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Coalition survey highlights CDS uncertainty

The CDS Coalition, a US-based group of stakeholders lobbying for appropriate clinical decision support ('CDS') software regulation, released on 26 February survey results, which found, *inter alia*, that a third of 48 respondent companies had abandoned CDS product development due to uncertainty about US Food and Drug Administration ('FDA') regulation of CDS.

"Compliance with FDA requirements are a major driver in the cost of developing software. Not knowing such an important factor has scared off many investors," explains Bradley Merrill Thompson, Member at Epstein Becker & Green. "Why wouldn't developers simply ask the FDA? Firstly, there is very little consensus within the agency regarding its approach. Second, having to ask for each and every iteration of the software is perilous for developers, because the software constantly changes."

FDA guidance is yet to be issued but has been promised since 2011. "Given the complexity of the issues, there will almost certainly be a need for FDA guidance, whether Congress legislates on CDS or not," adds Thompson.

IN THIS ISSUE

German court clarifies medical review portal monitoring duties

The German Federal Supreme Court ('FSC') released on 1 March its judgment in case no. VI ZR 34/15, in which it specified the monitoring duties of medical professional review portal operators, finding it necessary in some cases for such operators to verify the validity of user reviews.

The case concerned a dentist's filing for an injunction against a portal following a negative review by an anonymous user. The portal refused to delete the post, despite the dentist's claim that he may not even have medically treated the user. The FSC found in this case that the portal had breached its monitoring duties. "The court acknowledged that the operation of a review site bears a comparatively higher risk of personal rights infringements than other portals," explains Dr. Martin Gerecke, Senior Associate at CMS Hasche Sigle. "This risk is increased with reviews posted anonymously or under a pseudonym; such reviews make it more difficult for the doctor to take direct measures against the reviewer. Thus, to establish a balance between the portal operator's and the reviewer's interest, the portal operator needs to adhere to specific duties when receiving a complaint."

The FSC outlined those duties, requiring the portal to forward the dentist's complaint to the reviewer and to request evidence from the user of the treatment received, for forwarding to the dentist, albeit in an anonymised format. Further, an operator's monitoring duties "may not go so far that economic operation of the portal is no longer possible or is hindered in a disproportionate way," say Laura Bortels and Dr. Daniel Kendziur of Simmons & Simmons. Portal operators "should develop special compliance systems with regard to the court's verdict," believe Dr. Alexander Csaki and Clarissa Junge-Gierse of Bird & Bird. "Those systems might include best practice rules for clarification and verification in the event that a medical doctor/facility complains about unjustified allegations. Users should be informed that corresponding information might be requested, to discourage users from making unjustified allegations."

The FSC also maintained that medical professional review sites are legal, and may allow anonymous postings. "The judgment has created legal certainty in the interest of German public health services," add Bortels and Kendziur. "We await the decision of the Higher Regional Court of Cologne, to which the case has been remitted for a final decision."

Employee use of wearables in breach of Dutch privacy law

The Dutch Data Protection Authority ('DPA') has found that the processing of employee wearable data by employers is in breach of the Dutch Data Protection Act, explains an 8 March press release. The DPA's examination of two companies' processing of wearable data found that the data collected by wearables is personal health data and thus subject to strict legal requirements, and that in an employment relationship, in which the employee is dependent on the employer, consent to such processing of health data cannot be freely given.

"These cases show that EU data protection authorities are already transitioning to GDPR standards," says Erik Vollebregt, Partner at Axon Lawyers. "The application of when consent is given 'freely' anticipates the GDPR's criterion that consent can never be given freely in a situation of dependence."

The full report has not been released yet, so it is not known what instigated the examination. However, given that it fits with the DPA's Supervision Agenda for 2016 in which the authority stated that it would focus on health data, data processing within an employment context and the processing of data from wearables, the examination could have been an initiative of the DPA.

"Given the sensitive nature of the personal data concerned, it is to be expected that the DPA will continue to pay attention to the security of health data. Several data breaches relating to health data have been reported recently," adds Elisabeth Thole, Partner at Van Doorne.