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## Another important step in FDA's journey towards enhanced safety through full-scale "active surveillance"

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**By: Janet Woodcock, M.D.**

They say the longest journey begins with a single step. In 2008, FDA launched the [Sentinel Initiative](#) and thus began a long journey toward the challenging goal of developing a full-scale medical product safety monitoring program using an important scientific technique called "active surveillance," which complements our [FDA Adverse Event Reporting System](#) (FAERS). FAERS is already well developed and uses the equally important technique of "passive surveillance." Today, I'd like to recognize our progress along the way.

After a successful five-year pilot program, which began in 2009, FDA's [Mini-Sentinel](#) program is now transitioning, as planned, to the full-scale Sentinel System. I'd like to share with you the success of our

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Mini-Sentinel pilot program and some of FDA's visions for our new leg of the journey toward full-scale "active surveillance" under the new Sentinel System.

First, a quick discussion of the importance of "active surveillance": Over many years, FDA's program that we now call FAERS has been our main tool for assessing the safety of medical products. This system relies on patients, medical professionals, and product manufacturers to report to us potential safety issues of the products FDA regulates.

FAERS is an invaluable asset, and we're not seeking to replace it. However, the Sentinel System offers us the exciting possibility of not waiting for safety information to come to us in the form of reports, but rather it enables us to *go out and get that information*, adding greatly to our safety monitoring capability. This is active surveillance.

Over the past five years, the Mini-Sentinel pilot program has established secure access to the electronic healthcare data of more than 178 million patients across the country, enabling researchers to evaluate a great deal of valuable safety information. While protecting the identity of individual patients we can get valuable information from Mini-Sentinel that helps us better understand potential safety issues, and share with you information on how to use medicines safely. We have used Mini-Sentinel to explore many safety issues, helping FDA enhance our safety surveillance capabilities, and giving us valuable input in decision-making on drugs and vaccines.

We're now well on our way to developing a nationwide rapid-response electronic active surveillance system, Sentinel System, for monitoring the safety of FDA-regulated drugs and

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other medical products.

So where does our journey take us from here?

- FDA will build on the successes of the Mini-Sentinel Pilot. We have a variety of safety assessments ongoing under Mini-Sentinel that will continue and we will seek to expand our reach and capabilities with the Sentinel System;
- Mini-Sentinel gave us an important start, but it is essential to continue to develop and refine existing scientific methods to evaluate the data we access through the Sentinel System;
- We see Sentinel as a potentially valuable **national resource** for other safety researchers, besides those at FDA. Looking even further ahead, our hope is that, working with other scientific groups, we will be able to create a National Data Infrastructure that would enable other users (e.g., other governmental agencies, researchers from academia or industry) to access the Sentinel infrastructure for multiple purposes (e.g., medical product research, quality improvement);
- Not only will such access directly serve the public health, it will also help sustain these programs because stakeholders will have an incentive to provide support (financial and otherwise) for its maintenance and growth.

From the outset, the goals of the Sentinel Initiative have been large and of ground-breaking scale. We knew it would be years in the making, but Mini-Sentinel's successful completion marks important progress. We look forward to continuing and expanding our active surveillance capabilities as we now transition to the full-scale Sentinel program.

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