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Barriers to Medical Innovation

In the first installment of this two-part Health Capital Topics series on medical innovations, the top innovations for 2015 that were profiled at the Cleveland Clinic and TedMed Conferences were discussed. Although unique and influential technologies similar to the ones exhibited at these conferences are showcased every year, these potential innovations often succumb to insurmountable barriers before going to market, which barriers are a daunting challenge for innovators seeking to develop and implement new healthcare inventions. This article will explore the challenges and barriers to innovation in the healthcare sector, and discuss the probability of a less cumbersome and more effective process going forward.

Myriad barriers to healthcare innovation exist, including: (1) strict, overlapping healthcare laws and regulations; (2) disconnects between innovators and providers; and, (3) unfavorable reimbursement models. Innovation in healthcare is challenging in part because no matter how effective the device or technique, innovators must persist through the "*excessive*" rules and policies required of new medical drugs and devices before they may be sold to the public.[1] For example, various federal and state healthcare regulations govern the development of technologies and pharmaceuticals from preclinical testing, through the *Investigational New Drug Application* (IND) and three phases of the clinical trials (if applicable), until well after it is offered to the public; pharmaceuticals are even surveyed after they begin selling on the market.[2] For pharmaceuticals, the arduous process of taking a drug from the laboratory to the pharmacy takes approximately nine years.[3]

Once a technology is placed on the market, it tends to cause disruption at the organizational level because existing work processes are interrupted while the new technology is put in place and employees are trained on how to operate the device. Consequently, healthcare providers and organizations tend to be resistant to such change, even if the change is positive.[4] Such rifts that have inhibited medical innovations include:

(1) *"A management and front-line worker disconnect (leadership disconnect)*";

(2) "*A work environment that discourages knowledge sharing (physical disconnect)*"; and,

(3) "*Employees who are disengaged (organizational disconnect).*"[5]

Regardless of the source of resistance, innovators will need to overcome these rifts if their product is to achieve any success, because there are a number of steps in the innovation process that require consumer buy-in, as well as support from providers, manufacturers, and distributors.

Innovations in healthcare, similar to other industries, operate on an incentive basis, with profit typically being the main motivator, and the reimbursement disconnect with medical innovations is especially pronounced. The current fee-for-service reimbursement model, which "*reward[s] individual acts by individual people*," does not support the integrated care delivery models that are becoming increasingly prevalent in the healthcare industry.[6] Although the *Centers for Medicare & Medicaid Services* (CMS) recently announced a timeline to shift Medicare reimbursement from quantity-based to quality-based, this paradigm shift is still a number of years away. In addition to reimbursement disincentives, uncertain prospects for the future viability of medical innovation may discourage potential venture capitalists. Investors seeking to invest in emerging technologies must weigh the potential of future public policy shifts, price controls in the healthcare industry, "*shortening the life of patents*,"[7] and the research and development timeframe, among other considerations.

Although there are numerous barriers to healthcare innovation, the latest iteration in healthcare reform (i.e., the *Patient Protection and Affordable Care Act* (ACA), also known as "*Obamacare*") is causing a paradigm shift in the healthcare industry.[8] The influx of newly insured individuals; the shift from *volume-based* to value-based care; and, the emergence of *emerging healthcare organizations* (EHOs), such as *accountable care organizations* (ACOs) and *clinically integrated networks* (CINs), which aid in creating a continuum of care, may be the catalyst needed to motivate the increase in medical innovations in the United States.

Additionally, there has been a push by educators to incorporate innovation in education. Currently, most medical schools and graduate business programs do not address innovation in their class curricula, and academics recognize that future physicians and healthcare executives are not learning how to construct necessary systems and processes for deciphering problems and finding and administering solutions.[9] An article published in the Harvard Business Review

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advocated for healthcare c-suite executives, healthcare innovators, and teaming up with graduate school professors to provide students with lectures and projects that have a "*real world*" perspective. The authors also suggested that schools host "*entrepreneurs-in-residence*" to serve in a mentoring role for both students and faculty.

Although healthcare expenditures are approaching 20% of the U.S. *gross domestic product* (GDP),[10] productivity in healthcare has been slow to increase, compared with other industries.[11] Medical innovations, to increase efficiency and improve outcomes in the healthcare industry, are desperately needed.[12] The potential of new technologies that could dramatically change the healthcare industry may be hindered in part by intense regulatory scrutiny that hinders rapid and fluid change; a rift between innovators and providers; and, reimbursement and funding restrictions. However, catalysts such as the ACA and a systemic change in medical education may be able to break medical innovations free of entry barriers, potentially resulting in a sea change in the way healthcare is delivered, and a renewed focus on efficient, quality patient care.

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