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.