Jeffrey E. Shuren became the director of the Center for Devices and Radiological Health at the Food and Drug Administration (FDA) in January 2010. He previously served as Acting Center Director, beginning in September 2009. 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 technology to patients and health care professionals on a daily basis," says Dr. Shuren. "Rapid technological advances enable us to approve such innovations as a diagnostic test for the H1N1 influenza virus, an expandable prosthetic rib for children with abnormal growth conditions, and a test that can help detect ovarian cancer."

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 received his J.D. from the University of Michigan.

Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including acting deputy commissioner for policy, planning, and budget; associate commissioner for policy and planning; special counsel to the principal deputy commissioner; assistant commissioner for policy; and medical officer in the Office of Policy.

Dr. Shuren has served in a leadership role at FDA or on behalf of the agency on numerous initiatives, including

- reauthorization of the Medical Device User Fee Act, which dramatically shortens review times for device applications
- creation of the Sentinel Initiative, which works toward a national electronic system for monitoring medical product safety
- development of FDA’s Pandemic Influenza Preparedness Strategic Plan
- development of FDA’s Counterfeit Drug Task Force Report
- development of the Interagency Food Safety Working Report to the President
- implementation of FDA provisions of the Medicare Prescription Drug Improvement and Modernization Act
- development and implementation of the Interagency Import Safety Working Group’s Report to the President: Action Plan for Import Safety

From 1999 to 2000, Dr. Shuren served as a detailee on Senator Edward Kennedy's staff on the Senate Health, Education, Labor, and Pensions Committee. From 1998 to 2003, he also was a staff volunteer in the National Institutes of Health’s 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, Dr. Shuren oversaw the development of Medicare national coverage determinations for drugs, biologics, and non-implantable devices.

Committee on Energy and Commerce
U.S. House of Representatives
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

1. Your Name: Jeffrey Shuren, M.D., J.D. Director, Center for Devices and Radiological Health, Food and Drug Administration Department of Health and Human Services		
2. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes X	No
3. Are you testifying on behalf of an entity that is not a government entity?	Yes	No X
4. Other than yourself, please list which entity or entities you are representing: **N/A**		
5. Please list any Federal grants or contracts (including subgrants or subcontracts) that <u>you or the entity you represent have received</u> on or after October 1, 2011: **N/A**		
6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing:		
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	Yes	No
8. If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed:		
9. Please attach your curriculum vitae to your completed disclosure form.		

Signature: [redacted] **Date:** 9/8/14

Committee on Energy and Commerce
U.S. House of Representatives

Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

1. Your Name:

Jeffrey Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health,
Food and Drug Administration
Department of Health and Human Services

	Yes	No
2. Are you testifying on behalf of the Federal, or a State or local government entity?	X	
3. Are you testifying on behalf of an entity that is not a government entity?		X

4. Other than yourself, please list which entity or entities you are representing:

N/A

5. Please list any Federal grants or contracts (including subgrants or subcontracts) that you or the entity you represent have received on or after October 1, 2011:

N/A

6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing:

	Yes	No
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?		

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Signature: [redacted] **Date:** 9/8/14