WSGR ALERT

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MDMA-SUPPORTED STUDY PROVIDES POWERFUL EVIDENCE OF FDA REGULATORY CHALLENGES

For many in the life sciences industry, the regulatory approval process of the U.S. Food and Drug Administration (FDA) lacks predictability and transparency when it comes to product development. This lack of predictability and transparency directly translates into added costs for companies seeking regulatory approval of products and delay in time to market, which ultimately has an adverse impact on innovation, patient care, and jobs. Until now, this position has only been supported by anecdotal evidence.

With the help of industry, including Wilson Sonsini Goodrich & Rosati, the Medical Device Manufacturers Association (MDMA) provided the FDA with a number of examples of how current FDA policies and practices hamper innovation by creating unnecessary burdens on companies trying to innovate. In response, the FDA asked the MDMA to generate data to support the industry's concerns. As a result, the MDMA, in conjunction with the National Venture Capital Association, Dr. Josh Makower, and Aabed Meer, developed a survey and deployed it to the MDMA's members—amounting to more than 200 small- and medium-sized medical technology companies—to quantify the impact that the FDA is having on the medical device industry. Of particular interest, the study reported the following:

- On average, innovative new devices are available to U.S. citizens two full years later than patients in other countries. In some cases, American patients wait up to six years longer than patients elsewhere.
- To bring low-risk devices to market, companies must spend $31 million—$24 million of which is spent navigating the FDA approval process.
- To bring higher-risk devices to market, companies must spend $94 million—$75 million of which is spent navigating the FDA approval process.
- Almost half of the companies surveyed reported that the FDA personnel responsible for reviewing their product changed during the course of the review and one-third reported that appropriate staff members were not present at meetings between the companies and the FDA to review issues.

Visit http://medicaldevices.org/node/846 to view the survey results in their entirety.

Wilson Sonsini Goodrich & Rosati represents a substantial number of MDMA members, including many innovative medical technology companies, and has deep breadth of expertise in advising these companies on the issues that they face. For more information or questions about the survey or any related matter, please contact Casey McGlynn, David Hoffmeister, Philip Oettinger, Elton Satusky, or another member of the firm's life sciences practice.

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