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The ACA Has Clogged the Pipeline of MedTech Innovation

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The 2010 media was saturated in the triumphant, albeit hotly debated, arrival of change in many sectors of life, but spun tightly on the U.S. healthcare system. The year can be defined with tedious chatter, increased expectations, and a new sensation of hope and safety in many household across the country. This bubble of emotion was led by the introduction of the Patient Protection and Affordable Healthcare Act (the “ACA”), which created a new opportunity to access healthcare for millions of U.S. Americans across the country.

The promise of the ACA generated a wave of excitement for many underrepresented populations in the U.S. where access to medical intervention and healthcare was simply not available. The focus of the ACA was to provide healthcare coverage to millions of Americans without coverage. The ACA, although not without its flaws for patients, has expanded access to healthcare. Individuals with pre-existing conditions or those who couldn’t afford healthcare before the initiative was passed have new prospects available to them in healthcare that were beyond their reach before.

On the business front, as the ACA was saturated in standard political jargon for politicians to sift through before passing it into law, gaps, obstacles and new brick walls were constructed decreasing the chance for innovation and improvements in patient outcomes. For those of us within the medical device industry, the passing of the healthcare initiative provided the promise of new areas of growth as new medical mandates were implemented for improved, measureable patient outcomes and decreased medical costs. Initially, industrywide, emotions were mixed with some highly concerned about negative effects and others with excitement levels matching those of the nation’s uninsured population. What has proven to be true, the potential for increased access, improved patient outcomes and decreased medical costs have been overshadowed by bureaucratic obstacles, taxes, and uncertainties written into the healthcare act. Let’s explore that issue from the perspective of one small medtech company

After nearly 20 years of applied research and development, TecMed Inc. achieved a point where they could confidently bring their intellectual property (IP) to market. This IP includes technology that provides continuous, accurate, real-time blood glucose

measurements before, during, and after surgical procedures, as well as for patients in critical/intensive care environments at incredibly affordable costs. Sitting patiently on a shelf in the TecMed labs are additional innovative device designs and applications of the core technologies, including a consumer glucose measurement device that is not only more accurate than monitors on the market today, but is completely noninvasive. TecMed touts a library of patents and clinical proofs demonstrating their IP works and deeply understand the glucose measurement demand from the perspectives of patients, medical practitioners, and patient advocacy groups. In fact, TecMed's IP is directly aligned with the Affordable Care Act with its focus on technology and devices leading to better patient outcomes and medical cost savings. There is no question that what TecMed offers is not only something the medical market needs, it is something the market demands and is a technology that should be implemented as soon as possible.

Yet, as TecMed Inc. has fought to bring their IP to the public eye and into the public's hands, they have realized that having medical mandates and dealing with layer upon layer of medical and governmental bureaucracy that is still recovering from a complete ideological overhaul and systemic update, the pipeline that traditionally would bring our IP into the ready and willing hands of medical practitioners and home consumers has broken. As a company, we do not believe that the pipeline is irreparable. But, what we deeply believe is that our in-demand IP is currently stuck in some sort of systemic clog. Let me explain.

In recent U.S. history, when new medical technology was introduced into the market, small companies, like TecMed and the majority of medical device technology companies, would bring the device to the regulatory approval boards who would then certify the device and the path to the issuance of a Medicare code for billing purposes was relatively straightforward. This code is the code that would ensure the hospital and clinical practitioners would be reimbursed for the device and its utilization. The passing of the Affordable Care Act introduced uncertainties in this path to reimbursement for new medical technology and created a technological standstill. In their zeal to cut costs, the legislation has created a "loop error" where a reimbursement number will not be issued without proof that the device/procedure cuts costs and improves outcomes, but does not address how the device/procedure paid for or reimbursed in order to prove that it improves patient outcomes and reduces costs. You cannot get paid for the device until its efficacy is proven and you cannot get it proven until hospitals and physicians know they will get reimbursed for using/buying the device.

What this essentially means is that if there is no reimbursement code, hospitals, clinics, and other medical care environments cannot risk adopting new and innovative technology as there is no way to pay for it. In the short term, this means that patients do not have access to the new technology they need to thrive and the potential cost savings remain unrealized. In the long term, it means that companies who focus on medical device innovation will stop innovating as they go out of business or move overseas to more open markets and more straightforward regulatory/reimbursement paths. In the extended term it means medical innovation in the United States dies.

We understand the protections this pipeline clog affords. It protects hospitals, and perhaps patients, from new devices that have not fully proven their effect on patient outcomes and healthcare costs as compared to devices that are already in the market. However, it also kills medical device innovation. Innovation is expensive and time consuming; adding the

risk of reimbursement uncertainty diminishes access to critically needed capital investment, which will hasten the erosion of the US supremacy in medical device innovation.

This is a big idea to wrap your head around. People from all over the world come to the United States to access the innovative tools our medical community has to offer because we have had such open access to implementation and adoption of new medical technology. Individuals suffering from cancers, malformation, and both terminal and non-terminal illness come to our country for medical care because we have the advanced tools to help them. If our industry continues to be stifled by bureaucratic roadblocks, such as the inability for new devices such as those developed by TecMed, that are proven to be effective, safe and affordable, to market, we are slowly killing our exceptional healthcare system.

This is a big problem. It is a big problem because as we eradicate innovation, we erode the power of the U.S. healthcare industry. We take away the opportunity for medical practitioners to positively impact lives and make our world a healthier place where people can live fulfilled lives. Innovation is one of the key facets that keeps our medical system apart, and superior, to medical structures across the world. A strong medical industry feeds into a healthy economy as we know healthy people are not only more productive, but happier. A strong medical device industry is what builds and supports a strong medical industry. Without a healthy medical device and technology industry, the strength of our healthcare system wanes. We innovate and through device implementation, we improve lives and strengthen our country. The uncertainties and bureaucratic roadblocks imposed by the Affordable Care Act takes much of that away from us.

This is the monumental obstacle TecMed, and other small medical device companies face today. We have done the difficult work. Small medtech companies have designed, refined and proven technology that is life altering. There are patents on designs that will improve patient care and reduce medical costs. There is technology available that will help to save lives. Yet, the lack of a straightforward path to reimbursement, a Medicare billing code for new technologies, is what many companies both large and small are struggling with under the ACA. What is becoming very clear to the small medtech company, and more recently recognized by larger organizations, is that to get IP to market, we have to play into the politics of the national healthcare act.

For decades one of the questions that has plagued the medical community was how to continuously, accurately and affordably measure and manage blood glucose in critical care settings and how to measure blood glucose non-invasively. TecMed has created and refined solutions for these problems. The next task in opening up the pipeline for medical device innovation is to overcome the “ACA coding” problem as well. TecMed, and dozens of small medtech companies are far from giving up the fight in bringing their life-saving IP to market. In fact, they are fighting harder than ever, knowing, that the pipeline to improvement only is clogged. As the ACA continues to work out the bureaucratic ‘kinks’ in the system, medtech companies will continue to push to ensure individuals have access to the tools, technology and devices they need to thrive in medical care environments.