

Use of Non-FDA Approved Medical Devices: The Mesogun

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Weighing factors in determining whether to use a non-FDA approved medical device in patient treatments, such as the Mesogun used in mesotherapy, is not a straightforward proposition.

If the decision process stopped at the possibility of FDA enforcement, the answer is a quick “yes, use it”. The FDA has admitted that it lacks the authority to regulate the practice of medicine. Therefore, if a physician bases his or her decision to use a non-approved device on firm scientific rationale and sound medical evidence, that decision is considered the practice of medicine and is outside the purview of the FDA. But the inquiry does not end there.

Beyond the regulatory power of the FDA, which can still regulate the manufacture of these devices regardless of their use in practice, a physician must also consider the laws of the state where they practice medicine. Many states have enacted statutes specifically prohibiting the use of any device that has not been approved by the FDA. Alternatively, if state law does not specifically prohibit use of non-FDA approved medical devices, many states have enacted informed consent statutes which dictate the level of disclosure physicians are required to provide to their patients prior to using non-approved devices.

Of the states which have enacted informed consent laws, two primary legal standards apply in determining whether a physician has satisfied the patient disclosure requirement: one based on the physician and the other on the patient. The first standard, considered the majority view, is called the professional standard test. This test considers what a competent physician would believe the patient should know under his or her specific circumstances in order to give informed consent and proceed with treatment. The second standard, currently used in some 20 states, is called a patient or materiality-based standard. This standard uses as its criteria what a reasonable patient would consider material to his or her decision in accepting or denying the proposed treatment. It is important to keep in mind, though, that regardless of the legal standard applied in a particular state, the informed consent laws are a product of the fundamental right of every patient to determine what is to be done with his or her own body.

With this fundamental right in mind, even the considerably less stringent professional standard test described above has been interpreted in at least one state to mean essentially the same as the materiality-based standard. In New York, the state court held that the physician must determine whether the lack of FDA approval would be a factor in the patient’s assessment of risk to his or her own body and whether to forego the procedure as a result. The practical impact of this holding made it imperative, at least in New York, for physicians to disclose the unapproved status of the device to patients in order to comply with the informed consent statute.

Additional factors to be considered prior to using a non-approved medical device such as the Mesogun are the perspectives and stances taken on the devices by medical boards, hospital boards, and HMO boards. The viewpoints of these organizations should weigh into the assessment of potential liability for using such devices. For example, if a local hospital board feels that such a device should not be used,

this can be used to claim negligence or malpractice against a physician who uses the device despite this viewpoint.

Likewise, and perhaps even more so, physicians should consult with their professional liability carrier prior to using non-approved devices. Some carriers may not cover the use of such devices, leaving the physician who chooses to do so to proceed at his or her own risk should something go wrong and lead to a malpractice lawsuit. An important caveat, particularly with regard to the Mesogun, is the close scrutiny given by these professional liability carriers to elective cosmetic procedures such as those employing the Mesogun.

If after considering all the foregoing concerns, a physician decides to proceed and use the Mesogun, or other non-approved medical devices, he or she should plan a thorough and careful informed consent discussion with the patient. This discussion should be adequately documented. At the very least, the informed consent discussion should consist of an explanation of the nature of the device, the scientific basis for using the device in each particular situation, the benefits as well as the drawbacks or criticisms of the device, and other options for achieving the desired result.

Presenting the Mesogun at Medical Seminars

Under current federal law, the FDA must approve all pharmaceuticals and medical devices before they can be marketed. So are medical seminar presentations considered a form of marketing?

Marketing is defined in Black’s Law Dictionary as “[t]he act or process of promoting *and selling* products or services (emphasis added).” By this definition, the mere presentation of the Mesogun as a proper method of providing mesotherapy treatment to patients would not be considered marketing. However, if this act of “promoting” were coupled with the sale of the Mesogun, for example, having a representative from a Mesogun manufacturer available at these seminars, or remuneration to the presenter by a manufacturer or distributor of the Mesogun, this would likely make the presentation a form of marketing, and therefore a violation of federal law.

Because of the non-approved status of the Mesogun, physicians wishing to promote the use of this device at medical conferences and seminars should take the necessary precautions to avoid even the hint of an appearance of a partnership with a particular Mesogun manufacturer or distributor. Such a perceived partnership, it could be argued, would imply that the physician is acting as a salesperson for that particular manufacturer in giving his or her presentation.

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