Modification of Medical Devices

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Excerpt follows (pages 13 to 16):

In 1972, the FDA stated in a proposed, but never adopted, rule that the FDCA could not limit the uses for which a physician may prescribe an approved drug, as such use may include accepted medical practice.[1] Similar statements have appeared in numerous agency publications and in preambles to adopted regulations.[2] The doctrine has been alluded to in drug regulations, although not delineated specifically.[3] Importantly, the agency recognizes no difference in use of drugs and devices.[4]

The practice of medicine doctrine was articulated explicitly in the Food and Drug Administration Modernization Act of 1997 (FDAMA).[5] The relevant language reads:

> Nothing in this Chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

What constitutes a legitimate health care practitioner-patient relationship is not defined in FDAMA, and the applicable section further states that its provisions do nothing to limit the existing FDA regulatory powers.

The exact boundaries of the practice of medicine doctrine are unclear. At one extreme, there is little doubt that a physician may use a locally-fabricated device for the care of a specific patient without federal regulatory repercussions, provided the patient gives informed consent to such use – state or institutional controls notwithstanding.[6] Conversely, a physician who acquires a device or device materials through interstate commerce, fashions a non-FDA-approved device, and actively attempts to market the product to patients across state lines almost certainly violates the FDCA[7].

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[1] *37 Fed. Reg. 16,503 (1972).*

[2] *See* Preamble to the Final Rule Regarding New Drug, Antibiotic, and Biologic Drug Regulations, *52 Fed. Reg. 8803 (1987);* Stuart L. Nightingale, *Unlabeled Uses of Approved Drugs*, 26 DRUG INFO. J. 141 (1992).

[3] *See 21 C.F.R. § 312.2(d) (1999).*

[4] *See* FDA, 1991 FDA COMPLIANCE MANUAL, No. 7292.900.

[5] *See* Pub. L. No. 105-115, 111 Stat. at 2296.

[6] Smith, *supra* at 252.

[7] Federal Food Drug and Cosmetic Act.

Between these extremes, there is uncertainty. For example, courts and some commentators maintain that FDA may have authority to pursue regulatory action against a physician who knowingly causes a device to be shipped in interstate commerce for a purpose other than its approved use.[8] Analysis of modification of a legally marketed product is relatively straightforward where the party modifying that product is a medical device manufacturer. Under such circumstances, alterations that could affect significantly the safety and effectiveness of a device that result in a non-510(k) exempt product require submission of a 510(k) application. Regulatory obligations are less clear when the party modifying the product is a licensed physician employing the modified device for treatment.[9].

In sum, modification of legally marketed medical devices is a complex issue in federal medical product regulation. An initial question is whether device modification triggers the 510(k) process; that is, does the modification change the product's indication or have the potential to alter significantly its safety or effectiveness?

For modifications that conceivably could trigger the 510(k) process, the identity of the party making those modifications, and their intentions, become important. If that individual is a licensed physician using the modified product for patient treatment, it is very likely that the practice of medicine doctrine or custom device exemption will apply.

However, the protection afforded by the practice of medicine doctrine and the custom device exemption is destroyed by the active marketing or commercialization of the modified product.[10] Although the courts generally demonstrate considerable deference, promoting the modified device raises the possibility that a court could find that a physician is marketing a product and is subject to FDA regulation. Courts and some commentators seem to support a broad scope of FDA authority to pursue regulatory action against a physician who knowingly causes a device to be shipped via interstate commerce for a purpose other than its approved use.[11] Finally, use of a device primarily to gain in experimental data for marketing the investigational device exemption (IDE) regulations, superseding either the practice of medicine doctrine or the custom device exemption.

Furthermore, much of the same ambivalence that abounds regarding prescription drugs and the limits of physician discretion, is applicable in the arena of medical devices. Because of the uncertainties relating to what constitutes 'modification', it is prudent that

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[8] *See Evers, 453 F. Supp. at 1141*

[9] Smith, *supra* at 250.

[10] John J. Smith, *Regulatory and Legal Implications of Modifying FDA-approved Medical Devices, Journal of Vascular and Interventional Radiology* 11:19-23 (2000). (http://www.jvir.org/cgi/content/full/11/1/19#R8-0086)

[11] *United States v. Evers*, 453 F. Supp. 1141 (M.D. Ala. 1978) aff'd on other grounds, 643 F.2d 1043 (*5th* Cir. 1981)

physicians be diligent in seeking out information relevant to their modification of medical devices. FDA regulation over modification might arguably be construed to control aspects of the physician-patient relationship, but the fear of FDA action could actually prompt greater assiduousness on the part of physicians who are treating patients with modified medical devices.

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