Research Idea and Objective

Our objective is to determine whether our modern medication adherence platform, Pillsy, can be used to increase adherence of opioid agonists that are used in Medication Assisted Treatment (MAT) for opioid use disorders.

Medication Assisted Treatment (MAT) has been shown to be a viable means for treating opiod addiction, but it is underutilized. Swartz et al found that, "increased access to opioid agonist treatment was associated with a reduction in heroin overdose deaths". Adherence to opiod agonists such as Buprenorphine is also much lower than to other drugs. In a study on HIV-infected Opioid dependent released prisoners less than 50% of patients were adherent to Buprenorphine after 24 weeks. In another study, less than 25% of patients remained adherent to Buprenorphine after 1 year.

Pillsy acts like a digital medication coach that our company has developed over the past 2.5 years using principles of behavioral science, modern design, and highly scalable wireless and mobile technologies being used in the consumer tech industry. Our platform provides education and reminders using a combination of a mobile app, text messages, and automated phone calls. Pillsy also includes a Bluetooth-based smart pill bottle that automatically tracks doses and sends intelligent reminders. Our system also includes sharing of data with one's healthcare team, a feature that drives increased social accountability.

Pillsy was developed using principles of behavioral science that are espoused by several leading researchers, including Dr. Robert Nease, the former Chief Science Officer of ExpressScripts. A large analysis conducted by ExpressScripts, which is described in their 2011 Drug Trends Report, found that inattention and inertia are relatively more important in predicting medication adherence than other commonly cited conscious factors, such as cost and side effects. According to Dr. Nease, patients usually consciously intend to perform a healthy behavior, but they often find that it's easier to fall back on the more impulsive, unhealthy types of behaviors.

If Pillsy can be shown to improve medication adherence for Buprenorphine or another opioid agonist it could result in a solution that has improved efficacy and is also more cost effective than implantable solutions like Probuphine and Vivitrol, which cost over $800 per month. Because Pillsy collects data in use, the platform's effectiveness will improve as we get more users. Our system is designed to be able to use machine learning techniques to optimize things like the frequency and types of rewards and reminders based on past data.

Other systems such as Proteus and AICure have been designed to improve medication adherence. However, these systems are more "Big Brother" in that they require patients to self-monitor in ways that they may resent. In contrast, our system is more convenient and fun. We are also developing photo-verified pill counts and video-enabled direct observational therapy, which may be turned when a physician determines that level of monitoring is necessary.

Our founders have already spent 3+ years developing the core Pillsy platform. We're currently piloting in specialty pharma applications with funding being provided by specialty pharmacies and pharma companies. We have also been invited to pilot with a major chain pharmacy in Q1 or Q2 of 2018. Having seen the impact that opioid addiction has had on our home city of Seattle, we would like to apply our platform to helping people treat their opioid addiction issues.

Founder Bios

Our founding team has founded VC-backed startups and worked at some of the top tech companies in the world. We bring the scrappiness and executional abilities that are required to build a technology-based product as well as the hustle needed to close early deals.

Jeff LeBrun is our CEO. Prior to co-founding Pillsy, Jeff was led commercial development for two research-based startups. Jeff was a co-founder of Algal Scientific, an immune-focused biotech startup he started while he was in graduate school that was acquired by Kemin Nutrition. Jeff was also an early employee at Sakti3, a Khosla Ventures-backed electronics startup that was acquired by Dyson. Jeff has MS and MBA degrees from University of Michigan, where he was named the "Cause-based Entrepreneur of the Year", and a BS in Biology from University of Puget Sound.

Chuks Onwuneme is our CTO. Chuks has over a decade of experience writing software and leading engineering teams for Nokia and IBM. He also developed software ranging from Bluetooth applications to clinical trial software as an independent consultant. Chuks also founded a startup called Personify that helped to match corporate employees to community service opportunities.

Description of Product

We've already developed the foundation our adherence platform. We currently have over 2000 paying users and we are beginning pilots in specialty pharma applications. We are working with five pharmacies that in aggregate have licenses in all 50 states.

When a physician prescribes Buprenorphine, they will prescribe the "digitally-enhanced" version of Buprenorphine, which comes with our smart pill bottle and app. This combination product will be coded with a unique NDC after being approved through the FDA's 505(b)(2) regulatory pathway. This combination product will be reimbursed at a rate that is slightly higher than generic Buprenorphine but lower than implantable Buprenorphine.

This prescription will be routed to the appropriate pharmacy, where it will be filled by the pharmacist and given to the patient. The pharmacist will sync all of the important prescription data to the patient by pressing a button in their pharmacy software (this requires an integration with Pillsy). The pharmacist will give or mail it to the patient after providing brief counseling on how to use the product.

The patient gets a link to download the Pillsy app after they are setup in the pharmacy. When they open the app, data entered in the pharmacy automatically syncs, so there is no data entry required by the patient. The app walks them through some easy-to-understand instructions on how to use the smart pill bottles and also provides educational instructions to help reinforce the importance of taking the medication regularly

When the patient opens the pill bottle to take a dose, it automatically records the dose as "taken". They will also receive rewards ranging from encouraging messaging to daily credit towards their cellular data plan. In this way, staying adherent may provide them with immediate access sites like Youtube or Facebook as well as to access important social services sites.

If they forget a dose, they will get a series of progressively escalating reminders, including text message reminders, lockscreen notifications and automated phone calls. The smart pill bottle will

also beep and blink. Members of their care team may also be notified via text message if they miss doses with our "Pillsy Helpers" feature.

Depending upon settings entered at the pharmacy, the patient may be asked to randomly photograph their remaining pills and/or take a video of themselves swallowing the pill. These settings are considered to be more invasive and so may only be deployed with more difficult patients. This is consistent with guidance provided on monitoring of MAT.

Periodically, the Pillsy platform may also be configured to deliver surveys to the patient. These surveys may be configured to be delivered when patient's data begins to show signs of non-adherence. For example, a patient may receive survey asking why they stopped taking their medication regularly. This information will be reported back to the pharmacist and their doctor, so they may perform more personalized counseling in the limited amount of time they have to deal with each patient. Patients who report cost issues may receive different counseling than one that shows signs of undesirable side effects.

All of this information is relayed back to the patient's pharmacy and other members of their healthcare team (doctors, nurses, etc.) that's displayed in an easy-to-understand dashboard. Members of their healthcare team will review this information on a regular basis, focusing their efforts on patients who are flagged to show high risk levels based upon our system's algorithms and data. They will be able to type shared notes into the Pillsy system, so they can coordinate care around managing the patient's medications.

All of the most important stakeholders in the process for getting this product to patients will be aligned financially in addition to being aligned in their motivation to provide the best care. Participating pharmacists will be reimbursed through the drug benefit. Doctors who are participating in fee-for-service arrangements will be reimbursed for remote monitoring—CMS recently unbundled CPT code 99091, a decision that will make doctors more likely to take the time to review this type of remote monitoring data. Healthcare providers who work for value-based care organizations are already incentivized to adopt technologies that reduce negative outcomes related to adherence. Payers are aligned around preventing economic loss that's associated with opioid abuse.

Importantly, our platform enables family members, pharmacists, doctors and other members of a patients care team to view patient adherence data. This approach has been shown to lead to greater accountability, and better adherence than reminders alone. For example, smart pill bottles were shown to improve medication adherence from below 50% to 88% in kidney transplant patients after two years when providers also received information.

In summary, our system is really a series of interventions that includes multiple types of reminders, as well as sharing of data with caregivers who are armed with data and powerful communication tools that enable them to send the right message to the right person at the right time. Our system is easy-to-use and is designed in a way where it can be easily integrated into existing pharmacy and healthcare provider workflows.

Here are two additional videos describing the product.

- Pillsy User Experience Marketing Video: https://youtu.be/d1yIxHQiuOU
- Founders Demo Pillsy: https://youtu.be/jqmAA1jeSyU

Customer/Stakeholder Development Methodology

We've already engaged with hundreds of stakeholders. In addition, we've been contacted by over 100 potential customers after receive press coverage in summer, 2017. This has helped us to understand the market potential and several different value propositions for our product.

In the case of Buprenorphine, we believe that the best commercialization route is through the drug device combination pathway. This would result in creating of a new combination product that receives a unique NDC—something that enables doctors to prescribe the and bill the combination product through the drug benefit channel. We have already spoken with leaders at the regulatory consulting firm Camargo Pharmaceuticals, an expert in the 505(b)(2) pathway. Camargo confirmed that this pathway is feasible if we can demonstrate clinical efficacy.

We have also been approached by executives from multiple pharmaceutical companies with pain management products in their portfolios to discuss possible future collaboration. Firms like Pear Therapeutics and Proteus have further demonstrated FDA's willingness to consider "digital therapeutics" as a legitimate class of treatment. This is a new area of exploration for big pharma but there is an appetite to participate.

In order to further our customer research we intend to interview at least 10 more stakeholders who are directly involved in prescribing Buprenorphine, including physicians working at pain management clinics and University researchers who study opioid addiction. Dr. Ryan Hansen at University of Washington has served as an informal advisor in this area and has provided connections at University of Washington who may be interested in assisting with clinical studies. We will continue to conduct stakeholder interviews and obtain feedback on our solution until we are getting feedback that we have nailed down every important detail. An additional goal of this outreach would be to find a research partner to help conduct a Feasibility Study.

In addition, we will interview risk-bearing employers that may be interested in purchasing our solution. Preliminary interviews with employer stakeholders have shown that opioid addiction is thought to be a major factor in driving fraudulent workers comp claims. An extremely high percentage of workers comp claims at large employers like Walmart are attached to prescriptions for opioids. Education about technology-enabled MAT as a treatment option for opioid addiction may result in more proactive treatment if it can be shown that it results in reduced expenditures for employers. This could be extended even to employees that don't have health insurance if it's shown to reduce frequency of workers comp claims. We have been invited to present our solution to a group called the Employer Health Innovation Roundtable. Because of the increasing awareness around opioid abuse we believe that if we were to present our solution to this audience we may be able to land a commercial pilot for this application, even prior to completing the drug-device combination process.

Our company has already spent 3+ years developing our "digital medication coach" platform. We recognize that in order to advance commercially, we will need to start generating a deeper body of clinical evidence. While we have started doing this in other applications, we are personally interested in contributing to helping to fight the opioid epidemic. The sense of validation and funding provided through this Challenge would help us study the application of our platform to addressing Substance Use Disorder. The information that we gather during this phase could be helpful to prepare us for additional collaboration with NIDA, including to potentially lay the groundwork for a Phase 1 SBIR feasibility study.