MEMORANDUM OF MEETING
August 7, 2015
11:00 a.m. – 12:00 p.m.
White Oak

SUBJECT: Meeting with Advanced Medical Technology Association (AdvaMed)

ATTENDEES:

FDA: Stephen Ostroff, Robert Califf, Sally Howard, Jeff Shuren, and Josephine Tropea

AdvaMed:
Stephen Ubl, President and Chief Executive Officer, AdvaMed
Janet Trunzo, Senior Executive Vice President, Technology and Regulatory Affairs, AdvaMed
Nadim Yared, President and Chief Executive Officer, CVRx Inc.
Gary Pruden, Johnson & Johnson's Medical Devices Group
Michael Rousseau, Chief Operating Officer, Jude Medical

DISCUSSION HIGHLIGHTS:

- AdvaMed provided an overview of their MDUFA III regulatory survey that was completed by the medical device industry. The survey was administered to two audiences within the medical device industry—the CEOs and the regulatory affairs directors. The survey was broken down into the following sections: demographics, pre-submission process, 510(k) submissions, premarket applications, Clinical Laboratory Improvement Amendments (CLIA) waiver applications, general feedback, and FDA resources for sponsors.

- AdvaMed thanked Dr. Shuren and the Center for Devices and Radiological Health team for meeting with AdvaMed regularly during the legislative process for getting the 21st Century Cures Act passed by the House of Representatives on July 10. CDRH representatives and AdvaMed worked together on the proposed language for most of the device provisions in 21st Century Cures, including: priority review for breakthrough devices; third-party quality system assessment; valid scientific evidence; least burdensome concept training and oversight; recognition of standards, easing regulatory burden with respect to certain class I and class II devices; advisory committee process; humanitarian device exemption application; health software; and CLIA waiver study design guidance for in vitro diagnostics.

- AdvaMed and FDA discussed the reauthorization of MDUFA. Discussions officially kicked off at the July 13 public meeting where FDA, industry, patient and consumer groups, health care professionals, and other stakeholders spoke. The reauthorization negotiations with industry—and concurrent meetings with patient and consumer groups—will begin in September and continue through March 2016.

- AdvaMed and FDA discussed the National Medical Device Postmarket Surveillance System (MDS). Beyond clinical trials, real-life patient experience may reveal unanticipated device risks and confirm long-term benefits. A strong postmarket surveillance system can provide

more robust and timely benefit-risk profiles for devices so that providers and patients can make better informed health care decisions. Achieving a national system requires thoughtful input and active participation from many key national and international stakeholders.

Action Items

- No specific action items were identified.

Josephine Tropea
FDA Executive Secretariat