Insight

FDA Answers the Call from Congress and Industry

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The calls have been answered – at least in part. On March 27, the FDA's Center for Devices and Radiological Health (CDRH), released a first of its kind guidance document used in risk-benefit analysis of medical devices.

Specifically, the guidance focuses on the premarket approval (PMA) and the de novo process of review used to evaluate the safety and effectiveness of Class III medical devices – the most innovative, but also the most potentially risky devices.

The guidance document is a response to Congressional and industry demand for greater transparency into FDA's medical device review process. It reveals the principal factors that influence benefit-risk determinations, such as the type and duration of a risk or benefit; the probability that a patient will experience the risk; the availability of alternative treatments; and the value the patient places on treatment.

"This guidance clarifies this process for industry, which will provide manufacturers with greater predictability, consistency and transparency in FDA decision-making while allowing manufacturers and the FDA to use a common framework for benefit-risk determinations," said Jeffrey Shuren, M.D., director of CDRH.

With the FDA guidance set to apply to submissions already under review for decisions beginning on May 1, 2012, corporate and political influence is generating legitimate concerns surrounding the FDA's review process. According to a Union of Concerned Scientists survey, a veteran FDA scientist stated, "It used to be that administrations would come and go and we could go about the business of protecting the public. Now the lawyers and politicians seem to run the show and think they know better than the FDA."

Whether or not external pressures have significantly altered scientific review is unclear. However, it has been pervasive enough to prompt the FDA's release of a first-of-a-kind guidance for medical device manufacturers.

No matter what conflicts of interest may exist in the wake of MDUFA III reauthorization, Congress and industry must not interfere with the FDA's capacity to practice objective regulatory science when evaluating medical devices. Patient safety and efficacy must remain top priority in future MDUFA negotiations.

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