New Acting FDA Commissioner Sharpless: 4 policy issues to watch

FDA Alert
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With Dr. Scott Gottlieb's departure as FDA Commissioner, new Acting Commissioner Norman (Ned) Sharpless (formerly the Director of the National Cancer Institute) will inherit a number of high-profile, ongoing initiatives. It is yet to be seen how Commissioner Sharpless will seek to move these initiatives forward, and whether his current status as acting Commissioner (rather than a permanent, Senate-confirmed Commissioner) will impact his ability, politically, to drive change in these areas.

HHS Secretary Alex M. Azar has stated that there will be "no let up" in FDA's focus.

Given this indication of ongoing commitment from Secretary Azar, among the most pressing and high-profile issues to watch are opioid regulation; drug pricing; clinical trial reform; and e-cigarettes and youth vaping.

Opioids. This is one issue that is highly likely to continue to receive active attention from Acting Commissioner Sharpless, given the public health impact of opioids in the United States, and the continued political and media attention the topic has received.

Shortly before he departed the agency, Dr. Gottlieb announced that FDA will shortly be releasing a plan for new opioid packaging requirements, which likely will mandate that immediate release opioid products be packaged and
distributed in blister packs "to rationalize dispensing and prescribing." FDA has also recently proposed to require that any new opioid products be shown to be superior to existing opioid products in order to obtain FDA approval.

The transition to new agency leadership is unlikely to materially delay progress in these areas. Similarly, the FDA's recent initiative involving randomized opioid withdrawal studies to assess whether opioid efficacy declines with chronic use is likely to proceed apace, as is the planned collaboration with the National Academies of Science to develop evidence-based opioid prescribing guidelines.

**Drug pricing.** FDA has little direct statutory authority to control or influence drug pricing (for a detailed overview of FDA's role and limitations with respect to drug pricing, see this page). But under Dr. Gottlieb, FDA took a number of steps intended to indirectly reduce the costs of prescription drugs for patients, primarily by seeking to increase competition and improve the timing and efficiency of the generic drug and biosimilar approval processes, and by coordinating closely with the Department of Health and Human Services to implement other elements of the President's drug pricing blueprint, *American Patients First.*

While Dr. Gottlieb's efforts at enhancing generic competition during his tenure as Commissioner came as a surprise to some (because of his prior close ties to the innovator pharmaceutical industry), Dr. Sharpless's positions and plans regarding generic competition are not well known at this point. And with respect to implementation of the drug pricing blueprint, Dr. Gottlieb's longstanding professional and personal relationship with Secretary Azar certainly made for an effective working dynamic. Secretary Azar has publicly expressed admiration for Dr. Sharpless's background and expertise. The working dynamic that develops between these two public health leaders is yet to be seen.

**Clinical trial reform.** Dr. Sharpless and Dr. Gottlieb are reportedly of the same mind regarding the need for transformative change in how the clinical trial process operates, and the acting commissioner is likely to continue to push forward with several pending FDA Guidances meant to streamline and expedite the development of innovative new drugs and biologics and bring important therapies to patients more efficiently. Dr. Sharpless has previously been involved in initiatives to promote creative approaches to trial design rather than relying solely on conventional methods. In addition, Dr. Sharpless's perspective may impact the agency's further acceptance of "real world evidence."

**Vaping.** FDA faces a difficult conundrum with respect to e-cigarettes in that vaping has been viewed by many as less dangerous than traditional smoking, such that consumer transitions from "combustible" tobacco products to vaping are considered by some to be a change to a potentially less-harmful form of nicotine delivery. Yet at the same time, Dr. Gottlieb was very outspoken and assertive in his efforts to reduce what he characterized as an epidemic of vaping by teenagers.

Indeed, just last week Dr. Gottlieb reiterated the FDA's commitment to monitoring emerging health and safety information about e-cigarettes. This is consistent with earlier statements and an overall position that from the agency's perspective, additional regulations may be necessary in this area. The statements and position on e-cigarettes stands in contrast to the general deregulatory approach of the current Administration.

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