From FitBit to Quitbit: The Role of Federal Agencies and Consumer Electronics

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The annual International Consumer Electronics Show (CES), held each year in early January, is a showcase for the latest gadgetry trends. The recently-concluded CES 2015 featured innovation in a variety of forms, not the least of which are products with a health-related focus. From the FitBit to track steps to the Quitbit to track progress in quitting smoking, the number of products recording consumer behavior continues to proliferate.

Techies and ordinary consumers aren't the only ones interested in all things electronic, however. Numerous government agencies have jurisdiction over these products depending on their functionality, including the Federal Trade Commission (FTC), the Food and Drug Administration (FDA), and the Federal Communications Commission (FCC). A few products featured at this year's CES demonstrate this intra-agency overlap.

For example, the "Breathometer Breeze Breathalyzer" features the following claims: it can detect blood alcohol levels with the same degree of accuracy as policy breathalyzers, tell consumers when their blood alcohol content will be 0.0, and has a "home safe" function that allows consumers to call a car service or friend to help them get home safely. The product purportedly is a Class I medical device that can connect to smartphone apps via Bluetooth.

At least three federal agencies would have some level of jurisdiction over this product. The FTC's main concerns likely would be claim substantiation relative to the performance claims and consumer privacy. As the nation's leading public health agency, the FDA also has an interest in ensuring that the product is safe and effective and that representations regarding product performance are truthful and not misleading. Finally, given the use of radio spectrum and connectivity to smart phones, the FCC also would have jurisdiction over the manufacture, marketing, and use of these devices.

Similar degrees of overlap can be found with other products featured at CES such as the following:

- Pacifi Smart Pacifier – Takes temperature, records when medications are administered.
- OKU Skin Health Sensor – Uses an optical sensor to analyze the relative state of the user's skin to send readings on moisture, oils, and wrinkles.
- Liif – A "never forget" pillbox that reminds the users and caregivers when should be dispensed and sends alerts if it appears that doses are missed.
- Fitguard Mouthpiece – A mouth guard designed to help detect concussions and other brain injuries in contact sports.

All of these products connect to a smartphone app or other device. As such, like the Breathometer Breeze Breathalyzer, each of them is subject to the FCC's regulatory regime and likely would be under either the jurisdiction of FDA, FTC, or both given their intended use and product claims.

The lesson for companies marketing these products or seeking to incorporate technology into their existing products is the importance of regulatory awareness. It is key during the product development phase to determine which agencies may have jurisdiction over the product and how that may impact product functionality, claims, labeling, warnings, etc. Further, as a broader matter, it is important for companies in this sector to be aware of the governing agency's stated concerns relative to the "Internet of Things" and how these products and the information generated by them affect consumers. For example, in her remarks at CES, FTC Chairwoman Edith Ramirez's called on companies to enhance their data security and privacy practices to build consumers' trust relative to health-related devices. Marketers of health-tracking devices can best respond to these and other regulatory concerns by factoring them in to the products' design and functionality at the outset.

Kelley Drye has responded to industry's increased focus on technology by creating a cross-functional practice team that combines the consumer products knowledge of our Advertising and Marketing and Consumer Product Safety Practice Groups with the technical knowledge of our Telecommunications Practice Group. We assist clients with counsel related to wearable health technology and accompanying labeling relative to its potential classification as a medical device, as well as health and performance claims made in advertising and marketing and consumer product safety considerations.

We also advise clients regarding FCC regulatory requirements affecting the manufacture, labeling, importation, and marketing of consumer electronic devices that intentionally or unintentionally emit or use radio waves; spectrum allocations and rules concerning the design and use of unlicensed and licensed radio frequency devices in the United States; and regulatory compliance, investigation, and enforcement matters involving radio frequency devices.

As the fashion industry increasingly incorporates technology into their products, understanding the legal and regulatory parameters of these decisions has become ever more important. To hear the latest on the top legal issues relevant to the fashion and retail industry, including issues related to wearables, join Kelley Drye at our Fashion and Retail Law Summit next Thursday, January 22, 2015 in New York.