State of the Industry

40 Years of the Life Sciences Industry

Created by the medical technology and life sciences industry in 1979 to be its permanent solution to the volatile products liability insurance market, Medmarc has grown from a small, Bermuda-based, captive insurance program to insuring the life sciences industry globally. As we celebrate our 40th year, we are taking a look back to how the industry has changed over the decades and how Medmarc, throughout its history, has never wavered from our commitment to be the superior provider of liability insurance protecting to the industry we serve.

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Medmarc through the Years: 2009 – 2019

We started 2009 in the pit of the Great Recession. In January 2009 alone, 800,000 Americans lost their jobs. The unemployment rate escalated from 7.8% in January to 10% in October.

Businesses in nearly every sector felt the effects of the economic downturn. An Ernst & Young report from 2009 noted that high unemployment caused many people to lose their health insurance, which means they put off elective medical procedures. In response, the healthcare industry tightened its belt.

However, certain medtech companies emerged relatively unscathed. Biomedical technology firms that reported growth during the recession used high value-added manufacturing and invested in marketing, R&D and new products to stay profitable. Although smaller startups took a hit due to a decrease in financing and mergers and acquisitions, major players such as Johnson & Johnson, Medtronic and Boston Scientific fared well.

Medmarc also stayed ahead of the economic crisis. "We've remained somewhat resistant to prevailing economic conditions," says Medmarc Vice President and Chief Underwriting Officer Fran Stockwell. "Because medical device sales were down, premiums dropped, but our policyholder population increased."

"This period saw significant growth in policy count for Medmarc as we added new production resources to the West Coast and transitioned our focus to small and midsized companies in the medtech industry," says John Ajello, VP of Business Development & Marketing. Underwriters established new and improved relationships with local and regional retail brokers, the risk management department provided their services by reviewing contracts and visiting with insureds to improve their operations, and we reached thousands of brokers, clients, and industry insiders with webinars, blog posts, videos, and articles on issues relevant to the life sciences industry. As this was all happening, Medmarc agreed to demutualize and become part of ProAssurance, and in the process paid nearly $154 million in cash to its policyholders.

In 2015, Medmarc announced Medmarc Edge, an underwriting unit dedicated to quick turnaround for quotes and binders for small business. The service caters to lean medtech companies, medical device distributors and clinical trials. Due in part to the success of Medmarc Edge, Stockwell says clinical trials now comprise more than 20% of Medmarc's business.

3D, VR and Other Innovations

In recent decades, medical device technology has advanced from hardware to software to cloud connectivity. 3D imaging has entered the exam room, the operating room and dental offices. Additive manufacturing and 3D printing have allowed dentists to produce crowns, aligners and orthodontic models on site within hours. Traditional medical devices are now part of platforms that include educational apps, wearables and other tools. Virtual reality holds promise in the treatment of Parkinson's disease and certain psychological conditions.

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A few other breakthroughs over the past decade include the following:

- **Electronic Health Records.** Regenstrief Institute developed the first electronic medical records (EMR) system in 1972. Years later, advances in personal computing and web-based software led to widespread adoption in the 2000s. A government mandate to adopt an electronic health record (EHR) system by 2014 made it necessary. As systems advanced, medical device integration became possible, which allowed for data transfer from devices into EMRs. When implemented properly, connected devices help improve patient safety and quality of care.
- **3D Mammography.** The FDA approved 3D mammography, aka breast tomosynthesis, as a breast imaging procedure in 2011. The procedure produces numerous X-Ray images from multiple angles, which allows radiologists to view breasts in one-millimeter "slices." 3D mammography is especially effective for women with dense breast tissue and for women with a high breast cancer risk.
- **Transcatheter Valves.** Edwards Lifesciences received FDA premarket approval for its SAPIEN catheter-based aortic valve in 2011. It was initially approved for people at too high a risk for open heart surgery. The following year, it received an expanded indication for patients with intermediate risk of dying or suffering serious complications during open heart surgery. In August 2019, FDA expanded indication yet again; this time, for the treatment of severe, symptomatic aortic stenosis (AS) in patients determined to be at low risk of open-heart surgery. The device lowers risk of complications for people with debilitating heart disease.
- **Artificial pancreas.** In 2016, the FDA approved Medtronic's MiniMed 670G, the first hybrid closed-loop system for managing blood glucose. Instead of manually measuring glucose and administering insulin, or using two separate devices—glucose monitor, insulin pump—the artificial pancreas does it all automatically.

Legal Decisions and Shifting Perceptions

Karen Bartlett developed severe toxic epidermal necrolysis to the generic version of pain reliever sulindac. Bartlett sued its manufacturer, Mutual Pharmaceutical, on a design defect claim. The decision rose to the U.S. Supreme Court. In 2013, it concluded federal law pre-empted state law claims for not adequately labeling generic drug medications where federal law prohibits drug manufacturers from changing the label from the original brand-name drug.

"The decision protects drug and device manufacturers from design defect claims," says Medmarc Vice President of Claims Sonia Valdes. "This was a big win for pre-emption."

Over the past few years, it's become more of a challenge to argue pre-emption and otherwise defend medical device manufacturers. ***The Bleeding Edge,*** the shocking 2018 documentary produced by Kirby Dick and Amy Ziering, made national news and caused the industry to question FDA's 510(k) path. The impact also indirectly impacted legal protection.

"The courts are undoing a lot of tort reform for doctors, and pre-emption is falling by the wayside," says Valdes. "Time-tested defenses to medical device claims are coming under attack."

Looking Ahead

Medmarc continues to vigorously defend its medical device, diagnostics and life sciences customers. It also continues to innovate with new policy forms. The company now offers excess coverage, which applies when underlying limits have been exhausted. It also has a combined product liability and errors and omissions product which adds to its bodily injury/property damage coverage.

As Medmarc moves into its next decade of service, expect to see an increased U.S. presence with the addition of more underwriters. "This is an interesting chapter in our history," says Stockwell.

Medmarc will continue its legacy of supporting the medtech and life sciences industry through its communication with its brokers, insureds, and industry leaders, as well as its presence in regional and national trade associations and related conferences. This allows us to better understand the needs of our customers and create relevant and valuable products and services for decades to come.