HEADWINDS & TAILWINDS FOR AI AND DIGITAL HEALTH IN 2023

Artificial Intelligence (AI) Tools

Tailwinds

- Growing opportunities for AI companies to creatively innovate using data to improve diagnostics, support clinical care, and increase workflow efficiency
- Increasing ability for companies that bring AI products through the U.S. Food & Drug Administration (FDA) clearance process to protect products by building a regulatory moat and using marketing and regulatory maneuvers to attack competitors' unapproved products
- Emerging opportunities to create efficiencies in drug development and clinical trials through AI

Headwinds

- Increased focus from the U.S. Department of Health & Human Services on ensuring non-discrimination in the development and use of AI
- Escalating enforcement activity from the U.S. Federal Trade Commission addressing the misuse of data for training AI
- Increased regulatory complexity due to additional transparency requirements related to AI by state-based and international privacy laws

Digital Health

Tailwinds

- Promising data indicates high efficacy of certain digital health therapeutics (DTx) could eventually replace the need for traditional pharmaceutical and/or professional services in specific cases
- Growing interest in introducing legislation to permit direct Medicare reimbursement for DTx could accelerate investment and success of DTx
- Broadening opportunities for intellectual property protections (e.g., method of use patents) and market protections (e.g., Orange Book Listings, 3-year market exclusivity) for DTx used in combination with drugs and biologics
- Increased regulatory clarity with confirmation that existing FDA digital health policies continue to apply to software functions that meet the definition of a device

Headwinds

- Aggressive state-level enforcement against electronic prescribing, particularly for controlled substances
- Growing FDA interest in expanding regulatory and enforcement oversight as the industry advances
- Recently issued FDA guidance imposes premarket regulatory requirements for clinical decision support tools

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