

Making Sure Medical Devices Are Safe and Effective

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Modern medicine makes use of thousands of different kinds of devices, with new and revolutionary technologies being invented every year. New medical products, such as artificial hips, defibrillators, lasers for eye surgery, and coronary stents, must be approved by the Food and Drug Administration (FDA) before they can be sold in the United States. Companies must show that their new medical devices are both safe and effective. Often companies recruit volunteer patients on whom to test the new devices in statistically designed experiments called clinical trials. Companies submit the results of these trials as evidence that their devices are safe and work as claimed. I direct a group of 30 statisticians who review the statistical designs and data analyses that the companies submit. These reviews are team efforts by statisticians, clinicians, and engineers. I become personally involved in a review when the approval decision is unusually complicated or controversial. My training as a statistician is essential to my work both as a manager and as a scientist.

As a scientist, I am interested in developing new statisticalmethods to help the FDA make rapid and accurate decisions. For example, there is often information available about a condition or therapy before an experiment starts. We can then apply methods called Bayesian statistics that combine existing information with experimental results. Another of my personal scientific interests is in improving the evaluation of new devices used to diagnose medical conditions rather than to treat them. At the FDA we have used new statistical methods to evaluate, for example, microarrays for gene expression and digital mammography.

Statistics plays a very important role in the FDA, helping usmake scientifically based decisions that improve public health and protect everyone's safety. I am stimulated by both the scientific challenges and the responsibility to the public in this important work.