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Top 7 challenges facing the medical device market

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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 are able to 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 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.

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