FDA U.S. FOOD & DRUG ADMINISTRATION

From the Desk of Janet Woodcock

New drugs—and new uses for existing drugs—save lives, reduce suffering, and improve the quality of life for millions of Americans. I am continually challenged to make sure that FDA's regulatory process remains the world's gold standard for drug approval and safety. As part of my role as the director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA), I have led many of FDA's drug initiatives, including the introduction of FDA's "Critical Path" Initiative in 2004, which is designed to move medical discoveries from the laboratory to patients more efficiently.

The Critical Path Institute (C-Path), formed in 2006 as a response to that initiative, is actively seeking to make that vision a reality. This non-profit organization brings worldwide regulatory agencies (such as the FDA) and pharmaceutical companies together to further the science and collaboration necessary to accelerate rapid and safe drug development.

The Predictive Safety Testing Consortium (PSTC), one of many consortium within C-Path, is currently reaching out to industry partners in Pharmaceutical and Biotech sectors to contribute to a Biomarker Data Repository as part of a pilot project aimed at new and modified context of use (COUs) for kidney safety biomarkers. C-Path has a long history of data management in a controlled, de-identified manner that protects the data and contributors. Additional information on the Kidney Safety Biomarker Data Repository Pilot program is available on the C-Path website(www.c-path.org).

I support this effort and hope our industry colleagues will contribute. I look forward to the output of the pilot and hopefully in the future, the expanded repository.

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