

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: 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.

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 cyler 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.



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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.

