Laws That Kill Innovation Will Ultimately Kill People

Fri, 03/27/2015 - 11:02am

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February 2014 can be defined by updated DFA proposals supporting updated standards specific to blood glucose monitor accuracy standards for devices used in both home consumer and healthcare facilities. Twelve months later, February 2015 is finally seeing the conversations surrounding the new proposed standards that would notably raise the bar and tighten glucose monitoring system standards in the United Stated come to life. Prior to the standards proposed in 2014, US consumer glucometers were struggling to meet the ISO 15197 guidelines set by the International Organization of Standardization (ISO), which were updated in 2013. The FDA backed off of implementing these standards after studies demonstrating that only a little over 50% of existing monitors on the market could achieve the sufficient accuracy for 97% of readings to be within 20% of the laboratory reference measurement. The abandoned specifications required that measurements be within +/- 15mg/dL for blood sugars equal to or below 75mg/dL and +/- 15% for blood sugars above 75mg/dL.

This is where details might seem a bit loaded with jargon for those not immediately involved in the blood glucose monitoring industry, but it sets a standard for understanding the context for why this issue is so worth exploring. Current standards (ISO 15197:2003), those under which the majority of glucose monitors and continuous glucose monitoring systems have been approved for consumer and patient utilization today, were set at a range of +/-20% for blood sugars above 75mg/dL and +/-15mg for blood sugars equal to or below 75mg/dL. The specification allowed for 5% of all measurements to be outside of 25% of reference measure for all glucose metering devices. What this means in layman's terms is that for a device to be considered accurate, 5% of the time, measurements can be outside of the referenced accuracy standard by up to 25% and still be considered an accurate measurement tool.

In 2012, specifications for monitoring devices to be utilized in clinical environments were updated requiring them to meet Clinical Laboratory Standards Institute (CLSI) specifications known as POCT12. POCT12 standards further specify that 97% of all measurements must be within +/- 12.5mg/dL for blood sugars equal to or below 70mg/dL and 20% for blood sugars above 70mg/dL. This notably reduces the error margin of what an accurate measurement is.

Advocate groups and medical professionals have been pushing for more stringent glucose measuring standards for decades and see this tightening of regulation as a win for patients, if the standards can be met. Patients, medical practitioners and patient advocacy groups understand the potentially deadly, often devastating, impacts of uncontrolled blood glucose in patients within hospital care units and at home. Further impacting discussions surrounding current blood glucose measurement tools are the issues of inaccuracy and inconsistency. For individuals who regularly heed doctor advice and measure their blood sugars at home, inconsistent and inaccurate readings do little to prevent problems. In critical care and surgical units, the inability for medical practitioners to have accurate and timely measurements of changes in blood glucose has a negative impact on safety, healing, and costs. There is little surprise that the FDA has implemented some

changes and proposed others which potentially can save lives and millions of dollars annually for both consumers and medical care facilities.

In February 2014 the FDA proposed requiring measurements that are within +/- 15% for home/consumer meters, with 99% of measurements falling within 20% of the reference. Even tighter specifications are proposed for clinical meters requiring measurements within +/-10%, with all measurements reading within 20% of reference (or 15mg/dL for blood sugars equal to or below 70mg/dL). During the open comment period surrounding the proposed guidelines, which lasted from February to May 2014, more than 187 responses were received from 57 separate sources, most of whom overwhelmingly supported the changed, but fears no technology or devices currently available could meet such standards. To date, no further actions have been taken. Perhaps the major benefit is that it has opened the door to a much needed conversation regarding patient care and the integration of technology to support increased care standards.

This begs the question: Where is the solution; who will innovate technology to meet these standards? The problem, from a medtech perspective, is twofold. First, who has developed this technology and has proven its accuracy to the point where it can be safely taken to market? And second, once the technology exists, how can the medtech company bring it to market, recognizing the extreme, yet very real, barriers created by the Patient Protection and Affordable Care Act that was passed in the senate in 2009 and signed into law by President Obama in 2010.

The answer to the first question is quite simple. TecMed, Inc, a Wyoming corporation, has the created and refined IP over a 20 year period that answers to the increased accuracy demands presented by the FDA (patients, patient care advocacy groups, and medical care professionals) in hospital settings and for consumer devices. Technology designed for surgical procedures and use in critical care settings that is ready to be brought to market, demonstrated in recent and extensive laboratory studies, accuracy and reliability in measurement that are beyond the current standards, and as much as 12 times more accurate and reliable than currently used measurement systems.

More than 30 blind and double blind human studies from open heart surgical patients and thousands of laboratory studies have been completed demonstrating the capability of TecMed's IP to meet, and exceed, all existing and proposed blood sugar specifications. TecMed's IP is designed for automation that provides real time, reliable and accurate data for medical practitioners to make effective and timely decisions for blood sugar management during major surgical procedures and for hospitalized patients.

As an author, I think it is important that I recognize my role as a representative for TecMed, Inc., perhaps taking away from any inherent bias that might come across. However, regardless of my role, what doesn't change is the fact that the technology exists and is ready for market, and no other organization, device or technology is known that can meet the proposed 2014 FDA standards. As an advocate for the medtech industry, I would willingly celebrate other devices or innovations that meet these standards; however, to date, there are no other devices that I can write about with confidence.

The importance of blood glucose management is no longer debatable. The effects of appropriately controlled blood glucose leads to faster and more complete healing, recovery of mental acuity, and a reduction in hospital acquired complications. Those complications lead to longer hospital stays, death, increased infections, ventilator time, and readmissions; all of which add to the costs of patient care. In fact, the devastating impact of uncontrolled glucose is so well documented that in 2008, the Centers for Medicare and Medicaid Services ceased reimbursements for complications due to hospital failure to control blood sugar. More severe financial penalties were created and implemented with the passing of the Patient Protection and Affordable Care Act. By 2012, private insurance companies began to adopt reimbursement policies and non-payment guidelines for hospital incidents defined by "out of control blood glucose related incidents and complications." The search for the technology to alleviate the negative implications of uncontrolled blood glucose is far-reaching and well- documented.

At this point, we know there is proven, patented and patent pending technology that is ready to be brought to market. We also know that political decision makers understand the need for improved devices. We know the need for the technology exists and there is growing demand. We know the technology exists that answers directly to the needs outlined by political mandates, patient advocacy groups and medical practitioners. Why isn't it accessible? Now we meet one of the true roadblocks: The Patient Protection and Affordable Care Act ("Obamacare" or "ACA").

Under the current legislation, introducing new technology into the medical arena is chalk full of potentially unsurpassable barriers. Prior to the ACA, when new technology was brought to market, medical technology companies would bring their device to regulatory approval boards who would certify the device and set the stage for the issuance of a Medicare code for billing and reimbursement purposes. The path was fairly effective and allowed for the health care industry to flourish as a place for innovation and improved patient care. The passing of the ACA meant the previously straightforward path for integrating innovative technologies into the system was blocked and has brought a technological dead end to much of the medical device and technology industry. In a rushed effort to cut costs, the legislation created a "loop error" where a reimbursement number for new devices will not be issued without proof the device/procedure/medication will cut costs and improve patient outcomes without providing a means for reimbursement or payment for their use in collecting proof that it improves patient outcomes and saves money.

Essentially, this means that you cannot get paid for a device until both its medical efficacy and financial benefit are proven without clear guidance or specifications for how those parameters are measured (or by whom). In addition, you cannot prove its medical efficacy or financial benefit until hospitals and practitioners know how they will get reimbursed for using/buying the technology. In fact, through the ACA, bureaucratic and inter- and intra-agency regulation and specifications are at cross purposes to such an extent that even private citizens who wish to the pay for the use of the device out of their own pockets cannot receive regulatory approvals to use the device within a hospital care unit.

What does this mean for innovation, patient care, and improved patient outcomes and financial savings? It means that if there is no reimbursement code, hospitals, clinics and other medical care environments cannot risk adopting new, necessary and innovative technology because, quite simply, there is no way to pay for it due to a legislative oversight and overregulation. Looking at the immediate implications, we know that this takes away from medical practitioner's ability to provide the "best" and most innovative care for their patients in ways that follow both the ethical codes of medicine, but also the mandated specifications set forth by various legislative and regulatory bodies/agencies. It means that patients in the United States will not have access to technology they may need to thrive and the potential for cost savings remains unrealized. From a broader perspective, it leads to the death of innovation in the United States medical technology and device arena.

Companies who focus on medical device and technology innovation no longer have a clearly understood pathway to profit from innovation and will relocate their resources to more amenable environments for innovation such as India, Japan, Ireland, China and Dubai. Instead of growing the U.S. market, it means that foreign economies and will benefit from U.S. innovation while the U.S. economy and population will be overlooked. The ACA is what innovators describe as one of the proverbial final nails in the coffin of the U.S. medical device and technology industry. If changes are not made immediately in the medtech industry, the U.S. healthcare system, and the populations and economies that benefit from them will suffer grave, irreversible consequences. Not only will U.S. citizens die unnecessarily, the U.S. medical device industry will shrivel up alongside them.

The need for change is immediate and undeniable. Government regulatory and reimbursement mandates, insurance companies, patients, patient advocacy groups and medical health professionals all agree that there must be improvements in glucose measurement control for diabetics and hospitalized patients. The devastating impact of uncontrolled glucose is well-reported and well-understood. Yet, the political system

that is mandating change has created extremely challenging obstacles to the introduction new and innovative medical technologies. These are challenges that must be overcome before market introduction of much needed technology solutions that meet the very standards instituted by regulatory agencies and both government and private reimbursement specifications, in response to the outcries of patients, patient advocacy groups and medical health professionals. Further compounding the spiral, is the fact that technology exists today that more than answers patient and medical professional demands, regulatory specifications, and reimbursement mandates. All of the pieces of the puzzle exist, yet there is no way of putting them together at this time.

The question we find ourselves asking is, "Now what?" And I propose this question to you. Now what? The players in the medtech industry are generally small companies that lack the political clout and money to make big waves on their own. We deeply recognize the challenges that are in front of not only us, but the U.S. as a whole. In less than five years the ACA has taken the U.S. medtech industry from "recession proof" to struggling for survival. The medtech industry needs to find ways to make bigger waves through a common voice to ensure that much needed change happens. Public understanding and media outcry of this shattering dead-end is perhaps one strategy of overcoming the roadblock. Local, state and federal politicians and advocacy groups need to work together to push for change.

We know the problem. We have the solution. Now we just need the political, bureaucratic, and regulatory framework to make it happen. We all want to save lives; the life that may be saved could be your child, a family member, friend, or even your own. The frosting on top, is that not only are we saving lives, we can save money while doing so. Now, we just need clear and appropriate guidance, specifications, and standardized procedures from our regulatory and reimbursement agencies to make it a reality.