



OUTSIDE COUNSEL

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Liability for Off-Label Use

Like food, clothing and other necessities, medications and medical devices come with labels. The drug manufacturer must submit proposed labeling to the Food and Drug Administration (FDA) so that the medication¹ or device² can be approved.

The label of a drug, written by the drug manufacturer, includes information such as its indications, its contraindications and standard doses.³ Similarly, the label of a medical device must include information such as a statement of all conditions, purposes or uses for which the device is intended or prescribed.⁴

Despite what would appear to be “instructions” to physicians on how to prescribe drugs, the FDA does not regulate the practice of medicine, and therefore cannot regulate how doctors use drugs it has approved. See 21 U.S.C. §396. Therefore, physicians are free to prescribe drugs and medical devices “off-label,” which the U.S. Supreme Court has defined as the “use of a device [or drug] for some other purpose than that for which it was approved by the FDA.” *Buckman Company v. Plaintiff’s Legal Committee*, 531 U.S. 341, 350, 121 S.Ct. 1012, 1018 (2001). The Court recognized that off-label use of medical devices “is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” *Id.*

There are a number of ways a drug can be used “off-label.” These uses include prescribing a drug to treat a condition other than that for which it was approved, prescribing a drug for patient groups other than those for whom the drug was originally approved, or using a device in a part of the body that is different from the body part for which the device had been approved.

At least three legal issues pertaining to physicians emerge from off-label use of a medication or device. One issue is whether and under what circumstances the prescription would constitute a departure from accepted standards of care. A second issue is whether the physician has a duty to inform her



patient that she is prescribing the medication or device for a use that has not been approved by the FDA. The third issue is whether a plaintiff may argue at trial in a medical malpractice case that the medication or device was being used off-label.

The Standard of Care

Generally, off-label use of a medication or device will not constitute a departure from accepted standards of care. In fact, “doctors commonly exercise professional medical judgment and prescribe drugs for uses not within the indications articulated by the FDA.” *Sita v. Danek Medical Inc.*, 43 F.Supp.2d 245, 263 (E.D.N.Y. 1999), quoting *Weaver v. Reagen*, 886 F.2d 194, 198-99 (8th Cir. 1989). Put succinctly: “FDA-approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interests of the patient.” *Sita v. Danek Medical Inc.*, at 262-263, n. 13, quoting *Weaver v. Reagen*, 886 F.2d at 198-99.

In *Brown v. Speaker*, 2007 NY Slip Op 31069(U) (N.Y. Sup. Ct. April 25, 2007), Justice Joan Carey stated that the FDA “cannot establish the standard of care for the practice of medicine...” or for using devices “off-label.” She noted that the standard of care is established by the profession itself. Therefore, the fact that a drug or device is used off-label will not, in and of itself, constitute a departure from accepted standards of care.

What if a physician uses a medication for a purpose that is outrageous—such as prescribing penicillin to treat cancer? Would the physician be protected from a lawsuit because she prescribed the medication “off-label” or would she be liable for medical malpractice if the “off-label” use was not within accepted standards of care? Although there are no New York cases on point, to avoid liability the physician must presumably prescribe the medication for an “accepted” off-label use. As stated by the FDA, “a physician who engages in off-label uses has the responsibility to be well-informed about the device, and to base the decision to use it on sound medical evidence.” Food and Drug Administration, “Update on the Regulatory Status of Pedicle Screws,” Feb. 17, 1994. Thus, a physician “bears the risk of being sued for malpractice if the plaintiff is harmed by an unwarranted use of the drug or device.” *Sita v. Danek Medical Inc.*, at 262-263, n. 13 (emphasis added).

One additional limitation on the physician’s ability to prescribe medication for an unapproved use is that the drug must have been FDA-approved for some medical purpose. Thus, there can be liability if a physician uses a drug or device which was never approved at all. See *Retkwa v. Orentreich*, 152 Misc2d 691 696, 579 NYS2d 577, 580 (N.Y. Sup. 1991) (*Retkwa I*). In that case, the defendants treated the plaintiff with liquid injectable silicone, which, the court found, had not been approved by the FDA. The plaintiff sued the defendants for medical malpractice and lack of informed consent.

As stated by the New York Supreme Court, the medical-practice exception to the act could not, and was not intended to, protect a physician’s preparation of an unapproved illegal drug. *Retkwa I*, 152 Misc2d at 687, 579 NYS2d at 580. Thus, in *Retkwa I*, the New York Supreme Court held that the defendants could be held liable for medical malpractice and denied defendants’ motion to vacate the medical malpractice panel’s recommendation to find liability.

Lack of Informed Consent

Must a physician inform her patient that she is prescribing a medication or device “off-label”? The first case to consider that issue in

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New York was *Retkwa v. Orentreich*, 154 Misc2d 164, 584 NYS2d 710 (N.Y.Sup. 1992) (*Retkwa II*). The court recognized that the issue was one of first impression: whether information about the FDA status of an unapproved injectable substance is part of the information concerning “risk” covered by Public Health Law §2805-d(1).⁵ *Retkwa II*, 154 Misc2d at 165, 584 NYS2d at 710. The court framed the issue as whether the physician was required to tell the patient that the substance with which he was going to inject her had not been approved by the FDA. *Retkwa II*, 154 Misc2d at 168, 584 NYS2d at 712.

The court held that “[t]here can be little question that in assessing the risk of a drug or injectable substance, a reasonable patient would want information as to whether that drug or substance has been tested and/or approved by Federal authorities.” *Retkwa II*, 154 Misc2d at 168, 584 NYS2d at 712. The court concluded that it was “a reasonable assumption” that most patients would presume that the substance they were being given had been the subject of official testing, consideration and approval, and would rely on this presumption as part of the basis for their “consent” to the treatment. *Retkwa II*, 154 Misc2d at 168, n. 6, 584 NYS2d at 712, n.6. The court, therefore, found that plaintiff should be permitted to offer proof that a doctor working with liquid silicone would have informed the patient that it was not approved by the FDA and, therefore, that the failure to advise the plaintiff that the silicone was not FDA-approved was relevant to plaintiff’s cause of action for lack of informed consent.

The *Retkwa* case was somewhat unique, however, because the defendants were using a drug that, the court had found, had not been approved for any purpose. In addition, the plaintiff had an expert who was going to testify that the standard of care was to inform a patient that liquid silicone had not been FDA-approved.

However, if the drug or device has been FDA-approved, albeit not for the purpose for which it is being used, it may not be necessary to inform the patient that the drug is being prescribed off-label. Thus, in *Sita v. Long Island Jewish-Hillside Medical Center*, 22 AD3d 743, 803 NYS2d 112 (2d Dept. 2005), the court held that FDA regulations did not require the hospital to obtain his informed consent or to disclose the regulatory status of the pedicle screw system.⁶ Significantly, despite the dearth of cases in New York, courts in other states, for a variety of reasons, have generally held that a physician need not inform her patient that she is prescribing a drug “off-label” See generally Beck, James and Azari, Elizabeth, “FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,” Food and Drug Law Journal, Vol. 53, pp. 71-104 (1998) and cases cited therein.

Evidentiary Issues

Consistent with the position that off-label use of a medication does not constitute a departure from accepted standards of care,

courts have not permitted plaintiffs to submit evidence at trial regarding the absence of FDA approval to establish medical malpractice.

In *Spensieri v. Lasky*, 94 NY2d 231, 701 NYS2d 689 (1999), the plaintiff sought to introduce evidence that the package insert and labeling for birth control pills, reprinted in the Physicians’ Desk Reference (PDR), established the standard of care, and that the physician departed from the standard of care by not following the proscriptions on the label. The New York Court of Appeals held that the information contained in the PDR could not, by itself, be used as “stand alone proof” of the standard of care. 94 NY2d at 239, 701 NYS2d at 694. It did, however, acknowledge that the PDR may have “some significance,” and did not preclude testimony about the PDR in its entirety. 94 NY2d at 239, 701 NYS2d at 694.

Despite what would appear to be “instructions” to physicians on how to prescribe drugs, the FDA does not regulate the practice of medicine and cannot regulate how doctors use drugs it has approved.

Recently, the issue of whether expert testimony regarding off-label use could be used at trial was considered by Justice Joan B. Carey in *Brown v. Speaker*, 2007 NY Slip Op 31069(U) (N.Y.Sup.Ct. April 25, 2007). In that case, the plaintiff claimed that the defendant had used a particular laser to perform LASIK surgery that had only been approved by the FDA for use in certain patients, of which the plaintiff was not one.

The defendants moved, inter alia, to preclude the plaintiff from proffering expert testimony at trial that the FDA had approved the device only for use with particular patients. The defendants argued that physicians are permitted to use a medical device approved by the FDA in an off-label manner, and that the use of the laser in an off-label manner does not constitute a departure from accepted standards of care. Therefore, the defendants argued, the plaintiff should be precluded from offering testimony regarding the FDA regulations pertaining to use of the laser.

Finding that the FDA did not establish the standard of care, the court precluded the plaintiff from offering expert testimony that off-label use of the laser was, in and of itself, a departure.

Whether plaintiffs can introduce testimony regarding FDA approval in support of a lack of informed consent claim is unclear. In *Retkwa II*, the defendants moved to exclude testimony that the liquid injectable silicone was not FDA-approved. The court held that because plaintiff’s action was one for medical

malpractice and not products liability, the fact that the FDA had not approved the use of silicone would generally be inadmissible. *Retkwa II*, 154 Misc2d at 165, n.1, 584 NYS2d at 712, n.1. However, with respect to the lack of informed consent claim, the issue was “what the patient has a right to be told by her doctor.” *Retkwa II*, 154 Misc2d at 165, n.1, 584 NYS2d at 712, n.1.

The court held that, based on the background of the informed consent statute, the admission of evidence about lack of FDA approval would be entirely material and relevant to the issues in the case. The court found that the patient was entitled to information about the FDA status of liquid silicone so that she could exercise her “right to determine what should be done with [her] own body” and, therefore, evidence about the FDA status of liquid silicone was admissible. *Retkwa II*, 154 Misc2d at 169, 584 NYS2d at 713 [citation omitted].

As stated above, the *Retkwa* case was somewhat unique because the defendants were using a drug that had not been approved for any purpose and it remains to be seen whether that holding would apply in other contexts. Presumably, the issue would depend on whether the court found that the plaintiff could assert a claim for lack of informed consent based upon the off-label use of the drug and whether plaintiff could produce an expert to testify that the failure to provide information about off-label use was a departure from accepted standards of care.

1. 21 U.S.C. §355(b)(1)(F); 21 C.F.R. §314.50(e)(2)(ii).

2. 21 C.F.R. §814.20.

3. 21 C.F.R. §§ 201.56(d)(1), 201.57, 201.100.

4. 21 C.F.R. §801.5.

5. Lack of informed consent is defined as “the failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical...practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation.” N.Y. Public Health Law §2805-d(1).

6. The court did not comment on whether the physician would have this duty, but the reasoning behind the decision should apply to the physician as well.