

# Summary of Themes

## Workshop on New Financing Structures for Transformative Therapies

From curative treatments for Hepatitis C to gene therapy to immuno-oncology, a new age of transformative healthcare therapies has arrived. As more of these cutting-edge treatments are approved and marketed for rare, specialty and large populations, patients, providers and payers question how healthcare systems can sustainably afford them. In addition, many of these therapies are effective with very short courses of treatment and even single doses, and will potentially result in long durations of health for patients and high up-front costs for payers and systems.

On October 14, 2016, a select group of biotechnology and drug developers, academics, financiers, economists, providers and payers convened in Cambridge, MA to discuss how innovative financing could help expand patient access to transformative therapies in the United States. Co-hosts from the MIT Laboratory for Financial Engineering, Dana Farber, and Tapestry Networks sought to channel the cross-sector expertise present to address critical questions, including:

- How do we get transformative therapies to patients faster and cheaper while incentivizing the development of future transformative therapies?
- Who pays in the short and long-term: Taxpayers, consumers, or payers?
- Can financial engineering help make paying for transformative therapies, especially those that are curative in nature, more sustainable?

### Most participants agreed on the following underlying market principles

- *There is urgency.* Stakeholders need to work out better payment solutions before transformative therapies hit the market – not after. New therapies, in aggregate, will pose a challenge to payers' balance sheets. *"If we wait for the drugs, we may be too late,"* one participant advised.
- *Efficacy is important.* Payers want strong evidence that transformative therapies work in order to approve coverage, especially since payers tend to develop coverage criteria on an industry-wide basis. As one participant said, *"The first question is, does this work? That's important. For most of this to work insurers have to have similar policies. For portability, all insurers have to agree on similar criteria. If one insurer doesn't, others won't."* Financiers also factor in the efficacy of treatments when considering loans for specific conditions.
- *Value frameworks matter.* Participants agreed that stakeholders need to better distinguish the lifetime benefit and value of each therapy to determine if it is truly transformative – not only for the patient, but also for the manufacturer, the payer, and society.
- *Pricing uncertainty adds to complexity.* Lack of pricing certainty for transformative therapies – driven in part by the US's complex rebate system and high failure rates in biopharmaceutical development – and the limited ability to hedge future pricing risk creates an added challenge for healthcare compared with other markets. *"Healthcare can't lock in future prices ... there's no futures market."*

## Factors that will impact the application of innovative financing models

- *Regulatory environment:* Participants emphasized that many regulations and complexities present in the US healthcare system today impede the implementation of new approaches to reimbursement. Some suggested it may be necessary to “*blow up the system*” with a highly disruptive model or series of changes. As examples of key challenges, attendees cited patient portability across payers and the Medicaid Best Price provision’s chilling effect on industry’s appetite to offer alternative payment models.
- *Improved prevention and predictability:* With the advancement of genetic profiling and data analysis, participants anticipated that soon healthcare systems will be able to better predict which individuals will get specific diseases and reduce the uncertainty inherent in risk pools. The implications of enhanced predictability may include increased segmentation of specific patient populations from larger risk pools and erosion of the current risk-based model for health insurance. As one participant opined, “*If you know your house is going to burn down in 63 days, that’s not an insurance problem, it’s a financing problem.*”

## Charting the way forward

The majority of healthcare stakeholders were skeptical about consumer loan options for enabling access to transformative therapies; however, some felt it may be worth further considering how financing could fill a short-term gap for out-of-pocket expenses not covered by insurance.

Significant out-of-pocket costs, high deductibles, and co-insurance continue to be a challenge for patients, prompting some to turn to unfavorable financing options like payday loans and credit cards. Participants discussed whether other consumer financing approaches could offer more viable, immediate solutions to patients as more transformative therapies enter the market. Models under consideration include peer to peer loans, which already have healthcare precedents in elective areas where third parties offer structured loans through provider networks. “*The issue is the high deductible or uncovered healthcare costs. It’s hard to tell what this population looks like – there are not consistencies. People are looking for personal loans to cover uncovered healthcare costs ... This is happening today with us. Consumers are coming to us now – if we don’t step in, they will find a way on their own,*” a lender said.

Healthcare stakeholders noted that models to support access to transformative therapies may conflict with current out-of-pocket maximums of \$7150 per individual and \$14,300 per family mandated by the Affordable Care Act. Participants questioned if consumer loans would make sense in the current regulatory environment given that new therapies are likely to cost far more than the out-of-pocket maximums and may be covered, at least in part, by insurance.

Another major challenge to consumer models that attendees underscored is patients’ willingness to pay. “*Even patients who can afford a \$100 monthly iPhone payment get outraged at any out-of-pocket health expenses or co-pays,*” one stakeholder asserted. Many agreed that consumers in the United States do not have the appetite to take out personal loans unless all other options are

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*“There is appetite on part of the financial system to contribute. But part of the issue for pharma is cultural - pharma is challenged by looking for yield, but also has cash on their balance sheets. They could do credit programs but they’re not used to thinking about financial matters.”*

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exhausted, including appeals and protests to the payer, manufacturer, and government. Whether this attitude is relevant to transformative therapies for diseases that shorten life or markedly affect quality of life is not known, but some stakeholders anticipate that patients will be largely willing to do whatever is necessary to obtain such treatments.

**Most stakeholders agreed that payers could benefit from innovative financing models and risk-sharing vehicles that lenders, hedge funds and other institutions provide**

Stakeholders observed that traditional payers could face a solvency crisis if the cost of new transformative therapies is not offset by reductions in payment for care that result from the therapies. As a result, most attendees saw value in further discussing how payers could benefit from innovative financing solutions and engineering techniques, including options to amortize costs from expensive one-time treatments. Participants from academia suggested that third parties from the financing community would be well-positioned to work with highly complex payers – such as state Medicaid systems – to offer annuity payment models. Others discussed that payers and systems could also use financing from capital markets to help front-load the cost of widespread treatment for certain therapies – for example, in expanding immediate access to treatment for all HIV-positive patients around the world.

Participants emphasized that solutions are likely to vary depending on the payer. Medicaid, most agreed, is a unique payer that may be suited for annuity models because of the potential ability to access funding through municipal bonds, for example. Others noted that many private payers are not the final risk-bearers but instead share risk with reinsurers, stop-loss carriers and employers. They recommended that future conversations should include reinsurers, and large employers, who bear much of the healthcare costs in the US, at the table.

**Participants largely agreed that there will not be a one-size-fits all solution for paying for transformative therapies**

Most stakeholders agreed that nuances in durability, efficacy, application, population size, and other factors will make one type of financing solution more appropriate for certain diseases and therapies than others. Gene therapies will need a different approach, for example, than a drug like Sovaldi, and payment models for both of these curative therapies may differ from those for immunology.

Participants called for more research on the types of high-value transformative therapies in the pipeline – especially a closer examination on where they fit on the spectrum of curative to disease-modifying – in order to better assess optimal financing possibilities for each. Some therapies may be best suited for performance-based models that are established by contracts between manufacturers and payers; others may be able to leverage government-backed pools similar to vaccine reimbursement models.

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*“The big question is, is this an efficacy problem, an economic problem, or an ethics problem? ... Mixing ethics with economics is a holy mess ... But economics can help - it can be used to benefit all parties.”*

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**Proposed next steps: common language, modeling and real-world pilots**

At the close of the workshop, participants made several recommendations for actions that could be undertaken to further explore the application of innovative financing approaches for high-value transformative therapies.

These include:

- Pursue additional discussions across the financing and healthcare communities in ways that help each better understand one another's language, terminology, and regulatory constraints
- Advance conversations on risk-sharing and financing models by bringing reinsurers and stop-loss carriers to the table
- Model the current pipeline and populations affected as a foundation for exploring what types of approaches are most appropriate for specific therapeutic areas, and the implications for business models of stakeholders involved
- Pilot new payment models for gene therapies on analogous, existing healthcare services, namely organ transplants
- Pilot new payment models within a closed healthcare system like Kaiser to reduce variables and complexities across payer and provider systems

## About this document

*This meeting was invitation-only and used a modified version of the Chatham House Rules, whereby the names of attendees are a matter of public record but comments are not attributed to specific individuals or organizations. The views expressed in this document represent consolidated views of those who participated in this closed workshop, and are not intended to represent the particular policies or positions of the individual participants or their affiliated organizations.*

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## Participants

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