

Informal Announcements Are Reshaping FDA Regulations

By **Rachel Turow** (April 1, 2026, 1:23 PM EDT)

Over the past year, the U.S. Food and Drug Administration has embarked on a significant change from its traditional approach to regulatory policy.

Where once the agency's most consequential changes were channeled through the formal mechanisms of the Administrative Procedure Act — including notice-and-comment rulemaking, Federal Register notices and detailed guidance documents — today's FDA is increasingly making major policy pronouncements via press releases, podcasts, journal articles and, in some instances, social media.

The agency generally justifies this approach — sometimes coined podium policy — by citing to the need for speed and flexibility. And regardless of motivation, it is fundamentally altering the regulatory landscape for pharmaceutical and biotech companies and other stakeholders.



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From Federal Register to the Briefing Room: The Shift to Informal Channels

A number of the FDA's recent policy innovations provide a vivid illustration of this shift to informal policymaking. In June 2025, the agency announced the launch of the Commissioner's National Priority Voucher program — a fast-track review pathway for drugs aligned with national priorities — via a press release and a brief video featuring Commissioner Marty Makary.

Makary described the program, which offers one- to two-month reviews for qualifying drugs, as a commonsense approach to reducing inefficiencies. His announcement, however, did not provide much detail about the new program — such as the criteria for voucher allocation or the process for staff and public input — and the FDA has not followed the announcement with formal guidance or rulemaking.

Similarly, the FDA's decision to offer bonus payments to staffers who complete drug reviews ahead of schedule was rolled out in a staff presentation and subsequently reported in the press, rather than through formal policy channels.

The agency's stated rationale for bonus payments was to "recognize and reward staff who find ways to be more efficient." But the concept of bonus payments to staffers appears to depart from the FDA user fee process set forth in the Prescription Drug User Fee Act commitment letter and ratified by Congress, through which the FDA and industry negotiate and agree on how industry user fees are spent to support the drug review program.

And, without formal guidance or rulemaking to explain the bonus pilot, industry stakeholders have been left to wonder how the FDA is implementing it and how it aligns with the allocation of PDUFA dollars in the commitment letter.

Finally, the FDA's perhaps most consequential announcement this year — a move to make a single pivotal trial the default standard for most drug approvals — was announced in a two-page *New England Journal of Medicine* article co-authored by Makary and outgoing Center for Biologics Evaluation and Research Director Vinay Prasad, published on Feb. 18.

This change, which upends decades of regulatory precedent, was described as a means to reduce drug development costs and accelerate access. While these may well be benefits of the new policy, the absence of a detailed, consultative process has left industry guessing as to when this expedited development plan can be used and when FDA will still require two trials for approval.

The Value of Traditional APA Pathways

Efficiency and modernization are legitimate goals, particularly in the context of rapidly evolving science and urgent public health needs. But while the Administrative Procedure Act's formal rulemaking and guidance processes may at times seem to impose bureaucratic hurdles, they also serve essential legal and practical functions: ensuring transparency, enabling public participation and providing a durable administrative record.

Notice-and-comment procedures allow stakeholders — including industry, patient groups and the broader public — to weigh in on proposed changes, surfacing potential unintended consequences and building consensus. Formal guidance documents, published in the Federal Register and subject to public review, offer a clear, authoritative source for regulated entities to understand agency expectations.

These processes also confer legal durability. Policies adopted through APA-compliant channels are less vulnerable to reversal by future administrations and are more likely to withstand judicial scrutiny. They create a stable regulatory environment in which companies can make long-term investments with confidence that the rules of the road will not shift overnight.

The Industry Burden: Navigating a Fragmented Policy Landscape

For pharmaceutical companies and other regulated stakeholders, the proliferation of informal policy channels has created a new and significant burden. Where once a diligent review of the Federal Register and FDA guidance portal sufficed to stay current, companies must now monitor a wide array of sources: press releases, podcasts, journal articles, social media posts and media appearances by senior FDA officials.

This fragmentation complicates both regulatory compliance and strategic planning and forces companies to devote additional resources to regulatory intelligence, legal analysis and risk management — costs that ultimately may be passed on to patients and payors.

Moreover, the absence of formal guidance may lead to inconsistent application across therapeutic areas and review divisions. And, while long review times and complex review cycles may be subject to valid criticism, regulatory certainty is also recognized as a key driver of innovation. Its erosion may have an unintended chilling effect on investment and development, particularly for smaller companies less able to absorb regulatory risk.

Policies announced outside traditional APA channels also may be more vulnerable to reversal or challenge. The lack of public input and documented rationale for such policies may make it easier for future administrations to rescind or reinterpret them, potentially leaving companies stranded mid-development.

And, as a practical matter, without a formal administrative record, it is more difficult for companies to rely on such policies — even during the current administration — in regulatory submissions, litigation or business planning.

Finally, the absence of clear guidance also complicates global regulatory harmonization — which minimizes costs and burdens for industry — as other jurisdictions may be reluctant to follow U.S. precedents set by policies that are perceived as informal or potentially transient.

The Stakes for Industry and the Path Forward

The FDA's recent embrace of podium policy reflects a genuine, valid desire to modernize and accelerate drug regulation in an era of scientific and public health urgency. Yet, the shift away from APA-compliant pathways may lead to potentially significant unanticipated by-products, including diminished transparency, increased industry burden and the prospect of reduced policy durability.

For attorneys and regulatory professionals, the stakes are clear. As the FDA continues to experiment with new modes of communication and policy development, industry and the legal community will need to develop new ways to adapt and strategize in response.

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