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European Regulation Looms Over Mobile Health

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The mHealth Regulatory Coalition, an industry group that has been active in engaging FDA on evolving mobile health policies, is now extending its efforts to Europe as the European Union and several member countries are planning new regulations in the space.

The cumulative impact of these regulations, including forthcoming medical device legislation, might define mobile health care technology in Europe. Members of the coalition started mapping out an approach to mHealth advocacy in the region earlier this month.

The group intends to cover five key areas in Europe: regulating wellness versus disease; accessories to medical devices; standalone software in clinical decision making; regulation of pharmaceutical applications; and the EU's large privacy bill, according to Bradley Thompson, an attorney with Epstein Becker Green in Washington, D.C, who heads the coalition.

"While we [were] pushing ahead in the U.S., the member companies were coming to us and saying, 'Well, we've got the same issue outside the U.S. – for example, in the EU. Can you do something to help us?'" Thompson said in an interview. "The EU really is going through its own regulatory revolution both in the medical device realm ... but also more specifically in the area of software.

"So we concluded that there it was an awful lot easier to try and have an impact on those regulatory policies before they were developed, than after they were already set in place," Thompson said. "We felt like the time to do something was now, and we had to organize the stakeholders and have a discussion around that."

Thompson and 25 companies convened on a March 8 call to plan a piecemeal strategy for Europe on a country-by-country level. Influencing bigger efforts like the overarching medical device reforms in the works might be more difficult. (See *"Pre-Market Question Attracts Debate At EU Parliament Session On Device Reforms" – "The Gray Sheet," Mar. 11, 2013.*) "We're not going to try and tackle that because we're too small of an organization to have an impact on medical device regulation," Thompson said.

While it might be easier to influence regulations at the country level, the result might be a mishmash of different laws in different countries, Thompson said. "There is some concern that having a lot of variability of regulatory approaches ... will basically allow for economic barriers to be erected at that country['s] borders," Thompson said. "And so we don't have a position on it; we're going to be studying that some more, to see [if] it wouldn't be better to have a uniform EU rule that will allow for easier market access of the EU, of standardized regulatory and technical standards, being recognized across borders."

The group intends to reconvene by phone in about three weeks, at which time they should have a more concrete strategic plan for EU-wide action concerning the key areas mentioned above.

Wellness Versus Disease

In the EU, as in the U.S., Thompson argues that mobile applications designed to impact disease states are more highly regulated than applications promoting wellness. That becomes a problem for mobile health companies.

"There's simply a gray area between 'what is wellness?' and 'what is disease?'" Thompson said. "As we move forward in our medical and scientific understanding, we start to appreciate that the amount we exercise during the day; the diet we have during the day; the stress that we're under during the day; the amount of sleep we get at night; all of those things impact generally our health, our wellness – but they also have disease-specific implications.

"What marketers tend to want to do, is explain how these mobile apps can be used not just to generally make you feel better, but basically help you manage your health with regard to specific diseases or conditions," Thompson argued. "There's a lot of low-risk stuff that should not be regulated."

Accessories To Medical Devices

"The problem is, in a connected world, if you basically consider anything connected to a medical device to be a medical device, and regulate it to the same degree as a medical device, that results in a great expansion of the scope of what is regulated, and it results in kind of a up-classification of everything to whatever that parent device classification is," Thompson argued – with that regulation even bearing on standard equipment, like USB connectors.

"We're, all of a sudden, starting to connect medical devices to cell phones or connecting them to PCs, we're doing it

through Bluetooth, we're doing it through wired connections, and we're using these cellphones to transmit the data, to cell towers, which ultimately goes into someone's database ... all of these things start to get within the regulatory reach. And that's overkill."

Privacy Concerns

Europe may eventually be covered by a sweeping privacy protection law which could upend mobile health care technology developers' business models.

Thompson said, "In the EU, privacy really seems to be much more concerning than in the U.S. In the U.S., HIPPA is now [a] fairly old regulation; people generally understand what it requires – it's burdensome, but it's fairly mature in the way of requirements. In the EU, I guess we're seeing the number of new privacy requirements, and the trend is to be very draconian, very demanding in terms of the safeguards you have to take in order to protect the privacy of data." He further expressed worries about the unintended consequences of the new privacy law.

With the recent Treaty of Lisbon installing the protection of personal data as a fundamental right in the EU, new continent-wide regulation became necessary; with that necessity, the European Commission decided on a course of action that treated many industries similarly.

Thompson's colleague, Erik Vollebregt of Axon Lawyers based in Amsterdam, described the potential challenges in an interview. "It's a horizontal instrument that cuts across all fields of activity in the economy," he said. "And that means if there is not a particular exception applicable to a specific economic activity – like health care for example – this regulation regulates collection and processing of data completely the same."

Data profiling refers to the use of personal data compared to certain average representations of people, and making decisions based on it presents an important challenge, he said. Profiling might become critical in mobile health and digital health. Programs could gather data and inform doctors about potential problems, for example.

"The way profiling is defined now ... is something in online advertising that is really, really negative; that's something you don't want to happen," Vollebregt said. "On the other hand, if you look at profiling in telemedicine, you need to profile in order for the telemedicine service to work."

Unfortunately, the current regulation is "a horizontal statute which treats both of these activities in exactly the same way, without giving any meaningful exception, because that has been so limited now for health care," Vollebregt said. "So that makes it really difficult to do mobile health services."

Personal data is regarded as "dynamic" in Europe, which can present problems, he said. A company can do what it wants to with nonpersonal data that is not identified or identifiable with a particular person, but if a decrypter technology that can identify the person associated with the data becomes available, then the data may be considered personal under the regulations.

Vollebregt said that blinded clinical data can be considered personal because the data can often be unblinded for post-market surveillance purposes. "I've assisted several companies from the U.S. that were entering the European market with global health concepts," Vollebregt said, "and they had a lot of difficulties wrapping their minds around this dynamic concept of personal data."

Managing that data will become nettlesome, with the law requiring anyone processing data covering more than 500 people – a low barrier for many apps and services – to retain a "data protection officer."

The law perhaps offers a way out. Gathering the informed consent of the patients involved allows the gatherer to use data for a wider set of purposes, but that may also be difficult, Vollebregt warns. Companies have the burden of proof in showing the patients' consent was valid, and the law will not accept consent arising from a situation of "imbalance between the patient giving consent and the party obtaining the consent."

Vollebregt gave a hypothetical situation in which consent would be considered invalid for that reason: "Let's say you're in the doctor's office and the doctor says, 'Well, I'm going to prescribe that you use this [mobile health] solution, because I think it's good for you. Please sign here.'"

The health agencies of the EU have pushed for mobile health and other digital health solutions as a way of improving care; however, the agency responsible for conceiving the data protection law has a different set of goals.

Vollebregt categorizes the strategy as getting the "most bang for your regulatory buck," because the privacy law is subject to so much lobbying; a broad rule seen as a good method of protecting privacy may not consider health care applications.

The law might still flounder. A vote in the European Parliament on the proposal is scheduled for April, with the remainder of the year likely spent reconciling the Commission's, Parliament's and Council's visions for the bill. But the bill is facing an unofficial summer 2014 deadline – at that time, new elections for European Parliament will begin, and the Member States will be allowed to change the representatives of the European Council.