

FDA commissioner discusses future of cardiovascular medicine

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Advances in technology coupled with an increased use of social media and personal devices could offer new possibilities for treating patients and improving outcomes, but the new approaches must be rigorously evaluated, according to a column by Food and Drug Administration Commissioner Robert M. Califf, M.D., MACC, published today in the *Journal of the American College of Cardiology*.

In the paper, Califf looks at the future of [cardiovascular medicine](#) from a regulatory standpoint. Death from [cardiovascular disease](#) dropped 40 percent in the early 2000s and new drug and technology developments will likely further improve outcomes; however, Califf said he cautions that there is a potential for harm if systems for evidence generation and [health care delivery](#) do not improve as rapidly as technology and provide the guidance needed to use new advancements appropriately.

"Keeping pace with rapid technological change will present a key challenge," he said. "It will be critical for the FDA and the cardiovascular community to continue working together to create an evidence generation system capable of guiding practice in coming years."

The cardiovascular community is a leader in evidence-based medicine, but only about 15 percent of major practice guidelines are supported by high-quality evidence. However, according to Califf, dramatic improvements in the rate, quantity and quality of evidence generation are within reach.

"Almost all Americans now have [electronic health records](#), and [social media](#) combined with wearable devices are opening new frontiers in patient- and population-level data," Califf said. Califf also discusses the FDA's future role in nutrition and diet issues, acknowledging miscues, such as the broad recommendations on intake of cholesterol and carbohydrates, have "undermined public confidence and created opportunities for self-styled experts to profit from dubious advice."

He said that, beyond fundamental basics, there is not a clear-cut answer on what people should eat for optimal health and quality of life, but as evidence is generated across large populations, the FDA will look forward to a new era of studies in this area that take advantage of our evolving evidence generation system.

Other areas Califf discusses are phenotyping in early-phase clinical trials, integrative biomarkers and monitoring, targeted therapy, devices, regenerative medicine, disease at the beginning and end of life, and disparities.

More information: *Journal of the American College of Cardiology*, DOI: [10.1016/j.jacc.2016.07.001](https://doi.org/10.1016/j.jacc.2016.07.001)

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