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Investors Prepare to Navigate FDA Crosswinds Ahead of the J.P. Morgan Healthcare Conference

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Troutman Pepper Locke partners Chris Miller and Judy O'Grady sit down to discuss recent policy shifts at the FDA and what they mean for life sciences investors attending the 44th Annual J.P. Morgan Healthcare Conference on January 12th.

It's that time of year again: JPM Week in San Francisco, California. As one of the largest health care conferences in the world, industry decision-makers will come together to pressure?test business plans, preview pipelines, and explore fresh investment opportunities across the sector.

In a year defined by rapid policy evolution, the FDA regulatory landscape will inevitably be top of mind for life sciences investors. With significant changes and even more uncertainty, investors must translate policy shifts into diligence, valuation, and deal strategy to mitigate risk and capitalize on new market opportunities.

Changes at the FDA

Over the past year, there have been multiple changes in leadership within the FDA. With new leaders often come new priorities, and shifting positions must be accounted for when evaluating risk, R&D timelines, and deal structures.

Many products moving towards the end-stages of approval are still operating under developmental plans and trial designs that the FDA blessed prior to 2025. Previously, it was standard practice for the FDA to ratify existing trial designs at final approval if the results from the study were statistically significant, provided there were no new safety concerns.

But recent FDA activity suggests these plans may be provisional and subject to change, notwithstanding the FDA's original sign-off on the trial design. On more than one occasion last year, life sciences companies that expected final FDA approval instead received Complete Response Letters, with the FDA expressing concerns with the initially endorsed study design.

There have also been changes in long-held standards for program timing. In some cases, the FDA has struggled to consistently meet Prescription Drug User Fee Act (PDUFA) and other key dates, further complicating investor

expectations around timing.

With the possibility of more leadership changes and agency pivots, investors are likely to feel impact on valuation assumptions, exit timelines, and the perceived risk profile of late-stage assets.

Expedited Pathways

Several emerging and evolving FDA mechanisms are attracting heightened attention from investors. These tools could be powerful catalysts for development, but they also come with their own risk.

Priority Review Vouchers (PRVs) have sparked particular interest in the industry, promising accelerated review timelines of one to two months, versus the standard six to 10. However, details related to voucher-related approvals have been limited so far. Despite the promise of significantly accelerated time to market, investors should proceed with caution until FDA demonstrates consistency with PRV timeframes and greater transparency regarding the PRV process. While the program could provide significant upside, some have questioned the legality of the new PRVs. Overall, there are too many unknowns for one of the new PRVs to be the core foundation for regulatory strategy and valuation.

For AI- and ML-based products, the FDA finalized its guidance on Predetermined Change Control Plans (PCCPs), which are structured frameworks that allow certain algorithm updates without requiring a full new submission. In theory, this should reduce regulatory roadblocks for updates and propel AI advancements. However, there will still be costs for investors, and the costs may add up in other ways. For example, the FDA will expect adequate data, monitoring, and quality systems under these plans and FDA's approach to PCCPs is still evolving in the AI space.

The administration has also expressed support for adaptive study designs and single-arm trials to accelerate gene and cell therapies, particularly where there is unmet need. Considering these therapy programs often offer investors significant potential upside, additional flexibility in clinical trial design could further reduce time to market and give valuations a boost. However, it's important to consider additional post-market commitments that may be required.

Investor Playbook for 2026

As investors head into JPM Week and begin to sharpen their 2026 strategies, the current FDA environment calls for a more flexible, forward-leaning approach to regulatory risk and opportunity.

1. **Re-engage with the FDA to Confirm Alignment.** Consider whether to push for re-engagement with the FDA to confirm its current position regarding proposed trial designs, endpoints, and statistical frameworks, or alternatively, be prepared for the possibility of unanticipated roadblocks on the path to approval.
2. **Prepare for Potential Delays.** Potential timing and approval delays should be built into valuation models. Investors should also consider whether there is sufficient runway to absorb regulatory slowdowns.
3. **Prepare a Credible "Plan B."** A contingency plan is essential to risk-mitigation strategy. Investors should look for alternative data strategies, such as analyses of subpopulations with existing study data, as well as proposed workarounds if things don't go as planned.
4. **Leverage Expedited Programs with Caution.** Consider how expedited programs could improve time to market, but be cautious about building them into your initial assumptions. Evaluate how regulatory roadmaps and time to market may be impacted if a planned expedited pathway does not come to fruition.

Conclusion

For life sciences investors, the FDA's current regulatory posture offers both challenges and opportunities. Moving into 2026, life sciences investors should prepare for regulatory volatility, as well as recalibrate strategies to capitalize on new opportunities.

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