Opening Statement of the Honorable Greg Walden
Subcommittee on Communications and Technology
Hearing on "Health Information Technologies: Harnessing Wireless Innovation"
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It's not every day that the Subcommittee on Communications and Technology holds a hearing addressing FDA regulation. The fact that we are having such a hearing is a testament to the breadth of innovative uses wireless smartphones and tablets are bringing to nearly every aspect of our lives. There are literally thousands of apps in the various smartphone and tablet app stores in the health and wellness categories--everything from simple calorie counters to complex analytical tools. The more than 300 million wireless devices we depend on every day are revolutionizing health and wellness.

If I stopped here, this hearing could be about the success of bringing the innovation and investment of the wireless ecosystem to bear on the ever more costly health care system. And make no mistake, that could still be the outcome. But the specter of costly and time-consuming regulation – to say nothing of a 2.3 percent excise tax – looms large over this industry. Investors, wireless device manufacturers and application developers all face the uncertainty of an FDA regulatory regime that may or may not apply to them and the possibility of an additional excise tax that cuts into already thin margins.

The collision of worlds in the mobile health – or mHealth – market is a study in contrasts. The app economy is characterized by low barriers to entry, quick time to market, and the ability to adapt to quickly changing user needs. Medical devices, on the other hand, face a long and costly pre-market approval process at the FDA. We all want to ensure patient safety, but why would we treat mobile applications the same as a dialysis machine?

The answer may be that the wireless economy represents a tempting target for the 2.3 percent excise tax that the president's health care law placed on medical devices. While the IRS and the FDA have provided some draft guidance on how they will apply the medical device definition and the medical device tax, their analysis is not a poster child of clarity and leaves large parts of the economy wondering if they will be on the hook for what is essentially a tax on innovation.

The FCC and the Obama administration have both joined the wireless industry in trumpeting the "virtuous cycle" of innovation and investment in mobile technologies: investment in wireless networks and devices creates opportunities for app developers to create new and innovative uses for wireless services, which in turn spurs further investment in networks and devices. mHealth is part of this virtuous cycle that is driving faster speeds, lowering costs, spurring innovation and creating patient benefits. Given their interconnected nature, we should be aware that an impact on one segment has the potential to slow the entire cycle.

The overbroad application of FDA regulation and the Obamacare medical device tax are not, as some have suggested, outside the realm of possibility. In a 2012 report by the Institute of Medicine, one expert author suggested that all health IT products should be treated as Class III medical devices, which receive the highest level of regulatory scrutiny and could be subject to the tax.

Luckily, while these are not hypothetical concerns, they are also by no means foregone conclusions. Wireless has and can continue to bring the mobile revolution to our nation's health and wellness sector. But we must ensure that as we bring the innovation of the wireless economy to health and wellness that we not place unnecessary hurdles in the way of the developers and investors that are fueling mHealth.

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