

Medical devices on the front line of therapy

In the world of healthcare, biomedical devices have long been relegated to a secondary position behind molecular drugs for treatment of chronic illnesses. And, in light of the differences in their missions and characteristics, drugs and devices have never competed for position in the healthcare space—until recently.

The \$3.2-trillion healthcare industry is about to witness a revolution, and the medical device sector is at the heart of it.

Medical devices have been in use for hundreds of years, from tongue depressors to implants to pacemakers, and everything in between. For all the contributions to medicine that they made, medical devices have been considered as alternative therapies at best, and a last-ditch measure in treating their respective illnesses.

However, the medical device industry is changing at a rapid pace.

The market is growing—the need for better patient outcomes is fostering development of advanced biomedical devices in an age where such advancements are now possible. In addition, collaborative care is being emphasized increasingly in what was once a strictly clinical setting. Finally, as a new generation of devices is being designed, innovative partnerships between healthcare firms and other entities willing to share the risk of new product development and implementation are taking place..

The global market in medical devices is predicted to reach \$440 billion by 2018 which reflects a growth rate of approximately 4.4 percent per year. Contrast that with an anticipated annual growth rate of 2.5 percent for the prescription drug market.

What are the implications?

An entire world of new medical devices is enabling patients to become more hands-on with therapies, as well as simplifying treatment protocols. Devices developed for Type 1 diabetics can now monitor insulin levels, telemeter critical levels information to remote medical networks and adjust those levels, then administer doses as needed by the patient. All of this can be accomplished without significantly inconveniencing the patient.

Another new device monitors asthma attacks and helps administer the right dosage from a “smart inhaler” connected to a smart phone and app which sends data to a network of professionals as well as a collaborative community of other patients. Ideally, more will be learned individually and collectively about the disease, and how to optimally treat it.

Millions of individuals suffer from chronic, debilitating diseases such as advanced cardiovascular disease that requires continuous monitoring. Until recently, no existing application afforded patients complete freedom of movement and attendant peace of mind via a wireless, remote device. Medical device startup Nanowear changed all of that by producing a network of proprietary biosensors embedded within everyday undergarments such as brassieres and t-shirts. The product allows continuous remote

patient monitoring and simultaneously provides medical practitioners with a flexible, cost-effective platform to make informed decisions.

These are merely three examples within a large number of advanced wireless devices in use and under development, all part of the revolution moving medical devices to the front line of therapy.

Bioelectronics

Much of the progress made in bioelectronic medicine has been driven by university research, but it's now moving into development and testing labs. In 2013, British pharma company GlaxoSmithKline became so interested that they eventually funded some 25 investigations exploring disease biology and neural signaling. As evidenced by the Galvani venture cited in this article, GSK envisions their growing discipline eventually leading to a new class of metabolic, immune-inflammatory, respiratory, cardiovascular and other medicines.

Others are also heavily invested in the future of bioelectronic science. A handful of start-ups are now working toward clinical applications in bioelectronic science. The National Institutes of Health (NIH) is also advancing neuroscience with its Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. In time, NIH's findings should contribute valuable data on which nerves to target in the human body for the implanting of microelectronics which stimulate nerves—the end result being the mitigation of specific pathologies in patients.

Connected Care

One large aspect of this revolution directly impacts upon how medical devices interoperate within medical device networks and improve patient outcomes. Connected care is the real-time, electronic communication between patient and provider; it includes telehealth, remote patient monitoring and secure email communication between clinicians and their patients.

In many of today's medical devices, this is accomplished by wireless telemetry of encrypted data packets or in a continuous data stream from a medical device to a smart phone, to the cloud and then to a clinical system where health professionals can work with the data received, to help the patient. It is stated that as the healthcare system in the United States moves toward more accountable care, remote patient communication and monitoring will play an increasingly important role in patient services.

A new era in healthcare

With the medical device industry poised to change medicine as we have known it, manufacturers and savvy investors envision the next generation of medtech products moving to the front line of therapy.

Kris Famm, a Vice President of Research at GlaxoSmithKline said as much when he spoke at the 2016 FierceBiotech Executive Summit. Famm went so far as to predict that medical devices would move from “a last resort to an early line treatment.” He was essentially declaring that the next generation of medical devices may well supplant molecular drugs as the preferred form(s) of therapy.

This is unusual; nonetheless, we are seeing changes to this end already in the industry. GlaxoSmithKline is one of the world's largest pharmaceutical firms: their drug line consists of 93 drugs, 25 vaccines, 57 consumer healthcare products and even a handful of sports supplements.

As improbable as his prediction may sound, Famm is not the only executive in pharma making the prediction that medical devices are about to capture major market share. Backing up words with action, he recently became president of a new venture, Galvani, which combined forces with Google via their healthcare start-up *Verily*.

Believing that solving tough problems in medicine takes deep collaboration by industry experts, the partners are working together "...to amplify our collective impact and increase our probability of success."

These efforts are being replicated to one degree or another in the offices of many pharma and medtech collaborations—a relatively new idea which brings problem-solvers together to work with the hope of developing devices that were impossible to do little more than dream about, only a few years ago.

Dr. Munna Choudhury, consultant with AlacraMed, has been quoted as saying, "Pharma is becoming more dependent on medtech. There are more and more deals taking place with not-so-traditional players."

Pharma companies are continuing to search for other ways to grow revenues and gain an edge on their competition. With the proliferation of new medical devices, "value-added contracts" are becoming more common between willing participants in both industries.

One example is the new crop of mobile apps being developed by pharmaceutical companies and diagnostics laboratories to accompany their drugs. It also signals a more proactive position taken toward enhancing patient outcomes—although many are betting on even greater future advances in medical devices, especially those with connective technology.

With this innovation in technology, value-added partnerships and shared risk, comes a change in perception. Medical device manufacturers are proving that their products shouldn't be seen as a last resort for the desperately sick. Instead, they're quickly becoming a first-choice option—one that may soon overhaul the healthcare landscape.