

ORIGINAL RESEARCH

Legal and Regulatory Barriers to Reverse Innovation



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Abstract

BACKGROUND Reverse innovation, or the importation of new, affordable, and efficacious models to high-income countries from the developing world, has emerged as a way to improve the health care system in the United States. Reverse innovation has been identified as a key emerging trend in global health systems in part because low-resourced settings are particularly good laboratories for low-cost/high-impact innovations that are developed out of necessity. A difficult question receiving scant attention is that of legal and regulatory barriers.

OBJECTIVES The objective of this paper is to understand and elucidate the legal barriers faced by innovators bringing health interventions to the United States.

METHODS Semistructured qualitative interviews were conducted with 9 key informants who have directly participated in the introduction of global health care approaches to the United States health system. A purposive sampling scheme was employed to identify participants. Phone interviews were conducted over one week in July 2016 with each participant and lasted an average of 35 minutes each.

FINDINGS Purely legal barriers included questions surrounding tort liability, standard of care, and concerns around patient-administered self-care. Regulatory burdens included issues of international medical licensure, reimbursement, and task shifting and scope of work challenges among nonprofessionals (e.g. community health workers). Finally, perceived (i.e. not realized or experienced) legal and regulatory barriers to innovative modalities served as disincentives to bringing products or services developed outside of the United States to the United States market.

CONCLUSIONS Conflicting interests within the health care system, safety concerns, and little value placed on low-cost interventions inhibit innovation. Legal and regulatory barriers rank among, and contribute to, an anti-innovation atmosphere in healthcare for domestic and reverse innovators alike. Reverse innovation should be fostered through the thoughtful development of legal and regulatory standards that encourage the introduction and scalable adoption of successful health care innovations developed outside of the US, particularly innovations that support public health goals and do not have the benefit of a large corporate sponsor to facilitate introduction to the market.

KEY WORDS innovation, legal, healthcare, health system, barriers, regulation

INTRODUCTION

Although innovation is a hallmark of our species and therefore just as old, the term is a buzzword in most professional fields today and used to denote new ways of thinking that have the potential to improve people's lives and, in some cases, impel important societal change.¹ Over the past 20 years, the global health and development fields have embraced the concept of innovation as both a process and an outcome.

Reverse innovation, or the importation of new, affordable, and efficacious models to high-income countries from the developing world, is an offshoot of the innovation movement and has emerged as a way to improve the health care system in the United States (US). The opportunity for reverse innovation to bring needed solutions to a country struggling with enormous health care costs, inefficiency, and inequity, has led to increased interest in this model.

However, there are multiple barriers to implementing global innovations in the US, including legal and regulatory barriers relating to reimbursement, standard of care, and scope of practice, among other things. Virtually no research has been conducted to identify and study legal and regulatory barriers to reverse innovation in the United States. This paper reports on a survey of key global health informants to identify barriers to reverse innovation and initiate the process of making recommendations to facilitate the global spread of good ideas. Where legal and regulatory requirements threaten to stand in the way of global innovations, recommendations are needed to move forward with advocacy efforts for policy change that acknowledge the critical balance between safety and innovation.

BACKGROUND

In the development field, innovation has been defined by the US Agency for International Development (USAID) as “a new solution with the transformative ability to accelerate impact” that involves “new social and business models or policy, creative financing mechanisms, or path-breaking improvements in delivering essential services and products” to reach “sustained, scalable solutions to the world's complex problems.”²

Major global health organizations, including the Gates Foundation,^{3,4} the Program for Appropriate Technology in Health (PATH),⁵ and USAID's Global Development Lab, have embraced innovation since the mid-2000s as a critical interprofessional approach to understanding and reducing

health disparities and strengthening health systems in communities across the globe.⁶ These and other organizations take multiple approaches to support innovation, including providing financial support to innovations developed in the US, investing funds to identify and catalyze innovation in developing countries, and creating educational pathways to develop the next generation of innovators, and identifying innovations likely to accelerate progress toward the health targets of the Sustainable Development Goals.⁷

In large part, these efforts are focused on the promise of innovation to improve the health of communities in low-resourced countries. However, the innovation movement has dovetailed with the growing awareness that global health interventions should be used to improve health and health care in the US.⁸ This is particularly true where domestic health challenges share commonalities with challenges in the developing world. The US has historically not looked outside its borders for health care advances. However, as the world becomes more global and the value of other nations' practices become better known, and perhaps because the Affordable Care Act (ACA) opened widespread dialog regarding problems with the US health care system, there is growing recognition of the need to seek solutions beyond our borders. The concept of adapting global innovations for use in the Global North is often referred to as reverse innovation.

The term “reverse innovation” was first coined by Vijay Govindarajan, former chief innovation consultant for GE, to describe ideas “seen first or used first in the developing world before spreading to the industrialized world.”⁹ It was in the business setting where the profitability of looking abroad to identify innovative ideas that could be commercialized in domestic markets was first demonstrated. Pointing out how low-resource settings look for “value for many” instead of “value for money,” Govindarajan suggested that innovators in these settings must think in radically unconventional ways about how to achieve acceptable quality at a very low cost. In applying the term to the health care sector, DePasse and Lee¹⁰ define reverse innovation practically as “learning from and investing in poorer settings as one way to tackle problems in wealthier settings that require out-of-the-box solutions.”

Reverse innovation has been identified as a key emerging trend in global health systems not just because good ideas exist beyond our borders, but because low-resourced settings are particularly good laboratories for low-cost/high-impact

innovations that are developed out of necessity. The concept of the “research imperative” of low-resourced countries posits that structural and economic limitations create a research and development infrastructure that favors affordability, innovative service ecosystems, robust product development, and leapfrog technologies.¹¹

Along similar lines, advocates of “frugal innovation” argue that the West’s “more with more” model of innovation which uses heavy investment and natural resources to develop costly and sophisticated products is anathema to inclusive and sustainable development in both advanced and developing countries. Navi Radjou who defines frugal innovation as “a disruptive approach that strives to deliver more economic and social value to more people using fewer financial and natural resources” embraces a broad concept of innovation in both directions that can enable countries on both sides of the income divide to “cocreate affordable and sustainable health solutions that benefit everyone.”⁵

Key health areas where low-resourced countries can offer solutions to middle- and high-income country settings have been identified as rural health service delivery, health worker skills substitution (or task shifting), decentralization of management, education in communicable disease control, mobile phone or “mHealth” use, low technology simulation training, local product manufacture, health financing, and social entrepreneurship.¹² The Robert Wood Johnson (RWJ) Foundation acknowledged the broad potential of reverse innovation through their recent request for proposals to fund “Global Ideas for US Solutions,” which offered funding for projects, programs, and models developed overseas that promote health equity, including those that “build healthy places; build social connection across the lifespan; get and keep children healthy; integrate health and social services; and increase the health care system’s focus on the root causes of poor health.”¹³

Acknowledging the opportunity that reverse innovation offers to the health care sector, researchers and practitioners alike are striving to identify global approaches to address health system challenges in the US, as well as frameworks for domestic adaptation. Yet as health care researchers attempt to put reverse innovation into action, they come up against major obstacles, including collaboration challenges, change-resistant culture, and unsustainable public financing models for reverse innovation.¹⁴

Everett Rogers described 5 criteria that must exist before an innovation is accepted in any context: innovations must be better than alternatives,

relevant to local contexts, easily communicated, highly visible and trusted, and easily tested.¹⁵ Donald Berwick, former administrator of the Center for Medicaid and Medicare Services (CMS), offered criteria that govern how widely innovations will spread. In order to cross the gap between knowledge and practice, he suggested that health system leaders must create an environment that welcomes change and invests in early adopters, thus creating a context where innovations that are perceived as sound and relevant will spread.¹⁶

Embracing reverse innovation requires a focus on both the new idea and its implementation into use in a particular setting. The growing field of implementation science, defined as “the study of methods to promote the integration of research findings and evidence into healthcare policy and practice,”¹⁷ is focused on many of these questions across cultural and national borders. The National Institutes of Health (NIH) Fogarty International Center and NIH National Center for Advancing Translational Sciences describe the critical role of implementation science in global health to answer “hard questions such as how best to translate new findings into practice in different cultural settings.”¹⁸

A difficult question that has received relatively scant attention is that of legal and regulatory barriers to reverse innovation. However, recent innovation initiatives have specifically focused on the importance of legal and regulatory success in reverse innovation. The inaugural report of PATH’s Innovation Countdown 2030 initiative, which highlights high-impact innovations selected by entrepreneurs, investors, and innovators, included in the criteria selection the innovation’s “probability of success for regulatory approval.”⁵ Stanford’s Global Health Innovation Handbook teaches potential innovators that a “challenge that frequently derails global health innovators on their way to market is the added burden of regulatory requirements and clinical testing that is unique to the healthcare industry” and provides ideas to address this challenge.¹⁹

The recent RWJ Foundation request for proposals noted above asked applicants to consider in relation to their proposed innovation the “feasibility to implement, finance, and sustain” the project in the US.¹¹ These organizations correctly note the importance—and difficulty—of obtaining regulatory approval, which can be inferred from the context to mean approval by the US Food and Drug Administration (FDA) in the case of drugs and devices and institutional review board (IRB) approval in the case of clinical trials.

However, IRB and FDA approval are just 2 elements in the complex web of laws and regulations that govern health care, health products, and health personnel in the United States. Other potential barriers include private and public insurance reimbursement guidelines, standard of care issues, liability concerns, and scope of practice issues.

In health care and beyond, the US legal and regulatory atmosphere is not conducive to the importation of foreign ideas for a number of reasons, including the nation's history of advanced research and development (R&D) capabilities, as well as theories of US isolationism and ethos of self-sufficiency that are beyond the scope of this paper. For the last 200 years, the innovation flow has moved primarily from the US and other resourced countries with R&D capacity to less developed countries¹²; with one consequence being that the US legal and regulatory system is not prepared to support incoming innovations.

Further, the US health care system has never, until recently, considered affordability of a product or intervention a requirement or even a virtue,²⁰ and therefore the legal atmosphere is not structured to support development of low-cost alternatives when a comparative (albeit more costly) solution is available. In a 2013 study that compared specialty hospitals in India and the US, Richman *et al.*²¹ concluded that the regulatory environment surrounding the US health care market excludes or cripples realistic challenges by newcomers with innovative organizational forms.

Legal and regulatory barriers to reverse innovation contribute to a climate in the health care sector that stifles innovation among practitioners, discourages investment in new approaches, prevents value-based care, and isolates the United States from the global flow of successful health interventions.

METHODS

To understand the legal barriers faced by innovators bringing health interventions to the US, the authors conducted semistructured qualitative interviews with 9 key informants who have directly participated in the introduction of global health care approaches to the US health system. Because of the research question's exploration of complex and novel understandings of the legal landscape surrounding innovation, and the multifaceted ways these understandings have informed one another in diverse health care settings, a qualitative study design proved the ideal method.

Because the practice of "reverse innovating" global approaches to health care is still in a nascent stage in the US, eligibility for inclusion in the study was broad. Participants sought were professionals working at the intersection of health care, academia, and innovation who have direct experience at some point along the path of bringing international innovations to market in the US. To be included, participants had direct experience in one of the following: ideating a health care approach from outside the US with the sole purpose of bringing it to market in the US; adapting an international approach for use in the US market; or piloting, scaling, or bringing to market an international approach in the US market.

Academic researchers whose primary field of study includes health care law were also included to provide legal context for the paper. A purposive sampling scheme was thus employed by the authors to identify participants known to them through their work and research in the reverse innovation landscape. Because the key informants were all known to at least one of the authors, a sampling frame was not utilized to identify potential participants. Recruitment was accomplished via direct invitation by the authors, who contacted the innovator-participants via e-mail.

Semistructured interview methods were utilized by the authors in conducting key informant interviews. An interview guide was developed to explore specific questions related to the legal barriers faced by participants in their reverse innovation experience. Questions drew on the themes explored by the researchers in their literature review, and a second iteration of the interview guide was written to include new areas of focus after the first 2 interviews were conducted. Questions were open-ended to elicit meaning and context in pursuit of a rich, deep emic perspective from each participant.²²

Interviews were conducted over one week in July 2016. Phone interviews were scheduled with all 9 participants and each lasted an average of 35 minutes. Each author conducted 3 interviews with participants who were known to them. Because of technical limitations, the authors were unable to voice record the conversations. During the call and immediately after, the authors took detailed notes using pen, paper, and computer. Collected data included direct participant quotes and synthesis of participant comments.

The following questions were asked of participants: Tell me about an innovative approach to health care from abroad that you implemented in

the US? What has your biggest challenge been at getting it implemented/adapted? What legal barriers got in your way? What policy barriers got in your way? Are any of the barriers you identified unique to “imported” innovations or would they apply equally to innovations developed in the US? In addition to these questions, the authors used probes to follow up on questions and allowed the conversation to stray from the guide as appropriate to more deeply explore aspects of the research questions.

Thematic analysis was used to analyze the detailed notes taken by the authors during their interviews. Notes and findings were typed and shared between the 3 authors who searched the data electronically to independently assign codes to the collected data. Coded data were then shared between authors to facilitate the surfacing of major themes. In addition to reporting the barriers identified by the key informants, the authors provided background on particular issues where explanation would be useful to readers to explain the context of a key informant’s comments. Not intending to be exhaustive, this paper outlines in the broadest terms the potential legal barriers to reverse innovation and offers recommendations to facilitate a culture that embraces and promotes reverse innovation in the US health sector.

For the purposes of this study, the law (and adjective “legal”) refer to binding legislation and measures passed at the federal, state, and local level or emerging from judicial decrees and the regulations and guidance documents adopted to implement these measures. Because the approval process for drugs and medical devices from abroad is well documented, in this study, the authors focused on the legal barriers to health care system and service innovations, which include new models of care, behavior change and demand generation initiatives, insurance and reimbursement strategies, health work force and capacity-building models, and data collection, management, and use.⁵

RESULTS

The barriers identified by the key informants fell into 3 general categories: purely legal (e.g., not relating to interaction with a regulatory body), regulatory, and perceived legal and regulatory concerns (i.e., situations where fear of the legal and regulatory barriers resulted in an innovator not even attempting to bring a product or service to market).

Legal Barriers. In terms of purely legal barriers, several key informants raised the issue of tort

liability for health care providers who employ an innovative product or practice that may deviate from the standard of care. As background, a physician can be sued by a patient or their representative for medical malpractice (negligence) if “an act or omission by the physician during treatment deviates from the standard of care and causes an injury to the patient.”²³ Most jurisdictions adhere to a national standard of care that holds physicians to the ordinary skills, learning, and experience of the profession generally. “Innovations are, by definition, deviations from the ‘community standard’ of ordinary skills, learning and experience of a physician and therefore may expose innovators to liability” without the protection that following the standard of care provides.²¹ The standard of care changes over time as technology advances, but the evolution of the standard is slow, and therefore the fear of being outside the standard of care may inhibit physician uptake of an innovation.

One key informant noted the example of the NIFTY Cup, a simple plastic cup with a reservoir at its spout to help feed breast milk to preterm infants and babies who have issues breastfeeding due to cleft lip or palate. The cup was designed through collaboration between PATH, the Craniofacial Center at Seattle Children’s Hospital, and the University of Washington School of Dentistry.²⁴ The product is undergoing validation studies and Laerdal Global Health, a nonprofit manufacturer, will bring the cup to market for use in low-resource settings in the next few years. The question raised by the key informant was simple and at the heart of the reverse innovation discussion: would this low-cost innovation be taken up in the United States where the current standard of care for feeding children born with cleft palate (prior to surgical correction) is very effective but much more expensive, typically involving an extended stay in the hospital for monitored feeding.

The key informant raised this example to illustrate standard of care and liability concerns as well as to highlight disincentives to innovation such as reimbursement (would a patient’s insurance reimburse for NIFTY cup use?) and rigid hospital structures that may be resistant to change (would the hospital embrace use of this new, less expensive modality?).

Another legal concern raised by a key informant relates to allowing patients to undertake self-testing or to self-administer treatment that was previously provided by licensed health care providers. Moving products and treatments from the clinical setting

into the hands and homes of trained patients is a modality seen in developing countries where access to health care providers is often prohibitively expensive or inaccessible. FDA allows patients to administer self-care in certain cases, for example, self-injection of insulin and home dialysis. The key informant raised the issue of physician liability if the self-treating patient injured during self-treatment or if the patient misused the treatment.

Similar concerns have arisen with expedited partner therapy (the clinical practice of treating the sex partners of patients diagnosed with a sexually transmitted disease by providing medications to the patient to give to his/her sex partners without clinical assessment of the partner)²⁵ and distribution of Narcan to friends and relatives of drug users to reverse opioid overdoses.²⁶ Many states have specifically addressed this concern by passing laws broadly immunizing participating health care professionals, patients, and trained friends and family members from civil and criminal liability if appropriate communication and/or training is conducted in advance.^{25,26} These programs could serve as models for making more treatment and prevention modalities available for patient self-use.

This key informant raised the example of the Sayana Press contraceptive that provides a three-month dose of contraceptive in an injectable device that women administer to themselves. Self-injection of Sayana Press was approved by the United Kingdom's Medicines and Healthcare Products Regulatory Agency and has been recommended by the World Health Organization (WHO) in contexts where women have information, training, and support regarding use of the product. Sayana Press has been available from providers in Senegal, Uganda, Burkina Faso, and Niger since 2014, under a country-led introduction and research initiative coordinated by PATH.²⁷ In reference to reverse innovation, the key informant questioned whether this low-cost and convenient product would be approved in the United States and whether physicians would be too intimidated by the specter of legal liability to recommend this self-injectable product.

Approved clinical trials are the most effective method to evaluate and validate new or not widely utilized approaches and clinical trial results can lead to new standards of care. Even if an approach is proven effective internationally, as in some of the above examples, "proof of superiority to existing technology or standard of care in a clinical trial may be necessary for uptake by [high-income country]

early adopters, and more rigorous comparative and cost-effectiveness data may be needed to convince the [high-income country] early majority to change practice."¹⁰

Regulatory Barriers. *Task shifting—community health workers.* Many of the key informants discussed concerns relating to task shifting, which is defined by the WHO as the redistribution of tasks among health workforce teams. Under this model, used frequently in low- and middle-income countries (LMICs) where health care worker shortages are common, specific tasks are moved, where appropriate, from highly qualified health workers to health workers who have fewer professional qualifications in order to make more efficient use of the available human resources for health.²⁸ One particular form of task shifting—using community health workers (CHWs) as part of the public health team—has been found highly effective in numerous LMIC settings.²⁹

CHWs are typically community members who do not possess a formal health professional certificate but are trained to conduct a specific set of tasks to improve the health of communities experiencing critical health workforce shortages.²⁹ CHWs work as traditional birth attendants, village health workers, peer supporters, community volunteers, and health extension workers.

A 2002 Institute of Medicine report found that the United States has been very slow to adopt and integrate CHWs due to lack of reimbursement and sustainable funding, scope of practice, training and qualification issues, and insufficient recognition by other health professionals.^{30–32} However, in recent years, the United States is beginning to embrace the CHW model, and it may turn out to be the first widely adopted reverse system innovation embraced in the United States.

In 2013, CMS made a key policy change to the regulatory definition of Medicaid preventive services in 42 CFR 440.130(c), which previously stated that preventive services could only be provided by a physician. Now, other practitioners, not just physicians, can provide and be reimbursed for furnishing preventive services recommended by a physician.³³ Further, at the urging of prominent public health organizations, including the Centers for Disease Control and Prevention (CDC)³⁴ and the American Public Health Association,³⁵ the ACA included a range of provisions to enhance the role of CHWs in the US health care system. Notably, section 5313 of the ACA authorized the CDC to issue grants to organizations to improve health in

underserved areas through the use of CHWs. Several states have already included CHWs in their state Medicaid plans.³⁶

Notwithstanding the forward progress on the use of CHWs in the United States, several key informants noted continued barriers in this area. One mentioned the Women-Inspired Neighborhood Network (WIN) in Detroit, Michigan, that utilizes CHWs to connect residents with resources. Established in 2008, WIN was a collaborative response to the high infant mortality rate in Detroit. WIN collaborated with 4 metro-Detroit health care systems with significant investment from the participating hospitals and local foundations. The program overcame numerous legal and regulatory barriers, but most notably established a new position of health care worker and obtained funding where insurance reimbursement was not available. The key informant noted that WIN was able to overcome these barriers and succeed due to 3 factors: (1) strong global evidence that CHW programs are effective and save costs, (2) forward-thinking hospital executives open to new models of care, and (3) investment from foundations.

Another key informant concurred that a persistent barrier to his organization's use of CHWs is obtaining reimbursement for their use as well as credentialing of CHWs by states as a distinct category of health care worker. Credentialing CHWs was seen by interviewees as critical to achieving greater respect for CHWs among other health care professions, ensuring insurance reimbursement, improving working conditions and benefits, and creating opportunities for more sustainable funding. However, as noted in the literature, credentialing CHWs has some perils, including pushback from established categories of health care workers, placing a barrier to entry for the individuals best suited to the job (ie, members of low-income communities who may not speak English as a first language), and favoring credentialing and hard skills over community connections.³⁷

The current movement to resolve licensing and reimbursement barriers to the use of CHWs provides a useful model for the adoption of new innovations into the US health care system. Advocacy from public health organizations and a key CMS policy change finally moved the adoption of CHWs forward. Although the process was very slow, it is starting to bear fruit and might prove useful as a guide to future such initiatives.

International physician licensure. One key informant raised the issue of physician licensure in relation

to a telemedicine initiative he started in Mexico. Telemedicine itself is a medical innovation and is starting to flourish in the US after a slow start. Although effective in both patient outcomes and affordability,³⁸ the biggest obstacles preventing domestic US uptake of telemedicine have been lack of reimbursement and barriers that many states have erected or maintained relating to licensure.^{8,39}

Physician licensure is granted state by state, and generally, a physician must be licensed in the state where the physician is located and in each state where the physician's patients are located. Basic standards for licensure are largely the same across states, but there are different filing and administrative requirements that make it difficult and costly for physicians to establish multiple state licenses. Physicians trained outside the US can practice in the United States in very limited circumstances usually tied to an academic appointment for a limited time period. In order to obtain a permanent license in the US, foreign trained physicians must undertake a lengthy process that involves verifying medical school transcripts and diplomas, proving that they speak English, passing 3 separate steps of the United States Medical Licensing Examination, obtaining American recommendation letters, securing permanent residency or a work visa, and obtaining a space in a hospital residency program. Outside of the context of innovation, many health policy experts have complained that these burdensome rules are preventing foreign-trained physicians from practicing in the United States even when the need for physicians has expanded under the ACA.⁴⁰

One key informant related his experiences as chief executive officer of a company that is using licensed Mexican physicians to provide services to Spanish-speaking US residents, building upon the telemedicine services the company already provides in Mexico to Mexican citizens. The service is designed to fill a gap that exists in the limited number of Spanish-speaking physicians in the US. Although the organization could readily provide actual medical services to US patients, current licensure and reimbursement rules prohibit these services. As it stands now, the organization only provides health coaching and navigation services to US patients and connects them to US health care services but has found a solid niche in self-insured employers who are open to this new model as a way of reducing insurance costs. The reluctance of state licensing boards and payors to embrace this binational solution highlights roadblocks to new

models of care that, if studied and found to be safe and effective, could be a net benefit to the US health care system.

Reimbursement. Until relatively recently, the financing and reimbursement system for health care in the United States valued outcomes over cost-effectiveness. Under this paradigm, there has been no incentive to create a pathway for reverse innovations that promise to deliver low cost. A key informant from a major research university suggested that financial mechanisms that can derisk reverse innovations will be critical to their uptake so that there will be payment incentives. The informant suggested that demonstration projects are one strategy to support solutions to this problem that have the potential to offer stakeholder payors and providers clear examples of success.

These stakeholders must be involved at the initial stages of an innovation's demonstration to identify funding mechanisms, because in the current environment, small practice providers are too dependent on fixed reimbursement schema to have the flexibility to pilot or prove reverse innovation interventions. In turn, current reverse innovation implementation occurs in large research hospital settings where group practice providers are somewhat insulated from total dependence on reimbursement mechanisms, or in settings supported by large US foundations.

Further complicating reverse innovation implementation is how reimbursement happens practically, according to one informant. Reimbursement is typically based on diagnosis-related group (DRG) payments under which medical services are categorized and submitted for reimbursement to the treating provider or facility. Establishing new DRGs is time intensive and costly, and these factors serve to discourage new innovators from entering the market.²¹ Innovators, like all service providers, desire value from their unique contributions. The inert state of the US health care reimbursement landscape currently acts as a barrier to reverse innovations.

General Complexity of the US Health Care System. The majority of the key informants noted the complexity of the US health care system and its accompanying laws and regulations as an overall barrier to reverse innovation. The US health care system has been called a “clash among competing forces, not a system” and one in which individual health professionals focus on receiving payment for services in facilities that promote high-margin services from suppliers interested in protecting their intellectual property.⁴¹ A key informant who

leads a community-based organization with a health-related mission noted the difficulty he has had navigating these clashing forces. He proposed a diabetes management program delivered by CHWs to the chief executive officer of a managed care organization (MCO) only to be told that it would be hard to justify investing in the program because there was no guarantee that any one of their patients would stay with the MCO long enough to see a return on the investment. Our key informant complained that, because there is no way to understand where and to whom cost savings actually accrue, it is nearly impossible to demonstrate to any single investor their potential return on investment. This, in turn, prevents innovative approaches from becoming widely available and thus lowering costs and driving impact.

Perceived barriers. Related to the previous point that the complexity of the US health care system is a barrier, key informants also noted that *fear* of the legal and regulatory barriers they would face has kept them and colleagues from bringing innovations to the US market. While all our informants noted that a regulatory framework must prioritize patient safety, they stated that the current regulatory landscape disfavors low-cost products that do not have corporate sponsors. Further, several informants perceive a built-in bias, born of isolationism or parochialism, against interventions developed outside the United States, especially those developed in less developed countries.

Several also noted that lack of understanding of administrative processes and unwillingness to commit time and resources to a losing bid for regulatory approval prevents innovative new entrants from bringing their strategies to the market or clinic. One key informant noted that he had to be creative to address barriers in his bid to link his telemedicine service to US providers and had to convince his colleagues to proceed in the face of both real and perceived barriers. In fact, a critical main conclusion of the key informant interviews is that fear of the US regulatory process actively keeps innovators or organizations from even attempting to bring innovation to the United States.

CONCLUSIONS

Just as there is a clear pathway for drugs and medical devices imported to the United States from overseas, reverse innovators would benefit from a clear pathway for new health-related system and service innovations imported to the United States. Health

care is complex, and it is difficult to think of a single pathway that would be relevant to new payment models, new organizational models, new licensure models, etc., but energy should be devoted at the highest policy level to creating the guidance documents, checklists, demonstration projects, and funding opportunities that put the welcome mat out to the best global ideas in health care.

In conclusion, our key informant interviews made clear what is likely obvious to even the most casual observer of the US health care system—rampant conflicting interests and little value placed on low-cost interventions inhibits innovation and limit our ability to climb out of the complicated,

inefficient system of health care we have built around ourselves.

As the world becomes smaller from globalization, the tantalizing possibility of adopting successful health interventions developed in other countries runs up against the brick wall of a system that is averse to innovation. Legal and regulatory barriers rank among the most fearsome and forbidding aspects of this anti-innovation atmosphere for domestic innovators and reverse innovators alike. Safety and innovation can be fostered simultaneously and, of course, nothing is safer than a health care system that values high quality, accessible health care for all.

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