Glassmeyer/McNamee Center for
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Tuck at Dartmouth

DIGITAL THERAPEUTICS

THE FUTURE OF DIGITAL HEALTH TOOLS AND VIRTUAL CARE

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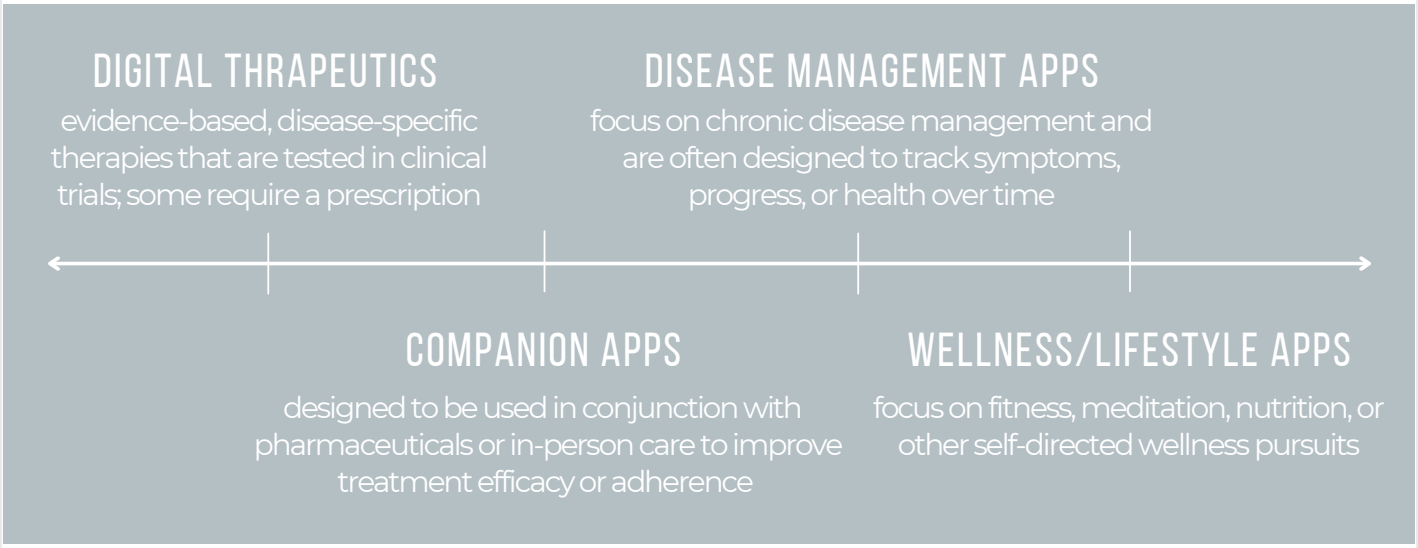
EXECUTIVE SUMMARY

Digital therapeutics (DTx) are an increasingly attractive field from a patient, provider, and investor perspective. Utilization of virtual care and digital health tools has surged in 2020 and 2021 with COVID-19 limiting access to in-person services. As providers have grown more comfortable with digital modalities, and patients have realized an increased need for self-service or on-demand digital health applications, there is a growing market for digital health interventions. Digital therapeutics are poised to gain traction over the coming years, but face hurdles to adoption related to regulation and reimbursement. Furthermore, these interventions face critical questions in terms of valuation, monetization, and distribution. Furthermore, DTx are still finding their sweet spot in terms of product market fit with regards to which disease areas are best suited to DTx and can provide maximum value creation by way of cost savings. DTx companies must also consider what business models and pricing schemes are most effective.

BACKGROUND

Digital therapeutics (DTx) are evidence-based, software-driven interventions designed to treat a disease by improving a particular clinical outcome [1]. Digital therapeutics sit at one end of the broader digital health spectrum:



[1] DTx Alliance

Omada, a leading digital health company, actually catalyzed the use of the term "digital therapeutic" following CDC approval of their fully digital solution targeting weight loss and blood sugar control for the diabetic population. This is important given that all prior approved diabetes prevention programs had been tested in brick-and-mortar settings [2]. However, as more digital tools have been developed, investors, providers, and patients seek clarity on how to categorize a diverse mix of products, necessitating a narrower definition of DTx.

DTx is best defined to mean evidence-based software-driven interventions that have been clinically validated and improve a specific outcome. Even Omada now refers to itself as a "digital care" provider, since it focuses on improving health outcomes for a broader patient population by leveraging a combination of devices and content. "A lot of products call themselves digital therapeutics," says Ian Chiang of Flare Capital Partners. "I tend to stick to more of a narrow category of companies like Pear – prescription based, with outcomes."

A specific subset of DTx, **prescription DTx (PDTs) are digital therapeutic interventions which have been clinically validated via randomized controlled trials, are approved by governing bodies like the FDA, and require a prescription from a healthcare provider for access.** Exapmles include Pear Therapeutic's reSET/reSET-O for SUD/OUD, Pear's Somryst for insomnia, Akili's EndeavorRx for ADHD, or Amalgam's iSage Rx for diabetes. The clinical trial design and approval pathways for more traditional pharmaceuticals are well defined, but regulators and review boards are still navigating best practices for evaluating DTx. Like traditional medicines, PDTs are tested in clinical trials for safety and efficacy and used under the supervision of a clinician, but **unlike traditional drugs they are designed to collect data in real time that can be used for population health management** [3]. Collecting real world evidence on an individual and population level allows PDTs to offer unique insight into progress and outcomes for diseases which have previously required in-person interventions.

[2] https://www.statnews.com/2019/10/29/prescription-digital-therapeutics-realizing-promise/#:~:text=Prescription%20digital%20therapeutics%2C%20or%20PDTs,deliver%20treatment%20anytime%20and%20anywhere.&text=They%20are%20designed%20so%20patients,and%20where%20they%20need%20it
[3] https://apnews.com/press-release/business-wire/technology-business-medical-research-corporate-news-smartphones-c28ce3911b9d42ef88d3e270fb1db439

Various industry thought leaders have weighed in regarding the recipe for success when it comes to developing a digital therapeutic. According to McKinsey, to enjoy widespread utilization, DTx developers should keep three principles in mind [4]:

1 MEANINGFUL OUTCOMES
reductions in insurance premiums, gamification and rewards, positive clinical outcomes

2 HUMAN CENTERED DESIGN
end-to-end experience, digital integration, comparable consumer digital products

3 WORKFLOW INTEGRATION
can be incorporated into a single clinical interface for providers, removes inefficiencies and automates workflow, enables provider collaboration

COVID-19 & DIGITAL THERAPEUTIC READINESS

Digital health usage surged amidst the COVID-19 pandemic, driven by an increased need for on-demand and virtual options for care. In addition to patient-driven demand, providers have grown increasingly comfortable delivering care via telemedicine [5]. Bronwyn Spira, CEO of digital care platform Force Therapeutics, notes that utilization increased by 141% since the onset of the pandemic, with both patients and providers seeking at-home solutions. Many patients were forced to postpone orthopedic surgeries for musculoskeletal conditions, but providers could utilize the Force platform to equip patients with at-home exercises. “We’re seeing a broader acceptance of digital care as simply 'care',” states Bronwyn, driving home the notion that **patients and providers are confident in the ability of digital tools to provide meaningful benefits and potentially replace in-person care at times.** This notion is reinforced by Selemon Asfaw, CFO of OptumHealth, who remarks that 70-75% of care was delivered in-person prior the pandemic, with those numbers now flipped. Further, Ian Chiang of Flare Capital Partners reiterates that “at the height of COVID, maybe 80-90% of encounters with doctors were digital.” He continues that, even if this stabilizes at a lower rate, **digital is likely still the future given preferences of millennial [and Gen Z] consumers**.

[4] https://www.businessinsider.com/digital-therapeutics-report
[5] https://medcitynews.com/2020/12/covid-19-is-bringing-digital-therapeutics-to-the-forefront-of-medicine/?rf=1

Health care is experiencing a digitally driven revolution. Widespread telemedicine usage is laying the foundation for more increased adoption of targeted, software-enabled interventions. Even as more of the population receives the COVID-19 vaccination, it is unlikely that we will see a drop in utilization of digital health tools given the convenience of digitally delivered care. **With a foundational trust in virtual care having been established through use of virtual doctor's visits, patients and providers will be increasingly receptive to a broader care ecosystem which includes digital medicine and more targeted technology-driven interventions, rather than simply the modality of videoconferencing applied to health care.**

Digital therapeutics are an example of such innovative, tech-driven care. As opposed to simply utilizing pre-existing video software in a healthcare context, these are specifically designed to target particular diseases and use technology to improve health outcomes. Digital therapeutics present a revolutionary opportunity to reframe the way we interact with traditional medications and prescriptions. Conversations with Chris Bergstrom, President of AmalgamRx (a DTx platform company) provide insight into the circumstances which have facilitated proliferation of these interventions. **"Telemedicine needs to be a precursor [to DTx]," Chris notes, "You have increased comfort with virtual care, and people start to consider what else is possible.** For example, a doctor might want to be able to provide virtual follow up tools and digital treatment options." Physicians will increasingly seek out FDA-approved and rigorously tested interventions that span beyond the duration of the telemedicine encounter, enabling patients to continue to engage in healthy behaviors via digital means. Chris' suggestion that **telemedicine proliferation was a required precursor to digital therapeutics aligns with Ian's suggestion that we will see an ecosystem of digital health offerings unfold**. This notion of sequential digital health proliferation, with telemedicine blossoming, followed by more disease-specific tools and interventions, aligns with the spike in usage over the past year. The increase in FDA approvals of DTx since 2020 and 2021 [6] is a signal of confidence in the DTx space. Investment priorities also align with this line of thought, signaling DTx as a high growth area. Resources are flowing into this sector and the key end customers – patients and providers – are demanding this technology.

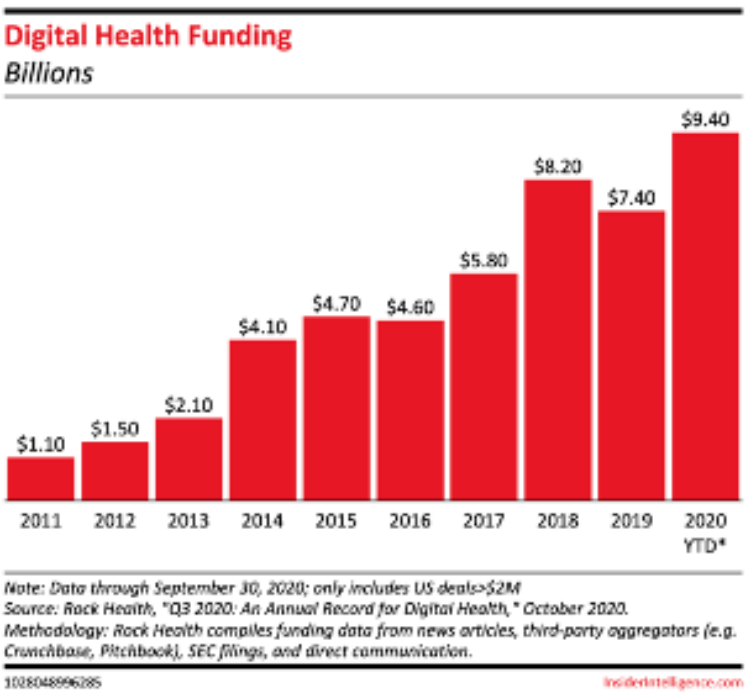
[6] https://www.forbes.com/sites/marenbannon/2020/12/23/8-digital-health-predictions-for-2021/?sh=3b4f53924976

This proliferation of digital therapeutic technology is happening as telemedicine is increasingly commoditized. **Virtually delivered care is more of a capability rather than a business model, and one which can be easily replicated. On the contrary, digital therapeutics offer rigorously tested and proven value propositions, focused on targeted clinical outcomes.** Telemedicine enables better care delivery and accessibility, but it does not deliver an intervention itself. **DTx therefore provide a specific, never-before-realized value proposition – a software-driven clinical tool that can both facilitate and deliver an evidence-based intervention**. Telemedicine has paved the way for DTx, and DTx presents a unique value add that telemedicine lacks. The ability to collect, aggregate, and facilitate analysis of health care data will enable DTx technologies to better demonstrate ROI and long-term health improvements compared to telemedicine.

MARKET OUTLOOK

The DTx space is expected to be a **$56 billion global market by 2025**, based on forecasts in 2020. This is up from 2019 forecasts, which placed the market size closer to $9 billion [4]. The increase is due largely to demand for mental health care amidst pandemic-fueled mental health conditions, as well as the rise in prevalence of chronic conditions like diabetes, obesity, and high blood pressure that will cost health systems billions of dollars if not addressed.

Furthermore, 2020 saw increased competition in virtual care modalities, as well as an uptick in M&A activity in digital health (ex. Teladoc-Livongo merger) [4]. According to Forbes' 8 Digital Health Predictions For 2021, PDTs will become widespread given that 2020 saw the FDA approve treatments covering substance abuse, ADHD and IBS [6]. We've also seen a rise in capital directed towards the digital health space, indicating investor activity and market optimism moving forward.



[4] https://www.businessinsider.com/digital-therapeutics-report
[6] https://www.forbes.com/sites/marenbannon/2020/12/23/8-digital-health-predictions-for-2021/?sh=3b4f53924976

OPPORTUNITIES / BENEFITS FOR STAKEHOLDERS

Digital therapeutics, particularly PDTs, empower patients, enable more continuous care while easing provider burden, and create value for payers in a way which aligns with value-based care reimbursement schemes.

PATIENTS AND CAREGIVERS

Patients & caregivers can enjoy increased access to reliable, high-quality evidence-backed interventions, as well as personalized on-demand care [7]. I would argue that health care has traditionally lagged behind other consumer-oriented industries in terms of prioritizing customer satisfaction, with abysmal NPS scores (cite average) and egregious waiting times for in-person care, whether in line at the pharmacy, at a hospital, or to see a specialist. The notion of care at the push of a button is immensely appealing. Consumers are also accustomed to having access to their historical data and usage metrics for services like utilities, online shopping, or cell phone plans. Health care data has typically been hidden behind the curtain of insurance claims, billing codes, and medical jargon, further disaggregated and spread out across episodic encounters spanning multiple geographies. Younger generations are accustomed to accessing their information and data in a user-friendly manner and will demand this with health care as well. Digital health tools, and specifically **DTx, are well positioned to meet these needs surrounding data availability, transparency, and optimization**.

PROVIDERS & HEALTH SYSTEMS

Providers & health systems can enjoy increased access to novel treatment options and the ability to prescribe DTx as a monotherapy or in conjunction with other in-person treatment to optimize care and outcomes. Further, DTx enables data-driven care management and clinical decision making [7]. This last claim is where I foresee the biggest shift in health care – **from reactive to proactive decision making, driven by AI mining an increasingly diverse set of data collected from DTx utilization.** Clinical decision support software, which is already widely utilized, can be trained using DTx outcomes to aid providers in designing the most effective treatment regimen according to a particular patient's profile, comorbidities, lifestyle, etc. Providers and health systems will also benefit if DTx are able to plumb data directly back into central EHR/EMR systems, with this interoperability facilitating a **wider-lens view for each patient and allowing providers to understand how the data coming in from a digital therapeutic intervention could interact with or impact other elements of a patient's medical record, which will be evolving in real time.**

[7] https://www.forbes.com/sites/sethjoseph/2020/08/26/covid-19-is-fueling-a-digital-therapeutics-revolution-but-the-road-to-maturity-travels-through-the-four-healthcare-ps/?sh=5d8e2f5431e6

PAYERS

Payers (i.e. private health insurers like United, Anthem, Aetna, Cigna, Humana, etc., as well as Medicare) will benefit from improved clinical and economic outcomes at patient and population levels, which drive cost savings and warrant reimbursement of these therapies. Furthermore, DTx facilitate expanded delivery of effective and engaging treatments without increasing clinical workforce and can reduce overall cost of care by reducing downstream hospitalizations and expenses [7]. Cost savings is key when it comes to justifying reimbursement of a therapy, and DTx can show how health outcomes are improving over time. **DTx facilitate longitudinal data collection, while also demonstrating how patients are tracking against particular clinical outcomes.** This is important because the health care system is moving away from 'fee for service' reimbursement (paying doctors/health systems back for each visit, surgery, etc) and towards 'value-based care' (paying when patients show long-term health improvements, given that this would translate into avoided costs later on). Therefore, there is opportunity to demonstrate value creation at both the individual and population level when patients show improvement over time by using DTx. **Furthermore, payers will be incentivized to cater to employers, who are motivated to offer convenient, accessible, and effective DTx to patients via employer-sponsored health plans in order to improve workforce retention and wellbeing.**

Industry leaders reiterate the value of digitally driven care. Bronwyn Spira of Force Therapeutics recalls: "My patients could really benefit from [digital care], so started using the clinic as proof of concept." She has been able to **demonstrate value by "taking cost and variation in care out of the system**...[and] monitoring remotely." Chris Bergstrom of AmalgamRx speaks more specifically to DTx with his belief that "software can be used to improve health outcomes, which has been proven in both trials and real-world outcomes." Such opinions reinforce the ability of DTx to improve accessibility and quality of care for patients, ease burden and facilitate ongoing remote treatment for providers, and deliver insights regarding health outcomes and population health data for providers.

[7] https://www.forbes.com/sites/sethjoseph/2020/08/26/covid-19-is-fueling-a-digital-therapeutics-revolution-but-the-road-to-maturity-travels-through-the-four-healthcare-ps/?sh=5d8e2f5431e6

CHALLENGES

Despite the opportunities presented by DTx, there are several key hurdles which must be acknowledged.

REGULATION

Gaining regulatory approval is key when it comes to demonstrating safety and efficacy. Professor Lindsey Leininger of the Tuck School of Business at Dartmouth remarked that it is critical to "focus on the regulatory pathway, as this is the ticket to success." Chris Bergstrom of AmalgamRx offers a refreshing take on regulatory challenges, noting that "if you're familiar with the process of running and designing clinical trials...it's not the biggest challenge. I'd say it's 80% understanding the process, 15% having a well-defined strategy [to gain approval], and 5% unknowns. That said, if you don't have experience or you're a new entrant, it can be tough." AmalgamRx has obtained FDA clearances for various therapies, either as part of their own portfolio or for partners, and Chris remarks that approval comes down to demonstrating a meaningful clinical outcome and being able to scale.

I would argue that, for many DTx, **demonstrating marked clinical impact can be challenging when particular best practices for clinical trial design have not been well-defined or broadly instituted**. As opposed to taking a placebo drug or utilizing a control group that receives the current standard of care, designing a 'placebo app' is more difficult to disguise, and a current standard of care which relies upon in-person or more traditional pharmaceutical intervention may be so drastically different from a fully software-driven intervention that **it may be difficult to shield clinical trials from multiple confounding variables that could damage result validity.** It is impossible to fully control for individuals' familiarity with digital health tools. Their inherent levels of trust and pre-emptive expectations of success or failure of a wholly digital tool may impact clinical outcomes for the intervention group. Due to these factors, **DTx companies will have to carefully design clinical trials to tease out the true incremental impact of a software-driven therapy compared to in-person care.**

REIMBURSEMENT

Unlike with traditional pharmaceuticals, where the price of drugs is linked to an industry-wide understanding of the expensive R&D that justifies a higher price point, **digital therapeutics have a much more variable R&D process**. "The reason that drugs can charge a certain price is because we assume it takes time and money to develop a drug," Ian Chiang of Flare Capital Partners states. "A lot of investors hope that once you get FDA approval, you can raise prices and payers will reimburse everything. However, payers [might think] that R&D for an app is significantly less than spending years developing a molecular or biological therapy. They'll wonder if this warrants the price."

I believe that this challenge of justifying pricing and reimbursement will require strategic framing. **Rather than benchmarking prices against traditional drugs, DTx companies will need reframe pricing expectations in alignment with software R&D costs.** DTx players will need to provide reference points and detailed breakdowns of R&D cost structures, referencing other digital health development processes and potentially software development costs across industries. I believe that for payers to consistently reimburse these software-driven technologies, **DTx companies and thought leaders will need to either advocate for reimbursement by presenting transparent and detailed R&D cost justification that warrants higher prices, or seek out lower price points and communicate the potential cost savings for payers at scale.**

The challenges of reimbursement are further exacerbated by the **bespoke nature of health care payers and reimbursement policies.** "The saying in the industry is 'once you've seen one payer, you've seen one'" jokes Chris Bergstrom of AmalgamRx, referencing the lack of a standardized approach to reimbursing digital health therapies. The lack of a well-defined coding or billing system for digital health interventions makes clear guidelines for reimbursement hard to come by, placing the onus on DTx companies to communicate the value and pricing justification for their therapy to each individual insurance provider / payer. Bergstrom mentions that it would be useful to have a central repository by which digital health tools can be curated and managed, just as they have for traditional medication formularies. I believe that the **development of an industry-wide and cross-payer digital health compendium will be necessary to facilitate accelerated adoption and distribution of payer-backed digital therapeutics.**

In order to justify reimbursement, **payers need to see that interventions are able to reduce costs for the insurer by healing patients or decreasing utilization of health care resources.** "FDA approval speaks to safety and efficacy, but not necessarily cost-effectiveness," notes Ian Chiang of Flare Capital. Even if DTx are able to obtain approval, they will still need to demonstrate that they can create value via cost savings. By demonstrating value in terms of reduced costs, this can help with the issue of reimbursement. Luckily, a key value proposition of DTx is the ability to collect data in real time. "Real world evidence should show value…[and then] these savings can be shared with the payer. We're missing systems to audit and track this," notes Chris Bergstrom, adding that "Amalgam is embedded in EMRs to better track digital therapy outcomes. If you have a fact-based record… you can demonstrate added value of the therapy and negotiate how to carve up value [with payers]." I would argue that, as more DTx come to market, they will need to continually report real world evidence trends and long-term clinical outcome improvements to payers to justify ongoing reimbursement. Furthermore, there are opportunities for 'conditional approvals' by which DTx can be approved with limited clinical trial results but then are required to report real world evidence outcomes from patients for a certain period of time. Once this 'trial period' has ended, this could mark a second 'full approval' phase and would serve as justification for payer reimbursement. Regardless, DTx companies will need to be creative to gain traction with insurance companies.

PRODUCT MARKET FIT: TARGETING THE "RIGHT" DISEASE AREAS

One of the challenges facing digital therapeutics is a question of product market fit. As evidenced by the FDA-approved therapies on the market, certain disease areas are a 'sweet spot' for this type of intervention, as **they can be treated via software and do not require a substantial in-person treatment component**. "Mental and behavioral health make sense for a more digital approach," points out Tuck School of Business Professor Lindsay Leininger. Ian Chiang of Flare Capital agrees, adding that, "Chemical pathway modification will require traditional pharmaceutical intervention, versus conditions you can address with cognitive behavioral therapy." Ian goes on to point out that telemedicine has largely allowed for heightened accessibility, with "the first wave of telehealth focused on urgent care and now more primary care." It stands to reason that more specialized interventions, like digital therapeutics, are well positioned to claim value as digital health moves into more targeted interventions. However, it is critical that **DTx focus on disease areas where they can demonstrate value.**

DTx companies can look to other digital health players that have found success by targeting areas of high impact. For example, Force Therapeutics, initially targeted physical therapy but "[it wasn't] a great product market fit, as this area is still very fee for service based." However, when an orthopedic hospital came to them as a solution for standardizing care and reducing costs at scale, Bronwyn immediately saw the opportunity to demonstrate Force's value proposition. This focus on value-based care and improving long term health outcomes while decreasing costs is critical for any successful digital health company. DTx companies will need to think creatively about how they can leverage data collection on an individual and population level to demonstrate clear cost savings and ROI.

Larger health players with more stake in service delivery components of the health care value chain have historically focused on digital tools that blend software-driven interventions with in-person care. Selemon Asfaw, of Optum, states, "Almost everything in health care needs some sort of physical touch, [such as] medication for diabetes...[or] diagnostic labs." He goes on to note that, while we will likely be able to complete more of these services via entirely virtual means, this may be a few years out. As a result, Optum focuses on interventions that can demonstrate high ROI. "[DTx] need[s] to be able to both improve long term health outcomes & cost reduction, not just provide assistance at a single point in time." **For DTx interventions to be successful, they must not only target an area of high impact and potential cost savings, but also a disease that can realistically be treated via software without foregoing quality or best practices.** However, even under the umbrella of mental and behavioral health, there are a wealth of conditions that could benefit from DTx, including several that have already seen some DTx traction like ADHD, insomnia, substance use disorder, and other psychiatric conditions.

Chris Bergstrom of AmalgamRx argues that it's less of a question of which disease area to target and that almost any indication can be suited towards a software-driven intervention given the right design thinking and ethnography. In fact, when asked if there are certain diseases better suited towards DTx, he notes that he had an expectation that DTx would be more suited towards treatment regimens with a stronger self-management component. However, he claims he's found that "there's not one right place to focus, but rather a '**pareto of high impact**' where you can deliver the highest impact digital care." He heralds the utility of AI to mine health care data points and identify critical gaps in care in order to determine where software-driven tools can intervene to close access and treatment gaps. In my opinion, this is one of the primary appeals of digitally-driven interventions coupled with predictive analytics. **If digital therapeutics companies can make an argument for developing a new solution targeting a specific patient population or disease based on identified gaps in care, this would further their unique value proposition and ability to demonstrate value**. That said, this will require the coordination of hospitals, health systems, and payers to provide access to an abundance of patient records to be mined with software. In the immediate future, I anticipate the majority of DTx companies will focus primarily on this initial product market fit niche of mental and behavioral conditions.

BUSINESS MODEL & ROUTE TO MARKET

DTx companies need to consider the proper business model that will allow them to effectively monetize and distribute these interventions. Many digital health companies have **historically opted for a direct-to-consumer approach**, offering pricing on a subscription basis. Others which offer their services to a health plans or employers utilize a per member per month type pricing approach. Opinions on optimal business model vary across the industry. According to Professor Leininger, she sees less of a role for the consumer facing models moving forward, but rather "more opportunity for … B2B plays that would be reimbursed by private insurers or Medicare in a value-based care payment arrangement." Much of the opportunity for B2B software revolves around clinical workflow augmentation to facilitate improved billing, interoperability, or otherwise ease provider burden. That said, she notes that "large employers and insurance companies… anywhere that is looking to keep costs down… there's an appetite for these technologies." **If DTx can clearly demonstrate ROI and seamlessly feed patient data into various medical records, then they can more easily pursue B2B arrangements** whereby an employer or health plan covers bundled access to a given DTx with their employee benefits or health plan coverage. Rather than pursing growth via the DTC route, these DTx will be able to expand reach and gain traction at a much quicker rate, obtaining users on an employer or health plan basis rather than in terms of individual member acquisition.

That said, it is critical that DTx companies consider the appropriate market segment for their intervention. "Companies like Pear might have too high of a price point for a customer like Medicare [versus private insurers or individuals]," notes Professor Leininger. "You have to think about the market segment just as much as you do the use case [of the data]." As beneficial as these interventions would be for lower income or higher risk populations, **DTx companies need to ensure that they are either targeting consumers in a DTC fashion at an appropriate price point, or that they are able to communicate value to the proper payers and justify B2B pricing.**

DTx companies should also consider a route to market via a larger health care player, either by way of partnership agreements or acquisition by United/Optum, CVS/Aetna, Anthem, Cigna, etc. Large health systems may also serve as channels to reach providers and gain traction in terms of new prescriptions. Commercialization via these larger players can afford benefits in terms of risk tolerance given larger patient populations. However, **scalability and interoperability** are the name of the game. Large players like Optum are beholden to shareholder returns and require a clear path to scalability, while health systems need proof that a given DTx will require little or no additional administrative effort. With regards to pursing distribution via acquisition, Selemon Asfaw of Optum notes that the importance of "de-risking, as proven and scalable models are much less risky when it comes to M&A. The digital space is crowded and payers care about return on investment and delivering on health outcomes. We've historically focused on models with some in-person component…" He goes on to add that it can be "more challenging to operationalize [purely digital models] with a lack of service component." This is an important consideration, and one that DTx companies should keep in mind. I find the notion of digital as a capability versus business to resonate strongly, and I believe that **as DTx are able to better demonstrate and communicate cost savings and value add, then their disease-specific digital tools will warrant categorization as a truly viable business model rather than simply a capability.**

FINAL SUMMARY

As telemedicine becomes more commoditized, this facilitates development of a broader ecosystem of targeted digital health solutions. Digital therapeutics present an increasingly attractive opportunity to make the highest quality of care more accessible and affordable, leveraging technology to reduce cost of care and improve health outcomes. These tools can collect contiguous data points on an individual's health and treatment compliance over time. This allows for identification of patterns and progress, while also facilitating efficacy and engagement tracking on an aggregate level. One of the key advantages of DTx over other digital health tools is this ability to collect, track, and benchmark data according to gold standard clinical outcomes as it enables DTx to demonstrate cost savings and ROI in a way that other non-FDA approved digital health apps cannot. The data generated by DTx is invaluable for a myriad of stakeholders, including: payers who demand proof of value creation and cost-savings to justify reimbursement; policymakers and thought leaders evaluating public health trends; physicians modifying treatment protocols and gathering data to make informed or AI-assisted diagnostic and treatment decisions; investors, who require clear ROI that has historically been more difficult to demonstrate in purely virtual contexts; and patients, who want to be empowered and armed with an understanding of their health trends over time. While DTx companies are still triangulating the areas of highest value creation, we will continue to see a proliferation of these tools focused on mental and behavioral health in the near future, so long as these players can obtain regulatory approval and subsequent reimbursement. In order to do this, DTx companies will need to be transparent about R&D costs, creative in their pricing strategies, and thoughtful in pursuing their optimal route to market.

APPENDIX

While there are no formal requirements for what constitutes a digital therapeutic, the DTx Alliance, a non-profit association founded in 2017 and dedicated to the advancement of digital therapeutics, has outlined several best practices for the development and commercialization of these tools. These metrics for success state that a DTx should [1]:

- Prevent, manage, or treat a medical disorder or disease
- Produce a software-driven medical intervention, delivered via software or complementary hardware, device, service, or medication
- Incorporate design, manufacture, and quality best practices
- Engage end users in product development and usability processes
- Incorporate patient privacy and security protections
- Apply product deployment, management, and maintenance best practices
- Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals
- Be reviewed and cleared or approved by regulatory bodies to support product claims of risk, efficacy, and intended use
- Make claims appropriate to clinical validation and regulatory status
- Collect, analyze, and apply real world evidence and performance data

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