Pfizer Quietly Adds Language Warning That ‘Unfavorable Pre-Clinical, Clinical Or Safety Data’ May Impact Business

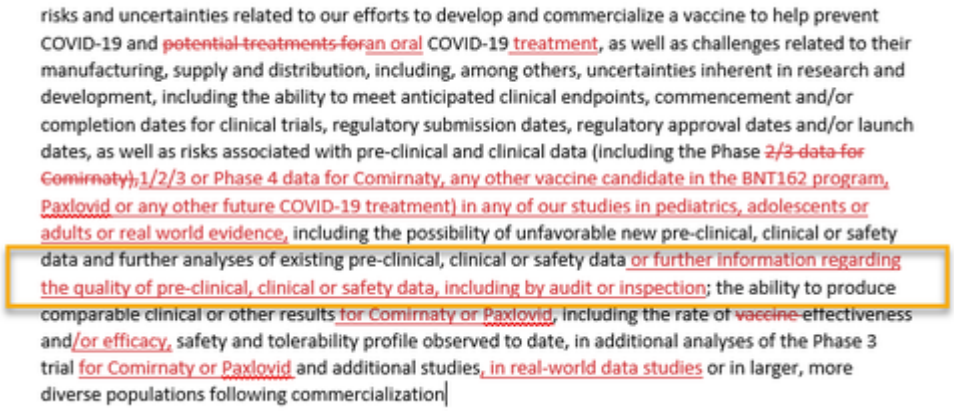
Description

USA: Two weeks ago, the FDA begged a Texas judge to delay production on the first monthly batch of 55,000 pages of Covid-19 vaccine data submitted to the agency by Pfizer. Originally, the agency was set to produce just 500 pages-per-month.

Now, **Pfizer – which just forecast $54 billion in Covid-related sales in 2022, appears to be anticipating some *bad news*,** as evidenced by several redline changes in their Q4 earnings releases.

As Rubicon Capital’s Kelly Brown notes on Twitter, the changes center around **disclosures of unfavorable safety data**.

For example, in Q4 they added: "**or further information regarding the quality of pre-clinical, clinical or safety data, including by audit or inspection**."



risks and uncertainties related to our efforts to develop and commercialize a vaccine to help prevent COVID-19 and ~~potential treatments for~~an oral COVID-19 treatment, as well as challenges related to their manufacturing, supply and distribution, including, among others, uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with pre-clinical and clinical data (including the Phase ~~2/3 data for Comirnaty),~~1/2/3 or Phase 4 data for Comirnaty, any other vaccine candidate in the BNT162 program, Paxlovid or any other future COVID-19 treatment) in any of our studies in pediatrics, adolescents or adults or real world evidence, including the possibility of unfavorable new pre-clinical, clinical or safety data and further analyses of existing pre-clinical, clinical or safety data or further information regarding the quality of pre-clinical, clinical or safety data, including by audit or inspection; the ability to produce comparable clinical or other results for Comirnaty or Paxlovid, including the rate of ~~vaccine~~ effectiveness and/or efficacy, safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial for Comirnaty or Paxlovid and additional studies, in real-world data studies or in larger, more diverse populations following commercialization

> Pfizer added new and peculiar items deep in its business risk disclosures re: clinical trial data, today in its Q4 earnings.
>
> (1/3)
> "…risks associated with…further information regarding the quality of pre-clinical, clinical or safety data, including by audit or inspection;" pic.twitter.com/2GCjs0Bj3r
>
> — Kelly Brown (@rubiconcapital_) February 8, 2022

The company also notes that Covid-19 may "diminish in severity or prevalence, or disappear entirely."

What's behind the curtain, Pfizer?

by Tyler Durden

Category

1. Health-Wellness-Healing-Nutrition & Fitness
2. Main
3. Politics-Geopolitics-Gov.-Events

Date Created
02/09/2022