The ORACLE is a free newsletter *of recent medical device regulatory & computer information that may be of interest to designers, and device Manufactures.*

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ESTABLISHED 1988
NEWSLETTER FROM **DELPHI CONSULTING GROUP** (**DCG**)
An Internet Based Medical Device Regulatory Service,
www.delphiconsulting.com

Delphi Consulting Group (DCG), *provides medical device regulatory (FDA) release to market via the 510(k) and PMA pathways. DCG is Internet based to boost efficiency and reduce costs*

Vol. 27, Issue 9 September 2021

Tracking Your Premarket Submission's Progress (Progress Tracker)

The FDA built a secure, web-based tracker that displays the Center for Devices and Radiological Health's (CDRH) progress in reviewing traditional 510(k) submissions. When you submit a traditional 510(k) submission to CDRH for review, your Official Correspondent can monitor the FDA's progress online in a simple, concise format.

The FDA offers online progress tracking to fulfill its Medical Device User Fee Act (MDUFA) commitments. (See MDUFA IV Commitments letter, page 11: "an industry dashboard that displays near real-time submission status.")
Track Your Submission

The FDA secures the information about each submission's progress so only its Official Correspondent can view it.

- If this is your Official Correspondent's first time tracking a submission online, the FDA automatically emails them a link to create a login password soon after the FDA starts its review.
- The FDA currently displays progress online for Traditional 510(k) submissions, the most common submission type.
- The FDA formally notifies you of your submission's status by emailing your Official Correspondent with official actions and requests.
- If you have questions about how the FDA informs you of your premarket submission's progress, email ccp@fda.hhs.gov.

Note: to make this work, you must set up account with **Okta**, a non-FDA entity, that has a cost. The Oracle believes the FDA should provide this as a no-cost. The Oracle calls this a non-starter.

User Fees (TAX), for FY 2022.

Attached to this document as a separate file is a listing of the User Fees (TAX) for FY 2022. The changes from FY 2021 is small. Fees (TAX), is up about 2.5%.

Despite these seven headwinds, the medical device market has strong momentum headed into 2022 and beyond.

By David Magnani

The medical device market is fast becoming a powerhouse of the global healthcare sector. The United States especially has seen prolific demand for medical devices over the past decade and a half. A growing geriatric population and trend toward therapeutic and rehabilitative treatments could push the global value of this market as high as 657.98 billion by 2028, according to 2021 market research.

Yet, for as prolific as the runway appears, the medical device market faces challenges—particularly once the pandemic is behind us. Here's a look at seven significant challenges facing medical device manufacturers today and how they could persist into the future as the market becomes more in-demand and more competitive on all fronts.

1. Disrupted supply chains

The Covid-19 pandemic crippled supply chains around the world, causing everything from delayed product deliveries to rising materials prices. Yet, demand for medical devices hasn't fallen. If anything, it rose in 2020. The result is a huge disparity between what medical device manufacturers can produce. Until global supply chains settle and device manufacturers get the materials they need, the market will remain depressed. Moreover, until raw material prices settle back to pre-pandemic levels, the cost of producing many devices could become prohibitive.

2. Rising healthcare costs

Speaking of rising costs, the already-high cost of healthcare continues to trend upward. For those who require medical devices to treat or manage a chronic condition, there's concern that these products will become unaffordable and out of reach. This is compounded by the fact that many medical devices exist outside traditional insurance coverage. Patients are left fighting for even partial coverage of new and innovative devices—or footing the bill themselves. For many, even some financial assistance form insurance isn't enough to bridge the gap between cost and need.

3. Regulatory challenges

The medical device market is lightly unregulated—except for the spaces where it's heavily regulated. This inconsistency ultimately makes it difficult for patients and device manufacturers alike. Unregulated devices aren't covered by insurance, which makes getting them into the hands of patients difficult due to cost concerns. Likewise, the FDA evaluation process for new devices is lengthy, expensive and largely cumbersome, which dissuades many startup device manufacturers from seeking approval. Until there's a more succinct and responsive approval process or a change to regulatory guidance, this gap will persist.

4. Cybersecurity concerns

As more and more devices become digital, cybersecurity concerns rise. Even something as simple as a Bluetooth-enabled device serves as an access point for data theft. Device manufacturers now find themselves facing concerns about patient privacy and protection per HIPAA, which makes manufacturing smart devices more complex and costly. A

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staunch cybersecurity approach can add months to the development timeline, zeros to the production cost and headaches when it comes to seeking approval from regulators. In simpler terms: data security isn't optional and it's creating challenges for manufacturers.

5. Counterfeiting and imitators

We live in an age of IP theft and iteration. Too often, a new and innovative product hits the market, only to see imitators and counterfeit examples alongside it within months. This is a devastating prospect for the medical device market, for a multitude of reasons. Responsible manufacturers bear the burden of doing things right, while counterfeiters flood the market with unproven devices. Patients can experience poor results or, worse still, illness or injury—all because they were duped by a clever lookalike. To perpetuate the problem, these knockoffs are competitively priced and often well-packaged, further mingling them as imposters. Everyone suffers at the hands of counterfeiters.

6. Recalls and lawsuits

In a market as diverse and demanding as the medical device sector, recalls and lawsuits are a frequent occurrence. Many times, the former preempts the latter. As they continue to iterate and innovate, many manufacturers recall old models as a precautionary measure—a move that costs money yet could save multitudes more by avoiding a lawsuit. Likewise, lawsuits are common in a market where definitive medical claims may draw scrutiny from the FDA and customer expectations are high. Device manufacturers need to set and maintain patient and practitioner expectations to avoid litigation. Here again, a better medical device approval process would deescalate tension and safeguard both producers and consumers.

7. Interdisciplinary competition

With the significant milestone of a Covid-19 vaccination in roughly 12 months, the world has seen the power of molecular drugs in the modern age. This, combined with amazing advancements in therapies like CRISPR and pharmacogenomics, is shifting the future of healthcare toward personalized solutions. While we're unlikely to see gene editing breakthroughs for at least another decade, forward-looking device manufacturers see the competition that'll come from molecular medicine. Curing a disease at the DNA level could eliminate a swath of medical devices from the landscape—the likes of insulin pumps, for example.

The market has momentum Despite these seven headwinds, the medical device market has strong momentum headed into 2022 and beyond. While 2021 is a pivotal year coming off a global pandemic, that is still hard to control, it's also an opportunity for medical device manufacturers to establish themselves in a market that's growing more and more in-demand with each passing year. Acknowledging these challenges and keeping them in focus serves to harden manufacturers, to help them stand tall in a market prone to change.

David Magnani is a Managing Partner for M&A Executive Search and Consulting. He has worked in professional services leadership roles for 25+ years, serving a broad range of industries, including the medical device industry. Since 2014, Mr. Magnani has focused on providing clients the expertise they need to advance their businesses via national executive search, placing interim executives or through expert freelance consultants.

Elizabeth Holmes Goes on Trial

Y*ou can fool some of the people some of the time, but not all of the people all of the time.*

July selection begins for the trial of Elizabeth Holmes, the disgraced founder of Theranos. Ms. Holmes promoted what she claimed was a simple blood test that would revolutionize health care, attracting prominent investors, assembling a star-studded board of directors and landing a partnership with Walgreens. She appeared on the cover on Inc. Magazine with the tag line "The Next Steve Jobs." In reality, the tests had significant problems, a Wall Street Journal investigation revealed. She has pleaded not guilty to allegations that she defrauded investors and patients. If convicted, she faces up to 20 years in prison. She became married while under indictment.

This is why media investigators and the FDA are a very good thing.

Keep iPhone, Apple Watches away from implanted medical devices, FDA says

Jackie Drees - Friday, August 27th, 2021

The FDA further supported its recommendations that patients keep consumer electronics, such as the iPhone 12 and Apple Watch 6, that may create magnetic interference at least six inches away from implanted medical devices, according to a study published Aug. 25 in *Heart Rhythm*.

Co-authored by four investigators from the FDA's Center for Devices and Radiological Health, the study builds on discoveries earlier this year that found the iPhone 12 Pro could provoke "magnet mode" of a Medtronic implantable cardioverter-defibrillator.

When a pacemaker enters magnet mode, it continuously paces without sensing the patient's own heart rhythm, which can lead to symptoms including irregular heartbeat, abnormal heart rhythms or even, in rare cases, more serious harm, the researchers wrote.

Small, rare-Earth magnets that are increasingly being used in smart watches, headphones, door locks and phone speakers, among other technologies, are strong enough to potentially trigger magnetic interference. For the study, researchers focused on the iPhone 12 and Apple Watch 6 but said the results could be broadly applied to any consumer electronic devices that may create magnetic interference, including other smart watches and cell phones.

In July, Apple published a list of products, including the iPhone 12 and Apple Watch, that may interfere with medical devices such as pacemakers and defibrillators

See your next month, and have the correct version the first time!