National data resource proves valuable in protecting nation's health

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A new Perspective in the *New England Journal of Medicine* discusses the evolution of the U.S. Food and Drug Administration's (FDA) Sentinel Initiative since its launch in 2008. Coauthored by the scientists at the lead organization, the Harvard Pilgrim Health Care Institute, and at the FDA and the Duke Margolis Center for Health Policy, the piece describes the evolution of the Sentinel Initiative from a pilot program designed to assess potential drug-safety signals in insurance claims into a core component of the FDA's evolving safety surveillance system. The Perspective will be published in the November 29 issue of the *New England Journal of Medicine*.

The Sentinel Initiative has created a national infrastructure for the FDA to monitor the safety and effects of marketed medical products while providing a high level of protection for the privacy and security of patients' health information. Partnering with more than 200 health system leaders, pharmacoepidemiologists, clinicians, data scientists, patient representatives, and other experts, the program uses a distributed data network containing curated electronic health data from 18 health plans and hospital systems, covering > 100 million people.

Sentinel has become instrumental in advancing the use of distributed health data systems to monitor medical product safety. Using this national data network, FDA regularly conducts safety analyses of the billions of hospital stays, outpatient visits, and pharmaceutical dispensings included in the Sentinel system. These analyses have informed many regulatory decisions made by the FDA and, in the past 2

years, have eliminated the need for postmarketing studies on nine potential safety issues associated with five products. Such postmarketing studies typically require years to design and complete, each at a cost of millions of dollars.

"The Sentinel Initiative will be an important tool to help inform FDA's implementation of its mandates under the 21st Century Cures Act, incorporating real world data into regulatory decision making for topics beyond safety assessments," said Rachel Sherman, M.D., M.P.H., Principal Deputy Commissioner of FDA.

As the Sentinel program approaches its tenth anniversary, additional opportunities exist for leveraging FDA's investment in the Sentinel System. "In the next few years the Sentinel System will have improved capabilities and will use new data sources and methods," said lead author Richard Platt, MD, MSc, Professor and Chair of the Department of Population Medicine at the Harvard Pilgrim Health Care Institute and Harvard Medical School and Principal Investigator of the FDA Sentinel System. "We hope to continue to harness the Sentinel System to advance knowledge for the common good, including broadening engagement with the public health community to support chronic- and infectious-disease surveillance activities by federal, state, and local public health agencies."

Provided by Harvard Pilgrim Health Care Institute