

Key Takeaways from Covington's Webinar about Digital Health Associated with Pharmaceuticals

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On February 1, 2018, Covington's Digital Health team hosted a webinar examining U.S. and EU regulatory issues for digital health associated with pharmaceuticals. Here are some key takeaways from that webinar:

- **Neela Paykel** from **Proteus Digital Health**, noted that "you need to think outside the box for how to engage, whether you're a pharma company or a digital health company. For pharmaceuticals, you have to understand that there's more risk tolerance in the technology space. For digital health companies, you have to understand healthcare regulation and appreciate all the regulations pharmaceutical companies are dealing with on a regular basis."
- **Grant Castle** from Covington's London office described how "it's tempting to think once you've understood the regulations, you can enter the market with a digital health product, but in many respects, that's the start of the challenge. Systems for pricing and reimbursement of digital health offerings have yet to evolve fully. It can also be challenging for a pharmaceutical company to offer digital health products where regulations might prohibit pharmaceutical companies from providing incentives to healthcare professionals for its products. Such issues mean that you need to think strategically." **Sarah Cowlshaw** added that digital technologies are being used in drug development, particularly to help collect real world evidence. Companies thinking about digital health in drug development need to consider other challenges such as data reliability, consent, and operability with other platforms.
- **Christina Kuhn** described how different centers within FDA might decide whether a digital health solution is regulated as a device and whether a digital health solution would affect a pharma company's responsibilities for a drug. **Wade Ackerman** noted that "companies approaching FDA should think carefully about how to present FDA with the information it needs to understand and assess the digital health innovation. How companies approach the

agency will depend on the particular digital health technology, including how it relates to a pharmaceutical product.”

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