FDA: A Bridge to Medical Innovation

As I travel around the country and meet with various groups I am often asked: "Is FDA making it increasingly more difficult to get medical products approved because it has become super conservative?" You might from time to time hear or read that "FDA is asking sponsors for many more studies – to avoid approving their product." Or, "FDA is fearful of approving something because of criticism if there are unexpected adverse events."

My Take is that our mission is BOTH to protect AND to promote the public health. Of course we must insist and will always demand a sufficient number of high quality scientific studies to assure we have the best possible understanding of benefits and risks before we approve a drug or a medical device for your use. But, we are constantly aware of the need to facilitate and accelerate the availability of these new life-saving and health-enhancing treatments because "lives are at risk."

If regulation by FDA is too slow or too cumbersome – not because of the need for scientific rigor but rather because we are too bureaucratic or risk adverse – then people suffer and die – people with cancers for which there is no therapy, or people with AIDS or Alzheimer's who await remedies. There are millions of victims of many hundreds of diseases for which today we do not have a solution.

So, to answer the questions: FDA has not changed its philosophy or its standards for medical product approval, and is in fact engaged in a rigorous process improvement effort to make the regulatory pathway more efficient, transparent and, yes, more rapid. But as we bring life-saving drugs and medical products to you, there is a universal reality: no drug will ever be 100% safe or 100% effective. Every drug has risks, and at times those risks could be life-threatening and even fatal.

FDA is doing a great deal to minimize these kinds of risks by learning as much about a drug as we can before we approve it. But we are also putting in place mechanisms to study a drug after we approve it so that we continuously learn and if necessary modify our approval decision or the drug's label for its intended use. And we are exploring better ways to keep you informed about managing the risks of medical products.

Just a few of our efforts include MedWatch (*www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm*), which is our safety information and adverse event reporting program; there is our Adverse Event Reporting System (*www.fda.gov/cder/aers/potential_signals/*) data base; there's a new quarterly report listing drugs with potential safety issues; and our Sentinel Initiative, a strategy for a national, integrated, electronic system for monitoring medical product safety. You can learn more about these programs on FDA's website, at *www.fda.gov.*

You also play an important role in the safe use of medical products. If you have questions about a medical product you are using, be sure to ask a health care professional. Keep a list of the medicines you take, and be alert for any unexpected effects. And report them to the FDA, because the more information we have, the better we can carry out our mission of protecting and promoting your health.

Be assured that we will take as much time as necessary to make the right decision about the risks and benefits of a drug. But also be assured that we will do everything we can to get medical products to you as rapidly as possible. Getting life-saving medical products to you quickly is not just our mission – it is our passion. FDA

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