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*Analyzing the Laws, Regulations, and Policies
Affecting FDA-Regulated Products*

Old Customs, Ancient Lore:
The Development of Custom
Device Law Through Neglect

Robert J. Klepinski

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I. INTRODUCTION

The custom device exemption of the Federal Food, Drug, and Cosmetic Act (FDCA)¹ is an often used, but little discussed, mechanism for providing patient care in individual cases where there is no marketed product to fill a specific need. Custom devices are devices that do not conform to an approved premarket application (PMA)² or cleared 510(k).³ They are manufactured in response to a specific request from a physician or dentist, in order to treat a patient's special need, or to conform to a special need of the healthcare professional.

The custom device exemption was a part of the Medical Device Amendments of 1976⁴ and, therefore, has been available to industry for years. Although custom devices have been provided to many physicians, the U.S. Food and Drug Administration (FDA) has never issued a regulation specifically covering custom devices. As discussed *infra*, FDA has mentioned custom devices as exceptions in other regulations,⁵ but these regulations do little more than track the statutory definition and, thus, provide industry with minimal help in trying to gauge the scope of the custom device exemption. Furthermore, FDA has never issued guidance on this topic, although suggested guidance has been submitted to the agency by industry under 21 C.F.R. § 10.20.⁶ Custom device law has developed, therefore, out of the few compliance actions taken by FDA against custom devices. FDA guidance on this issue not only would help industry understand the scope of this provision, but also would more effectively realize Congress' intent in establishing the custom device exemption.

II. STATUTORY ELEMENTS

Section 520(b) of the FDCA governs custom devices.⁷ Under Section 520(b), a device is exempt from the PMA and 510(k) requirements if, under a prescription for an individual, it "necessarily deviates" from a performance standard or other applicable requirement and it is not generally commercially available.

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¹ Federal Food, Drug, and Cosmetic Act, June 25, 1938, ch. 675, 52 Stat. 1040 (21 U.S.C. §§ 301 et seq.).

² Federal Food, Drug, and Cosmetic Act, June 25, 1938, ch. 675, § 515 (21 U.S.C. § 360e).

³ *Id.* § 514 (21 U.S.C. § 360d).

⁴ Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (May 28, 1976).

⁵ 21 C.F.R. §§ 812.3, 807.85(a).

⁶ FDA, Dockets Management, No. 2004D-0476, Draft guidance customs devices, for filing pursuant to 21 CFR 10.20 (Oct. 20, 2004) (submitted by Robert J. Klepinski on behalf of AGA Medical Corp.), <http://www.fda.gov/ohrms/dockets/dailys/04/oct04/102604/102604.htm>.

⁷ 21 U.S.C. § 360j(b). The section, in its entirety, states:

(b) **Custom Devices.**—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

The elements of section 520(b) may be restated as:

- The device necessarily deviates from a performance standard or a PMA requirement.
- The device is not generally available for commercial distribution.
- The device is intended to meet the special needs of an individual patient, who is named, or to meet the special needs of a healthcare professional in his/her practice.
- The device is not generally available or generally used by other practitioners.

When section 520(b) was written, a performance standard was required under section 514 for all Class II devices, therefore, section 520(b) addressed both Class III and Class II devices. If the requirements of section 520(b) are not met, the device is considered adulterated and misbranded and will be subject to an enforcement action.

As discussed *supra*, FDA has not promulgated any regulations or guidances covering custom devices, so there are no written definitions for the statutory terms set forth in section 520(b). Based on a limited number of FDA compliance actions, industry has come to understand the terms to be defined as follows:

Necessarily deviates.—The device cannot be manufactured according to statutory and regulatory requirements and still meet the needs of the requesting healthcare professional.

Not generally available for commercial distribution.—The device is not available for purchase or use through any other legal means (i.e., it is not marketed by any source, nor is it the subject of a clinical trial).

Not generally available.—Use of the device has not become customary or a regular course of conduct in the healthcare community.

Individually named patient.—A specific patient whose name is provided to the manufacturer. It cannot be a general class of patients or a potential patient.

Special needs.—A healthcare professional needs a custom device to use in his/her practice because of a physical need or other environmental constraint in the practice (e.g., a scalpel or glove for a physician with a hand deformity or a requirement unique to a medical facility that precludes the use of generally available devices).

III. LEGISLATIVE HISTORY

The custom device provision was a part of the Medical Device Amendments of 1976, and the legislative history of those amendments does shed some light on the scope of section 520(b). The legislative history states that Congress intended that this provision allow physicians to provide care for individuals whose needs could not be met by devices currently on the market. For instance, the Senate Committee Report stated:

(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).

“The Committee is aware of the special relationship that each health practitioner has with his patients. It is also aware of the need to develop special customized devices to meet the particular need of a given patient.”⁸ The Senate Committee also stated that “it recognizes the need to exempt such devices so that innovation is not stifled and so that custom fitting or sizing would not be prohibited.”⁹

The legislative history raises the distinction between “customized” and “custom” devices, the latter being the term used in the eventual statute. Customized devices have come to be viewed as those that are later modified for a considerable number of patients, while custom devices are manufactured for a specific patient. The House Committee Report distinguished the two terms acknowledging that “some practitioners must use devices with customized features as a regular part of their practices.”¹⁰ The House Committee cited “orthopedic and other prosthetic devices, dental devices, and specially-designed orthopedic footwear” as examples of custom devices, where “important features are customized.”¹¹ These were normal products, which then were fitted to patients.

Both Houses of Congress expressed concern, however, that the exemption be limited and not be misused. The Senate Committee Report stated:

Those medical devices which are ordered for individual patients, to qualify for this exemption, may not be used as a course of conduct and may not be generally available through commercial channels to the professions. It is the intent of these provisions to allow physicians to order custom-made products but not to permit manufacturers to circumvent standards-setting and scientific review requirements by commercially exploiting these products.¹²

The House Committee, likewise, intended that the exemption be “limited,”¹³ but rejected an across-the-board rule that the exemption be inapplicable where an individual practitioner uses custom devices as a “course of conduct.”¹⁴ The House Committee noted that use of a custom device should not be used as a loophole to avoid other requirements of the FDCA and stated:

[Custom] devices are not exempt from otherwise applicable provisions of the proposed legislation, such as provisions with respect to investigational use, banning, restriction, adulteration or misbranding. Thus, the [FDA] may act when a practitioner’s use of a custom device is repeated to such an extent that the practitioner is in effect conducting unsupervised experiments or is otherwise using a device in violation of the act.¹⁵

Congress also obtained the perspective of public health regulators at that time. During the House floor debate, Representative Tim Lee Carter (R-KY) included material in the legislative history from Health, Education, and Welfare (HEW) Undersecretary Margaret Lynch, who stated:

[I]t is essential that the custom device provisions not become a loophole that will allow the marketing of dangerous or deceptive products. ... It should

⁸ S. REP. NO. 94-510, at 13 (1976).

⁹ *Id.*

¹⁰ H.R. REP. NO. 94-853, at 44 (1976).

¹¹ *Id.* at 45.

¹² S. REP. NO. 94-510, at 13.

¹³ H.R. REP. NO. 94-853, at 44.

¹⁴ *Id.* at 45.

¹⁵ *Id.*

also be made clear that FDA would be able to take necessary action to curb a practitioner's use of a custom device on several patients, where this use is repeated to such an extent that the practitioner is in effect conducting unsupervised experiments, or allowing the marketing of a product that would otherwise be unlawful. We recognize the difficulty of drafting a provision limiting use of custom devices as a course of conduct that prevents abuses, but does not prevent use of custom products where justified by medical need.¹⁶

The House bill language was chosen as the basis for section 520(b), with modifications from the Senate version, but the intent of both Houses of Congress was consistent and clearly expressed. Repeated use of a custom device may be acceptable, as long as such repeated use does not result in commercialization or in an unsupervised clinical trial. In other words, there is a line that can be crossed—when a device is being used as an investigational device or is being commercialized it is no longer a custom device.

Although the legislative history on section 520(b) is not extensive, Congress' intent in enacting this section can be gleaned. Specifically, section 520(b) is intended to allow physicians to obtain custom devices in order to provide care for individuals whose needs cannot be met by devices currently on the market. Congress wanted to ensure that this section not be overused or abused, and that its provisions be construed somewhat narrowly. Since enactment of section 520(b), industry seems to have worked within the parameters of this section, but many compliance questions have arisen over the decades.

IV. FDA REGULATION UNDER SECTION 520(B)

Since the enactment of section 520(b), FDA has had difficulty drafting regulations to implement the law. The agency continues to understand the difficulty of striking a balance between proper use of the exemption and misuse. As mentioned *supra*, at the time the Medical Device Amendments were enacted, HEW Undersecretary Lynch acknowledged "the difficulty of drafting a provision limiting use of custom devices as a course of conduct that prevents abuses, but does not prevent use of custom products where justified by medical need. FDA will endeavor to strike the necessary balance in its regulations implementing Section 520(b)."¹⁷

Despite the fact that the agency has not issued a regulation or guidance on the scope of section 520(b), FDA has mentioned that section in other medical device regulations. For instance, the Investigational Device Exemptions regulation (IDE regulation)¹⁸ includes a definition of custom device and defines a custom device using virtually the same language as that used in the statute.¹⁹ In fact, the IDE regulation goes further than

¹⁶ 122 CONG. REC. H1724, 5847-60 (daily ed. Mar. 9, 1976) (statement of Rep. Tim Carter).

¹⁷ *Id.*

¹⁸ 21 C.F.R. pt. 812.

¹⁹ *Id.* § 812.3(b). The regulation states:

(b) *Custom device* means a device that:

- (1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
- (2) Is not generally available to, or generally used by, other physicians or dentists;
- (3) Is not generally available in finished form for purchase or for dispensing upon prescription;
- (4) Is not offered for commercial distribution through labeling or advertising; and
- (5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

the explicit statutory language and exempts custom devices from the IDE regulation unless the device is being used to determine safety or effectiveness for commercial distribution.²⁰ Similarly, the premarket notification regulation uses virtually the same definition for custom device as is found in the statute, and also exempts custom devices from 510(k) requirements.²¹

Yet, nowhere does an FDA regulation or guidance specifically address implementation of section 520(b), including the difficult questions raised by Undersecretary Lynch. Regrettably, industry still is working to “strike the necessary balance” in the absence of FDA regulation or guidance.

V. LITIGATION HISTORY

There is a paucity of litigation interpreting section 520(b). The most well known is *Contact Lens Manufacturers Association v. FDA*,²² where the primary issue on appeal was FDA’s consideration of the Contact Lens Association’s reclassification petition and the agency’s treatment of a certain type of contact lens. As a secondary issue, the Contact Lens Association argued that the contact lenses were custom devices because they were subject to the individualized prescription of a healthcare professional who had examined and measured the patient’s eyes.

The court disagreed with the Contact Lens Association’s characterization and, instead, deferred to FDA’s interpretation of section 520(b). FDA refused to accord custom device status to the contact lenses in question because such lenses were “generally available to or generally used by other physicians.”²³ Additionally, FDA pointed out that a lens “is merely a variation within an approved range of powers and anterior and posterior surface contours. . . . [P]rescriptions for all but the most pathological eyes are likely to be replicated again and again and are thus to be ‘generally used.’”²⁴

Another, more recent case also addressed the custom device exemption. In *Sharp v. Artifex, Ltd.*,²⁵ the plaintiff sued defendant Artifex for injuries suffered after implantation of a pedicle screw fixation device. Artifex argued, among other things, that the device was exempt from premarket and reporting requirements because it was a custom device.²⁶ The court held that there was an issue of material fact concerning Artifex’s defense, but noted that FDA had determined that the pedicle screw fixation devices were not subject to the custom device exemption.²⁷

²⁰ *Id.* § 812.2(c)(7).

²¹ *Id.* § 807.85(a). The regulation states:

(a) A device is exempt from the premarket notification requirements of this subpart if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or
(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

²² 766 F.2d 592 (D.C. Cir. 1985).

²³ *Id.* at 599.

²⁴ *Id.*

²⁵ 110 F. Supp. 2d 388 (W.D. Penn. 1999).

²⁶ *Id.* at 394.

²⁷ *Id.* at 395.

In short, 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. Even though each individual patient will need one specific combination of parameters, those parameters can be covered by the approval or clearance, thus a device is not a custom device if it can be produced within the bounds of the approval or clearance.

A. *What Is a Custom Device?*

Under section 520(b), a device is considered a custom device and is exempt from the requirements detailed in sections 514 and 515 if:

- (1) The device is
 - not generally available in finished form for purchase or for dispensing on a prescription, and
 - not offered through labeling or advertising for commercial distribution, and
- (2) The device is intended
 - for use by an individual patient named in the prescription, or
 - to meet the special needs of a physician or dentist or other healthcare professional in his/her practice, and
- (3) The device is not generally available to or generally used by other practitioners.

But what, exactly, is a custom device? Often, it is easier to explain what is not considered a custom device under the FDCA. Devices that are available in a wide range of sizes are not custom devices simply because the physician prescribes a specific size for an individual patient. For example, contact lenses, such as those discussed in *Contact Lens Manufacturers*, are prescribed to fit each individual patient, but are not considered custom devices. The individual prescriptions are a part of the intended use of the device and are covered in the initial approval or clearance obtained for the product.

Similarly, devices intended to be modified by the healthcare professional to fit patients may not necessarily be custom devices, as discussed above in the legislative history. For example, dentures often are adapted by the dentist to fit a specific patient, but this does not make them custom devices. Such devices should be approved or cleared in a manner that recognizes the need for later modification and the scope of the approval/clearance should cover the range of modifications to be performed by the healthcare professional.

Devices used to conduct a clinical trial clearly are not custom devices. Congress stated in section 520(b)'s legislative history that it is improper to conduct a clinical trial under the guise of custom device manufacturing.²⁸ Similarly, section 520(b) is not the proper vehicle for testing the feasibility of a new product idea. If a healthcare professional or a manufacturer wants to try out a new product idea, the proper route is through sections of the FDCA or regulations concerning clinical trials (e.g., 21 C.F.R. § 812).

²⁸ See H.R. REP. NO. 94-853, at 45 ("Thus, the Secretary may act when a practitioner's use of a custom device is repeated to such an extent that the practitioner is in effect conducting unsupervised experiments or is otherwise using a device in violation of the act.")

Some examples may help to explain how devices can be considered custom devices under the FDCA. The following categories of devices have been used in the past.

Unusual size.—A device may be cleared/approved for a range of sizes that are expected to cover the whole patient population, and a manufacturer may have a range of sizes available for a device. If a patient of an unusual size presents to the doctor, it may be appropriate to create a custom device for that patient, because the range of cleared/approved sizes may not work for that particular patient.

Allergy.—If a small number of patients are allergic to a certain material in a device, such as the titanium can of an implant, a specially-coated device or one made with different materials can qualify as a custom device. If the number of patients with such an allergy grows to commercial quantities, however, the device may lose its status as a custom device.

Unusual patient disease state.—A physician may seek an innovative way to treat a patient with a device where no device exists to treat a unique case by designing a device for use by the individual patient.

Physical aspect of doctor.—Devices can be made to accommodate a physician who has an unusual body structure (e.g., missing or differently-shaped fingers), and these devices could be considered custom devices. Such devices could include latex gloves.

Practice of medicine.—The particular environmental needs of a hospital or doctor's office could require devices to be customized only for use in that office. An example may be a facility that needed different and specialized controls on all of its equipment, and could not use commercially available devices.

The difficult interpretive area is the one at which the FDCA was specifically directed. What if a patient has a need never seen before and a physician has an idea for a device, never before contemplated, that might cure or mitigate the need? If it is a product idea that the physician wants to study, it is outside the statutory definition. But if it is the first device and the goal is to help the current patient, it fits exactly within the statutory language. This is the crux of most compliance activity by FDA in the area of custom devices.

B. How Many Custom Devices Can You Make?

One of the most difficult issues for medical device companies has been how to determine the number of custom devices that can be made before manufacture of the device becomes an intent to commercialize the device.

As discussed *supra*, both Houses of Congress indicated a desire to limit the number of devices produced under section 520(b).²⁹ The question is, when is the manufacture of a custom device “limited,” and when does it become “commercialized”?

FDA has recognized the difficulty in establishing this balance point. In the 1990s, the Center for Devices and Radiological Health's Office of Compliance personnel took the position that only one of any particular device could be made as a custom device. The reasoning was that once a custom device was produced, a specification for the device would exist so the next device produced, therefore, could not be a custom device. As discussed in this article, this position is not supported by the legislative history.

²⁹ H.R. REP. NO. 94-853, at 44 (stating that “there are instances in which the limited use of so-called ‘custom devices’ is appropriate”). The Senate Committee Report stated that the intent of section 520(b) was “to allow physicians to order custom-made products but not to permit manufacturers to circumvent standards-setting and scientific review requirements by commercially exploiting these products.” S. REP. NO. 94-510, at 13.

Subsequently, FDA announced that the agency was attempting to produce guidance on custom devices. During that process, the Office of Compliance apparently changed its position regarding a limit of one custom device manufactured. In a public speech, an Office of Compliance representative suggested that a company should be able to count its multiple uses of a custom device on its fingers, and would be more comfortable if the company could count them on only one hand. The point was that custom device use should be limited, but does not necessarily have to be limited to just one device. No written guidance was promulgated by the agency, however, during this time period.

In the *Federal Register* publication of the Final Rule on Treatment Use under the Investigational Device Exemption Rule,³⁰ FDA described the FDCA section on custom devices by stating, "the provision usually covers only a single device and is not frequently applicable." Other than a recitation of the language of the statute, however, no support or justification for this position was provided by the agency.³¹

In the author's experience, many company standard operating procedures (SOPs) have allowed around ten custom devices per year. FDA inspections of these SOPs did not result in compliance actions. Although it is outside the author's direct experience, it is believed that multiple custom devices were common in the orthopedic industry.

So, at times, FDA has either condoned or actively spoke of allowing ten of a type of custom device to be produced. At other times, FDA reverts to stern admonishments that it never allows more than one custom device to be manufactured. The variance appears to depend on context and who in the agency is speaking or writing.

Despite the lack of FDA regulation or guidance, two things are clear. First, Congress did not intend to allow an investigational study to be avoided by using custom devices. Second, Congress did not intend to allow commercialization of a custom device. Each time a custom device is requested by a healthcare professional, the manufacturer must go through the statutory analysis of whether the device is a *bona fide* custom device. Beyond these two certainties, there is no specific number on which a manufacturer can rely. Two devices may be too many if the intent is outside the statutory definition while many may be produced if the statute is followed.

One mode of analysis proposed by FDA in a seminar was whether there were enough annual occurrences of the need for the device that a feasibility study could be conducted. FDA recognizes that some devices are used so infrequently that it is cost-prohibitive for the manufacturer to even seek a Humanitarian Device Exemption.³² Looking at the possibility and feasibility of conducting a study is one way of calibrating whether a

³⁰ Final Rule on Treatment Use Under the Investigational Device Exemption Rule, 62 Fed. Reg. 48,940-48 (Sept. 18, 1997).

³¹ *Id.* Section 4 states:

4. Custom Devices

FDA has not issued a guidance document concerning custom devices, but a custom device is defined in Sec. 12.3(b). A custom device is one that:

- (1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
- (2) is not generally available to, or generally used by, other physicians or dentists;
- (3) is not generally available in finished form for purchase or for dispensing upon prescription;
- (4) is not offered for commercial distribution through labeling or advertising; and
- (5) is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

Because all the preceding criteria must be met for a device to qualify as a custom device and because the use of a custom device is exempt from the IDE regulation (Sec. 812.2(c)(7)), the provision usually covers only a single device and is not frequently applicable.

³² For the definition of a device falling within the Humanitarian Device Exemption, see 21 U.S.C. § 360j(m).

device is still in the custom device class. This is not a long-term solution, because one cannot run a feasibility study indefinitely.

Of course, the current situation is not satisfying for the lawyer or regulatory professional looking for, if not certainty, at least a generally safe path to recommend to medical device manufacturers. The manufacturer first must go through the elements of the statute to make sure the device satisfies all of the elements—an analysis that must be done for each successive device of the same type, whether it is the second or the tenth. Once the statutory concerns are addressed, there is no magic number that can be relied on by the manufacturer. Generally, it is considered safe to manufacture five or ten of a custom device, and for some devices, such as disposable latex gloves for a physician with an unusual number of fingers, dozens or perhaps hundreds could be made as custom devices.

Because of this great variety of types of custom devices, it is unlikely that FDA could establish a clear “safe harbor,” indicating the maximum number of custom devices one could manufacture. But some explicit, written guidance can be created, based on prior experience and the statutory intent. There is no statutory support for the position that only one custom device of a type may be manufactured. As discussed *infra*, foreign regulatory bodies have considered this issue and arrived at a number larger than one. FDA should normalize its practice and follow this path.

C. Storage of Custom Devices

Another issue that often concerns device manufacturers is whether and how they can store custom devices. In the past, there has been inconsistent treatment by FDA field investigators regarding storage of custom devices, and various interpretations have been used to determine when storage of custom devices is improper. One interpretation, not rooted in the statutory language or legislative history, is that it is improper to store a custom device at all, because such storage, in effect, creates inventory. Perhaps proponents of this theory thought that “inventory” demonstrated improper intent by the manufacturer, in that “short-run” products were being commercialized and were not true custom devices.

Contrary to this theory, however, there are some practical reasons why limited storage of custom devices is not improper under the FDCA. First, some custom devices may take a long time to manufacture and sterilize and a patient or physician may need the device before manufacture can be completed. Once a physician learns of the unusual health condition of a patient and determines that, for example, three or four devices may be needed each year, why not have the manufacturer make three? The statutory elements still may be satisfied in this scenario. If a patient’s unusual health condition is life threatening, why make an artificial barrier by saying that the manufacturer must start from scratch each time the device is needed for that patient?

Second, it is not uncommon for a healthcare professional to be unsure of the exact size needed when the custom device is requested. In the case of an implantable device such as a heart valve, for example, the physician may not know the size needed until the patient is in the middle of surgery. Even the most conservative interpretation of the statute would not suggest that the manufacturer must wait to begin manufacturing the custom device until that patient is in the middle of surgery. Moreover, it is not uncommon to ship two or three sizes of a device to the physician so an appropriate size is available during surgery. The company then instructs the physician to return the unused devices because they could not be legally used on another patient and meet all of the statutory requirements for a custom device.

Return of unused custom devices raises another question: What is to be done with the returned devices? Is the manufacturer required to destroy them? In addition to being wasteful, such a requirement does not seem to be supported by the statute or legislative history.³³ A more logical approach would be to store these extra custom devices in a quarantined area in case a *bona fide* request is made in the future. The important thing is to make sure that the practice of storing returned devices does not become commercialization of the product.

Reliance on custom device "inventory" as evidence of improper intent is an example of the inconsistent criteria used by FDA to determine when a device is a genuine custom device. It will be difficult to achieve the necessary consistency in the absence of FDA guidance on this topic.

VI. CUSTOM DEVICES OUTSIDE THE UNITED STATES

Jurisdictions that regulate medical devices may have some provision for custom devices, and general concepts concerning custom devices, such as those discussed in this article, appear in laws around the world. Two jurisdictions, the European Union and Canada, are discussed below.

A. *European Union*

The Medical Device Directive (MDD), issued in 1993, governs most medical devices marketed in the European Union. (There also are separate directives covering *in vitro* diagnostics and active implantable devices.) The MDD includes provisions on custom-made devices. The MDD provides:

"[C]ustom-made device" means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The above-mentioned prescription may also be made out by any other person authorized by virtue of his/her professional qualifications to do so.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices.³⁴

Custom-made devices may be marketed in the European Union if they meet the applicable conditions in the MDD, most of which are set out in Annex VIII to the MDD. Under Annex VIII, the manufacturer must provide a "statement" that includes the following information:

- (a) data allowing identification of the device;
- (b) a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient;

³³ There is at least one implant company that has been doing just that in response to an FDA Form 483 observation in the 1990s.

³⁴ Council Directive 93/42/EEC, 1993 O.J. (L 169) (MDD), art. 1, para. 2(d).

- (c) the name of the medical practitioner who made out the prescription and the name of the clinic;
- (d) the particular features of the device;
- (e) a statement that the device conforms to the essential requirements set out in Annex I, and where applicable, indicating which essential requirements have not been fully met, together with the reasons.³⁵

Custom-made devices are not allowed to bear the CE marking.³⁶

The custom-made device manufacturer also must make available certain information for the competent national authorities, including documentation allowing an understanding of the design, manufacture, and performances of the product, including the expected performances, so as to allow assessment of conformity with the MDD's requirements.³⁷ The manufacturer also must take all measures necessary to ensure that the manufacturing process produces products manufactured in accordance with the "statement" that is required to be made for custom-made devices.³⁸

The Council Directive concerning active implantable medical devices, issued in 1990, also includes a definition for custom-made devices. The Active Implantable Medical Devices Directive (AIMD Directive) states:

“[C]ustom-made device” means any active implantable medical device specifically made in accordance with a medical specialist's written prescription which gives, under the medical specialist's responsibility, specific design characteristics and is intended to be used only for an individual named patient.³⁹

Custom-made active implantable devices may be marketed in the European Union if certain requirements are met, most of which are set forth in Annex VI of the AIMD Directive.⁴⁰ These devices cannot include the CE marking.⁴¹

As with devices covered by the MDD, manufacturers of active implantable custom-made devices must provide a "statement" that includes the following:

- data allowing the device in question to be identified;
- a statement affirming that the device is intended for exclusive use by a particular patient, together with the patient's name;
- the name of the doctor who wrote the prescription and, if applicable, the name of the clinic concerned;
- the particular features of the device as described by the medical prescription concerned; and
- a statement affirming that the device complies with the essential requirements in Annex I to the AIMD Directive, and, where applicable, indicating which essential requirements have not been wholly met, together with the reasons.⁴²

The manufacturer also must make available certain information for the competent national authorities, including "documentation enabling the design, manufacture and

³⁵ MDD, Annex VIII, para. 2.1. The requirements in Annex I, as referenced in paragraph 2.1, subpart (e), are lengthy, and include requirements concerning design, construction, and labeling.

³⁶ MDD art. 4, para. 2. The CE mark would indicate that the product has complied with the Directive and may be marketed throughout the European Union, which is not true for a custom device.

³⁷ MDD, Annex VIII, para. 3.1.

³⁸ *Id.*

³⁹ Council Directive 90/385/EEC, 1990 O.J. (L 189) (AIMD Directive), art. 1, para. 2(d).

⁴⁰ AIMD Directive art. 4, para. 2.

⁴¹ *Id.*

⁴² AIMD Directive, Annex VI, para. 2.1.

performances of the product, including the expected performances, to be understood, so as to allow conformity with the requirements of this Directive to be assessed.”⁴³

Annex VI also requires that the manufacturer take “all necessary measures to see that the manufacturing process ensures that the products manufactured conform” to the statement required by Annex VI.⁴⁴

B. Canada

Canadian law also includes provisions concerning custom devices. Custom-made devices are defined as:

“[C]ustom-made device” means a medical device, other than a mass-produced medical device, that:

- (a) is manufactured in accordance with a health care professional’s written direction giving its design characteristics;
- (b) differs from medical devices generally available for sale or from a dispenser; and
- (c) is
 - (i) for the sole use of a particular patient of that professional; or
 - (ii) for use by that professional to meet the special needs arising in the course of their practice. (*instrument fait sur mesure*)⁴⁵

Under this definition, mass-produced devices prescribed to meet a specific patient’s needs (e.g., hearing aids, contact lenses, eye glasses, and orthotic and prosthetic devices), would not be considered custom-made devices in Canada.

Canadian regulations spell out certain requirements for custom-made devices. For instance, a person is prohibited from importing or selling a Class III or IV custom-made device unless the Minister of Health has issued an authorization for its sale or importation.⁴⁶ A person seeking an authorization may apply to the Minister for such authorization, and the regulations spell out what must be included in the application, including the name of the device, its class, the diagnosis, treatment or prevention for which the device is required, the name and address of the healthcare facility, and the known safety and effectiveness information for the device.⁴⁷ Notably, the regulations do not require that the name of the patient be provided.

The Minister of Health is required to issue or shall issue an authorization for selling a Class III or IV custom-made device if:

- (a) the benefits outweigh the risks;
- (b) the health or safety of patients will not be unduly affected;
- (c) a licensed device that would adequately meet the requirements of the patient is not available in Canada; and
- (d) the authorization is not being used by the manufacturer or importer to circumvent the general device requirements.⁴⁸

⁴³ AIMD Directive, Annex VI, para. 3.1.

⁴⁴ *Id.*

⁴⁵ Food and Drugs Act, R.S.C., ch. F-27 (1985) (Can); Medical Devices Regulations (MDR), SOR/98-282 (Can), s. 1.

⁴⁶ MDR, s. 70.

⁴⁷ MDR, s. 71(1).

⁴⁸ MDR, s. 72(1).

The authorization also must specify the number of units of the device authorized to be sold or imported, meaning that “batch releases” may be requested as part of the application process.⁴⁹

Custom-made devices must be labeled as such,⁵⁰ and the manufacturer or importer of a custom device must maintain distribution records as required by the general device regulations.⁵¹ Healthcare professionals are required to report incidents involving custom-made devices within seventy-two hours after the occurrence.⁵²

These foreign regulations include common-sense provisions on volume that should be consulted by FDA in interpreting the FDCA. The statement that custom devices should not be mass produced is equally applicable to the FDCA. The recognition that a “batch” of custom devices could be made should constitute part of U.S. practice because it is consistent with legislative intent.

VII. CONCLUSION

The custom device exemption, although frequently used, is infrequently discussed by regulators. The practice has grown by lore passed down from regulator to regulator and among industry professionals, rather than by regulation. The exemption was established by Congress to provide for specific needs of patients and healthcare professionals, and the exemption can provide an efficient mechanism for providing patient care in cases where there is no marketed product to fill the need. Congress’ intent was to allow a limited number of devices to be manufactured, and not to allow for commercialization of the custom device. The need for custom devices still exists today, but the question of how many devices can be manufactured still lingers. Occasional FDA pronouncements that only one custom device may be made have no support in the FDCA. It is hoped that FDA soon will provide regulation or guidance on custom devices, so that both the regulated industry and FDA have a clearer joint understanding of the law in this area.

⁴⁹ MDR, s. 72(2). Health Canada, Health Products and Food Branch, has published draft guidance on How to Apply for Authorization to Obtain Custom-Made or Special Access Devices (Apr. 10, 2003) *available at* http://www.hc-sc.gc.ca/dhp-mps/acces/md-im/special_e.html.

⁵⁰ MDR, s. 75(c).

⁵¹ MDR, s. 76.

⁵² MDR, s. 77.