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August 28, 2013

Office of the National Coordinator for Health Information Technology
Department of the Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Comments by Office of the National Coordinator for Health Information Technology, Department of Health and Human Services, on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology [Docket No. HHS-OS-2013-0003]

Dear Madam, Sir,

On May 30, 2013, the Office of the National Coordinator (ONC) published a *Federal Register* notice seeking comments on the elements ONC, the U.S. Food and Drug Administration (FDA), and the Federal Communication Commission (FCC) should consider as they develop a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.

The attached white paper outlines some factors related to innovation that the agencies, and in particular FDA, should consider as they put together the government's strategy. More specifically, it identifies outdated aspects of the existing FDA regulatory framework and suggests significant changes to address the unique aspects of health IT. It also advocates for a holistic approach among FDA, FCC and ONC to avoid confusion, duplication and regulatory conflict.

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Epstein Becker & Green, P.C. is a national law firm that focuses on healthcare. With one of the largest healthcare law practices in the United States, we regularly work with medical device manufacturers, software developers, payers, providers, investors and employers with regard to health regulatory policy. In this white paper, we approach the issues raised in the *Federal Register* notice from the perspective of a focus on e-health technologies.

If you would like any further information on any of these topics, we would be pleased to help in any way we can.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Barry A. Green", is centered below the text "Respectfully submitted,". The signature is fluid and cursive.

Epstein Becker & Green, P.C.