Chairman Lipps and Members of House Health Committee,

Pear Therapeutics (US), Inc. ("Pear") welcomes the opportunity to provide public comment on House Bill 688 (Lipps). Pear is a commercial-stage healthcare company pioneering a new class of software-based medicines, sometimes referred to as Prescription Digital Therapeutics ("PDTs"), which use software to treat diseases directly. Our vision is to advance healthcare through the widespread use of PDTs with an initial focus on supporting patients struggling with behavioral and mental health conditions. In particular, Pear's reSET® and reSET- O® are the first mobile applications to be authorized to treat disease by the FDA. These products specifically treat Substance Use Disorder ("SUD") and Opioid Use Disorder ("OUD"), respectively.

PDTs are prescribed by a licensed prescriber, either alone or in combination with drugs. Similar to pharmaceuticals, PDTs undergo rigorous clinical development via clinical trials designed to seek FDA authorization to safely and effectively treat disease. PDTs are evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. PDTs are only available via consultation with a licensed healthcare professional who then prescribes the digital therapeutic. PDTs are designed to expand access and convenience for patients, improve reach for clinicians, and lower cost for payors by reducing and/or augmenting human intervention, providing for more efficient care. PDTs can help mitigate many treatment barriers by offering accessible and consistent evidence-based treatments, available to patients 24/7.

To treat serious disease, it is imperative that the treatments patients use are recommended by a licensed provider or fit within an existing care plan. Whether it is a pill, electronic device, or mobile app - treatments for serious disease must adhere to a high standard as patients trust these products to improve their health outcomes. Provider recommendation is important, yet there are hundreds of mobile apps that purport to help treat disease - and we know that providers do not have the time to vet all of them. FDA authorization provides a smaller set of already vetted products for providers to review - products which have been shown to have a statistical correlation with positive health outcomes. Being prescription-only means that manufacturers cannot reach patients without the provider involved. In other words, the only way that manufacturers can support patient access is by educating providers and payers on the clinical value the product provides to patients. Products available directly to consumers can use direct-to-patient marketing techniques without undergoing the level of clinical rigor that PDTs are subject to. The incentives are therefore different for PDT manufacturers - where PDTs are judged by their clinical value to patients and other apps can be judged by their ability to market well to patients.

To date, PDTs have been officially authorized by the FDA in two ways: via the De Novo pathway and a 510(k) pathway which uses previously authorized PDTs as predicate devices. Fundamentally, a product is not FDA authorized until the FDA provides public Market Authorization for the product to be marketed with disease treatment claims. Products which purport to have authorization without an official letter from FDA are either in review phase or in pre-submission. These phases have chances of failure as the FDA can find clinical evidence insufficient for market authorization. For reference, the FDA has authorized 9 PDTs to date, with dozens more in the review or pre-submission phase. Currently authorized PDTs include treatments for addiction, insomnia, post traumatic stress disorder, gastrointestinal conditions, nightmares and pediatric ADHD. Products may purport to be authorized by FDA under emergency use authorization - which is only in effect during the COVID-19 public health emergency. These products have been brought to market without official FDA review of clinical efficacy.

As we all know the addiction epidemic continues to ravage our nation and the state of Ohio. Despite significant efforts by governments to expand access to treatment services, only 10% of patients with addiction conditions receive the necessary/required behavioral treatment.[1]For patients suffering from substance use disorder due to cocaine, cannabis and stimulants (such as methamphetamine) there are no FDA-approved medications that support patients in their recovery. There is a clear need for innovative treatments that are accessible and efficacious to support patients struggling with addiction.

To that end, the current legislation (HB 688) proposes creating a pilot program for both Medicaid and Ohio's Department of Mental Health and Addiction Services to purchase PDT codes and utilize them with their care population. The agencies would be able to evaluate the effectiveness of FDA authorized PDTs and make valuable recommendations towards incorporating them into the standard of care for substance use and opioid use disorders. The pilot would also allow for the department of Medicaid to make decisions around adding the drug class of PDTs to the Prescription Drug List for its members.

Ohio has been a leader in the utilization of PDTs in addiction. Ohio's Department of Mental Health and Addiction Services has concluded 2 SOR grant programs that impacted >750 people across Ohio and is currently working on a third program that will impact an additional 378 individuals. In the 2 completed programs, there were 18 provider organizations who treated patients with PDTs across the major urban centers of Columbus, Cincinnati, Dayton, and Akron - as well as several suburban and rural areas across the state. Further, over 80% of patients who were prescribed treatment downloaded the product and 70% of those patients completed their

[1] Substance Abuse and Mental Health Services Administration, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP 20-07-01-001, NSDUH Series H-55)" (2020), https://www.samhsa.gov/data/report/2019-nsduh-annual-national-report.

treatment. Of the patients who utilized the PDT, 80% engaged with the product in hours where providers were not available and 79% were retained in the therapeutic in the last month of treatment. These programs have been promising and create a reason to believe that PDTs can be a critical part of standard of care in Ohio. HB 688 provides an opportunity to deploy PDTs at scale across Ohio to impact a broader set of individuals and support providers as they determine how to include PDTs in their care plans.

At present, there are 2 products which have been authorized by the FDA for treatment of SUD and OUD: reSET® and reSET-O®, respectively. reSET® is intended to increase abstinence from a patient's substances of abuse during treatment and increase retention in the outpatient treatment program[2]. The therapeutic content of reSET® was validated in a pivotal, randomized clinical trial of 399 patients seeking treatment for SUD in ten nationwide community treatment programs. Patients were randomized to either treatment as usual (TAU) consistent with intensive outpatient treatment, or reduced TAU and reSET®. Patients treated with reSET® (n=206) had higher rates of abstinence in the final 4 weeks of treatment (40.3%) than those in TAU (17.6%; n=193; p=0.0004). There was also increased treatment retention at the end of the 12-week study in the reSET® group (76.2%) compared to TAU (63.2%; p=0.0042).[2] reSET® did not demonstrate a significant difference in unanticipated adverse events. reSET-O® is intended to increase retention of patients with OUD as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for adult patients currently under the supervision of a clinician[3]. The pivotal trial of reSET-O® randomized 170 adults with OUD to treatment as usual (TAU: buprenorphine maintenance therapy plus contingency management) or TAU plus the digital therapeutic for 12 weeks2 14. 82% of patients in the reSET-O® group (n=91) stayed in treatment vs. 68% of those in the TAU group (n=79), and this was significantly different (p=0.0224). The AEs observed were not adjudicated to be device related[3].

A real-world observational study evaluated reSET-O® in 3,144 individuals with OUD. 80% completed at least 8 of 67 possible therapeutic modules, 66% completed half of all modules, and 49% completed all modules. 74.2% of patients were retained through the last 4 weeks of treatment.[4] A recent claims data analysis of the first reSET-O®-treated patients (n=351; 82.6% Medicaid enrollees) showed a 33% reduction in the incidence of all-cause inpatient stays, emergency department visits, partial hospitalizations, and inpatient observation events, in the six months post-reSET-O® initiation vs. the six months prior to reSET-O® initiation (IRR:0.67;

[2] reSET Clinician directions for use. Pear Therapeutics, Inc. 2020.

[3] reSET-O Clinician directions for use. Pear Therapeutics, Inc. 2020.

[4] Yuri A. Maricich, Xiaorui Xiong, Robert Gerwien, Alice Kuo, Fulton Velez, Bruce Imbert, Keely Boyer, Hilary F. Luderer, Stephen Braun & Karren Williams (2021) Real-world evidence for a prescription digital therapeutic to treat opioid use disorder, Current Medical Research and Opinion, 37:2, 175-183, DOI: 10.1080/03007995.2020.1846023

p<0.05). [5]Concomitant decreases in clinician services were observed although there was an 8% increase in case management services. The reduction in hospital and medical services utilization, coupled with an increase in case management services (indicative of greater engagement with recovery services) is in line with previous independent observations. Together with the robust pivotal data, the RWE data support the engagement and clinically meaningful outcomes associated with PDTs in this difficult to treat population.

In summary, HB 688 is a bill which further expands Ohio's leadership role in both addiction treatment and in pioneering the use of FDA authorized prescription digital therapeutics to treat serious disease. This bill further supports providers by giving them more evidence-based and vetted tools to support patients and does so in a way that integrates these tools directly into care plans for patients. PDTs can help make care more accessible for people who struggle with addiction conditions and provide support in times when providers may not be available. This program builds upon the strong work done by Ohio's Department of Mental Health and Addiction Services to enable access to these products at a scale sufficient to impact a state-wide population. Pear supports this legislation and applauds the state of Ohio for its continued efforts in combating the addiction epidemic.

[5] Velez FF, Colman S, Kauffman L, Ruetsch C, Anastassopoulos K. Real-world reduction in healthcare resource utilization following treatment of opioid use disorder with reSET-O, a novel prescription digital therapeutic. Expert Rev Pharmacoecon Outcomes Res. 2021 Feb;21(1):69-76. doi: 10.1080/14737167.2021.1840357. Epub 2020 Nov 4. PMID: 33146558.