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Food, Drug And Device Law Alert - FDA Finalizes Guidance On Benefit-Risk Factors To Consider Regarding Medical Device Availability, Compliance, And Enforcement

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The Food and Drug Administration (FDA) recently issued a final guidance titled “[Factors to Consider Regarding Benefit-Risk in Medical Device Availability, Compliance, and Enforcement](#).” The guidance is largely unchanged from the draft version released in June.

More specifically, the guidance states that the FDA has the authority to limit the availability of violative medical devices and to pursue other compliance and enforcement actions related to violative medical devices. The agency recognizes, however, that to protect and promote public health, decisions regarding these actions should be made while focusing on the impact on patients.

The guidance notes that failure to consider the short-term and long-term impact of noncompliance could result in regulatory actions with unintended adverse effects (e.g., shortage of medically necessary devices like the seemingly frequent drug shortages).

The FDA states that in assessing benefit-risk factors for purposes of medical device product availability, compliance, and enforcement decisions, it will consider “relevant and reliable evidence and data available to the Agency at the time of a decision – including reliable patient preference information from a representative sample – on a case-by-case basis, to help ensure that informed and science-based decisions are made to the greatest extent practicable.”

This guidance then identifies and seeks to clarify the benefit and risk factors the FDA will consider when faced with decisions relating to the device availability, compliance and enforcement. The benefit factors include:

- Type of benefit(s) – examples include the effect of the device on patient treatment plans and quality of life; impact on survival; and how much the medical device can aid in improving patient function, preventing loss of function, or providing relief from the symptoms of the disease or condition that the medical device is intended to treat
- Magnitude of the benefit(s)
- Probability of the patient experiencing one or more benefit(s)
- Duration of effect(s)
- Patient preference on benefit

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Lynn C. Tyler, M.S.

Partner
Indianapolis

P 317-231-7392
F 317-231-7433
lynn.tyler@btlaw.com

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- Benefit factors for healthcare professionals or caregivers – whether the device improves the way HCPs or caregivers care for patients
- Medical necessity – whether there are alternative devices

The FDA also considers several risk factors individually and in the aggregate:

- Severity, types, number and rates of harmful events associated with the use of the device
 - Device-related death or serious adverse events
 - Device-related non-serious adverse events
 - Device related events without reported harm
 - Duration of harm
- Probability of a harmful event
- Probability of the patient experiencing one or more harmful event(s)
- Number of patients exposed
- Nonconforming product risks - whether nonconforming devices have been distributed and if so, how many
- Duration of exposure to population - the length of time between initial patient exposure to the device and the point at which the risk of harm is successfully addressed
- False-positive or false-negative results - important risk factors for diagnostics
- Patient tolerance of risk
- Risk factors for healthcare professionals or caregivers – whether the risk may have an adverse impact on the clinician or caregiver.

One difference from the draft version is that the final version states that it relies on the definitions for serious injury and malfunction from 21 C.F.R. Part 803.

The guidance also identifies a number of “additional factors” that FDA considers when assessing the availability, compliance, and enforcement decisions for a violative device, including:

- Uncertainty - the degree of certainty of the benefits and risks of a device. The final guidance expands on the draft version by adding that (1) the type of clinical information available (e.g., clinical trial data, real world evidence derived from registries or commercial experience), (2) the degree to which the available information is representative (sample size, generalizability of the sample to the population exposed to the device), and (3) the statistical inferences and limitations that can be drawn from the information, are all issues that may inform the assessment of uncertainty.

- Mitigations - actions taken by the manufacturer, FDA, or other stakeholders to recover benefit or limit risk or harm
- Detectability - whether a nonconformity could be identified, either by the manufacturer or by the user
- Failure mode - the specific method or type of failure
- Scope of the device issue - whether the risks identified are inherent to similar devices of the same type
- Patient impact is the impact on the health and quality of life of patients if a particular compliance or enforcement action is, or is not, taken
- Preference for availability - whether patients and caregivers would prefer to have access to the device relevant to the nonconformity or regulatory non-compliance and whether patients and caregivers adequately understand related benefits and risks
- Nature of violations/Nonconforming product - whether the violation was systemic or non-systemic in nature as well as the extent of any product nonconformity
- Firm compliance history - the manufacturer's regulatory history and initiative in identifying and correcting issues, the repetitiveness of such issues, and the manufacturer's communication with FDA

Finally, the guidance discusses a number of specific examples of application of these various factors. The final version adds one hypothetical to the draft version.

As always, it is important to recall that FDA guidance documents do not have the force of law, but rather represent the FDA's current thinking on a topic.

A copy of the guidance can be [found here](#).

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device Group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; Beth Davis at (404) 264-4025 or beth.davis@btlaw.com; or Alicia Raines Barrs at (317) 231-7398 or alicia.rainesbarrs@btlaw.com.

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