

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: 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.

- 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 (LRRRA) in 1986. The LRRRA 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



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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 LRRRA's passing, Medmarc wound up its Bermuda operations and reorganized as a Vermont-domiciled RRG.

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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."

