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[1]

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FDA Is Suffocating the Small Businesses It Should Be Helping

Some companies can't afford CDRH's inconsistent and capricious approach.

By: Jim Dickinson

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For as long as I can remember, CDRH has done a poor job of helping small businesses work through the choking thicket of agency regulations. Despite statutory directives to do better, the center is failing these companies, though small firms are widely regarded as major drivers of the U.S. economy.

Certainly, the center's Division of Small Manufacturer Assistance has helped hundreds of companies. But it too often gets bogged down in regulatory warfare with small firms whose products and leadership don't fit into a tidy bureaucratic box. Neither the division nor the agency's ombudsman's office has been of much help in those cases.

That is a problem. Large companies have the resources to deal with and survive a maze of regulations; small companies often do not. Jeffrey Immelt, chairman and CEO of General Electric, is the chairman of President Obama's council on jobs and competitiveness. Speaking on Fareed Zakaria's television show GPS in September, Immelt said small businesses "have all the problems GE has, only on steroids."

Companies like GE, IBM, and J.P. Morgan, he said, can "muscle through" regulatory pressure, but "if you're a \$50 million business, it's just so much harder." Immelt called for a simplification of regulations to keep small companies from being steamrolled.

Immelt's words certainly ring true when it comes to the device industry. Joining a long list of small companies that have tangled with FDA—including TMJ Implants, Utah Medical Products, Myo-Tronics, Laerdal, Andersen Products, and Bio-Clinical—is Electromedical Products International (EPI; Mineral Wells, TX). The 20-person company boldly objected after CDRH published a proposal threatening its only product.



The company's Alpha-Stim cranial electrotherapy stimulators (CES) use minute levels of electrical stimulation to treat labeled indications of pain, anxiety, depression, and insomnia. CES products are pre-amendment devices, which means they have been on the market since before FDA began regulating medical devices according to the Medical Device Amendments of 1976. When the amendments were passed, CES products were in a group of devices placed into Class III and regulated through the 510(k) program. The measure was intended to last only until FDA could decide whether to require premarket approvals (PMA).

In August, the agency moved toward making a decision. FDA issued a proposed rule that would require a product development protocol (PDP) or premarket approval (PMA) to be filed for CES devices. As an alternative, manufacturers can request that the devices be reclassified into Class II.

CDRH is basing its proposal on a 33-year-old recommendation. In 1978, the Neurological Devices Panel found a lack of adequate data about the effectiveness of CES devices and urged FDA to require that PMAs be filed for them. In its current proposal, CDRH also cited six undocumented risk issues with the CES devices.

EPI president Tracey B. Kirsch, whose husband invented CES technology, accused CDRH of being either biased or incompetent. Others have made similar accusations about CDRH, most notably Cyberonics, with regard to the agency's handling of its controversial Vagus Nerve Stimulator.

After FDA published its proposal, EPI released a fact sheet about the rule change. "The PMA process was put into place as a method of obtaining FDA approval for new devices, so the idea of going through a PMA process for a device that has been legally on the market for over 30 years is a bit unusual, to say the least," it reads.

Alpha-Stim and other long-marketed devices face a tortured reclassification process, and may even face temporary removal from the market pending PMA approval.

Kirsch says the Alpha-Stim delivers very small amounts of electricity, so little that it is measured in thousandths of an ampere. It is powered by a 9-V battery for home use and is portable. This is in contrast to electroconvulsive therapy devices, which must be used in a doctor's office and are designed to deliver 5–8 A to patients, who must be anesthetized. Kirsch says Alpha-Stim has a proprietary waveform pattern that "returns the body to normal, thereby relieving pain, anxiety, insomnia, and depression."

Kirsch notes that the company has already filed two PMAs since 1995, neither of which has been acted on by FDA. "We have no problem obtaining a PMA if we can get a fair review of the science," she says, pointing out that FDA has ignored several studies that the company has provided, despite the agency's obligation to examine all scientific evidence. "Every scientist we have talked to does not agree that the [dropped] studies should be dropped."

EPI says it would prefer the devices be classified as Class II, which would allow it to continue marketing them without filing a PMA. The company admits that requiring PMAs for CES devices could be useful, but it has reservations about FDA's ability to smoothly implement such a move. "The arbitrary and capricious manner in which FDA reached its conclusion [regarding the current proposal] leads one to be concerned about the biased, arbitrary, and capricious evaluation CES will receive from FDA in the review process," the fact sheet reads.

The company says that in 2009, it provided FDA with 44 studies conducted on Alpha-Stim and 100 studies that were conducted on other CES devices. Fifty-three of the 144 studies date from after 1993, all but eight of which were "brushed aside," the company says, "in an off-handed manner."

FDA's proposal, published in the Federal Register, explains that many studies about the technology were excluded from further review because they were conducted on very specific populations (e.g., alcoholics) and

therefore were not representative of the general population of people suffering from insomnia, anxiety, or depression.

EPI protested, arguing that FDA's definition of "valid scientific evidence" doesn't discount studies simply because they were conducted on a specific population. "Anxiety, insomnia, and depression are ubiquitous in all populations and each study has inclusion criteria and various methods of evaluating outcomes in accordance with the scientific method," the company's statement says. "FDA discredited each of the eight studies for various reasons without addressing a single positive finding in any of the eight. None of the studies were discredited in a manner that would meet the criteria imposed in FDA's own definition of 'valid scientific evidence.'"

Kirsch and her company also challenged the six potential health risks of CES treatment that FDA listed, which included the following:

- Worsening of the condition being treated.
- Skin irritation.
- Headaches.
- Seizure.
- Blurred vision (from electrodes being placed over patients' eyes).
- Potential adverse effects from electrical stimulation of the brain.

The company's fact sheet dismisses these risks, noting that "no data showing the likelihood of any of the potential risks was provided, nor were any references provided showing how the six potential risks were reached." According to the sheet, the same risks have been cited by FDA every time the issue has come up since 1976, meaning "it can only be presumed that [the risks] are from outdated sources." In addition to its allegations that the risk data are obsolete, the company claims that "at least half" of the potential problems listed "have never been reported by any actual Alpha-Stim user in 30 years of business."

Kirsch scoffed at the notion that the devices would cause blurred vision. She says it has been many years since the treatment procedure involved placing electrodes over the patient's eye sockets. "We're inspected every two years by FDA, and we know that these things don't occur," she says.

The company says it has provided FDA with "detailed and true data" of all potential health risks. It says all were minor and self-limiting, with no more than 1 in 1000 patients reporting side effects such as headaches, skin irritation, vertigo or nausea, anger, and tinnitus. "The risks to health outlined by FDA were not commented on or discussed in the proposed rule," the fact sheet says. "Alpha-Stim has been on the market for over 30 years and has been the subject of many research studies that examined potential side effects, so FDA's concern that it poses a significant risk to health is not well-conceived or based on fact."

According to Kirsch, EPI's largest customer is the federal government, with the Veterans Administration, Defense Department, and the National Institutes of Health on its client list. "I hope FDA reviews this with the other government practitioners, to hear their success stories," she says.

About "99% of our customers consider Alpha-Stim to be effective," she says. "There are many letters of support from doctors and patients in the FDA public docket."

Kirsch says the worst-case scenario for a patient using the Alpha-Stim is that they won't respond to it. "We don't see the types of side effects that you can have with drugs," she says. "There should be no safety issue."

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reviews that aren't necessary."

"The entire ability of our business to grow has been blocked by FDA over the last 30 years," Kirsch says. "FDA serves an important function, but it is stifling innovation in this country. I don't know if it's due to bias or incompetence. They may not have the experience to review this industry."

Consistent with its poor handling of complaints from small businesses, CDRH did not respond to a request for comment on Kirsch's concerns.

Considering how FDA has dealt with EPI, the promise that President Obama made on taking office in 2009 to shape a government that "spend[s] wisely, reform[s] bad habits, and [does its] business in the light of day" now seems naïve.

At FDA, regardless of who's occupying the White House, presidential appointees are usually quickly "captured" by the bureaucracy they were sent in to tame and become apologists for it, not reformers. And so we should expect CDRH to continue to fall short when it comes to helping small businesses.

EPI is also concerned with the economic analysis FDA included with the proposal. The company says that, by concluding that requiring manufacturers to file PMAs would not significantly impact society, FDA's analysis paints the CES market as small and meaningless.

Kirsch says that despite the agency's appraisal of the CES market, the rule will directly impact the firm's 20 employees as well as its distributors around the country. "We've gone out of our way to comply with their regulations, but then they step out of bounds," she says. "They shouldn't be spending [money] on