The Small Business Health Care Access and Affordability Problem: Can Innovation in Health Distribution Systems be the Cure?

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ABSTRACT

This paper explores conceptual models for alternative means of health care delivery as well as both barriers and enablers of innovation. At the same time, a top concern expressed by small business owners and entrepreneurs has been access to health care, and its costs. A longstanding pattern of cost increases for health care exists, and according to projections, these increases will continue. As such, it is suggested that such a trend impedes entrepreneurs, and thus remains a drag on the economy. Innovators' thought processes typically lead to changes ranging from those that are incremental to some that are radical, occasionally disrupting entire industries or creating new ones altogether. Innovations may be entirely new, while in other instances a transfer of ideas from one context to another may lead to change. Health insurance has dominated the national conversation of U.S. lawmakers and their respective constituencies in connection with the Affordable Care Act (ACA), yet in many ways insurance costs merely mirror that which is paid to providers for the delivery of health care services (via claims), plus insurers' administrative overhead. Systems in use also are burdened by fraud, waste, and inefficiencies, across-the-board, in both the insurer- and provider-operating spheres. Scenarios involving radical innovation are not new, and the provider-side has not been adequately included in the debate about health care in America.

Keywords: small business, entrepreneurship, economy, innovation, health care distribution (a.k.a., delivery), disruptive technologies.

INTRODUCTION

Entrepreneurial thinking generally entails innovative thinking that causes change(s) to an existing paradigm (Kuhn, 1996). Creative thinkers imagine new ways of accomplishing an existing task, either in an incremental manner, or are inspired with an as-yet unthought-of approach that leaps ahead to an entirely new way of doing things. The process of entrepreneurial innovation is at the heart of how new procedures or inventions replace or supersede existing paradigms. Joseph Schumpeter discusses the role of entrepreneurs as introducers of new approaches to solving existing problems (Schumpeter, 1939). In 1985 Peter Drucker published *Innovation and Entrepreneurship* (Drucker, 1985), in which he wrote that "systematic innovation consists in the purposeful and organized search for changes, and in the systematic analysis of the opportunities such changes might offer for economic or social innovations." Nevertheless, serendipity and ignorance may play a role in the process of innovation in that the practical implications of new discoveries and inventions may not be recognized at the time of their first appearance (Kuhn, 1996).

Innovation in health care is poised to bring revolutionary advancements ("Cleveland clinic unveils top 10 medical innovations most likely to be game changers," 2016; Daemmrich, 2017) to patient diagnostics, treatment, and (most importantly) prevention, but as with anything new, there are barriers (Adang & Wensing, 2008; Barnett, Vasileiou, Djemil, Brooks, & Young, 2011; Hofmann, 2007; Johnston et al., 2016) to adoption and widespread diffusion.

The Patient Protection and Affordable Care Act,[1] as amended[2] (also known by abbreviations such as the PPACA, or ACA, or its popular nickname, Obamacare) focused on health insurance ("Patient Protection and Affordable Care Act," 2010), but not health care delivery from the vantage point of the provider-side, i.e., those who serve in clinical and administrative roles within the health care industry. For instance, "administrative costs in U.S. healthcare are the highest in the developed world" (Terhune, 2017). This exploratory paper posits that if innovations in the delivery (what marketers would refer to as channels of distribution) could be more easily disseminated, insurance costs could come down. The impetus for such an effort is expressed concerns on the part of small businesses about access and the affordability (or unaffordability, as the case may be) of health care. Even as revisions to, or a replacement of, the ACA has been discussed, the conversation remains dominated by topics such as the cost of health insurance premiums, access to coverage under a policy, what is or should be covered (or not), and the presence or lack thereof of insurers in various markets (e.g., geographically, by county and state; provider networks).

LITERATURE REVIEW

Scholars whose focus is primarily innovation have thus far developed an increasing stream of contributions to the literature in connection with healthcare and opportunities for entrepreneurial actors. It should be noted though that innovation by its nature has tremendous overlap. For instance, faster CPU processing speeds, Artificial Intelligence (AI), and image recognition software might aid radiologists in analyzing diagnostic data (Jha & Topol, 2016; Nelson, 2017); multiple enablers are entailed in such a scenario, including engineering/hardware

[1] Patient Protection and Affordable Care Act, Public Law 111 - 148 (H.R. 3590) C.F.R. (2010).
[2] Health Care and Education Reconciliation Act, Public Law 111 - 152 (H.R. 4872) C.F.R. (2010).

enhancements, software development, and likely, training (Grover & Niecko-Najjum, 2013) for the radiologist (to facilitate the diffusion of the innovation).

Using the terms "healthcare AND innovation," a search of the Ebsco database *Entrepreneurial Studies Source* was conducted after applying filters as follows: academic journals/scholarly articles and full text, years 2007 to 2017. Among the (116) search results, it was observed that Omachonu and Einspruch (2010) introduced a conceptual framework for innovation in healthcare delivery. Such work is highly relevant here, yet the impetus for this present paper was a suspicion that "innovation" has not been the primary topic as compared to "insurance" in a national conversation (i.e., vigorous debate) about health care in the U.S. The overarching context is that the Affordable Care Act has been associated with a failure to produce affordability for small businesses and individuals (Lahm, 2014), excepting certain segments of the populace at large, e.g., those who may receive subsidies ("Unsubsidized shun exchanges," 2015).

Using the same database and filters as above and the terms "small business AND Affordable Care Act" produced a much smaller set of results (13). Upon deselecting only scholarly sources as a filter, results were expanded to 33 items. Six of these were conference proceedings or journal articles from a single academic author; seven others (of the 33), roughly twenty percent of the resulting hits, were from a single trade journal, *Franchising World*. Switching to an alternative Ebsco database, *Business Source Complete*, while applying filters for full text/scholarly articles returned 30 results (with the date range automatically adjusted to begin at the year 2010). Subsequently, additional databases were consulted. As compared to the strategy above wherein Ebsco-branded databases were selectively searched one-at-a-time, ProQuest *ABI/INFORM Collection* (as the name suggests) is comprised of several databases that one may search concurrently; this is also true of Ebsco databases. One reason for varying search strategies is that along the way, it was of interest where possible, to gain a better sense of which scholarly disciplines may or may not have engaged the same subject matter at hand.

ProQuest provides a different set of filters, though with some similarities to Ebsco. With filters set as follows: full text, peer reviewed, scholarly journals, years 2007 to 2017, and location set as "United States," using the term "small business AND Affordable Care Act," 1367 results were found. However, one issue that was determined through the above and other searches, is that the scholarly disciplines of either entrepreneurship or small business have thus far produced a dearth of research pertaining to the impact of the Patient Protection and Affordable Care Act (PPACA — regularly shortened to ACA) on small businesses/entrepreneurs. At the same time, the popular and trade press, government and private sector entities (e.g., NFIB), and others have produced a plethora of content and reactions to the ACA (pro and con). For the sake of illustration, unchecking the filter for peer review and allowing all source types significantly more hits in terms of results (15,295 in total), comprised of: wire feeds (2,640); reports (5,657); trade journals (3,475); scholarly journals (1,817); newspapers (996); dissertations & theses (9); other sources (386); magazines (302); blogs, podcasts, & websites (13).

Reversing these settings on the same search described above demonstrated that many of the 1367 results (peer reviewed) appeared in outlets that were not specific to small business/entrepreneurship. For instance out of twenty items that were displayed in the very first page of the ProQuest search results, sorted by relevance, sixteen of these were from a single outlet, *Health Affairs*.

Further searches utilizing a variety of databases and search terms, including the one that was first introduced in this section, "healthcare AND innovation," allowed for the gradual development of two local "master" databases using bibliography management software. One of these, comprised of 412 artifacts, focused on topics such as the impact of the ACA (Obamacare), on individuals, small businesses, and the economy. The other local database was comprised of 402 artifacts, concerned with health care distribution/delivery, innovation, and barriers to either. Using the combination of these two databases, the conceptual paper that follows addresses our findings under a qualitative research framework (Glesne & Peshkin, 1992; Huberman & Miles, 1994; Maykut & Morehouse, 1994; Strauss & Corbin, 1990, 1994).

DISCUSSION

The first part of the discussion below is largely derived from an analysis of inventions and innovations that have the potential to improve the quality of healthcare, and at the same time reduce the costs of diagnosing and/or treating medical conditions. The following is a description of these innovative areas with brief definitions, reasons the innovations are needed at this time, how implementing the innovation will more efficiently improve the quality of healthcare, and in brief, barriers to the same. After this initial analysis pertaining to inventions and innovations is presented, the plight of small businesses and entrepreneurs is discussed.

Precision Medicine

The shift from provider-centric diagnosis and treatment of healthcare problems using the approach of a patient-centric process of diagnosing disease and then using precision treatments is entering the clinical environment because of vastly greater efficiencies in genomics testing and analytics. Precision medicine is defined as "an emerging approach for disease prevention and treatment that takes into account people's individual variations in genes, environment, and lifestyle" ("The precision medicine initiative," 2015). While there has been a great amount of attention paid to genomics (McManus & Gough, 2016; Olson, 2017) as the key to unlocking the potential for precision medicine, the advances seen to date and planned for the future depend upon involving several disciplines.

In his 2015 State of the Union address, President Barack Obama announced new funding for the National Institutes of Health to create the Precision Medicine Initiative (PMI) "All of Us" program (Collins & Varmus, 2015). The potential benefits from PMI to vastly improve approaches to preventing and curing disease, while at the same time reducing the costs of doing so, has the medical field very excited and hopeful. Advances in sequencing an individual's human genome are linked with innovative techniques for biomedical analysis, and improvements in tools for analyzing large databases that contain genetic data, biological samples and diet and lifestyle information ("The precision medicine initiative," 2015), will hopefully result in the creation of specific treatments that will resolve a person's medical problem.

Using PMI as the pathway for curing cancer is the first area of focus. Cancer is the leading cause of death in the U.S., and the frequency of its occurrence as our population ages is increasing According to James Watson, predictor of the double helix structure of DNA and Nobel laureate in medicine, "most cancers could … be curable by 2022" ("Cancer cure in sight in 5-10 years," 2012). Other researchers predict that by 2020 precision medicine will transform the delivery of healthcare. Figure 1 - *Transformation of Health Care Delivery Enabled by*

Precision Medicine (derived from Olson, 2017) provides examples of expected changes in the delivery of healthcare.

According to the Precision Medicine Initiative "All of Us" program sponsored by the National Institutes of Health, the advent of new methods for treating individual medical conditions, especially cancer, is upon us. A critical building block needed to support PMI is the creation of a collection electronic health data records that is comprised of participants of all ages, sex, and socioeconomic backgrounds from diverse racial and ethnic groups, and from geographic locations. It has been proposed to enlist one million or more U.S. consenting participants that will agree to join the cohort and will stay involved as longitudinal follow-up is conducted (Hudson, Lifton, & Patrick-Lake, 2015, p. 21). The goal is to have readily available information about genomic biomarker profiles, identifying and monitoring health and diseases, following clinical trials, and the of results therapeutics developed using precision medicine techniques (Hudson et al., 2015).

As with any significant innovation there are problems to be resolved and barriers to overcome. The lack of funding or obstructing government regulations are the typical problems encountered in a project like PMI. The initial problem being worked on today is the daunting task of amassing enough volunteers to agree to participate in the project so as to have a large enough database to allow researchers "correlate things like genetic mutations, environmental pollutants and exercise patterns with the subject's health outcomes" (Pittman, 2017, quoting Pro eHealth editor Arthur Allen). Assembling the PMI Cohort of one million or more volunteers who will agree to provide their medical records to the research community, both initially and on an ongoing basis haws proved to be difficult. "Privacy is a big reason so many early recruits don't want to hand over their records. The NIH wants access to every aspect of participants' medical history, and with larger and larger hacks of databases, there's no guarantee the NIH will be able to protect patients' medical records even with a new, ultra-secure system" (Pittman, 2017).

Immunotherapy

The medical definition of immunotherapy is "a treatment to stimulate or restore the ability of the immune system to fight infection and disease" ("Medical definition of immunotherapy," 2016). Also known as biotherapy, this intervention relies upon substances from living organisms may occur naturally in the body or those that can be synthesized in the laboratory. The objective of cellular immunotherapy (CI) is to create patient-specific drugs (via precision medicine) that will seek and destroy the patient's tumor cells ("Cleveland clinic unveils top 10 medical innovations most likely to be game changers," 2016).

Patients will no longer undergo non-targeted expensive chemotherapy treatments. Expected outcomes are treatments that will destroy cancer tumor cells without the negative side effects associated with chemotherapy (Copeland, Raynor, & Shah, 2016). "Cancer drugs typically have a profoundly harsh systemic impact on the body, particularly chemotherapies that blast all growing cells indiscriminately" (Carroll, 2013). The process of immunotherapy has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of acute lymphoblastic leukemia (ALL) and Non-Hodgkin lymphomas. Healthcare providers, applying adoptive T-cell therapies can find and remove T-cells from a patient. The T-cells are modified by grafting chimeric antigen receptors (CAR) onto the T-cell using a technique called adoptive cell transfer. The T-cells (CAR-T cells) are now re-introduced into the patient, locate tumors,

and kill the cancer cells in tumors. Early results have been very encouraging with reported remission rates as high as 90 percent ("Cleveland clinic unveils top 10 medical innovations most likely to be game changers," 2016).

What problems stand in the way for the future success of immunotherapy? The initial concern for researchers is to gain a greater understanding of how biologic molecules react with cancer cells in tumors. What makes the cancer cells in a tumor receptive to CAR-T cells that have the mission of attacking and killing the tumor? An important element in the research process is the availability of responses from patients who have participated in clinical trials. Apparently current rates of participation is not sufficient to the point of making progress difficult (Copeland et al., 2016). Another hurdle to overcome is the need for the participation of additional medical laboratories that can generate CAR-T cells. Currently there are only a handful of specialized laboratories that are staffed with clinicians who have the training and experience to create the CAR-T cells that will be reintroduced into the cancer patients from which the original T-cells were harvested. The risk of injecting CAR-T cells that are deficient is adverse reactions or even the death of the patient (Copeland et al., 2016).

A major barrier is the current high cost of immunotherapy. Some treatments have exceeded $250,000, most of which has not been reimbursed by health insurance companies. Even though there have been some very exciting successes, the need to demonstrate to the healthcare community that cellular immunotherapy is an effective treatment — both in the short-term and the long-term — remains (Copeland et al., 2016).

Telehealth and Telemedicine

Telehealth refers to any aspect of healthcare that is delivered from or to the patient and the healthcare provider using telecommunications devices. Telehealth includes remote clinical services such as diagnoses, treatment, and monitoring and providing nonclinical services (Copeland et al., 2016). Telehealth encompasses telemedicine. Telemedicine refers specifically to the use of electronic communication devices that use medical information for the benefit of the patient (Rouse, 2016). For example, telemedicine can monitor a patient's blood pressure for those with heart conditions or blood sugar levels for diabetics or other vital signs from the patient sitting in their own home. Healthcare providers use telemedicine techniques to share patient medical information with other healthcare providers — any record that can be saved and sent in a digital format including lab results, x-rays, MRIs and CT scans. Lastly, and a great efficiency enhancer, is the ability of telemedicine to have patient and provider or providers communicate with each other in real time, allowing the patient to be involved with their own medical decisions (Rouse, 2016).

Providers are critical to the success of telehealth and telemedicine and often initiate the process of communicating electronically with their patients. It is interesting to note the first incidence of telemedicine occurred during the Civil War when the telegraph was used to order medical supplies or to send information for medical consultations (Rouse, 2016). It is the expectation of healthcare innovators that as telehealth gains acceptance it will provide a more convenient way for consumers to access and increase self-care while potentially reducing office visits and travel time thus achieving the goal of modern medicine – better quality healthcare at a lower cost to consumers.

Clinicians are skeptical about the effectiveness of telehealth. Providers have built their healthcare practices based on face-to-face meetings with their patients, establishing a positive rapport that allows for a successful clinical relationship. Some doctors are concerned the lack of

proximity to their patients will diminish their ability to diagnose health conditions that they discover more readily when the patient is in the same room. Finally, many healthcare providers feel they do not have adequate formal training to practice healthcare in a remote setting from their patients (Brooks, Turvey, & Augusterfer, 2013). Clinician's view telehealth technologies as inconvenient or hard to learn. Over the past half century healthcare providers have become used to having their patients come to their place of business – their medical office or clinic or a local hospital. Telehealth is more convenient for the patient.

Resistance from providers has been expressed in terms of "I have to go to a special room to teleconference with my patient" or "I have to learn how to operate another new technology that I am not sure will be effective" or "Using telehealth requires establishing new protocols, new documentation and record keeping requirements" (Brooks et al., 2013). Clinicians experience difficulties in obtaining medical reimbursement from insurance providers for telehealth treatments — licensure, credentialing, and reimbursement obstacles. Most providers must be licensed in each state where they practice telehealth as well as the state where their physical location exists. Gaining licensure from several states is time consuming and expensive. Often state medical regulations are in conflict (Brooks et al., 2013).

Even the American Medical Association (AMA) has created a barrier — a requirement that a doctor and patient must physically meet at least once a year so the patient may undergo a physical examination. This requirement is being met by a doctor having a remote patient go to a local physician for the physical examination. However, the patient's doctor must take the time to create the in-person examination (Brooks et al., 2013). The problem of obtaining reimbursement for telehealth services rendered unto a patient has yet to be fully resolved. Many third-party administrators do not reimburse for telehealth services, or only pay for a small subset of services. Not solving this problem will certainly inhibit the use of telehealth (Brooks et al., 2013).

Finally, there is an absolute need to have infrastructure that provides connectivity between the provider and the patient for telehealth and telemedicine to function. As we have learned, early efforts at telehealth used the telegraph or telephone as the method of communicating. In today's world, connectivity may be achieved through copper or fiber optic telephone lines, broadband (cable), or satellite transmission of data using the Internet and computers. Therein lies a substantial roadblock to the adoption of telehealth — a lack of universal access with sufficient throughput in many rural areas of the United States. Hopefully, the necessary infrastructure will grow to encompass those patients living away from their healthcare providers (Li & Wilson, 2013).

3D Bioprinting

The process of creating body parts using a printer attached to a computer has moved past the experimental stage and is now an accepted technology in the world of healthcare. Medical applications for 3D-printers today include "customized prosthetics, implants, and anatomical models, tissue and organ fabrication" (Dodziuk, 2016, p. 285). In an article published in the *Harvard Business Review,* Hendricks (2016)" observed:

> Medical technologies often are expensive when they enter the market, becoming cheaper over time, but many of the new 3D-printed solutions are coming in at a reasonable price point. This shift has the potential to disrupt the alarming

> trajectory of rising health care costs at exactly the moment when aging Baby Boomers will be putting more pressure on the health care system.

The process of building three-dimension body parts involves the addition of successive layers of material, one on top of the other as the print-head moves back and forth, based on a digital model of the part to be reproduced. 3D body parts are highly precise and efficient when compared to prior forms of creating a body part using removal techniques (drilling, sanding, cutting, etc.). Already 3D Printing of body parts has been used in successful surgeries and treatments such as ankle replacements, 3D-printed casts which heal broken bones 40 to 80% faster than plaster casts, and facial prostheses and even ears (Hendricks, 2016).

The next advance is to use 3D Bio-printing to increase the supply in the organ donor market by using bio-ink made up of a person's own stem cells to print tissue for ears, kidneys, and livers with predictions of fully functioning organs available in the next 10 years. Imagine, 4D printing — creating a body part using 3D printing and then having that body part change shape after it was made (Dodziuk, 2016). The printing of complex organs (kidneys, livers and hearts) is difficult in that these organs require as many as 30 different cell types (Kirkpatrick, 2017). The potential demand for 3D printed body parts is enormous. The ability to meet that growing demand is upon us. Currently the adoption of 3D printed body parts is relatively low as the adoption of 3D printed prostheses, casts, lungs and livers is in its nascent stage.

Adam Feinberg, associate professor of materials science and biomedical engineering at Carnegie Mellon University says, "We need a lot of cells, and some cells are just hard to come by, or very costly to get" (Kirkpatrick, 2017, p. 17). Todd Goldstein, a 3D bio-printing researcher and director of Northwell Ventures 3D Printing Laboratory, Manhasset, New York, explains one of the significant problems of providing body parts printed with bio-ink is the need for having a blood supply to keep viable. Creating pieces of soft tissue to mend organs such as the liver, kidney, and heart, can be quite challenging to bio-print, given the need to support constant, consistent blood flow (Ibid, p. 16).

The other unknown facing 3D printing is the role of the U.S. Food and Drug Administration (FDA) in ensuring printed body parts meet high quality standards. The FDA regulations currently include a provision in federal law that exempts "custom" medical devices from FDA review. The FDA is currently reviewing its stance regarding 3D printing of body parts and is collecting input from medical researchers and other industry members to answer its concerns as to who will actually be providing the printed body part and who will be held liable, the printing manufacturer or the engineers or clinicians at the hospital? (Mathers, 2014).

Medical Virtual Reality (VR)

Virtual reality (VR) headsets are available in retail stores and through Internet merchants. Users of a VR head mounted display experience an imaginary environment that is presented in 3D with sounds, and often including vibrations as well. Innovators have devised virtual imaging technology to solve or represent some medical processes. Medical virtual reality is used in medical education, various types of therapies that train, diagnose, and treat in a variety of situations (Carson, 2015). Augmented reality (AR) offers similar features as virtual reality but in a different manner. Virtual reality inserts the viewer into the virtual environment — it replaces the real world with a simulated one.

On the other hand, AR uses computer generated enhancements, in real time, and the user becomes "inter-active" with the surrounding world they are viewing ("Cleveland clinic unveils top 10 medical innovations most likely to be game changers," 2016). Innovators have developed some interesting applications for medical virtual reality treatments. Two interesting treatments using VR are described in an article by Erin Carson, written for the TechRepublic's *Week in Review* newsletter (Carson, 2015):

Exposure Therapy

Psychiatrists treat patients with anxiety disorders – fear of flying, post-traumatic stress disorder (PTSD), fear of heights – by using VR to help them confront their fears. VR is used to immerse patients into highly realistic simulations that are used to overcome a person's fear.

Pain Management

Newspapers and television news reports are full of items discussing the epidemic of the addictive misuse of opioids. While opioids are effective in controlling pain, doctors are searching for other less addictive methods. VR has the ability to reduce the suffering of pain, say from a severe burn, by distracting the patient.

Surgical Instrumentation

One of the fascinating uses of augmented reality has been the use of AR technology to replace microscope oculars or high definition cameras in complex ophthalmological (retinal) or neurological (brain) surgeries. The AR stereoscopic systems are used to generate visual representations of the focus of their surgery ("Cleveland clinic unveils top 10 medical innovations most likely to be game changers," 2016).

VR and AR face some problems with the healthcare industry accepting their treatments as effective and cost saving. The acceptance of virtual reality and augmented reality should be somewhat easier than an unknown technology since VR headsets are in use across America. The bump-in-the-road for these technologies comes with the need for creating computer generated "realities" and the education of practitioners as to the use of VR and AR.

The Small Business Health Care Access and Affordability Problem

After an unusual act of intervention by editing the law that Congress had passed (as a mandate to purchase health insurance) and asserting that the intent of the legislation was a "tax," ("National Federation of Independent Business v. Sebelius, Slip Opinion, No. 11–393," 2012) the United States Supreme Court upheld the ACA as constitutional in 2012. The Affordable Care Act has not solved a problem about which small businesses have voiced concerns as a top issue for decades: health care access and affordability (Bettencourt, 2016; Phillips Erb, 2015; Thompson, 2015). The ACA (Obamacare) not only has resulted in more costly premiums, these have been accompanied by higher deductibles, increased copays and total out-of-pocket costs,

and shrinking provider networks (Appleby, 2015; Rosenthal, 2016; Wade, 2015). Small businesses also struggle to navigate the law's complex provisions and its requirements for compliance (Amato & Schreiber, 2013). This complexity translates to new work for attorneys and CPAs, and "of course, increase[d] operating costs for most businesses" (Neiburger, 2011, p. 62).

The Affordable Care Act and Small Business: Economic Issues, a report from the Congressional Research Service, stated: "According to CBO, the employer penalty is expected to raise about $130 billion over 10 years" (Lowry & Gravelle, 2014, p. 13). So beyond the fact that the Supreme Court defined the ACA as a tax, this tax was with forethought on the part of Congress, imposed on the very entities that are responsible for creating new opportunities that in turn, drive economic development ("The small business economy," 2012; Trivedi, 2016). The aforementioned Congressional Research Service report also indicated that among the reasons that less than 4% of the small businesses that could have claimed a health insurance tax credit (back in 2010) cited were: a lack of affordability of the insurance that would be associated with that credit, the credit was too small to make claiming worth the effort, and "the rules were too complex" (*Ibid*, Summary).

Health Care Insurance versus Health Care Innovation:

The ACA has imposed an extremely complex regulatory burden ("Rules and Regulations," 2010; "Treasury and IRS Issue Final Regulations Implementing Employer Shared Responsibility Under the Affordable Care Act for 2015 ", 2014; Turner, 2011), thereby increasing operating costs associated with compliance, while at the same time insureds have experienced higher premiums and out-of-pocket limits along with shrinking networks. Quoting Pitts, a former FDA Associate Commissioner, "At the end of the day, we should unite against our common enemy — disease" (2015, p. 63). Yet, besides imposing certain minimum coverage standards in insurance policies (Barrineau & Dastagir, 2013; "National Federation of Independent Business v. Sebelius, Slip Opinion, No. 11–393," 2012), it is completely unclear as to how the ACA has done anything to mitigate the detrimental impact of such a common enemy as disease or increase the quality of health care. It should also be noted that these coverage requirements resulted in the cancellation of millions of individual and small business policies (Gottlieb, 2013; Myers, 2013; Roy, 2013).

The word "quality," unto itself, is comprised of a mix of fuzzily connected, overlapping components and processes, to a point where it might even be considered an idiom. Nevertheless, regardless of the product or service, one might typically include constructs such as: access (this may include anything from parking and convenience to affordability and availability to various population segments); speed and or timeliness of delivery; fitness for the application at hand (in health care, this would entail an accurate diagnosis and an appropriate treatment plan – this does not necessarily guarantee efficacy, for there are conditions which may not be treatable); appropriate and expected levels of disposability (e.g., diapers made to be discarded) versus durability (tools with a lifetime warranty); and reliability. The aforementioned list is neither exhaustive nor one that considers implied attributes that are often associated with notions of quality (e.g., those that are advertised), such as the amount of status that is conferred upon the user who has accessed certain desirable (but difficult to obtain) goods or services.

As well, the notion of affordability is similarly challenging. In accordance with the tenor of the national conversation, this often refers to the cost of insurance coverage and the additional

expenses that fall outside of that coverage. However, a breakthrough drug might be considered very expensive, but if it could ward off an even more costly therapy by slowing or halting altogether the progression of a disease, the total financial outlay might be mitigated. Given that insurers are typically corporate-like in their organizational form and operations (i.e., notwithstanding any public posturing of being member-focused, they are driven by quarterly and annual performance), it could be argued that insurance companies are not structurally suited to look far enough ahead. In addition, insurers are highly regulated:

> "The Affordable Care Act holds health insurers accountable to consumers and ensures that American families receive value for their health insurance premium dollars. One such mechanism is the 80/20 rule, or Medical Loss Ratio (MLR) rule" ("The 80/20 rule: How insurers spend your health insurance premiums," 2013).

Essentially the MLR law means that 80 percent of the revenues collected by insurers must be directly associated with the payment of claims, and the remaining 20 percent is to cover administrative costs and profits.

CONCLUSION

Based upon the predictions of leading consulting firms and other entities ("Cleveland clinic unveils top 10 medical innovations most likely to be game changers," 2016; Copeland et al., 2016; "Top health industry issues of 2017: A year of uncertainty and opportunity," 2016) that have previously identified important health care trends and converging technologies, a selection of important developments involving innovative approaches has been discussed. At the same time, many of these face barriers to implementation. It should also be noted that many new processes or procedures often involve more than one area of innovation. Therefore, addressing all of the offshoots and interconnections — technological or otherwise — have necessarily been summarized for present purposes.

The emphasis in lawmakers' and regulators' chatter about *health care* has focused almost entirely on *health insurance*. Yet, health insurers are merely gatekeepers to access. If the cost of health care delivery, that which is being underwritten — an expensive collection of products and services associated with both clinical and administrative tasks — insurance costs could come down for both individuals and small businesses. "We cannot afford, in terms of dollars or lives, to continue the blame game. In order to deliver on the promise of affordable and quality healthcare for all citizens, all the players in the healthcare debate must work together" (Pitts, 2015). Bottom line, the insurance industry is at the very least not geared to support innovation, and arguably is designed to resist paying for possible improvements. And, the regulatory environment, further exacerbated by the ACA, serves to maintain this status quo.

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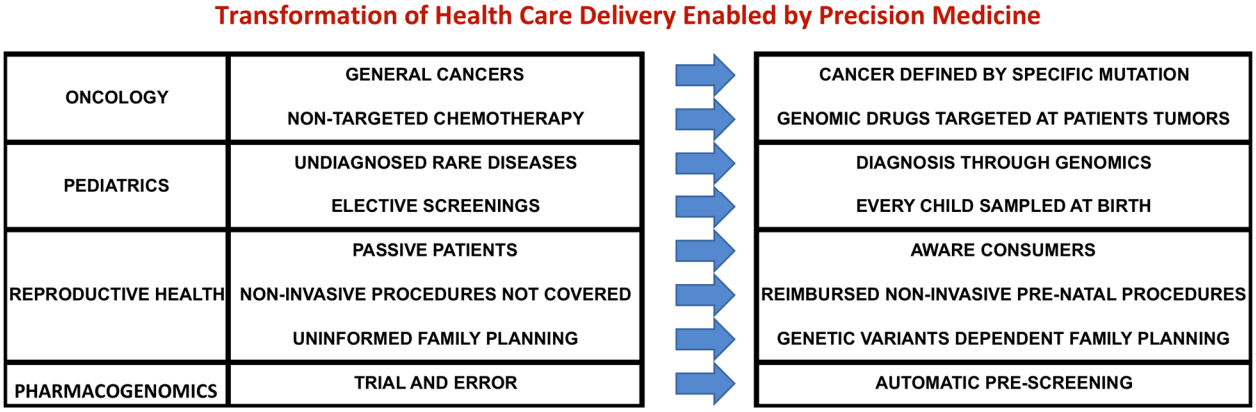
APPENDIX

Figure 1



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