

[Print this Page](#)

Originally Published [MDDI](#) May 2006

News Trends

CDRH, FDA Anniversaries Prompt Memories, Reveal Challenges

[Maria Fontanazza](#)

During the past century, devices have made extraordinary progress. This year FDA celebrates two anniversaries—100 years of regulating foods and drugs, and 30 years (this month) since the passage of the medical device amendments. What are some of the changes to the device industry during these years?

“When the first Pure Food and Drug Act was passed in 1906, medical devices were really an afterthought,” says Jonathan Kahan, partner at Hogan & Hartson (Washington, DC). “They were only regulated as adulteration and misbranding of products.” Medical devices were defined in the Federal Food, Drug, and Cosmetic Act of 1938, but it wasn’t until 1976 that a set of rules specifically for the medical device industry came into place.

In the years since the device amendments were passed, devices and FDA processes have jointly become more sophisticated. “The 510(k)s that we submitted in 1976 were about three or four pages long. Now they’re literally hundreds of pages long, supported by clinical data,” says Kahan. He notes that the 510(k) submissions of 30 years ago were backed with technical, preclinical, biocompatibility, and electromagnetic compatibility data, but not clinical data.

The premarket approval (PMA) process has also changed. “When we first submitted clinical studies, they were basically single-arm historically controlled studies. Now, the major paradigm is for the randomized control trial for both 510(k)s and PMAs,” says Kahan.

Larry Pilot, partner at McKenna, Long & Aldridge (Washington, DC) was involved in the planning for the amendments, which began in 1970. Looking back, he says, one of the biggest disappointments is the current state of the review process. “Where there were devices subject to PMAs that needed advisories, that [review] system seemed to work well for the first half-dozen years without becoming overly cumbersome. The system now seems to be much more oppressive.”

Phil Phillips, a former deputy director in CDRH’s Office of Device Evaluation, says that although reviews may take longer these days, it’s difficult to compare the current review and regulatory environment with its early years. “You have a more-complex regulatory program that’s more demanding on documentation, and at the same time, you’re getting more-complex products.” Phillips is director of the medical device practice at Becker & Associates Consulting Inc. (Washington, DC).

Since 1976, FDA has also implemented a few significant laws—the Safe Medical Devices Act of 1990, the FDA Modernization Act of 1997, and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)—without changing the basic structure of the amendments. “Each of those more or less refined the system. You still have Class I, II, and III devices, and 510(k)s, IDEs, and PMAs,” says Phillips. “You have to give Congress credit back in the 1970s when they were trying to determine how to regulate medical devices. The regulatory framework they set up in 1976 is still pretty much the same that exists today.”

“FDA’s actions in creating special 510(k)s, de novo 510(k)s, and modular PMAs have improved the process [of getting devices onto the market]. It’s difficult to quantify that improvement,” says Barry Sall, senior regulatory consultant at Parexel International (Waltham, MA). “Hopefully, MDUFMA II will include other provisions that will speed the review process and get devices that benefit patients out to them quicker.”

However, now that 30 years have passed, CDRH also faces a potential staffing problem. Many employees that began working in the agency in the 1970s will be eligible for retirement. CDRH will have to prepare for the shift from regulatory veterans to staff that have less familiarity with the industry.

“As we go forward, there could be an exodus of some very seasoned regulators and an influx of new talent that require a tremendous amount of training to become effective FDA regulators.” Phillips says the agency is bringing in people who don’t have a lot of experience working in an industrial or government setting. “One of my fears is people coming into FDA that don’t have an appreciation for what it’s like to be a responsible federal regulator.”

Despite the challenges that FDA faces daily, Phillips says the agency is strong enough to continue moving ahead as it has through the years. “There’s a tide that ebbs and flows. Are there going to be troubled times for FDA? You bet, because there have been periodically over the last 30 years,” says Phillips. “I take my hat off to FDA for what it’s done. It’s a solid organization comprising some of the best people in federal government today.”

FDA has planned several centennial celebrations in U.S. cities throughout this year. Information can be found at www.fda.gov/centennial/default.htm.

Copyright ©2006 Medical Device & Diagnostic Industry



It’s difficult to compare CDRH now with its early years, notes Phil Phillips.