FDA INSIGHTS

What the CDRH Doesn't Do

Seen by many as an all-powerful federal office, the Center for Devices and Radiological Health does have its limits.

BY DOROTHY B. ABEL

The views and opinions in this article are those of the author and do not necessarily reflect those of the US FDA, the US Department of Health and Human Services, or the Public Health Service.

The Office of Device Evaluation (ODE) is located within the Center for Devices and Radiological Health (CDRH) at the FDA. This office is responsible for reviewing the information provided by a manufacturer of the medical device to determine whether the device can be used in a clinical study or if it can be marketed, depending on the type of document submitted. Although there are many responsibilities associated with this task, there are numerous misconceptions about the breadth of the ODE and CDRH oversight. Members of the Peripheral Vascular Devices Branch in the ODE have identified some of the most common misconceptions and summarized them herein.

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THE CDRH DOESN'T...DESIGN STUDIES

The medical device regulations set requirements for the type of information needed to get approval to study or market a device. The regulations do not specify how studies are to be conducted (ie, either preclinical or clinical studies); rather, the ODE comments on the protocols provided by sponsors.

Given the diversity, complexity, and novelty of the devices regulated by the ODE, set protocol requirements could stymie innovation in evaluating devices. Although the expertise available to review information in the CDRH is continually expanding, the resources available to industry in designing appropriate studies cannot be matched within the Center. Additionally, much of what is learned by CDRH personnel comes from the files that they review and, as such, this information is confidential and cannot be shared with other sponsors. Much care must be taken to guide the sponsors into conducting appropriate testing while staying within the bounds of confidentiality and the limitations of the regulations.

THE CDRH DOESN'T...CONDUCT TESTS TO EVALUATE SPECIFIC DEVICES

The ODE does not actually conduct testing of devices. The sponsor of the application does the testing, and the ODE critiques the information provided, looking at the type of testing conducted, the way the testing was done, the results, and the conclusions. Help in evaluating the information provided comes from other offices within the CDRH, and if necessary, from other centers within the FDA. The CDRH does have laboratories, but these labs are not responsible for conducting testing on individual devices; they generally conduct basic research or research related to a family of devices.

THE CDRH DOESN'T...APPROVE MATERIALS OF CONSTRUCTION

Part of the evaluation of medical devices includes evaluating material properties, such as strength, stability, and biocompatibility. These properties are assessed in the context of the device constructed using a specific material. Although using a material that has been previously reviewed by the CDRH in a different device can help to provide a knowledge base upon which to build, there is no list of materials that are approved by the FDA.

THE CDRH DOESN'T...REGULATE THE PRACTICE OF MEDICINE

The FDA regulates interstate commerce of medical devices—not the practice of medicine. The Food, Drug, and Cosmetic Act (the Act) specifically states that "nothing in this Act 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." There are rules, however, that clinicians must follow with respect to medical device use, particularly related to the use of investigational or unapproved medical devices.

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THE CDRH DOESN'T...ESTABLISH TRAINING REQUIREMENTS OR ENTER TURF BATTLES

Every approval order for a medical device approved through the premarket approval (PMA) process includes language regarding restrictions on the distribution of the device. These requirements address whether the device is restricted to prescription use and/or is restricted with respect to training. Regarding training, when appropriate, the language in the approval order states that the labeling for the device must specify the requirements that apply to the training of practitioners who may use the device. The ODE does not mandate which medical specialty can use the device. For example, the labeling may list the endovascular skills needed to use a device, but the labeling will not state that use is limited to those trained in cardiology.

In general, the ODE does not mandate how a manufacturer ensures that users of their devices are sufficiently trained. Commentary on the training program may be provided, however, and additional language may be added to the approval order regarding training, such as the need to assess the adequacy of the training program and to report on this assessment in the annual report to the PMA. When changes are made to such training programs, the ODE is notified and generally works cooperatively with the sponsor to minimize the potential for adversely affecting the effectiveness of the training program.

With respect to clinical studies, manufacturers have the responsibility to select appropriate investigators. As for marketed devices, the ODE does not mandate the medical specialty that can participate. Similar to training, the ODE does not provide certification for either users of devices or investigators.

THE CDRH DOESN'T...REVIEW HIPAA LANGUAGE

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) has resulted in modifications to informed consent documents. It is not the responsibility of the ODE to review the disclosure documents required by the HIPAA; that is, the sponsor has the responsibility to ensure that their forms are in compliance with HIPAA requirements. More information regarding these requirements can be found at www.hhs.gov/ocr/hipaa/.

THE CDRH DOESN'T...ESTABLISH REIMBURSEMENT POLICY AND CODES

The Centers for Medicare & Medicaid Services (CMS) are responsible for determining reimbursement policy and codes. The ODE works with CMS, providing expertise in product areas, but only has defined procedures for providing input on devices under clinical investigation. When the ODE approves a new investigational device exemptions (IDE) application, a reimbursement code is assigned. This code identifies the device as either experimental or non-experimental/investigational. CMS generally does not reimburse for the unique devices that would be categorized as experimental. Such devices are not being studied to demonstrate substantial equivalence to a legally marketed device for a 510(k) clearance. Also, the device has either been changed significantly for a new intended use or such a device has not been previously approved for any indication for use.

THE CDRH DOESN'T...EVALUATE COST-EFFECTIVENESS

Some IDE studies include endpoints beyond those covered under the medical device regulations, such as cost-effectiveness. As a rule, the ODE does not require that such endpoints be removed from the study, but the ODE does not review the adequacy of the study design to answer such questions. They do not review the data collected regarding these endpoints, nor do they consider these data in determining whether the device should be cleared for marketing.

THE CDRH DOESN'T...ESTABLISH THE STANDARD OF CARE

If a medical device is approved by the FDA, it does not mean that the new device should be considered the new standard of care for the indicated use. To get a PMA approved for a device, the device must be demonstrated

to be "reasonably safe and effective" for the intended use according to the medical device regulations. It does not need to be better than the current standard of care. In other words, FDA approval provides new treatment options.

THE CDRH DOESN'T...CONTROL WHAT IS SUBMITTED FOR OUR REVIEW

The CDRH does not have the ability to require manufacturers to submit an application, unless submission is required to address a specific regulatory problem. For example, we can require a manufacturer to submit a marketing application for a modified device they are distributing in the US in absence of FDA approval for the modification, but we cannot require them to submit an application for a device they market outside of the US simply because it is perceived by the medical community to be a good device. Similarly, we cannot require a manufacturer to market an earlier generation of their device if they want to wait to go to market until they have adequate data to allow marketing of a later generation.

THE CDRH DOESN'T...PERFORM MIRACLES

The CDRH cannot magically make data appear to allow for approval of a device that is perceived to be a good device. As noted previously, the CDRH is limited to reviewing information that is provided to them. In addition, although the CDRH has highly qualified individuals who work with sponsors to put together quality submissions, they cannot act as consultants. Finally, those who work for the CDRH do not have supernatural talents that allow them to single-handedly decipher conflicting information in submissions, to memorize each device feature, study design, list of investigators, or even the deficiencies they wrote, or to finish their work yesterday.

What the CDRH can do is work cooperatively with all stakeholders to facilitate the scientific evaluation of devices and to expedite the introduction of beneficial devices. ■

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