The Changing New Healthcare Environment

…and Requisite New Research Approach

Introducing the

TPA NETWORK
Research Consortium

***About* TPA NETWORK**

TPA NETWORk has been at the forefront of innovation in the healthplan administration industry since 1985. Its experience dates back to the beginning of the industry, nearly sixty years ago, when the firm's principals helped to shape and develop some of the earliest forms of group health insurance. **TPA NETWORK** has represented more than two hundred TPAs at hearings before the U. S. Congress; conducted research, published articles and provided guidance on topics of interest to the self-funded community; facilitated more TPA mergers and acquisitions than any other entity; and helped creative companies and entrepreneurs successfully position, package and introduce their innovations to the self-funded market.

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I. THE DRAMATICALLY CHANGING HEALTHCARE LANDSCAPE

Healthcare has entered a new phase of dramatic fundamental change and rapid transformation that will not be slowed by those wishing to preserve the status quo based on fear, uncertainty or doubt. The entry of non-traditional players into the healthcare industry is disrupting existing business channels, redefining future revenue pathways and causing new collaborations and making for strange bedfellows. The digitalization, decentralization and democratization of healthcare will quickly make many currently employed business models, across the entire healthcare ecosystem, outmoded and ultimately obsolete. Moreover, this change is occurring, in large part, as a result of the new and different "attitudes" that they bring from other industries with respect to organization, operations, consumerism, etc.

The following is brief summary of the many ways in which we and "the experts" believe the healthcare industry will change over the next several years and why it is that payors and others in the industry will have to adopt and adapt to these important, game-changing developments.

Record Investment in Healthcare from New and More Diverse Sources

Motivated by the promise and potential of the value-based transformation of healthcare, a record-setting level of investment in new technologies, solutions, services and business models that will facilitate cost reduction, benefits maximization and transparency in healthcare is occurring as there exists an abundance of opportunities in this space that make it exciting and lucrative for many type of businesses. These new investors, many from outside the space and younger, think quite differently than those who have run the industry for decades and they are disrupting things as never before in healthcare.

Introduction and Application of Transformational Technology to Healthcare

Legacy infrastructure overburdens healthcare organizations with excess costs from inefficient, wasteful processes, little interoperability and inadequate analytics. The recent deployment within the healthcare industry of transformational technologies such as artificial intelligence, machine learning, Big Data analytics, blockchain -- and the introduction and adoption of Product-as-a-Service (XaaS), Platform-as-a-Service (PaaS) and (DaaS) Data-as-a-Service business models to the healthcare industry – has caused everyone to rethink their product and services offerings, the way in which they conduct business, and how they will fulfill their missions.

Rapid Movement to Value-Based Healthcare

The term "value" in healthcare been redefined as expectations change with respect to care quality, patient experience, reimbursement models, etc. As a result, our healthcare system is being reevaluated and reengineered to make providing a higher quality of care at a lower cost an essential priority for providers and payor organizations alike. This emergence of value-based reimbursement models has shifted the "risk" from payors to providers which is resulting in what essentially amounts to paradigm shift. Nonetheless, a few years back, the *Health Care Transformation Task Force,* representing some of the nation's largest health systems and payers, pledged to convert three-quarters of their business to value-based healthcare arrangements in short order…and they have. *See expanded discussion below.*

Changing Roles of Payors, Providers and Patients

Long-established, deep-rooted norms, distinctions and roles between and among payors, providers, administrators and consultants are being reexamined and challenged as the entire healthcare ecosystem looks to evolve, adopt and adapt to new models of delivering healthcare and paying for it. As these traditional boundaries dissolve and industry segments morph, the focus of healthcare delivery will move from being process and provider-centric to one that is more participatory, patient- centric and supportive of shared decision-making.

Empowered Healthcare Consumerism

The acceptance of healthcare consumerism has led to greater demand for and access to information and data, increased empowerment and a changed role for consumers of healthcare services, products and healthplans. To better accommodate plan participants, access to healthcare services will have to be less limiting, more accommodating (any time, at any place) and more interconnected to facilitate the modern, integrated experience that consumers have elsewhere, and now expect/demand in healthcare.

Drive Toward Personalized, Evidence-Based Treatment

The approach to, and purpose of, medical treatment will shift from one focuses on symptoms, cures and invasive and episodic care to one that is more predictive and preventive in nature, less invasive and more holistic. Today, there is widespread acceptance that all aspects of medical treatment and care must be based in evidence. The now more pronounced trend toward personalized and precise medical treatments (e.g., precision medicine) is resulting in faster and improved outcomes at a much lower cost. As a result, there will be a movement away from "blockbuster" drugs to more personalized medicines.

Demand to Better Leverage Data

Until recently, it was a *lack of data* that was thought to have hampered our ability to achieve better healthcare outcomes. Today, with the application and increased use of new data-related technologies in healthcare, we can now access the enormous amount of valuable disparate data that resides in multiple siloed systems and to consolidate, normalize, structure and transform it from data that was previously thought to be useless into data that is meaningful, valuable and provides actionable insight. Today, there now exists *an overabundance of data* to consider as even a single patient encounter generates a great deal of clinical, financial, patient satisfaction and administrative data. To successfully navigate the transition to value-based healthcare, data will need to be organized, normalized and safely stored on enterprise-wide platforms; and shared between payors, providers and TPAs by facilitating a high level of interoperability amongst an increasingly larger number of systems.

New Responsibilities Attendant to Data

There now exists widespread recognition that there is a need to employ new technologies to use data as a key means by which to optimize the delivery and purchase of healthcare services. This may be a more complex task than it appears to be in this new, rapidly changing environment that now requires the careful consideration of best practices, evidence, individual preferences and expense. Appreciating the newfound value of data to uncover new, large-scale opportunities to improve care, enhance access and lower costs, healthcare executives place themselves at (competitive, financial, legal, regulatory) risk by basing critical business and healthcare delivery decisions on information and data that is incomplete, fragmented and not truly supportive of a global, all-inclusive perspective.

New and Novel Product, Service and Data Monetization Models

As a result of the fundamental changes that are occurring in healthcare, there now exists new ways to leverage assets (and other non-tangential capabilities and resources) that were previously thought to be invaluable and to monetize them. The industry will see a rapid dissolution of traditional segment boundaries as new technologies are integrated across the board and become the norm, open new revenue streams that will drive sustainability in the healthcare industry. By example, the acceptance of cloud-based systems as the core platform across multiple market segments will enable the healthcare data monetization model.

II. Impact of New Health Innovations

Estimates suggest that as many as ten thousand new health innovation come to market each year, in just the United States alone (the overwhelming majority of which are medical devices) and there is no evidence to suggest we are at all approaching a steady state in terms of the impact of technology on healthcare at all levels. This, coupled with the fact that the life cycle of new technologies is decreasing, creates enormous challenges with respect to the capacity to effectively evaluate and implement them. (See Appendix A: *Emerging New Medical Technologies and Health Innovations*).

Historically, innovations in technology have served to forge the shape of the healthcare system and its capabilities by providing a seemingly perpetual purpose for redefining and advancing the system subsequent to the rapid, wide-spread diffusion of well-financed innovations. This is facilitated by the aligned and mutually reinforced incentives of R& D companies and payors where the former has an incentive to develop innovations that offer an advantage over existing technologies, regardless of the cost. The availability of these new innovations can them become a critical factor in the selection of a health plan, healthcare facility or health system. The availability of these new and better technologies increases the demand for care and associated coverage to mitigate its cost. This perverse mutually reinforced alignment between supply and demand that is peculiar to the United States.

It is interesting to note that innovation and the introduction of new technologies make things better and less expensive in every industry, except healthcare, where the introduction of new technologies may make things better, but increase costs. Yes, in healthcare, innovation actually increases cost. In part, this is because most people are not familiar with these facts about emerging technologies:

- On average, new healthcare innovations and medical technologies improve quality of medical care and medical outcomes (although does not apply to every technology in every clinical use).

- Many new medical technologies and health innovations are either ineffective or redundant and do not improve either quality of care or medical outcomes and it is difficult to discern which are effective and which are not at the time they are introduced or being evaluated.

- On balance, the introduction of new medical technologies and health innovations, increases healthcare costs (although some may actually reduce costs by preventing expensive medical consequences, replacing more expensive alternatives, etc.).,

- The incentives and regulations built into our healthcare system (e.g., reimbursement systems, provider reward structures, legal considerations, patient demands) lead to the under-diffusion of efficacious and cost-effective technologies, and over-diffusion of ineffective and cost-ineffective technologies.

- Despite their love-hate relationship with medical technology and health innovation, Americans cannot get enough; demanding the latest and greatest from their providers (who are generally happy to oblige). On the one hand, new medical technologies, devises and procedure are celebrated for saving lives and improving health status and quality of care. On the other hand, advances in medical technology are vilified as a leading factor responsible for unending escalation of healthcare costs.

- Empirical evidence *(from a variety of studies over the past few decades)* shows that medical technology accounts for one-quarter to one-third of the increase in healthcare expenditures over time, contributing greatly to situation whereby it is simply no longer possible to provide the best available healthcare to every American, regardless of cost.

The situation as it exists relative to emerging medical technologies and health innovations can be better understood when they are classified into one of three categories, defined by their health benefit per dollar of spent, and evaluated as such.

1. Category I, the category with the greatest benefit includes low-cost antibiotics for bacterial infection, a cast for a simple fracture, or aspirin and beta blockers for heart attack patients. Not all treatments in this category are inexpensive however: HIV cocktails are very costly each year after year, but they are very much a health innovation home run in that they keep patients alive, year after year.

2. Category II includes technologies and health innovations (including procedures) whose benefits are substantial for some patients, but not all. A good example of this would be angioplasty, a procedure whereby a stent is used to prop open blocked blood vessels in the heart. It has proven to be very cost-effective for patients when treated within twelve hours of a heart attack, buts is value is questionable for the majority of patients who undergo the procedure later even when the value for them is less clear. In great part, this is because angioplasty is a procedure that is generously well compensated for by our healthcare system, whether it's used correctly or not, which reduces the overall value of the innovation.

3. Category III includes new treatments, technologies and health innovations whose benefits are small, limited or supported by little scientific evidence. These include expensive treatments like proton-beam accelerators to treat prostate cancer, for which the prevailing evidence appears to suggests that there is no known added medical value for this treatment when compared with less expensive treatments. Notwithstanding the aforementioned, if a hospital builds a proton accelerator, at a cost of $100 million or more (making it the single most expensive medical device ever built) it will have every incentive to use it as frequently as possible, regardless of the evidence. As a result, the number of proton-beam centers in the country has skyrockets while the number of patients seeking to use them has not kept up.

Understanding this, it is not "medical technology" or "health innovation" per se that is driving healthcare cost increases, it is the ***type*** of medical technology or health innovation that is developed, adopted and then diffused throughout our healthcare system that central. As it turns out, much of the increase in observed longevity, better health and medical outcomes is generated by Category I treatments while most of the spending growth is generated by Category III. This is not at all surprising in that our healthcare system pays for nearly any technology, at any price, without regard to economic value, a practice which it is uniquely, and perversely, designed to encourage.

Further, despite its cost and impact on healthcare inflation, the use of many advanced, yet common, technologies in healthcare is so far behind other industries that some of the ideas that today's new healthcare innovators and entrepreneurs are pitching feel transported from the late 1990s. We are just now starting to employ simple technologies that have been mainstays in other industries for years. An example of which would be a new device that enables patients to get an idea on the cost of certain medications or procedures, similar to what has been available to shop for airline tickets for years.

III. VALUE-BASED HEALTHCARE FOCUS

Payors and providers desire to provide the best care possible, but the fee-for-service model has failed them because of its perverse incentives for provider to increase the volume of services deliver and no incentive to improve health outcomes. As a result, costs continue to rise dramatically with no commensurate improvement in quality of care. As result, rather than providing the best possible care, payors that continue to persist with a fee-for-service model spend most of their time managing inefficiencies and trying to solve the same problems.

This situation has caused a reevaluation and redefinition of the term "value" in healthcare to accommodate expectations that are changing with respect to care quality, patient experience, reimbursement models, etc. This is resulting in the reengineering of our healthcare system to make providing a higher quality of care at a lower cost an essential priority for providers and payor organizations alike, ergo "value-based healthcare".

Value-based healthcare (a/k/a value-based or evidence-based benefit design) is a demand-side approach to health policy reform and it is catching on in a very big way as the nation's largest payors implement it: some 45% of Aetna's 2016 overall healthcare spend was through value-based care models; in 2014, BCBS plans spent more than $65 billion on value-based care (~ 20% of total medical claim dollars spent); and in 2017, Anthem estimated that nearly 60% of its total reimbursements were paid through value-based care models.

Value-based healthcare promises to benefit everyone. Patients will get better health outcomes at a lower cost. Providers will realize see delivery efficiencies and higher patient satisfaction. Payors will benefit from more effective cost control and reduced risk. Healthcare innovators will price-align their new offerings to patient outcomes. The country will benefit from reduced healthcare spending and better overall health. Here's how.

Value-Based Model vs. Fee-for-Service and Capitated Models

Provider Compensation. In the old models, compensation and success is tied to the volume of healthcare services delivered. In the value-based model, providers are compensated based on patient health outcomes such that the "value" in value-based healthcare is derives from the relative health outcome obtained versus the cost of delivering those outcomes. In value-based care agreements, providers are rewarded for helping patients improve their health, reduce the effects and incidence of chronic disease, and live healthier lives in an evidence-based way. Value-based payment models vary although most can be broadly categorized as being shared savings, bundled payments, shared risk and global capitation.

Plan Design. The value-based care model seeks to increase healthcare quality and decrease costs by using financial incentives to promote cost-efficient healthcare services and consumer choices (by example, discouraging the use of low-value clinical services when benefits do not justify the cost). This is generally accomplished with enrollee cost-sharing and other health plan design elements to encourage enrollees to consume high-value clinical services that have the greatest potential to positively impact the patient's health. By aligning patients' out-of-pocket costs and premiums directly with the value of healthcare services the value-based approach seeks to reduce the barriers to, and provide incentives for, the greater use of high-value treatments (through lower costs to patients) and reduce us of low-value treatments (through higher costs to patients). As such, value-based plans are designed with the tenets of "clinical nuance" in mind, understanding that medical services differ in the amount and quality of health produced and that the clinical benefit and satisfaction derived from a specific service depends greatly on the consumer using it, as well as when, where and how the service is provided.

New Measures. Another key differentiating feature of the value-based model is its reliance upon various measures and indicators. These include quality measures to assess the delivery of care by a healthcare system, facility or provider; process measures to assess the performance of providers re: the provision of care and value-based use of resources and services among their patient base; clinical measures to describe patient health status; measures of causal factors; indicators of patient satisfaction and (the importance of) access; etc.

Challenges of Implementing and Achieving Value-Based Healthcare

Data and *Evidence*. Realizing the benefits of value-based healthcare may not come easy as "evidence" becomes a critical factor to its success. Indeed, the transition to value-based healthcare will require the generation of much, much more evidence than has been previously required. Further, it will require improved and greater availability, transparency and integration of clinical outcome data across all industry participants (e.g., payors, providers, patients, medical device and life sciences companies) to track, calculate, and report on the metrics that define value. It not entirely clear however, exactly what level of evidence will be required and by whom as, in the diverse value-based healthcare environment, payors and providers may have different goals, values or priorities and therefore require different types, levels and quality of evidence. Moreover, they may evaluate that evidence against different measures and over different time periods.

Attitude. Healthcare industry executives, plan sponsors and their benefits consultant advisors must overcome the tendency to overemphasize the importance of cost reduction as, in the value-based model, there needs to be a greater focus on clinical best practices that automatically enable efficiency. It is also well-known that healthcare professionals and administrators are slow to adapt to change and few have the agility, capability and resources necessary to stay current in this arena.

Focus. Whereas in the past, a patient suffering from long term multiple sclerosis would likely benefit most from the measurement of his/her pain, gait and muscle flexibility rather than their compliance with medications. Driven by the imperatives of value-based healthcare, new medical technologies and health innovations (like wearables, measurement apps, remote patient monitoring) will enable the gathering of (now valuable and useful) patient-generated data and patient reports of outcomes much more easily. These will only become adopted and put into widespread use when they become covered by more and more payors (and this will only occur when these innovations are proven to demonstrate that connected care approaches result in a positive and cost-effective impact, as defined by the payor or provider.

Responsibility. Patient must be held accountable for risky health behaviors, non-adherence, etc.

Culture. We must to change the culture of "the doctor knows best" to focus more on patient preference.

Game-Changing Consequences of Value-Based Healthcare

Health Analytics. With a shift in focus away from siloed information hubs to a patient-centric ecosystem comprised of increasingly more integrated partners, health analytics (including data acquisition, algorithms, reporting, etc.) will become paramount.

Alignment. The alignment of technology, industry, academia, government and patient demand.

Personalization and *Patient Engagement*. Cloud-hosted services (backed by machine learning) that are connected to mobile apps and wearable technologies -- and the widespread and effective use of artificial intelligence -- will provide insights that help individuals engage with their own health. This, and the shift to more personalized health, will result in providers and patients co-designing the most appropriate healthcare approaches among available options and pursuing value as the patient defines it.

Value-Based Healthcare and Health Innovation

As it relates to the adoption and treatment of new medical technologies and health innovations, in a value-based system, medical technology and health innovation companies will need to be more evidenced-based in their efforts to demonstrate that their new innovation offers value that is superior to existing offerings. In this regard, as it relates to the research and evaluation of these new medical technologies and health innovations, to achieve buy in from the most healthcare stakeholders, it will be important to design research studies that align all stakeholders with respect to data, methodology, and approach.

IV. Evaluating Health Innovations in a Value-Based World

As noted above, the influx of new health innovations will subside anytime in the near future; in fact, it is very likely that the introduction of new technologies and innovations will actually increase at an accelerated rate and continue to disrupt the healthcare industry fueled by new concepts like value-based healthcare. In this rapidly changing healthcare environment, these questions certainly need to be answered:

"What are the new "metrics" to be used to define and measure "value"?" What is value in healthcare?

"How do we effectively evaluate new innovations within a value-based model"

"How do we migrate from cost-increasing to cost-reducing technology?

"How do we manage problems of scale & cost as technology enables more personalized care?"

"How do we improve adoption of high-value innovation to optimize both quality of care and cost to the plan?"

The answers to these questions must come soon as each day more and more medical technologies and health innovations emerge from pilot testing and into production environments. The evaluation of new health innovations in a value-based environment may be more difficult than initially apparent for several reasons.

Absence of Useful Research

Unbelievably, *less than two percent* of the available studies conducted on new medical technologies either evaluated or compared them to those presently employed treatments, that work just as well, but cost less. (But why should they: providers and patients are isolated from the actual cost of treatment and healthplans generally pay for anything?). Further, these studies are of little value because many included serious design flaws. By example, in many cases, the economic impact of a medical technology is often based on the price paid for the purchase of a piece of equipment or medication or the procedure fee paid to a provider. As a practical matter, the total economic impact of a new medical technology or health innovation should actually be measured in much more broad terms that consider and reflect the real world factors of offsetting savings and induced costs.

- An all-inclusive approach toward medical technology assessment would include, by example, not only the actual capital cost of the subject technology itself but also all of the implementation and operating costs attendant to the technology which, often times, are greater than the original capital investment because of the associated implementation, operating, administrative and supervisory personnel; technology-specific training, expanded insurance, additional supplies and space. These factors need to be considered when assessing a complex new technology versus a new medication of medical device that may be more expensive to purchase but be less expensive to administer.
- The adoption of a health innovation can affect the utilization of other healthcare services, effects that are what can be characterized as the "induced" costs/savings of a medical technology. By example,
    - the addition of a new medical imaging device may lead to the increased ordering of other tests to confirm a diagnostic that would not otherwise have arisen or, alternatively, it may cause there to be no further need for other diagnostic procedures;
    - the use of a new diagnostic test may induce a treatment that would not otherwise be considered; or identify an alternative course of action to avoid a treatment;
    - new medical technologies, and their induced procedures, may cause complications and side effects that require further tests and treatments; or complications and side effects may be avoided with a new medical technology that offers a safer clinical strategy than otherwise possible;
    - new technologies and health innovations that extend life may require more extended periods of care, often in institutional settings and at considerable expense; yet they may prevent disease and save resources that would otherwise be spent for diagnosis and treatment (recognizing however, that the common opinion is that few preventive technologies are actually cost savings).

Lack of Evidence-Based Research

If there isn't much useful research on new medical technologies and health innovations, there is going to be less that can be considered "evidence-based" as that term is being used in the value-based healthcare discussion

Need for Universal Definitions

As it relates to healthcare technology assessment, there is a lack of commonly used definitions. By example, the term "medical technology" has traditionally been defined rather broadly to include drugs, devices, surgical procedures, and the organizational support systems within which medical care is delivered. A more expanded version of the term "health innovation" may be more applicable in the new value-based construct as it would possibly include new direct clinical care approaches (such as diagnosis and treatment protocols); innovations in health care delivery, organization and financing; health interventions intended to change health awareness, lifestyle, diet, or environmental exposures; medical and assistive devices and technologies, behavioral change strategies, etc. The term "value" is also a moving target and will likely continue to evolve as the new value-based construct is implemented on a more widespread basis and refined. This evolving definition of value will likely be based on changing clinical, financial and preference factors.

Necessity for Common Measurements

Whereas in the past we have been comfortable with the notion of using "cost-effectiveness" as an appropriate criterion for measuring and guiding the adoption of new medical technologies and health innovations, on occasion, other gauges have been employed as a supplemental means by which to temper what might otherwise appear to be an entirely quantitative approach to determining value (e.g. taking into consideration items such as nondiscrimination and equity as it relates to the disadvantaged).

In the future, a new and evolving definition of value will likely result in technology assessment measures that are not only quantitative but also somewhat qualitative incorporating more fundamentally various clinical, financial and preference factors. These new measures will be the ones by which the assessment, adoption and diffusion of new medical technologies and health innovations will be evaluated in the value-based world. This will also encourage medical technology and health innovation evaluation across multiple dimensions of value, especially ones that extend to beyond just price.

Competing or Misaligned Incentives

As discussed in greater detail below, a core tenet of value-based healthcare is the need for realignment of all of the participants in the healthcare eco-structure. In the transition from a *volume*-based to a *value*-based system (where better medical outcomes, lower cost, increased patient preference, etc. are now a key consideration), there is a need to identify these misalignments and to provide guidance in reducing and mitigating them to payors, plan sponsors and plan participants alike. On the supply side, the transition to value-based care has equally important implications. Medical device manufacturers, by example, will want to focus more on developing medical devices that optimize care deliver in ways that ascribe to the new definition of value in healthcare. Also, in that the transition to value-based care shifts the financial risk from payors to providers, it will require them to change how they evaluate innovation as they will be forced to seek the means by which to improve the quality of care of their patient populations so as to reduce cost the cost of delivering care and thereby their financial risk. Care will have to be taken with respect to the performance measures and financial incentives used in these payment models so as not to encourage the continued use of treatments, therapies and medical technologies that either serve to save money in the short term or improve care in accordance with a value definition that relies on too narrow a set of quality measures that might potentially limit patient access to new health innovations.

V. NEW APPROACH TO HEALTH INNOVATION ASSESSMENT

Distinct and apart from the fee-for-service and capitation-based healthcare models, value-based healthcare comes with an inherent responsibility to overcome the historical, ongoing and persistent reluctance of both the medical community, and the public at large, to come to grips with the fact that the unimpeded acceptance and adoption of the perpetual torrent of new and costly medical technologies, health innovations and therapeutic strategies – without regard to value – is recklessly leading to the unsustainability of our healthcare system and thereby requiring that difficult decisions be made regarding the fundamental values and practical aspects of health care delivery. Some of these are discussed below.

Developing a New Definition of Value

"Value" and "values" have been present in healthcare since the beginning: what is new about the value-based movement is its focus on placing value/values at the center of healthcare as a means by which to ensure that limited resources are used to provide the greatest possible benefit (value) to patients. Until recently, the basic value equation has been: value = benefits/costs. As this is a dynamic versus static process, the term "value" will continue to evolve as the new value-based construct is implemented on a more widespread basis and refined.

In the past, value was often referred to in the context of being "efficacious" and "cost-effective". As a result, new medical technologies and health innovations just needed to prove that they were both and they were typically accepted, adopted and covered; the concept of comparing a new health innovation to the status quo with respect to "value" was unheard of. In today's new and evolving healthcare ecosystem, what represents value is often related to whose perspective is taken and what the decision context is…whether that be from a perspective of patient, payor (public, commercial or individual), provider, manufacturer, society, etc. Further, how each of us understands and defines "value" differs based on a multitude of factors, including our role (patient, clinician, or payer), health status, demographics, geography, and economic situation.

Understanding this, an important challenge in defining value is to understand how value differs for each stakeholder and appreciating the need to learn to capture measures of value that align with each definition.

- For payors, value may be defined by resource utilization
- For providers, value may found in improved workflow management and clinical outcomes.
- For patients, however, value may be tied to the experience and care outcome.

In the value-based healthcare world there is a greater recognition of what patient's value when defining health and care outcomes and allocating limited resources. Indeed, one of the goals of value-based healthcare is to empower patients to be better stewards of their own health. As such, value in the future will be based on clinical, financial and patient preference factors.

Developing a New Value Assessment Framework

The transition to a value-based model necessarily brings with it a need to develop a new "value assessment" framework with an eye toward drawing a relationship between price and perceived value; developing a broader set of quality measures; and defining new dimensions of value. Unlike in the past when only efficacy and cost-effectiveness were assessed, in the value-based model a solid, consistently administered and independent value assessment process is critical to actually evidencing value.

To address these challenges, there is a need to create a (ERISA-cognizant) "value assessment" framework with an eye toward drawing a relationship between price and perceived value; developing a broader set of quality measures; and defining new dimensions of value. The development of this system should serve as a catalyst for ERISA-based to transition to value-based model by providing proof of value.

There will be a need to shift the focus of existing measures from process to patient outcomes. The concept of patient-centered measures embraces the notion that optimal outcomes are achieved when they are personalized to incorporate patients' and caregivers' individual goals and the value they place on possible outcomes. These patient-centered measures include patient experience, quality of life, improvements in functional status and evidence-based behavioral interventions. They will be used to provide information that will help patients and their providers make informed healthcare decisions in assessing the value of healthcare options.

A value-based approach to healthcare recognizes that an individual's perception of "value" isn't based on a universal definition. Clinical benefits, risks, and costs will vary across patients. By example, one patient may prefer a more efficacious treatment despite more side effects, while another may prefer a less efficacious treatment having fewer side effects. Understanding this, instead of measuring quality and cost, in a value-based system outcomes and experiences should be measured; the patient's view of their healthcare experience should be measured; and whether or not a patient is able to lead a healthy, productive life should be measured.

At the same time, while effectiveness (efficacy), cost-effectiveness, quality of life and satisfaction of personal preferences are of great importance, it is possible for a medical intervention to be all of the above, but still of limited value for an individual patient. By example, the recommendation of heart surgery to an older patient whose main concern is becoming tired after a brief stroll may rightly qualify as the provision of an evidence-based, cost-effective and high-quality treatment, it still does not give the patient the outcome they value. In a value-based system, providing care to patients that does not add value from the patient's perspective is not only wasteful it could lead to more harm than good, as all healthcare is associated with some amount of risk. *This is yet another reason why there is a need to expedite the widespread us of pharmacogenomics to identify those medications that could result in the prescribing of enormously expensive medications when others would do as well or better…or cause harm.* The underutilization of healthcare services also reduces value, as patients do not receive care that adds value to their lives, which may also lead to greater cost down the line. A value-based approach focuses on funding procedures of the highest value to patients to try to make the best use of limited resources and to avoid waste with the use of low-value interventions. *This is key in an ERISA environment where the prudent, reasonable, fair and equitable use of plan assets is paramount.*

Presently, there are more efficacious and cost-effective interventions, medical technologies and innovations available than can be afforded. A new way of thinking about the optimal use of resources is needed, and it may be here in the form of value-based healthcare. Ensuring that limited resources are used for healthcare services that provide outcomes that patient's most value, rather than a focus just on efficacy and cost-effectiveness, will help to ensure that resources are used optimally. Value-based healthcare puts what patients value front and center by helping to ensure that they receive the care that can provide them with outcomes *they* believe to be important and that limited resources are focused on high-value interventions. Value may need to be defined in a flexible, personalized and tailored way.

In the value-based world value cannot simply be measured in dollars and cents; it must be measured in terms of one's overall quality of life and the patient's personal preferences. As such, we need to shift from traditional metrics such as mortality rates and quality-adjusted life-years (QALY) gained and move towards tracking patient-focused outcomes and preferences. Today, value involves measures such as clinical outcome (improving blood test parameters) and system-level outcomes (reducing the level of non-attendance at outpatient clinics). In a value-based system the focus will shift to patient outcomes (improving an individual's quality of life) and population outcomes (reducing health inequalities).

Cost-Effectiveness Analysis, Value-Based Healthcare and ERISA

As a nation, in the aggregate, we are worried about the spiraling cost of healthcare. Individually, we are worried that we will not have access to specific medical interventions because our health plan may not pay for it. Reflecting this incongruity or paradox, with no consensus about the "appropriate" techniques for gauging the value of (current or emerging) medical interventions, medical technologies and health innovations), methods such as cost-effectiveness analysis are not used for making decisions about federally sponsored healthcare. That is not the case however with respect to value-based health.

As stated elsewhere, healthcare appears to be the only industry where the introduction of new technology and innovation actual increases costs rather than decreases it. Given this, if each new medical technology or health innovation increases healthcare costs, the question facing the healthcare industry (and society in general) is how much new technology and innovation is appropriate? To answer this question, some standard criterion has to be established and agreed upon as to what is "appropriate". If we assume that the objective of innovation in healthcare is to improve health outcomes, then each new clinical application of the innovation, theoretically (or ideally), should lead to an improved health outcome and, the more we spend on new technologies and health innovation the more the overall health of the subject population should improve. However, in the real world, we know that each use of such new technology utilizes scarce and limited healthcare resources…and there are diminishing returns at the margin and the higher the incremental cost per additional unit of health improvement.

Given this reality, the criterion for resource allocation that logically follows from this construal of the objectives of advancing health innovation is the construct of cost effectiveness: if a new medical technology or health innovation produces health outcomes at a lower cost per unit than the existing technology, it should be adopted; otherwise, it should not. The guiding principle being that those clinical practices and interventions having a low cost per unit of health benefit should have priority over those practices and interventions having a higher cost per unit. Whereas cost-effectiveness analysis is relevant to, and has been used, in policy making for clinical care interventions applied at the population level (using measures of life expectancy and quality of life), it has not been generally thought to be widely employed as a decision-making tool for individuals in their assessment of healthcare value, but this is likely to change as it becomes more common as payors shift the burden of healthcare decisions to the individual under the value-based healthcare model.

The employment of cost-effectiveness in the measurement of value within the value-based environment is entirely appropriate as it is comparative in nature in it assessment of the comparative impacts of expenditures on different health interventions. Essentially, it compares the health effects that result from alternate uses of a given amount of healthcare resources. Cost-effectiveness analysis measures incremental effects, so the impact on health is measured by differences in quality attributable to the intervention as compared with the alternate choice. As such, *the appropriate measure should be incremental cost-effectiveness: the difference in costs due to using one intervention instead of another divided by the difference in their health outcomes.*

A barrier to applying cost-effectiveness analysis to new technologies generally is that decisions about adoption often are required before satisfactory data on effectiveness or even full cost are available. This is something that needs to be immediately addressed, especially as it relates to its potential implications in an ERISA setting.

Need for New Health Innovation Research and Assessment Process: Comparative, Value-Based Effectiveness Research (CVER)

As noted above, *less than two percent* of the available studies conducted on new medical technologies either evaluated or compared them to those presently employed treatments, that work just as well, but cost less. Further, these studies are largely of little value because many included serious design flaws. By example, in many cases, the economic impact of a medical technology is often based on the price paid for the purchase of a piece of equipment, a medication or a fee paid to a provider for a procedure. (As a practical matter, the total economic impact of a new medical technology or health innovation should actually be measured in much more broad terms that consider and reflect the real-world factors of offsetting savings and induced costs.) It follows that there is almost no medical technology or health innovation research that is "evidence-based" as that term is used in the value-based healthcare discussion. *Lastly, there appears to be no past research, or current research, being conduct is specific to the ERISA community, largely because of conflicting interests and regulatory constraints.* Given the situation described above, as it relates to value-based healthcare, we believe that the most appropriate research and new health innovation assessment process would be a variation of Comparative Effectiveness Research (CER) known as Comparative, Value-Based Effectiveness Research (CVER). To understand why this is the case, it is important to understand CER. It is with this in mind that we embarked upon the creation of the **TPA NETWORK Research Consortium**.

To begin, the mission of CER appears to be so logical as to be self-evident; to provide comprehensive resources regarding "interventions" for patients and clinicians to better inform decisions between alternate management strategies for disease, that go beyond efficacy and objectively examine their real-world effects and outcomes. "Interventions" include not only the elements of direct clinical care such as diagnosis and treatment protocols, but also innovations in healthcare delivery, organization and financing, as well as interventions intended to modify health awareness, lifestyle, diet or environmental exposures. The key elements of CER are (*a*) direct head-to-head comparisons of active treatments; (*b*) study patients, clinicians, and interventions that are representative of usual day-to-day clinical practice; and (*c*) a focus on evidence to help patients, clinicians and policy makers to make informed choices care tailored to the characteristics of individual patient.

As a logical consequence of the CER, and as a result of the increased momentum of patient-centered care, the Patient Centered Outcomes Research (PCOR) model of CER appeared and introduced another facet to understanding value that recognized studies about group-based (average) treatment benefits are inadequate to guide clinical decision making at the individual level. This approach recognized that not only do we seek to understand clinical heterogeneity so that treatment effectiveness can be better tailored to individual characteristics, but also the patient's perspective – their preferences for different treatments – are a crucial part of the value proposition in healthcare.

Despite the seemingly self-evident mission and promise of CER, significant constraints have actually been codified into the PCOR model of CER, which is emerging as the de facto method for conducting CER. Unfortunately, as it relates to its use in value-base healthcare assessment, the current PCOR approach to performing clinically relevant CER may be a suboptimal approach. In great part, this is because the law governing PCOR Institute (a government-sponsored organization charged with investigating the relative effectiveness of various medical treatments established as a part of the Affordable Care Act) prohibits it from developing or employing "a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of healthcare is cost effective or recommended". Indeed, according to PCORI Executive Director Joe Selby, *"You can take it to the bank that PCORI will never do a cost-effectiveness analysis." Given this position, it is doubtful that the recommendation of PCORI will be of much value to ERISA plan sponsors wishing to implement a value-based healthcare program where (unlike in the insurance and managed care sectors) the prudent (equitable, reasonable and non-discriminatory) use of plan assets is required.*

Notwithstanding the aforementioned, the good news is that this limitation is not inherent to CER but rather to the PCOR and its "safe" incarnation. Indeed, another hybrid form of CER has emerged that facilitates semi-quantitative comparisons across the domains of cost, benefit and value as it by including a comparative "effectiveness" dimension which enables the critical examination of efficacy, quality of life and cost in the context of the basic value equation (value = benefits/costs). This more critical form of CER is "comparative value-based effectiveness research" (CVER), an approach we intend to employ.

As it relates to process, (as discussed in greater detail below), we intent to utilize pragmatic trials, as they arguably combine the advantages of randomization (high internal validity) and observational research (high external validity). Pragmatic trials (also called practical trials) are effectiveness trials; they study interventions in typical practice and in typical patients, another foundational feature of CVER. Because pragmatic trials are, by definition, intended to inform decision makers, they align with the goals of CVER. They contrast with efficacy trials, which establish whether an intervention works under ideal circumstances and which typically exclude patients with comorbid conditions, advanced age, and other features. In a pragmatic trial, study patients have the typical comorbid diseases of those who receive the compared treatments in usual practice, and their demographic characteristics closely resemble the typically treated patients (or the study may oversample key demographic groups). They compare active treatments provided in typical hospitals, outpatient settings, and practitioners. The researchers choose the outcome measures to meet the needs of decision makers, sometimes using decision analysis to identify the factors that should sway the decision.

Adopting Value-Based Healthcare: The ERISA Complication

This discussion is intended to address some of the legal and regulatory compliance concerns facing TPAs, plan sponsors and others in the self-funded ecosystem as they transition to value-based healthcare and prepare to deal with the wide scope of novel issues that are inherent to it and the emerging new health innovations that challenge the status quo that need to be viewed and handled differently that in a fee-of-service setting.

The *Employee Retirement Income Security Act of 1974 (ERISA)* was enacted to encourage employers to sponsor benefit plans and minimize potential conflicts with existing state laws. As a result, the regulation of employee benefit plans falls primarily under federal jurisdiction. ERISA is extremely relevant to healthcare law and policy because approximately half of the country's population has employer-provided health coverage.

The transition to value-based healthcare, and the handling of new health innovations in that new setting, creates special concerns for those plans that are regulated under ERISA (that may not exist for fully insured and managed care plans). This is because a strong argument can be made that the regulatory compliance requirements under ERISA for employer healthcare plan sponsors are more encompassing, burdensome and onerous than those imposed on insurance companies and managed care entities by their state regulators. In great part, this is for one simple reason: the premiums and employee contributions paid to insurance companies and managed care organizations become the property of the insurer or HMO once collected. Under ERISA however, these monies immediately become "plan assets" and have to be handled in a very particular way.

ERISA protects participants by requiring that those persons who exercise control or authority over plan assets or the plan's management do so subject to fiduciary responsibility. Under ERISA, the plan must be managed for the exclusive best interest of the plan's participants; all expenditures must be prudent; and all payment and expenses must be reasonable. This is critical as it pertains to the adoption of value-based healthcare by ERISA plan sponsors as, under this construct (versus the fee-for-service model), not all healthcare services are treated alike with respect to freedom of access, reimbursement and choice. In most cases, current ERISA compliance approaches are still geared to the old healthcare model with few paying attention to the need to readjust their compliance approach to reflect the potential new risks on the horizon. Moreover, while certain kinds of violations of ERISA are blatant and obvious, violations often arise in complex and challenging situations such that even diligent and well-intentioned plan sponsors can find themselves as defendants in lawsuits alleging a breach of their duties under ERISA. These lawsuits can impose personal liability on fiduciaries.

The perception that the fee-for-service model is evil and largely responsible for what is wrong with healthcare care today has become convention. However, some do not agree that value-based healthcare is the solution. They argue that proponents of value-based care say they want to control provider incentives because they don't trust providers to act in the patients' best interest. Instead, they ask patients to trust that providers will spend limited plan assets wisely on their behalf, when in fact, they will make more money if they spend *less* on their patients. They argue that a model that rewards patients for opting for more efficient healthcare delivery interventions could be a successful strategy for aligning providers and payors and lowering cost but, on the other hand, it could lead to patients electing treatment options spurned by the lure of shared savings incentives that could work against them if they require and truly need higher levels of treatment.

In this regard, payors and plan sponsors alike may not fully appreciate the risk to the plan participant that particular healthcare needs will not be covered or that the "affordable" coverage (made possible by the move to value-based healthcare) may be viewed (by a defense attorney) as compromising quality or the participant's choice of provider. While these may not appear to be reasonable, or even logical, criticisms of the new model, it's not difficult to image an attorney making such a case in court, possibly winning. Now is a good time to remember the famous saying of NY State Chief Justice Sol Wachtler that a grand jury could "indict a ham sandwich" if it wanted to.

Understanding this, the following is list of regulatory concerns, issues and challenges that payors and plan sponsors should consider as they make the transition to value-based healthcare and consider the adoption and implementation of new medical technologies and health innovations.

- There is a need, and possibly an obligation, for ERISA payors to stay abreast of emerging new health innovations, and to be able to evaluate them as efficacious and cost-effective means of treatment.
- A payor's or plan sponsor's decision not to implement proven healthcare solutions may open them up to patient concerns that they have failed to actively manage their healthcare plan.
- Legal, ethical and policy implications may result from the promotion of short-term cost savings (but increased cost in the long term) because of the consequences that could arise from complications, health deterioration or the need for the patient to seek out additional medical care.
- Short and long-term term issues may arise related to delaying the adoption of a new medical technology of health innovation in the hope that the plan participant may be employed (or alternatively covered) by a different employer with different policy (with the idea being to essentially transferring the risk).
- Risk and liability may arise when payors and plan sponsors realize that a "one size fits all or most" approach to healthcare conflicts with evidence-based therapies and treatments.
- Challenges related to provider buy-in and the impact of engaging with payors over denials resulting from plan documents that do not have up-to-date polices and provisions relating to new medical technologies and health innovations may arise (perhaps creating liability re: treatment delays and suboptimal therapy.
- Optimizing utilization and effectiveness in the value-based setting requires the development and timely dissemination of educational materials to support industry ecosystem partners, plan sponsors, brokers, consultants and plan participants. Not acting accordingly may create unnecessary risks in this regard.
- Issues having consequences may arise related to the approval of a new technology on case-by-case basis.
- Issues with significant consequence may arise in the adoption and implementation of new medical technologies and health innovations relating to discrimination, privacy and security.
- Compliance issues may arise related to the imprudent use of plan assets.
- The adoption of value-based healthcare and new health innovations will require many key plan document terms to be redefined including "medical necessity", "experimental", "investigational" and "value". Plan procedures, policies, practices and protocols must be reconsidered and new terms defined related to under what conditions and circumstances "coverage" is extended to include new health innovations
- A host of issues arise with respect to how the adoption of some new innovations may create concerns and risk related to the plan's use, or not use, of them. By example, it is conceivable that a payor could be placed at risk for failing to adopt and effectively implement PGx testing causing the patient to believe that, as a result, a potentially preventable medical condition or situation developed. Likewise, a patient experimenting with "recreational genomics" may read the results and start to question their health status and/or health risk, requesting something of the plan based on an inaccurate or imagined cause. Payors would be wise to anticipate these situations and take pro-active measure to mitigate the risk they pose.
- Re: PGx testing, new protocols will need to be created to protect against the disclosure of genetic information in the underwriting process (e.g., Individual Health Questionnaires (IHQ's), renewal claims data) including sharing deidentified patient data in aggregate terms that does not disclose specific PHI.

At this early stage in the transition to value-based healthcare, it is uncertain as to which of the issues identified above should cause the most concern. It is however clear that the move to the value-based model will increase the compliance burden on payors and plan sponsors alike and cause them rethink their current FFS-oriented procedures, policies, practices and protocols as it relates to compliance in the new value-based world order.

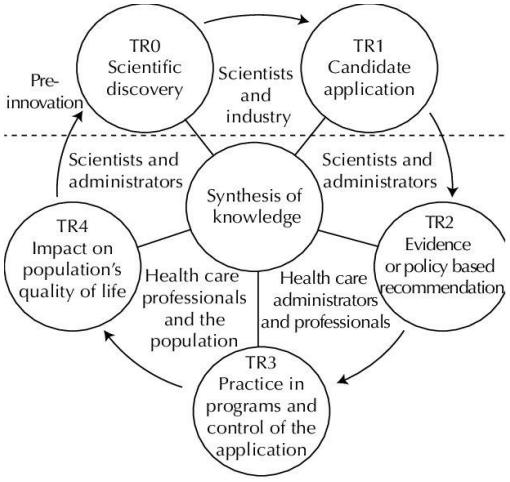
VI. Research Consortium HEALTHCARE TRANSLATION SERVICES

Below is a description of the **Research Consortium**'s services and competitor organizations.

Translational Research

Healthcare "translation" is defined by the NIH as "the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and populations, from diagnostics and therapeutics to medical procedures and behavioral interventions." Essentially, it looks to "translate" findings in research into medical practice, meaningful health outcomes and enhance human health and well-being.

In that translational medicine seeks to coordinate the use of both new knowledge in clinical practice *and* to incorporate clinical observations into scientific hypotheses in the laboratory, it is bidirectional in nature, encompassing so-called bench-to-bedside factors (aimed at increasing the efficiency by which new therapeutic strategies are developed through basic research are tested clinically) and bedside-to-bench factors (that provide feedback about the applications of new treatments and how they can be improved). Translation often implies the expediting or acceleration of the assessment, adoption, implementation (and possible commercialization) of into clinical medicine to close the gap between "what we know" and "what we practice." The benefits of translational medicine are realized on a timeline measured in decades, versus other research which often focuses on achieving shorter-term results without pretense of generating gamechanging results.



A full discussion of the typical translational research process is beyond the purpose of this document however, this graphic illustrates the five stages of translational research, the interested and involved parties and the multi-stream framework.

The increased interest in translational medicine services has been fueled by the need to deal effectively with the torrent of new medical technologies and health innovations migrating from the workbench and into practice. The increased interest is also driven by the lack of available, adequate research; and a lack research facilities focused on the comparative evaluation of new innovation for the value-based construct. These issues and challenges can be overcome with translational medicine, thereby leading to the more rapid validation of new medical technologies and health innovations.

The **RESEARCH CONSORTIUM** will conduct innovative, high-impact, translational science projects by building interdisciplinary, multi-institutional research teams including investigators from the basic, clinical, and applied sciences. Essentially, the initiative that we are embarking upon will look to use, refine and possibly even develop new methods and tools by which to translate emerging health innovations into practice; provide a means by which to determine the value and effectiveness of those innovations; and help to break down the barriers that slow the wide-spread adoption rate amongst patients, providers and payors alike. To accomplish our translational research objectives, we will focus on developing resources and services that facilitate comparative value-based effectiveness research (CVER) aimed at improving the and adoption of research evidence into clinical practice. We look to translate discoveries into practice, break down the barriers that slow the process of determining the effectiveness of those methods, and work to bring about change that improves human health.

We are particularly interested in those health innovations for which there is a bias or skepticism on the part of the general public, providers and payors with respect to the efficacy and cost-effectiveness of the treatment. As such, our first health innovation focus is on pharmacogenomics (as it is the foundation of value-based health-care) and our next study will likely focus on *CBD/Cannabidiol* as means by which to effect opioid substitution in the management of chronic pain. Other future focuses may be on health wearables, mobile technologies.

Graphic Source: Angélica Baptista Silva, PhD in Public Health, and Professor at the Federal University of Rio de Janeiro

Alternative Service Providers

For TPAs and plan sponsors, little exist in the way of affordable new technology and health innovation assessment and translation services and *nothing exists as it relates implementation support and case management services as envisioned herein.* While the largest payors have the resources needed to perform these functions in house – or engage the services of high-end research firms – most TPAs are small companies with limited means and they can only follow the "big boys" or wing-it. Further, TPAs want products and services designed for them…not insurers or HMOs…ergo our belief that our offering will be unique. The following is a discussion of the **Research Consortium*'s*** competitors and their alternative translation services offerings.

- Pharmaceutical, Therapeutics & Medical Technology Assessment Committees

  It is imperative that all payors perform the requisite due diligence in evaluating the clinical, financial, operational and strategic impact of new technologies on payors, providers and patients. Understanding this, most of the large health insurers, managed care organizations and public/government payors have *Pharmaceutical, Therapeutics and Medical Technology Assessment Committees* that are responsible for systematically evaluating new pharmaceuticals, therapeutics and medical technologies; new applications of existing technologies, and new uses of existing pharmaceuticals using evidence-based processes.

  These committees often assume they will be covering the same group of patients a decade from now and focus on the best long term interest of the patients. They use an evidence-based decision-making process, putting stronger emphasis on clinical data than expert opinion. Besides evaluating the efficacy and safety of drug treatments, in the past prior to the adoption of the value-based model, these committees also made a value judgment about cost vs. benefit. The committee's goal is to objectively evaluate the clinical, financial, market and operational impact of new medical technologies and health innovations on the payor.

  In evaluating the medical necessity or investigational status of new or existing services and procedures these committees may include, but not limit their consideration to, electronic literature searches; independent technology evaluation programs and materials published by professional associations, technology assessment entities, appropriate government regulatory bodies; national physician specialty societies and associations. These committees are typically staffed by an interdisciplinary team of key stakeholders that often include a consumer representative; clinical leaders; epidemiologists and representatives of specialty services, pharmacy and therapeutics; an attorney; clinical review and appeals experts (and may also seek input from specialists and professionals relevant to the topic under review).

- Private Translation Service Organizations

  Many large-scale payors use third-party medical-evidence-based information companies like the Emergency Care Research Institute (ECRI) which provides member organizations with broad access to health technology assessment information and research results to make decisions about medical devices, drugs, procedures, systems of care and behavioral health interventions that are based on the best analysis of available evidence. Its *Health Technology Assessment Information Service* functions as a member-funded co-op for the development and dissemination of evidence-based health technology assessments.

  Hayes, Inc. focuses on evidence-based assessments of emerging health technologies on behalf of its (hospital, healthcare system, government agency and health plan) clients. It evaluates a wide range of medical technologies and clinical programs to determine their impact on patient safety, health outcomes, resource utilization and return on investment. Hayes consultants also sit on health system committees to provide insights and support around clinical issues, policy decisions, clinical standards and best practices.

  The Institute for Clinical and Economic Review is a non-profit organization that evaluates drugs and their cost-effectiveness. In large part, it is funded by the insurance industry. Though it claims to be unbiased and patient-focused, *it is alleged* that ICER consistently ignores patient reported outcome data when compiling its reports, the results of which are framed in a way that benefits its insurance industry funders.

APPENDIX A:

Emerging New Medical Technologies and Health Innovations

The following is a list, in no particular order, of new medical technologies and emerging health innovations that are in various stages of development and diffusion. Several, have already been put into clinical use.

- Precision Medicine and Personalized Care
- Genetic/Genomic (DNA) Testing (Diagnostic, Prognostic, Rx)
- Medical Cannabis and Cannabidiol (CBD)
- Medical Wearables / Wireless Monitoring
- Capsule Endoscopes
- Bluetooth-Enabled Smart Inhalers
- Tele-Nutritionist and Tele-Dietitian Consultations
- Remote, High-Risk Patient Monitoring (RPM)
- Nutrigenomics (i.e., which foods to eat and to avoid)
- Non-Invasive Liquid Biopsies
- Companion Diagnostic (CDx) and Biomarkers
- Neuroscience-Based Wearable to Treat Obesity
- 3-Dimensional Printed Body Parts (stents, casts, bones)
- NeuroAD Therapy System (to treat mild Alzheimer's)
- Scalp Cooling (to reduce chemotherapy hair loss)
- Implantable Neuromodulation Device (re Sleep Apnoea)
- Medications to Treat Hearing Loss
- Virtual Primary Care and Robotic Check-Ups
- Regenerative Treatments for Orthopedic Injuries
- Needle-Free Drug Delivery Technologies
- Advanced Implantable and Bioresorbables Devices
- Embracing New Attitudes Toward Health Data Ownership
- Using EMR, Lab and Radiology Data in Plan Management
- Facilitating Patient Contributions to Medical Research

and Re-Assessing the Cost-Effectiveness, ROI, Value and Outcomes of Questionable Treatments e.g., dialysis, chemotherapy, spinal injections, hormone replacement therapy, elective C-sections, PSA screening, unneeded CTs, ultrasound and pre-op tests, etc.)