National Alliance

New Prescription Digital Therapeutics (PDTs) in Behavioral Healthcare Delivery

September 2, 2021

National Alliance
of Healthcare Purchaser Coalitions
Driving Health, Equity and Value

Speakers

MODERATOR
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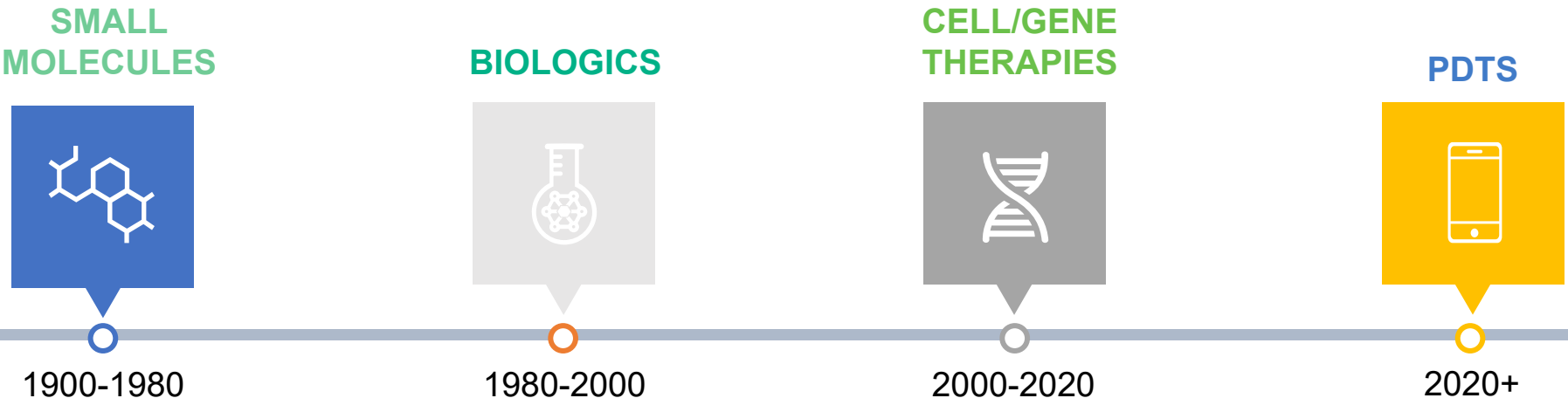
Prescription Digital Therapeutics (PDTs):

A new therapeutic class that is being integrated into standard of care



PDTs = Software to treat human disease

- Safety and efficacy tested in randomized clinical trials[1,2]
- Product label authorized by FDA[3,4,5]
- Pricing and reimbursement pathways designed to reflect health economic value[6]
- IP, quality, regulatory, and compliance barriers to entry

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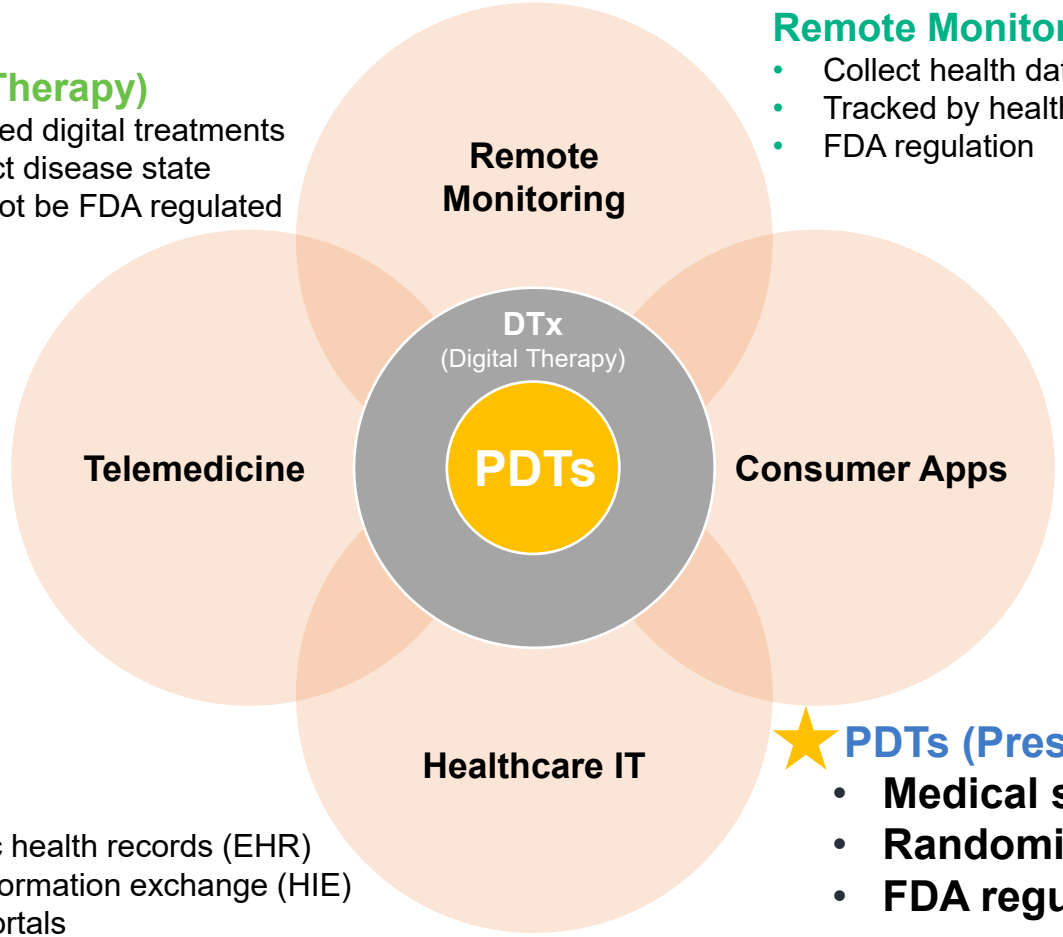
PEAR THERAPEUTICS

Prescription Digital Therapeutics (PDTs) are a sub-category within digital health defined by clinical efficacy, FDA market authorization, and reimbursement

DTx (Digital Therapy)
- Evidence-based digital treatments
- Directly impact disease state
- May or may not be FDA regulated

Remote Monitoring
- Collect health data
- Tracked by healthcare professionals
- FDA regulation



Telemedicine
- Video diagnostic consultation
- Remote health services
- Support long-distance healthcare

Consumer Apps
- Promote wellness
- No FDA regulation
- Free / at patient's cost

Health IT
- Electronic health records (EHR)
- Health information exchange (HIE)
- Patient portals

★ PDTs (Prescription Digital Therapeutics)*
- **Medical software to treat disease**
- **Randomized clinical trials**
- **FDA regulation and authorization**

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PEAR THERAPEUTICS

PDTs have effectiveness and safety data

in the label for market authorization by the FDA

	Prescription Digital Therapeutics (PDTs)	Traditional Wellness Apps*
Deliver disease-specific, evidence-based treatment via mobile devices	✓	No
FDA-regulated software as a medical device (SaMD)	✓	No
Evaluated and clinically-validated for safety and effectiveness	✓	No
Receive FDA-marketing authorization	✓	No
Intended to be used as adjunct to standard outpatient treatment	✓	No
Label describes indications and intended use, supporting appropriate clinical use	✓	No

*defined as a health and wellness app that is not regulated

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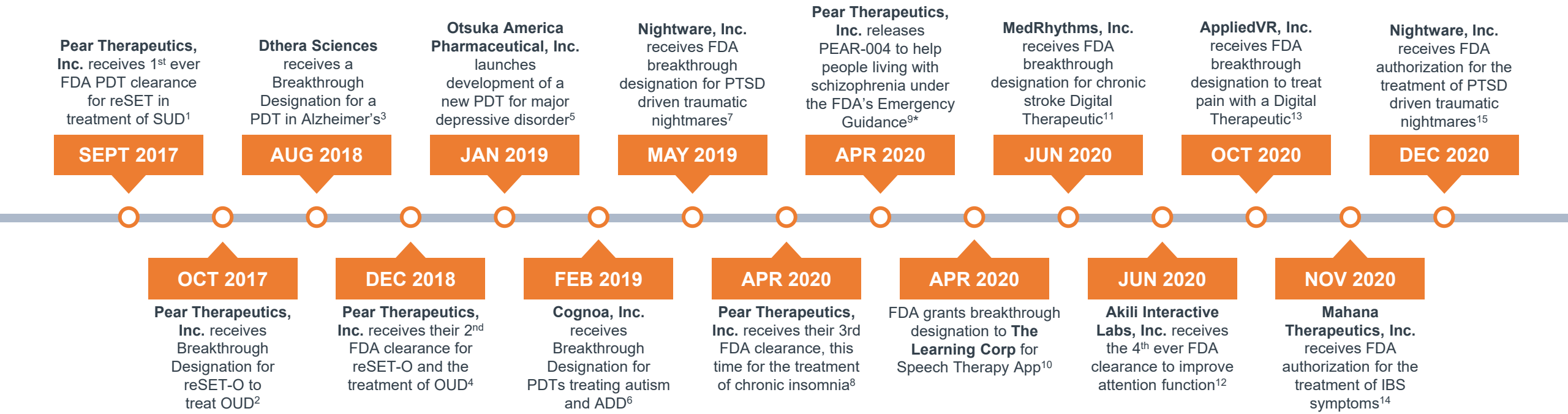
PEAR THERAPEUTICS

The digital therapeutic industry has exploded in the last several years 6 FDA Authorized Prescription Digital Therapeutics and 8 FDA Breakthrough Designations Granted



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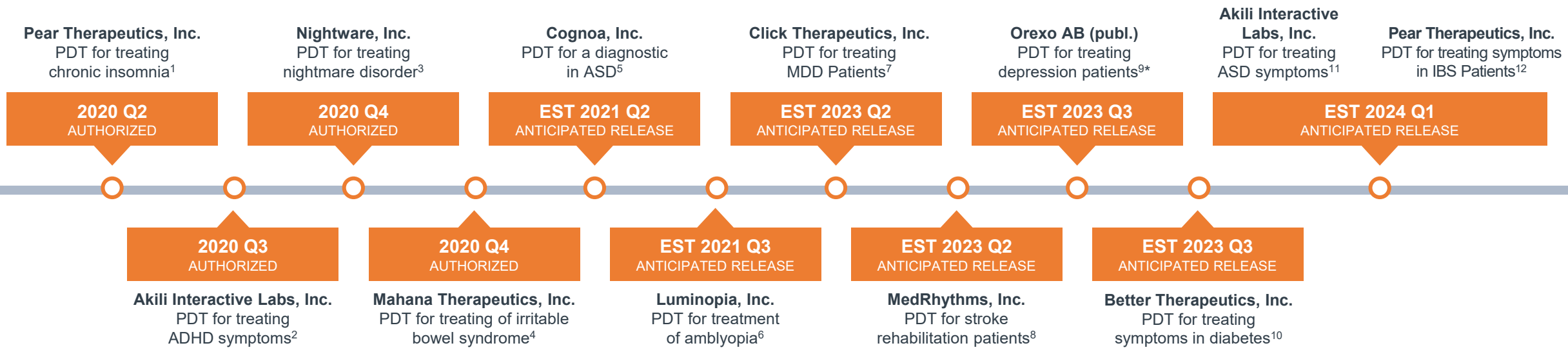
PEAR THERAPEUTICS

An additional 8 PDTs may be authorized by early 2024

with at least 13 other companies potentially developing product candidates
in preparation to submit to FDA for review



Companies developing candidates for potential FDA submission:

1. AppliedVR, Inc.
2. Happify Health
3. GAIA AG*
4. Big Health
5. Biofourmis, Inc.
6. Propeller Health
7. Apricity Health
8. Yao – The Bard, LLC
9. metaMe Health, Inc.
10. Bold Health Limited
11. Headspace, Inc.
12. Cognito Therapeutics, Inc.
13. Constant Therapy Health

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PEAR THERAPEUTICS

PDTs follow the traditional therapeutics model

Pharmaceutical with effectiveness claims to treat disease

Software with effectiveness claims to treat disease

Prescription
Patient diagnosed by physician and product is prescribed

Payment
Reimbursed via pharmacy or medical benefit

Fulfillment
Dispensed via a specialty pharmacy/Patient Services Center

Use
Patient uses product according to directions for use

Follow-up
Patient follows up with clinician

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PEAR THERAPEUTICS

About The Hartford

- The Hartford is a leader in property and casualty insurance, group benefits and mutual funds
- With more than 200 years of expertise, The Hartford is widely recognized for its service excellence, sustainability practices, trust and integrity
- Employees: 18,500 with total of 35,000 total members
- Headquarters: Hartford, Conn
- As part of our Stigma-Free program we are educating, advocating, and activating programs that help dispel stigma associated with mental health and addiction in the workplace
- In September 2020, The Hartford became the first employer to add Prescription Digital Therapeutics (PDT) for Substance Use Disorder (SUD) and Opioid Use Disorder (OUD) to a prescription drug plan

We saw that PDTs could be a potential solution
To support SUD and OUD treatment

PDTS Demonstrate Their Value During Covid-19

To reduce potential exposure to COVID-19, the FDA issued temporary authorization of digital health devices for treating psychiatric disorders

The Kennedy Forum, Shatterproof, Pear Therapeutics, And Others Created The Recovery Access Coalition in June, 2020

Aimed at eliminating access barriers for substance use disorder-focused FDA authorized digital therapeutics

"Addiction is a disease that **thrives in isolation**. Because of social distancing, COVID-19 has already put **millions who live in recovery** from substance use disorders, including opioid use disorder, at extreme risk. The inability to regularly access traditional forms of care will only compound the problem—thus an **urgent need for more remote treatment options."**

Patrick J. Kennedy, founder of the Kennedy Forum

Vetted by internal and external SMEs

All supported adding PDT for SUD / OUD to our formulary

- Recognition of significant gaps in treatment today
- Proven to improve treatment adherence
- Supports overall awareness of this new form of treatment
- Interested in our learnings and outcomes

Role	SME
Internal Clinical	• Medical Director • Nurse specializing in behavioral health
External Clinical	• Shatterproof Head of Policy and Quality • OptumRx Chief Pharmacy Officer • ConsumerMedical Clinical team • Health Transformation Alliance Pharmacist
Internal Digital	• Team member focused on digital solutions

SME Feedback

"Delighted" that The Hartford is considering covering

Tools provide short-term support during a vulnerable period

Expectation that federal payers will cover since it is FDA approved

Will only be successful if prescribers know to use it

Not a silver bullet, but another tool to support individuals facing addiction

It can only do good, no harm

The Business Case

"Low Cost, No Down-side, Opportunity to Be a Leading Voice in New Treatment"

Why	Description	Success Measures
Low cost Supports abstinence and treatment adherence	Minimal downsides: • No side effects • Low cost	10% of eligible patients being treated to use PDT over 12 months Decreased relapses Reduced average patient spend
Be the catalyst to test, evolve, and promote this new form of treatment	PBMs are slow to evaluate new, non-traditional Rx Plan sponsor advocates are needed Will provide additional utilization data to influence the evolution of this treatment space	Share our experience, including the results (good or bad)
Continue to lead in the nation's conversation about the opioid crisis	Support our members and their families by continuing to discuss SUD and OUD and offer meaningful support	Share our experience with the Benefits community and the business community at large

Can our PBM Administer?

The process was easier than expected.

- Added Rx codes to formulary (preferred brand)
  - 11-digit NCPDP Product Identifiers
- Trained PBM call center (and other partners)

Questions for Speakers and Medical Directors

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Upcoming Webinars and Meetings

Mental Health Index: August results
September 17 | noon-12:30 p.m.

Annual Forum
November 8-10 | See website for details

All times are Eastern Time

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- Registration is open
- Early Bird Rates:
  - Non-Member - $650.00
  - Member Rate - $450.00
- Hotel Discount Rate - $229/per night until October 15, 2021

COVID-19 ANNOUNCEMENT: Based on the current environment and for the health and safety of all our attendees, we will require all attendees to be vaccinated