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Mansfield Rule Certified 2022-2023

Understanding Emergency Use Authorization Issues with COVID-19 Vaccine, Healthcare Risk Management, ft. Christopher Tellner

Christopher Tellner, KD partner in Blue Bell, Pennsylvania, was quoted in a Healthcare Risk Management article published on January 25, 2021.

Current COVID-19 vaccines have not undergone the process for full FDA approval, but have been authorized under a streamlined process known as an emergency use authorization (EUA), notes Christopher Tellner, JD, partner with Kaufman Dolowich Voluck in Blue Bell, PA.

Because the vaccines have only received an EUA, they are technically considered experimental and are subject to regulations that may affect whether employers are permitted to mandate their use by employees, he says.

Section 360bbb-3(e)(1)(A)(ii)(III) of the Food, Drug, and Cosmetics Act – 21 U.S.C. § 564 provides that people be informed of "the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."1

Because COVID-19 vaccines are authorized through EUA, as opposed to having been authorized via FDA approval, this section of the Food, Drug, and Cosmetics Act applies to the current vaccines, Tellner says. This section appears to require the Department of Health and Human Services to ensure people are informed of their right to refuse the vaccine, he says, but the EUA is silent on this topic.

"While this section may serve as grounds for employees to challenge mandatory vaccination requirements imposed by employers, it is too early at this time to determine the likelihood of success of such a challenge," Tellner says. "Should the current vaccinations eventually achieve full FDA approval, this section would no longer serve as grounds for a potential challenge to mandatory vaccination requirements."

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