

Endotec To Countersue FDA In Response To Injunction Attempt

Endotec President Michael Pappas says his firm will countersue FDA in response to a federal lawsuit seeking a permanent injunction against the company.

FDA announced Oct. 6 that the government had filed suit against orthopedic implant manufacturer Endotec in U.S. district court on Aug. 29. The complaint alleges that Endotec distributed the *Buechel-Pappas* total ankle replacement system and other total joint replacement devices without an approved PMA and outside the scope of approved investigational device exemptions (“The Gray Sheet” Oct. 9, 2006, p. 6).

A review of recent correspondence between the U.S. Department of Justice and Endotec, plus interviews with Pappas and Endotec legal counsel Vello Veski, indicate that the case centers on conflicting interpretations of the custom device exemption of the Food, Drug & Cosmetic Act.

Under Section 520(b) of the act, a device is exempt from premarket clearance and approval requirements if it meets a narrow set of conditions: it must be made in a specific form for a specific individual patient or be intended to meet the special needs of a physician; it must “necessarily deviate” from otherwise applicable FDA requirements in order to comply with the individual physician’s order; it must not generally be available for commercial distribution; and it must not generally be available to or used by other physicians.

In a May 11 letter to attorney Veski, the Justice Department explains that **all** of those conditions must be satisfied for a company to qualify for the custom device exemption (emphasis included).

Pappas told “*The Gray Sheet*” that Endotec has sold between 30 and 40 non-PMA-approved devices over the past five years. The firm maintains that its actions do not violate the law because the items sold were custom devices.

“The critical part is that the device cannot be available elsewhere, which it isn’t – there are no mobile-bearing devices ... there are none available – and they have to be made specifically for the patient, and these were made specifically for the patient. They weren’t just taken out of inventory,” Pappas said in reference to the Buechel-Pappas ankle implant.

The only FDA-approved ankle replacement available in the U.S. is J&J/DePuy’s *Agility* total ankle system,

which is two-component and fixed-bearing. Endotec’s ankle replacement system is three-component and mobile-bearing.

FDA and the Justice Department disagree with Pappas’ explanation. “The injunctive action relates directly to Endotec’s continued distribution of unapproved devices through the misuse of the Custom Device Exemption contained in section 520(b) of the Act,” DoJ stated in its May 11 letter to Veski.

FDA notified Endotec in a March 15, 2002, warning letter that devices distributed by the firm did not meet the criteria for custom devices and were therefore not exempt from regular premarket requirements.

The distributed devices “are not intended for use by an individual patient named in a physician’s order and made in a specific form for that patient. Nor are they intended to meet a particular anatomical need of [the doctors who received them] or a particular unique practice need of [the doctors] that is not shared by other physicians in their field,” the warning letter said.

Competing Definitions Of Custom Devices

The intent of the custom device exemption is “very limited,” said a former CDRH Office of Compliance staffer who was the center’s expert on custom devices until his retirement from FDA in February 2005.

Changing the size of a product for individual patients does not qualify it as a custom device, he explained in an Oct. 11 interview.

Endotec “presented the argument that they would make these upon demand and each one had to be a little different, and for years when I was at the agency we tried to advise them that this isn’t a custom device – that changes in size don’t constitute a custom device. They use the same manufacturing materials; they use the same manufacturing process. So it’s no different than making a 12-French catheter versus a 20-French catheter; you’re just making different sizes,” said the former FDAer, who asked not to be named.

“The key issue here is they are customizing, they are tailor-making to fit the specific individual, which comes down to nothing more than changing the size ... but the device itself is still an ankle implant and it still has the same intended use,” he said. The range of sizes, he added, could be factored into “any PMA or 510(k).”

In addition, he said, the fact that Endotec's distribution of the sized-to-order devices is "likely to recur" is a sign that the device does not qualify for the custom exemption. "The fact that they have sold 35 – doesn't that seem to indicate that it's likely to recur and they are going to get a 36th or 37th request?"

"Just the sheer numbers of what they've distributed establishes that it is likely to recur. And if it is likely to recur, then they have to go – just like everybody else – and get approval."

Endotec's arguments are "just a blatant attempt to get around the requirement for a PMA," the former FDA staffer said.

"I'll admit that the language [of the law] isn't clear [but] I think the congressional intent ... is clear," he added.

According to Pappas, however, FDA's interpretation of the law is "so narrow as to make it impossible for any custom device to exist."

Endotec is "happy to have the courts determine some appropriate definition" of custom devices, he said. "We don't accept the FDA's interpretation."

Endotec's attorney Veski said that Congress' intent with the custom device provisions, passed in 1976, was to allow surgeons – not the government – to determine what is best for their patients.

"Dr. Buechel has in essence manufactured and implanted these joints into people, and I think the FDA is saying that he can't do that. We're saying that Dr. Buechel is practicing medicine and he knows far better what's best for his patients than the FDA does," Veski told *"The Gray Sheet."*

He added that neither "FDA nor Congress has jurisdiction over the practice of medicine."

The firm stresses that FDA has never issued guidance on the topic of custom devices ("The Gray Sheet" April 26, 2004, p. 7). And, it says, FDA's March 2002 warning letter "simply stated that the custom device exemption did not apply to the Buechel-Pappas ankle."

"Despite repeated requests for clarification of the custom device exemption, Endotec has simply been accorded the status of a child where a parent simply says, 'Because I said so,'" Veski wrote in a May 19 letter to the Justice Department.

"Endotech is pleased that the FDA took this action because it may result in a reasonable interpretation of the clauses providing these exemptions," the firm said in an Oct. 12 draft press release. "Although these clauses have been in place for 30 years, the FDA has yet to publish, as is customary, guidelines on their meaning. Perhaps now the court will help establish such guidelines."

Limited Precedent Favors FDA

Only a few court cases have dealt with the issue of custom devices. In the 1985 case *Contact Lens Manufacturers Association v. FDA*, the U.S. Court of Appeals for the D.C. Circuit considered an argument

by the Contact Lens Manufacturers Association that contact lenses were custom devices because each patient requires a different prescription.

FDA disagreed, arguing that contact lenses are available and used by other physicians, and that minor variations in lens size are within physicians' general

use of the products.

The court sided with FDA's interpretation.

In short, as Bob Klepinski, officer at law firm Fredrickson & Byron and former regulatory attorney for Medtronic, explains in a recent article in the *Food and Drug Law Journal*, "products such as contact lenses can obtain approval through a PMA or clearance through a 510(k) because the approval or clearance can be broad enough to cover a range of individual patient sizes and needs."

Petition For Reclassification Remains Unanswered

Endotec submitted a petition for reclassification of its Buechel-Pappas total ankle replacement system from Class III to Class II in September 2001 ("The Gray Sheet" March 21, 2005, p. 21).

At FDA's request, the firm submitted additional information in October 2005. FDA has not yet ruled on the petition. Endotec plans to raise the issue of reclassification in a countersuit, Pappas said.

"We don't care if we antagonize the FDA," he said. "We feel we have an obligation to this country to see that our people get the best medical care that they can, and the FDA right now is a burden to that – at least in the area of the ankle."

– Morgan Weiland (m.weiland@elsevier.com)

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