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Inefficiencies at FDA Delay Patient Access, Increase Costs of New Medical Technologies

WASHINGTON, D.C. – Stephen J. Ubl, president and CEO of the Advanced Medical Technology Association (AdvaMed), today released the following statement regarding a new study that assesses the impact of device regulation on continued medical innovation:

“This report is a wake up call for those who want to promote medical innovation and preserve American jobs. The United States is the world’s leader in the development of innovative medical technology, helping to save lives here and around the world and making significant contributions to the national economy in the process. Dr. Makower’s study shows that timely patient access to new technologies and industry competitiveness are being held back because of inefficiencies that must be addressed.

“A regulatory environment that is marked by needless delays and inefficiencies makes it harder for medical innovation to thrive and companies to survive. These delays particularly hurt small companies and their ability to produce next generation technologies. Worse, they keep technologies from waiting patients and their physicians.

“We support efforts such as improving reviewer and manager training, developing specific guidance for product types, improving the de novo process and developing specific metrics to improve consistency. We urge FDA to review the findings of this study and we are committed to working with them to address these issues.”

The report can be found <http://www.advamed.org/NR/rdonlyres/040E6C33-380B-4F6B-AB58-9AB1C0A7A3CF/0/makowerreportfinal.pdf>

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AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. For more information, visit www.advamed.org.