On July 15, 2014, FDA issued a draft guidance entitled “Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics,” which describes the benefit and risk factors that FDA may consider during the review process for a 510(k) submission (“draft guidance”). This draft guidance applies to both diagnostic and therapeutic devices. FDA makes clear at the outset that the draft guidance is not intended to change the 510(k) premarket review standard or impose extra burden on a 510(k) submitter to provide additional performance data.

During review of a 510(k) submission, FDA must determine whether a new device is “substantially equivalent” to a legally marketed “predicate device.” As the first step in the review, FDA first considers whether the new device and the predicate device have the same intended use. In the second step, FDA considers whether the new and predicate devices have the same or a different technology. If the technologies are different, then FDA decides whether the different characteristics raise different questions of safety and effectiveness. The newly issued draft guidance addresses the next step in the 510(k) review.

The draft guidance describes the principal benefit-risk factors that FDA may consider after the Agency has determined that there are different technological characteristics between the new and predicate devices, and that the new device that does not raise different questions of safety and effectiveness. The factors discussed in the draft guidance assist FDA in determining whether the new device is “as safe
and effective” as the predicate device and, ultimately, whether FDA can make a substantial equivalence determination. The draft guidance includes examples of benefit-risk evaluations during a 510(k) review.

FDA explains in the draft guidance that performance data may be necessary to assess safety and effectiveness. Performance data may include data from both non-clinical and clinical testing. The principal benefit-risk factors that FDA may consider are then provided, with a description of each factor. FDA makes clear that not all the factors may be applicable to each 510(k) submission and that each factor is considered in comparison to the predicate device.

The draft guidance includes many of the same benefit-risk factors discussed in the FDA guidance issued in March 2012, “Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications,” which discusses the principal benefit-risk factors FDA considers during the review process for premarket approval (PMA) applications and de novo classification requests. The benefit factors that reviewers may consider during the review of a 510(k) submission include the type of benefit(s); magnitude of the benefit(s); probability of the patient experiencing one or more benefit(s); and the duration of effect(s). The risk factors listed in the 510(k) draft guidance include severity, types, number and rates of harmful events associated with the use of the device; probability of a harmful event; probability of the patient experiencing one or more harmful event(s); duration of harmful events; and risk from false-positive or false-negative results for diagnostics.

FDA also lists “additional factors” that FDA may consider during the review of a 510(k) submission. One noteworthy “additional factor” is “patient tolerance for risk and perspective on benefit.” This factor was also discussed in the PMA/De Novo Guidance, and FDA held a public workshop in 2013 regarding ways to incorporate patient perspectives on “meaningful benefits” and “acceptable risks” of new medical devices (see our previous post). The draft guidance also lists the “benefit for the healthcare professional or caregiver” as a factor that FDA may consider. FDA states that its review of a 510(k) may take into account whether the device may benefit healthcare professionals or caregivers by improving the way they care for the patients and consequently improving patient outcomes.

Finally, FDA discusses how postmarket data may play a role in the review of a 510(k). FDA indicates that FDA may consider the extent to which postmarket controls could be considered as a mechanism to reduce the extent of the premarket data for 510(k) submissions.

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