# FDA New Intended Use Regulation: Drug and device manufacturers face significant new risks associated with off-label use of their products

## "INTENDED USE" RULE PREDICTED EFFECTS:

Drug and medical device manufacturers in the U.S. have increased potential exposure in off-label promotion cases.

Manufacturers' communications about new uses of lawfully marketed products may not be safe harbored.

There are concerns in the life sciences industry that, in 2022, the FDA's new "intended use" rule will affect manufacturers' safe-harbored communications about new uses of lawfully marketed products in the U.S.

This follows the publication by the FDA, in August 2021, of a final rule amending its regulations defining "intended use." This amendment includes changes that expand the types of evidence that are deemed relevant to determining whether a lawfully marketed drug or device has a new intended use and whether a product is intended for use as a drug or device.

The implications for potential enforcement actions are significant: FDA, DOJ, State AGs, and private parties may assert a new intended use based on purely internal company conduct — for example, brand strategy documents that reflect off-label uses, a product design that makes an off-label use likely or maybe even possible, company-acquired data substantiating the off-label use and analyses of those data, or call plans that include specialists unlikely to prescribe or use the product on-label. On the basis of such evidence, the government could assert a misbranding violation under the theory that the labeling does not provide adequate directions for the new, off-label "intended use." And that could be true even absent direct communications about the off-label use between company representatives and prescribers or patients. DOJ and whistleblowers may, on this basis, take the position that manufacturers have caused the submission of materially false claims for payment to the federal healthcare programs in violation of the False Claims Act.

To assure the immediate implications of the final rule are adequately considered and enforcement risk is mitigated, life sciences companies should consider establishing a cross-functional, senior team representing the key risk management functions of the organization, along with appropriate input from the medical and commercial functions, to consider the degree to which the FDA's approach to intended use potentially affects non-promotional communications of the type that were historically regarded as categorically permissible.

Moving forward, specific proposed activities should be reviewed with a view specifically to assuring that the risk of enforcement under the new intended use definition is adequately considered. That enhanced review should include the company's lawyers in addition to its regulatory affairs personnel.

## TIPS FOR MITIGATING RISK UNDER THE NEW "INTENDED USE" REGIME:

- A senior team representing the key risk management functions of the company should consider the impact of the new rule on policies governing nonpromotional communications.

- Legal should be involved in reviewing new proposed activities to assure that the risk implications of the FDA's broader interpretation of intended use are adequately assessed.

**Contacts**
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