(Re)positioning the 'Drug Market' to Compete on Ecosystem Value:

A New Strategy Story

Part of Blue Spoon's 'Harnessing the Carnival' Series on Market Innovation Across the U.S. Health Economy

A Punk Rock Ethos of Disruption®

Author:

John G. Singer, Executive Director

john@bluespoonconsulting.com
917.538.4239

Blue Spoon Consulting Group, LLC

www.bluespoonconsulting.com

New York City

Disclaimer:

Blue Spoon Consulting does not have a financial relationship with any brand mentioned in this document. All insights and assumptions regarding market strategy are based on public information.

Any market interaction discussed in this document has not been intended nor has it taken place.

Which is the opportunity.

Author's Note

Parts of this story were written and published in 2020, a few months before Covid-19 shook the world's economy and exposed how central "healthcare" was, and is, to economic performance. Some details here have changed since then – people have moved; companies have been acquired; brands have changed or disappeared – underscoring that any effort to cast a narrative frame over the tumult we are still living through is bound to be partial and subject to revision.

But the broad arc of this briefing note, and the entanglement of anxieties it aims to unpack and connect as one system of thought, is still contemporary -- unfortunately, the big themes and strategies haven't really changed. Which is part of the problem.

We hope you read it in that vein. 🤘

Market Access Innovation

The bigger problem with a $4 trillion economic system that tolerates stagnation and celebrates short-term gains: "innovation strategies" designed around technologies when they should be designed around new economic thinking.

The real innovator's dilemma: who innovates the innovators?

Value is deeply embedded in particular ways of seeing the world. It is a subjective concept.

It can be defined in different ways, but at its heart is the production of not just new products and services, but new outcomes. How these outcomes are produced, how they are shared across an economic system, and what is done with the earnings that are created from their production (reinvestment) are questions that sit at the center of the discursive war the pharmaceutical industry as a whole is now fighting with its market around "value-based pricing."

The health care (and life sciences) industry – particularly in the United States -- has never followed the rules of conventional economic theory. The dynamics have always been exotic, the gravitational pull of QALY and a mathematical paradigm assumes away complexity and human interaction, and the ability to capture and quantify "value" is based on the premise that a piece to health (e.g., the drug component) can be isolated and optimized independently from its environment. The globally influential Institute for Clinical and Economic Review (ICER) is a leader in promulgating this view.

Health care products and services are also unique from normal consumer goods (say, for example, a refrigerator or automobile), which are economically inert – their value is known at purchase: what happens when a pharmaceutical goes "live" and gets used in the real world is often radically different than what happened in controlled clinical trials used for regulatory approval and labeling promotion. This implies **experience over an extended period of time** (i.e., 'continuous health engagement') is a more accurate logical frame to define, describe and negotiate "value".[1]

Health happens at a system level, never just one thing, but many things simultaneously and interactively. If you ascribe to this line of reasoning, then the entire global health economy (projected to be $24 trillion by 2040[2]) can logically be seen as contributing to outcomes in some fashion – everything is in the "production boundary" for health. The space of opportunity, then, is for creative leadership to reshape a $24 trillion economy into new systems of health production.

Outcomes become markets. "Value" becomes system vision.

As the feature/benefit story of a product – its technical merits – become less relevant to strategy, less sustainable as a source of advantage and harder to protect with manufacturing (see, for example, hospitals in Switzerland dis-intermediating Novartis and Gilead Sciences to handle

production and lower the cost of cancer cell therapies[3]), "experience" embedded in a new system of health engagement becomes the carrier of value. **This shifts the premise – the market reasoning -- for performance-based contracting; instead of price for an isolated intervention (i.e., drug), the negotiation moves to a new meta-narrative about investing in the production of health and public value.**

This Briefing Note helps set the conditions for the "drug" industry to rethink and reframe market strategy **around a new theory of value**.

It does so by enabling big new thinking, new concepts and new capabilities born from a different perspective. The end state is business leaders armed with new understanding, new positioning and a next generation of management skills for market innovation.

Strategy is about shaping the future. As long as the field of play is seen as "drug market," then the unit of analysis and action will always be bounded within the context of "drug" pricing. As long as we regard humanity as separate from nature, understand healthcare and life sciences as distinct industries, treat public health independently from economic health, or think of government as an entity apart from 'the market' it regulates, then we shouldn't be surprised when we fail to build exciting new visions for the future.

We have to change the primary material conditions for strategy and imagination.

The old blueprint rules.

If instead we want market innovation, a new narrative with the ability to inspire and persuade and differentiate, then we have to change the primary material conditions for strategy and imagination. We have to start creating with a non-fragmentary worldview, a new connection of elements where the production of health is the organizing idea for competition, a new gravity field around which a new system of markets coheres and evolves as a simultaneous whole.

Said differently, in the next healthcare, 'outcomes' is the good being exchanged, the market forces to intentionally design and use as the basis for negotiating price based on system value.

Pharmaceutical companies are uniquely positioned to give the global health economy new direction. By leading and "pricing" based on system vision, they have an opportunity to become keystones holding new economies together.

It's the new master storyline to change the subject.

/ jgs

Themes

What is "Value" in Healthcare?

Not long ago, Humana – a for-profit American health insurance company (and key account for most pharmaceutical companies) with revenue of $56 billion -- convened some of the healthcare industry's greatest minds to build a consensus on the definitions of oft-used but rather nebulous concepts such as 'value-based care' and 'population health'.

There was just one problem: The experts couldn't figure it out, either.

Although the participants could find some common ground on what "value-based payment" is, they couldn't agree when it came to "value-based care."

The 18 panelists — which included representatives from Humana, the Robert Wood Johnson Foundation, the Geisinger Health System, the University of Pennsylvania and Centene Corporation (but did not include representatives from the pharmaceutical or medical device markets) — agreed, for instance, that value-based care should apply to both individuals and populations and would be determined by measuring outcomes and cost. But they were divided about whether 'patient experiences' should be highlighted, how to cohere on a standard for outcomes or whether there should be a duration factor in calculating value. "I was actually a little surprised," Meredith Williams, M.D., market president for Humana based in Louisville, Kentucky, told *FierceHealthcare*. "I thought there would be more consensus. It was a very revealing process to all involved."[4]

Healthcare is defined by groupthink on a staggeringly consequential scale.

Merck and Company encountered a similar static drift trying to collaborate with the largest payer in the United States to find, and then presumably advance, common business goals centered on improving patient outcomes.

During its work with Optum (part of UnitedHealth Group, Optum is a pharmacy benefit manager and care services business operating across 150 countries in North America, South America, Europe, Asia Pacific and the Middle East) on a "Learning Laboratory," Merck and Optum explored different outcomes-based risk-sharing agreements for *drugs* it was developing to prevent Alzheimer's disease and clostridium difficile (C-diff) infection, an acute bacterial condition that can be treated in either inpatient or outpatient settings.

"Throughout our work together [with Optum], we realized there were a variety of **gaps between our languages, methods, and value drivers,**" said Susan Shiff, Senior Vice President of Merck and head of the company's Center for Observational and Real World (CORE) organization. "Our work is not remotely close to done. But we're closing in on the first — and, perhaps, most important — goal: mutual understanding."[5]

It's hard to align on value using old anchors of meaning and logic of the industrial age. Quoting Lionel Robbins of the London School of Economics, who in 1932 quipped: **"We all talk about the same things, but we have not yet agreed what it is we are talking about."**

A New Era Needs a New Strategy Story

The center-of-gravity for a modern strategy is at the system level, not the technical-input level. It's a completely different conceptual frame for creative leadership.

The dominating narrative influencing the direction of spending on health (and life sciences) worldwide centers on "value" as an end state, the Great Transformation for all stakeholders to achieve. It's the new big picture for a 21st-century, globally connected health economy.

The contexts may differ – Europe or the United States; big pharma or medical device company; retail pharmacy or e-commerce giant; government payer or private insurer; integrated delivery network or small group practice – but its effect on the thinking behind strategy and the behavior of financial operations has been to spark a search for meaning across the board: "value" is now core to the question governing how to **position business and play in the emerging economy for 'health outcomes,' a space worth $24 trillion by 2040.**[6]

Except no one seems able to tell you what value means, or how to get there.

A big reason for the fuzziness is that **a theory of value is not set in stone, not wed to conventional accounting methods.** "Value is not a given thing, unmistakably either inside or outside the production boundary," says Mariana Mazzucato, Professor of Innovation and Public Value at University College London. "It is shaped and created within the context of new markets." The concept, in other words, is entirely subjective; it can be molded to fit the purpose of an organization and, in the process, affect the organization's evolution.

Which is the opportunity for creative leadership.

A 'value strategy' for the next health care should be approached as vision for a new economic system ("ecosystem"). Rather than comprising the discovery and commercialization of discrete interventions, it is methodology to steer and invest in the process to create health. When Intermountain Healthcare – one of the largest healthcare providers in the United States, with 24 hospitals and a medical group of 2,400 physicians – spins off a new company "that aims to help providers, payers and other stakeholders transition to value-based care," the integrated delivery network is, in effect, **creating a market in a new method of health production.**

Their story is not about "fixing" health care.

Intermountain believes its expertise and capabilities can be repackaged into a new market offering, one that can eventually become a path dependency – a new care standard – in primary prevention (the same business objective Merck was attempting to achieve in aligning with Optum to prevent Alzheimer's). And through a new process of producing health (or preventing disease), Intermountain sees a commercial opportunity from helping other hospitals and physicians capture revenue from new reimbursement models, bundled payment arrangements, bonuses based on reducing hospitalization, and even billing for the social determinants of health.[7]

"The new company, known as Castell, is built on Intermountain's preventive primary-care model as well as other best practices. It will provide analytics software and other digital technology to address virtual care, patient experience and social determinants of health; manage affiliated networks; and offer access to Intermountain's latest initiatives.

"We have an extremely strong play book that can be leveraged by other providers and payers to help them manage patients from a quality, cost and management of risk perspective," said Rajesh Shrestha, the president and CEO of Castell who is also Intermountain's vice president and chief operating officer of community-based care.'[8]

Definition: "value" is a process by which health is created…it is a flow, not an end state.

The new moat Intermountain is digging to protect its new market is through the provision of a new, branded standard of care for primary prevention. They are moving to create and scale a path dependency to their version of QWERTY, the keyboard layout named for the first six letters on the top from left to right. (In the days of mechanical typewriters, the very inefficiency of this keyboard layout gave it an advantage over alternative layouts because mechanical keys would jam less frequently. Once people learned how to type using the QWERTY layout, they resisted change. This social inertia meant its arbitrary initial advantage got locked in.) Intermountain's goal is similar: locking-in progressively more agents of health production to their method of primary prevention, developing a new pool of knowledge that may be virtually impossible for a competitive service to duplicate.

Their strategy is market driven, not mission driven.

Intermountain wants their system vision to become woven into the fabric of health delivery, preferred by most because of past preference for it -- the bigger the network, the stronger the company's position. **Intermountain's roadmap is easy to see if you're using the right lens: create and curate a new 'infrastructure for outcomes' by which subsequent innovations do not seek to supplant Intermountain's standard, but are incented to cluster around it in order to improve its performance**. Make it as easy as possible to participate. Integrate forward with end users/customers at scale. (Shire was reaching for something similar in marketing a new care standard for hemophilia.[9] Merck KGaA collaborated with NHS England in a novel market access deal for Mavenclad, which included Merck agreeing to build and manage a new data collection and IT infrastructure for multiple sclerosis for 10 years.[10])

"You can't install complexity," writes Kevin Kelly, Editor-at Large for Wired Magazine. "[Entrenched systems] are biased against large-scale drastic change. The only way to implement a large new system is to grow it. And the way you grow one is to start with a small network that works, then add more sophisticated nodes and levels to it over time." This is the strategic response Walgreen's Boots Alliance intends to execute against the threat from Amazon.[11]

Plato once argued that storytellers rule the world. His great work The Republic is in part an exploration of the nature of leadership and the

structure of society. Plato recognized that stories form character, culture and behavior: "Our first business is to supervise the production of stories, and chose only those we think suitable, and reject the rest."

Today, very little energy is needed to invent tools and technologies, but ever-more effort is needed to manage the tornado of innovation and agree on what pattern of transactions to cohere around (as Susan Shiff from Merck discovered). The new narrative for value innovation from a pharmaceutical company starts with system entrepreneurship: become a node to comprehensively and creatively bring forth, aggregate and manage the means of health production as an interactive whole.

It begins with a new positioning of all actors as being central to the collective value creation process.

A New System of Markets

Creating and competing on "value" is, ultimately, about bringing to life a new socio-economic arrangement, a new system of markets organized on the production of health over time, not "price" (**see Figure 1: A New Economic System**). It requires a deeper interrogation of the concepts on which most of today's global health economy is organized and what its components are trying to do.[12]

First and most fundamental, what are markets?

They are not things in themselves. They are the result of a shaping process involving the interaction of many processes and stakeholders – including government -- leading to a new context for demand. When Pfizer launched Lipitor in 1997, it did so without clinical data by inventing a new dominant context within which to manage cholesterol: **it invented demand for a new care standard**. It was a simple storyline -- "Lower is Better" – that turned Lipitor into one of best-selling drugs of all time, with more than $125 billion in sales over 14 years.[13]

Big stuff happens when you combine things in new ways. Doesn't matter if those things are countries, industries, markets or brands, new leverage and new power is born in the remix, in the space 'in between' the pieces.

The end state is interdependency, a new system.

This is a structural point. The very fact that a market is constructed through the strategic imagination and creative leadership of business managers – of people -- means that pharmaceutical companies can fashion outcomes as markets, and direct (or influence) the social, clinical, technological, governmental and physical infrastructure – the market forces -- to build the production of health in a way that benefits its business. What is required is unique understanding about how value is conceived, created and curated over time.

"Drug" companies have the stored energy and capabilities to take the current $8 trillion health economy as whole in a new direction. It means working with a view of growth and value not through the lens of "drug" company, but system leader.

A new commercial model, in other words, stands on new mode of being.

'Big design' becomes the methodology to first define what is inside and outside the boundaries of health production, and then assemble the capabilities and storyline to forge demand – *create* the market – for the new system of health, in which "drug" is positioned as keystone. It is a methodology to invent new stories of value creation that transform health economic thinking at scale, worldwide and with all customers, giving direction to investments in health development and technical change. Instead of tangible product, the new narrative becomes the thing to negotiate market access and new pricing models around.

This requires a new understanding of strategy as actively 'shaping' and 'creating' markets as economic systems that benefit the broadest number of people, including society. Which is currently the business model of One Medical. And it's a compelling case on how to sustain economic value with a new system vision.

One Medical is taking on a large chunk of the $3.5 trillion health-care industry in the United States, which is riddled with inefficiencies, impersonal care and old technologies that don't talk to each other and leave patients

struggling to find and track their medical records. **One Medical essentially cut the Gordian Knot to design and position a new system health from scratch, and then grow it to its current valuation: $2 billion.**

"In health care, almost every stakeholder group is frustrated and so we looked to solve a lot of these needs simultaneously by starting from scratch and [putting] the member at the center of the experience," said Amir Dan Rubin, President and CEO.[14]

Founded in 2007, One Medical is successful because it provides **a seamless, consumer-grade health experience** -- on-demand care and easy mobile booking -- and by selling its services through B2B marketing, targeting big companies who offer access to One Medical as a perk to employees. Google and SpaceX are among those employers.

New management concept: 'Total System Leadership'

As **'total system leadership'** emerges as a management innovation, situations previously suffering from polarization and inertia become more open, and what were previously seen as intractable problems become perceived as opportunities for innovation.[15] Short-term reactive problem solving becomes more balanced with long-term value creation. And organizational self-interest becomes re-contextualized, as people discover their and their organization's success depends on creating success for the larger systems of which they are a part.

In pricing and positioning its $2.1 million gene therapy cure for spinal muscular atrophy, Novartis is bringing to market not just a new drug, but also an entirely new system of care to accommodate its adoption and payment. As part of its outcomes-based contract with payers, Novartis is working with a "new negotiating model" that integrates structural changes in early screening for SMA and **"curated" benefit design** to accelerate patient access and pay-over-time reimbursement.[16]

Novartis (and Spark Therapeutics, who presented at ISPOR New Orleans 2019 their strategy to create and compete on health system value) is breaking ground with an approach consistent with the idea of an **'outcome economy' as a new operating philosophy** and way of seeing. Irrespective of market context, it's a break from legacy. Here's perspective from the World Economic Forum:

"In the outcome economy, companies will shift from competing through selling products and services, to competing on delivering measurable results important to the customer. This is a much more challenging prospect. Among other things, providers will require a deeper understanding of customer needs and contexts in which products and services will be used.

Value based on output [from a new system design] also entails quantifying results in real time.

Both of these requirements have been nearly insurmountable obstacles to scale – until now. It is the advent of digital technologies that makes the outcome economy possible.

The outcome economy will have many implications for businesses. Companies will need more and better data to calculate costs, manage risks and track all the factors required to

deliver the promised value. Provider risk will increase, too, as markets move to value based on outcomes, but so will the reward. New financial instruments and forms of insurance will emerge to help enterprises manage the risks associated with guaranteeing outcomes.[17] *Pricing practices will also change, as it becomes possible to model the probability of delivering outcomes. Success in this environment will require* ***greater cooperation among markets*** *than ever before."*[18]

In Zolgensma, Novartis has brought to fore a new vision of "value" created at a system level. The problem in launching "the most expensive drug ever" is positioning its storyline to fit:

- **Entrenched market context** of commercial payers (predominately in the United States), whose business models are not aligned to "care" about benefit over a "lifetime" because of high member churn rates (per new data from the Bureau of Labor Statistics, more than 2 million workers and their families lose or transfer to new commercial health plans every month in the United States[19]); and

- **Entrenched marketing context** of the pharmaceutical industry, where credibility to claim "value" has been seriously undermined from decades of heavy spend on drug marketing, DTC advertising in the United States, bad actors, and illogical price increases (the 10 U.S.-based pharmaceutical companies spent a total of $47.5 billion on marketing and selling in 2017).

The most important skill for strategic competition -- between countries; between companies; between brands and businesses -- isn't technology development, it's the 'process knowledge' needed to develop new industry ecosystems.

There are three core capabilities that system leaders develop in order to foster a collective process of creating value:

1. The first is the ability to see the larger system. In any complex setting, people typically focus their attention on the parts of the system most visible from their own vantage point. This usually results in arguments about who has the right perspective on the problem. Helping people see the larger system is essential to building a shared understanding of complex problems. This understanding enables collaborating organizations to jointly develop solutions not evident to any of them individually and to work together for the health of the whole system rather than just pursue symptomatic fixes to individual pieces.

2. The second capability involves fostering reflection and more generative conversations. Reflection means thinking about our thinking, holding up the mirror to see the taken-for-granted assumptions we carry into any conversation and appreciating how our mental models may limit us. Deep, shared reflection is a critical step in enabling groups of organizations and individuals to actually "hear" a point of view different from their own, and to appreciate emotionally as well as cognitively each other's reality. This is an essential doorway for building trust where distrust had prevailed and for fostering collective creativity.

3. The third capability centers on shifting the collective focus from reactive problem solving to co-creating the future. Change often starts with conditions that are undesirable, but artful system leaders help people

move beyond just reacting to these problems to building positive visions for the future. This typically happens gradually as leaders help people articulate their deeper aspirations and build confidence based on tangible accomplishments achieved together. This shift involves not just building inspiring visions but facing difficult truths about the present reality and learning how to use the tension between vision and reality to inspire truly new approaches.[20]

The transformational remit for new market leaders is the ability to creatively explore a new territory, quickly assemble a new intellectual viewpoint, and then design the new infrastructure – the nervous system – around it to manage the means of producing health over time.[21]

A New Economic System ("Ecosystem")[22]

A System of Markets Designed to Interoperate in Diabetes (Illustrative)

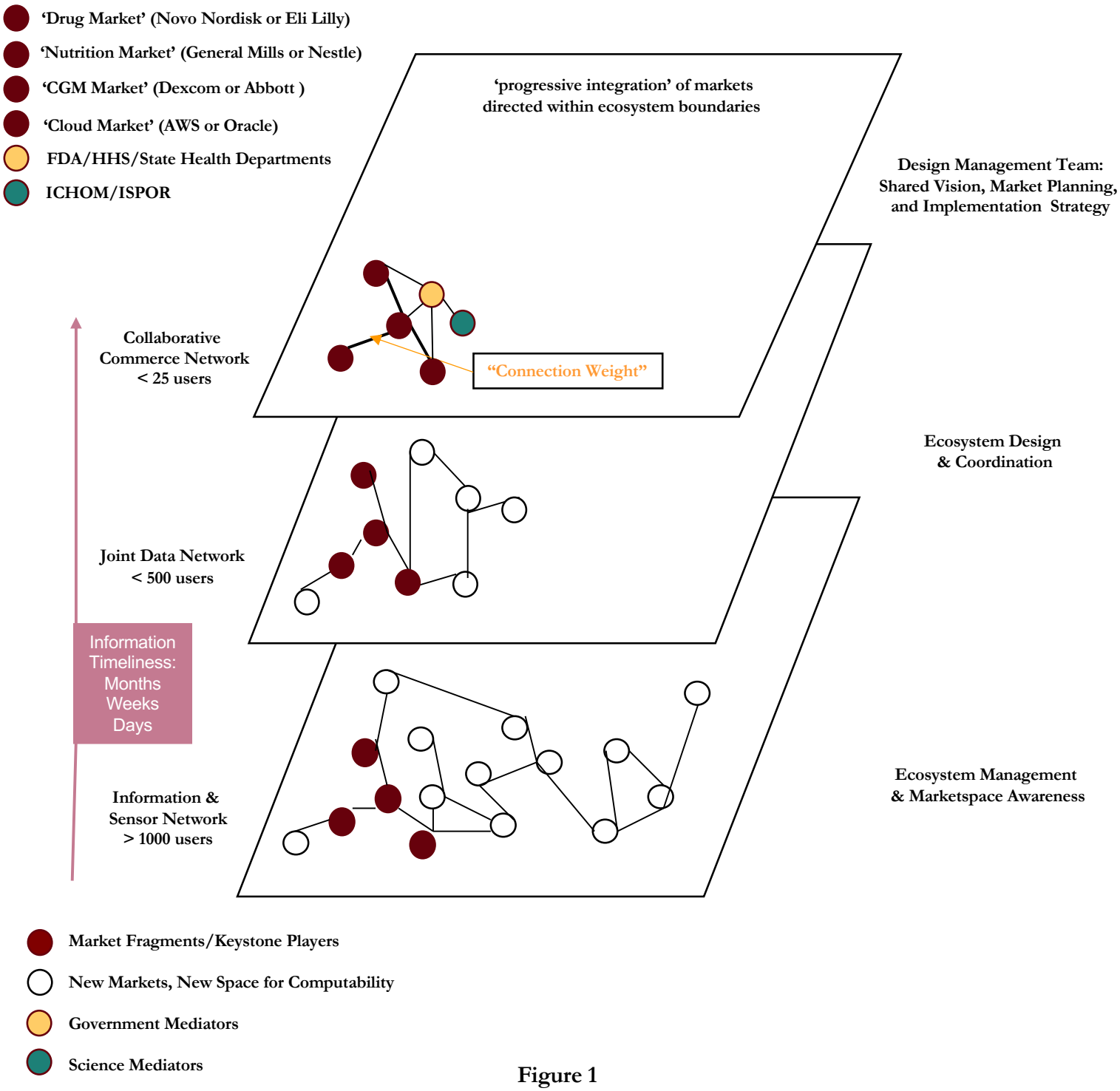
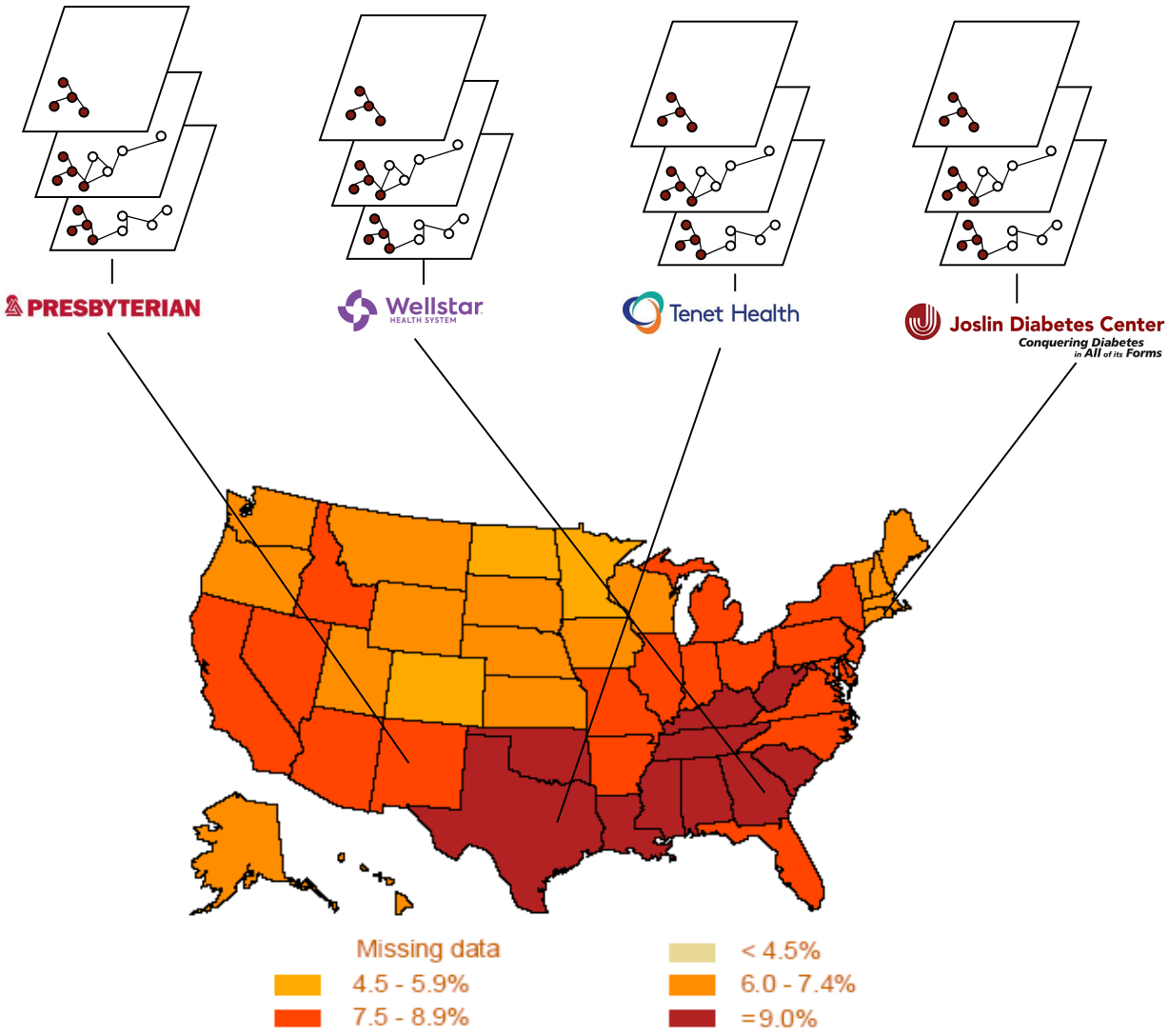


Figure 1

Regionalized Market Approach:
Design and Deploy a Portfolio of Business Ecosystems for Diabetes
Customized for Regions, IDNs, Centers of Excellence, Accounts



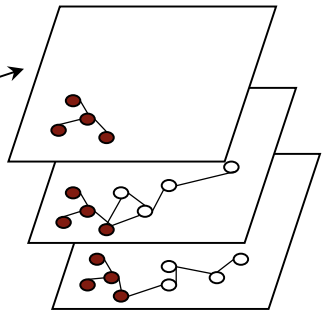
Age-adjusted Percentage of U.S. Adults Who Had Diagnosed Diabetes
2013

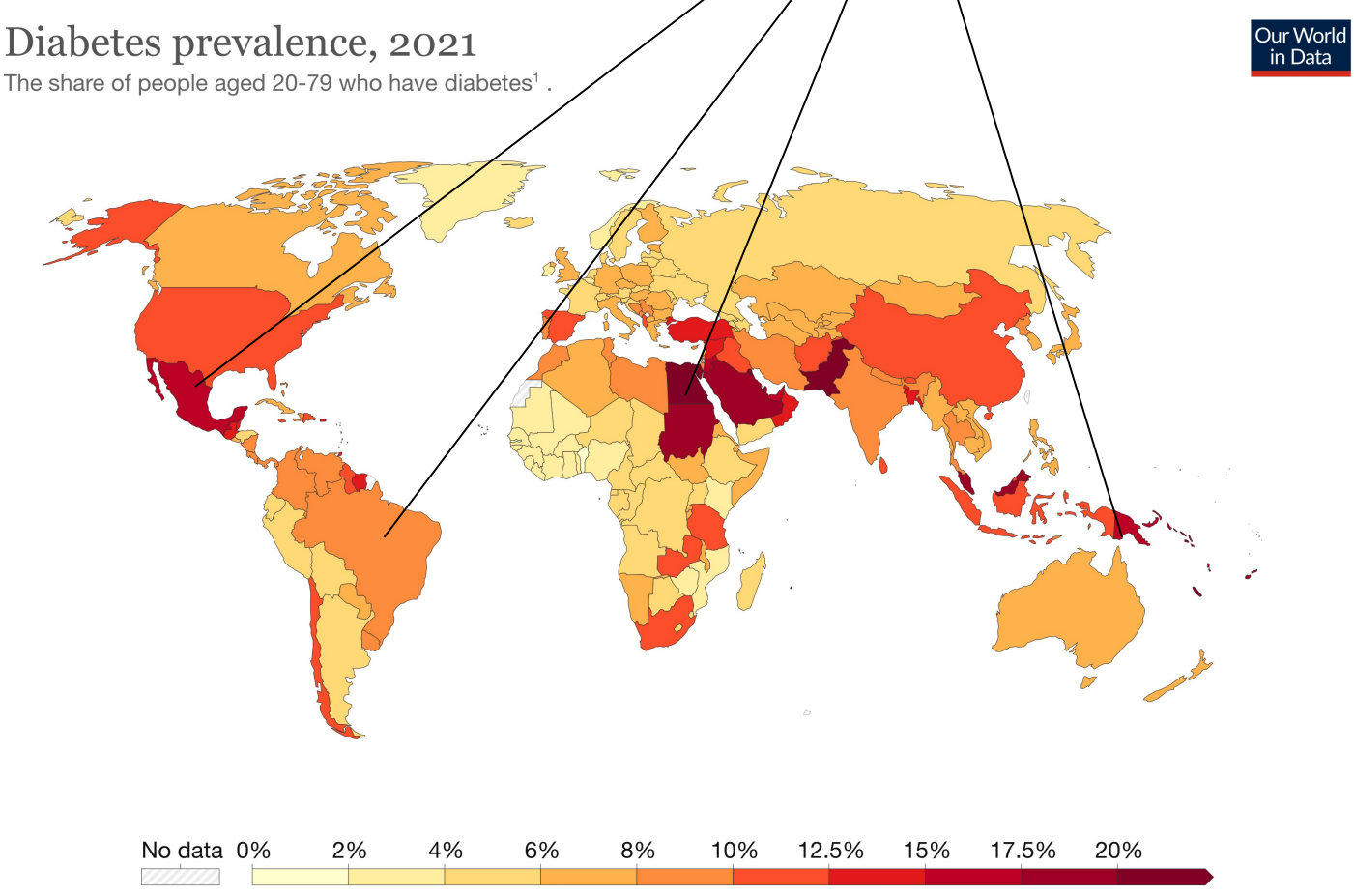
Source: CDC's Division of Diabetes Translation.
National Diabetes Surveillance System (available at: http://www.cdc.gov/diabetes/statistics)

Figure 2

Strategic Vision for a Global Market Scope
Create New Health Ecosystems Worldwide

System-Level Performance Measures
- Health outcomes (population level)
- Resource utilization (direct and indirect)
- Economic performance (state and country)
- Market dynamics (ecosystem components)
- Emergence (innovation and ideas)





Pricing Based on 'Ecosystem Value'

Trillions are at stake for the pharmaceutical industry to figure out a new strategy story, positioning born from a different orbit of thought and action, one that creates leverage and power to negotiate pricing based on the value of new economic systems.

Sage Therapeutics should be able to price its experimental depression pill at the "value it'll provide" for patients despite industry-wide political scrutiny over the cost of drugs, CEO Jeff Jonas told CNBC in an interview published the last week of July 2019.[23]

When asked on CNBC's Power Lunch, the network's program focused on real-time coverage of the stock market, how Sage expects to price the drug amid intense drug price rhetoric from Washington, Jonas said, "Every company pays attention to macro factors."

"We believe if [the drug] continues to perform the way it has, with rapid onset and durable effects, and not requiring chronic pharmacotherapy, that it really could be a game-changer," Jonas said. "It's premature to talk about pricing in that respect. But we feel we should be able to price it for the value it'll provide for patients." Sage is advancing the experimental oral drug, known as SAGE-217, for treatment-resistant depression. The drug could be lucrative for Sage, analysts predict, as roughly 20 percent of people with depression don't respond to available treatments.

But the question remains: what is the composition of "value" Sage plans to use for price and access?

Manufacturing costs may not suffice as a credible argument for premium pricing. The production costs of specialty drugs are often unrelated to their price, as is widely known by payers and policy makers -- shortly after Gilead launched Solvadi with a $100,000 retail price, researchers put the manufacturing cost of a twelve-week course of Solvadi as between $68 and $135.[24] Novartis and Gilead Sciences are now discovering the strategic effect of that awareness, with hospitals in Switzerland taking on the production of their new cancer therapies.

And a sales forecast for SAGE-217 based on its convenience and efficacy (the 'technical merits' conceptualized in its target product profile) will run headlong into the new reality of today's "drug market" where payers, governments and the public see pharmaceutical companies as extracting value, not creating it. Misreading the temperature and depth of this change in the environment – trying to impose old models and promises on a new situation -- has consequences: Spravato, Janssen's new nasal spray for treatment resistant depression (and competitor to SAGE-217), is set to launch at a price of $32,400 and expectations for peak sales of $3 billion. ICER has a different perspective. It says Janssen "needs to shave 52 percent off the price" to deliver "fair value" given that there wasn't enough evidence to show it was better than a generic.[25]

The emerging market in pharmaceuticals has more to do with outcomes than geography:

- **In Migraine Prevention.** Aimovig (Amgen) sales of $59 million for 1Q2019 are "well below estimates," and more than 40 percent of Aimovig prescriptions are given out for free. Teva's Ajovy is excluded from Express Scripts.

- **In Cholesterol Lowering.** Repatha (Sanofi) is still under-performing. Its launch price of $14,000 has been cut several times, with a current price of $5,850 (60 percent less). Praluent 1Q2019 sales "missed by a long shot."[26]

- **In Congestive Heart Failure.** At launch, Entresto (Novartis) had a $5 billion sales vision. Current sales are $420 million, and unlikely ever to reach that goal.[27]

Strategy requires a sense of the whole that reveals the significance of the respective parts.

Strategy at a system level is about finding proportionality between the pieces, setting up the right sequence of integration, and benefitting accordingly. You have to fit the mix to the moment, as if setting sound levels on an equalizer or color combinations on a computer screen. **It's the composition of value that determines price and path to alignment with payers and providers.** This approach repositions HEOR (and medical science liaisons) as a keystone to dynamically balance and analyze the unmet needs of key accounts, and bring to market "innovations in the way we assess outcomes with contextual considerations," per Richard Chapman, Director of Health Economics, ICER.[28]

A new health ecosystem becomes a new care standard. The 'positional value' of government is policy innovation, to shift from being "regulator" to becoming a "mediator" between competing economic systems and the production of public value.

New value frameworks become the basis for new economic models. These, in turn, form the basis for new go-to-market stories that combine "drug + infrastructure for outcomes" as equal parts in a new story about health system value. Nutrition, co-morbidities, care navigation, the home environment…all can be visionary new areas to creatively explore, experiment with and sustain as part of collaborative innovation and alignment, not only with key accounts, but also with adjacent markets and government, where **real-world evidence strategy is positioned to help direct State investments into the new health economy designed through system entrepreneurship.**

Where Novartis is flailing with Entresto is seeing economic value only through the lens of drug development and promotion. Novartis customers see value through the lens of integrated care delivery. Here's how Novartis customer Humana is approaching reducing hospital readmission for congestive heart failure, the same metric the Entresto brand team is using to negotiate risk-sharing contracts with payers worldwide:[29]

As part of its strategy to reduce the rates of hospital readmission from congestive heart failure, Humana is creating a new care pathway simultaneously solving for food insecurity and linking nutrition with pharmaceuticals to improve outcomes for people with CHF.[30] *Humana is setting new conditions for the production of health in a way that creates "new member value" and "new capabilities" that lead to innovation-led growth.*

Humana revenue rose 13.9 percent to $16 billion in the second quarter of 2019, reflecting an "outcomes-focused operating model and aligning physician incentives around a holistic view of member health."

"Data" strategy is fundamentally about 'data-on-purpose' – intentionally finding 'space for computability', opportunity to create an information advantage ('specialized cognition') by giving direction to artificial intelligence. The objective is to know things others don't.

In an effort to solve the "we don't have the data" problem (and to compete effectively against Haven Healthcare, the new venture from Amazon + JP Morgan + Berkshire Hathaway), Humana is building its own healthcare infrastructure from scratch to actively cultivate and create its own data. Humana has a team dedicated to harvesting open source data sets from sources spanning the Environmental Protection Agency, the United States Census, the Bureau of Labor Statistics, discharge and utilization data from the Centers for Medicare and Medicaid Services, Worker's Compensation claims and a host of others, connecting them to their extensive internal data sets.[31] The end state is a capability where machine learning and artificial intelligence could be applied to "enable a [progressively] better understanding of patient and community health needs and better knowledge around barriers to health that exist outside of the clinical setting."

This is not about data as exhaust, but **'data on purpose'** to give direction to artificial intelligence and the invention of new health experiences, services and value-based insurance benefits.

In other words, Humana (like Kaiser, CVS Health and Merck KGaA) is designing its own health infrastructure to solve for fragmentation, connect social determinants of health with new payment models and incentive structures for physicians, and **develop predictive models to plan interventions at a whole system level.** The aim is value impact at a broad level, the space Pfizer is now moving into with new executive leadership from IQIVA and a "new mission to engage with health systems in new and novel ways."[33]

For the "drug" industry, inventing a new pricing model based on health ecosystem value requires a re-orientation of economic model development and emphasis: its boundaries should extend beyond "drug" as the only thing that matters in the production of health. Rather than data being created to justify regulatory questions around drug claims (i.e., Is the product safe? Is the product technically sound?), a new value strategy "dissolves" the drug component in a new system of health engagement. The logic is inverted. The thing that leads the pricing negotiation is 'ecosystem value', not the technical merits of "drug."

Fast to find the new is only one half the innovation equation; fast to let go is the other important half.

The Great 21st Century Rearrangement

The tightly-bound company (or country) can't be at the core of deliberation for strategy, not anymore. Call it the great 21st century rearrangement.

The definitions of "enterprise-wide" and "market" dissolve completely, moving beyond the edges of company's/country's assets or its own sources of information, shifting to an ecosystem-centered perspective.

There's a new ambition by government, payers and providers worldwide to collaborate with industry (pharmaceutical as well as medical device) in a process of shaping a different future: co-creating markets and new value, not just 'fixing' markets or redistributing value. It's a wholesale economic reorientation that calls for a different understanding, new initiative and strategic imagination to bring vision and direction to organizations that are operating in markets that demand a whole new approach.

"What's stopping pharma and the NHS working together more often, and in more parts of the UK?"

The question was asked in a new report from industry association the ABPI and the NHS Confederation, written as part of a drive to promote NHS-industry collaboration. The report ('Working with the NHS') identifies some of the persistent barriers to greater collaboration, and candidly surfaces and explores practical challenges, including lack of resources as big an issue as lack of trust of drug companies.[34]

The report recognizes the benefits of collaboration with industry are significant, **"including better patient outcomes, a more sustainable NHS, and a boost to the economy**." The benefits of well-managed and well-targeted joint working projects to patients and the NHS – and pharma -- are widely accepted on both sides, "but these remain relatively few and far between, and frequently do not get scaled up or adopted by the health service in other regions," said Niall Dickson, Chief Executive of the NHS Confederation.

The story is consistent worldwide.

"Oklahoma has dedicated an enormous amount of time to structure value-based contracts with industry that so far have not been very meaningful," said Nancy Nesser, Oklahoma Health Care Authority pharmacy director.[35] The deals OHCA has in place apply to treatments covering a total of approximately 1,700 patients, a meager slice of the 808,000 beneficiaries with coverage through the state. "We've met with 27 pharmaceutical companies more than once, more than twice — most of them we met with at least three times," she said. "And we only have four contracts to show for that."

Louisiana: The Entrepreneurial State

Western governments (as well as China) are increasingly thinking big about health system transformation. They are fundamentally reconsidering their traditional role in the health economy, giving direction for technological change, and investing in that direction. Creating health markets not only fixing them.

"This isn't a race to the bottom based on drug price," said Alexander Billioux, Assistant Secretary of Health, Louisiana Department of Health, **referring to his ground-breaking dialogue with industry for market access** to hepatitis C medicine, "but new forms of transparency and working

together with industry to achieve system value."[36] Billioux is the force behind the state breaking ground and becoming the first in the United States to install the Netflix-subscription model for hepatitis C.

He was describing the posture his team took negotiating with Gilead Sciences, Merck and AbbVie on a winner-take-all RFP (valued at $700 million/year), with an end state Louisiana described in terms of outcomes: the disease being eradicated in Louisiana within five years. It's not just a rogue idea. The 'Netflix-Model' is also being deployed in Washington state and Australia to eradicate hepatitis C, and by the **NHS to address "market failure" in the research and development of antibiotics**.

You can either get in front of change, or become a victim of it

"Having a full pipeline of antimicrobials is critical in our efforts to address antimicrobial resistance," said UK Health Minister Nicola Blackwood, "but currently not enough pharmaceutical companies are investing in the development of new drugs. This project is an important step but it will only address global market failure if other countries do the same, which is why we want to involve as many countries as we can and share our learning from this work."[37]

You can either get in front of change, or become a victim of it. It's notable that none of the hepatitis C players took the initiative and proactively approached Louisiana with ideas for new value frameworks, or the NHS with new economic models.

Isolated pockets of market innovation aside, the default posture by the pharmaceutical market remains, for the most part, reactionary to government and payer initiative and QALY as an economic theory of value. Drug companies are forced to defend an operating model they've been successful with in the past, one that's organized on supporting "drug" development and promotion, instead of selling into the future by developing a new theory of value and a new market in outcomes-based healthcare.

Medtronic: Going Beyond 'Our Value is to be Valuable'

Medical device companies are ahead of pharmaceutical companies in setting objectives for commercial strategy, redesigning financial operations so that it flows in the service of customers, and going 'above brand' with business models and **B2B marketing that tie performance of products and services to payment incentives and customers' operational efficiencies.** The medical device industry, in other words, is working with a comprehensive vision about the production of health that's conceptualized in collaboration with key accounts.

Surgical Care Affiliates, a $2.5 billion revenue company that manages outpatient surgery centers for procedures like colonoscopies **(a $2.4 billion market with "value" for Entyvio)** and joint replacement **(a $22 billion market for JNJ)**, has 215 value-based care contacts in which providers' reimbursements are based on cost and quality measures rather than volume of tests and procedures performed. Caitlin Zulla, chief financial officer at SCA, refers to outcomes-based contracts as "snowflakes" because they're

highly customized, something that revenue-cycle management technology **(a $160 billion market)** can handle easily.

"Value-based care is one of our primary growth strategies," Zulla says. The deals typically have terms of three to five years, and providers agree to hit cost and quality targets that may include infection rates **(a "value driver" Merck was trying to align on with Optum)**, rates of patient readmission to hospitals **(a performance metric for Entresto)**, and the timing of antibiotic treatments **(a service Pfizer could theoretically develop to support its antibiotic business)**. If SCA falls short, the payers get to claw back a portion of the reimbursements.[38]

"This is a big step, and what we bring to this and what Lehigh brings to this are complementary capabilities with the desire to improve outcomes," said Medtronic CEO Omar Ishrak. It has become a blueprint for Medtronic market strategy worldwide and across disease states.

Medtronic, the world's largest medical device company, has **more than 1000 value-based contracts** requiring the company to reimburse hospitals for select costs if its Tryx anti-bacterial sleeve fails to prevent infection in patients who receive cardiac implants.[39] Medtronic goes deep with its strategy to relate intimately with customers, embedding itself in the business of hospitals and providers in order to improve *their* operational efficiencies, accelerate *their* technology innovation, and ultimately create what the customer wants. It strikes long-term deals as learning relationships, where Medtronic and its customers each invest, increasing the "value" twice as fast as one's investment. **The strength of the relationship is built by the information that each is willing to share.**

Early last year, Medtronic inked a partnership with Lehigh Valley Health Network (LVHN), a large hospital network in northeastern Pennsylvania, to try to create — and demonstrate — value.[40] The five-year initiative will couple Medtronic's medical device expertise with Lehigh Valley Health Network's clinical expertise. They'll work together to create new processes to produce health in more than 70 medical conditions, many of which overlap with drug markets.

Medtronic and LVHN aim to reach 500,000 patients in Northeast Pennsylvania and cut costs of care by $100 million. The company wants to help the hospital system develop a new care standard to detect signs of respiratory compromise **(shared market space with AstraZeneca[41])** earlier, with the goal of reducing adverse events by at least 20 percent. LVHN will compare results with existing patient data from its eight Pennsylvania hospitals to measure health outcomes and quantify savings. For some treatments, Medtronic will get paid based on those results.

"This is a big step, and what we bring to this and what Lehigh brings to this are complementary capabilities with the desire to improve outcomes," said Medtronic CEO Omar Ishrak. It has become a blueprint for Medtronic market strategy worldwide and across disease states.

Everything is in the production boundary.

GE Healthcare: Collaborating with Customers to Create Digital Tools

Healthcare isn't technology. No one gains advantage from letting technology

lead strategic visioning. The organizing idea to cohere around is outcomes understood and approached in a way that a competitor does not see, or cannot do. The positional value of all things digital and tech-related is as a commodity input, like electricity.

Technology is a means, not an end. It enables strategic imagination. GE Healthcare is another manufacturer tying payments to real outcomes. They are looking at macro-level outcomes and aligning with clients to help them reduce the costs of care**.** That includes everything from the role GE's imaging products play in providing care to product maintenance and location of devices to optimize utilization. Currently, the company has entered partnerships with six clients that **assume significant risk based on how well products produce outcomes**. Another three partnerships involve analytics-based "command centers" that equip patient flow decision-makers with data to avoid surges and ebbs in care.

The role of technology is as a service to make the customer smarter

Partners HealthCare, a Boston-based hospital network that includes Brigham and Women's Hospital and Massachusetts General Hospital, two of the United States' most prestigious teaching institutions, and GE Healthcare have a 10-year collaboration "to rapidly develop, validate and strategically integrate deep learning technology across the entire continuum of care."[42]

The collaboration will be executed through the newly formed 'Massachusetts General Hospital and Brigham and Women's Hospital Center for Clinical Data Science' and will feature co-located, multidisciplinary teams with broad access to data, computational infrastructure and clinical expertise. The initial focus of the relationship will be on the development of applications aimed to improve clinician productivity and patient outcomes in diagnostic imaging.

"This is about creating digital tools that will have a profound impact on medicine," said John Flannery, CEO of GE Healthcare at the time of the announcement. "By leveraging AI across every patient interaction, workflow challenge and administrative need, this collaboration will drive improvements in quality, cost and access." The process is organized around shared investment and accountability.[43] Over time, the groups will create new business models for applying AI to healthcare and develop products for additional medical specialties like molecular pathology, genomics and population health.

The rule is simple: whoever has the smartest customers wins.

This may require sharing previously proprietary knowledge with the customer (in negotiating with the hepatitis-C players, Alexander Billoux 'opened the state's books' so the manufacturers could see for themselves the finances for Louisiana). It may be as simple as sharing what the company knows about the customer with the customer herself. "The aim is to rebalance the traditional asymmetrical flow of information; almost any technology that is used to market to customers, such as data mining, can be flipped around to provide intelligence to the customer."[44]

The role of technology, in other words, is a service to make the customer smarter.

"The future of healthcare is about recognizing the needs of the system, then aligning technologies, services, and activation of new methods to support the system," GE Healthcare Managing Helen Stewart said. She was describing the strategic intent behind GE partnering with Navicent Health in a six-year shared risk initiative to improve clinical and financial outcomes for Navicent, the second largest hospital in Georgia.[45]

Outcomes first. Inputs second.

Outcomes Happen at a System Level

Value is not a neutral concept.

Strategic transformation for sustainable, high quality growth in the pharmaceutical industry will come from conceptualizing and executing against a new narrative that goes well beyond promoting the technical merits of a physical product. The future is less about using RWE to "get a new claim in the label" (to support drug promotion), more **about experimenting with and actualizing new systems of health and pools of knowledge** in which drug is but one component embedded within a broader health experience.

The strategic shock from a world in transition should prompt changes in thinking and understanding, not minor tweaking at the edges. We need new capabilities, and to evolve the capacities of existing ones, to succeed systemically

The system is the thing to value.

Market boundaries and industry structure are not given and can be reconstructed by the actions and beliefs of industry players. This is what's called *the reconstructionist view*. Assuming that structure and market boundaries exist only in managers' minds, the stories in our heads, practitioners who hold this view do not let existing market structures limit their thinking. To them, new demand is out there, largely untapped. The crux of the problem is how to create it within the context of new markets.

The most valuable innovations are not the ones with the highest performance, but the ones with the highest performance on the widest basis – the "highest per widest." Outcomes happen at a system level – never just one thing, but many things simultaneously and interactively over time. For the pharmaceutical industry, HEOR innovation centers on strategic imagination and leadership to get in front of system change, rather than become a victim of it. In other words, **becoming the invisible mind guiding the invisible hand.**

The point is not to be right at the outset – an almost impossible task – but to be able to adapt as the new strategy unfolds and interacts with the market. Advantage goes to the side that can most quickly adjust itself to the new and unfamiliar environment called outcomes-based healthcare.
Pharmaceutical companies have the opportunity to develop a framework that allows it to shape a new type of health economy by reframing economic thinking creatively. Rather than static discussions framed in the conventional way, they can shape the debate about the actual composition of value that goes beyond isolated interventions and niche impacts; how to invest strategically in key areas, such as research and development, health education, human capital formation (particularly critical given the global shortage in HCPs), and even what will increase a country's GDP.
Said differently, the art of strategy in the next health care will be expressed in navigating the space between value extraction and value creation. It's the composition of value that matters. The end state is positioning to enable pricing based on the production of health over time.

It begins with a new strategy story.

A Disconcerting Synergy

The blow-up-your brain collapse of a $90 trillion global economy tells us more about the foundational fragility of our strategies and strategic thinking that it does about the future of healthcare. It also shows the infinite power of inertia, the incentives buried deep in the bedrock that reward defending the past, which only calcify the legacy model further into the old industrial cortex.

There is a disconcerting synergy at play from all corners. A repeated fragmentation of focus, a scattering of thought and action whose effects register at the self-foundation bounding identity and permission to lead.

The mass of analysis on the 'Future of U.S. Health Care' now flowering from the analysts do little more than skim the shallows of the problem-solution space.[46] We are sitting astride a stark rupture in the historical timeline, a wholesale destruction of contexts.

The next healthcare works with a new system of thought – a different set of cognitive ingredients – that breaks the shell of received opinion, of canned, familiar and tired interpretations of "value" and "transformation." Which is to say the future needs to be presented with a new orientation for strategy to invent.

We are leaking time.

- fin -

Endnotes

[1]"Risk Sharing / Performance-Based Arrangements for Drugs and Other Medical Products" – **ISPOR Short Course Program,** Sunday, May 19, 2019.

[2]"Future and potential spending on health 2015-40: development assistance for health, and government, prepaid private, and out-of-pocket health spending in 184 countries," ***Lancet*,** ISSN: 0140-6736, (2017) Vol: 389, Issue: 10083, Page: 2005-2030.

[3]"Swiss to Take On Big Pharma With Cheaper Cancer Treatment," ***Bloomberg*,** July 28, 2019

[4]"Humana Asked Experts to Define 'Value-Based Care.' They Couldn't Do It." ***FierceHealthcare***, June 14, 2019.

[5]"Defining Value – The Foundation of Outcomes-Based Risk-Sharing Agreements," ***Health Affairs Blog***, March 16, 2019.

[6]Ibid "Future and potential spending on health 2015-40: development assistance for health, and government, prepaid private, and out-of-pocket health spending in 184 countries," ***Lancet,*** ISSN: 0140-6736, (2017) Vol: 389, Issue: 10083, Page: 2005-2030.

[7]"UnitedHealthcare, AMA Push New ICD-10 Codes for Social Determinants of Health," ***HealthLeaders***, April 3, 2019.

[8]"Intermountain Launches Value-Based Care Spinoff," ***Modern Healthcare***, July 16, 2019.

[9]See "Shire to Present New Data at ISTH 2017 to Advance Standard of Care in Hemophilia," Corporate News Release, June 23, 2017.

[10]"NHS England Chief Hails 'Precedent Setting' Outcomes Deal with Merck," ***pharmaphorum***, November 10, 2017.

[11]"Walgreens CEO: Microsoft Will Help Create 'Ecosystem' to Simplify Healthcare," ***Forbes***, January 15, 2019.

[12]"2018 Global Health Care Outlook: The Evolution of Smart Health Care," Deloitte

[13]"It Took a Brilliant Marketing Campaign to Create the Best-Selling Drug of All Time," ***Associated Press***, December 28, 2011.

[14]"How Tech-Infused Primary Care Centers Turned One Medical Into a $2 Billion Business," ***CNBC***, July 28, 2019.

[15]See "With New Gene Therapy, Novartis Assumes 'Total System Leadership," ***LinkedIn*** Post by John G. Singer, May 28, 2019.

[16]"Are Novel Concepts of Value Ready for Prime Time?" – **ISPOR Breakout Session**, Monday, May 20, 2019.

Endnotes

[17]See "MIT Group Brings Together Stakeholders to Brainstorm How to Pay for Curative Therapies Over Time," ***AJMC***, June 18, 2019.

[18]"Industrial Internet of Things: Unleashing the Potential of Connected Products and Services," **World Economic Forum**, 2018.

[19]Ibid "MIT Group Brings Together Stakeholders to Brainstorm How to Pay for Curative Therapies Over Time"

[20]"The Dawn of System Leadership," ***Stanford Social Innovation Review***, Winter 2015.

[21]See "Apple, Amazon and the New Health Infrastructures," ***LinkedIn*** (John G. Singer), October 26, 2017.

[22]John G. Singer "Ecosystem-centered Business Strategy," **2009 3rd IEEE International Conference on Digital Ecosystems and Technologies**

[23]"Sage Therapeutics Should Price Its Experimental Depression Pill on 'Value' Despite Political Pressure, CEO Says," CBNC, July 24, 2019.

[24]"Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale Treatment Access Programs in Developing Countries," ***Clinical Infectious Diseases***, 58(7) (2014), pp. 928-36.

[25]"Cost-Effectiveness Watchdogs Skewer Novartis' MS Drug Mayzent and J&J's Depression Spray Spravato" – ***FiercePharma***, June 21, 2019.

[26]"Praluent's lower list price isn't yielding better sales yet" – ***BiopharmaDive,*** April 26, 2019.

[27]"Novartis' Entresto Flops Crucial Heart Failure Trial, Imperiling $5B Sales Goal," ***FiercePharma,*** July 29, 2019.

[28]"Can Meaningful Models be Constructed for Rare Conditions**," ISPOR Breakout Session**, Wednesday, May 22, 2019

[29]"Novartis Signs on to Value-Based Pricing for Entresto," ***Managed Healthcare Executive***, May 4, 2016.

[30]"Value-based Healthcare Insights: A Payer Perspective," Presentation by Roy Beveridge, Chief Medical Officer, Humana, at ICHOM 2019.

[31]"Humana CEO, Bruce Broussard on Q2 2019 Results – Earnings Call Transcript." Seeking Alpha, July 31, 2019.

[32]"Kaiser to Launch Social Care Network," ***Modern Healthcare***, May 6, 2019.

[33]"Pfizer's John Doyle Champions Value-Based Healthcare" interview on SoundCloud at BIO 2019, published August 1, 2019.

Endnotes

[34]"Mistrust of Pharma Still Blocking NHS Collaborations" – ***PMLive***, June 21, 2019

[35]"In Oklahoma, a Warning for Proponents of Value-Based Pharma Payment" – ***Morning Consult***, February 6, 2019

[36]"Able to Cure, Able to Pay: Closing the Widening Gap" – ISPOR Educational Symposium sponsored by the National Pharmaceutical Council. Sunday, May 19, 2019.

[37]"NHS to Try Out New Subscription Style Payment Model to Pay for Antibiotics," ***Pharmafile*****, July 9, 2019**

[38]"Surgical Firm Drives Growth Via Value-Based Care," ***CFO Magazine*****, May 15, 2019.**

[39]"Medtronic Moves to a New Health-Care Model: Pay Only if it Works," ***Wall Street Journal*****, February 19, 2018.**

[40]"Medtronic Takes Another Step Toward Value-Based Care," ***CNBC*****, February 28, 2018.**

[41]"AstraZeneca Inks Outcomes-Based Contract with Highmark for COPD, Asthma," ***Drug Delivery***, April 17, 2018.

[42]"Partners Healthcare and GE Healthcare Launch 10-Year Collaboration to Integrate Artificial Intelligence Into Every Aspect of the Patient Journey," News Release from Partners Healthcare, May 5, 2017.

[43]"GE, Medtronic Among Those Linking With Hospitals for Value-Based Care," ***Healthcare Dive***, March 29, 2018.

[44]"New Rules for the New Economy: 10 Radical Strategies for a Connected World," Kevin Kelly, Penguin Books, 1998.

[45]"Navicent Health Partners with GE Healthcare on Analytics for Clinical and Financial Outcomes," ***Healthcare IT News***, February 27, 2018.

[46]"Did the Coronavirus Reveal the Future of U.S. Health Care?" Morgan Stanley, May 18, 2020.