

**Opening Statement of Chairman Fred Upton  
Health Subcommittee Hearing on “Examining Federal Regulation of Mobile  
Medical Apps and Other Health Software”  
November 19, 2013**

Mr. Chairman, thank you for holding today’s hearing on the federal regulation of mobile medical apps, software, and other health technologies as medical devices. We began this work last Congress as part of the enactment of the Food and Drug Administration Safety and Innovation Act. Innovation in this sphere must be protected, which is why we included a provision in the law on the regulation of these technologies, including medical apps.

In March, three Energy and Commerce subcommittees, including Health, held hearings on this important topic. At the hearings, we heard from a broad spectrum of witnesses, including a patient group and the Food and Drug Administration. The witnesses believed that these technologies have the potential to transform health care and help millions of patients, adding that in order to continue that progress, patients, doctors, innovators, and Congress must work together to ensure that any regulation of health information technologies protects innovation and patients.

In recent months, the FDA has taken significant action in this area. The FDA’s decision to step in and regulate *some* of these technologies – by their own admission not all but some – is something I think most people view positively. The issue for this committee is *how* the FDA seeks to regulate in this space and what that means to patients and innovators both now and in the future.

I commend the FDA for its recognition that it needed to act in this space. However, I also recognize that the FDA today is ill-equipped with its current regulatory tools to manage such an undertaking. Therefore, I promise to work with the FDA to modernize these tools and regulations moving forward.

Vice-Chairman Blackburn, along with a bipartisan group of colleagues from this committee, has put forward one such proposal. It would give the FDA new and updated tools to regulate medical apps and other technology as software rather than as medical devices. It is my hope that FDA takes this offer of support seriously and will commit to working with this committee on the bipartisan, commonsense proposal we will examine today.