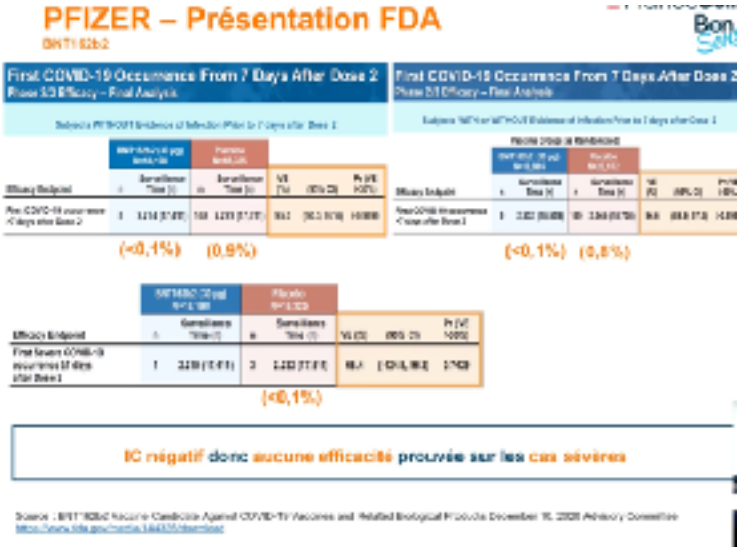
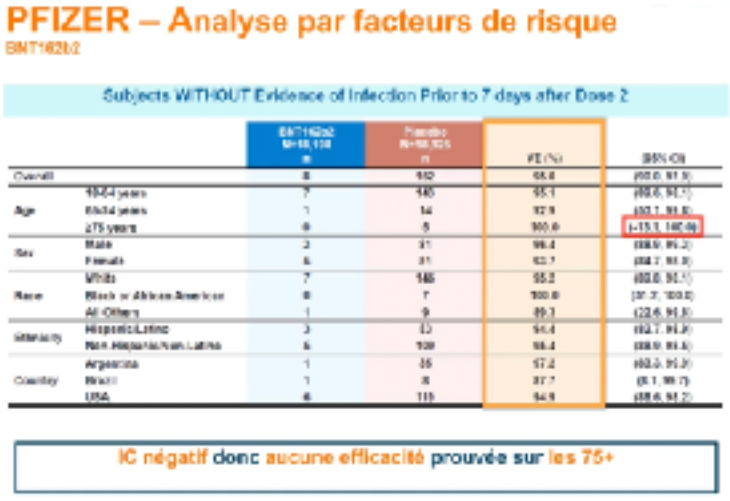
February 6, 2022

LATEST UPDATE COVID

Injection Pfizer - The dossier

File for 4 "Vaccines" have been "approved" by the FDA and the EMEA for a phase 3 to end in 2023, in emergency authorization





Issues with Pfizer's submitted dossier. The Pfizer FDA dossier claimed 95% efficiency. The detail review shows much different results

- Review done between April and Sept 2020, points to difference of infection of 0.1% for vaccinated and 0.8% for Placebo, so the over 80% efficacy. However, it proves that the COVID is only 0.8% infectious (much lower than expected - so COVID is not an issue generally). Further Pfizer (and the others) used a high proportion of persons with risk factors (Pfizer obesity 35%)
- Severe cases differences between vaccinated and placebo is not significant.
- Looking at age groups, the data shows no proven efficacy for the persons over 75 years of age. For info the flu vaccine efficacy reduces drastically with age groups.

•The average follow-up of the patients in the tested group was from a few days to 4 months, for an average 2 months.

•In addition, the report shows 409 vaccinated patients with symptoms but without being positive, against 287 in the placebo group.

•The expected incidence for all three companies (Pfizer, Moderna, J&J) was 1.3%, 075%, 1.4%… Flu is generally 20-30% children, 5-10% adults. With so few cases (placebo or others) 164/36,000 Pfizer, 151/30,000 Moderna).

•Curious is that China gave the Genome in January 2020 and Pfizer started in April 2020. This is recognized as an impossible timeline to publish a protocol and to get it approved…

•Last, Pfizer and the other never measures the antibodies which would have given the "exact" information of the efficiency and lasting effect of the vaccines… but that was never done

Pfizer Dossier should never had been approved, certainly not as emergency. The efficiency is much lower than mentioned even with the original alpha strain. Dossier show no efficacy for 75 years old and up - no long term effects verification as reviews lasted 4 months max with 2 months average. All three companies never measured antibodies to see efficacy or length of effect. ?????

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Official files were never accessible

People have successfully collected certain clinical data for a legal action in Quebec involving the approval of the file in general and in "Emergency Authorization".

Phase 3 Requirements

This is the last testing phase before a vaccine can be approved. The main focus it to demonstrate efficacy and safety

Emergency Use Authorization Requirements

An EUA must meet the following four statutory criteria to be considered. The goal of these criteria is to ensure that even in an emergency, the public is receiving the best, safest, most appropriate care possible.

1. There must be a serious or life-threatening illness caused by a specified chemical, biological, radiological, or nuclear agent.
2. It must be reasonable to believe that the product covered by the EUA is going to be effective for the intended use—diagnosing, treating, or preventing either an illness or condition caused by a specific agent, or an illness or condition caused by an approved or authorized medical countermeasure deployed against the agent.
3. The known and potential benefits need to outweigh the known and potential risks.
4. There must be no adequate approved, alternative medical countermeasures available for the situation.

Ventavia accused of wrongdoing

The Clinical lab Ventavia was accused of wrongdoings in the management of the Pfizer/BioNTech studies. These included falsification of data, "unblinding" of patients (researchers could see who received the vaccines, lack of training of vaccinators, and no follow-up of adverse events.

Typical phases timelines for Vaccines

- Pre-clinical phase last 1 to 10 years and involves mostly animals
- Phase 1: is done typically with few dozen healthy humans to assess short term safety, immune response and dosage. If accelerated it can be completed in 2 to 3 months
- Phase 2: This involves several hundred volunteers, normally is various age groups, for a continued assessment of on safety and immune response. The efficacy is not measured. If accelerated, the timing is 3 to 4 months
- Phase 3: The aim for real vaccine is to measure efficacy and safety using several thousand persons. This is done with placebo double blind control groups to measure short term and start long term safety. The timing should be 6 months to a year, but continuing for a couple of years for long term safety

Benefice / Risk assessment needs data

Normally, benefit reflects the benefit of therapy, compared to the risk of not doing it. Here the cards are turned over. There is practically no risk of not taking the doses, but a risk of taking them, even if small…

Lethality of Covid-19 - Benefit

- Covid 19 is associated at 94% with Co-morbities since the start.
- Today with current variant, no one , all ages dies from Covid alone.
- Lethality was 0.001% for under 20s, and 10% for over 80s and drops radically in last autumn.

Covid-19 effects - Risk

- The Pharmacovigilance process is poor, and relies mainly on self reporting, meaning that reporting is below 10%.
- Despite that the ANSM in France reports:
  - 42 severe cases per million after the 3rd dose (twice that of 1st and 2nd)
  - 3.86 deaths per million after 3rd dose)

Today risk for Covid -19 is inexistent for persons with no co-morbidities

Reported Risk is small but greatly underreported, unacceptable for a product in test case

Benefit a Vaccine is almost nil with so little mortality - Risk is not nil, specially of young healthy