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FDA Medical Device Regulation and Informed Consent

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New medical devices are subject to a regulatory scheme designed to ensure safety and effectiveness that is administered by the United States Food and Drug Administration (FDA). Gaining approval to market a device for a specific clinical indication may be time-consuming and costly, particularly for one that poses a potentially unreasonable risk of patient injury and represents genuinely new medical technology. The difficulty of gaining FDA approval has led to the use of devices for indications other than those approved by the FDA and to the clinical use of products that lack any formal FDA approval. Such non-FDA approved uses raise the question of what patients subjected to these products should be told as part of the informed consent process.

FDA Medical Device Regulation

Current FDA regulation of medical devices is based on the Food, Drug, and Cosmetic Act (FDCA) as modified by the Medical Device Amendments of 1976 (MDA). The MDA substantially changed U.S. device regulation, integrating many features that had previously existed only in drug regulation. New devices are generally subject to a premarket notification system under section 510(k), requiring a manufacturer or other sponsor to notify the agency of its intention to market the product. After this notification, the FDA must affirmatively grant permission for marketing to proceed. Certain devices that pose a potentially unreasonable risk of patient injury are also subject to a premarket approval process, another established drug regulation device that typically involves clinical trials. The overall goal of this regulatory scheme is to ensure that a marketed medical device is safe and effective for the indications described on its FDA-approved product label.

Enforcement of the FDCA is primarily the responsibility of the FDA. The agency directs its enforcement actions against parties who market products that either lack any FDA approval or that are marketed for an indication other than that approved by the agency (so-called off-label use). Importantly, it is a long-standing regulatory doctrine that a licensed physician may use a legally marketed device for any indication that he or she believes is appropriate, regardless of whether that use is agency approved (1). This "practice of medicine" doctrine recognizes that the FDA regulates devices, not medical practice (2). The agency can, however, regard the acquisition of a

device for a nonapproved indication as a marketing activity and act against the physician who does so. This concern notwithstanding, enforcement actions stemming from the use of nonapproved devices are primarily directed at manufacturers and other individuals who actively market such products, not the physicians who use them.

The heart of the device regulatory scheme is a three-tiered classification system under which pre-1976 products are classified by the risk they pose to patients, with an increasing regulatory burden as the device ascends in class.

Class I Devices.—These are products that do not pose a potentially unreasonable risk of patient illness or injury. Such products are regulated only via general controls, such as general labeling requirements and good manufacturing practices. These controls apply to all class I devices as well as to devices of classes II and III. The FDA does not assess these products individually nor is there a requirement that safety and effectiveness of the individual product be established prior to marketing. Examples of products in this category include tongue depressors and crutches.

Class II Devices.—These present a greater risk of harm than do class I devices and are subject to additional regulation in the form of special controls, which may be established by the FDA. Although regulation may be more stringent than with class I devices, there is no individual FDA evaluation of these products. Generally, this class includes higher-technology products that do not by themselves maintain life, such as cardiac monitors, tampons, and oxygen masks.

Class III Devices.—These are "represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or that "present a potentially unreasonable risk of illness or injury" (3). Technically, all products in this class are subject to a premarket approval process, which requires that a manufacturer establish the safety and efficacy of the device prior to its marketing. Pre-1976 class III devices, however, are "grandfathered" and may continue to be legally marketed until the FDA requests safety and efficacy data and the manufacturer fails to provide it, or the supplied data fail to demonstrate safety and efficacy. Products substantially equivalent to pre-1976 class III devices also enjoy this regulatory reprieve. Class III includes implantable devices, such

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as stents and heart valves, as well as products used within the body, such as angioplasty catheters and coils for embolization.

Devices developed after 1976 are split into two groups, those that are substantially equivalent to pre-1976 devices and those that are genuinely new products. A party seeking to market a new device must generally notify the FDA of its intention to do so under the MDA's premarket notification system, often referred to as 510(k), the statutory section outlining the requirement. Should the FDA determine that a device is substantially equivalent to a pre-1976 device or represents an evolutionary change of such a device, that device is classed with its pre-1976 equivalent and may be marketed subject to the same regulatory standards applied to the existing product. Thus, substantially equivalent devices do not escape regulation, but they are only subject to the regulation faced by their pre-1976 predecessor.

Genuinely new devices developed after 1976, which by definition have no pre-1976 equivalent, are automatically considered class III devices. Technically, the FDCA does allow reclassification to class I or class II in certain instances, although this does not apply to any device whose potential risk to patients would place it in class III (3). Practically speaking, this reclassification provision is rarely, if ever, used with potentially high-risk products. Accordingly, any such genuinely new device is subject to a formal premarket approval process. This process requires reasonable assurance that the device is safe and effective for its intended use. Safety and efficacy are generally established via clinical trials that focus on specific clinical applications.

The device regulatory scheme has important implications, particularly for genuinely new medical products developed after 1976 that carry a degree of patient risk, which places them in class III. These devices are automatically subject to the premarket approval process prior to any legal marketing. The clinical trials that underlie this process are often involved, time-consuming, and costly, and typically yield approval for only a single clinical application. The cost alone may be sufficient to prevent a manufacturer or other sponsor from pursuing marketing of the product. The time involved in conducting clinical trials also makes it difficult for FDA approval to reflect the latest medical developments. Furthermore, the practice of medicine doctrine, which allows physicians to use an approved device in any manner they see fit, may dissuade the sponsor of an already approved product from seeking formal FDA approval for additional clinical indications.

In practice, the new device regulatory system has produced a climate in which cutting-edge technology frequently lacks FDA approval for any indication or for the indication for which the technology is being used. Physicians, particularly those in procedure-based specialties, are often faced with clinical circumstances in which a reasonable course of treatment involves use of a non-FDA approved device. These clinical demands are widely believed to have led to

significant use of non-FDA approved devices, which raises the question of what patients should be told regarding the regulatory status of devices used in their care.

Informed Consent and Non-FDA Approved Devices

It is well established that competent adults have the legal right to control their medical care, a concept embodied in the doctrine of informed consent. In the context of non-FDA approved medical devices, the question becomes whether the regulatory status of those devices must be regularly included in the consent process.

Basic Concept of Informed Consent

The adequacy of any informed consent is dependent on state law. The majority of states employ a *reasonable practitioner* standard to assess the consent process, a standard that asks what a reasonable practitioner would have disclosed to the patient in similar circumstances. This standard is generally established by physicians testifying as experts. A growing minority of states use a *reasonable patient* standard, which focuses on what information a reasonable patient in like circumstances would need to know to make an informed decision. The latter standard is generally considered more demanding, as it effectively takes the act of establishing the standard from the physician and places it with the jury or judge. Importantly, neither standard demands that all known information on a procedure be revealed to the patient.

In addition to legally adequate consent, a plaintiff must also show at trial that the inadequate consent led to injury and to actual damages. In practice, this means that informed consent is usually only an issue when there has been an unfavorable outcome for the patient.

Case Law: Informed Consent and Non-FDA Approved Devices

We are unaware of any major reported cases involving informed consent and non-FDA approved devices used in radiology. An analogy, however, may be drawn to ongoing litigation involving pedicle screws, which are orthopedic devices commonly used in spinal fixation. In the mid-1980s, these products were twice submitted to the FDA under section 510(k) for use as spinal fixation devices. Twice the application was refused, with the agency on at least one occasion citing potential safety problems (4). The manufacturer subsequently resubmitted a 510(k) application that labeled the devices generic bone screws, substantially equivalent to existing devices. With this generic labeling, the FDA found the product was substantially equivalent and sanctioned its marketing. Despite the lack of specific FDA approval for spinal use, the screws were commonly used off-label for spinal fixation (5). A considerable number of patients

unsatisfied with their results filed suit, often claiming that they were never informed of the device's regulatory status.

A federal class action suit addressing pedicle screws is being litigated in the Federal District Court for the Eastern District of Pennsylvania (*In re Orthopedic Bone Screw Products Liability Litigation*). As part of this litigation, the court examined the informed consent issue. In doing so, it applied Pennsylvania law, which follows a reasonable patient standard: a provider must inform a patient of "those risks which a reasonable man would have considered material to his decision whether or not to undergo medical treatment" (6). The court noted that FDA regulatory status does not speak directly to the medical issues surrounding a particular procedure. It dismissed extensive FDA informed consent requirements for clinical device trials as a regulatory consequence of being engaged in clinical trials, not a part of the basic doctrine of informed consent. Finally, the court observed that off-label use of a medical device is a matter of medical judgment on the part of a physician, adding that a physician cannot be held liable for failing to advise a patient as to the regulatory status of a device. In conclusion, the court found that Pennsylvania law did not require that the FDA status of a device be revealed as part of the informed consent process.

Two years earlier, however, the same Federal District Court, again applying Pennsylvania law, suggested a different result in the case of a patient who underwent a discectomy and fusion with pedicle screws, a procedure later shown to be medically unnecessary (7). While not rendering a final judgment on the facts of the case, *Corrigan v Methodist Hospital* held that use of a non-FDA approved device may represent a risk that should be addressed in the informed consent process. Notably, the court (*In re Orthopedic Bone Screw Products Liability Litigation*) specifically disagreed with this result.

Other courts are also split on this issue. In *Klein v Biscup*, the pedicle screws were implanted into a patient without any mention of their regulatory status. Here, an Ohio court held that the FDCA does not regulate medicine, and that once a product has been approved for marketing it may be used by a physician in a manner that differs from its approved use (8). Faced with a similar situation, a Tennessee court in *Shadrick v Centennial Medical Center* held that disclosure of a device's regulatory status is a question of fact to be decided by a jury (9). The latter case was decided in a jurisdiction that uses the majority reasonable practitioner standard.

Analysis: Informed Consent and Non-FDA Approved Devices

The cases cited above demonstrate the legal uncertainty that currently surrounds informed consent and non-FDA approved devices. Although *In re Orthopedic Bone Screw Products Liability Litigation* appears to represent the view of most courts that the regulatory status of devices is not material to the informed consent process, the outcome in any given case is likely to be dependent on the particular facts before the court. Such case-specific factors may include the regulatory status of the device (ie, approved for another indication or lacking any approval), the clinical indication in question, and support in the medical literature for the nonapproved use. The number of factors and their complex interaction make the outcome in any given case, whether in a reasonable provider or a reasonable patient jurisdiction, difficult to predict.

Conclusion

The FDCA, as modified by the MDA, has created a comprehensive system for the regulation of medical devices to ensure their safety and effectiveness. An unintended consequence of the system appears to be the use of non-FDA approved devices in clinical practice. Where such devices are employed, it is uncertain what a patient should be told as part of the informed consent process. Given this uncertainty, a prudent approach may be to consider informing the patient of the regulatory status of a device. This is particularly true when a device lacks any FDA approval. Such an approach may serve to prospectively address a potential legal pitfall in the clinical use of such devices.

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