HEADWINDS & TAILWINDS FOR FDA-REGULATED INDUSTRIES IN 2023
(EXLUDING DRUGS AND BIOLOGICS)

Devices & Diagnostics

Tailwinds

- Congress' failure to pass the VALID Act allows labs to continue serving as innovation incubators and compete favorably against IVD manufacturers or be considered attractive acquisition targets by IVD manufacturers [CAA23]
- New CDS guidance could drive developers to FDA and create regulatory moats that limit competition to companies succeeding through FDA process
- The Biden administration signaled renewed interest in creating an expedited pathway for Medicare coverage following its reversal of the Trump administration's initiative
- Recent 1-year extension of the transitional pass-through status for medical devices whose status would have ended on December 31, 2022
- FDA and Congress continue to facilitate the growing focus on devices for psychiatry and neurology
- Recent guidance clarifies that FDA's existing digital health policies continue to apply to software functions that meet the definition of a device

Headwinds

- Congress' failure to pass the VALID Act for FDA regulation of lab-developed tests (LDTs) maintains lack of parity in LDT and in vitro diagnostic (IVD) development [CAA23]
- FDA Clinical Decision Support (CDS) guidance attempts to restrict unregulated software, potentially hindering CDS innovation
- New authorities permitting FDA to issue a use-specific ban on a medical device may increase agency scrutiny of off-label uses of medical devices by healthcare professionals [CAA23]

Vaccines

Tailwinds

- Major pandemic preparedness legislation likely to be introduced during the next Congress to strengthen the Medical Countermeasures Enterprise
- Likely proliferation of new respiratory vaccine launches (RSV, flu, COVID-19, pneumococcal)
- Potential increased vaccine uptake due to certain Part D cost-sharing elimination provisions under the IRA starting in 2023

Headwinds

- Impending investigations related to the COVID-19 response may inflame anti-vaccine sentiment amid already declining COVID-19 and flu vaccine uptake
- High-volume, low unit cost vaccine products are likely to come under scrutiny through Part B price negotiation provisions of the IRA
- Recent litigation indicates manufacturers, distributors, providers, and facilities involved in the COVID-19 and monkeypox responses may still face liability under state tort law, despite the presumed protection from liability under the PREP Act

Clinical Trials

Tailwinds

- Industry's growing reliance on decentralized trials creates opportunities for technology-enabled clinical research services vendors and tech vendors
- Potential regulatory flexibilities for entities with innovations that can support FDA's focus on improving diversity in clinical trial populations and for service providers that facilitate identification and enrollment of diverse populations
- Growing FDA acceptance of the use of technologies—such as AI-generated "digital subjects" and real-world evidence data mining—to reduce trial costs over the coming years may help tech innovators and life sciences manufacturers

Headwinds

- FDA's growing push for diversity may increase regulatory burdens and the complexity of clinical trials for manufacturers
- Increasing FDA pre- and post-market data demands drive up expenses for drug, device, and biologics manufacturers

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

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