

Why In-House Attys Must Buck Up And Work With Regulators

By **Michele Gorman**

Law360 (July 26, 2018, 2:01 PM EDT) -- Too many in-house lawyers and other business leaders are hesitant to truly get in the sandbox and work with regulators on shaping policies that could have a huge impact on their technology, according to experts, who warn that the downside could be policies that hamper the benefits of innovation and companies' bottom lines.

The digital transformation and innovation of mobile devices, blockchain, 3D printing and autonomous vehicles, to name a few, present new opportunities and risks for businesses across industries. How that plays out is determined in large part by regulation, and innovators should collaborate with regulators to create policy under the Trump administration, according to Crowell & Moring LLP's recent 2018 Regulatory Forecast.

From established companies to startups, leaders at companies across industries appear frightened by the idea of directly collaborating with federal, state and global regulators, said Cheri Falvey, a partner in Crowell & Moring's recently launched digital transformation practice and former general counsel of the U.S. Consumer Product Safety Commission.

She urges legal departments not to fear working with regulators in Washington, D.C., and instead encourages attorneys and other leaders to embrace the chance to participate in policy formation because new technologies may require rules in antitrust, enforcement, health care, intellectual property, privacy and cybersecurity, tax, trade, and other areas.

"If we wake up and find out down the road about a regulatory limitation we weren't anticipating, it can have a serious impact on business," she said. "The White House has said it wants to achieve a regulatory framework that will enable innovation. Right now, companies have an opportunity to engage with regulators and help shape the digital transformation for years to come."

Banks and other financial institutions are forging ahead with blockchain, the U.S. Food and Drug Administration is overseeing regulations for 3D printing of medical devices and the Federal Aviation Administration and the White House are searching for a balance for unmanned aircraft system regulation, the firm pointed out in its report.

New technologies are often unfamiliar to regulators; helping them learn more about innovative ideas and understand the accompanying advantages and risks can result in exceptional policy outcomes, Falvey said. If a regulator asks, say, for information about autonomous vehicles, a wise company will be an asset for the agency by teaching the technology and possibly enhancing its competitive edge.

“There is so much innovation happening, and most agencies are resource-constrained because they have huge mandates from Congress and a million things to do,” Falvey said. “You know your product and your data better than everyone, so that’s how you can help the regulator.”

Technological developments far outpace regulatory and legal frameworks. Where regulators often react to wrongdoing and proceed with caution, entrepreneurs usually respond to what they view as market demand and move at a faster pace, said John Yates, partner-in-charge of Morris Manning & Martin LLP’s technology practice who has worked with entrepreneurs for the past three decades.

To avoid policies that deter innovation, Yates advises companies to join with regulators to make reasonable regulations that anticipate growth and change.

“Companies at some point in time are going to face regulators, so they have to decide whether they want to ask for permission or beg for forgiveness,” he said.

In the health care industry, digital transformation is reshaping the work of device makers, medical providers and app developers, and helping the government keep up with those changes comes with the territory.

For the past several years, entrepreneur Drew Schiller has been actively working with the FDA, Office of the National Coordinator for Health IT, and Centers for Medicare & Medicaid Services to advance their understanding of technology and its impact on health care. He co-founded and now serves as the CEO of Validic, which has helped guide health systems, payers and companies through the complications related to patient-generated data for remote care.

Validic’s current focus is the reimbursement side of digital health. Schiller was pleased when CMS recently included three reimbursement codes for remote monitoring in its updates.

“While there is still work to be done on these codes to make them more conducive to provider success and patient outcomes, this is an important recognition from CMS on the value remote monitoring offers the industry,” Schiller said in an emailed response.

In his view, bringing together stakeholders is the only way to represent the variety of perspectives needed to create an interoperable health care system and to understand the technological, operational, regulatory and legal perspectives to decide on the best path forward.

The reasons why companies should want a place in the sandbox when it comes to shaping policy across all levels of government are almost innumerable.

One regulatory issue now affecting thousands of corporate legal departments is the European Union's General Data Protection Regulation. Enacted on May 25, the GDPR forces companies or firms in any country that offer products or services to EU residents, or that store and collect data on those individuals, to gain explicit consent to keep personal data and allow consumers to have their details deleted.

Other policies making waves in the country are at the state level, Falvey said, including Illinois' Biometric Information Privacy Act that established standards for how employers must handle state employees' biometric identifiers and information, as well as California's landmark privacy bill that will give consumers the ability to control how online companies use and share their personal information and to request its deletion.

Combine the states' policies with the GDPR, and suddenly the collection and use of data on biometric and geolocation data become a paramount legal consideration, Falvey said.

In-house lawyers willing to collaborate with regulators must do more than just sit in a room together, said Falvey, who suggests they propose specific and practical business ideas that enable the technology and provide assurance to regulators that the concerns about legal risks are being met.

Still, she acknowledged that some companies might avoid regulation because the process isn't a one-size-fits-all approach for every business.

"But if you shape the way you want to see the policy come out, and come up with a voluntary self-regulating opportunity that really understands the technology, you're going to have much more of a welcome reception from the regulators and be able to work better with them," she said. "I do see it as a necessity."

--Additional reporting by Joyce Hanson and Allison Grande. Editing by Rebecca Flanagan and Emily Kokoll.