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QUOTED. March 8, 2018. Peter Mullenix.

by

Friedman Rubin attorney Peter Mullenix isn't happy with US FDA's plan to ask for more adverse event reports in a summary format, arguing that it could negatively affect public health. Check out what he wrote to the agency here.

"Malfunction events that do not lead to death or serious injury are blessings, but they are not irrelevant. They are the canary in the coal mine. Miners do not need a quarterly, bundled summary of dead canaries. Similarly, patients need to know about all malfunctions, because they might not be so lucky as the earlier patients who escaped injury." –Peter Mullenix, partner, Friedman Rubin

Find out more: <u>Stakeholders To FDA</u>: <u>It's A Bad Idea To Ask For More Adverse Events In Quarterly Summary Reports</u>

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