GENNewsHighlights

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FDA's Caution: Friend or Foe?

Most can agree that regulating the safety and effectiveness of drugs and medical devices is for the protection of public health. The FDA is appointed this responsibility, but is it failing? The time-consuming and costly approval process could be preventing life-changing treatments from reaching the market; however, more lives could be at risk if safety were sacrificed for speed. The topic of the most recent Intelligence Squared U.S. debate, “The FDA’s Caution is Hazardous to Our Health,” had panelists vehemently arguing for or against this motion.

On the team defending the motion was Scott Gottlieb, M.D., currently a resident fellow at the American Enterprise Institute and formerly FDA deputy commissioner, with his partner Peter Huber, senior fellow at the Manhattan Institute. The pair debating against the motion was Jerry Avorn, M.D., professor of medicine at Harvard Medical School, and his teammate David R. Challoner, M.D., vp of Emeritus for Health Affairs of the University of Florida.

Dr. Gottlieb began the discussion by saying FDA trials are becoming more stringent, requiring greater statistical certainty. He emphasized that the biggest problem with FDA today is a focus on math over medicine. "We can't have an FDA ruled by statistics," stated Dr. Gottlieb. "People will die waiting for drugs."

Dr. Gottlieb and Huber made it clear they are not against the FDA, but they have a problem with the development time of its trials and the limited use of accelerated approval. They noted the success of drugs that were fast tracked during the AIDS crisis in the late '80s and early '90s.

The notion that “targeted drugs are a rarity is disconnected from reality,” said Huber. "We've seen targeted drugs succeed using fast track.” He later added that drug disasters can be avoided by validating biomarkers and almost all major diseases we face cannot be beaten with one-size-fits-all drugs.

Drs. Avorn and Challoner disputed that the benefits of FDA trial requirements outweigh risks of delayed drugs. They cited that drugs and devices that have been cleared and gone to market have still killed people. “Absence of evidence is not evidence of absence,” Dr. Avorn said, noting that more rigorous testing is needed and can be done quickly.

The audience cast their votes before and after the debate and whichever side changed the most minds won. Pre-debate 24% were for the motion, 32% against, and 44% undecided. Results post-debate showed that 53% were now for the motion, agreeing that the FDA is too cuatious. Thirty-eight percent were against, and 9% undecided.

What are your thoughts on the issue? Do you think the FDA is too cautious or does it need to be more rigorous? Share your thoughts in the comments. Watch the full debate by clicking here and going to the "Video/Audio" tab.