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ALERTS

Food, Drug And Device Law Alert - FDA's Final Guidance Restricts Sharing Patient-Specific Information

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The Food and Drug Administration (FDA) recently issued a brief final guidance titled "Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request" in order "to clarify [its] position regarding manufacturers appropriately and responsibly sharing 'patient-specific information'…"

The final guidance defines patient-specific information as "information unique to an individual patient or unique to that patient's treatment or diagnosis that has been recorded, stored, processed, retrieved, and/or derived from a legally marketed medical device." For purposes of the final guidance, patient-specific information does not include any interpretations of data aside from those interpretations of data normally reported by the device to the patient or the patient's healthcare provider.

The final guidance places two limitations on providing patient-specific information to patients: (1) the patient must request the information and (2) "[a]ny labeling is subject to applicable requirements in the FD&C Act and FDA regulations." As to the latter point, the guidance notes the FDA is aware that when medical device manufacturers share patient-specific information with patients, they may also "provide them with supplemental information or other materials (e.g., descriptions of intended use, benefit and risk information, instructions for use) that may be considered labeling."

Further, the guidance states that if a manufacturer provides patient-specific information to a patient, the information provided should be "comprehensive and contemporary," i.e., the most recent data on the device. The FDA also recommends that "manufacturers advise patients to contact their healthcare providers should they have any questions about their patient-specific information."

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or the chair of the firm's Food, Drug and Device Practice Group, Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com.

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