

Jeffrey Shuren, M.D., J.D., Director of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration

Dr. Jeffrey Shuren is currently the Director, Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA). Prior to becoming Director, Dr. Shuren served as Acting Director for the Center for Devices and Radiological Health. Previous to that, he 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; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, he joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services and then returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009. Dr. Shuren received both BS and MD degrees from Northwestern University under its Honors Program in Medical Education and JD from the University of Michigan Law School.

Dr. Shuren oversees the Office of the Center Director (OCD) which provides scientific, policy and managerial leadership and direction to the seven offices comprising the CDRH. OCD provides advice and consultation on policy matters about medical device and radiological health issues to the Commissioner and other FDA officials, Congress, the Department of Health and Human Services, the Public Health Service, other government agencies, the scientific and academic communities, and representatives of regulated industry. It communicates agency initiatives and guidance to consumers and industry in support of the public health. Other activities supported by OCD are the CDRH Ombudsman who investigates outside complaints and resolves disputes, and the Medical Device Fellowship Program.

ORAL REMARKS
OF
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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE
COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
“PROGRESS IS POSSIBLE: TACKLING THE CHALLENGES ON GAO’S HIGH
RISK LIST TO MAKE GOVERNMENT WORK BETTER”
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Senator Carper, thank you for the opportunity to participate in today's roundtable.

In January 2009, GAO designated the FDA, including oversight of medical devices, as a High-Risk area because the agency was facing challenges that threatened to compromise its ability to protect the public health.

In 2011 and 2013, GAO reported that the FDA continued to make progress to varying degrees in its High-Risk areas; however, sufficient risk mitigation had not been attained and most areas remained on the GAO's High-Risk List. Starting in 2013, we made a concerted effort to get off the GAO's High-Risk List the next time it was issued, which would be in early 2015. We were successful and here's why.

We took every GAO recommendation to heart and religiously applied the criteria GAO uses to evaluate the risk of a program. GAO has stated that before making a high-risk designation, it considers the corrective measures an agency may have planned or has underway to resolve a material weakness and the status and effectiveness of these actions. GAO reviews the effectiveness of an agency's planned or ongoing corrective actions to address a material weakness using the following criteria:

- 1. Whether the agency has demonstrated strong commitment and top leadership support to resolving the problem;**
- 2. The agency's capacity to address the problem;**
- 3. Whether a corrective action plan exists that defines the root cause, solutions, and provides for substantially completing corrective measures, including steps necessary to implement solutions GAO recommended; Whether a program has been instituted to monitor and independently validate the effectiveness and sustainability of corrective measures.; and**

- 4. Whether the agency has the ability to demonstrate progress in implementing corrective measures and in resolving the high-risk area.**

In considering whether a corrective action will be substantially completed in the near term, GAO requires evidence leading to a high level of certainty the action will resolve the problem within the 2-year period covered by the term of the Congress to which a high-risk update report is addressed.

FDA regulates devices based on their level of risk with more requirements imposed on higher risk devices than on lower risk devices. FDA classifies devices into three categories – Class I for low risk, Class II for moderate risk, and Class III for high risk devices, which generally require the conduct of clinical studies to warrant FDA premarket approval. A device that has not yet been classified is automatically a Class III high-risk device until the FDA determines otherwise. In 2009, 26 types of devices on the market prior to 1976 when Congress enacted the Medical Device Amendments had been placed automatically into Class III but were being regulated by the FDA as Class II moderate-risk devices.

GAO recommended that the FDA expeditiously take steps to reclassify each of these 26 device types to assure they were being appropriately regulated. This is a very labor-intensive process involving the issuance of a proposed order followed by public comment and an advisory committee meeting, after which we can issue a final order.

To implement GAO's recommendation, we established a team that reported directly to me. A Deputy Director of our largest premarket review office was assigned day-to-day responsibility for the initiative and we assigned additional and dedicated staff to the effort. We developed a risk-based strategy and corrective action plan, sought public comment, and made adjustments to the plan based on that feedback. We sought authority from Congress to ease barriers to reclassification, for which we were

partly successful. We developed metrics, milestones, and tracking capabilities as well as made reclassification a Center priority and sought ways to streamline processes and improve program management – and made progress reports available on our website.

Today, of the 26 device types, we have issued final orders for 22 of them and for the remaining 4 we have issued proposed orders and held advisory committee meetings. We plan to issue final orders, and conclude the initiative, in the next few months.