With the popularity of live-case demonstrations continuing to grow, the FDA is aiming to make sure they are conducted in adherence with safety and regulatory guidelines.

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In an interview published in the October 2004 issue of *Endovascular Today*, Barry T. Katzen, MD, expressed several concerns regarding the increased frequency of live cases. Although the FDA has allowed live cases to be conducted, the Agency shares many of Dr. Katzen's concerns.

The promotion and protection of public health is the responsibility of the FDA. As such, consideration of the educational benefits of live cases must be weighed against the risks, including individual patient safety risks and the broader risks associated with investigational devices being presented as the latest and greatest technologies before they have been demonstrated to be reasonably safe and effective for their intended use—that is, before they have received FDA approval. Acceptance of a new technology or device in the absence of valid scientific evidence often impedes the ability to obtain the necessary evidence. In addition, there is the potential for an audience member to assume that they will be able to achieve comparable results to the expert in the absence of adequate training and experience.

Although the FDA has little influence over the presentation of live cases using marketed devices, there is regulatory oversight for those using investigational devices. The current FDA regulation of these cases is described below.

WHAT CONSTITUTES A LIVE CASE?

A live case can, as the name implies, be presented live, but it may also be transmitted over the Internet or taped and used after the procedure has taken place. Live cases are most commonly presented at meetings, offering experienced physicians the chance to share their skills with the use of the device and performance of the procedure with their colleagues. This can be quite educational; however, the appropriate use of a live case from a regulatory view has been the recruitment of investigators or patients. By law, promotion of investigational devices is prohibited, and the devices cannot be advertised during the case as being safe and effective for the use for which they are being investigated.

WHY IS THE FDA INVOLVED IN LIVE CASES?

Every aspect of the evaluation and use of investigational devices is regulated by the FDA. For significant risk devices, this includes obtaining an approved Investigational Device Exemption (IDE). The IDE regulations include requirements related to patient protection, as well as study conduct rules. When something is planned during the investigation that could affect the rights, safety, or welfare of a patient, prior FDA approval is needed. Clearly, informed consent is needed from a patient whose treatment is to be broadly viewed, as this affects the rights of the patient. In addition, it is possible that the procedure time could be extended, which could affect the safety of the patient.

There may also be additional unanticipated risks associated with live case demonstrations. As such, the FDA has regulatory oversight of live cases. In addition, there are times where scheduled live cases can require a deviation in the protocol, such as breaking randomization. The benefits of allowing the protocol deviation need to be weighed against the potential impact on the integrity of the study data in these cases. Finally, FDA looks at whether the case appears to be promotional. For example, when enrollment in the study is almost complete, there may not be a need to recruit investigators or patients, so the purpose of the case from a regulatory view would be questionable.

requesting approval. In addition, the sponsor must specify whether the case will be conducted at a current investigational site.

If the case is to be conducted at a site other than that approved as part of the IDE, a request must be included to add an investigational site. The sponsor also needs to state whether the approved protocol will be used. If the sponsor intends to deviate from the approved protocol (eg, break randomization), they must provide a detailed explanation of the intended deviations and discuss why these deviations will not affect the integrity of the study.

In addition, the sponsor must indicate that the Patient Informed Consent Form has been appropriately revised or amended to reflect any necessary intended protocol deviations and to advise the patient that the procedure will be performed live. If the FDA determines that adequate information has been provided with respect to the purpose of the live case and that adequate patient protection measures will be followed, the supplement will be approved and a letter issued. There is a statutory review time of 30 days, so any live case request should be submitted at least 30 days in advance of the case. As with any change in an investigation that affects the rights or safety of the patient, institutional review board approval must also be obtained prior to conducting the live case.

ARE THERE CHANGES ON THE HORIZON?

As predicted by Dr. Katzen in his interview, government agencies are taking a critical look at live cases. Agency concerns include those presented by Dr. Katzen, as well as concerns regarding additional patient safety and the promotion of investigational devices. The discussions at the Agency are preliminary, but there could potentially be changes in FDA policy regarding live cases coming as early as next year. If and when such changes are implemented, look to this section of *Endovascular Today* for an update. ■

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