From: A Message from the Commissioner

o: <u>FDA-Wide</u>

Subject: OCC Personnel News

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From the Desk of the Commissioner



Dear Colleagues,

I want to share with you that Stacy Cline Amin will step down as Chief Counsel, effective today.

Stacy has led the Office of the Chief Counsel (OCC) since September 2018, working closely with the OCC deputies and serving as a trusted advisor to the Commissioner's Office and Center leadership.

During a time of unprecedented challenges at the FDA, Stacy has played a critical role in nearly every aspect of our COVID-19 pandemic response efforts, including record numbers of emergency use authorizations (EUAs), guidances, warning letters and enforcement actions. Most notably, she helped establish the guidelines that the FDA would follow to ensure our scientists could conduct independent, transparent, and science-based reviews of vaccine safety and efficacy. In addition, Stacy was a key leader to the teams responsible for the first two COVID-19 vaccine EUAs last year.

In addition to her pandemic work, Stacy has navigated difficult legal issues and litigation challenges across the agency's entire portfolio. In those efforts she has proven to be a skilled tactician and fierce advocate for the agency and for public health. She has defended the FDA's public health prerogatives in countless venues, both public and private, and has worked closely with the U.S. Department of Justice, Office of Management and Budget, and other interagency colleagues to advance the FDA's priorities.

In particular, Stacy has been instrumental in advancing our policies around food safety, e-cigarettes and the foundational Tobacco Control Act rules, medical device safety and innovation, the biologics transition, human gene therapy and regenerative medicine, animal and plant biotech, compounding, and opioids, to name just a few.

On a personal note, I will always be grateful to Stacy for her rigorous legal analyses and thoughtful advice and counsel that she has provided me during my tenure. It is Stacy's combination of integrity and intelligence, however, that most characterizes her time as Chief Counsel at the agency. It is this integrity and commitment to the law that allowed us to navigate some very difficult times. Please join me in thanking Stacy for her strong leadership and service to the agency and wishing her well in her future endeavors.

I am pleased to announce that Mark Raza will serve as Acting Chief Counsel upon Stacy's departure. Since 2011, Mark has served as Principal Deputy Chief Counsel. He currently leads the OCC COVID-19 emergency response team and has played an integral role in the agency's pandemic response. Mark joined OCC in 1990 and has worked in the areas of biological products, devices, emergency preparedness and response, information disclosure, and litigation (both civil and criminal), among others. He served as Acting Deputy Center Director for Policy in the Center for Devices and Radiological Health and completed a detail in the Center for Biologics Evaluation and Research's former Office of Therapeutics Research and Review. He is a graduate of Harvard Law School and Boston College.

Mark will work closely with Liz Dickinson, who will remain in her important role as Senior Deputy Chief Counsel, continuing to provide leadership strength and continuity, alongside the other OCC deputies.

We are grateful for their dedication to the FDA's important public health mission and their continued commitment to OCC.

One of the FDA's great strengths is its talented and dedicated OCC staff, and I am confident that it will continue to be in steady hands.

Sincerely,

Stephen M. Hahn, M.D. Commissioner of Food and Drugs

