Arnall Golden Gregory LLP

Client Alert

Contact Attorney Regarding This Matter:

William H. Kitchens
404.873.8644- direct
william.kitchens@agg.com

FDA Announces Public-Private Partnership to Enhance the Development of Regulatory Science for Medical Devices

On December 3, 2012, the Food and Drug Administration (FDA) announced the formation of the first public-private partnership (PPP) to improve public health through the application of shared knowledge in medical device regulatory science. Regulatory science refers to the development and evaluation of new tools, methods, standards and applied science to assess the safety, efficacy, quality, and performance of FDA-regulated products. The focus of the PPP will be on speeding the development, assessment, and review of new medical devices throughout the product life cycle.

The new Medical Device Innovation Consortium (MDIC)[1] is an independent, nonprofit corporation, created by LifeScience Alley® (LSA)[2] , a biomedical science trade association. The MDIC is designed to create a collaborative environment where the industry, non-profit organizations, and government can work together to advance pro-competitive medical device research so that the medical device community can keep pace with the needs of the patients in the United States in a more timely manner.

The MDIC will receive input from industry, government, and other nonprofit organizations. MDIC will prioritize the regulatory science needs of the medical device community and fund projects to help simplify the process of medical device design and pathway to market for these innovations.

The aim is for the MDIC to bolster the country's investment in regulatory science research by pooling people, funding, resources, and ideas to develop new tools, models, and methods that may be utilized to better and more efficiently evaluate new devices. Under the memorandum of understanding between FDA's Center for Devices and Radiological Health and the LSA, which led to the creation of the MDIC, FDA employees will be authorized to collaborate with the MDIC on MDIC-supported research and other projects.

Membership and participation in the MDIC will be open to representatives of organizations that are substantially involved in medical and/or medical device research, development, treatment, or education; the promotion of public health; or who have expertise in regulatory science.

1 The MDIC is the first ever PPP created with the sole objective of advancing medical device regulatory science. The intent is to be a national 501c(3) organization that operates in partnership with the FDA.
2 LSA is a Minnesota-based trade association serving over 680 member organizations.

Arnall Golden Gregory LLP
Attorneys at Law

171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031

1 Biscayne Tower
Suite 2690
2 South Biscayne Boulevard
Miami, FL 33131

1775 Pennsylvania Avenue NW
Suite 1000
Washington DC 20006

www.agg.com

The MDIC will be governed by a Board of Directors that will oversee the MDIC's subcommittees. Subcommittees will represent industry sectors or technology areas (e.g., modeling, interoperability, orthopedics, neurological devices). The intent is for each subcommittee to be responsible for establishing working groups chartered with identifying key issues affecting their industry segment. Then, the working groups will bring forward project plans for prioritization.

The formation of the MDIC offers the prospect of rapid advancement of regulatory science in the medical device industry over the next few years. By providing a mechanism for FDA staff to collaborate with the MDIC on MDIC-supported research and other projects, device manufacturers should be better equipped to bring safe and effective medical devices to market more quickly and at a lower cost.