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.

MEDMARC. Treated Fairly | 40 YEARS

Medmarc through the years: 1979-1989

Forty years ago, researchers were still experimenting with MRI imaging. Cardiologists had no stents to work with. Jimmy Carter was president. And a group of medical device leaders established an insurance company that finally gave their industry the means to procure sufficient insurance at reasonable rates.

Since its founding in 1979, Medmarc (Medical Device Mutual Assurance and Reinsurance Company) has insured the companies behind tens of thousands of life-saving and breakthrough devices. For four decades, it's witnessed dramatic advancement in technology, played a role in landmark regulations and legal decisions, and supported groundbreaking innovation. Here, in the first of a five-part series, we take a look at Medmarc's first 10 years.

Why an insurance company?

The 1970s got off to a rocky start for the medical device industry. Pacemaker lead failures, dislodgement, and battery depletion before 24 months caused dozens of emergency surgeries. In 1975, hearings took place to discuss the thousands of miscarriages and injuries that stemmed from the Dalkon Shield intrauterine device (IUD).

These well-publicized complications made insurance companies wary of issuing product liability insurance to any medical device company, even those with no history of legal action. Insurers either declined to issue coverage or quoted sky-high premiums.

"The highest insurance limits you might be able to find were a half million dollars, or if you were fortunate, a million dollars," says Medmarc Vice President, Chief Underwriting Officer Francis Stockwell. "Even back then, that wouldn't stretch far."

In response to this insurance crisis, 31 members of Health Industry Manufacturers Association (HIMA, later AdvaMed) formed Medmarc. HIMA provided administrative support and helped members develop a feasibility study and a long-range plan. With an insurance solution rooted in the industry, medical device and diagnostics companies had the safety net needed to support new product development.

"Even small volume companies could be exposed to millions of dollars of potential liability from lawsuits," says Stockwell. "There's no doubt that risk stunted innovation."

1979-1989 breakthrough devices

As the 1970s came to a close, emerging and established medical device companies released a string of breakthrough devices. A few standouts include:

- Fenwall CS-3000 blood and cell separator (1979): This automated device eliminated contamination risk associated manual methods. It also allowed blood donors to give more frequently.
- Implantable cardioverter-defibrillator (1980): Pioneered in 1969 and implanted in a patient for the first time in 1980, the device detected cardiac arrhythmia and corrected it with an electric jolt.

Phone: 800.356.6886 ext.1360 | Email: MedTechLifeSci@medmarc.com
4795 Meadow Wood Lane | Suite 335 West | Chantilly, VA 20151

- The angioplasty balloon catheter (1980): The device relieved chest pain and prevented heart attacks without vessel bypass surgery.
- Personal blood glucose meter (1980): Miles Laboratories developed the first home-use device, which especially helped people with type 1 diabetes manage the disease.
- The Jarvik 7 total artificial heart (first implanted, 1982): Dr. Robert Jarvik's aluminum and polyurethane device was considered revolutionary. Its first recipient, Dr. Barney Clark, lived 112 days with the device. The medical community considered Clark a hero.
- Automated external defibrillator (1985): The AED dramatically increased survival rates for heart attack sufferers.
- Dornier HM1 lithotripter (1980): The Dornier HM1 made extracorporeal shockwave lithotripsy (ESWL) possible. The procedure allowed doctors to break up kidney stones without surgery for the first time.

By the late 1970s, the Medical Device Amendments of 1976, which gave FDA authority to regulate medical devices, was firmly in place. The law gave FDA authority to oversee safety and efficacy, as well as to develop a risk-based classification system.

Despite high inflation and the unemployment rates around 10%, medical device and diagnostics industry grew significantly during Medmarc's first decade. From 1980 to 1981 medical device shipments rose 16% and continued a similar growth pattern through the remainder of the decade.

"The pioneering work done by so many cardiologists ignited a lot of exploration in technology at that time," says Stockwell. "Circumstances were right for a lot of investors, as well. It was quite lucrative."

With a stable business climate in Bermuda, where Medmarc initially was established as a captive insurance company, Medmarc grew to become the leading products liability insurer for medical device and diagnostics companies. During this time Medmarc insured companies' breakthrough technologies. One such company produced advanced cytology automation for Pap smear screenings.

"It was almost heretical to think a machine could do a better job of identifying normal cells than a human," says Stockwell. "But indeed it did, and the technology proved to be quite reliable."

Moving on shore

In response to the liability crisis, Congress passed the Liability Risk Retention Act (LRRA) in 1986. The LRRA requires insurance groups to be licensed in one U.S. state, but they may accept liability risks in all 50 states.

As part of the Act, Congress created two entities: risk retention groups (RRGs) and purchasing groups (PGs). Both entities could offer various types of third-party liability insurance.

At that time, Medmarc wanted to expand its capacity to better satisfy its growing customer base. Shortly after LRRA's passing, Medmarc wound up its Bermuda operations and reorganized as a Vermont-domiciled RRG.

"To convert from an offshore captive to a U.S.-based insurance company…gave us more legitimacy," says Stockwell. "We were also more accessible, which made our customers more comfortable. That led to a period of rapid growth for us."

Medmarc broke new ground by giving the medical device and diagnostics industry viable insurance coverage. With its support, many of these companies developed breakthrough devices that made surgery safer and less invasive.

"It was a time of explosive growth," says Stockwell. "We tried, and I think we succeeded, to accommodate much of that growth. We made some expensive mistakes in judgment, but we learned from those. We were able to harness what was once considered an unpredictable industry and bring some stability to its insurance market."

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.

MEDMARC. Treated Fairly | 40 YEARS

Medmarc through the Years: 1989 – 1999

Through the 1980s, the medical device industry enjoyed significant growth and breakthrough technology. Building on that success, the 1990s brought refinement, precision and speed.

Robotic and laser surgery allowed patients to recover faster with less pain and fewer complications. Widespread use of the Internet meant more publicly available information accessed quickly. Advances in radiation treatment allowed clinicians to more precisely target tumors, reducing side effects.

In the insurance industry, Medmarc continued to match pace with the industries it served. In only five years, the company almost doubled in size. To accommodate this growth, Medmarc converted from a Vermont-domiciled risk retention group to a traditionally licensed insurance company, Medmarc Casualty.

"The transition gave us more control," says Medmarc Vice President and Chief Underwriting Officer Fran Stockwell. "It also allowed us to expand our risk management services and hire more employees to keep up with the appetite."

Additional staff meant Medmarc could provide more personal service to its customers as they expanded operations and developed more products. Sales representatives could also spend more time visiting with brokers, which allowed Medmarc to maintain steady growth.

Its hard work paid off. Two years later, in 1993, Medmarc received an A. M. Best Excellent (A-) Rating, reflecting 14 successful years.

The industry recognized Medmarc not only as a leader, but as a groundbreaking company in a rapidly evolving industry.

1989-1999 breakthrough devices

In an era marked by the arrival of AOL and the "birth" of Dolly the Sheep, the medical device industry developed technology to make existing devices safer and more effective. A few transformative devices of the decade include:

- Loma Linda University Medical Center (LLUMC) James M. Slater Proton Treatment and Research Center (1990): Though not a product, the James M. Slater Proton Treatment and Research Center at LLUMC became one in the eyes of its insurer, Medmarc. The center was the world's first hospital-based treatment center to offer proton therapy for prostate, lung, brain, and other cancers. Proton therapy, pioneered by Dr. Slater at LLUMC, is considered the most precise form of radiation therapy today.

  Because it involved a new way of using radiation, liability insurers didn't know what to make of LLUMC's new treatment center. Most policies have an exclusion for radiation. According to Medmarc Assistance Vice President George Ayd, "Medmarc knew there was a way to cover the technology. We got creative and wrote a customized policy to cover the device and its unique exposures to products liability loss."
- Ventricular Assist Device (1992): This mechanical implantable pump helps move blood from the heart's lower chambers through

the rest of the body. Abiomed released the first FDA-approved VAD, the BVS 5000 biventricular assist system, as a "bridge to transplant" device: it kept blood pumping while patients waited for a heart transplant. Today, patients with severe heart failure may also have VADs implanted permanently.

- Palmaz-Schatz Balloon Expandable Stent (1994): Dr. Richard Schatz and Dr. Julio Palmaz developed the first FDA-approved coronary stent, improving quality of life for heart patients in a way balloon angioplasty alone could not. Stents act as a scaffold, keeping blood vessels open to improve blood flow to the heart. They remain a frontline treatment for heart disease.
- Laser surgery (1995): The FDA approved the first commercial excimer laser-based refractive surgery system, LASIK, in 1995. It's now the most popular vision correction surgery performed worldwide.

As laparoscopic and laser surgery became more widespread in the 1990s, physicians used these processes to remove cancerous tumors, to treat certain dermatological conditions, and for dental and general surgery. Lasers make very precise cuts and produce less bleeding than traditional surgical procedures.

- CyberKnife (1999): With the arrival of the CyberKnife Robotic Radiosurgery System, cancer patients had a noninvasive way to receive concentrated doses of radiation. The only fully robotic radiation delivery system, Accuray's CyberKnife was initially approved by the FDA to treat tumors in the head and the base of the skull. Today, it's used to treat prostate, lung, brain, spine, head and neck, liver, pancreas, and kidney tumors, as well as certain gynecological conditions.
- daVinci Surgical System (1999): Although the AESOP system by Computer Motion holds the title as the first FDA-approved robotic device for endoscopic surgery, daVinci wins as the first FDA-approved robot for general laparoscopic surgery. The daVinci uses tiny incisions and offers incredible precision, which allows for less scarring, faster recovery time, and fewer complications than other minimally invasive approaches. Most major hospitals and a growing number of outpatient surgical centers now feature some type of daVinci system.

Medical device legal developments

While medical device manufacturers introduced products that improved safety and efficacy and reduced complications, the courts decided several cases around product liability. Medtronic v. Lohr, decided in 1996, determined the relationship between the Medical Device Amendments of 1976 (MDA) and negligence and product liability complaints.

In a suit that escalated to the U.S. Supreme Court, plaintiff Lora Lohr argued that a defective Medtronic pacemaker caused her serious injuries. Medtronic countered that the MDA pre-empted Lohr's state law negligence claims.

> "The transition [to Medmarc Casualty] gave us more control," says Medmarc Vice President and Chief Underwriting Officer Fran Stockwell. "It also allowed us to expand our risk management services and hire more employees to keep up with the appetite."

The Supreme Court rejected Medtronic's pre-emption argument as "implausible, for it would grant complete immunity from design defect liability to an entire industry that, in Congress' judgment, needed more stringent regulation," according to the opinion. Justice Stevens argued that the MDA was not intended to pre-empt "traditional common-law remedies against manufacturers and distributors of defective devices," as long as they paralleled federal requirements.

"The outcome determined how much protection companies could expect under the law," says Stockwell. "It indicated how much shielding there might be against very expensive lawsuits."

In its first decade of business, Medmarc's overarching goal was to bring stability to a highly unstable industry. Through the 1990s, the company's growth mirrored that of a dynamic industry. As technology enabled more specialized medical devices, Medmarc raised the bar by offering more targeted, personal service.

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.

MEDMARC. Treated Fairly | 40 YEARS

Medmarc through the Years: 1999 – 2009

As the calendar approached the year 2000 there was a collective sigh of relief: the world did not end when the clock struck midnight.

Industry and the general public feared the worst from the "Y2K bug," which was expected to affect computer systems and software in virtually every industry, including healthcare, beginning January 1, 2000.

The problem stemmed from computer code that used dates with two-digit years (08/23/19 for example). When the clock ticked to January 1, 2000, everyone assumed these codes would cause programs to revert to 1900. At best, the error would cause dates to display incorrectly. At worst, it would cause society to screech to a halt.

The United States government spent billions to address the Y2K bug. Beginning in earnest in 1998, the FDA identified and contacted nearly 2,000 medical device manufacturers, urging them to identify compliant, noncompliant and not-yet-fully tested devices.

As manufacturers worked to fix coding errors, healthcare providers and patients worried whether their X-Rays, MRI machines, radiation equipment, blood analyzers, infusion pumps and implantable devices would work in 2000. If these or any other devices failed or gave improper readings, lives worldwide would be at risk.

"You can imagine the anxiety because of what was foretold," says Medmarc vice president and chief underwriting officer Fran Stockwell. "We worked with our customers to understand their trepidation, and we prepared for the eventuality of liability claims."

Whether it was because of unnecessary fear or aggressive Y2K compliance efforts, when the clock struck midnight, any issues that surfaced were relatively minor. "It passed without incident," recalls Stockwell.

Innovations in the Aughts

Call it the aughts, the 00s, or the double-zeros, the first decade of the 21st century owns several innovations, especially in diagnostics and testing equipment. For example, a new AIDS-related diagnostic test, the OraQuick Advance Rapid HIV-1/2, released in 2002, produced results in 20 minutes. Previous tests took several days to process. It was the first rapid HIV test to earn FDA approval, and allowed people to learn their status in a single visit. This meant more HIV-positive patients got the early treatment they needed.

Devices in general got smaller and faster during this time. Portable defibrillators, one of which saved former President Lyndon B. Johnson's life during a heart attack, became smaller and easy enough for a layperson to use. We see them now in schools, sports arenas, gyms and even in people's homes. "This is a life-enabling change, especially for people living in remote areas that would have to drive hours to reach a hospital," says Stockwell.

MR Imaging and PET imaging have improved dramatically in sensitivity and speed. Beginning in 2001, clinicians starting combining PET with CT to improve image quality and provide a high spatial resolution framework.

Phone: 800.356.6886 ext.1360 | Email: MedTechLifeSci@medmarc.com
4795 Meadow Wood Lane | Suite 335 West | Chantilly, VA 20151

MRIs advanced from 1.5Tesla (T) to 3T during this decade, allowing for faster, higher quality imaging. "What used to take several hours to process has been diminished to minutes, with improved accuracy," says Stockwell.

Thermal cycler technology used in genetics research also progressed in the 2000s, allowing for faster polymerase chain reaction (PCR). Thermo Fisher Scientific brand Applied Biosystems™ issued the GeneAmp™ PCR System 9700. The device helped scientists Eric Lander and Matthew Meyerson publish the first genome-wide study of lung cancer. It was one of the first comprehensive studies of a cancer genome.

Expanding coverage in a changing market

After a downward trend caused by a deflated dotcom bubble, merger and acquisitions picked up pace around 2003. For Medmarc, that meant longtime customers such as Boston Scientific grew so large it became more feasible for those companies to self-insure. Others became successful and got acquired by larger companies.

"We've watched many customers grow to become larger companies," says Stockwell. "But because of M&A activity we started seeing fewer 20-year relationships."

In 2001, Medmarc acquired Noetic Specialty Insurance Company, a non-admitted property and casualty insurer approved to do business in all 50 states and in the District of Columbia. The acquisition allowed Medmarc to write surplus lines, often called the "safety valve" of the insurance industry.

"We could write policies for risks other carriers wouldn't cover," says Medmarc assistant vice president George Ayd. "We could also make our policies more customized for our insureds."

With the addition of Noetic Specialty Insurance, Medmarc's growth continued through the 2000s. Support from Independent Medical Specialty Dealers Association (IMDA) allowed Medmarc to provide coverage to medical device distributors, a growing market for insurers.

"Liability traditionally rested on the manufacturer," says Stockwell. "That changed over time." Stockwell says distributors now comprise about 20% of Medmarc's customer base.

Legal Decisions

Landmark legal decisions in the 2000s emphasized the need for an insurance partner with extensive life sciences risk management experience.

Buckman Co. v. Plaintiffs Legal Committee, ultimately decided by the U.S. Supreme Court in 2001, concerned whether the Food, Drug and Cosmetic Act (FDCA), pre-empted a state-law fraud-on-the-FDA claim. Plaintiffs originally asserted that Buckman Co., which manufactured bone screws that allegedly injured plaintiffs, falsely represented to the FDA that the product was safe.

> "You can imagine the anxiety because of what was foretold," says Medmarc vice president and chief underwriting officer Fran Stockwell regarding Y2K. "We worked with our customers to understand their trepidation, and we prepared for the eventuality of liability claims."

The Supreme Court decided federal law does pre-empt state-law fraud-on-the-FDA claim. To rule otherwise would hamper FDA's evaluation of devices, the court ruled.

In 2008, the Supreme Court again ruled in favor of medical device innovation. In Riegel v. Medtronic Inc., the Court ruled that the pre-emption provision of the FDCA's Medical Device Amendments of 1976 overrides most state law negligence claims against devices approved under FDA's rigorous premarket approval (PMA) process. Medmarc, AdvaMed, the Medical Device Manufacturers Association and the international defense attorney organization DRI filed an amicus brief with the Supreme Court.

The decision would limit the number of lawsuits against "bedrock" devices and assured FDA's ultimate regulatory authority. At the time, however, no one could have predicted these protections would come under attack in the decade to come.

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.

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.

Phone: 800.356.6886 ext.1360 | Email: MedTechLifeSci@medmarc.com
4795 Meadow Wood Lane | Suite 335 West | Chantilly, VA 20151

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.