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The United States Food and Drug Administration (FDA) is developing new guidelines requiring higher and more scientific standards than under the Bush administration. Under the Bush administration, many of the Bush FDA appointees were former pharmaceutical industry or medical device company employees which approved deadly drugs like Vioxx, Avandia and Trasylol and defective heart devices from Medtronic or Guidant.

Two recent studies found major safety problems with FDA accepted clinical trials involving heart regulating devices such as pacemakers or defibrillators over the last decade, as well as stents used in heart vessel procedures. The issue of defective medical devices being repeatedly approved by the FDA has come under scrutiny since the 2008 Supreme Court decision that immunized medical device manufactures from any lawsuits if the medical device was FDA approved.

Hopefully, under the Obama administration, the FDA will once again become more concerned about patient and consumer safety than with corporate profits and having the FDA serve as another marketing and sales arm of the drug and medical device industry.

Among other complaints, FDA officials said that the researchers involved in the JAMA report had applied scientific criteria used to evaluate studies of experimental drugs to trials of devices, which they said are run differently for technical and regulatory reasons.
Reached by e-mail, Dr. Rita Redberg, a professor at the University of California, San Francisco, who was one of the principal investigators, said that while some FDA criticisms of her study were reasonable, she rejected others. She said the central finding that the agency had accepted many cardiac device trials that lacked scientific rigor was valid.

"We are glad to hear that the FDA is taking action to address the missing data and loss to follow-up that we have identified," Dr. Redberg said.

Dr. Shuren said the agency-sponsored review had found enough problems with the quality of clinical trial data submitted to the agency to justify making changes to FDA policies.

"It is not acceptable, and that is the reason we are making the changes in the program we are making," he said.

He added that the agency had begun to make such changes in late 2007, about the time Dr. Maisel and other researchers had begun their review. For example, agency reviewers started using a standardized checklist about three years ago to assess the scientific merits of trial designs submitted by manufacturers.

Dr. Shuren said he thought the quality of human test data reviewed by the agency since then had improved. However, he added that the agency expected to put out guidance to device manufacturers in the coming year outlining the type of scientific criteria it expects in clinical studies. He said the agency was conducting a similar quality review of human studies used to approve other implanted devices like artificial hips and spinal implants.

Janet Trunzo, an official of the Advanced Medical Technology Association, a trade group in Washington that represents device makers, said in a statement that the scientific data that the FDA already requires from manufacturers is rigorous and involves many other studies besides clinical trials. Ms. Trunzo added that the group was still reviewing the JAMA study but noted the reports' authors stated that they had not reviewed such additional data.

A spokeswoman for the trade group said Tuesday that the organization would comment on the new F.D.A. study guidelines when they are released.

Dr. Robert G. Hauser, a cardiologist at the Minneapolis Heart Institute and a critic of the FDA's device-approval process, said that the disputes between the two groups of researchers seemed secondary given some of their shared findings. Dr. Hauser, who has helped bring problems with implanted defibrillators to public attention.

"I think both studies have merit and should encourage the FDA and the medical community to join together to fashion a scientific regulatory process that critically evaluates new products and technologies," he said.
