

**From:** A Message from the Commissioner <[message@fda.hhs.gov](mailto:message@fda.hhs.gov)>

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**To:** FDA-Wide <[FDA-Wide@fda.hhs.gov](mailto:FDA-Wide@fda.hhs.gov)>

**Subject:** Personnel Update -- Anand Shah, M.D., Deputy Commissioner for Medical and Scientific Affairs



## From the Desk of the Commissioner



Dear Colleagues,

I am delighted to announce that Anand Shah, M.D. has returned to the FDA from the Centers for Medicare & Medicaid Services (CMS) as the Deputy Commissioner for Medical and Scientific Affairs. Dr. Shah will support me in leading the agency's operations as it relates to medical and scientific affairs. He is responsible for developing and leading high-priority FDA policy initiatives and will oversee cross-agency teams in support of our agency's public health mission.

Dr. Shah began his government service at the FDA. He has provided guidance to industry and academia on medical product development, clinical trial design, and regulatory pathways to accelerate public access to new and effective therapies. He co-led and scaled Information Exchange and Data Transformation (INFORMED), a science and technology incubator designed to harness the power of big data and advanced analytics to improve disease outcomes. Dr. Shah developed organizational and technical infrastructure for modern approaches to evidence generation in support of regulatory decisions.

He is a widely recognized authority on how innovative medical products are developed, regulated, financed, and delivered. Dr. Shah's efforts have focused on the development and implementation of innovative approaches to value-based health care delivery and expanding competition and consumer choice. He recently served in two senior leadership roles at CMS. Until recently, Dr. Shah was the Senior Medical Advisor for Innovation at CMS, where he was the primary counselor to the Administrator for agency-wide policy related to medical and scientific innovation. Previously at CMS, he served as Chief Medical Officer of the Center for Medicare & Medicaid Innovation where he led the clinical design of novel payment and service delivery models including those for primary care, specialty care and prescription drugs.

At CMS, Dr. Shah established consensus with our Department of Health and Human Services (HHS) partners on a number of critical policy initiatives including aligning payment and prevention to increase Medicare beneficiaries' access to novel antimicrobials, expanding patients' access to new cell and gene therapies, and streamlining Medicare access to breakthrough technologies that have the potential to improve health outcomes and the quality of care. He led a significant cross-agency effort to bridge gaps in access that patients often encounter between FDA approval and CMS coverage of medical products. Dr. Shah recently led CMS efforts on innovation to deliver on President Trump's executive order to protect and improve Medicare for our nation's seniors.

Dr. Shah is an attending radiation oncologist at the National Institutes of Health (NIH) where he specializes in the early detection, surveillance, and treatment of prostate cancer. He developed and leads an NIH survivorship clinic in the care of patients on cancer clinical trials.

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Dr. Shah served as an Adjunct Senior Fellow at the Leonard Davis Institute of Health Economics at the University of Pennsylvania. He has led the development and evaluation of novel risk-based Medicare payment and service delivery models at Columbia Business School. He completed a health economics fellowship at the University of Pennsylvania where he developed and applied significant expertise with economic, financial, and valuation modeling of emerging therapeutics. Dr. Shah was on Duke University faculty where he led the Center for Excellence in Surgical Outcomes as its Associate Director. He has received research funding from government and philanthropic sources. His scientific track record includes publications in the New England Journal of Medicine, Cancer, and Nature Reviews Drug Discovery. Prior to his government service, Dr. Shah served as an advisor to a U.S. venture capital firm.

Dr. Shah was chief resident during his radiation oncology residency at Columbia University. He concurrently earned his M.D. from the University of Pennsylvania and an M.P.H. in health care management and policy from the Harvard School of Public Health. Dr. Shah graduated with honors from Duke University with a degree in economics. He also served as a Canada-U.S. Fulbright Scholar.

In my first few weeks with you at the FDA, I have been overwhelmed by the mission-driven ethos that inspires our efforts to deliver for the American people. A key priority of mine is to recruit, retain, and develop exceptional professionals across our agency who are committed to protecting and promoting the public health. I am proud to recognize the skills of talented leaders, such as Dr. Shah, who are deeply committed to the mission of the FDA. He joins Amy Abernethy, M.D., Ph.D., Principal Deputy Commissioner; Anna Abram, Deputy Commissioner for Policy, Legislation, and International Affairs; Frank Yiannas, Deputy Commissioner for Food Policy and Response; and Keagan Lenihan, Chief of Staff, on the senior leadership team in the Office of the Commissioner.

Please join me in welcoming Dr. Shah to our team.

Sincerely,

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

