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# Woodcock Takes On Rare Disease Challenges In Retirement, Keeps FDA, Industry At Arm's Length

by Sarah Karlin-Smith

Recently retired US FDA Principal Deputy Commissioner Janet Woodcock will be advising the **Haystack Project**, with the goal of helping rare disease organizations encourage creativity in drug development programs without jeopardizing regulatory success, Woodcock told the *Pink Sheet* in an interview.

Janet Woodcock's post-FDA plans are starting to take shape and include a new advisory role at the **Haystack Project**, a rare disease nonprofit.

The decision to join the organization, a coalition of ultra-rare and rare disease patient groups, is indicative of how she plans to spend her retirement.

"I have always tried to help patients," Woodcock told the ***Pink Sheet***. "I don't plan in my retirement to really have much involvement in drug development. But I do want to help the nonprofit side. Particularly people with rare diseases suffer so much and drug development is so difficult for them. And so, you know I want to help inany way I can."

Woodcock believes she can help rare disease groups navigate the delicate balance of determining how to craft drug development programs to meet their unique circumstances without jeopardizing their ability to get to market.

"My own belief is you cannot look people in the eye and say there's no way you'll ever have a therapy developed for you, except by accident or something, that just isn't right," she said. "So, we have to find a way to help people especially with ultra-rare diseases. But it takes a lot of effort

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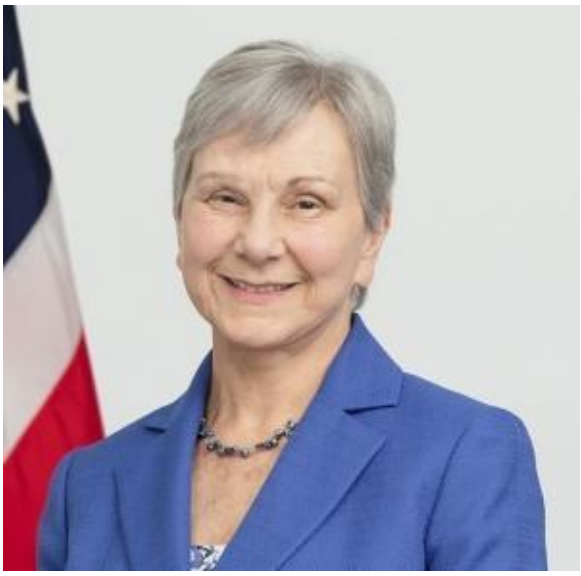
and creativity, but not too much creativity in the sense that you're not going to be successful getting through the regulatory process. So, I think it's that balance that I can help with."



Science, not advocacy, will be her focus, Woodcock added. She has been giving advice to several groups of "the same flavor:" patient-focused nonprofits that are tackling disease areas with few or no treatment options.

"I have been remarkably busy," Woodcock said, though laughed that some of that is due to a major gardening project.

Also on Woodcock's near-term agenda is a talk in Dublin, Ireland on improving pharmaceutical quality, and speaking to a group of female biotech executives.

But she does not plan to work directly with or represent any specific company, having previously indicated she has little desire to work inside the pharma industry. (Also see "*With Woodcock's Retirement, US FDA Loses A Renaissance Woman*" - Pink Sheet, 16 Nov, 2023.) **Haystack**, like many patient and disease-focused groups, does have industry partners and funding.

Woodcock also does not plan to directly interact with the FDA through her work at **Haystack** or other projects.

**Haystack** is focused on both the approval and postmarket access challenges faced by rare disease patients.

"Dr. Woodcock's guidance will help us prioritize efforts to ensure that patient-centered processes yield information that is not only useful, but used by reviewers, that out-of-date conflict-of-interest policies do not prevent review panels from receiving insight and information from disease-specific experts, and that review teams include individuals with experience in small population sciences, all long-time priorities for us," CEO Kara Berasi said in a statement.

"It is also unacceptable to bring new treatments to market and not have them reach the patients for whom they were intended," Berasi added. "**Haystack** was born almost 10 years ago out of a need to address the gap in patients' understanding of payer policies and practices that can, often unintentionally, keep rare and ultra-rare patients from receiving the care they need."