MEDTECH INSIGHT
CITELINE COMMERCIAL

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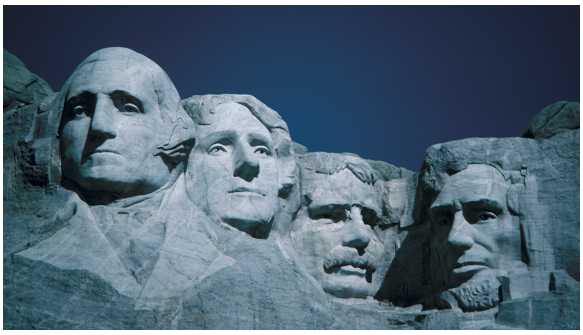
Immortalizing Janet Woodcock

by M. Nielsen Hobbs

Offering a regulatory Mt. Rushmore to place the outgoing principal deputy commissioner in historical context.

What more can you say about Janet Woodcock? The US Food and Drug Administration's principal deputy commissioner, who will soon be retiring after 37 extraordinary years at the agency, has meant so much to the agency and industry that it can seem hard to find the words to express our sentiments. Woodcock's departure isn't exactly a wedding or a funeral, but it remains a very emotional life event for many in the pharmaceutical family.

Pink Sheet's Sarah Karlin-Smith penned a masterful *2021 profile* and her story last year on the *news of Woodcock's retirement* offers more articulate and complete description of Woodcock's tenure and legacy, but at risk of dancing about architecture, I'm going to Photoshop about regulatory science and place her among the agency's Titans on a Rx version of Mt. Rushmore.



Of course, no comparisons are perfect, and using Mt. Rushmore – originally conceived as a tourist attraction and carved into land sacred to the Lakota Sioux by a confederate sympathizer – invites particular complications. Nevertheless, the mountain-sized presidential busts seem to match the scale of Woodcock's impact. Enjoy the image above and read about her monument-mates below.

Harvey Washington Wiley

Officially considered the first FDA commissioner,
Harvey Washington Wiley was in fact chief chemist in the U.S. Department of Agriculture, but he gets the designation because he was instrumental in passing the Pure Food and Drugs Act, and his tenure at the "agency," which did not yet have the FDA name, is dated from Jan. 1, 1907, when the law went into effect.

Least anyone think that judicial involvement in FDA decision-making is a recent phenomenon, "the use of saccharin, bleached flour, caffeine, and benzoate of soda were all important issues which had to be ultimately settled by the courts in the early days under the new law," FDA's biographical page for Wiley notes.

It is fitting that his middle name evokes the father of our country, and so Wiley gets the George Washington spot on our regulatory Rushmore.

Frances Oldham Kelsey

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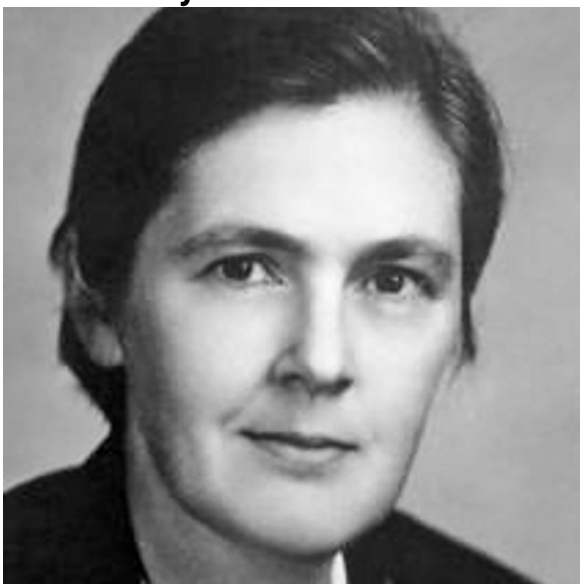

Washington on the actual Mt. Rushmore is Thomas Jefferson, his long-time compatriot and rival. There was no enmity between Wiley and Frances Oldham Kelsey, the legendary medical reviewer who takes the Jefferson spot in our regulatory monument, but they are best known for their different focuses: Wiley mostly for his tireless focus on food quality, and Kelsey for her success in preventing thalidomide from coming onto the U.S. market. The agency's food/drug divide can be clearly seen in their two careers.

Kelsey joined the FDA in 1960, and "one of the first applications she was assigned was for thalidomide, which was already available in dozens of countries around the world. Dr. Kelsey, despite constant pressure from the company, refused to approve the application because of its inadequate evidence," FDA said.

Thalidomide, of course, was soon found to be a significant teratogen, and the "impact of the near

disaster here helped to pass a pending bill that fundamentally changed drug regulation, the 1962 Drug Amendments," FDA said.

That law, the Kefauver Harris Amendment, did not address the safety issue that thalidomide raised directly, but created an efficacy requirement for new drugs, boosting the amount of data that sponsors would need to submit.

Kelsey would stay at the FDA for several more decades as the impact of the legislation her careful review helped spawn was fully felt. In the years that followed, submissions would become so voluminous that evaluations would slow under their weight. The resource strain would eventually become too great and industry would be asked to contribute user fees to provide FDA the resources that the agency needed to complete its drug reviews.

David Kessler

One might expect that Wiley could fill the Theodore Roosevelt spot on our monument, since it was during his presidency that the Pure Food and Drugs Act was enacted. But the TR slot goes to David Kessler, commissioner from 1990 to 1997. Teddy Roosevelt, a trust-busting Republican, managed a policy agenda that could seem contradictory to modern observers, just as Kessler was the last chief of FDA to span administrations of both parties.

Given that the commissioner is now a Senate-confirmed position, it seems unlikely there will ever be another cross-party commissioner, just as Teddy Roosevelt's Bull Moose campaign is probably the last high-water mark for third-party presidential candidate performance. There will never be another candidate, or a commissioner, with that kind of cross-cutting appeal again.

Roosevelt's muscular diplomacy set the stage for the American Century, just as Kessler's activist, review-focused, media-savvy tenure created the template for the modern FDA commissioner. He presided over the initial implementation of the user fee program and accelerated approval regulations, but also took high-profile enforcement actions against orange juice and tomato products for misleading uses of the term "fresh."

And like our 26th president was, Kessler is bespectacled.

Janet Woodcock

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Abraham Lincoln is at the far edge of Mt. Rushmore, and so is Janet Woodcock. Just as Lincoln is credited with saving the union, Woodcock can be said to have preserved FDA's drug review functions by fighting to modernize them. When she became director of the Center for Drug Evaluation and Research in 1994, sponsors would submit their NDAs in tractor-trailers full of paper. As she leaves FDA, it seems possible that products could eventually get supplemental indications based on real-world evidence generated from patients that sponsors never recruited.

Woodcock's critics see her focus on efficiency and flexibility as not worth the potential cost of letting possibly unsafe or ineffective drugs onto the market, just as Lincoln's reelection was endangered as the casualties from the Civil War mounted.

But just as Union industrialization and numerical superiority were critical to victory, among Woodcock's final projects is looking to extend data analysis and organizational efficiency into inspections, another reform spurred by a risky product – this time baby formula, not a drug.

Who Would You Carve In Stone?

No list is complete without a discussion of who was left off, and with only four slots to fill on regulatory Rushmore, there are many prominent FDAers left unchiseled.

For example, it does not seem to be just recency bias to say that both of President's Trump commissioners deserve consideration. Scott Gottlieb exhibited Kessler-esque energy and bipartisan appeal; Stephen Hahn held the agency together during the scientific and political tumult of Covid. But both had such relatively brief tenures that the stoney heights of our monument eluded them.

Janet Woodcock Retires From US FDA: 'I'm Trying To Tie Up All The Loose Ends'

By Derrick Gingery

26 Jan 2024

On the eve of departure after more than 37 years of service to FDA, the agency's principal deputy commissioner discusses her legacy, issues that others will take up, and preparing the agency for change in a Pink Sheet interview.

Read the full article here

WHO IS ON YOUR LIST?

Frances Kelsey, of course, is also just known for one big thing, but one that helped set FDA on a new path. That neither of the women on our version of Mt. Rushmore were a commissioner (though Woodcock was a long-term acting one) might also prompt a reconsideration. FDA has had two female commissioners, Jane Henney and Margaret Hamburg, whose tenures were full of accomplishments, but they did not transform the agency.

Walter Campbell, whose second tenure at the helm of the agency (1927-1944) included the initial implementation of the Food Drug & Cosmetics Act, would also seem to be a potential candidate.

Which FDAers would you put on the imaginary mountain top? Let me know who and why (email at top of article) – but keep in mind, the National Park Service says the façade cannot accommodate another bust, so if you want someone on, you are going to have to suggest who you want to take off.

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