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James Boiani Quoted in "FDA Final Guidance on Drug/Device Classifications Misses the Mark, Attorneys Say"

Medtech Insight

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James A. Boiani, a Member of the Firm in the Health Care and Life Sciences practice, in the firm's Washington, DC, office, was quoted in *Medtech Insight,* in "FDA Final Guidance on Drug/Device Classifications Misses the Mark, Attorneys Say," by Michael Cipriano. *(Read the full version – subscription required.)*

Following is an excerpt:

US FDA's final guidance on the classification of products as drugs or devices contains some useful clarifications for industry, but experts remain concerned that the guidance contains too much room for the agency to continue its tendency of classifying products under the more heavily-regulated drug pathway. ...

James Boiani, an attorney at Epstein Becker & Green, said in an interview that the final guidance "provides some helpful general principles with regard to thinking through the line between drugs and devices."

Still Room For Bias?

Boiani specifically points to a query included in the "frequently asked questions" section of the guidance, asking how a product is classified if it meets the definition of a drug and a device.

FDA answers that generally, "the product would be classified as a device, unless it falls within a special category (for example, apparatuses used in the preparation of compounded positron emission tomography drugs are classified as drugs, see 21 USC

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321(ii)).”

Boiani says that the term “special category” is “a bit nebulous.” He says it should ideally be replaced with a policy that classifies products that fit the definition of devices as devices going forward.

Related reading:

October 18, 2017: *Pharma & MedTech Business Intelligence’s The Pink Sheet Daily*, “Combo Product Classification Guidance Doesn’t Fix All Existing Problems, Experts Say,” by Michael Cipriano. *(Read the full version – subscription required.)*