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Compliance 360° Part 8: Patient Influence On US FDA's Enforcement Strategy

by Shawn M. Schmitt

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this eighth installment, former FDA investigations branch director Ricki Chase explains how the role of the patient influences FDA's enforcement strategy and discusses the agency's recent industry guidance on benefit-risk factors.

Patients are playing an ever-increasing role in how US FDA approaches its compliance and enforcement priorities, former agency investigations branch director Ricki Chase says.

Indeed, FDA's Center for Devices and Radiological Health "has been increasingly interested in the patient experience and what role that should play in both regulatory and compliance decisions," Chase says in the eighth installment of Compliance 360°, a podcast series from *Medtech Insight* on FDA compliance and enforcement issues. (*Scroll to the bottom to find the podcast player.*)

"This can most recently be seen as a strategic initiative for patient engagement in the center's 2016-2017 plan, and a recent guidance document

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relating to benefit-risk factors and patient preference indicators."

Strategy

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That guidance, "*Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions*," was issued by the agency on Dec. 27, 2016. Part of an ongoing effort to harmonize benefit-risk considerations throughout CDRH, the document proposes a broad framework for considering benefit-risk factors in medical device availability, compliance and enforcement decisions. (Also see "*FDA Finalizes Post-Market Benefit-Risk Guidance*" - Medtech Insight, 30 Dec, 2016.)

"When considering compliance and enforcement priorities, FDA may consider the benefits of the device, and those benefits may include the effect of the device on the treatment plans and survival; the degree to which the device is beneficial or effective; likelihood of experiencing a benefit and the longevity of the benefit; patient preference; caregiver or clinician benefit, such as improved patient outcomes or clinical practice; and the availability of alternative devices," Chase says.

Chase is compliance practice director for Lachman Consultant Services, a firm she joined in June 2016 after spending 16 years at FDA, where she was also an investigator, medical device specialist and supervisory investigator.

FDA's benefit-risk guidance "provides insight into what the agency will expect to know when making their prioritization decisions and allows you to prepare in advance to provide a strong response should one become necessary," she said. "As is the case for success in almost all regulatory and compliance endeavors, preparation is the key. Keeping up with the FDA's changing ideas about what data should support submission, approvals, compliance and enforcement will help place you one step ahead of your competition."

Listen to the podcast via the player below:

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