FDA pledges support for med tech initiative

MATTHEW PERRONE - AP Health Writer - Associated Press

The Food and Drug Administration said Monday it will collaborate with medical device manufacturers on a public-private partnership designed to speed up the development of new medical technology.

The agency said it hopes to offer guidance to the Medical Device Innovation Consortium, a new industry-backed group that aims to simplify the design and testing of medical devices.

FDA Commissioner Dr. Margaret Hamburg noted that many medical device companies are small businesses and don't have the research budgets to find more effective ways of testing their products. She said the new group would pull information and ideas from industry, government and academia.

"This can best be done by making sure we're applying the best science to the task and bringing together the best minds, no matter where they are found," Hamburg said, in a teleconference with reporters.

The agency's pledge follows criticism from device industry advocates, who have lobbied Capitol Hill for more than a year to fix an FDA review process which they say is forcing some companies out of business.

Medical device makers have criticized the FDA for an overly burdensome system of reviewing devices, which they claim slows down development of important new therapies. They point to some device companies that are launching their products in Europe first, although experts agree the bar for approval is lower overseas. Congressional Republicans have held several hearings to scrutinize the agency's system in the last two years.

In recent months the FDA has been highlighting efforts to slash red tape and accelerate review times.

The new consortium will take suggestions from its members on initial projects for research. The group has raised about a half-million dollars in funding from industry members, but hopes to double that amount in the first year, according to the group's interim director, Maura Donovan.

The Medical Device Innovation Consortium was created by LifeScience Alley, a Minnesota-based group that includes companies like Minneapolis-based Medtronic Inc., the world's largest medical device company. The group also includes research institutions like the Mayo Clinic and the University of Minnesota.

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