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July 21, 2011

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
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To the Committee:

I applaud the restraint exercised by the U.S. Food and Drug Administration (FDA) in its proposal to refrain from regulating most mobile medical applications. It is heartening to read that the FDA wishes to encourage, rather than hinder, the development of new apps.

However, the best way to encourage life-enhancing innovations is to refrain from the regulation of *all* apps, not just the ones that are deemed insignificant or low-risk.

As a practical matter, the cost and complexity of undergoing regulatory approval constitutes an unreasonable barrier to entry for app developers. This barrier disproportionately hurts new, small firms.

App regulation would also engender a false sense of security. Mobile medical apps that are FDA-approved will not be examined or used with the same vigilance that would occur in a naturally skeptical marketplace, creating a situation that is *more* dangerous than it otherwise would be.

As a moral issue, to regulate mobile medical apps is to engage in a style of “preventive law” that unfairly presumes guilt and incompetence on the part of the entrepreneur. The proper prospective mechanism to determine whether an app is suitable for use is the free market, not the government. Left to function freely, the market will sort out apps more accurately and more quickly than the FDA, and at no cost to taxpayers.

Sincerely,

Jared M. Rhoads