ABSTRACT. This paper examines the future of U.S. healthcare industry. The paper identifies a collection of unprecedented forces that will dramatically reshape industry boundaries, structures, and practices over the next two decades. Key findings include: 1) Regulatory and legislative policy uncertainty raises questions about the long-term relevance of the Affordable Care Act (ACA), 2) industry transformation will be marked by significant and protracted structural changes as innovations in digital technologies, health sciences, health consumer engagement and medical practices play out, 3) regulatory directives and care delivery objectives will drive increased industry transparency, information sharing, and collaboration, 4) advances in genomics will reconceptualize disease typologies, diagnostic tools, and therapies, and, 5) a heightened emphasis on the quality of the health consumer experience will push policy makers and care providers to reform business models and industry economics. The paper concludes with implications and recommendations.

Keywords: U.S. healthcare industry; Affordable Care Act (ACA); technology


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Introduction

The U.S. healthcare industry is in a state of flux. Rocked by divisive politics and entrenched interests, the industry is a strange brew of economic inefficiency, breakthrough science, startling technologies, and dramatic geographical variation in costs and clinical outcomes. It is an industry that is highly respected, but also an industry that ranks among the least of its peers in
developed nations. Moreover, even following the landmark passage of the ACA, approximately 10 percent of its poorest citizens still have no coherent health coverage plan, and many newly enrolled citizens cannot find physicians or care givers willing to offer needed services. However, amidst all of these contradictions, the U.S. healthcare industry may be on the verge of its best opportunity to put such disparities in the past and realize its brightest days. The stakes are high and the hence the motivation for this study.

The importance and role of the healthcare industry in the lives of each U.S. citizen cannot be underestimated. Recent events, particularly the passage of the Affordable Care Act, in 2010, have compelled many industry players to re-examine their strategies. But other forces, perhaps more profound than new legislation, suggest more dramatic discontinuities in store for the U.S. healthcare industry. The goal of this paper is to elucidate those forces and their dynamics and carefully examine the future of this systemic industry so vital to the welfare of American society and its economy. The motive is simple. Health is systemic and also one of the key predictors of the current capacity and the future prognosis for a society. Understanding the future of the healthcare industry and its possible trajectory is vital for the health of the nation, its citizens. Perhaps most importantly, good public policy rests on a solid understanding not only present problems, but on what can be, and the factors that will shape the course of the U.S. healthcare industry.

Is it possible to chart the future path of the U.S. healthcare industry? Yes and no. Prognostication is a necessary art, fraught with assumptions that prove false and unforeseen developments. Nonetheless, when it comes to health, the benefits outweigh the risks. This paper attempts to provide frameworks that will aid in thinking about the future of the U.S. healthcare industry. While the healthcare industry is manifestly complex, a conservative approach can pay dividends. The goal is to paint with a broad brush over the next two decades. The hope is to generate productive discussion within and among industry players, policy makers and care providers.

The paper argues that the U.S. healthcare industry will undergo three definable stages of transformation during the next two decades fueled by five macro forces that will drive and sustain unprecedented industry transformation. By 2030, the U.S. healthcare industry will be radically different from today. The U.S. healthcare industry will transition from a nation centric structure to a global structure of networked patient populations, correlated genomic and therapeutic data stores, globally-distributed health innovations, intense competition and transformative public-private partnerships for public health.

Many of the early elements of this future are visible today. As a host of innovations push the industry to more precisely tune its activities to the detailed biological characteristics of each individual, the industry will undergo a protracted period of sometimes volatile upheaval that will ultimately lead
to a stepwise improvement in global wellness. Such a conclusion emerges from an analysis of current and prospective industry features and critical trends. As the industry progresses, U.S. healthcare will be ever more intricately tied to the global health market and its specific populations and individuals. Ultimately the compounding effect of all the innovations, breakthroughs and developments contribute to a new industry structure that promotes greater collaboration among industry players, more transparency into industry activities, and more adaptive or elastic models of healthcare delivery and organizational operation. Ultimately, wellness for each individual will be the mission and focus at the industry level and among all of the players in the global healthcare ecosystem. Perhaps most surprising will be that healthcare will dramatically move from a push model of public health to a pull model of public health definitively driven from individual demand.

**Methodology**

Anytime one attempts to create a forecast one confronts the challenges of reasonableness and accuracy. Some might argue that it is foolhardy to forecast an industry as complex and uncertain as the U.S. healthcare industry. The argument has merit. Although many industries face disruption and change due to technological developments, the U.S. healthcare industry not only faces technological disruptors but also political, regulatory, scientific, cultural and economic disruptors. Already, the U.S. healthcare industry is buffeted by uncertainties about the future of the ACA. The passage of the ACA in 2010 accelerated the private sector’s penchant to merge and consolidate in the hope that scale will offer some shelter at the regulatory bargaining table. The question is open as to whether consolidation and scale will improve efficiency and patient outcomes. Time will tell.

Nonetheless, given the pivotal nature of the U.S. healthcare industry, it is vital to explore its future. The goal here is to provide a descriptive view of its future at a level that will inform decision makers. The analysis confines itself to a qualitative and descriptive form of inquiry rather than attempt to generate a parametric model of the future. The forecast is built upon a multidisciplinary analysis of trends and events found in a systematic review of the literature and secondary data sources. The baseline for extrapolation is based on existing knowledge in a diverse set of domains that are found in the health disciplines but also critical domains outside the healthcare industry.

The purpose here is to outline the major topographical features and suggest a vision for how the industry might progress. In so doing, the hope is to outline many elements that will provide insights for various players to navigate what is expected to be a volatile and uncertain path and to make appropriate decisions. At the same time the forecast attempts to identify
critical signposts and roughly position them on a general timeline. It is hoped that future quantitative modeling efforts can build upon the qualitative conclusions proposed here.

Here is the process used to formulate the frameworks employed in the paper. First, the literature review chose significant, visible and uncontroversial macro trends. In other words, unless trends pass a very high bar and appear to have a high probability of persistence, the trend was rejected. Second, the methodology identified secondary and tertiary developments that could give rise to future trends and contribute to the long-term shape of the industry. Third, some attention was given to “dark horse,” or “long shot” developments that might alter industry trajectories. For example, no one foresaw the revolutionary discovery of the CRISPR/cas9 scheme for precision gene editing (see Doudna and Charpentier, 2014 for a technical description of the technique). CRISPR r/cas9 technology emerged from a serendipitous cross-disciplinary set of discoveries, which even in retrospect are startling.

Fourth, the methodology employed here is conscious of potential lag effects, adoption rates, learning effects and limits to social adaptation in societies, institutions, and market factors that might delay or inhibit the impact of major trends. Fifth, the methodology identified limitations in the analysis and the impact of miscalculation or errors in assumptions.

The next step of the process was to examine the trends and formulate a stage model to better understand and elaborate a possible stepwise progression of key trends that might evolve and influence the structure and practices in the industry over time. To construct each stage in the model and affix time frames, critical developments were identified. For example, the cost curve for the complete sequencing of an individual whole genome is a critical event in the widespread personalization of medicine. Estimates suggest that mass adoption of individual whole genome sequencing becomes feasible at a cost less than $500 USD and should be possible by 2023 (Hood, 2013). Current prices for whole human genome sequencing range from $2500 to over $5000 USD depending on coverage, technology generation, and use case. Exome sequencing is less expensive (i.e. only sequencing the part of the individual genome that translates proteins) is less than $1000 USD and up depending on coverage and use case. Genotyping that provide targeted and selected scans of the human genome are least expensive at around $200 or more (e.g. the consumer grade service 23&Me). Thus, the $500 whole human genome sequencing is the game changer. 2023 is the expected time frame and thus was used to structure the stage model.

An industry timeline was developed across three major stages with proximate end points. Each stage was formulated and positioned temporally according to judgments about the impacts of the five major trends. Thus, the first stage was anchored amidst the rollout and impact of government regulation and revisions related to the ACA in the second decade of the 21st
Century with proximate interval endpoints of 2010–2020. The second stage is anchored around the cost curve and wide-spread adoption of whole human genome sequencing, expected to occur early in the third decade (2020–2030). The third stage of industry transformation is anchored around the convergence of proven practices in machine learning, self-directed care, and a stabilization of care continuity models that emphasize cross-generational wellness from in vivo care to post-death conservation of genetic information early in the fourth decade (2030–2040).

With regards to the stages, it must be pointed out that other events may enhance or inhibit the velocity of change and thus the endpoint. For example, significant health initiatives introduced in the United States, Europe and China (e.g. the “Moonshot” cancer initiative suggested by U.S. Vice-President Joe Biden in 2016), or an unforeseen Crispr/Cas9 black swan event with genetic therapies or genetic tampering could alter industry trajectories. Similarly, known factors such as changing demographics in the United States restructure the U.S. population by 2040 and global middle class growth rates in the 2030s will alter industry profit pools and change global health consumption patterns. Such factors make health consumption variable and introduce significant uncertainty in the out years of this analysis.

**The Current State of the U.S. Healthcare Industry**

Conservative estimates from the World Health Organization (WHO, 2012) put the global spend on health-related matters at $6.5 trillion. The Economist Intelligence Unit (The Economist, 2014) expects global health costs to grow at 5.2 percent per year. The global health marketplace is fueled by growing economies that demand more health services but also by similar issues as found in the U.S., including poverty, aging populations, chronic obesity, communicable and infectious diseases and new expensive therapies. As more economies grow and developing nation incomes rise, 1–2 billion additional affluent individuals will demand better care and fuel an appetite for advanced medical interventions over the next 20 years. Thus the pace of growth in global healthcare spending, particularly in developing nations, is expected to accelerate rapidly for the foreseeable future.

The healthcare industry in the United States accounts for almost half (44.3 percent) of the $6.5 trillion that is spent on healthcare globally (WHO, ibid.). Currently, the United States, alone, spends more per capita approximately US$ 8,362 on healthcare than any other nation. U.S. government subsidies for healthcare amount to the largest line item in the U.S. Federal budget (OECD, 2012). A report issued by the Office of Actuary at the Centers for Medicare and Medicaid Services estimates that at an average 5.8
percent growth rate, U.S. healthcare costs will rise to $5.4 trillion or 20 percent of U.S. gross domestic product by 2024 (McCarthy, 2015).

The U.S. Federal Government, alone, spent an estimated $1,017.7 billion in 2015, up from $820.7 billion on healthcare in its 2010 Budget. When state and local government spending is included, the U.S. will spend $1,309.9 billion on healthcare for a population of 321.4 million in 2015. Including all healthcare expenditures (public and private), the U.S. spent some 17.5 percent of GDP or $3.0 trillion on healthcare in 2014 (Hartman, Martin, Lassman, Catlin, & National Health Expenditure Accounts, 2015). According to the U.S. Centers for Medicare and Medicaid, preliminary estimates indicate that total spending on healthcare in 2015 increased 5.5 percent, to $3.1 trillion ($9,695 per capita) (Martin, Hartman, Benson, Catlin, & National Health Expenditure Accounts, 2016).

But a controversy rages about the quality of healthcare in the United States compared to other developed economies (Forde, Morgan, & Klazinga, 2013). At a gross level the volume of dollars spent by the U.S. does not correlate well with health outcomes. While it is widely agreed that the U.S. has the most advanced and responsive healthcare system, spends the most on research, and has the most highly trained medical workforce, it does not have the best health outcomes in important areas (McKee, 2010). A study (National Research Council and Institute of Medicine, 2013), ranked the U.S. last among 17 developed nations in terms of quality of care. Infant mortality, according to the U.S. Center for the Disease Control ranks the United States as 27th among the wealthiest nations. Moreover, with regards to infant mortality, state variations are enormous and disturbing in the U.S. For example, the U.S. average infant mortality rate is 5.9 per 1000 live births whereas the U.S. State of Mississippi is 9.3 per 1000 live births – similar to the infant mortality rate in Lebanon.

Overall life expectancy is also lower in the U.S. when compared to other OECD countries (Kelley, 2007). Recent studies have noted a widening dispersion of life expectancy rates by income in the in the U.S – a so-called longevity gap. Life expectancy is increasing for upper income groups, but is moderating or declining in lower income groups (National Academies of Sciences, 2015).

Nor does the U.S. lead in the number of practicing physicians per capita or hospital beds per capita. Recent data from a study in the Annals of Family Medicine (Petterson et al., 2012) suggests that the number of practicing primary care physicians may be declining (due to retirement and voluntary retirement). The Association for American Medical Colleges (2015), in an econometric analysis noted that despite uncertainties regarding health policy, changes in care methods, and estimation of physician retirement rates, demand for physicians will likely outpace supply through 2025. Further adding to the anomalies in the statistics is that top care institutions in the U.S. rank at the
top globally among medical practices and outcomes. Bottom line, if a U.S. citizen lives close or can travel to a world-class care center in the U.S., they will get the best possible care available anywhere. In other words, clinical outcomes are not evenly distributed across the United States healthcare system.

Operational and cost issues also plague the industry. A large literature outlines the industry challenges in great detail. But the problems can be summarized. Severe industry fragmentation leads to uneven practices and pricing that do not correlate well with health quality outcomes (M. E. Porter & Teisberg, 2004). A lack of pricing transparency and clinical outcomes information makes it difficult for health consumers to make price/value decisions on care options, to anticipate out-of-pocket costs for care or shop for elective treatments or procedures. The current industry is oriented toward providing treatments post diagnosis with minimal incentives for preventative care, which exacerbates the negative impact of preventable chronic diseases on industry economics. Historically, significant government subsidies to defray citizen costs have not been adequate for lower income citizens. Until recently, access to care has been provided primarily by high cost hospitals and their emergency units that are designed for acute care. Most lower income citizens get medical care but at irregular intervals, without regular checkups, and often too late. Lower income aged citizens are better covered by government subsidized programs such as Medicare (DeNavas-Walt, Proctor, Smith, & U.S. Census Bureau, 2014).

Demographics, lifestyle and culture exert a significant effect on the current composition of care in the United States (e.g. poverty, aging population, declining birthrates, population migration and immigration). Chronic obesity, particularly chronic childhood and adolescent obesity, fueled by unhealthy diets, limited aerobic physical activity, and lack of early detection threaten to dominate all other pathologies as they give rise to a chain of chronic disease as each cohort ages (i.e. diabetes, heart disease, stroke, premature joint deterioration, and a host of secondary diseases, including cancer). In the United States the four common causes of chronic disease are a lack of physical activity, poor nutrition, tobacco use and excessive alcohol consumption. By 2025, approximately 49 percent of the U.S. population will have a chronic disease (Wu, 2000). As the chain of chronic disease ripples throughout the population, the lifetime cost of treatments is compounded. According to the Centers for Disease Control (2013), 133 million Americans have at least one chronic disease and chronic diseases are now the cause of 7 out of every 10 deaths.

Other industry problems exist and have been well documented. The industry is plagued by fragmentation in business models and processes, an uneven distribution of profits, a concentration of margins among industry producers (pharmaceuticals, biotech and medical devices), radical dispersion in the quality of clinical outcomes, and a preferred use of emergency care depart-
ments for diagnosis and treatment of a wide spectrum of conditions are the most visible problems (Caldwell, Srebotnjak, Wang, & Hsia, 2013). In addition, even after the ACA, significant gaps in access and care service levels exist in government-led and subsidized programs.

Porter and Teisberg (ibid.) enumerate many business and economic problems that contribute to the ineffectiveness of the U.S. healthcare system. They point out that the industry is fragmented and characterized by unhealthy or non-existent competition. They also note that, “when competition is found it often lacks coherence and occurs at the wrong level over the wrong things and in the wrong geographic markets at the wrong time.” Furthermore, decades of healthcare reform have failed. Later, Kaplan and Porter (2011) noted that while competition is essential, it must shift from the level of health plans and hospital groups to “the prevention, diagnosis and treatment of individual health conditions or co-occurring conditions.” More recently, M. E. Porter, & T.H. Lee (2013) concluded that the U.S. healthcare industry must move to structures where all industry segments promote health outcomes, employ standardized practices organized around disease types and focus on patient-centered, value-adjusted clinical outcomes.

The current state of the industry cannot be understood without understanding The Patient Protection and Affordable Care Act of 2010 (ACA) and as amended by The Health Care and Education Reconciliation Act of 2010 (HCERA). Also known as the Affordable Care Act, the law completely reshapes the architecture of subsidies, insurance coverage, actuarial models, collaboration among the industry players, and expectations concerning the provision and management of care.

As of late 2015, the full impact of the ACA is unknown, particularly in coverage rates, insurance costs, and impacts on industry economics. In particular, a 2012 ruling by the Supreme Court (U.S. Supreme Court, 2012, Nat’l Fed’n of Indep. Bus. v. Sebelius) upheld the ACA, but in doing so also ruled that each State has the right to determine the degree of participation in ACA. Thus each State has the right to opt-out of the ACA Medicaid Expansion provision and health exchanges. Many problems remain: under enrollment of younger citizens plague actuarial assumptions for ACA plans, 19 states that have yet to participate in Medicaid expansion, an estimated 20 million plus low-income citizens that have not engaged or have low engagement with ACA services due to high deductibles, minimal or no access to participating care providers, and a lack effective skills to consume care. As a consequence, the full impact of ACA on the structure of the industry or on total healthcare spending will only be known with the passage of time.

To some critics, the combination of healthcare policy, regulations, mandates, taxes, subsidies, research funds and the related healthcare apparatus qualifies the ACA as a government within a government. Some would even suggest that healthcare today exerts greater power over its citizens than the
indigenous governmental structures themselves. And even the most ardent supporters of current legislation remain concerned with the rapid growth of government agencies who interpret, implement, and enforce regulations promulgated by the ACA.

In summary, the current state of the healthcare industry in the United States is a picture of fragmentation, inefficiency, sometimes dysfunction, and epidemiological hazards, mixed with assets of great promise. The prognosis is best seen as guarded. If all of the players in the industry can collaborate, the industry can reach a transformational and healthy future. It is on that however unlikely outcome some skeptics may lament, that the analysis of the future state of the U.S. healthcare industry begins.

The Future State of U.S. Healthcare Industry

The forecast focuses on five transformative and unprecedented forces that will drive the U.S. healthcare industry for at least the next two decades. The combined impact of the five forces has begun to unfreeze the industry and will soon unleash a perfect storm of transformation. Because health is integral to the health of the economy and the nation, executives, policy makers and citizens must understand the opportunities that transformation presents for everyone.

Each force gives rise to a series of healthcare trends that have the potential to reset and radically change the definition and structure of the industry. Taken together the macro-trends generate a complex storm of change for the industry – a mix of opportunity, uncertainty, pessimism, and optimism. The perfect storm will cause policy makers to embark upon a sustained policy revision process or unwittingly hold back community health outcomes in their geographies. Understanding how these forces will conspire and in turn shape critical healthcare trends forms the basis for a 3-stage model of industry transformation discussed here.

If the analysis is valid, a very different industry structure will evolve over the next two decades. This includes more flexible business models, new health services, new health consumption preferences and patterns, more competitive and efficient health markets, precise and locally-relevant health outcomes and the emergence of highly interconnected health business ecosystems that will serve not only U.S. populations, but will serve and will be served by a growing internetworked global healthcare industry. The industry will continue to be characterized by traditional oligopolistic elements and key power players (e.g. large pharmaceutical firms, multi-line insurance companies, national healthcare providers, the Federal Government). The industry will witness the emergence of a vast network of global digital business platforms that serve interconnected business ecosystems. Health needs will be served by a global
constellation of established industry players, new entrants, start-ups, and individuals driven to collaborate by massive databases of disease profiles, practice experience and public-private insurance programs. The U.S. will see increased transparency in health services pricing correlated in real-time with clinical outcomes. Care institutions will become increasingly responsive to health consumers and other constituencies, and incorporate new partners, innovations, and technologies with less friction (Vitalari, 2015).

Because the perfect storm is no respecter of national boundaries, the increasingly global consumer will travel or migrate, permanently or temporarily, to where they receive the best health outcomes. Hence all policy makers, particularly in the United States, will increasingly be held accountable by a global standard of care that will be evermore transparent to everyone. Anyone who follows the industry has already seen the rise of international comparisons. These comparisons will only become more precise and more frequent as the industry moves through the perfect storm.

**Five Transformative Forces – A Perfect Storm**

The first decade of the 21st century produced a constellation of social, economic, scientific, and technological change and reset the foundation for the healthcare industry. Economic change came in the form of greater financial transparency, global recessionary pressures, fluidity in global labor markets and a destabilization in financial markets. And as noted earlier, legislative and regulatory change as seen in the Affordable Care Act (ACA) in the United States.

Other social dynamics conspired to shape sensibilities with regard to healthcare in the United States. The growing problems with obesity and a better understanding of its causes began to shape social policy especially with regard to children and teenagers. Many of these social and behavioral dynamics influenced the payment priorities for healthcare as seen in many revisions to Medicare and Medicaid coverage as well as payment schedules and policies of private payers.

From a scientific standpoint, truly historic breakthroughs characterized the first decade beginning with the unexpectedly early sequencing of the human genome in 2000. This breakthrough dramatically changed global research priorities and has led to additional breakthroughs in genomics, diagnostics, drug formularies (pharmacopoeias), and new therapeutic modalities such as the use of stem cells, the immune system and targeted medicines using a variety of newly discovered pathways. Experts suggest that a succession of major breakthroughs will continue (Hood, 2013; Blau & Liakopoulou, 2013).

Digital, information, computational and network technologies also continued their torrid pace of development leading to ubiquitous personalized mobile devices, vast digital networks covering the planet (i.e. The Cloud) and
unprecedented computational power that supports the analysis of massive data sets. In addition, technological advances led to an unexpected but now dominant paradigm, the widespread use of social networks as seen in Facebook, LinkedIn and specialized networks in healthcare such as Patients Like Me, that enable entirely new levels of ad hoc and structured collaboration. Similarly, the rapid expansion of digital data opens new horizons for virtually every segment of the industry.

Figure 1 illustrates the five key forces and related healthcare trends:

1. The Patient Protection and Affordable Care Act of 2010 (ACA) and related implementation directives.
2. Advances in digital, information, computational and network technologies.
3. Advances in the “omics” sciences including genomics, proteomics, transcriptomics, gut metabolomics, microbiomics, and related high-speed sequencing, micro-fluidics, advanced assays, and single cell analytics.
4. The rise of the global middle class and its related impact on the global demand for healthcare, healthcare innovation, lifestyle changes, and consumption of healthcare services and products.
5. A new consumer ethos that expect an active, engaged consumer experience augmented by electronic interaction, social networks and real-time response spurred by the development of social networks (e.g. Facebook, LinkedIn, Patients Like Me) and the rapid adoption of high performance digital mobile and wearable devices.

**Figure 1** The Perfect Storm: Five Forces Conspire to Transform the U.S. Healthcare Industry

<table>
<thead>
<tr>
<th>The Five Forces</th>
<th>Engaged Mobile Health Consumer Experience</th>
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<tbody>
<tr>
<td>Affordable Care Act (ACA)</td>
<td>Personalized Care Delivery &amp; Treatment Modalities</td>
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<tr>
<td>Patient Protection</td>
<td>Precision Therapeutic Agents and Devices</td>
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<tr>
<td>Affordable Care Act 2010</td>
<td>Elastic Organization Models</td>
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<tr>
<td>Digital Technologies &amp; Infrastructure</td>
<td>Digital &amp; Information Healthcare Infrastructure</td>
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<tr>
<td>Revolution in Biological, Omics &amp; Materials Sciences</td>
<td>Global Healthcare Industry Economics</td>
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<tr>
<td>Rise of the Global Middle Class</td>
<td>Machine-assisted healthcare</td>
</tr>
<tr>
<td>Active Health Consumer Engagement</td>
<td>Bionic, synthetic and machine-assisted</td>
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<tr>
<td></td>
<td>Active health consumer engagement and personalized wellness</td>
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Each of these five forces drives a secondary set of critical trends that shape many aspects of the healthcare industry and provides important clues as to the future structure and configuration of the U.S. healthcare industry.

**Force Number One: The ACA**

The Patient Protection and Affordable Care Act of 2010 (generically known as the ACA, or eponymously as “Obamacare”) as amended by The Health Care and Education Reconciliation Act of 2010 (HCERA) is a 2,407 page law that has already altered the trajectory of the U.S. healthcare industry. The provisions of the ACA are staged over time, but many of the provisions began to take effect in 2013 and 2014. According a U.S. Census survey, the uninsured rate which ranged between 14.5 percent and 15.5 percent of the U.S. population from 2008 to 2013, declined to 10.4 percent of the population by the end of 2014 (Smith and Medalia, 2015). Although not statistically significant, the decline in the uninsured rate, illustrates the early impact of the ACA on the U.S. population. Thus, in the aggregate, approximately 32.3 million non-elderly individuals currently lack medical coverage. However, based on ACA participation at the end of 2015, a recent study by the Kaiser Family Foundation estimated that almost half of the uninsured could qualify for coverage under existing federal assistance programs (Garfield et al., 2016).

Other impacts of the ACA have been noted. Since the ACA was passed, merger and acquisition activity has increased as healthcare systems respond to provisions in the laws for community health organizations, and private insurers work to leverage costs over a larger population. State and local governments have restructured their agencies to make way for health exchanges and some have adopted expanded coverage for Medicaid. The ACA expanded federal funds and eligibility for Medicaid (i.e. a federal and state jointly funded, means-tested, health insurance program for low-income households). Under the ACA each state was originally mandated to provide Medicaid health coverage for U.S. households below 138% of the poverty line (i.e. single household: $11,770 * 1.38 = $16,242, household with 4 members: $24,250 * 1.38 = $33,465). However, the ACA Medicaid provision was subsequently modified and ruled optional for states by the U.S. Supreme Court (U.S. Supreme Court, 2012). As of December 2015, 32 states (including the District of Columbia) have adopted ACA Medicaid Expansion, 16 states have not adopted ACA Medicaid Expansion, and 3 states are undecided. Because some states do not support Medicaid expansion, it is estimated that approximately 3 million poor individuals are not covered by health insurance (Garfield and Damico, 2016).

The law has many components and provisions that specify payments schemes, essential services, and best practices. The aim is to provide care for all U.S. citizens through a combination of public and private agencies. The
goal is to move the industry to a value and outcomes-based care delivery model. Aside from the ongoing political debates (i.e. single payer system, employment impact, etc.) the program aspires to reduce complexity and provide a combination of incentives and sanctions that encourage those practices that lead to the greatest transparency, value and health outcomes for U.S. citizens. The ACA employs the U.S. Internal Revenue Service (IRS) as an enforcement and compliance mechanism. As the chief taxing agency of the U.S. Federal Government, the IRS enforces the penalties and taxes specified in the ACA for compliance and non-compliance. An individual mandate requires that all individuals acquire coverage or pay a penalty. Any employer which has 50 or more employees must offer coverage to all employees or pay a penalty for each employee not covered to share responsibility for the government’s coverage.

The ACA stipulates and pays for preventative care. It mandates guaranteed issuance – no one can be denied health coverage even with pre-existing conditions. It eliminates lifetime caps on insurance benefits. The ACA establishes a baseline health benefits package that must be provided by all insurers and it taxes premium health benefit packages (i.e. so-called “Cadillac” plans) that exceed $10,200/year in benefits for individuals and $27,500 for families. It makes insurance available for small businesses and individuals via new electronic healthcare exchanges and provides premium and cost-sharing subsidies through the exchanges.

The law specifies many reforms to Medicare especially the transition from “fee for service payments” to “bundled payments” for greater efficiency, and the use of an Independent Payment Advisory Board (IPAB) to recommend changes to Medicare to promote the adoption of cost-saving measures and adoption of best practice treatments. In the details are included specifications for Accountable Care Organizations with specific incentives for care organizations that reduce and streamline their operations. The law also mandates the development of “community health organizations” to deliver care at a local level for non-trauma level care. In addition, the law calls for increased collaboration and information sharing among players in the industry.

In particular, the ACA mandates new levels of collaboration among insurers, providers, caregivers and patients. Ultimately, the ACA will drive a new range of information technology solutions and interconnections among existing and future systems for the transaction and retention of healthcare information. The ACA, together with other legislation and directives (i.e. HIPAA, HITECH, ICD-10), will also force an unprecedented level of standardization of health records, therapeutic outcomes data, and industry transparency.

Provisions for industry transparency and increased information sharing and collaboration among industry players will likely give rise to new health platforms to facilitate such collaboration. In addition, the ACA in light of other Health and Human Services (HHS) initiatives (e.g. Blue Button) will
spur third parties to offer a range of add-on services ranging from secure data storage solutions for individually accessible health records (Tanner and Brennan, 2013; Sivek, 2013), to APIs and health platforms that support mobile and personalized devices.

In turn these mandates are likely to spur new innovation in biometrics and bio-informatics as regulators seek to reduce Medicare costs through bundled payments and encourage protocolization among care providers. Bundling or bundled payments (sometimes called episode payment or package pricing) refers to the practice of providing the patient with a single fee for a full cycle of treatment and care for a given medical condition and tied to specific outcomes. Protocolization or protocol-based treatment is an industry term for the use of proven standardized and accepted protocols for treatment. Protocolization is an inherent concept in the ACA and related incentives for Accountable Care Organizations (ACOs) and incentivized reimbursement schemes in the post-ACA Medicare environment. A by-product of protocolization is reduced discretion for physicians, patients and payers when choosing treatment options, but with greater control over treatment outcomes and cost experience. Protocolization is often inherent in bundled payment approaches. Both methods increase transparency for the patient and third party costs, delivered value, and clinical outcomes experience, thus enhancing patient decision-making in choice decisions.

In addition, a significant concern among health professionals and health systems are liabilities or ineligibilities for reimbursement if not applying the latest techniques to reduce costs and share information. Specifically, as noted earlier, the ACA (Section 3022) and related HHS guidelines call for the establishment of Accountable Care Organizations (ACO). Accountable Care Organizations are a group of coordinated providers that provide care to patients. However, the ACA ties Accountable Care Organization reimbursements to quality metrics and reductions in cost as per a specific population of patients. It is important to note that there has been significant contention with the Centers for Medicare and Medicaid Services (CMS) over the nature of the quality metrics and the efficacy of particular practices. A key issue is repeatability. In other words, some organizations find great success with certain cost reduction techniques but when applied elsewhere similar results are not seen. Nonetheless, providers are incentivized to embark on a continuing plan to reduce costs, implement best practices, and invest in infrastructure that supports redesigned processes.

The pursuit of ACO compliance is expected to spur greater use of information technology and use of lean methodologies for process and organizational redesign. In January of 2013, Health and Human Services announced a “final ruling” on the HIPAA and HITECH Acts (Subtitle D which addresses privacy and security concerns) which went into effect on March 26, 2013, but required compliance by September 23, 2013. The omnibus rule stipulates
greater protection for patient information and covers hospitals, doctor’s offices, health insurance providers, universities, self-insured companies and multiple line insurance companies. The regulations also cover “business associates,” that is any entity involving the handling or use of personal health information.

To fully understand the monumental impact of the ACA on the industry, it's must also be considered in conjunction with the The Health Information Technology for Economic and Clinical Health Act (i.e. HITECH Act) – enacted under Title XIII of the American Recovery and Reinvestment Act of 2009. Of most importance to this analysis is the stipulation for the meaningful use of electronic health records, additional regulations regarding what needs to be included in such records, and additional security and privacy provisions, by 2015. The core requirements outlined in the HITECH Act must be implemented according to a timetable with specific stages of compliance and corresponding incentive payments and penalties.

The ACA in conjunction with the HITECH Act is expected to drive business model innovation in the industry. Because the ACA mandates greater collaboration and information sharing among industry players, it is expected that the industry will see the development and deployment of new health platforms that range in function from exchanging health records, sharing insurance information among providers and payers, providing support for home healthcare, and consolidating personal health information. To meet ACA regulatory mandates all players in the industry will be required to exchange more information and make that information available to government agencies, third parties and consumers.

Even if the Act is partially repealed and amended by future administrations, Congresses, or the Supreme Court, the payment model, insurance marketplace, and the structure of collaboration among industry players has already been altered. It is important to note the significant controversy and uncertainty currently surrounding the ACA. The ACA is monolithic and massive. In the Fall of 2013, the initial rollout of the Federal insurance exchange, millions of previously privately-insured citizens lost their existing plans, forcing the President to alter the implementation timetable and reverse previously promulgated guidelines for private insurers. Public support for the legislation has declined since its passage and key provisions have been delayed at the time of this writing. Politics also threaten to defund the bill. The CBO has revised cost estimates for the implementation of the ACA several times and now reports it will cost 45 percent more than estimated in 2010 when the legislation was passed. HHS and CMS are behind in the implementation. Moreover, the bill was not designed to support a graceful and progressive revision process and hence the future of the ACA is uncertain in view of the political and legal environment.
Force Number Two: Digital Technologies and the Internet of Things

The digital revolution affects virtually every industry. The healthcare industry is no different. Digital and information technologies encompass many different hardware and software components and layers including computers (mainframes, servers, PCs), data bases, electronic communication networks, the Internet, software, cloud services, apps, integrated applications, mobile phones, wearable devices, PCs, supercomputers, information systems, software, digital displays, cameras, and digital sensors. Many industries, such as healthcare, also employ many specialized digital devices adapted to or constructed for specific tasks (e.g. robotic surgical or radiological instruments, bionic prosthetic devices, lab devices, etc.).

Many parts of the healthcare industry have already experienced the benefits of technological advances and better medicine, including better and faster diagnostics, continued advances in drug design, rapid developments in gene sequencing, and the exploitation of bio-informatics, large data sets and computational analytics. Perhaps the most transformational digital technology may well be the so-called Internet of Things (IoT) that encompasses wearable medical grade devices, home sensors, and hundreds of connected devices at care facilities to track and monitor patients, drugs and internal supply chains.

Connected Health and Digital Medical Care

Kvedar (2015) argues that the Internet of Things (IoT) may prove to be a better way to deliver care. He envisions a connected health consumer that is continuously monitored by attractive medical-grade wearable computing devices and sensors. Data from the wearable devices inform primary care professionals, provide alerts to the individual, and powerful offsite computers provide health recommendation and wellness coaching, based on each individual’s unique data stream. In the process, physician can focus more time on critical care issues.

Digital technologies, particularly mobile phones, wearable devices, multiple medical-grade sensors and continuous real-time wireless connections to the cloud motivate a reconceptualization of healthcare. Digital advancements drive down the cost of monitoring vital signs and health progress. Consider a patient that complains of unexplained heart palpitations. In the past such indications might lead to hospitalization or a battery of tests. Today, depending on the history of the patient, the cardiologist may simply prescribe the fitting of a small non-invasive medical-grade monitoring device to be worn on the upper chest for a period of time to collect detailed data on heart function as the patient goes through their daily activities.

The use of mobile devices and the changes in consumption patterns have begun to shape health practices and the industry’s vision about new methods for health delivery. More and more smartphone owners use devices to collect
health-related information and monitor preventative health activities such as exercise and diet. Companies, like Apple, FitBit, Garmin, and Jawbone, sell biometric devices to measure steps, sleep patterns, calories, water consumption, temperature, and general activity. And a plethora of apps on Apple iOS and Google Android smartphones assist users in tracking personal health related information. Apple has also created ResearchKit, an open source software framework for the secure collection of medical study and clinical trial data and other opt-in health research activities via their mobile device platform.

In addition to consumer-grade and medical grade wearable tracking devices, social networks also have consumer and medical grade versions. While Facebook, Instagram, LinkedIn and Twitter are well known, medical-focused and medical grade social networks have grown significantly in the last 5–7 years. Examples include Patients Like Me, where individuals will share disease and treatment information along with clinical outcome with others who have similar diseases. Social networks for physicians, nurses and other care provider have emerged and often include specialized information and practice sharing forums. AthenaHealth, a health practice platform for physicians, recently acquired ePocrates, an electronic medical reference and information tool, for clinical use. Current trends suggest such tools and networks will grow and be augmented with artificial intelligence systems to provide guidance advice and opinions. IBM’s Watson, cognitive computing systems, can read over 6 million pages of information per second and forms new associations as additional data is ingested.

Topol (2015) and Agus (2016) also envision significant use of digital technologies in the delivery of care. Digital technologies that connect the doctor and patient relationship potentially give health consumer more information and control over their health. From a care provider perspective, digital technologies could reduce unnecessary or inconvenient patient visits, recommend more precise preventive therapeutic protocols, and for chronic and acute populations, deliver higher quality care. Continuity of care may also benefit, as different care providers over different care episodes maybe better informed at the point of care. In addition, portable electronic healthcare records, coupled with machine-based analytical tools may provide care givers, physicians and specialist with a more comprehensive and up-to-date patient profile with epidemiological and individual patient trends correlated with the latest research and practices. Nonetheless it is important to point out that machine-supported and remote monitored clinical practice is at a very early stage. Other complexities exist. For example, a recent study indicated that the use of tele-monitoring devices with elderly individuals in post-discharge setting did not reduce re-admittance or improve health outcomes (Dharmarajan & Chaudhry, 2016). More clinical research is needed to sort out where such tools excel and where they don’t (Berkman, 1984; Cohen & Wills, 1985).
Digital Health Systems and Data-driven Medicine

Information technology has been in use for over 40 years in healthcare enterprises. Traditionally, care organizations used information technology to augment patient health records, lab management, administrative functions, accounting, finance, inventory, data management, and regulatory reporting. Health insurers, medical device manufacturers, and life sciences companies have been more aggressive in the use of information technology and have for some years employed advanced computation for drug development, precision manufacturing, fraud detection, and more recently, use of mobility and cloud-based solutions in products and services. Currently, many suppliers of health products and services are developing ways to imbed wireless technologies into devices to work with external apps, communicate over the Internet to provide machine diagnostic information, download new software, or collect usage information for future product development. Health insurers, in particular, have invested heavily in data analytics to better understand treatment efficacy and patient adherence. In addition, some insurers are testing insurance discounts and incentives for customers that use health trackers and commit to a recommended regimen and lifestyle activities. Given the impact of such data on actuarial assumptions, even in the aggregate, it is likely that insurers will expand such efforts going forward. Such efforts could eventually dovetail with clinical data to provide health guidance to individuals.

It is expected that the emphasis on accountable care organizations (ACO), bundled payments, protocolized procedures and medicine, the pursuit of greater patient engagement, and the emergence of new tiered health delivery models will require that health enterprises move away from the industry era model of organizational structure and move to more elastic organizational structures (Vitalari, 2015).

The experiences at Kaiser Permanente, Partners Health, Virginia Mason, the Cleveland Clinic, MD Anderson Cancer Center, and the cloud-based health platform provider, Athena Health, illustrate the benefits of information technology in cost management and improvement in the patient experience. As Porter and Lee (2013) document, a combination of information technology and changes in organizational structures (i.e. Integrated Practice Units) along with process rationalization can also improve patient outcomes.

Mobility and big data have already begun to impact the operations of healthcare organizations of all types. Even before the ACA, regulatory demands from the FDA and HHS generated massive amounts of digital data to monitor medical experiments, clinical trials, drug manufacturing, patient privacy, and digital instrument tracking. More recently, patient demands for mobile and Internet access to data and the use of lab-on-a chip technologies for drug development have forced healthcare enterprises to become more adaptive as drug discovery times decline and patient demands for more responsive service models increase.
As a consequence, the industry has shown a great deal of interest in the management and analysis of big data and the use of analytics, in particular predictive analytics based on large robust data sets. The rapid development of cloud-based services has radically reduced the cost of high-powered computation and data storage for healthcare organizations. Healthcare organizations can use cloud storage and computation to augment rather than invest in expensive data centers to analyze and mine their data. In addition, new service providers offer sophisticated analytic tools and technologies. The use of the cloud in medicine also sets the stage for the future. Medical datasets are growing at all levels, from the size of individual datasets to the size of collective longitudinal data within disease area and among patient populations. For example, personal health records will become massive. Since the human genome consists of 3 billion base pairs, a patient record in the future will include an individual fully-sequenced genome and a cumulative sequenced family genome, demographic, individual-specific epidemiological history, medical intervention and care episode history, medications and allergies, plus other personal and wellness data all in multimedia formats. When considered for a population, new methods for data handling and analysis will be required and is currently one of the fastest growing research areas in institutes and universities. Data-driven medicine will increase in stature over time and become a consistent part of individual and population centered care. Again, work must be done to sort out practice and increase the signal to noise ratio in the datasets. Today, only the top care institutions are currently in a position to mine massive datasets. Eventually all institutions will need to become effective in the use of massive datasets.

Thus, we can expect a continuous stream of data-driven developments spurred by new innovations in biometrics and bio-informatics, particularly in computational and mass data storage structures and the use of machines to provide preliminary or predictive diagnoses to guide physician diagnoses and treatment regimens.

Movement to a Digital Health Industry

At the industry level, virtually every aspect of the industry is undergoing digital transformation. Collaboration, cost efficiency, a pursuit of greater strategic agility, and better customer satisfaction motivate the use of mobile, social, cloud technologies, and data analytics. The ACA and the need to become more cost efficient, in particular motivate health firms to establish cross-industry partnerships. At the clinical level, the desire to decrease administrative overhead and to facilitate a much more extensive physician-to-physician collaboration drives the use of mobile apps, physician social networks, and specialized knowledge exchanges. The recent growth in the use of patient portals and mobile apps attempt to improve patient engagement,
improve the patient experience and expand patient access to medical information and medical education. The development of health exchanges and portable electronic health records, as mandated by the ACA, will also spur the development of a range of privately funded health platforms to support many aspects of healthcare and health literacy, from home healthcare tools, medical telepresence, remote consultations, rural telepharmacy, tele-stroke care, real-time mobile cardiovascular monitoring tools, and many others.

Significant change can happen at the industry level when a government sponsored healthcare program is designed to facilitate efficient and transparent public-private partnerships via a common networked business platform; especially one that mandates guaranteed issuance and universal access to services. For example, Belgium has been a leader in using a national health platform, known as Crossroads Bank, to link together diverse healthcare providers, both public and private, in a common health platform and health ecosystem accessible to all citizens via a common health card. The result is a competitive ecosystem of providers with a common patient and social services record.

In summary four key digital healthcare trends that will shape the industry in the coming years:

1. Health platforms – general and specific technology and business platforms that will support branded care networks, care facilities, specific medical conditions and categories of care, specific modes of care (e.g. rural, home), data sets and related analytics, specific social networks for patients and care providers, and financial, regulatory, industry activities.

2. Health ecosystems – the development of health platforms will engender the development of collaborative partnerships among diverse sets of industry players organized to provide services for specific medical conditions, payment bundles, research consortia, and other third parties interested in adding services and expertise to specific care ecosystems.

3. Personalized, participative, and predictive medicine – continued developments in mobile devices, self-tracking, social networks and big data sets will give greater impetus for the emergence of personalized medicine with greater patient engagement and focus on prevention. Advances in the omics sciences and the growth of the global middle class reinforce this trend.

4. Massive data sets, analytics and cognitive computation – the health industry generates prodigious amounts of data, that is isolated and difficult to share. New regulations will drive big data in healthcare. As a consequence, the data is already drawing interest and innovation in new types of data structures, analytic methods, and the latest generation of specialized machines (e.g. SAP HANA, IBM Watson) to make sense out of the data.
Force Number Three: The “Omics” Sciences

The word “omics” is a modern neologism to denote multiple domains of study in biology and biological technologies related to understanding the makeup of cells in organisms. The omics sciences are the result of a profusion of biological, chemical, physiological, technological, and computational developments. The most well known examples are breakthrough discoveries about the human genome and human genetics including DNA, RNA proteins, the roles of bacteria and viruses, and many other biological components and processes. Current advances in next generation sequencing (NGS) continue to reduce the cost of whole human genome sequencing. The reduction in gene sequencing economics will provide each individual with a complete and detailed baseline genomic map and the ability to index that individual map with each new research result and practice or therapeutic innovation by disease type.

The “omics” movement gained rapid speed once the human genome was sequenced in 2001 when the Human Genome Project (HGP) published its long awaited results. For the first time in history, science had a map of all of the genes in the human genome. The initial sequence of the human genome unleashed a global torrent of new research that continues to accelerate today.

The explosion in the knowledge and understanding about how human biology interacts and is affected by other biological organisms, natural and artificial environments, and historical events has been rapid and profound. In recent years, developments in genomics, proteomics, microbiomics (i.e. Human Microbiome Project), transcriptomics, pharmacogenomics, cognitive genomics and supportive technologies such as advanced high speed whole genome sequencing (Eid et al., 2009; Margulies et al., 2005), individual panomic databases (Blau, 2012; Blau & Liakopoulou, 2013) for cancer treatment (i.e. cancer pathologies morph as they progress), biomolecular engineering and synthetic biology (Cheng & Lu, 2012; Smith, Wilding, Hunt, Bennett, & Bundy, 2014), single cell analysis (Kleparnik & Foret, 2013), microfluidic devices and chips (Barata, van Blitterswijk, & Habibovic, 2015) have transformed research, cancer care drug development, diagnostics and treatment.

Even before the human genome was sequenced, medical researchers discussed the potential impacts on medical practice, particularly in the case of cancer (Dulbecco, 1986). Now some 30 years later, the results of the omics revolution are felt in almost every area of medicine, not only cancer, but drug development, diagnostic procedures, toxicology, therapeutic interventions, prevention, genetic counseling, and inherited disease. As mentioned earlier, the recent unexpected discovery of the precision gene editing technology, known as Crispr/Cas9 (Doudna & Charpentier, 2014), opens a whole new area of exploration, medical possibilities, and ethical issues.
Some industry experts envision a medical future based on a detailed genetic map of each individual and their family members that pinpoints genetic problems, faults and potential weaknesses. This data is then used to create preventative health plans that include therapeutic interventions, diets, and other behavioral guidelines. Leroy Hood (2013), a proponent of systems biology, and one of the inventors of critical technologies for high speed genetic sequencing, argues that the future of medicine, some ten to fifteen years out, will be radically transformed. Hood sees a time in the near future where “…each patient will be surrounded by a virtual cloud of billions of data points, and we will have the tools to reduce this enormous data dimensionality into simple hypotheses about how to optimize wellness and avoid disease for each individual” (Hood, ibid.). Medicine will move to a combination of proactive and predictive diagnostics that “…detects diseases at the earliest detectable phase, weeks, months, and maybe years before symptoms appear,” followed by drugs that will push the disease-perturbed systems back to normal (Hood, ibid.). In this future world, medicine will increasingly focus on prevention and wellness. Galas & Hood (2009) calls it P4 Medicine, that is, medicine practiced to be predictive, preventative, participatory (i.e. engaged patients), and personalized (i.e. based on each person’s unique genome).

The implications for understanding the future trajectory of the healthcare industry are threefold. First, since the omics revolution is at an early stage of development it will likely continue to be rich source of innovation for the industry. Second, omics has the potential to radically reconceptualize society’s definition of the minimum and maximum of what is considered to be wellness going forward. Third, the redefinition of wellness has significant implications for the elements of care, the cost of care, and the role of the individual, the healthcare provider, the government, and the limits of care. As a result, assuming the economics, privacy, and ethical concerns can be worked out, the developments in the omics sciences will revolutionize virtually every aspect of medical care with radical implications for treatment regiments and industry structure.

In summary the omics revolution will drive key healthcare trends that will shape the industry in the coming years:

1. High Speed Sequencing (also known as NGS – next generation sequencing) – leading to whole human genome sequencing for an individual for less than $500 USD.

2. Micro Fluidics – includes various technologies to sift, screen and isolate cellular level and molecular level elements in biological materials which revolutionize diagnostics.

3. Single Cell Analysis – related to microfluidics, but focus is to isolate and analyze single cells within complex collections of cells and cell systems.

4. Systems Biology – treats the human body as a system composed of subsystems. In genomics all biology can be viewed as information and how
that information is manipulated and expressed. Hence, therapies and interventions can be used with the information expressed in different biological subsystems.

5. Real-time Diagnostics – the combination of microfluidics, non-invasive sensors and portable computing suggests that health will be monitored in real-time as a matter of course in everyday life.

6. P4 Medicine (Galas & Hood, 2009) – personalized, participative, preventive and predictive, a vision of medicine based on genomics and systems biology that is focused on the unique genetic characteristics of the individual who plays an active role with others in the pursuit of wellness.

**Force Number Four: The Rise of the Global Middle Class and the Global Health Consumer**

The healthcare industry has long been a global industry with global collaboration in many areas. Collaboration has been particularly notable in the handling of global epidemics and infectious diseases. Since World War II, the United States has led the global healthcare industry in scientific advances and technology.

However, given the size of the indigenous U.S. healthcare market, U.S. policy makers and U.S. healthcare company executives formulated strategies primarily for the U.S. population and considered other markets primarily as export market. Until recently, with the growth of emerging economies, primarily the BRIC (i.e. Brazil, Russia, India & China) nations, much of the global healthcare outlook for the U.S. healthcare industry was heavily influenced by the so-called G7 markets. Even today, U.S. healthcare economics are influenced by the notion of west to east innovation export policies.

But that logic will change radically over the next decade. In the first decade of the 21st Century a new factor began to influence the healthcare. In terms of dollars spent, the U.S. healthcare industry is the largest, but the global middle class will soon outdistance the U.S. market in both the proportion of discretionary income spend and absolute numbers of health consumers. The growth of the global middle class profoundly changes the profit shares for the U.S. health industry complex and reorders investment priorities. The growth of the middle classes in China, India and Brazil have already altered the indigenous structure of the U.S. healthcare industry, particularly in the producer segment, although care providers have taken note as U.S. citizens begin to take medical holidays in India and Singapore. As a result, companies in the industry have begun to change their business models and become much more attentive to the nuances and needs of various local markets outside the U.S.

The global middle class is an ambiguous and debated classification, with range endpoints from a low of USD $10 income/day to $50, $77, $82 or $100 income/day at the upper end, depending on differing studies. At the
narrowest range ($10–$50 income/day) the size of the middle class was estimated to be 1.4 billion in 2011. At the broadest range, defined as individuals in the annual income endpoints set at $4,000 USD at the low-end to $20,000 USD at the top end, the size of the global middle class in 2012 was estimated at approximately 2 billion people (Naim, 2008; Kharas, 2010; Kharas & Gertz, 2010; Kochhar, 2015)

The implications of a global middle class of this size have dramatic implications for the future of the U.S. healthcare industry and in particular on its policy calculus and apparatus. Today, the impact of the growing global middle class is not considered in the evolution of the healthcare industry in the United States. However, U.S. healthcare firms will be attracted to the growth in healthcare demands of the global middle class and will adjust their strategies and organizational models. Global healthcare firms will also face increased competition from new indigenous firms and innovators in growth economies.

The rise of the global middle class also means new markets and, most importantly, sub-markets. As seen in the growth of the global mobile industry, companies like Apple, Google and Samsung cater to many micro-markets within the major national markets. The use of apps and a global business ecosystem of partners in local markets, means that these firms engage in what is called mass differentiation (Vitalari and Shaughnessy, 2012). Mass differentiation structures the company and the architecture of its products and services so that they can uniquely serve the unique needs of micromarkets across the globe. For example, Apple’s iPhone coupled with its App store, enables a huge business ecosystem of Apple partners to provide unique apps that makes the Apple product offering relevant and customizable to each micro-market and each individual in that micro-market. Thus the iPhone is just as valuable and relevant to a customer in Kuala Lampur as it is in Chicago, or Bucharest. The elastic architecture of a company that employs the mass differentiation strategy enables individuals in those markets to choose how they want the products to perform and how they want to consume a company’s services. Mass differentiation, employed in a healthcare setting, enables a reciprocal and virtuous synergy between the health consumer and the provider that dynamically shapes the offerings and services of a healthcare provider and producers as attempts are made to serve the global middle class.

The development of the global middle class also spurs global healthcare innovation. Consider the recent experience in the BRIC countries. Developing nations and emerging economies generate unique product requirements, their settings can be seen as a unique crucible of needs that foment innovation. In the BRIC nations, indigenous health industries have developed in response to those unique needs and are already producing innovative health products and innovative health services for export. Known as reverse innovation (Govindarajan and Trimble, 2012), unique epidemiological factors and local
economics provide a crucible for new approaches to medical problems (Shamsuzzoha et al., 2013), services and products (DePasse and Lee, 2013). For example, low-cost, ultra-portable ECG, and ultrasound medical devices have been developed in China and India and then exported back to developed nations. Singapore and India, in particular, have developed significant medical tourism industries in recent years, sometimes alone and, in other cases, in partnerships with U.S. medical schools and hospitals.

The final impact of the global middle class on the healthcare industry is the growth in new cross-cultural integrated datasets. The largest growth in the use of the Internet is seen in developing nations. Interestingly, these countries not only consume data, they generate data. Mobile device growth, particularly smart phones, is growing most rapidly in emerging nations. As a consequence, the global middle class will fuel an explosion in medical data, providing a new window into disease susceptibility, disease propagation and epidemiologies. When considered in the context of the advances in the omics sciences, big data, particularly panomic data on a global scale, will fuel further transformation of therapeutic invention and the provision of care.

Therefore, as the global middle class increases, millions of individuals, particularly in China and India, will rise out of poverty and turn their attention to health. The growth will fuel indigenous health companies and service organizations that will, in some cases, compete with existing healthcare industry players. When these developments are seen in conjunction with the digital technologies and global networks, it becomes reasonable to forecast a trans-global healthcare industry that is likely to rival individual national healthcare industries, with some players and providers operating in multiple global markets with a scale unprecedented in healthcare markets today. Thus, as time marches on, it is likely that U.S. healthcare industry players may take a more strategic direction from the global healthcare marketplace.

**Force Number Five: The Engaged and Active Health Consumer**

In the last decade, many industries have found that when it comes to sustained consumption of goods and services, consumers expect an engaging experience. Known now as customer engagement, the essence of the engagement is an accessible, attractive, authentic and appreciated experience across all the services and products an organization offers, before, during and after the sale.

Many industries have also learned another transformative consumption dynamic. Social networks influence and educate their members and affect product and service demand. Social networks introduce individuals to new goods and services, facilitate the search for the goods and services, and ultimately influence the choice of products.
But engagement does not end with the sale. Twenty-first century consumers expect products and services that are elastic, that is, each product or service can be configured and augmented according to individual needs. As noted earlier, mobile smart phones provide apps that enable each consumer to radically tailor the “phone” to their individual use cases. Amazon, Apple, Google and Netflix use complex algorithms and sophisticated databases to remember and learn what their consumers might like, want and need, and encourage consumers to actively tailor their consumption experience. Individuals now expect substantial elasticity in their products, services and consumption experience.

Demand for product and service elasticity dramatically alters the expectations for healthcare consumption engagement and experience. A small number of current and a large number of future health consumers will expect the ability to actively tailor their health goods and services across all care modalities and episodes. Examples are already seen in healthcare today – payment options, deductibles, adherence programs, real-time pain management, managed chronic disease options, and cancer strategies. This is just the beginning. The health consumer will demand individual more.

The “power of the pull” is reshaping thinking about the Affordable Care Act. Greater coverage and access for underserved populations is a social good. However, in the years since the ACA passed, policy makers have realized that mere access is not enough, rather health consumer engagement is necessary. Underserved populations while covered may not consume. Younger healthy individuals may opt out and pay a penalty. One size does not fit all and the new generation expects options and the ability to pick and choose what they want. Policy makers too will be faced with the new consumer.

Technology may also offer some hope. In his book, The Internet of Healthy Things, Dr. Kvedar (2015), dreams of a time in the not too distant future where consumers and patients are continuously connected with online health platforms through the use mobile and wearable devices. In the background, analytics understand preferences, behaviors and diets, while physicians interpret their patients’ data with the assistance of machine assisted learning tools and predictive analytics.

A Three Stage Model for Future Industry Evolution

The five forces create a perfect storm of disruption in healthcare markets and the makeup of the U.S. healthcare industry. But how will the disruption unfold? A three-stage model of the U.S. healthcare industry was briefly introduced earlier. This section proposes a three-stage model to outline a broad progression for the industry and how the five forces will conspire to transform the industry.
The use of a stage model is important given the complexity of the industry and the transformative elements in place. The time horizon of the stage model (~25 years) is based on the notion that the “perfect storm” will take some time to play out, given the magnitude of change and the ability of industry players and individuals to learn and accommodate change. Moreover, given the ambitious nature of the ACA and inability to get the laws and regulations right on the first attempt, without significant revision, the industry will go through a necessary period of adjustment and resolution due to political and regulatory processes and lag effects, along with normal innovation, adoption and diffusion cycles related to technologies and practices. Nonetheless, this analysis assumes that the stamina and persistence of the five major transformative factors will endure and transform the industry for at least the next 30 years while producing other co-factors that will continue to disrupt the U.S. healthcare industry for some time.

The U.S. healthcare industry will undergo, at least, three defined transformations over the next two and a half decades (see Figure 2). The current U.S. healthcare industry (Stage 1) is characterized by flux and uncertainty as it attempts to depart from its current state. Stage 2 is a pivotal stage since it must adjust to massive changes in the legislative and regulatory environment and relentless impacts from the five transformative forces.

Stage 3 depends on a significant cultural and individual change. By 2030, considerable infrastructure and knowledge will exist to enable care systems to focus on comprehensive wellness, but only if individuals have embraced a more participatory and self-engaged, self-directed and self-determined consumption of health. By 2030 the infrastructure services and product will support such a lifestyle. Practical medical knowledge about genetic history, prevention, lifestyle choices, nutrition, and interventions will vastly exceed what practitioners and health consumers have today. In addition, much of the information and knowledge will be available real-time, so that healthcare will be active and present at all times, but not in the way care is considered today.

Stage 1 health is episodic and prompted largely by acute events. Stage 2 will move to health prompted by an avoidance of chronic conditions and prevention, already seen to some degree today but not evenly distributed among the U.S. population. Stage 2 and Stage 3 will assume high throughput genetic sequencing that will enable the mass consumption of genomics related interventions and treatments and a systems approach to care, driven by massive data sets of personal bio-sensed data collection, massive augmentation by machine cognition and analytics, and a radically different approach to wellness that we see today.

Each stage of the industry evolution relies on key developments and milestones in the areas of regulatory policy, digital, information and computational technologies, and advancements in genomics. The milestones represent
critical path elements in the evolution and transformation of the industry to a primary focus on wellness and individualized health consumer outcomes.

**Figure 2** Projected Stages of Transformation for the U.S. Healthcare Industry

**Stage 1 (2010–2020)**

The U.S. healthcare industry is currently in the midst of Stage 1. As noted early, the performance of the U.S. healthcare industry is mixed. High costs and highly variable clinical outcomes sounded alarms across the industry and among local, state and federal policy makers. Rising health costs began to assume a significant portion of not only the Federal budget but also all levels of the private sector. The stage model begins in 2010 with the passage of the ACA as the critical exogenous event for industry disruption.

In 2016, the industry is in the midst of consolidation. The ACA has reduced the number of U.S. citizens without coverage, but approximately 10 percent (32 million) citizen still remain without coverage due to gaps in the coverage models. Costs continue to be a focus. In particular public opinion considers drug costs too high and the ACA has significantly increased deductibles and out-of-pocket costs for some middle class segments. As noted earlier, the most recent statistics on overall health costs for the U.S. have begun to rise again after several years of moderation. Of particular concern is the 18 percent of U.S. GDP consumed by health costs.

With 4 years left in Stage 1, the ACA continues to dominate the landscape. Law makers and policy makers have not yet amended the ACA nor outlined a path for revision to the law. The other four transformation forces are accelerating and offer great hope for a new era of care. Table 1 provides a summary of the current and anticipated developments in Stage 1.
Table 1 Industry Developments in Stage 1 (2010–2020)

- Implementation of ACA, HCERA, HITECH, ICD-10 statutes
- Consolidation begins in all areas of the Industry
- Accountable Care Organizations & ACO pilot projects begin to clarify best practices
- Global expansion in “omics” sciences & systems biology. Breakthrough in gene editing technology (e.g. Crispr/cas9)
- Early adoption and experimentation with mobile health devices sensors, apps, machine advice & self-tracking
- Big data, analytics & artificial intelligence, computation converge
- Cloud infrastructure & services spur health platforms
- Social networks & media inspire new health models
- Rise of global middle class begins to shape health industry investments & consumption patterns

Stage 2 (2020–2030)
Stage 2 becomes a critical stage for the advancement of the industry. It will either mark a substantive departure from the past or a stumbling block for the U.S. health industry and the future health of U.S. citizens. A critical factor in the industry’s development during the second stage will be for the U.S. Congress and government health regulators to establish an effective refinement and amendment process for the ACA and related health legislation. The current ACA must be re-architected for a flexible amendment and revision process. ACA regulators will also need to become more efficient in the implementation and promulgation of the ACA and enforcement of directives derived from the ACA legislation. Efficiency across the entire industry will be key as well as a redistribution of investment into new tools, technologies and practices. This forecast assumes that the refinement process will be substantially complete and accepted at the latest by 2025. If policy makers cannot accomplish this task, the ACA may collapse under its own weight or fail to keep pace with advances in Stage 2.

A second key development expected in Stage 2 is the availability of low-cost high throughput (less than $500 USD) whole human genome sequencing around 2023. The introduction of whole genome sequencing, along with the related diagnostic tools will rapidly reshape medical care. The changes will come quickly. Experience with breakthroughs in targeted drugs, such as Gleevec (imatinib) and other tyrosine kinase inhibitors (TKIs) that targeted specific forms of leukemia, radically and quickly altered care modalities for chronic myelogenous leukemia, and rapidly altered drug development strategies. Rapid adoption of the drug Harvoni for the cure of Hepatitis C saw high cure rates with low side effects. The assumption here is that the same adoption rates can be expected from the availability of inexpensive genomic sequencing when considered in the context of related developments in the omics sciences and disease treatment. However, adoption will depend on effective use of individual genomic information in practice, resolving privacy issues regarding the collection and access to detailed individual genomic data.
and insurance coverage given pre-existing genomic conditions. Such issues are not new but need resolution.

A third key foundational element is a new approach to care, described here as “directed care.” Directed care will be driven by the increased use of digital health tools by health professionals, health consumers, and care provider organizations. Directed care is about the effective and collaborative division of labor between care professionals, health consumers and machines.

The care professional is positioned in the midst of powerful technologies that can radically and seamlessly amplify human medical expertise. As seen in Figure 3, the care professional (e.g. physician, nurse, specialist), the health consumer plus advocates, and health organization are supported by web of information and technology. All elements in the directed care are networked and can communicate and collaborate. Today, directed care is seen in online reference tools (e.g. AthenaHealth ePocrates), IBM’s Watson that leverages artificial intelligence and machine learning technologies, expansive data sets and massive computational power which provide both reference and advice. Assistive machine technologies will only get better over time. Figure 3 further illustrates the cohesive set of data input streams and resources that will be available to the healthcare professional and the health consumer. An important differentiator of the directed model of care is the comprehensive and integrated nature of the support. In the directed care model, the health professional understands not only the direct elements of a particular treatment, but has access to the latest research related to the treatment, its costs, other relevant tests under various conditions (e.g. prior treatments, concurrent diseases, and genetics might affect the decision or course of care.

Early examples of directed care are seen at Partners Health Care (Kvedar, 2015) and Kaiser Permanente (Kanter, Lindsay, Bellows, & Chase, 2013) where system wide electronic health records are available to provide care givers associated with the system a unified view of the patient. Several pilot projects using IBM’s Watson Supercomputer at health providers such as the University of Texas MD Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, Wellpoint illustrate the potential of machine augmentation in diagnostic and treatment activities (Doyle-Lindrud, 2015). Of course, these early examples must be shown to meaningfully impact medical outcomes and meet value expectations.

Directed care will move the industry toward the active care, personalized wellness model that will emerge in Stage 3, and will provide the foundation and natural transition to those future individualized care modalities. Under the directed care model, physicians, specialists, and patients will begin to have a unified view of care. The increasingly unified and directed model of care will drive a more comprehensive definition for the continuity of care. In particular, work on accountable care organizations, bundled payments and protocol-driven care will drive all segments of the industry to focus on value.
and outcomes. As a consequence, health consumers will be aided by greater transparency into the efficacy and cost of various procedures. Consumer awareness will be amplified by better digital information sources, self-tracking and greater consumer use of artificial intelligence and machine assistance in the areas of diet, exercise and other preventative options. Health consumers will begin to expect health professionals and health organization to view continuity in care from gestation to death and beyond to the next generation.

**Figure 3** The Anatomy of Directed Care

Directed care will also reinforce ACA mandates for local community health and efficiency, and more reliance on para-professional occupations to support continuity of care across all care episodes. The increased role of para-professionals in healthcare, particularly in nursing care specialties, is expected to grow significantly in Stage 2. The role of physicians and specialists will continue to expand and will be the primary drivers of care, but it is also likely that new modes of care will develop that are preventative and advisory in nature, enhanced by big data prescreens that narrow areas of diagnostic inquiry and leverage expert interpretive skills.
A fourth key development in Stage 2 will be the transformation of healthcare organizations, particularly the role of the acute care organization (Vitalari, 2015). The ACA and the implementation regulations as propagated by HHS and CMS will force health organizations to adopt network-centric and elastic business models. Acute care organizations will see traditional organization boundaries open and link to other acute care organizations, neighborhood care providers, groups, and non-traditional care providers. The main difference in stage 2 is that all care providers will be networked and hence any care episode, whether routine assessment or minor treatment at a local clinic will be recorded in an electronic health record that will be transferable and accessible. In addition, technological advances in cloud technologies, software, and universal connectors will enable organizations to interconnect virtually at will and partner on a moments notice to deliver care.

By mid to latter Stage 2, the structure of the industry will be understood as a dynamic map of capabilities, embedded in a constellation of global health platforms, similar to how Apple or Google are structured to provide their services and products (see Vitalari, ibid.; Vitalari and Shaughnessy, 2012; Soda and Zaheer, 2012). At the middle of this constellation of health platforms and providers will the health consumer.

The Stage 2 industry structure will not be a linear value chain model with goods and services flowing from producers to providers, but rather an electronically networked collection of capabilities that will link together based on medical need, disease expertise and experience, and expediency. Traditional categories of industry capabilities will still exist, but the activities of each will be more transparent and the regulatory model will mandate the sharing of data and greater collaboration. Players will link based on clinical outcomes more readily than under the present industry structure. Because medical science and practice are moving towards an individual focus, both producers and care providers will need to more efficiently partner to deliver solutions.

It is not only regulation that will drive these changes. The other three forces, particularly growth features of the global middle class, will drive both industry producers and care providers to restructure and flexibly collaborate in order to remain competitive and able to serve the billion-person marketplace. Monolithic health systems, based on an industrial era model of organization, will have difficulty with the move to directed care, the rise of personalized medicine, and the demands of a knowledgeable health consumer. All organizations will need to adopt new more elastic models of organization that enable trans-organizational partnering to fulfill the multitude of health consumer demands on a global basis.

Table 2 summarizes the key development expected to play a role during Stage 2 and support the prevention and wellness model of care that will emerge in Stage 3.
Table 2 Expected Industry Developments in Stage 2 (2020–2030)

- Revision and amendment of ACA, HIPAA/ HITECH, ACO & FDA regulations, trans-border privacy amendments.
- Industry consolidation grows with emergence of global health systems & internetworked global health platforms and health ecosystems.
- Healthcare labor markets diversify with expansion of new para-professional occupations augmented by machine learning, intelligence, and decision support.
- Early forms of personalized medicine emerge through “directed care” health delivery models augmented with new class of para-professionals. Physicians’ roles move to care, strategy, care continuity, and specialist interpretation and intervention.
- Big data, cognitive computing, analytics drive the “directed care” movement and solidify ACO & protocolization in industry.
- Early adoption of whole human genome sequencing (<$500), gene therapies and immunotherapies for cancers and other diseases, and genetic epidemiology transform diagnostics, care strategy & treatments.
- Health information availability, transparency and utility leads to higher levels of personal health awareness, monitoring and self-direction.
- Global middle class health care consumption & panomic data accelerate health delivery & genomic therapeutic innovation.
- Elastic business models transform firm structures and support “directed care” delivery models to serve massively differentiated global health needs.

Stage 3 (2030–2040)

Stage 3 of the industry’s evolution will be largely driven by the wide diffusion of low-cost high speed sequencing of individual whole human genomes on a global basis introduced in Stage 2. The omics sciences will drive and inform many interventions and care approaches. By 2030 it is reasonable to assume regularity in using human genomic data and microbiomics data of all forms to create an individualized care model that will span from conception to natural death. Stage 3 will reflect experience working with individual genomes in clinical settings in Stage 3. In addition, the directed care model will have accumulated unprecedented volumes of individual medical data as well as research data on diseases at levels of details and in more settings than ever possible before. It is only recently that the medical community has been able to identify the role of emotional response, psychology, and situation stimuli on changes in individual biology and overall health. By 2030, these interactions will produce much more detailed models of the exogenous and endogenous factors of individual health. The use of whole genome sequencing, not only as a baseline, but also throughout an individual’s life and care episodes, will lead to the emergence of a holistic personalized model of care with a focus on total wellness.

It is in Stage 3, that the full effect of the combined force of all five transformative forces comes into play. Assuming current trends, some 15 years out, technology, science, and global economics will have expanded their influence and will likely also produce additional breakthroughs. Since each force is significant in its own right, it is reasonable to expect that each force...
will have sufficient runway to offer new and unforeseen developments at that time.

Similarly, by Stage 3, health tracking technologies will have advanced significantly. Non-invasive real-time health monitoring of health should be routine and widely deployed, not only for improved care but for improved economics. It is also assumed that biometric sensors will be integrated into home environments and clothing. The flood of sensor data will also be better understood by Stage 3, such that the signal-to-noise ratio of such data will be increased and made useful, predictive, and actionable. A decade of experience with directed care should have sorted out key questions regarding privacy and security of patient records and their role in health industry collaboration.

Stage 3 should see an actively engaged health consumer with an emphasis on prevention, participation and wellness. With so much knowledge available and augmented heavily by machine-intelligence and access to global databases, an individual will be well equipped to pursue their overall wellness. Policy makers and health providers will need to include wellness objectives into public health policy while being mindful of individual constitutional freedoms. Wellness will need to be considered in the context of individual freedom, not simply social or economic expediencies.

In Stage 2, but in particular Stage 3, policy makers will be confronted continually with the definition of a social good and how to define good in a pluralistic, multi-cultural democracy. Consumers by Stage 3 will be conditioned to expect individually tuned regulatory frameworks. Policy makers will have the tools, but it will require a similar transformation of the policy apparatus as is commensurate with the transformation of health. Only time will tell how these capabilities will play out and be adopted. One thing is sure, many issues will be hotly contested and debated in Stage 3, and the current ACA and related policy framework will seem antiquated.

One can also envision epidemiology of global health being transformed. As a result, it is hopeful that the role of policy making and regulatory behavior may be conducted through a different lens. For example, policy makers in 2030 may be using whole population models to forecast disease patterns and the provider requirements for given age cohorts based on collected genomic data. Policy discussions are likely to be very different than today, having greater evidence-based rationale for decisions. It is not unlikely that governments may try to shape policy in a way that incentivizes individuals and communities in the aggregate to move community wellness toward particular outcomes. Nonetheless, overall wellness is likely to be a significant shared value in Stage 3.

As seen in Table 3, Stage 3 will continue to see regulatory revision. Much of the debate and discussion will take place on a global scale with opinions tracked across billions of individuals, each able to comment on their own experiences with treatment modalities and preferences about care. In addition,
the distribution of medicines, both prescription and over-the-counter may change radically, and these categories may no longer be relevant in a world with ubiquitous robotics, desktop factories, and synthetic genomic “printers.”

Finally, the question of how care will be delivered is worthy of discussion. Today, the hospital or clinic is the center for most care. It is highly likely that in Stage 2, the industry will begin to transition to a much more explicitly layered model of care, beginning with the introduction and emphasis on community health organizations (i.e. local clinics) with hospitals or specialty clinics handling specific diseases. In Stage 2 and early Stage 3 hospitals will still largely treat major trauma events (e.g. accidents and disasters). However, given what is now being witnessed in military battlefield care, it is also likely that some trauma care may be decentralized.

Given current research in the omics sciences, stem cell research, robotics, and nano-scale materials, Stage 3 will see the emergence of replaceable organs, bones and limbs, either made from the individual’s own cells or the individual’s own cells plus bionic materials or synthetic biological components. In this context, care modalities will first adapt to these developments particularly in trauma and acute cancer treatments. It is likely that those treatments will happen in larger care centers with controlled environments and staff that have the necessary level of skill to produce the right outcome reliably. In Stage 3, such centers may exist virtually anywhere on the planet and accept cases from any other place on the planet. It is not unreasonable to also expect a growing market of synthetic biological materials to enhance or replace natural human biological elements from the smallest molecules to entire organs. By, the end of Stage 3 (2040), the U.S. and the international healthcare industry will be share little, other than health consumers, with the current U.S. healthcare industry.

Table 3 Expected Industry Developments in Stage 3 (2030–2040)

- Revision of regulations to manage and support active and personalized care focused on overall wellness of entire U.S. population from pre-conception, during life and beyond to progeny in the next generation.
- Consumer adopts active and personalized model of health consumption based on personalized, precise, participatory, predictive, and preventative medical care.
- Global competition, trans-border flow of synthetic genome products, individuals with synthetic genome transplants or alterations.
- Global directed care systems provide trans-border care, some vertically integrated, other dispersed health ecosystems, with tiered pricing for mass differentiated health outcomes.
- Preventative medicine begins preconception and use of consumer collected pre-symptomatic markers with real time correlation global panomic and genetic epidemiological data sets.
- Individualized and custom drug formularies & treatments by disease provided by micro-drug factories or desktop “printers.”
- Appearance of bionic, biosynthetic materials and organs, modified or enhanced germ lines, molecules, and organs create ethical, regulatory, policy, and security challenges.
- Global genotypes and diseases virtually mapped and codified across all global populations.
Conclusions and Implications
Given the magnitude and trajectory of the five forces and their three-stage progression over the next 15–20 years, the U.S. healthcare industry is set for massive transformative change. As envisioned, the transformational process will be protracted with one series of transformative event after the other.

The analysis indicates significant developmental momentum in each of the five forces. Taken together the five forces provide ample capacity to transform the industry. When the trends are plotted over time, the cumulative effect drives a major conclusion: the healthcare industry in the United States in twenty years will have a different culture, different processes and a different calculus regarding wellness.

Implications
What are the implications? To better understand the implications of the analysis, it was useful to examine the stage model from its impact on five stakeholders or segments in industry: 1) the health consumer, 2) care providers, 3) payment plans, 4) producers and innovators, and 5) regulators. What emerges from this perspective are the dominant characteristics of each stage of industry evolution relative to each stakeholder’s arena. Figure 4 provides the major themes that emerge from the analysis for each of the stakeholders.

Figure 4 Summary of Industry Implications by Segment Idea

<table>
<thead>
<tr>
<th>Segment</th>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Consumer Experience</td>
<td>Fragmented &amp; Unmanageable</td>
<td>Manageable &amp; Accessible</td>
<td>Active Wellness, Individualized, Engaged &amp; Coherent</td>
</tr>
<tr>
<td>Care Providers</td>
<td>Traditional Care</td>
<td>Directed Care</td>
<td>Personalized Care</td>
</tr>
<tr>
<td>Payments &amp; Plans</td>
<td>Fragmented &amp; Dysfunctional</td>
<td>Accountable</td>
<td>Individualized &amp; Incented</td>
</tr>
<tr>
<td>Producers and Innovators</td>
<td>Mass Consumption</td>
<td>Modular &amp; Elastic</td>
<td>Elastic &amp; Individualized</td>
</tr>
<tr>
<td>Policy Makers &amp; Regulators</td>
<td>Plan, React &amp; Push Policy &amp; Regs</td>
<td>Amendable &amp; Accountable</td>
<td>Participatory, Amendable &amp; Accountable</td>
</tr>
</tbody>
</table>
Figure 4 crystalizes the significant change each segment will need to make. Producers, particularly life sciences companies, will move first and aggressively, in order to survive and thrive in the global market place. Consumers, too, will likely make the transition most easily, as expectations exported from other industries will have acquainted consumers with an increasingly engaged and individualized consumer experience. In the U.S. continuity of care across care episodes is either integrated by a primary care physician, membership in a single integrated care system (e.g. Kaiser Permanente) or integrated by the memory of the health consumer or the tedious work of a close advocate. Care is received from many different care givers, in different settings, and across different dimensions of care. EHRs are necessary for continuity of care, but not sufficient. Continuity of care is intricately intertwined with engagement. By stage 3, continuity of care should be much better and the health consumer and health profession should have a much better and more comprehensive picture of care history.

However, care providers and regulators are likely to find the transition most difficult and for different reasons. Care providers, whether an individual practice, community health organization, clinic, surgical center, hospital system or hospice center, will face significant procedural, process, occupational, workplace and technology changes in the move to Stage 2. The directed care model is information intensive and as a consequence depends heavily on information technology professionals and significant capital investment. Moreover, care providers have a large and diverse workforce and substantial retraining will be required. Those providers without good IT organizations and those that lack technological savvy will be at a serious disadvantage. As a consequence, the producer segment, which includes information technology firms, may need to co-invest with care providers to assist in the transition.

Regulators are ill prepared for the pace of transformation and innovation forecasted here. The perfect storm will prove frustrating as obsolete policy frameworks fail to move from the treatment based model of medical care to a more participative, directed and individualized form of care. Wellness may seem like an unlikely panacea to the policy maker. Moreover, current regulator frameworks are static push models where legislation is negotiated, passed and considered done. It is then delivered to government agencies to implement the law. For complex legislation like the ACA, the administrative implementation process takes years and often goes beyond what was originally envisioned by the legislator. In a rapidly changing industry such policy-making frameworks are dysfunctional and ineffective. One might hope that the current failure of policy makers in the realm of healthcare policy may engender a corresponding transformation of policy making itself. At present the policy process is ill-equipped to counsel a rapidly changing and evolving industry. Policy architectures and frameworks must become much more amenable and accountable, and ultimately participative to meet 21st Century demands.
The payments and plans segment may do the best. Already, plan providers have modified their actuarial assumptions to operate within the ACA environment. Some have lost money with the ACA and some have exited. Payment and plan companies are basically financial institutions. If the payout ratios become more favorable due to government intervention and improving health outcomes, as this analysis suggests their future looks much better in Stage 2 and Stage 3. Advances in health outcomes produce potentially favorable actuarial risk arbitrage opportunities.

Recommendations and Strategies
So what are the prescriptions for building a strategy, navigating the developments and extracting value from the impending industry transformation? From a strategic standpoint, the best overarching strategy is to begin to build flexibility into your organization. Traditional models of organization have difficulty rapidly incorporating new innovations, particularly technology. Health enterprises whether public or private must become elastic otherwise they will fail to keep pace with the changes ahead.

Since compliance with industry regulatory mandates and fostering a great consumer experience depend heavily on digital and information technologies, a key assessment is to determine the organization’s technological readiness. To thrive and operate in Stage 2 requires the right digital technologies and information architecture. As more organizations adopt the directed care model, greater demands will be made on IT and technology professionals for consistent and reliable operations. Prepare to have the capability to collect, manipulate and communicate massive data sets, far larger than any seen before.

The Health Consumer
The analysis projects significant improvement in the health consumer experience during Stage 2 and 3. The analysis leads to the following recommendations for the health consumer:

• **Begin today with a new view on health.** Most age groups alive today, including the baby-boomers have the opportunity to become active and engaged health consumers and self-trackers. An active approach to health increases the probabilities of good health.

• **Parents** should monitor developments in genomics, and if possible, consider whole genome sequencing for themselves and their children as it becomes affordable. Similarly, work to understand the key chronic illnesses that plague the U.S. and make the necessary lifestyle changes, to avoid childhood obesity and diabetes.

• While the aged may not have the opportunity to participate in advanced genomic treatments, it is likely that their children and grandchildren will. As a consequence, there may be value to have your genome sequenced within
the next decade, for the benefit of your children or other family members. Such information and your medical history may be very valuable for subsequent generations.

**Care Providers**
- Hospitals and Healthcare Systems must infuse their enterprises with proven digital and information technology practices and talent. Antiquated IT systems and platforms are a critical liability.
  - Capital acquisition and capital campaigns will be essential to navigate Stage 2 of the industry’s development. Compliance and the directed care model will both require capital for information technology. Key strategies such as lean approaches and the introduction of elastic organizational models will be necessary to cope with the increased use of para-professionals to maintain care levels and incorporate new talent pools.
  - Continue to leverage outpatient care. Cost reduction strategies and avoidance of in-patient risks (e.g. MRSA infections) as well as positioning internal processes to support home and remote telemedicine and monitoring platforms will pay dividends as units adjust to Stage 2 developments.
  - Adopt protocol-based treatment models, bundled payments, integrated practice units, ACO architectures and lean methodologies.

**Payments and Plans**
Payment and plan organizations adapted most rapidly to the ACA. However, as of 2015, reversals in the ACA implementation policies have thrown the reimbursement segment of the industry into flux. It is unclear how this will play out.

While speculative, it is possible that a tiered pricing model may emerge as early as Stage 2. Thus, it may be useful to explore supplementary insurance products to cover gaps in the ACA. Some payment companies are already using this strategy with add-on Medicare plans.

- **Tiered pricing** could be demanded by middle and upper income, highly engaged, self-tracking, wellness driven consumers. Since the ACA essentially specifies disincentives for so-called “Cadillac Plans,” smart upper middle class and affluent consumers will likely be interested in supplemental plans that they can purchase in addition to company plans. Other health consumers may also be interested, but it is difficult to isolate groups since the economic gaps in the ACA are unclear. Moreover, some policy makers disapprove of tiered pricing under the belief that it undermines the future of a single payer system.

- **Underwriting**, in general, is changing in the insurance industry, especially health plans in light of the new government subsidies or restriction injected into the economy. However, health plans will need to develop much
more flexible plans as development in the “omics” sciences move into therapies and practices. Consider how to support individualized medical plans based on a fully sequenced genome, correlated with big data, and operationalized with custom diets and lifestyle recommendations. Each individual will have a different risk profile and will demand different insurance products and nuanced health plans. The actuarial implications are complex.

- **Work to envision** what a Stage 3 health plan will look like. Since by stage three, the industry will have much greater epidemiological understanding of populations and sub-populations, it may be worthwhile to explore global business products that support a mass differentiation strategy concomitant with your risk tolerance. Also, it is important to begin discussions with legislators and policy makers regarding the characteristics of payment models and insurance plans appropriate for Stage 3 conditions.

**Producers and Innovators**

Industry producers and innovators comprise a broad set of players and actors, from university institutes, researchers and professors, to life sciences, medical device manufacturers, and information technology and mobile device companies. Most are well capitalized, global, and at the vanguard of industry developments. Many also greatly influence the direction of the industry and its therapeutic interventions. This study and analysis is heavily influenced by trends generated by producers and innovators and by their thought leaders.

Perhaps the most challenging elements of this analysis for producers concern their business models, especially monetization of intellectual property in Stage 2 and Stage 3. Ultra-low cost genomic sequencing will be virtually available to anyone and so will synthetic genome “printers,” and desktop chemical factories that will alter barriers to entry. Scale alone will not help because the scale and value of the global middle class consumer will overshadow any individual company’s market power. In the current political environment large scale pharmaceutical, life science and medical device companies are convenient targets for national politics. Nonetheless, economics matter and international competition will drive down profit shares over the long run. Volume rather than margin will be a more likely avenue for profitability and growth.

Now that biology has essentially become an information science, producers will need to keep pace with the latest developments in digital and information technologies and practices. Of particular importance will be digital security and physical and digital protection of intellectual property. This will be particularly difficult as Stage 2 and 3 will require an even greater use of co-development partnerships across a more extended global business ecosystem. It is highly recommended that producers aggressively pursue the development of safe and ultra secure collaborative platforms and the use of modular manufacturing and modular supply chain approaches.
Specifically:
• Pharmaceutical, life science and medical device companies need to aggressively move away from internal organization structures that stand in the way of the easy formation of cross-disciplinary teams in development activities, manufacturing and in customer partnerships.
  • Be mindful of network effects in your industry. Small nimble innovators that understand network effects can band together quickly to challenge incumbents. As genomic advancement progresses, network effects and new elastic business models will drive competition in Stage 2 and particularly Stage 3.
  • Producers must become participative. Early experiences among producers with Patients Like Me, suggest that participative models for all phases of development may become more prominent and valuable as the global middle class evolves.
  • Producers must realize that they will be held increasingly accountable for any missteps in the areas of privacy, synthetic genomic patents, and inadvertent unleashing of reproducible biological hazards.

Policy Makers and Regulators
The ACA is perhaps the largest piece of legislation ever put into law in the history of the United States. But it is not just the ACA; it's all of the progenitor legislation that stretches back into the 1990s and related implementation guidelines, rules and regulations.

Policy-making methods and frameworks in modern democracies have amendment provisions. However, political agendas often stifle the amendment and repeal processes necessary to make large laws work. As a consequence, the lack of participation in the developments of law and the reluctance to change leads to a dysfunctional accretive process that simply adds more elements to the regulatory process over time, rather than timely and effective legislation.

In a context like healthcare policy-making failures are unacceptable. Policy makers and politicians must build laws that assures the same quality processes in public policy formation as, ironically, the ACA, intends for the healthcare industry.

Specifically:
• Policy makers must design policy to be amendable and expect that complex laws will not be perfect upon initial passage. Good public policy formation demands continuous improvement and compromise over months and years following passage.
  • Policy makers regulating an industry must also be students of the industry and try to forecast developments. Given the development trends, there is a likelihood that the ACA, no matter how comprehensive, may lose it relevance.
over the next twenty years or less. Thus legislators and policy makers must prepare for a continual and protracted renewal process for health legislation and policies at all levels of government.

The current state of the healthcare industry is not sustainable. This analysis shows a path forward and suggests that a perfect storm of powerful forces will conspire to disrupt and transform the industry. The process of change will be difficult and protracted, but much will be learned and the United States and the rest of the world have the opportunity to significantly advance the wellness of U.S. citizens and global citizens with good policy and breakthrough innovations. Whether U.S. policy makers and industry players weather the perfect storm, only time will tell. However, the five forces know no bounds. Others in the world will not stand idle. Nor will innovation. If U.S. policy makers fail, Americans will suffer. Other national policy makers have access to the same perfect storm and can profit form it. The perfect storm may be turbulent but it can also lead to safe harbors and a dramatically healthier future for those that harness it.

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