
EPSTEIN BECKER & GREEN, P.C.

ATTORNEYS AT LAW

1227 25TH STREET, NW, SUITE 700

WASHINGTON, DC 20037-1175

202.861.0900

FAX: 202.296.2882

EBGLAW.COM

BRADLEY MERRILL THOMPSON
TEL: (202) 861-1817
FAX: (202) 861-3517
BTHOMPSON@EBGLAW.COM

April 2, 2012

VIA EMAIL

Mr. Bakul Patel
Policy Advisor
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, Rm. 5456
Silver Spring, MD 20993-0002

**Re: Request for Re-proposal of the FDA's Draft Guidance on Mobile Medical
Applications: Docket No. FDA-2011-D-0530**

Dear Bakul:

The undersigned organizations respectfully request that the FDA re-propose the guidance on mobile medical applications before issuing it in final form.

We recognize that, thanks to your efforts, the draft guidance is a significant step toward the appropriate regulation of mobile health technologies. We also believe, however, that based on the depth and breadth of comments submitted to the docket, significant revisions are necessary, revisions that would warrant an opportunity for the public to review and comment again. Skipping that step would risk failure to stimulate the innovation the healthcare community requires and acknowledge the meticulous effort on the part of the public to review and suggest changes to the draft guidance.

We do share your desire to move quickly on this. Since there has already been one round of comments, perhaps this next comment period could be shorter, for example 60 days.

Bakul Patel
April 2, 2012
Page 2

If you have any questions or would like to discuss this further, do not hesitate to contact me.

Very truly yours,

A handwritten signature in black ink, appearing to read "Bradley Merrill Thompson", written in a cursive style.

Bradley Merrill Thompson
On Behalf of the mHealth Regulatory Coalition and:
Intermountain Healthcare
Eli Lilly & Co.
Logical Images
Isabel Healthcare
GreatCall, Inc.
Roche Diagnostics
WellDoc Inc.
Continua Health Alliance

Cc: Jeff Shuren, M.D., J.D., Director, Center for Devices & Radiological Health