FDA INSIGHTS

Custom Devices

Clarification of the FDA definition of custom devices.

BY DOROTHY B. ABEL, WITH HAROLD PELLERITE

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Many manufacturers and clinicians have used the rationale that a device is a custom device and, therefore, does not require FDA approval or oversight for its use. In reality, the custom device definition rarely applies.

Look up the word *custom* in the dictionary and you may learn that *custom* used as an adjective means:

1. Made to order.
2. Specializing in the making or selling of made-to-order goods: a custom tailor.

This definition explains the assumption that a "custom device" is simply a made-to-order medical device. Not surprising, however, is that the FDA has a specific definition for a custom device. Former FDAer and expert on custom devices, Harold "Wally" Pellerite, now with Quintiles Consulting, sheds some light on the FDA definition and some common misconceptions.

Q: What is the FDA definition of a custom device?

A: The statutory definition of a custom device is found in Section 520 (b) of the Federal Food, Drug, and Cosmetic Act (the Act) (Table 1). A practical, working definition is:

A custom device is a new, unique, one-of-a-kind device that is needed for a specific individual; it is for clinical use only and not for study purposes. Further, it is unlikely that this type of device will be needed again, or that any further need for this type of device will occur so infrequently that it would be impracticable to conduct even a feasibility study to determine safety and effectiveness.

Q: What do people often call custom devices that do not fit into this definition?

A: The most common mistake made by manufacturers and clinicians is assuming that by satisfying one section of 520(b), they meet the exemption. Often manufacturers mistakenly consider changes made to the size and/or shape of a device or changes in the materials of construction to meet the needs of a specific patient to be a custom device. Similarly, there is a belief that having a prescription for a specific individual makes the device a custom device. Although these scenarios meet the requirement of making the device for an individual, there are multiple requirements identified in 520(b) that must be met in order for the device to qualify as a custom device. Most notably, the type of device must not be generally used or have the potential to be generally used.

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Similarly, making the device for only one doctor is assumed to make the device a custom device. However, if the doctor is likely to use the device again, the use should either be under a clinical study or the device should first be cleared for marketing by the FDA.

Q: What is an example of a custom device?

A: One example would be the case in which a fetus was in trouble and needed an external pacemaker. The manufacturer worked with the physician to design a completely new 3-F, dual-lumen pacing lead. This was not a modification to an existing lead; they had to start from scratch to design the lead. As this was a brand new device that would only be used once and it was for a new indication, the lead was regulated as a custom device.

Q: If a PMA-approved device is modified from the approved design at the request of a clinician to allow for treatment of a patient with a failing device, can the device be distributed as a custom device?

A: A single occurrence that is not likely to occur again may be permitted. However, the manufacturer and the

clinician would need to determine whether this, or a similar need, is likely to recur. If so, the manufacturer would need to file a PMA supplement requesting to market the modified device, or the device would need to be used under the Investigational Devices Exemptions (IDE) provisions. (Information about IDEs can be found in the January/February 2003 issue of *Endovascular Today*.)

Q: If a physician takes pieces of devices to make a new device (eg, stents and graft material to make a new endovascular graft or heart valve), is that a custom device?

A: This question is a bit more complicated and fact dependent. All licensed practitioners are permitted to use approved devices for any use in a legitimate doctor/patient relationship, as practice of medicine. As such, combining marketed devices may be permitted under the Act's "Practice of Medicine" exemption, but only if the two devices do what they are intended to do according to their respective labels (Section 906 of the Act). If the combination is actually a new device with a new use, it becomes a Class III device, and the physician would likely need to have an approved IDE or marketing approval, even if he or she only used the device in his or her own practice. It is important to note that the courts have held that when a physician uses a device on a patient, this is considered to be commercial use, even if the physician does not charge for the device. The court points out that each time a device is used on a human, it is "Held for Sale," in "Domestic Commerce," and therefore it falls under the jurisdiction of the FDA and is subject to the Act.

Q: How do the rules for custom devices differ from those for other devices?

A: It is important to understand that the exemption for a custom device is, practically speaking, only an exemption from the "Premarket Approval" requirements under section 515 of the Act. This means that the device can be provided without having FDA approval. Technically, a custom device is subject to all other provisions of the Act, including registration, listing, Good Manufacturing Practices (GMP), etc. However, for a true custom device, the agency recognizes that the physician and the manufacturer are working together to create a new device. That device is not likely to be produced again and, as such, has its own unique Master History Record. The physician's involvement in the design and construction is such that the normal GMP and labeling requirements would appear to be overly burdensome. As such, there may be other exceptions to requirements that the FDA may allow.

This is the case only for a "true" custom device. What we see happening all the time is manufacturers starting out with what may be a custom device but then making it available upon request to the same physician or to other physicians as word of its use spreads. It is not uncommon for a device to start out as a custom device and subsequently lose that status since the use changes to "likely to occur." The device ceases to be a custom device as the manufacturer is really using the same basic manufacturing process and materials to produce the unit. It may be "customized" for a specific patient, but it is not a custom device as defined in Section 520 (b). Once the device is no longer a custom device, it must have an FDA approval or be used in a clinical study that is conducted in accordance with the IDE regulations.

TABLE 1. FROM SECTION 520(B) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Custom Devices

520(b) Sections 514 and 515 do not apply to any device, which, in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 515 if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device —

(A)(i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

(ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and (B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

Q: What are the ramifications for inappropriately identifying a device as a custom device?

A: A device that does not have FDA approval or an IDE is adulterated and misbranded and, therefore, subject to regulatory action such as seizure. The physician and manufacturer may be subject to regulatory sanctions such as injunction, prosecution, and possibly civil money penalties. Further, the Department of Justice has proceeded with fraud cases against physicians and manufacturers, as both may have falsely received reimbursements from CMS and/or other insurance carriers.

> "It is the role of the Institutional Review Board of the facility to oversee any use of an unapproved device, and it would be wise to extend that to any use of a custom device."

In addition, facilities may be held liable in civil cases for permitting the use of these unapproved devices in their facility. It is important to note that it is the role of the Institutional Review Board of the facility to oversee any use of an unapproved device, and it would be wise to extend that to any use of a custom device.

SUMMARY

The law requires that Class III devices be approved (or part of a study) prior to being used on humans. It is important to understand that Congress intended the custom device provision to be available for the medical anomaly that comes up in medicine. It is only for the clinical use that is so unique or limited that it is unreasonable and/or overly burdensome to apply the premarket requirements of the Act. Custom devices are not used for study purposes. In fact, if a sponsor is collecting safety and effectiveness data, then by definition, the device cannot meet the definition of a custom device. ■

Dorothy B. Abel is a Regulatory Review Scientist with the US FDA Center for Devices and Radiological Health in Rockville, Maryland; she is also a regular columnist for Endovascular Today. *Ms. Abel may be reached at (301) 443-8262, ext. 165; dba@cdrh.fda.gov. Harold "Wally" Pellerite is Director, Strategic Compliance for Quintiles Consulting and may be reached at (301) 272-3278.*

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