A Prospective Analysis of the Future of the U.S. Healthcare Industry

Nicholas P. Vitalari, Ph.D.

Senior Research Fellow, Center for Digital Transformation
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Senior Research Fellow, Center for Digital Transformation, University of California, Irvine, CA, USA

ABSTRACT

This paper provides a speculative and prospective analysis of the structural changes in the U.S. Health Care industry following the passage of the Patient Protection and Affordable Care Act of 2010 (PPACA). The paper argues that a powerful constellation of forces will generate a perfect storm of transformation that extends beyond the regulatory event of 2010. The paper begins with a review of the present state of the industry and then presents four major forces that will shape the industry. Based on the four forces, the paper plots a three-stage model that forecasts the industry’s evolution over the next 25+ years. Key findings include: 1) while the PPACA has notable qualities, it is far from perfect and must undergo substantive and systematic revision and amendment, 2) advances in digital/information technologies, the “Omics” sciences, and growth in the global middle class will generate successive structural changes among industry participants, 3) the industry will progressively witness increased industry-related transparency, information sharing, and collaboration, 4) the “Omics” sciences, in particular, will reshape industry practices through a re-conceptualization of disease typologies, diagnostic tools, and therapies, and, 5) expectations exported from other industries will prompt a heightened emphasis on the health consumer experience with system impacts on health care delivery, care provider roles, business models and industry economics. The paper concludes with implications and recommendations.

INTRODUCTION

Flux best describes the current state of the U.S. health care industry. Following the passage of the Patient Protection and Affordable Care Act of 2010 (PPACA), virtually every component of the industry, namely the industry players, firm structures, industry economics, regulation, labor and the delivery of care must be reassessed.

This paper argues that the U.S. healthcare industry will go through three stages of evolution. Already halfway through the first stage, the industry will restructure within an atmosphere marked by uncertainty in the regulatory environment, continued scientific advancement, digital transformation, and global economics. By 2030, the U.S. health care industry will be radically different from today and ever more intricately tied to the global health market and its populations.

This paper begins with a brief examination of the current state of the U.S. health care industry, the myriad of problems that confront the industry, followed by a brief description of The Patient Protection

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1 This work was funded in part through generous grants from Qualcomm Foundation and SAP.
2 The author may be contacted at nvitalar@uci.edu or via LinkedIn at http://www.linkedin.com/in/nickvitalari/. 
and Affordable Care Act of 2010 (PPACA). It then turns its attention to the future of the health care industry in the United States. To understand how the industry will change, an analytical framework of key forces explores key developments that will shape the industry in the next two decades. Each of these forces drives their own set of health industry impacts. Collectively, these forces combine to destabilize the health care industry in the short-run. In the long run the industry will move toward a model of what is termed “directed care.” Directed care is envisioned as a precursor and foundation for the arrival of true personalized medicine beginning in the latter part of the third decade of the 21st Century.

By 2030, the industry will move toward a structure that supports personalized medicine, which at its core, is predictive and preventative, driving medical practice to be predominantly focused on wellness. The analysis then plots the implications for the industry over the next two decades, in three stages. 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 health care delivery and organizational operation.

THE STATE OF THE U.S. HEALTH CARE INDUSTRY

Conservative estimates put the global spend on health-related matters at $6.45 trillion3 and rapidly growing – fueled by poverty, aging populations, a growing global middle class, chronic obesity in developed and developing societies, 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. Thus the pace of growth in global health care spending, particularly in developing nations, is expected to accelerate rapidly for the foreseeable future.

The health care industry in the United States accounts for almost half (44.3 percent)4 of the $6.45 trillion that is spent on health care globally. Currently, the United States, alone, spends more per capita on health care than any other nation and its government subsidies amount to the largest line item in the U.S. Federal budget5. By 2020, estimates suggest that the U.S. will spend $4.6 trillion on health care – approximately 20 percent of U.S. GDP.6

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4 Ibid.
6 The question of affordability of care in the U.S. drives much of the debate in health care policy. Health and Human Services and its Centers for Medicare and Medicaid Services closely manage reimbursement policy. As a result, the rate of growth in U.S. health care costs have plateaued at around 7 percent/annum. However, at that rate, the total spend will be double the current spend in approximately 6 years.
The U.S. Federal Government, alone, will spend an estimated $882.2 billion on health care in its 2013 Budget. When state and local government spending is included, the U.S. will spend $1.48 trillion on health care for a population of 316.8 million. Including all health care expenditures (public and private), the U.S. will spend some 17.5 percent of GDP or $2.9 trillion on health care in 2013.

But the volume of dollars spent by the U.S. does not correlate well with health outcomes. While the U.S. has the most advanced and responsive health care system, spends the most on research, and has the most highly trained medical workforce, it does not have the best health outcomes. The U.S. ranks 38th when compared with other developed nations in terms of health outcomes. In a recent study published by the National Research Council, a prestigious panel of researchers, physicians, and epidemiologists ranked the U.S. last among 17 developed nations.

Nor does the U.S. lead in the number of practicing physicians per capita or hospital beds per capita. Moreover, recent data from a study in the Annals of Family Medicine, suggests that the number of practicing primary care physicians may be declining (due to retirement and voluntary retirement). As the provisions of the PPACA come into effect in 2014 with an influx of previously uninsured citizens, access to primary care physicians may decline faster without a requisite increase in physicians.

Other industry problems exist and have been well documented. The fragmentation and uneven distribution of profits, a concentration of margins among industry producers (pharmaceuticals, biotech and medical devices), quality of clinical outcomes, and use of emergency care departments for diagnosis and treatment of a wide spectrum of conditions are the most visible problems.

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7 World Health Organization. World Health Report 2000. Geneva, 2000. See also summary, World Health Organization Assesses the World’s Health Systems, http://www.who.int/whr/2000/media_centre/press_release/en/index.html. Detractors argue that such comparisons are flawed and subject to error due to incomparable demographics, delivery scale, measurement, methodology, or are simply outdated. However, it seems unlikely that even the most generous adjustments would move the U.S. significantly in the rankings.


Currently, the U.S. health care industry is a vast collection of public and private organizations, individuals and occupations (See Figure 1).

Figure 1: Examples of Occupational Diversity in the Health Care Industry

<table>
<thead>
<tr>
<th>Producers</th>
<th>Care Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Professors, researchers and lab assistants</td>
<td>• Medical specialists, physicians, nurses, nurse practitioners, nurse specialists and para-professionals</td>
</tr>
<tr>
<td>• Physician</td>
<td>• Administrators, executives, managers and supervisor</td>
</tr>
<tr>
<td>• Designers</td>
<td>• Board members, advisors, shareholders, philanthropists</td>
</tr>
<tr>
<td>• Engineers</td>
<td>• Psychiatrists, psychologists, genetic counselors</td>
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<tr>
<td>• Specialists</td>
<td>• Pharmacists</td>
</tr>
<tr>
<td>• Nutritionists</td>
<td>• Nutritionists</td>
</tr>
<tr>
<td>• Statisticians, information scientists and technologists</td>
<td>• Statisticians, information scientists</td>
</tr>
<tr>
<td>• Manufacturing specialists</td>
<td>• physical therapists, chiropractors</td>
</tr>
<tr>
<td>• Executives, managers and supervisor</td>
<td>• volunteers</td>
</tr>
<tr>
<td>• Board members and shareholders</td>
<td>• Lawyers</td>
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<tr>
<td>• Lawyers</td>
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<table>
<thead>
<tr>
<th>Regulators and Influencers</th>
<th>Plans and Payers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Local, state and federal elected &amp; appointed officials, NGOs</td>
<td>• Administrators, executives, managers and supervisors</td>
</tr>
<tr>
<td>• Regulatory agencies, regulatory panels, advisory panels</td>
<td>• Actuaries, statistician, information scientists and technologists</td>
</tr>
<tr>
<td>• Lobbyists, activists, unions NGOs, and association</td>
<td>• Financial analysts, accountants</td>
</tr>
<tr>
<td>• Third-party rating organizations and international standards bodies</td>
<td>• Physicians, researchers, advisors, consultants</td>
</tr>
<tr>
<td>• Investigators, enforcement personnel and prosecutorial and judicial authorities</td>
<td>• Information, technologists</td>
</tr>
<tr>
<td>• Physicians, nurses, nurse practitioners, nurse specialists and para-professionals</td>
<td>• Sales and customer service agents</td>
</tr>
<tr>
<td>• Engineers, statisticians, analysts, information scientists and technologists</td>
<td>• Claims adjusters, counselors, advisors, ombudsmen, and adjudicators</td>
</tr>
<tr>
<td>• Lawyers</td>
<td>• Lawyers</td>
</tr>
<tr>
<td>• Media, opinion leaders, spokespersons, and social media and networks</td>
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</tbody>
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Each segment has different perspectives, practices, interests and desired outcome profiles. In theory the common objective is the betterment of patient outcomes, wellness and community health. But the complexity often suboptimizes clinical outcomes. Moreover, riddled throughout the industry is a complex establishment of international, federal and state agencies, programs, regulatory bodies, public payers (e.g. Medicare and numerous others) and private payers that often contradict, overlap, compete and conflict.

12 A huge body of literature, too voluminous to cite here, has documented the problems in the U.S. health care industry. But the problems can be summarized as industry fragmentation leads to uneven practices and pricing that do not correlate well with health quality outcomes. The current industry is oriented toward providing treatments post diagnosis with minimal incentives for preventative care, which exacerbates the negative impact of preventative chronic diseases and an aging population on the underlying economics of the industry. Significant government subsidies to defray citizen costs have not been adequate and hence care is provided primarily by high cost hospitals and their emergency units that recoup their unfunded costs through negotiated settlements with Medicaid, Medicare, Children’s Health Insurance Program, Military-related programs, the Indian Health Service and state-government-run plans and private health care insurance plans. In the end most U.S. citizens get medical care but lower income levels receive care irregularly and often too late. See DeNavas-Walt, Carmen, Bernadette D. Proctor, and Jessica C. Smith, U.S. Census Bureau, Current Population Reports, P60-245, *Income, Poverty, and Health Insurance Coverage in the United States: 2012*, U.S. Government Printing Office, Washington, DC, 2013.

17 The problem of use of emergency units for general care is structural, profound and expensive. A recent Stanford University study of 76.6 million emergency room visits showed that charges for common conditions that could be treated elsewhere were high and highly variable. See N. Caldwell et al., “How Much Will I Get Charged for This? Patient Charges for Top Ten Diagnoses in the Emergency Department,” *PLOS One*, 8(2), 2013.
Porter and Teisberg\(^\text{14}\) enumerate many business and economic problems that contribute to the ineffectiveness of the U.S. health care 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 health care reform have failed. They argue, along with many other experts,\(^\text{15}\) 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." In other words, the health care 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.\(^\text{16}\)

The current state of the industry cannot be understood without understanding The Patient Protection and Affordable Care Act of 2010 (PPACA) and as amended by The Health Care and Education Reconciliation Act of 2010 (HCERA). Also known as the Affordable Care Act, the law 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 2013, the full impact of the PPACA is unknown and its implementation timeline is uncertain. In particular, a 2012 ruling by the Supreme Court\(^\text{17}\) upheld the PPACA, but in doing so also ruled that each State has the right to determine the degree of participation in PPACA. Thus each state has the right to opt-out of the PPACA Medicaid Expansion provision and health exchanges. Nonetheless, most of the provisions of the PPACA, along with new Medicare regulations and experiments (e.g. accountable care organizations)\(^\text{18}\) suggest a greater emphasis on the use of data, evidence-based medicine, and mandates for greater transparency and collaboration among industry players. But how these trends and timetables play out is uncertain.\(^\text{19}\) As a consequence, the full impact of PPACA on the structure of the industry will only be known with the

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passage of time. But the dramatic import of the legislation is clear: the structure and operation of the health care industry in the United States will change.20

Another element that characterizes the current state of the industry comes from the patient population itself. Demographics alone 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). Epidemiologists examine demographic groups to understand disease from the specific and dominant behaviors of each demographic cohort (i.e. epidemiological profiles and behaviors of specific U.S. populations). From this perspective, a significant longitudinal shift has occurred in the United States. In 1900, the leading causes of death were infectious diseases (i.e. pneumonia, tuberculosis, and diarrhea) and the average life expectancy was 45 years. In 2010, the average life expectancy was 78.7 years and the leading cause of death and disability was preventable chronic disease.

Chronic obesity, particularly chronic childhood and adolescent obesity, fueled by unhealthy diets and limited aerobic physical activity, 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). As the chain of chronic disease ripples throughout the population, the lifetime cost of treatments is compounded. According to the Centers for Disease Control, chronic diseases are now the leading cause of death and disability in the United States with the four common causes of chronic disease being lack of physical activity, poor nutrition, tobacco use and excessive alcohol consumption.21

The industry is not without its bright spots. Major investments in genetics research and the sequencing of the human genome in 2000, and the emergence of the Omics sciences (i.e. genomics, microbiomics, metabolomics, proteomics) may significantly alter the way the industry understands wellness. While the original vision of gene therapy has not been realized, other unexpected therapeutic interventions have emerged, such as adult stem cell therapies, targeted medicines based on new understanding of cell function and signaling, as well as the identification of correlations between inherited gene defects and various disease states. At a global level, the combined research, as well as advances in sequencing technologies and microfluidics, holds great promise for disruptive and breakthrough changes in treatment modalities and health delivery models.

20 To some critics, the combination of healthcare policy, regulations, mandates, taxes, subsidies, research funds and the related health care apparatus qualifies it 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 spectacle of rising health care costs, particularly in the United States. For example, in 2008, all government spending on healthcare was $1,155.1 billion. Today those expenses have grown by $330 billion, a five-year growth rate of 28.5 percent. The industry continues to debate whether the PPACA and related Medicare regulations will slow the growth.

Finally, advances in computer and information technologies (i.e. biometrics, bio-informatics, digital and information technology, mobile devices, ubiquitous digital broadband networks) and new care models are beginning to alter care and practices in research institutes and hospitals.\textsuperscript{22,23,24} In particular, mobile devices, big data, social networks, and integrated health information systems with electronic health records (EHRs) and health platforms that make use of The Cloud (e.g. Athena Health) provide a new and more effective health consumer experience. Unfortunately, the cost is significant to move to these new practices and often individual health systems cannot afford the investment to move to the new information intensive infrastructure. Several other trends have recently appeared as a result of advances in digital technologies. In particular, the advent of the smartphone and related mobile health apps, sensors and devices, that can be acquired over-the-counter, have inspired a segment of consumers to closely monitor personal health related statistics on a daily basis.

In summary, the current state of the health care 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, including the population 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 begins.

**ANALYTICAL FRAMEWORK AND INDUSTRY ANALYSIS**

Given the complexity of the health care industry, any attempt to forecast its direction will be subject to error. Nonetheless, despite the many moving parts, there are major macro trends that together may overcome even the most complex and intransigent industry structures or political standoffs. These major trends, in turn, generate intermediate health-related trends, natural incentives and behaviors that will shape the next 20 years of the industry.

Amidst the backdrop of trends, one major aspect of the twenty-first century is the massive impact of shifting economies and the growth of emerging markets. While the subject of this analysis is the U.S. health care industry, global economic change is driving creative destruction in all industries. Creative destruction is in full force in the health care industry sponsored by a confluence of factors that have intertwined to produce a perfect storm of change. One need only to observe the sources of drug innovation (small companies), or reverse innovation in the medical device arena (BRIC nations), or disruption from the genomics revolution (globally distributed), or the medical tourism movement (e.g.


India), to see creative destruction in process originating not only from activity in the U.S. but from innovation across the planet. So the transformation of the industry must be seen against the global macro socioeconomic trends.\textsuperscript{25}

The purpose here is to outline the major topographical features and suggest a vision for how the industry might progress, not to provide a \textit{high-resolution map} of the future. 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 path and to make appropriate decisions. Five key assumptions drive the analysis:

1. Broad global socioeconomic trends will exert significant impact on capital investments, allocation of resources, innovation, and share of industry profits.\textsuperscript{26}

2. Traditional industry analyses that rely on static, or strictly linear views (see Figure 1) of industry value chains fail to uncover the impact of the now pervasive network effects on industry structure. With the widespread availability of robust communications networks, value networks in twenty-first century industries reconfigure regularly to increase the customer value proposition, new innovations, and in the health care industry, optimal wellness. For example, each time Apple introduces a new iPhone model, new components, new materials, and new suppliers are employed. Thus this paper views the emerging health care industry and marketplace as composed of a constellation of fluid, globally interconnected value networks where alliances, partnerships, and collaborations will be much more dynamic than in the past. Therefore, the actual structure and configuration of the health care industry is better conceptualized as a series of maps that vary according to disease typologies, consumption patterns, appetite for wellness, sources of innovation and massively differentiated market dynamics.\textsuperscript{27} \textit{Mass differentiation}, in particular, naturally emerges within large diverse global markets. To make mass differentiation work, companies must adopt elastic models of organization as has

\textsuperscript{25} Though outside the scope of this paper, it is vitally important to understand the impact of various levels of poverty, particularly extreme poverty and its impact on health care policy, definitions of wellness, and the inter-relatedness of pan-global health outcomes in both low-income and high-income geographies. As health outcomes improve globally, eradication of poverty, care of the poor and access to continual and timely health services will increasingly exert influence on health policy decisions everywhere.


\textsuperscript{27} Recent examples support this networked view of the health care industry: the rise of modular manufacturing and small-scale clinical production in pharmaceuticals, PPACA mandates for information sharing and collaboration, use of cloud and mobile technologies with outpatient, home, and rural patients, and rapid response vaccine production and pandemic rapid response consortia.
appeared in a range of other industries (i.e. telecommunications, information services, mobile devices, insurance, financial services, heavy manufacturing), in the last decade.  

Figure 2: An Illustrative Traditional Value Chain View of U.S. Health Care Industry

3. The U.S. health care industry will undergo, at least, two transformations over the next two decades (see Figure 2). The current state of the industry (Stage 1) is best characterized as flux and uncertainty. It will then undergo an uneven period of adjustment and resolution (Stage 2) for a decade or more as the industry adjusts to massive changes in the regulatory environment, uncertainty and negotiation regarding revisions to the PPACA, rapid adoption of new digital, information and computational technologies, and the developmental stages of scientific advances generated from micro-

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29 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 (~30 years) is based on the notion that the changes will take some time to play out. Moreover, given the ambitious nature of the PPACA 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 (Stage 2). Nonetheless, other major transformative factors such as digital technologies, advances in science, and global economics will also transform the industry over a longer period of time. Of course, the time frames chosen are relative and will vary depending on how the actual events play out.
fluidics, molecular and single-cell level diagnostics, targeted medicines and early genomic-inspired therapeutics, and the emergence of a “directed care” delivery model. Stage 3 will commence with proven, very low cost, high throughput genetic sequencing that will enable the mass consumption of genomics related interventions and treatments and inaugurate the industry’s move to a systems biological model of 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.  

**Figure 3:** Projected Stages of Transformation for the U.S. Health Care Industry

4. The world of medicine and business is becoming more elastic. Elastic is the term to describe companies and organizations that use new structures (e.g. business platforms, business ecosystems, the Cloud, mobility etc.) to maintain fluid or agile organizational structures that enable extended partnerships, broader collaboration, and better responsiveness to changes in the business environment. The use of these new structures, which is a major departure from industrial era enterprise organizational structures, enables companies and institutions to more easily adapt and, most importantly, to

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incorporate new partners, new innovations, and new technologies faster, with greater collaboration and with less friction.  

5. 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 (see Appendix A). 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.

However, unless the economics of health, the quality of care and the industry’s regulatory issues are sorted out in Stage 2, the industry will likely get stuck in protracted political stalemate and deliver only nominal changes and benefits. As Porter and Lee argue, a value agenda is essential for the industry to evolve and for care providers to survive and be successful:

The transition will be neither linear nor swift, and we are entering a prolonged period during which providers will work under multiple payment models with varying exposure to risk. In this environment, providers need a strategy that transcends traditional cost reduction and responds to new payment models. If providers can improve patient outcomes, they can sustain or grow their market share. If they can improve the efficiency of providing excellent care, they will enter any contracting discussion from a position of strength. Those providers that increase value will be the most competitive.

An Analysis of the Next Generation Health Care Industry

Despite the historic intractability of the U.S. health care industry, its current problems, and its resistance to change, there is good reason to believe that the industry now stands on the threshold of transformative change.

At least four critical forces will drive the U.S. health care industry for at least the next two decades, if not more. From an analytical perspective, each trend gives rise to a series of health care

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32 Recent challenges to the regulatory specifics in the PPACA and Congressional wrangling regarding funding or de-funding of particular elements of the legislation and it implementation lend additional uncertainty to the industry’s trajectory.

33 Porter and Lee, October 2013, *op. cit.*

34 There are other forces that continue to drive the industry and most other industries, but are systemic and difficult to assess. For example, demographics, particularly aging populations and the jobless young, have massive implications for the economics of the health care industry. So, too, does epidemiology, particularly diets and lifestyle factors, which can adversely contribute to health economics and treatment outcomes (e.g. chronic disease and morbidity). Global poverty is also a factor that exerts influence on the health care industry, particularly in light of the United Nations Millennium Development Goals - http://www.un.org/millenniumgoals/. 
trends that have the potential to radically change the definition and structure of the industry.\textsuperscript{35} Understanding how these forces will conspire and in turn shape critical health care trends forms the basis for the analysis and support of the 3-stage model briefly introduced earlier.

If the analysis is valid, a very different industry structure will evolve over the next two decades, with more flexible business models, a more differentiated service structure that will encompass not only U.S. populations, but an industry that will serve and will be served by a growing internetworked global health care 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 health care providers, the Federal Government), but it will also see a vast network of global digital business platforms that serve interconnected business ecosystems of other established industry players, start-ups, and individuals with greater collaboration among all industry players and increased transparency in industry transactions and care outcomes.

**Four Transformative Forces**

The first decade of the 21\textsuperscript{st} century produced a constellation of social, economic, scientific, and technological change. Each of these reset critical foundational elements of the health care industry. Economic change came in the form of greater transparency, global recessionary pressures and fluidity in global labor markets and a destabilization in financial markets. The historic economic changes, in part, fueled the political will in the United States to pass key health care legislation as seen in the PPACA.

Other social dynamics combined to shape sensibilities with regard to health care in the United States. The growing problems with obesity began to shape social policy especially with regard to children and teenagers. Many of these social and behavioral dynamics influenced the payment priorities for health care, as seen in many revisions to Medicare and Medicaid coverage, as well as payment schedules and policies of private payers and informed key elements of the PPACA.

From a scientific standpoint, truly historic breakthroughs characterized the first decade beginning with the unexpected 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 and targeted

\textsuperscript{35} Since each of the four macro trends will continue to evolve over this period, players will be driven to greater levels of collaboration and more elastic and innovative business models to keep up with industry change and remain competitive. The new business models will employ greater levels of digital and information technologies, particularly cloud technologies, massive data sets (big data), greater use of sensors, and common technology platforms in order to meet new patient needs and an increasing emphasis on health outcomes.
medicines using a variety of newly discovered pathways. Experts suggest that a succession of major breakthroughs will continue.  

Digital, information, computational and network technologies also continued their 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 health care 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 4 illustrates the four key forces and related health care trends. They are:

1. The Patient Protection and Affordable Care Act of 2010 (PPACA) 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 health care, health care innovation, lifestyle changes, and consumption of health care services and products.

**Figure 4:** Four Key Forces in the Transformation of the U.S. Health Care Industry

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36 Leroy Hood, op. cit.
Each of these four forces drives a secondary set of critical trends that shape many aspects of the health care industry and provides important clues as to the future structure and configuration of the U.S. health care industry.

**The PPACA**

The Patient Protection and Affordable Care Act of 2010 (PPACA), as amended by The Health Care and Education Reconciliation Act of 2010 (HCERA), has already altered the future of the U.S. health care industry. Since the PPACA was passed, merger and acquisition activity has increased as health care systems respond to provisions in the laws for community health organizations. State and local governments have restructured their agencies to make way for health exchanges. And the IRS, the chief taxing agency of the U.S. federal government, is preparing to oversee penalties and taxes specified in the PPACA.

The law has many components. It 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 PPACA 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 health care exchanges and provides premium and cost-sharing subsidies through the exchanges. 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 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.

The full implementation of the bill has already generated thousands of pages of regulations. 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

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38 The full text (2,407 pages) of the Patient Protection and Affordable Care Act, also known as the Affordable Care Act, may be accessed here: http://www.hhs.gov/healthcare/rights/law/index.html.

39 The brief high-level summary of the PPACA here, in no way, plumbs the full scope or depth of the law, its mandates, philosophy or stipulations. Few have read the entire law and it suffers from its own weight of complexity. As a consequence, since its inception, it has generated enormous controversy and debate. The law is designed to be a comprehensive statement and set of mandates that directs virtually every facet of the industry and thus sets a new course for health care in the United States. This analysis takes an apolitical position and assumes that some form of the law will survive. Second, it assumes that given the complexity of the industry and interests served by the law, no one, no matter how prescient could construct a usable piece of legislation on the first try. Therefore, the most obvious policy making omission is the lack of accompanying legislation that establishes a policy revision framework that enforces a continuous process of improvement and compromise.
“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.

From an industry perspective, the law introduces new structures and new economics. It is estimated that the law now guarantees care and services for 30 million citizens, many of whom received care from providers via the emergency room at major hospitals. Under the law these individuals will now be eligible to receive the full range of care, including preventative, curative, and palliative care.

In particular, the PPACA mandates new levels of collaboration among insurers, providers, caregivers and patients. Ultimately, the PPACA will drive a new range of information technology solutions and interconnections among existing and future systems for the transaction and retention of health care information. The PPACA, 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 PPACA, 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,40 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 is an industry term for the use of proven standardized and accepted protocols for treatment. Protocolization is an inherent concept in the PPACA and related incentives for Accountable Care Organizations (ACOs) and incentivized reimbursement schemes in the post-PPACA 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 other parties into costs, 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 PPACA (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 PPACA ties Accountable Care Organization reimbursements to quality metrics and reductions in cost as per a specific population of patients. As a result any collection of 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.

The PPACA must also be understood in conjunction with earlier legislation -- 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 PPACA, in conjunction with the HITECH Act, is also expected to drive business model innovation in the industry. Because the PPACA 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 include exchanging health records, sharing insurance information among providers and payers, providing support for home health care, and consolidating personal health information.

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41 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.

42 According to a study by Becker’s Hospital Review, “Medicare ACOs proliferated within the past year. CMS named the original 32 Pioneer ACOs in December 2011 and the first 27 Medicare Shared Savings Program ACOs in April 2012. It added 87 more ACOs to the MSSP program in July 2012 for the program's second performance period, and 106 ACOs for the program's third performance period, which began Jan. 1, 2013. CMS expects to add another 100 to 200 ACOs within the next two years.” For the list of ACOs see Molly Gamble and Heather Punke, “100 Accountable Care Organizations to Know,” Becker’s Hospital Review, August 14, 2013, http://www.beckershospitalreview.com/lists/100-accountable-care-organizations-to-know.html.

43 In January of 2013, Health and Human Services announced a “final ruling” on the HIPAA and HITECH (Subtitle D which addresses privacy and security concerns) Acts 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 (PHI).

44 Such violations are costly. Recently HHS settled and fined Affinity Health Plan, $1,215,780 plus the implementation of a corrective action plan for HIPAA/HITECH violations after a copier with a hard drive containing confidential patient information on as many as 3,344,579 individuals was returned to leasing agents without erasing the information contained on the copier hard drives.
meet PPACA 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.

Figure 5 provides a summary of the expected impacts of the PPACA on the structure and operation of the industry. The PPACA creates an environment in health care that drives these health care trends:

1. Affordable Care Organizations (ACOs) – a major mandate for care delivery organizations with CMS incentives.
2. Industry transparency – a series of mandates including health exchanges require new information sharing activities.
3. Industry collaboration – PPACA forces industry collaboration through a range of provisions (e.g. reporting requirements, ACOs), incentives and disincentives.
4. Protocolization – inherent in the logic of the PPACA as well as in the practices driving ACOs. Outcomes will fuel the drive to protocolization.
5. Bundled payments – motivated by cost control, patient transparency, and outcomes, bundling drives the industry to explicit linking of cost to value and then to quality outcomes.
6. Tiered health delivery models – an unintended consequence of the PPACA will drive some health consumers to purchase, and some physicians, to provide premium services not covered under the law but deemed worthy in the market for those that can afford them.
7. Health ecosystems – Given protocolization and the move to outcomes-based care, large and small care provider systems will associate and link together in new ways.
8. Health platforms – protocolization will drive the need for business platforms that support specific health modes and also support a range of other specialty needs as well as interconnections between health consumers and health systems.

Even if the Act is partially repealed by future administrations, Congresses, or the Supreme Court, the payment model, insurance marketplace, and the structure of collaboration among industry players has

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45 A number of health platforms for individuals and physician have already emerged to support specific disease types and the uptick in self-tracking behavior by engaged health consumers. In addition, health platforms can serve underserved communities, for example see T. Teijeiro, P. Félix, and J. Zammarón, “An Open Platform for the Protocolization of Home Medical Supervision, Expert Systems with Applications,” (2013) 2607-2614.
already been altered.\textsuperscript{46} It is reasonable to expect, that despite the uncertainty regarding the final disposition of the PPACA, the trends identified above will persist.

\textbf{Figure 5: Health Care Trends Fostered by the PPACA}

\begin{figure}
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\includegraphics[width=\textwidth]{health_care_trends.png}
\end{figure}

\textbf{Digital and Information Technologies}\textsuperscript{47}

The digital revolution affects virtually every industry. The health care industry is no different. In fact many of the elements of the PPACA are predicated on existing and future developments in digital technologies. Many parts of the health care 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 computation analytics. But it is all at an early stage and the transition to these technologies has

\textsuperscript{46} It is important to note the significant controversy and uncertainty surrounding the PPACA currently. The PPACA is monolithic and massive. In the Fall of 2013, the initial rollout of the Federal insurance exchange and millions of previously privately-insured citizens lost their existing plans, forcing the President to alter the implementation timetable and reverse previously propagated guidelines for private insurers. Public support for the legislation has declined since its passage and key provisions have been delayed at the time of writing. Politics also threaten to defund the bill. The CBO has revised cost estimates for the implementation of the PPACA 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 PPACA is uncertain in view of the political and legal environment.

\textsuperscript{47} 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, super computers, information systems, software, digital displays, cameras, and digital sensors. Many industries, such as health care, 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.).
been very difficult for the industry (e.g. transition to ICD-10 coding, implementing EHS, responding to mobile health initiatives). Each new digital innovation requires massive investments, training and organizational change.

Nonetheless, the digital revolution is pushing and pulling the entire industry. Digital technologies transform the health care in three fundamental ways: 1) at the health consumer level, 2) at the enterprise level, and 3) at the industry level.

Consumer Level

At the consumer level, three major developments significantly change the vision and modality of patient treatments -- social networking, mobile, and analytics. The rise and rapid adoption of social networks such as Facebook and LinkedIn, as well as health social networks like Patients Like Me, has made it easy for individuals to share information and support.48

The second major trend is the rapid adoption of mobile communication devices and wearable computing and self-tracking.49 Consumption behavior and preferences have been significantly shaped by mobile device use over the past decade and, more recently, with the advent of smart phones. Consumers now demand a consistent customer experience whether on a mobile device, in a store, or on their desktop computer. Moreover, when mobile devices are considered in conjunction with social networks and media, the customer becomes not a single customer per se, but a customer in an ecosystem of other customers, friends, and social network members, all with experience and opinions.

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.50 In recent years, the emergence of wearable computing devices that interface with the smart phone has captivated a growing number of individuals who collect and track their own health information. More and more smart phone owners use their devices to collect health-related information and monitor preventative health activities such as exercise and diet. Companies, like Nike, FitBit, 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. Given the continuing advancement in biometric sensors and the development of other types

49Gary Wolf, “Know Thyself: Tracking Every Facet of Life, from Sleep to Mood to Pain, 24/7/365,” *Wired Magazine*, 17.07, 2009
of wearable computing, more health data will be available to consumers. While the diagnostic value of
detailed data of this nature is hotly contested within the medical community, highly health-engaged
consumers will drive demand for use of this data and other sensors.\textsuperscript{51} It is no longer the rare physician
that must advise their patient while the patient looks up the latest research on a drug’s contraindications
and side effects or has their advice compared to other noted experts. Or worse has their advice shared
realtime with hundreds of Twitter or Facebook followers during the consultation -- all outside the confines
of HIPAA.

On the professional side, physicians and other care providers employ social networks and mobile
technologies for their own benefit and for the benefit of their patients. Companies like MedAdherence\textsuperscript{52}
provide health platforms for use with mobile phones to assist patient engagement and physician
monitoring of therapeutic compliance and at the same time provide patient education in realtime.

**Enterprise Level**

Information technology has been in use for over 40 years in health care enterprises. Traditionally,
care organizations used information technology for patient records, lab management, administrative
functions, accounting, finance, inventory, data management, and reporting. Producers have been more
aggressive in the use of information technology and have for some years employed advanced computation
for drug development, precision manufacturing, and more recently, mobility and cloud-based solutions in
products and services.

It is expected that the emphasis on ACOs, bundled payments, protocolization, 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.

When considering the impact of digital technology at the enterprise level, it is useful to
distinguish between care delivery organizations (e.g. hospitals, clinics) and industry producers (e.g.
medical device makers, drug makers). As we’ve seen in other industries, some health enterprises have
already become more flexible and have adopted more elastic structures and have invested heavily in
information technology.

\textsuperscript{51} Dr. Larry Smarr at the University of California, San Diego is at the vanguard of a concept known as the “quantified self” or
self-tracking aided by mobile and other specialized devices. Smarr has been collecting detailed medical data on himself and
monitoring other vital functions daily by computer. His collection of detailed data provided an early diagnosis of his Crohn’s
and the California Health Foundation notes that 60 percent of U.S. adults are self-tracking, see Susannah Fox and Maeve

\textsuperscript{52} MedAdherence, LLC. “MedAdherence and Verizon Foundat
ion to Work Together to Expand Mobile Health Services to
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 document, a combination of information technology and changes in organizational structures (i.e. Integrated Practice Units) can also improve patient outcomes.\footnote{Porter and Lee, October 2013, op. cit.}

Mobility and big data have already begun to impact the operations of health care organizations of all types. Even before the PPACA, 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 health care 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. In turn, these developments spurred new innovations in biometrics and bio-informatics, particularly in computational and mass data storage structures\footnote{Personal health records are likely to get quite large, since the human genome consists of 3 billion bases pair, a patient record in the future could include an individual genome and a family genome, demographics, medical history, medications and allergies, lab tests and results, digital image, plus other personal and wellness data. When considered for a population, new methods for data handling and analysis will be required and is the subject of work in research institutes and universities.} and the use of machines to provide preliminary diagnoses to guide physician diagnoses and treatment regimens (e.g. IBM’s Watson cognitive computing collaboration with Memorial Sloan-Kettering Cancer Center and Cleveland Clinic and Care Core National).

**Industry Level**

At the industry level, virtually every aspect of the industry is undergoing digital transformation. At the industry level there is a growing recognition of the value of using cloud technologies, particularly as a vehicle to establish cross-industry collaboration, as well as to facilitate physician-to-physician collaboration, patient access to medical information and medical education. The development of health exchanges, as mandated by the PPACA, will also spur the development of a range of privately funded health platforms to support many aspects of health, such as home health care tools, telepresence, remote consultations, rural telepharmacy, tele-stroke care, mobile cardiovascular tools, and many others.\footnote{Erin Bartolini and Nicholas McNeill, *Getting to Value: Eleven Chronic Disease Technologies to Watch*, NEHI, Cambridge, MA, June 2012.}

Significant change can happen at the industry level when a government sponsored health care program is put in place, 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 health care providers, both public and private, in a common 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.

Continued advances in digital and information technologies will have significant impact on the industry. Of particular importance is the interplay between digital and information technologies as an enabler of the other three major forces driving the industry’s transformation.

Figure 6 provides a summary of the impacts of the digital revolution on the health care industry which, in turn, drives key health care 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 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 health care. 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.
Figure 6: Health Care Trends Fostered by Advances in Digital and Information Technologies

The Omics Sciences

Developments in the omics sciences (e.g. genomics, proteomics, microbiomics, pharmacogenomics) and systems biology (e.g. low-cost high speed gene sequencing, panomic databases) will continue at their current pace. The implications are profound. Advances in targeted treatments for a range of medical conditions (e.g. precision medicine), including previously intractable forms of cancer as seen in particular types of leukemia (e.g. CML) and variants of other cancers based on patient genetics, and the particular genetic mutation and progression of the disease, are expected to continue.\(^{56}\) Advances in microfluidic systems have enabled new forms of diagnostics and new forms of molecular and single-cell level research. Theranos, a new start-up, now offers proprietary diagnostic technology for thousands of blood tests ranging from the routine to complex genetic tests using non-invasive (i.e. finger prick) analyses of minute drops of blood.\(^{57}\)

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, a proponent of systems biology, and one of the pioneers of 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. Medicine will move to a combination of proactive and predictive diagnostics that “…detects diseases at the earliest detectable phase, weeks,

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\(^{56}\) According to John V. Heymach, a lung cancer specialist at MD Anderson Cancer Center, Houston, “It’s likely that more than half of tumors [lung cancer] have some type of alteration we can target with a drug.” Ron Winslow, “Gene Breakthroughs Spark A Revolution in Cancer Treatment,” \textit{Wall Street Journal}, August 13, 2013.

months, and maybe years before symptoms appear,” followed by drugs that will push the disease-perturbed systems back to normal. In this future world, medicine will focus on prevention and wellness. Hood 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 initial sequence of the human genome unleashed a global torrent of new research on cell biology, systems biology (i.e. the interaction of different human biological systems and organs) as well as the genetics of symbiotic systems (e.g. gut biomics). The work led to a greater understanding of medical conditions and their progress.

Parallel advances in ultra-rapid gene sequencing, in micro-fluidics and single cell isolation mean that it will be possible to construct a complete genomic map of each individual for less than $500 in about a decade, or perhaps sooner. Since the genomic map does not change, this will provide each individual with a baseline and the ability to index that individual map with each new understanding of each new disease.

As mentioned earlier, some scientists, such as Larry Smarr, have correlated their genetic information with the latest research to find personal diseases earlier than visible in traditional diagnostic tests. As consequence, 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.

Figure 7 provides a summary of the impacts of the omics revolution on the health care industry. These impacts will, in turn, drive key health care trends that will shape the industry in the coming years:

1. High speed sequencing – the goal is to sequence an entire human genome (i.e. whole genome sequencing) for an individual for less than $500.

2. Microfluidics – includes various technologies to sift, screen and isolate cellular level and molecular level elements in biological materials.


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.

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58 Leroy Hood, p. 11-13, op. cit.
5. Realtime diagnostics – the combination of microfluidics, non-invasive sensors and portable computing suggests that health will be monitored in realtime as a matter of course in everyday life.

6. P4 medicine\(^59\) -- 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.

Figure 7: Health Care Trends Fostered by Advances in the Omics Sciences

![Diagram of Rapid Advances in the Omics Sciences leading to High Speed Sequencing, Micro Fluidics, Single cell Analysis, Systems Biology, Realtime Diagnostics, Personalized Medicine, Predictive Medicine, Preventative Medicine]

The Global Middle Class

The health care industry has long been a truly global industry with global collaboration in many areas. Since World War II, the United States has led the global health care industry in scientific advances and technology. As mentioned earlier, the U.S. health care market is the largest market to date.

But that will change over the next decade. In the first decade of the 21st Century a new factor began to influence the health care. In terms of dollars spent, the U.S. health care industry is the largest, but the global middle class will soon outdistance the U.S. market in both spend and numbers of health

consumers. The growth of the global middle class will profoundly change the profit shares, investment priorities, and structure of the U.S. health care industry, particularly in the producer segment, although care providers will change too. As a result, companies in the industry will need to change their business models and become much more attentive to the nuances and needs of various local markets.

The global middle class is defined as individuals in the annual income range at around $4,000 to $20,000, which in 2012 was approximately 2 billion people. The impact of the growing global middle class is not often considered in the evolution of the health care industry in the United States. However, U.S. health care firms will be attracted to the growth in health care demands of the global middle class and will adjust their strategies and organizational models. Global health care firms will also face increased competition.

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 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. Mass differentiation is the 21st century equivalent of market segmentation, except it is done on a more granular level and also 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 will shape the offerings and services of health care providers and producers as attempts are made to serve the global middle class.

The development of the global middle class also spurs innovation. Consider the recent experience in the BRIC countries. In the BRIC nations, indigenous health industries have developed and are already producing innovative health products and innovative health services for export. Known as reverse innovation, unique epidemiological factors and local economics provide a crucible for new

60 George Eliades et al. p. 3-4, op. cit. Bain forecasts that while the overall global profit pool for the industry will increase from $520 billion in 2010 to $740 billion in 2020 (a CAGR of 4%), a significant part of the growth will be in emerging markets. In the process, aggregate profit for the global health care industry will decline marginally because most of the global growth will be from “...increased volume in the delivery of care, while another significant source of growth will come from smaller sectors like contract research or manufacturing...particularly in emerging markets.”


62 Mass differentiation goes beyond mass customization and also requires elastic business models. For a discussion of mass differentiation and elastic business models see Vitalari and Shaughnessy, pp. 15-20, op. cit.

approaches to medical problems, services and products. 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 health care industry is the growth in big data. 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 rising 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 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 health care industry players. When these developments are seen in conjunction with the digital technologies and global networks, it becomes reasonable to forecast a trans-global health care industry that is likely to rival individual national health care industries, with some players and providers operating in multiple global markets with a scale unprecedented in health care markets today. As a consequence, it is likely that U.S. health care industry players may take a more strategic direction from the global health care market place as time marches on.

**Figure 8:** Health Care Trends Fostered by the Rise of the Global Middle Class

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Forecasting Changes in the U.S. Health Care Industry

The four forces create the basis for disruption in health care markets and the makeup of the U.S. health care industry. But what will the disruption lead to? A three-stage model of the U.S. health care industry was briefly introduced earlier. This section uses the three-stage model to forecast how the four forces will combine to make real changes in the industry.

However, any speculative analysis must be subject to a few caveats. First, the current state of the industry is in flux and some would say disarray. The size and nature of the PPACA legislation and the way the law was passed have generated considerable controversy that will likely continue. In addition, the confusion is further compounded by problems encountered in the implementation of the PPACA, its related laws and its economics. So although the PPACA has many important and valuable mandates and provisions, it also has significant shortcomings that will need to be worked out over multiple years, through a heavy dose of political compromises, legislative amendments, judicial rulings, and administrative adjustments. As of the writing of this report, it appears that, at best, such adjustments will take at a minimum at least 5 years.

Second, the current malaise in the U.S. economy may ultimately delay the progress of the U.S. health care industry. Growth in U.S. GDP, job creation, and real disposable income has been nominal. Inflation growth is nominal too. Macroeconomic factors affect capital investments and practice improvements in any industry. At this juncture, the progress of the U.S. health care industry is heavily dependent on capital investment. Nor can the economic assumptions related to the PPACA and its success be ignored. One thing is clear -- stagnant economic growth and new entitlement legislation is never a good combination.

Third, epidemiological and demographic trends are problematic for the U.S. health care industry in the near term. Preventative chronic diseases, an aging population, and declining birthrates are troublesome because they alter actuarial assumptions -- particularly in payment plans. However, the increase in self-tracking behavior could lead to more engaged health consumers that will provide motivation to manage diets and improve lifestyles. Coupled with effective public health information and PPACA incentives, it may be possible to turn the tide in childhood and teenage obesity and obesity in general. And there are some signs that as the U.S. economy improves, family formation may increase. In short, the key to an epidemiological transformation will be a change in individual behavior. If the current march to preventable chronic disease cannot be resolved, the downstream economic impacts are so dire that this issue alone may overwhelm even the best public policy.

Fourth, it is clear that the omics revolution and the emergence of the global middle class are wild cards. No doubt they are major forces, but the impacts could be either extreme or nominal. The omics
revolution could be a socio-economic game changer. Aside from traumatic care (i.e. accidents, suicide, catastrophes) advances in the understanding of the various genomes and related diseases could restructure major segments of health care services and change individual behavior over the next 20 years. While the omics revolution will require changes in public policy over the next two decades, it is not possible to forecast unforeseen problems or major breakthroughs in this area. Similarly, the growth of the global middle class will be a major disrupter, but the degree of disruption will be dependent on the rate of growth in emerging economies and their stability.

Fifth, it may be possible, that a speculative, forward-looking analysis of this type might be too optimistic or too conservative. Many examples point to an upper limit on the amount of change humans can absorb in a period of time, but this is difficult to estimate. Or, some may argue that two of the four forces, digital and information technologies and the omics field are developing at an accelerating geometric rate. In this case, the time scale used in the paper for developments in technology and science may be overly conservative. Yet, one should not underestimate outright resistance to change or the intractability of the political process.

A Three-Stage Model of Industry Evolution

The three-stage model was formulated by taking the health care trends generated by each of the four forces and identifying critical path items that would need to take place in order to drive the industry forward. In so doing it is possible to construct a rationale for a timeline of sorts that roughly places the developments in time and thus suggests paths of industry development, issues and problems. Ultimately the goal is to look at the progressive development of the industry, as suggested by the framework, and derive conclusions, implications, and qualifications (caveats) from the analysis.

Appendix A identifies critical path items in regulation, technology and genomics that will define the progress of the industry. Each critical path item performs a gating function because each critical path item is a development or accomplishment that enables subsequent changes in the health consumer experience, the provision of care, the production of health products, payment plans, and regulation. From these critical path milestones, the three-stage model was constructed and the expected timing of developments was categorized for each stage (see Figures 9, 10, and 13). For example, in Stage 1, the model summarizes key legislative, practice, scientific and technological developments, most of which have taken place at this point.

Stage 1

To provide continuity in the stage model, it made sense to begin stage 1 in 2005. At this point in the industry, it was becoming clear that the payment model in the industry must change. From a policy standpoint it was increasingly untenable for the richest nation in the world and the largest economy to
have inferior health outcomes and a significant number of its citizens not covered with regular medical care. The statistics were not kind to Medicaid and total health care costs continued to rise along with new medical issues, most notably preventable chronic disease. In 2010, the PPACA was passed. However, prior to the passage of the PPACA a growing consensus about best practices consolidated and much of that practice was codified in the PPACA. As noted earlier, other major forces conspired to disrupt the industry. Thus, Stage 1 is important in that it marks the key trends and disruptors. Stage 1 set the stage for major transformation of the U.S. health care industry in Stages 2 and 3.

Figure 9: Expected Industry Developments in Stage 1

Stage 2
In Stage 2 the industry will begin to adjust to changes in the regulatory environment and to capitalize on developments in technology, genomics, and the developing global middle class. A critical factor in the industry’s development during the second stage will be for Congress and the regulators to establish an effective refinement and amendment process for the PPACA and related legislation. This forecast assumes that the refinement process will be substantially complete and accepted by 2020. If policy makers cannot accomplish this task, the PPACA may collapse under its own weight. The PPACA must be made flexible; otherwise it will not be able to cope with a continuing stream of medical innovation that will occur in Stage 2.

It is also believed Stage 2 will usher in a new approach to health care, called “directed care.” To understand the concept of “directed care,” it is important to remember that Stage 2 will continue to develop and sustain the four major forces and their secondary trends. So as time marches on digital and
Information technologies will improve, the omics sciences will advance, the global middle will expand, and organizations will adapt. In particular, work on accountable care organizations, bundled payments and protocolization 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. This consumer awareness is likely to be amplified and extended by better information sources, self-tracking and greater use of artificial intelligence and machine assistance in the areas of diet, exercise and other preventative options.

**Figure 10: Expected Industry Developments in Stage 2**

- Revision and refinement of PPACA, HIPAA/ HITECH, ACO & FDA regulations, transborder privacy, synthetic genomes
- Consolidation grows with emergence of global health systems & internetworked global health ecosystems
- Personalized medicine emerges through "directed care” health delivery models augmented with new class of para-professionals
- Health care labor markets diversify with expansion of new para-professional occupations
- Big data, cognitive computing, analytics drive the "directed care” movement and solidify ACO & protocolization in industry
- Elastic business models transform firm structures and support "directed care” delivery models to serve a mass differentiated global health needs
- Genomic sequencing (<$500) & microfluidics/"lab on a chip," genetic epidemiology & panomic data transform diagnostics & treatments
- Social networks & media inspire new consumer-led & physician-led health model innovations
- Global middle class health care consumption & panomic data accelerate health delivery & genomic therapeutic innovation

Stage 2: Adjustment & Resolution (2015 - 2025)

It is also assumed that the same complex of big data, artificial intelligence, and machine assistance will become de rigueur within the care provider community of researchers, physicians, specialists and a growing number of paraprofessionals. As a consequence, it is reasonable to envision that Stage 2 will mark the emergence of a directed care model driven by major changes in industry operation as seen in Figure 11.
The term “directed care,” is a way of describing a modality of care that is driven, with the aid of digital devices, information systems, large data sets, and other machine assistance, plus social network and other practice trends (e.g. bundled payments, protocolization, high parameter diagnostics). Directed care will move the industry toward personalized care that will emerge in Stage 3, and will provide the foundation and natural transition to individualized care modalities that will take longer to develop and gain acceptance. Under the directed care model, physicians, specialists, and patients will begin to have a unified view of care. Examples of the early stages of directed care are seen at Partners HealthCare and Kaiser Permanente, where system wide electronic health records are available to provide care givers associated with the system to have a unified view of the patient. The pilot projects between IBM and its partners have been instrumental in demonstrating the feasibility of this approach.

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67 It is also important to point out that most health care providers are currently finding it very difficult to move to electronic health records despite HHS incentives and disincentives under the HITECH Act. See Joseph Conn, “Fewer Certified EHRs for Stage 2 may Pose Problems for Hospitals, Doc Practices,” ModernHealthcare.com, September 25, 2013. Hannah Winston, “Veterans Affairs, Defense Depts. Spend Billions in Effort to Coordinate Records,” The Center for Public Integrity, August 27, 2013, [http://www.publicintegrity.org/2013/08/27/13253/veterans-affairs-defense-depts-spend-billions-effort-coordinate-records](http://www.publicintegrity.org/2013/08/27/13253/veterans-affairs-defense-depts-spend-billions-effort-coordinate-records). Nonetheless, the next 5-7 years should see significant progress on EHS.
Watson Supercomputer, The Cleveland Clinic, Sloan-Kettering / Wellpoint illustrate the power of machine augmentation in diagnostic and treatment activities. Of course, these early examples must be shown to meaningfully impact medical outcomes and meet value expectations. However, the trends are visible and can be expected to grow.

As a consequence directed care will be marked by greater collaboration and transparency for physicians, patients, and other care providers. Porter and Lee chronicle the impact of what they call, Integrated Practice Units, which promote intense interdisciplinary collaboration around disease types at institutions like Virginia Mason Medical Center. Due to the value and superiority of outcome from a collaborative model of care, it is reasonable to expect that such models will flourish in Stage 2, further aided by big data, digital technologies and machine augmentation. As noted earlier, the industry has endeavored to understand the role that new types of collaboration, particularly via social networks and integrated information systems, can play in health care. The National Council for Community Behavioral Healthcare recently released a standardized framework to understand levels of integrated health care. The framework identifies five levels of collaboration and ties the collaboration to levels of integration among underlying systems and procedures.

Directed care will also drive further diversification in the health care labor markets, and most likely with PPACA mandates for community health and efficiency, more reliance on para-professional occupations. As digital technologies, advanced computation, information technologies and analytics advance, roles within the industry will change. The increased role of para-professionals in health care, particularly in nursing care specialties, has already changed the provision of care. 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 pre-intervention and advisory in nature. Consider the impact that paramedics have made in the industry and the expansion of that role, particularly in States like Texas. It is reasonable to expect that this trend will accelerate as directed care grows.

Stage 2 will likely see the greatest transformation of health care organizations. The PPACA and the implementation regulations, as propagated by HHS and CMS, will drive a move for health organizations to adopt elastic business models that will see traditional organization boundaries expand...

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71 Machine augmentation in health care is not without controversy as has been the general debate about each new round of machine intelligence. See Jonathan Cohn, “The Robot will See You Now,” The Atlantic, March 2013.
72 Porter and Lee, op. cit.
and become more porous under the weight of mandated collaboration, information sharing, and transparency. 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 better be understood as a dynamic map of capabilities and associations with the health consumer at the middle (See Figure 12). In addition, a consumer-centric model will be strongly reinforced by bundled payments, protocolization, business models of other industries, increased use of digital devices by consumers, and the emerging directed care model.

Figure 12 conceptualizes the industry, not as a linear or traditional value chain model, as shown in Figure 2 earlier, but rather as a collection of capabilities that will tend to link together or form together based on medical need, protocolization, and expedience. As we can see, the traditional categories of capabilities will still exist, but the activities of each will be more transparent. The regulatory model will mandate greater collaboration in the sharing of data and players will link based on clinical outcomes more readily than under the present industry structure. In other words, with medical science and practice moving to an individual focus, both producers and care providers will need to partner more efficiently to deliver solutions. It is less likely that a single producer will be able to go it alone in the delivery of therapeutic agents or devices, or a single care provider to offer all the necessary protocols to serve a diverse patient community.

Not only regulation will drive these changes. The other three forces, particularly the attractive growth features of the global middle class, will drive both industry producers and care providers to restructure and flexibly collaborate to remain competitive and able to serve billion person markets in a mass differentiated manner. 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 the trans-organizational partnering to fulfill the multitude of health consumer demands on a global basis.

It is likely that Stage 2 will witness widespread elaboration and growth of health platforms. Health platforms will provide the “electronic glue” that will facilitate industry collaboration, stitch together diverse partnerships and standardize information transfer. Early examples, like Qualcomm’s 2Net, illustrate the power of specific health platforms tailored to collect and route data from individuals to companies and support related analytics. Such health platforms will enable greater flexibility and elasticity in the operation of enterprises as they connect with the health consumer and deliver services.
By the later years of stage 2 (around 2023, or earlier), it is expected that the industry will see the widespread availability of low-cost high throughput whole genome sequencing. The availability of whole genome sequencing, along with the related diagnostic tools that will develop in parallel, will begin to rapidly reshape the industry from a genomics perspective. Combined with advancements in big data, care providers will alter 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. The assumption here is that the same can be expected from the availability of inexpensive genomic sequencing when considered in the context of related development.
If this assumption is correct, new pressure will be put on the policy infrastructure as it deals with requests from the population to get its genomes sequenced.

**Stage 3**

Stage 3 of the industry’s evolution will be largely driven by the wide diffusion of low-cost high speed sequencing of whole human genomes and a natural evolution of the directed care model. In Stage 3, whole genome sequencing and the directed care model will lead to the emergence of a holistic personalized model of care for a sizable number of individuals in the United States, but also among the ranks of the global middle class which by 2025 will be approaching 3 billion people. The target is to reliably sequence a whole human genome for less than $500. Industry experts predict, using current trends, that this will occur in about 10 years. Low-cost whole human genome sequencing will enable personalized medicine for virtually everyone, and in turn usher in a radically different approach to health care.

It is in Stage 3 that the combined force of all four transformative forces will come into play. Assuming current trends, some ten 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 elements at that time. Most importantly, technology, science and economics are dynamically intertwined and hence by Stage 3, the industry will have significant experience with all three, and hopefully positive experience with the regulatory course being initiated presently.

Stage 3 will benefit greatly from the foundation built in Stage 2. A decade of experience with directed care should have sorted out key questions regarding privacy and security regarding patient records and their role in health industry collaboration. It is expected that current developments in in-memory data manipulation (e.g. SAP’s Hana) will have become commonplace at a scale much larger than available today. As a result, the data structures needed to rapidly manipulate truly massive petabyte and exabyte data sets will be a reality. It is also assumed that both slightly invasive and non-invasive biometric sensors will have progressed to the point of becoming standard fare and likely integrated into home environments or wearable computing. The flood of sensor data also will likely be better understood by the mid-point of Stage 3, such that the signal-to-noise ratio of such data will be increased and made useful, predictive, and actionable.

The omics sciences will likely be driving many interventions and care approaches. By 2030 it is reasonable to assume regularity in using human genomic data of all forms to create a personalized care model that will span from conception to natural death. Trauma care will also be influenced by omics developments and knowledge and it is likely that palliative care also will be mindful of an individual’s genetics.
One can also envision epidemiology being transformed. As a result, it is expected that the role of policy making and regulatory behavior may very well be conducted from 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. Of course, there is danger in this line of reasoning and policy makers will need to tread lightly to protect individual liberty and freedom. Nonetheless, overall wellness is likely to be a significant shared value in Stage 3.

Stage 3 will likely and hopefully see a more engaged health consumer with an emphasis on prevention, participation and wellness. With the knowledge available, an individual will be well equipped for the pursuit of overall wellness. Again, policy makers and health providers will need to be wise in how wellness objectives are pursued. With the data, it is not entirely impossible to envision a restrictive or prejudicial regimen developed around the concept of wellness and care. Wellness will need to be considered in the face of individual liberty. The individual health consumer at this point will be armed with much more data about their constitution and their development. They will also be subject to realtime assessments of their health and the constant analysis and perhaps guidance and alerts of machines programmed to do good. 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 PPACA and related policy framework will seem antiquated.

As seen in Figure 13, Stage 3 will likely 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.”

74 In Stage 2, but in particular Stage 3, policy makers will be confronted continually with the definition of good and how to define good in a pluralistic, multi-cultural democracy. The advances in health care will seriously challenge policy makers to render judgments that go beyond the number and simplistic instrumental arguments, such as the greater good. 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.
Finally, the question of how care will be delivered is worthy of some discussion. Today, the hospital or clinic is the center for most care. The industry is hospital centric now. 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), but given what is now being witnessed in military battlefield care, it also likely that some trauma care may be decentralized.

Given current research in the omics sciences, stem cell research, robotics, and nano-scale materials, late Stage 2 and certainly Stage 3 will see the emergence of replaceable organs, bones and limbs, sometimes made from the individual’s own cells and in other cases the individual’s own cells plus bionic materials or components. In this context, care modalities will 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.

**Conclusions and Implications**

Given the magnitude and trajectory of the four forces, the U.S. health care industry is set for massive transformative change. As envisioned, the transformational process will be protracted and take place over at least the next 20 years. The analysis indicates significant developmental momentum in each
of the four forces. Taken together the four forces seem to provide ample capacity to transform the industry over a protracted period. When the trends are plotted over time, the cumulative effect drives a major conclusion: the health care industry in the United States in twenty years will have a different culture, different processes and a different calculus regarding wellness.

Implications

But what will the industry look like at different stages over time? What other characterizations can be made? 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 14 provides the major themes that emerge from the analysis for each of the stakeholders.

Figure 14: Summary of Industry Implications By Segment

<table>
<thead>
<tr>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health Consumer Experience</strong></td>
<td>Fragmented &amp; Unmanageable</td>
<td>Manageable &amp; Accessible</td>
</tr>
<tr>
<td><strong>Care Providers</strong></td>
<td>Traditional Care</td>
<td>Directed Care</td>
</tr>
<tr>
<td><strong>Payments &amp; Plans</strong></td>
<td>Fragmented &amp; Dysfunctional</td>
<td>Accountable</td>
</tr>
<tr>
<td><strong>Producers and Innovators</strong></td>
<td>Mass Consumption</td>
<td>Modular &amp; Elastic</td>
</tr>
<tr>
<td><strong>Policy Makers &amp; Regulators</strong></td>
<td>Plan, React &amp; Push Policy &amp; Regs</td>
<td>Amendable &amp; Accountable</td>
</tr>
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</table>

Figure 14 describes the type of transition each segment will need to make. Clearly each segment will change significantly. 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.

However, care providers and regulators are likely to find the transition most difficult, 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 as forecasted here. This 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. Moreover, current regulator frameworks are static, research plan, and push models where legislation is negotiated and passed and considered done. In a rapidly changing industry like health care, such policy-making frameworks are dysfunctional and ineffective. One might hope that the current failure of policy makers in the realm of health care 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 amendable and accountable, and ultimately participative to meet 21st century demands.

The payments and plans segment is likely to do the best. Already, plan providers have modified their actuarial assumptions to operate within the PPACA environment. Some believe that the government’s entry actually enhances the prognosis for their businesses by, in effect, underwriting the underclass and ultimately eliminating many of the hidden subsidies and deals worked out between payers/plans and care providers to subsidize indigent and low-income care. 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 forecasts, their future looks much better in Stage 2 and Stage 3.

**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. 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. Clearly, to be able to thrive and operate in Stage 2 requires the right digital 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. It will be critical 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:

- **Gen Xs and Gen Ys** have the opportunity to become active and engaged health consumers and self-trackers. Given the positive developments on the horizon a reasonable course of action is to foster health when young. The longer Gen Xs and Gen Ys maintain current health the more likely will be their ability to partake of new health discoveries ten years hence and substantially increase life expectancy and quality of life.

- **Parents** can monitor developments in genomics, and if possible, consider whole genome sequencing for themselves and their children as it becomes affordable. Aggressive management of obesity in selves and children will help avoid chronic disease.

- While many boomers 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, if only for your children or other family members. Such information and your medical history may be very valuable for subsequent generations.

Care Providers

- Hospitals and Health Care Systems must infuse their enterprises with proven digital and information technology practices and talent. Antiquated IT systems and platforms are a critical liability. As care goes digital the gap will increase.

- Capital acquisition and capital campaigns will be essential to navigate Stage 2 of the industry’s development. Compliance alone will require capital for information technology. But also will the directed care model. 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 protocolization, integrated practice units, ACO architectures and lean methodologies. First, HHS/CMS will reward all four practices. Second, the move to these practices will make your organization more agile, elastic and adaptive to change. Third, these practices will also equip your organization with the experience to more easily partner with external entities, adding additional elastic properties to your organization.

Payments and Plans

Payment and plan organizations have adapted rapidly to the PPACA. However, as of the Fall of 2013, reversals in the PPACA implementation policies have thrown the reimbursement segment of the industry into confusion. 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 PPACA.

• Tiered pricing could be demanded by highly engaged, self-tracking, wellness driven consumers. Since the PPACA 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 PPACA are unclear.

• Underwriting, in general, is changing in the insurance industry but, in particular, it is changing in health plans in light of the new government subsidies and restrictions injected into the economy. However, health plans will need to develop much more flexible plans as development in the omics sciences moves 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.

Nonetheless, perhaps the most challenging elements of this analysis for producers concern their business models, especially monetization of intellectual property in Stage 3. Ultra low-cost genomic sequencing will be virtually available to anyone and so too 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.

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 break down and 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 PPACA is perhaps the largest piece of legislation ever put into law in the history of the United States. But it is not just the PPACA; 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, more recently, 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 health care policy-making, failures are unacceptable. Policy makers and politicians must build laws that assure the same quality processes in public policy formation as, ironically, the PPACA, intends for the health care 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 trend, as discussed here, there is a likelihood that the PPACA, no matter how comprehensive, may lose it relevance over the next twenty years.

Summary

The current state of the health care industry is not sustainable. This analysis shows a path forward and suggests that a set of powerful forces will combine 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 has the opportunity to significantly advance the wellness of U.S. citizens and other citizens with good policy and breakthrough innovations.
ACKNOWLEDGEMENTS

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Appendix A

**Critical Path Milestones Regulating the Evolution of the U.S. Health Care Industry***

<table>
<thead>
<tr>
<th>Regulation &amp; Organization</th>
<th>Technologies</th>
<th>Genomics</th>
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<tr>
<td><strong>Stage 1 Milestones</strong></td>
<td></td>
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<tr>
<td>(2005-2015)</td>
<td>Resolution of conflicts and unintended consequences from initial PPAC provisions &amp; mandates</td>
<td>Mobile devices, sensors &amp; wearable computing</td>
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<td></td>
<td>Resolution of HIT/TECH, HIPAA, and EHR initiatives and practices</td>
<td>Cloud architectures and technologies with appropriate security and privacy provisions</td>
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<td></td>
<td>Implementation of ICD-10 medical coding conventions</td>
<td>Widespread implementation and adoption of wireless networks</td>
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<td></td>
<td>HHS and CMS internal trials and experiments in mHealth, cloud, open sources, big data and analytics</td>
<td>Massive data sets, bio-informatics and analytics</td>
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<td></td>
<td>Launch of Accountable Care Organization Pioneer Program and publication of findings</td>
<td>Widespread adoption of social networking, social media, and crowdsourcing</td>
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<td></td>
<td>Blue Button initiative for health record availability to patients</td>
<td>Experiments with quantified self, and self-tracking of personal health data</td>
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<td></td>
<td>M&amp;A and consolidation in life sciences companies and health delivery systems</td>
<td>Early use of patient and physician social networks</td>
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<td>Early use of robotic guided radiation and surgery</td>
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<td></td>
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<td>Early stage health-specific business platforms (e.g. Qualcomm 2net, AthenaHealth, Epocrates)</td>
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| **Stage 2 Milestones** | | |
| (2015-2025) | Refinement of best practices for Accountable Care Organizations (ACO) | Consumerization of medical diagnostics and self-tracking of health via digital devices and sensors | Inexpensive and rapid whole genome sequencing (< $500) per individual |
| | Fee allowances for a multi-tiered, price-differentiated health care delivery system | Passive/active and non-invasive biometric sensors (i.e. breath, sweat, galvanic, optical, motion) | Inexpensive multi-panel blood-based diagnostic technologies |
| | Proliferation of para-professional health occupations | Modular medical devices designed to be elastic and enable extension by a global ecosystem of partners | |
| | Health ecosystems focused on disease types | Refinement of cognitive computational strategies for physician diagnosis, treatment recommendation, and augmentation of para-professional diagnoses. | |
| | FDA modification of regulations for self-diagnosis based on machine-based analysis of biometric data | Mastery of big data set panomic longitudinal and time series data analysis | |
| | CMS modification for regulations for increased diagnostic tests prescribed either by physician or individual. | Development of strong anonymization and protection techniques to protect individual security and privacy and enable full access transpopulation research for improvement of care using medical records and outcome data. | |
| | CMS approval for subsidized genome sequencing for all U.S. citizens | | |
| | Approval by FDA of small disease population drug approval | | |
| | Strong policies for security and privacy safeguards of citizen medical data | | |
| | Public policy safeguards for synthesized genomic products | | |

| **Stage 3 Milestones** | | |
| (2025 -) | Wellness-driven person-centric health care (in vivo to death) supported by a multi-tier health delivery system subsidized in full or in part depending on means testing. | All occupational categories in health delivery supported by decision support aids, cognitive computing for all aspects from skill development to practice | Genomic-driven prevention, diagnostics, prediction and therapeutics. |
| | Fully elastic health production and health delivery companies, organizations, and institutions that can re-organize and adapt based on environmental circumstance or need. | Non-invasive diagnostic technologies available for mass consumption on a global basis. | In-vivo therapeutic interventions |
| | | Patient data stored in cloud for realtime access and digitally written on non-volatile, non-destructive forms of data storage. | Rise of synthetic genomics in therapeutic interventions and correction errors of an individuals genomic network |
| | | | Generation via stem cell and/or synthetic generation of human organs, vaccines |

* Key breakthroughs or lack thereof in three domains will accelerate or retard the evolution of the U.S. Health Care Industry. Due to the fundamental demand for health services, the industry will continue to evolve but with significant social consequences and underlying health science and technologies advance.