FDA: New Warnings – A Sign of Success

After a drug has been on the market and is being widely used you may hear that the FDA has learned of side effects and adverse outcomes in a group of patients taking those drugs. Some have raised concerns that this indicates a failure of our system for understanding risk when a drug is approved for the market.

My take is that the opposite is true. Our system for detecting and acting upon signals of concern works very well. FDA cannot, and never will be able to know or anticipate everything that can be known about a drug before it is widely distributed and used by millions and millions of very different people under very different circumstances.

For example, recently the FDA requested that manufacturers of certain antibiotics make labeling changes including adding a Black Box warning addressing the risk of tendinitis and tendon rupture. In this case the FDA learned from a new analysis and evaluation of available literature and post-marketing adverse event reports.

When the FDA learns of a potential new side effect associated with taking a drug or medical device, this is a sign of the success of our regulatory oversight, not its failure. With this new information not only can we better advise healthcare professionals and patients like you and your family, but we can also target unique patient groups for whom the benefits or the risks of taking the drug are unique.

FDA's job is to quantify the benefits and risks associated with drugs and to explain both to healthcare professionals and patients. This is to allow better and more informed decisions as to when and how the drug should be prescribed and used. When we warn you and your family about a potential new side effect of a drug that also has great benefits it is a success in furthering our mission of both protecting and promoting your health.

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About Andy's Take

Through this communications column on the FDA Web site, Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., will discuss weekly FDA issues of interest to the American consumer and occasionally preview upcoming FDA issues and events.

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