TOP OF MIND

A Pause for Some COVID-Related Clinical Trials are Routine and Necessary to Ensure Patient Safety and Effectiveness

Clinical trials for COVID-19 vaccines and treatments once again captured headlines this week.

- On Monday, Johnson & Johnson paused its 60,000-person Phase III vaccine trial due to an "unexplained illness" in one of the volunteers.
- On Tuesday, Eli Lilly temporarily stopped its 326-person Phase III antibody trial because of a "potential safety concern."
- This week's developments followed a similar pause in AstraZeneca's Phase III vaccine trial due to "a single event of an unexplained illness" in September.Their trial was subsequently resumed in five countries following approval from regulatory authorities.

These three developments may seem worrisome. In fact, the opposite is true. **Clinical trials are routinely paused to ensure the medicine being tested is truly safe and effective.**

Experts have pointed out that, if anything, it would be more concerning if *no* adverse events were reported in a large, late stage trial like Johnson & Johnson's.

A global spotlight: These developments shed light on yet another new phenomenon of the coronavirus pandemic: global consumers have never before paid such close attention to clinical trials.

But the spotlight merely reveals that the process is working. While time is of the essence, regulatory authorities have resolved not to cut corners. With over 38.5 million global cases and 1 million deaths from COVID-19 to date, there is simply too much at stake for us to expect any less.

—Kelly Anderson, Director of International Policy, Global Innovation Policy Center, U.S. Chamber of Commerce

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