Jeff Shuren MD, JD

DIRECTOR – CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

Jeff Shuren is the Director of the Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration. The center is responsible for assuring the safety, effectiveness, and quality of medical devices; assuring the safety of radiation-emitting products (such as cell phones and microwave ovens); and fostering device innovation.

"Our center experts and programs help get safe and effective technologies to patients and health care professionals on a daily basis and continue to assure devices are safe and effective once on the market," says Dr. Shuren. "Rapid technological advances enable us to approve innovations that make a difference in people's lives. I could not be more proud of my fellow colleagues at CDRH, the family we have built, and what we have accomplished together on behalf of the American public."

Dr. Shuren received his B.S. and M.D. degrees from Northwestern University under its Honors Program in Medical Education. He completed his medical internship at Beth Israel Hospital in Boston, his neurology residency at Tufts New England Medical Center, and a fellowship in behavioral neurology and neuropsychology at the University of Florida. He subsequently joined the faculty of the University of Cincinnati. He received his J.D. from the University of Michigan. He is board certified in neurology and a member of the State of Maryland bar.

Dr. Shuren has held various policy and planning positions within the FDA's Office of the Commissioner from 1998 to 2009, including Medical Office in the Office of Policy; Assistant Commissioner for Policy; Associate Commissioner for Policy and Planning; Special Counsel to the Principal Deputy Commissioner; and Acting Deputy Commissioner for Policy, Planning, and Budget.

From 1999 to 2000, Dr. Shuren served as a detailee on Senator Edward Kennedy's staff on the Senate Health, Education, Labor, and Pensions (HELP) Committee. From 1998 to 2003, while at the FDA, he also served as a staff volunteer in the National Institutes of Health's (NIH) Cognitive Neuroscience Section, where he supervised and designed clinical studies on human reasoning.

As Director of the Division of Items and Devices, Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS) from 2001 to 2003, Dr. Shuren oversaw the development of Medicare national coverage determinations for drugs, biologics, and non-implantable devices.

Dr. Shuren became the Acting Director of CDRH beginning in September 2009 and was appointed the permanent Director in January 2010. During his tenure, Dr. Shuren has envisioned and implemented initiatives to modernize the regulation of medical devices through a holistic, patient-centric, customer service-focused, total product life cycle (TPLC) approach to oversight and the organizational structure of CDRH. These efforts include conceiving and co-founding the International Medical Device Regulators Forum (IMDRF) to foster global harmonization and the Medical Device Innovation Consortium (MDIC) to advance regulatory science in support of developing innovative technologies and improving device safety and cybersecurity; envisioning and supporting the establishment of the National Evaluation System for health Technology (NEST) to generate real-world evidence to support device authorizations and identify and characterize safety signals; launching the Case for Quality Initiative to improve device quality and safety and facilitate the adoption of advanced manufacturing technologies; the Breakthrough Devices Program and Safety and Performance Based Pathway to address the unmet medical needs of people and foster the development of safer, more effective technologies; the Collaborative Communities Initiative to drive the development of community-generated solutions within the medical device ecosystem; the Network of Experts to expedite and expand access to external expertise to inform center decision making, and the Parallel Review Program with CMS to streamline the pathway from FDA authorization to CMS national coverage determination; and spearheading CDRH's efforts on patient engagement and the science of patient input, including creation of the Patient Engagement Advisory Committee (PEAC), advancing the development of digital health technologies and the creation of the Digital Health Center of Excellence, and piloting the Total Product Life Cycle Advisory Program (TAP) to expedite patient and health care professional access to and spur greater investment in the development of breakthrough devices.