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# Where is "Safe and Effective" in BioNTech's March 2022 SEC disclosure?

The previously unknown German biotechnology company BioNTech collaborated with the American pharmaceutical company Pfizer to bring out its COVID-19 vaccine. BioNTech contributed the mRNA technology and Pfizer contributed its extensive experience in conducting clinical trials, manufacturing, logistics, marketing, etc. The vaccine has now come to be known as "Pfizer", despite the proprietary mRNA technology developed by BioNTech. The precise connections between Pfizer and BioNTech are publicly opaque and masked in confidential contracts.

BioNTech has been publicly traded on the NASDAQ Global Select Market since 10 October 2019, where it is designated as an "immunotherapy developer"[i]. As such, it is obliged to submit a form 20-F to the Securities and Exchange Commission (SEC). Form 20-F is the primary disclosure document required of foreign private issuers listing equity shares on exchanges in the United States and requires comprehensive disclosure about the company, including information about risks related to its business operations.[ii] This is important as undisclosed risks could expose the company to liability, and potentially to huge lawsuits and class actions. BioNTech's 20-F SEC document submitted on March 30th 2022[iii] reveals extraordinary discrepancies between Pfizer/BioNTech's public statements about their COVID-19 product and the disclosures in the filing.

For example (p. 12) BioNTech states ***"We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine and/or variant-specific formulations to obtain permanent regulatory approval*** *in the United States, the United Kingdom, the European Union, or other countries where it has been authorized for emergency use or granted conditional marketing approval."*

On p. 6, BioNTech admits ***"Significant adverse events may occur during our clinical trials or even after receiving regulatory approval****, which could delay or terminate clinical trials, delay or prevent regulatory approval or market acceptance of any of our product candidates."* In addition, the commercial nature of the operation is apparent in this statement *"We face significant competition from other makers of COVID-19 vaccines and* ***may be unable to maintain a competitive market share for our COVID-19 vaccine****."*

BioNTech's lack of prior pharmaceutical development or manufacturing experience is well-known, but still disturbing to read in the face of the mass scale of administration of their COVID-19 vaccines to billions of people globally: *"Our COVID-19 vaccine was granted emergency use authorization.……****Prior to this, we had not sold or marketed any products in our pipeline****."* They link their future commercial viability specifically to sales of this product: ***"Our revenue depends heavily on sales of our COVID-19 vaccine, and our future revenues from our COVID-19 vaccine are uncertain."***

Just as surprising, given the fact that the vaccines have been in use since December 2020, is the disclosure (p. 8) that ***"the durability of immune response generated by our COVID-19 vaccine … has not yet been demonstrated in clinical trials****"*

Continuing on the safety profile of their COVID-19 vaccine, they admit the possible severity of side effects, even *"previously unknown"* and even *"after approval",* but again link those only to profits, not the health or wellbeing of vaccine recipients, *stating "Our future revenues from sales of our COVID-19 vaccine depend on numerous factors, including: the safety profile of our COVID-19 vaccine,* ***including if previously unknown side effects or increased incidence or severity of***

***known side effects as compared to those seen during clinical trials are identified with our COVID-19 vaccine with widespread global use after approval.*"**

The SEC filing also categorises the product as an immunotherapy, in the statement on p. 9 that ***"mRNA drug development has substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies."*** This would also accord with their NASDAQ designation as an "immunotherapy developer".

Although it is now 18 months since this product was brought to market, the filing says on p. 41 that *"product candidates may prove to have a stability profile that leads to an unfavorable shelf life. This poses risk in supply requirements, wasted stock and higher cost of goods."* They also raise potential issues with temperature control and viability during transportation, stating *"Our product and product intermediates are extremely temperature sensitive, and **we may learn that any or all of our products are less stable than desired**. We may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our product candidates and result in delays or interruptions to clinical or commercial supply."*

The possibility of cross-contamination, which has long been suspected, is also admitted: *"Due to the number of different programs, **we may have cross contamination of products inside of our factories, CROs, external contract manufacturing organizations, or CMOs, suppliers or in the clinic that affect the integrity of our products."***

BioNTech's ability to adhere to good manufacturing processes (GMP) is also called into question by the following paragraph: *"GMP requirements govern manufacturing processes and procedures, including record-keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in our products and product candidates. **Poor control of the GMP production processes can lead to product quality failures that can impact our ability to supply product**, resulting in loss of potential product sales revenue, cost overruns and delays to clinical timelines for our clinical programs, which could be extensive."* The potential for a product quality failure only references a negative impact on *"potential sales revenue"*, with no mention of any possible health impacts.

Despite the fact that the COVID-19 vaccines are already being distributed and administered to the entire world population, the filing ends with a statement questioning whether regulatory approval will ever be granted for their products, ***"The FDA, the EMA or other comparable regulatory authorities may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates."***

This SEC filing raises serious questions and concerns regarding the huge disparities between what the public is being told and what the company is admitting to in this official document. We must demand immediate answers to these questions and full accountability from BioNTech, Governments, Regulators and Public Health Agencies.

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[i] https://www.nasdaq.com/articles/biontechs-ipo-values-it-at-%243.4-billion-in-one-of-the-largest-biotech-listings-of-all-time

[ii] https://www.sec.gov/divisions/corpfin/internatl/issues0501.htm

[iii] https://investors.biontech.de/node/11931/html#ic5e06a05a31d4c4491031d3208cef8c2_2806