HEADWINDS & TAILWINDS FOR DRUGS & BIOLOGICS MANUFACTURERS IN 2023

Drugs & Biologics

Tailwinds

- Implementation of recent provisions that modernize the accelerated approval program may help address uncertainty [CAA23]
- Recent protection of imaging drugs from reclassification preserves regulatory certainty [CAA23]
- Decreased competition for HCT/P companies that successfully navigate FDA approval
- Orphan drug approval and exclusivity for an entire disease—rather than a subset of patients—through the Catalyst decision presents a win for companies seeking such exclusivity
- Establishment of the Emerging Technologies Program by Congress to facilitate drug design and manufacturing innovation could create substantial opportunities for new manufacturing technology and service providers to assist in re-shoring and may be a boon for companies developing new manufacturing technologies and for drug and biologic manufacturers due to potential reductions in R&D and manufacturing costs [CAA23]
- Establishment of a new biosimilar pipeline [IRA]
- Emerging efficiencies gained from the rapid innovation during the COVID-19 pandemic (e.g., fast reviews, virtual inspections) may help bring products to market more quickly
- Reduced legal risk and financial implications for value-based pricing arrangements with commercial customers due to regulatory developments that create the ability to report a distinct Medicaid Best Price for value-based arrangements
- Advanced digital and analytics tools that better enable data capture of real-world evidence will facilitate negotiation of value-based pricing arrangements with commercial customers for higher-value therapies
- Multi-year delay in the effective date of the drug rebate rule reduces pressure to abandon rebating practices in lieu of purchase price reductions [IRA]
- Greater certainty regarding the contours of the impending drug pricing reforms of the IRA enables strategic decision-making regarding realignment of product portfolios and pricing and contracting strategies [IRA]
- Legal and financial risks relating to Medicaid Best Price have been significantly reduced by a successful outcome in industry litigation challenging CMS' attempted revision of the Best Price exclusions for certain patient assistance programs

Headwinds

- Continuing shadow of the Makena withdrawal proceedings may discourage use of the accelerated drug approval pathway
- Emerging and potential impacts of the Genus decision on regulatory protections and reimbursement if certain drugs are reclassified as devices
- Significantly increased regulatory burdens for companies that must now invest in clinical trials to support approval of tissue-derived human cells, tissues, and cellular and tissue-based products (HCT/Ps) as biologics, when such HCT/Ps did not previously require FDA approval
- Potential adverse impacts of Catalyst court decision on orphan drug development since Congress did not reverse the Catalyst decision—despite FDA's push for reversal
- Potential increased scrutiny of manufacturers—particularly located outside the U.S.—due to manufacturers' reliance on sources outside of the U.S. for medications and raw materials due to COVID-related product shortages
- Increasing pricing pressure on high Medicare-spend specialty drugs in anticipation of implementation of the IRA's Medicare negotiation provisions, which will establish maximum fair prices for certain Part D drugs starting in 2026 and Part B drugs in 2028 [IRA]
- Increased pricing pressure primarily on older products due to the IRA's requirement that manufacturers pay a rebate when Parts B/D drug prices rise faster than inflation [IRA]
- Additional financial pressure if upcoming increases in manufacturer liability during the catastrophic Part D phase result in higher manufacturer costs when implemented in 2024
- Manufacturer patient assistance programs may not effectively safeguard patient access to drugs due to increased adoption of co-pay maximizer programs by health plans and caselaw that reaffirms the fraud and abuse risks for provision of such support to federal health care program beneficiaries
- Growth of 340B drug discount program and uncertainty regarding the ability to limit 340B covered entity use of 340B drugs
- Increasing risk of erosion of confidential commercial pricing under state-level drug price transparency laws
- Continued scrutiny of pharmacy benefit management tactics by the Federal and state governments will maintain a spotlight on use of rebating practices in lieu of purchase price reductions, despite delay of the drug rebate rule such practices [IRA]

CAA23 = The Consolidated Appropriations Act, 2023
IRA = The Inflation Reduction Act

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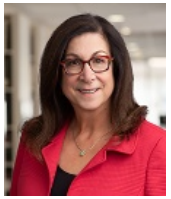

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