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## FDA Update: Recent Trends and a New Regime

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Norman E. (Ned) Sharpless, M.D., recently took the helm as Acting Commissioner of the US Food and Drug Administration (FDA). Dr. Sharpless most recently served as the director of the National Cancer Institute, part of the National Institutes of Health (NIH), which serves as the government's principal agency for cancer research. Dr. Sharpless's appointment comes on the heels of the resignation of former Commissioner Scott Gottlieb, M.D. on April 5, 2019.

Dr. Gottlieb was an agent for change at the FDA. He led initiatives in combating the opioid crisis, curbing the marketing of e-cigarettes to youth, promoting innovative pathways for Digital Health, reducing drug prices by promoting generic competition, and accelerating approvals of new drugs. Dr. Gottlieb was an active user of social media and published numerous press releases to garner attention and support for his initiatives.

Dr. Sharpless no doubt will create an agenda of his own. Given his background in cancer research, he likely will forge ahead with some of Dr. Gottlieb's initiatives—particularly in accelerating approvals of drugs and biologics for oncology indications and promoting the development of gene and cell therapies. He also likely will continue to deter the marketing of tobacco products to kids by, for example, wielding the agency's enforcement powers. Sharpless also has expressed interest in big data—i.e., harnessing the power of analytics on large data sets—to inform healthcare decisions, and we may expect to see continued initiatives to collect real-world evidence globally.

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