



STATE OF HAWAII
DEPARTMENT OF HEALTH
KA 'OIHANA OLAKINO
P. O. Box 3378
Honolulu, HI 96801-3378
doh.testimony@doh.hawaii.gov

LATE

**Testimony COMMENTING on SB0446
RELATING TO PRESCRIPTION DIGITAL THERAPEUTICS**

SENATOR JOY A. SAN BUENAVENTURA, CHAIR
SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES

Hearing Date: February 6, 2023

Room Number: 225

1 **Fiscal Implications:** Undetermined

2 **Department Testimony:** The Department of Health (DOH) offers comments on conducting a
3 study on the feasibility of doing a pilot program to integrate digital therapeutics approved by the
4 federal Food and Drug Administration.

5 The Department does not do clinical trials and never has it done so in the past. Therefore,
6 conducting such a feasibility study should reside with another department with sufficient
7 experience.

8 The pilot seems to involve users engaging with digital therapeutics through mobile apps that
9 either offer guidance or techniques to work with a drug regimen to address complex conditions
10 like cancer treatment, or use motivational means to promote changes in behavior, to delay or
11 prevent chronic disease. While innovative, the field faces uncertainties and challenges such as
12 patient learning curves and healthcare provider adoption.

13 Thank you for the opportunity to testify.

14 **Offered Amendments:** Please strike the “department of health” as referenced
15 throughout this measure.



SB446 Digital IOP: DOH to study the feasibility of a pilot program to integrate prescription digital therapeutic products approved by the FDA in outpatient treatment programs for persons with substance use disorder and persons with opioid use disorder in the State.

COMMITTEE ON HEALTH AND HUMAN SERVICES

Senator Joy A. San Buenaventura, Chair

Senator Henry J.C. Aquino, Vice Chair

Monday, Feb 6, 2023: 1:00 Room 225

HAWAII SUBSTANCE ABUSE COALITION (HSAC) Supports SB446

Aloha Chair, Vice Chair and Distinguished Committee Members My name is Alan Johnson. I am the current chair of the Hawaii Substance Abuse Coalition (HSAC), a statewide organization of substance use disorder and co-occurring mental health disorder treatment as well as prevention agencies and recovery services.

As a result of the pandemic with increasing behavioral health needs and that the use of technology has improved, the healthcare systems are primed for the adoption of digital health, making it an ideal time for implementing new and convenient digital care options.

WHAT IS PDT?

Prescription digital therapeutics (PDTs) are **a type of treatment that use mobile software applications to help prevent, manage, or treat medical and behavioral health conditions**. PDTs delivers evidence-based therapeutic interventions and behavioral therapies via software on a tablet or smartphone.

- **Complements the existing treatment** of a substance use disorder or opioid use disorder.
- **PDTs can continue on after formal treatment.**

Some of the Prescription Digital Therapeutics (PDTs) are approved by the FDA for substance use disorders, especially for various applications that lead patients with stimulant use disorders **to track their substance use, cravings, and triggers**. Besides having a role in treatment, PDTs can also help manage a condition and improve a health function.

At this time, PDTs are not covered by insurance carriers but that may change soon.

PRESCRIPTION

PDTs are intended to **provide cognitive behavioral therapy, as an adjunct to a clinical management treatment, for patients 18 years of age and older, who are currently enrolled in outpatient treatment under the supervision of a clinician.**

- FDA approved PDTs are generally a **12-week (90 day) prescription-only** treatment for patients.

- **Different software for opioid treatment vs substance use (Meth, alcohol, marijuana)**

NOT REPLACEMENT FOR TREATMENT

Not intended to be used as a stand-alone therapy for substance use disorder (SUD). PDT does not replace care by a licensed medical practitioner and is not intended to reduce the amount of face-to-face clinician time.

- PDT do not represent a substitution for a patient's medication.
- **Patients often have complex problems, which require formal treatment.** Patients with substance use disorder experience mental health disease and co-morbid medical problems at higher rates than the general population. Patients with substance use disorder also have higher baseline rates of suicidal ideation, and suicide attempts, and suicide completion. Clinicians should engage in their normal care practices to monitor patients for medical problems and mental health disorders, including risk for harming others and/or themselves.

OUTCOMES – SHORT TERM – YES, BUT NO DATA ON LONG TERM EFFECT YET

The long-term benefit of treatment with PDT on abstinence has not been evaluated in studies lasting beyond 12 weeks (90 days) in the SUD population. The ability of PDT to prevent potential relapse after treatment discontinuation has not been studied.

- The findings reported in two recent research papers published by *Advances in Therapy* related to use of PDTs for substance use disorder and opioid use disorder **provide real-world evidence of clinical and cost effectiveness, strengthening the evidence base for these technologies and suggesting a role for these technologies** in the efforts to help patients recover from these often-chronic and deadly conditions.¹
- PDT trials show significant **benefits** on key clinical outcomes relevant to the specific indication, such as **retention in treatment or abstinence** for SUD treatments.
- **The long-term benefit of PDT treatment on abstinence has not been evaluated** in studies lasting beyond 12 weeks (90 days) in the SUD population. The ability of PDT to prevent potential relapse after treatment discontinuation has not been studied.
- The effectiveness of PDT has not been demonstrated in patients currently reporting opioids as their primary substance of abuse.

SUMMARY

The National Institutes of Health (NIH) calls for a goal of digitizing behavioral therapies to allow greater access, standardize treatment protocols, reduce barriers to care, and increase health equity.

¹ Brezing CA, Brixner DI. The Rise of Prescription Digital Therapeutics in Behavioral Health. *Adv Ther.* 2022 Dec;39(12):5301-5306. doi: 10.1007/s12325-022-02320-0. Epub 2022 Oct 15. PMID: 36242730; PMCID: PMC9569000. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9569000/>

The prevalence of substance use disorders (SUDs) and mental health burdens has increased, fueled by the COVID-19 pandemic, Opioid and psychostimulant over use as well as related complex health conditions have resulted in devastating costs in loss of human life and/or functioning as well as are also accompanied by significant increases in healthcare costs related to utilization of acute care services.

Despite these alarming changes, **the need for high-quality, evidence-based treatment for SUD has outpaced the supply of care.** Factors contributing to this significant treatment gap include:

- 1. stigma,*
- 2. limited access to treatment due to segregation of SUD programs from other medical and surgical care settings,*
- 3. a shortage of clinicians trained in SUD management,*
- 4. high cost, limited coverage of SUD treatment services by insurance and third-party payers, and*
- 5. poor retention of patients in treatment*

The majority of the estimated 40.3 million people aged 12 years or older who met criteria for SUD in 2020 did not receive substance abuse or mental health services treatment.

Technology has the potential to address the SUD treatment gap.

These new therapies would be evidence-based interventions prescribed and initiated by treating providers and delivered on mobile devices.

We appreciate the opportunity to provide testimony and are available for questions.



Medicine and treatment incorporated with digital technologies of all kinds may improve patient health, reduce clinician workload, lower costs, reduce health disparities, and expand access to needed treatments.

February 5, 2023

Senate Health Chairwoman Joy A. San Buenaventura
Hawaii State Senator, District 2
Hawaii State Capitol, Room 213
Honolulu, HI 96813

Dear Chairwoman Buenaventura:

My name is Mark Mendoza, and I am the Director of State Government Affairs for Pear Therapeutics. Pear Therapeutics is a leader in developing and commercializing software-based medicines called prescription digital therapeutics. We aim to redefine care through the widespread use of clinically validated software-based therapeutics to provide better outcomes for patients, smarter engagement and tracking tools for clinicians, and cost-effective solutions.

I am writing in support of Senate Bill 446, which would require the Department of Health to study how a pilot program for FDA authorized prescription digital therapeutics (PDTs) for substance use disorder (SUD) and opioid use disorder (OUD) could be created. FDA authorized PDTs are software-based disease treatments intended to prevent or treat a disease that are regulated by the U.S. Food and Drug Administration. It is important to note that PDTs are adjunctive/complementary tools that support treatment as usual, and are not designed to supplant the provider-patient relationship.

PDTs offer a number of benefits that are particularly helpful for patients who need SUD or OUD treatment: PDTs are available in both English and Spanish; they offer “on demand” access that can be utilized day or night; they overcome transportation barriers for those who need treatment; they demonstrate positive healthcare outcomes; and they help remove stigma from treatment. These features are essential to making our behavioral healthcare system more equitable, accessible, and inclusive.

We applaud the State of Hawaii’s current behavioral health initiatives to tackle SUD and OUD, and believe a pilot program for FDA authorized PDTs would build on the state’s current successes and further broaden access to services for more Hawaii patients. We look forward to continuing the conversation and discussing a pathway for patients to access these important healthcare tools.

Thank you so much for your consideration of SB 446 and for always championing healthcare solutions that break down equity and accessibility barriers present in our healthcare system.

If you have any additional questions about FDA authorized PDTs, please contact me at 310-984-0746 or via email: mark.mendoza@peartherapeutics.com

Respectfully,
Mark Mendoza
Director, State Government Affairs
Pear Therapeutics

SB-446

Submitted on: 2/6/2023 10:15:31 AM
Testimony for HHS on 2/6/2023 1:00:00 PM



Submitted By	Organization	Testifier Position	Testify
Jill Puckett	Testifying for Otsuka America	Support	Written Testimony Only

Comments:

Thank you, Madam Chair for hearing this bill and Senator Keohokalole for introducing innovate legislation.

It is crucial that we stay ahead of the curve as advances are made in brain science and innovative methods of delilvering healthcare, whether through telehealth, or other applications such as digital therapies that are developed to augment treatment.

This study will do just that and we strongly encourage support. Because opioid use disorder and substance use disoders often overlay underlying mental health conditions we encourage this study to also include digital therapeutics for mental health treatment. In that we are asking that you please consider behavioral health as a whole in this bill.

We appreciate your consideration.

Mahalo,

Jill Puckett