FDA: New Early Safety Systems

The FDA has recently posted on our web site the first of what will be quarterly reports that list certain drugs that are being evaluated by the FDA for potential safety issues.

My take is that making you aware of concerns about adverse outcomes or side effects of drugs is similar to giving you a forecast of an impending weather system: we get clues but then we must follow up with science and tracking data to give us more meaningful information. Like with hurricane watches and warnings, we want to have as much information as early as possible. But we may have to wait to find out if the problem is real, how serious it is, and whether it will affect us personally.

As the FDA gathers new and early safety data on the drugs that are being taken by millions of people, you will know as early as possible if we have a concern. The first report we have posted includes a table that lists 20 drugs along with the potential safety issue associated with each drug. The drugs have been identified based on a review of reports in FDA's Adverse Event Reporting System (*www.fda.gov/cder/aers/potential_signals/default.htm*).

What does this mean for you? It means that if you see a drug you are using on the report, know that the FDA has begun an analysis to determine whether there is a safety problem. This is because we have received reports that lead us to believe we need to look more closely at that particular drug. You should not stop taking the drug, but you should discuss our concerns with your physician.

The FDA will continue to develop even more sophisticated tools of science and technology to detect the earliest signs of drug side effects. However, like the weather, it is very important to realize that these early signals may end up not being a problem – or the problem may only be a minor one – or one not relevant to your condition.

As always, the FDA of the 21st century is on the early watch – and diligently on the lookout to provide information to you and your physician so that together you can make the best decisions that will protect and promote your health. FDA

Andy

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

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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