceptable. These various measures of success make comparability between studies and treatment methods virtually impossible (Darke et al. 1991).

While billions of dollars are spent on treatment, it is not clear what success is. In fact, due to this final goal not being clear, many policymakers, practitioners, and academics have resorted to assuming success as reducing opioid overdose deaths, hence the recent reduction in deaths was seen as a success by the Trump administration (Ault 2019).

4.d. NO TRANSPARENCY OF COSTS: THIRD-PARTY PAYER PROBLEMS

With insurance and government playing a large role in health care, the impact on addiction treatment is large. Currently, an estimated 87% of every dollar spent on health care is spent by a third party (Herrick 2007). Therefore, the consumer will continuously demand higher quality care with little consideration for the price. The producer, when aware of the patient's price insensitivity, is less inclined to control costs and provide less expensive alternatives. Further, with a lack of price transparency, it can be next to impossible to find out what a procedure costs. This results in waste and inefficiency, and an inflated market. Moreover, with many companies now offering health care plans with high deductibles and high co-pays, the incentives for consumers to be economical with their money increases. Higher co-pays affect the ability to seek treatment (Hayami and Freeborn 1981).

Another problem with third-party payer systems is the issue of moral hazard. Being insured, makes individuals behave in more risky ways. Individuals might exercise less, eat more junk food, etc., since they are insured. This will then increase the demand for health care and increase costs (Hubbard and O'Brien 2019). Third-party insurance payments distort perceptions of cost and change behavior. Further, a low marginal cost of care increases healthcare usage allowing for multiple relapses (moral hazard issues) and their treatment. Providers are also less likely to focus on containing costs (Seville, Schecter, and Rappleye 2017, Alvarez 2017). The stronger demand for addiction treatment will lead to higher prices, particularly if supply is inelastic.

We see the perverse nature of the insurance market in the market for urine tests or "liquid gold," as it is called. One of the ways to test for drugs is from a urine test. The basic test is the dip test. If there are ten lines, the insurance companies typically pay $10/line. Next, to double-check the results (both positive and negative), further tests are done via Gas Chromatography Mass Spectroscopy. Here the insurance pays $200/line. Finally, to quantify the amount of drugs taken, a third test using Liquid Chromatography Mass Spectroscopy is used, where one can charge $400 per line. This could result in a payout for a lab or hospital of over $6000 per patient for drug screening tests if going over the whole procedure (Segal 2017).[19] There is no incentive for the producer (treatment centers or labs) to incentivize here as the patient is not sensitive to the high price as insurance covers the cost of the drug test.

In 2015, it was found that patients with opioid abuse or opioid dependence diagnosis billed private insurance $63,356 compared with all other patients who, on average, billed insurance $11,404, a $52,000 difference (Fair Health Inc. 2016). This of course results in higher premiums for everyone.

[19] Not all agencies do this, for example, Dominion Diagnostics typically charges reasonable rates.

Insurance also stifles the development of treatment models, as was the case for the Minnesota Model of addiction treatment. Once insurance started covering the MN model of 28 days of treatment, it stifled creativity and prevented the natural evolution of the model (McElrath 1997). This is because the impact of insurance paying for a treatment model seems to be freezing the best practices of the day, which prevents innovation.

Further, government payments can also stifle innovation. An Iowa community-based program to help alcoholics, once it became funded by the state and federal government, immediately resulted in costing double and resulted in helping fewer alcoholics (Peele 1990).

Insurance only pays for certain established protocols like the ASAM levels of care framework. Innovations outside of this are usually not funded. Innovators working outside the system use fee for service models, grants, angel investors, etc. This makes innovation harder, especially when competing with established moneyed interests. When Naltrexone was approved for treating alcoholism, a chain of California treatment centers started using Naltrexone, but had to suspend operations after a few months as insurance companies did not reimburse such treatment without further costly studies (1997).

As public and private insurance have increasingly played a prominent role in addiction treatment, many treatment centers might have to change their financing models to stay viable. Further, innovations can be stifled, as non-conforming firms might face an increased demand from their patients to accept insurance resulting in these firms having their hands tied. Currently, about half of addiction treatment programs do not take insurance primarily due to credentialing requirements. To get insurance credentialing and Medicaid certification, the treatment programs will have to hire professional staff with the proper degrees[20] to get

[20] It is unlikely these professional/credentialed staff will have been educated in diverse methods to treat addiction.

reimbursed. Secondly, these centers will have to get the proper technology to maintain proper electronic records and be able to bill insurers resulting in investment in staff knowledgeable in Information Technology. All these required changes reduce innovation and increases costs (Andrews et al. 2015, 829). One such group, Adult & Teen Challenge, a faith-based organization, having a successful program helping addicts, has opened some of its centers to state licensure, which allows for payment from private insurance, Medicaid, and payments from local and state governments. This licensure means they now have medical or clinical detoxification and MAT (Reneau 2019), and they open themselves to more control and straitjacketing via regulations which will reduce future innovations and would provide fewer options to patients if all that occurs is more programs focusing on MAT.

4.e. AFFORDABLE CARE ACT STRAITJACKET

The passage of the Federal Mental Health Parity Act (2008) opened up new funding for people with addiction to get care. This came on top of the passage of the Patient Protection and Affordable care Act (PPACA) (2010) that allowed young adults up to age 26 to get insurance coverage through their parents' insurance plans. Thus, the laws increased the pool of funds paid by a third-party payer for drug addiction treatment. However, the PPACA created numerous other problems in medical care, including addiction treatment.

Electronic Medical Records[21] require a major upfront investment in computers and software costs. These high fixed costs can create barriers to entry. This has forced doctors to be part of larger networks to take into account economies of scale (Knight 2019). Doctors are joining a larger network and are given less freedom to innovate. Doctors are moving from private or

[21] Some of these reforms started with The Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009.

physician-led practice to large integrated and, at times, oligopolistic health care systems. The PPACA results in getting salaried doctors, making it hard to innovate as it involves working under the stricture of your employer and following standards of care, resulting in a reduction in the art and flexibility of medical care.

5. FRONTIER INNOVATIONS

While frontier innovations are difficult under a perverse ecosystem, they not impossible. This section will look at some frontier innovations.

5.a. MASSACHUSETTS MODEL

One such innovation was the primary care shelter in place model called the Massachusetts Model (Bose 2020). The shelter in place model used a non-narcotic approach to treating addiction. It used the primary care system, which allows for more flexibility to innovate, builds relationships with providers, and provides a much-needed quarterback instead of silos. The model is primarily an outpatient home detoxification program and does occasionally refer patients to hospitals and residential detoxification, if necessary (McAuliffe and McAuliffe 2010). The primary care model offered lifelong access to care, avoiding episodic care. The success rate (sobriety) after one year in the program has increased from 37% to 60% as the process was refined based on natural history studies. Over 250,000 patients had gone through the program before it was shut down (Selbrede 2014), as it was seen as a threat to fortress innovators. The model had around 50 clinics and satellite locations located within communities across the state of Massachusetts instead of a central location. A working paper using county-level panel data found a robust negative association between the presence of clinics in the past period and opioid mortality (Bose and Jacob 2018).

Because the primary care model was an integrated practice, it allowed for urine tests to be completed in-house, where the total charge was $70, and office visits were billed at a maximum of $90. After one year, the cost totaled $10,805 plus medication costs (primarily Vivitrol) which is similar in cost to a 7-day Inpatient detox program. Further, the total cost in the second year of treatment amounted to $1,614.17 (Kishore 2010). Therefore, this model was more affordable and had a higher success rate as measured by sobriety. This indicates a frontier and disruptive innovation. It could be further improved if the inefficiency of the third-party payer system was not the primary method of payment.

As a primary care program, it got around the issues of slotting and licensing that were derived from ASAM standards of care by not calling the treatment detox but rather de-addiction. Using the primary care model allowed one to overcome some of the restrictions that insurance might bring since insurance covers primary care.

5.b. OTHER INNOVATIONS ON THE FRONTIER

Numerous other frontier innovations exist in opioid addiction treatment. Most, if not all of them, focus on working outside insurance boundaries and silos and are cash or grant-based models. One benefit of frontier innovations is that ideas can be tried, and failed models shut down. Some frontier innovations focus on upper-income clients. For example, Amen Clinics use brain scans and other evaluations and charges thousands of dollars to help patients.[22] Some frontier innovations focus on lower- and middle- income clients and can include massage therapy, acupuncture, and reiki. These cost between $40 to $75 per session to help patients stop misusing prescriptions or using illegal drugs (Wroblewski 2019). Aromatherapy has also been used to help patients (Platter 2019).

[22] https://www.amenclinics.com/services/ (accessed November 1, 2019).

Other innovations at the frontier have come with the redefinition of what addiction is. For example, Mate says that when we try to treat addiction, we should focus on healing the pain and trauma, which will then treat the addiction (2008). This redefining has resulted in a culture of innovation around treatment that includes things like kundalini yoga, mindfulness, compassionate inquiry therapy, etc. These new options are working to mainstream themselves by making their work evidence-based (Harris 2019).[23] One researcher suggests that self and social identity is a "central part of the explanation of addiction", and hence recovery is an "existential threat" for an addict. For this reason, one's social identity needs to be changed from being tied to drug user communities to sober communities for successful treatment (Pickard 2020, Bose 2021). Hence working under a different understanding of addiction is characteristic of a frontier innovation.

6. CONCLUSION

Addiction treatment, like other facets of health care in the US, is highly regulated and needs breakthrough innovations at the frontier. However, the current ecosystem is prohibitive to innovations at the frontier. Innovations in the fortress, like the long-lasting buprenorphine implant (Probuphine), can be developed. An affordable and effective opioid addiction treatment centers were once available in the state of Massachusetts based on the primary care "shelter in place" model. However, they were shut down by interest groups since the innovation was outside the fortress.

While many politicians have good intentions in terms of wanting to solve the opioid addiction crisis, the current ecosystem

[23] Getting funding for the studies that need to be done is quite expensive. Even LAAM and Naltrexone obtained federal funding for clinical trials (1997).

is not geared towards optimal outcomes. Unsound proposals lead to expensive and inefficient outcomes. Politicians may be able to gain by focusing attention on a problem even if their policy response is ineffective or even harmful.

Entrepreneurs should be encouraged to come with new solutions, and policymakers could change funding patterns that might include prize money. Temporary laws are useful when institutions are trapped in a suboptimal equilibrium, possibly due to path dependence. The temporary law could create a new starting point which results in a better market equilibrium. Temporary laws also allow for easier political bargains by various interest groups that might prefer the status quo, as stakes are lower (Ginsburg, Masur, and McAdams 2014). Some of this is happening with the COVID-19 pandemic in terms of loosening restrictions on prescribing Buprenorphine and Methadone, but more needs to be done (Bose 2020-2021, Dooling and Stanley 2021). The incurable brain disease model of addiction has failed so far to yield "much practical therapeutic value" (Courtwright 2010) and should be carefully reevaluated as it implies only palliative care is possible.

Large uniform social solutions needing credentialed elites seldom come up with optimal solutions, as is the case in current addiction care. Innovations at the frontier must be encouraged so entrepreneurs can come up with solutions that will help people transition from harm reduction to harm elimination to harm avoidance at a lower cost.

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