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QUOTED. Aug. 31, 2018. Marc Scheineson.

by

Medical app regulation has been a rapidly changing field and area of focus for US FDA over the last several years. Most recently, the agency approved the first direct-to-consumer app-based contraceptive, *Natural Cycles*. See what Marc Scheineson, an attorney and FDA vet who heads Alston & Bird's food and drug law practice, said about the app here.

"Everybody's watching this. You can envision situations in which the mother may have some genetic predisposition to a serious disease or a birth defect and clearly not want to get pregnant. If she gets pregnant and she's using this, there are product liability cases based on wrongful death where someone is killed. But there can also be product liability cases based on wrongful life, where someone gives birth to an impaired child and they require medical services for an entire lifetime, and the parent can try to get damages based on that." –Marc Scheineson, attorney, Alson & Bird

• Find out more: <u>O&A</u>: <u>What Do FDA</u>'s <u>Recent Medical App Approvals Mean For Industry?</u>

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