



Wow! Or Yeow?! 2026 Summary

Kinexum's 9th annual Wow! or Yeow?! FDA Year in Review and a Look Ahead was streamed on January 30, 2026. **Zan Fleming**, founder and executive chairman of Kinexum and former Supervisory Physician at FDA, moderated the panel.

The session opened with **David Fox**, partner at Hogan Lovells and former FDA Associate Chief Counsel, who provided a data-rich overview of FDA activity in 2025. He emphasized that, despite political turbulence, overall drug approval numbers aligned with historical averages. He noted an increase in CBER decisions, including approvals and Complete Response Letters (CRLs). He concluded by mentioning drops in the development of vaccines and cell and gene therapies.

Frank Sasinowski of Hyman Phelps then described 2025's key rare disease approvals. He began with Forzinity, a drug for Barth disease, as an application of the new FDA Plausible Mechanism Pathway, which accelerates approval of gene therapies for rare, severe genetic diseases with well-characterized etiologies. He then described two other approvals that used this pathway: Kygevvi and Vykat XR. Lastly, he counteracted the assumption that CBER had reduced accelerated approvals.

Steven Grossman, former long-term Director of the Alliance for a Stronger FDA, then delivered a wide-angle assessment of the FDA's cultural drift. He warned of an erosion of science based, bottom-up decision making. He pointed to FDA's reduced reliance on advisory committees and its policymaking by press release as structural threats to transparency and institutional trust.

Peter Stein, former Director of the FDA CDER Office of New Drugs, provided a nuanced counterweight. He stressed that most FDA staff are still operating as always. Nonetheless, he agreed that politically driven decisions exert disproportionate damage by unsettling staff who expect scientific independence. Peter reemphasized that bottom-up review culture is foundational to FDA integrity, and warned that top-down interventions, diminished advisory committee usage, staff losses, and resource strain compromise the time and deliberation necessary for rigorous scientific review.

Timothy Franson, Principal at Faegre Drinker Biddle & Reath and former VP of global regulatory affairs at Eli Lilly then outlined the "three-legged stool" of public health: development, surveillance, and prevention. He emphasized that drastic changes to surveillance systems or prevention infrastructure inevitably shift pressure onto the development leg, making strong therapeutic pipelines essential buffers against system instability. Franson argued that FDA programs and incentives supporting antimicrobial development, vaccines, pediatric therapies, and emergency countermeasures become even more vital when upstream public health measures erode.

Frank Sasinowski returned to highlight growing disruption caused by FDA's public release of CRLs. He described the longstanding "rhythm" of FDA-sponsor interactions and warned that the publication of CRLs—often written as exhaustive lists of criticisms—creates litigation risks, misleads investors, and distorts regulatory intent. **David Fox** argued that the *timing* of publication is the issue, as the CRL is only part of the series of interactions between a sponsor and FDA and thus lacks necessary context.



Jodi Scott, device expert at Hogan Lovells, shed light on recent developments in CDRH and on the use of artificial intelligence at FDA as a whole. She noted the recent influx of applications for devices with AI components. She then described how FDA is integrating AI into the fabric of regulatory oversight, including risk-based inspection targeting and enhanced adverse event signal surveillance. She also mentioned the evolution of quality management systems, which traditionally focused on hardware but now must account for software development.

Ricardo Carvajal, a food law expert at Hyman Phelps, connected changes in FDA food regulation to those in the medical sphere. He highlighted the willingness of current FDA leadership to bypass procedural requirements in pursuit of priority initiatives. He reminded the panel that FDA created the Good Guidance Practices (GGP) regulation to prevent policymaking by speeches, press releases, and other informal communications. He noted that recent actions, including FDA's approach to synthetic colors, contradict GGP, demonstrating the top-down approach also noted by previous panelists in the medical space.

The session concluded with an exchange on the role of Congress in regulating FDA. **Steven Grossman** spotlighted institutional barriers to regulation, including FDA's recent lack of transparency. **David Fox** emphasized that Congress is likely to include significant additions to PDUFA by the time it is reauthorized in September 2027. He mentioned the THRIVE Act, drafted by the Kitalys Institute to facilitate the development of interventions promoting healthy longevity, as a potential future addition to PDUFA. **Frank Sasinowski** predicted that Pediatric Priority Vouchers would be another hot topic during PDUFA reauthorization.

Following the close of the main session, the panel continued to informally discuss related topics before the portion of the audience that remained. **Frank Sasinowski** discussed how top-down decision making had led FDA to allow approvals based on single trials with confirmatory evidence and to the creation of National Priority Vouchers. **Peter Stein** argued that the precedent for a single trial with confirmatory evidence was set in 1997 and requires the sponsor to meet rigorous criteria. He agreed with **Steven Grossman's** opinion that this pathway is not appropriate in all cases. **Zan Fleming** added that safety endpoints are generally less suited to the pathway than efficacy endpoints. **David Fox** predicted that, under the current administration, a broader range of products would be approved with this pathway, and products for non-life-threatening conditions would become eligible. **Peter Stein** believed that rare diseases would be the largest benefactors.