

Publications

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DOJ Launches New Civil Enforcement Branch with Implications for Regulated Industries

Key Takeaways

- **New DOJ Civil Division Branch Established:** The Department of Justice (DOJ) announced last month the creation of a new office within the Civil Division focusing on matters under the consumer protection and public health statutes.
- **Two Sections, Distinct Missions:** The Enforcement Section will pursue cases under consumer protection and public health statutes, while the Affirmative Litigation Section will bring suits against states, municipalities, and private actors that are alleged to have obstructed federal policies. The reorganization does not create new statutory powers but consolidates DOJ's affirmative litigation functions.
- **Immediate Relevance for Regulated Industries:** The Branch's early priorities signal increased scrutiny in areas where health care, consumer product practices and federal funding intersect with political or policy-driven enforcement. Companies operating in these sectors should evaluate compliance protocols and be prepared for a more active civil enforcement environment.

The U.S. Department of Justice has created a new civil litigation office aimed at ramping up proactive enforcement, with early priorities that signal direct implications for health care, pharmaceutical and consumer-products companies. On September 25, 2025, the DOJ announced the creation of the Enforcement & Affirmative Litigation Branch, a new office within the Civil Division. While the new office's scope is broad, its initial focus includes areas highly relevant to regulated industries — including health care providers, drug and device marketing, and consumer product labeling. The development reflects the DOJ's continued use of civil enforcement as a policy tool and may foreshadow more litigation activity with both regulatory and constitutional dimensions.

As described in DOJ's announcement, the Branch consists of two sections: the **Enforcement Section** — which will bring affirmative cases under statutes such as the Federal Food, Drug, and Cosmetic Act, Consumer Product Safety Act, and Federal Trade Commission Act — and the **Affirmative Litigation Section**, which will represent the United States in lawsuits against states, municipalities and private actors that allegedly obstruct or undermine the administration's policies.

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What This Means for Regulated Industries

This restructuring signals DOJ's commitment to dedicate more resources to proactive civil enforcement, potentially leading to an uptick in high-impact litigation affecting public health, consumer protection, and federal policy implementation. The Branch's creation also reflects the DOJ's continuing use of civil enforcement as a policy tool to advance administration priorities — complementing criminal investigations and amplifying oversight across regulated sectors.

For companies in the health care, pharmaceutical, and consumer-products industries, this development stresses the importance of ensuring marketing, labeling, and promotional practices comply with existing federal standards. The Branch's initial focus areas suggest increased scrutiny in these spaces, particularly where product communications intersect with public health or political attention. This focus also follows the administration's broader expansion of False Claims Act (FCA) enforcement as it relates to gender-affirming care. The administration has signaled that such cases will be a priority area for civil enforcement, aligning with its early-established White House initiatives on protecting minors and regulating federally funded medical practices.

How Companies Can Prepare Now

As DOJ shifts resources toward affirmative civil enforcement, companies should take practical steps to stay ahead of potential risk. Here's what organizations can do now:

- Review existing marketing, labeling and promotional protocols for alignment with federal law
- Monitor DOJ enforcement trends — particularly in politically sensitive or policy-adjacent areas
- Reassess compliance infrastructure to ensure it's responsive, well-documented and audit-ready
- Consult counsel proactively when risk areas emerge

In this environment, it is critical for organizations to maintain robust compliance protocols, monitor evolving enforcement priorities, and consider proactive engagement with counsel if potential issues are identified. Polsinelli's government investigations team has extensive experience and is ready to assist with addressing the government's investigation and enforcement priorities.