Jennifer Kreick in BioWorld: 'Lack of Clinical Trial Diversity Could Have Consequences'

February 26, 2021 Jennifer Kreick

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BioWorld quoted Haynes Boone Associate Jennifer Kreick in an article about potential risks for drug and device companies related to lack of clinical trial diversity in late-stage clinical trials.

Here is an excerpt:

A final guidance the FDA released in November suggests that the days of ignoring segments of the intended treatment population until safety signals flare in real-world use are coming to an end. The guidance instructs sponsors to enroll trial participants who reflect the characteristics of clinically relevant populations with regard to age, sex, race and ethnicity. It also discusses ways of including people with comorbidities and other special populations in phase III trials.

The guidance sets an industry standard, Jennifer Kreick, an associate with Haynes Boone, told *BioWorld*. “It’s a really good starting point,” she said of the guidance, adding that more regulatory action is sure to follow.

Potential litigation

The guidance, and the push for greater trial diversity, also could open the door to a new kind of failure-to-warn lawsuit. Typically, such suits test new arguments, under state law, to go after companies for failing to disclose known safety information. Those suits are generally shot down due to preemption based on the FDA’s approval of the label.

But given the standards set in the guidance and the pressure for more data and trial inclusivity, it’s conceivable companies could face legal challenges for failing to include specific subpopulations in their trials when those groups are part of the intent-to-treat population.

While Kreick isn’t aware of any such court challenges now, she said it is potentially a risk, especially in egregious cases when a sponsor intentionally excludes a significant subpopulation from a trial. Of course, it would be up to the courts to decide whether the failure-to-warn claims would be preempted by the FDA’s approval of a product, despite the trial exclusions.

In her practice, Kreick is advising drug and device companies to pay close attention to the guidance and to question every proposed exclusion when designing a trial. It’s no longer acceptable to “cut and paste” the exclusionary criteria from one trial to the next, she said. Sponsors should do an analysis of the criteria for each phase of a trial.

At the same time, sponsors must do a balancing act to reduce the possibility of having a trial fail because of inclusion of participants with certain comorbidities, Kreick said. Again, the FDA guidance offers suggestions on how to handle that, especially in drug trials.

To read the full article, click here.