FDA Pfizer authorization (Comirnaty): Key points to consider and discuss.
These points are an aggregate of many minds, including Dr. Robert Malone.
23 Aug 2021

General talking points

- Why mandates if herd immunity isn't possible?
- What happens 8 months after boosters?
- What's the plan for the next variant?
- Why we're messing with vaccine injury liability if the vaccines are safe and effective?

There are now TWO LEGALLY distinct (Pfizer vs. BionTech), but otherwise identical products, based on two FDA letters, as well as a press release. The analysis of these FDA products below is preliminary and subject to change.

Letter to Pfizer
https://www.fda.gov/media/150386/download

- **DOES NOT GIVE FULL APPROVAL**
- Extends EUA to allow supply of current Pfizer under EUA because limited supply of BioNTech version.
- "The products are legally distinct with certain differences that do not impact safety or effectiveness. (page 2, Pfizer letter)
    - here FDA quietly admits that the licensed Pfizer vaccine and the authorized Pfizer vaccine are identical with regard to safety/efficacy, but they are "legally distinct." *That's code for one has manufacturer liability, while the other doesn't. It is also code for "we don't want to impose a mandate on the EUA product cause it is illegal, but we can probably get away with a mandate on the licensed product."*
    - page 12 AA (Conditions with Respect to Use of Licensed Product). This tells you that yes, we licensed the vaccine, but...there is a lot of the old vaccine out there, actually "a significant amount" and this amount will be considered an EUA and will continue to be used.
    - Now, why would they do that? Why specify that identical versions of the product will be legally different? Because they need the license to impose the mandates. But **they need the EUA to evade liability**.
    - **Along with the license comes liability for the manufacturer.** (While all EUA products were given a liability shield.)
    - Unfortunately, **our federal governments would prefer us to be without recourse if we are injured, rather than have Pfizer defend its product in court**. So, the feds want us to THINK the vaccine we are receiving is licensed, which will make people submit because they think it can now be mandated, but instead we are almost certain to receive the EUA vials instead, to save Pfizer's behind. Yes, a

stingy CICP injury program exists, but **it has not paid out for a single COVID vaccine injury yet**.

- Warning about myocarditis and pericarditis

Letter to BioNTech (COMIRNATY): (signed by Mary Malarkey) – MARKET AUTHORIZES BLA (APPROVAL)
https://www.fda.gov/media/151710/download

- For "active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older."
- Analysis of […] adverse events reported […] not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.
- 13 Post marketing studies required
    - Pediatric (3 studies) < 6m to <15 y
    - Myocarditis and pericarditis (6 studies), with UP TO 5 years follow up
    - Pregnancy – teratology (1 study)
    - Dose levels, VA, effectiveness in Kaiser system (3 studies)
- The FDA bypassed/disregarded the normal advisory committee and public comment process for this license. See p2 "We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, ***did not raise concerns or controversial issues that would have benefited from an advisory committee discussion***."

Press release
https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

- "On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older."
- **The efficacy claims are based on outdated data.** The press release indicates that the basis of the efficacy claims was as quoted below. However, those data are outdated, and captured with strains of virus (Alpha, Beta) that are no longer predominant. The efficacy claims are therefore invalid – it is quite clear that the vaccine is much less effective in preventing infection by the currently circulating strain (Delta)
    - "Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty was evaluated in

approximately 22,000 people who received the vaccine and 22,000 people who received a placebo 16 years of age and older."
    - "Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease. "
    - "More than half of the clinical trial participants were followed for safety outcomes for at least four months after the second dose. Overall, approximately 12,000 recipients have been followed for at least 6 months."
    - "The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. The vaccine is effective in preventing COVID-19 and potentially serious outcomes including hospitalization and death."
- **The decision is premature. Regarding the risks of myocarditis and pericarditis.** Per CDC, those risks are still being assessed and may be at least 2.5 times higher than previously known. FDA does not have access to the new assessment as it has not been completed.
    - "the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes."
- **FDA ongoing safety data monitoring is inadequate.** Yet the FDA indicates otherwise.
    - "The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct postmarketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty."
    - In its letter to BioNTech, the FDA states ""\" We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis. Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks."
    - The first sentence says that VAERS will be incapable of assessing known serious risk
    - The second sentence says that the other pharmacovigilance systems that by law FDA employs (supposedly about 20 different databases when they were bragging about them last October) are similarly incapable of assessing known serious risk

- **The risks in pregnancy remain unknown.**
    - "although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty during pregnancy."
    - The prescribing info says: "There is a pregnancy exposure registry for COMIRNATY. Encourage individuals exposed to COMIRNATY around the time of conception or during pregnancy to register by visiting https://mothertobaby.org/ongoingstudy/covid19-vaccines/ ." **WHY ARE THEY DOING A PREGNACY STUDY?**
- **This was a politically motivated delaying action by FDA**-- to give the White House the license it demanded, which will not actually go into effect until the new product arrives. FDA presumably knows how long that will take, whether soon or not. Pfizer might already have the newly labelled vials ready to go in factories, but not yet shipped across state lines.
- **FDA has licensed the BioNTech vaccine for 16 and up**
- All of the authorized vaccine on shelves and in freezers will remain only authorized, until the new product with Cominaty labelling arrives.
- 3d or booster doses and vaccine for 12-15 year olds remains under EUA
- **Why not also approve the Pfizer version? Why leave it under EUA?**
- **When the press says the "Pfizer vaccine is fully approved." It is not.** The vaccine that is likely to be supplied for some time, WILL BE THE Pfizer – EUA vaccine. So any mandates based on full approval are meaningless.
- **THE BLA acknowledges LONG term myocardial issues with a 5 year follow up consistent with the lower range for LTFU for Gene Therapy Products.** Is FDA quietly acknowledging the Gene Therapy classification? These products have been classified by FDA as Gene Therapy Products which require UP to 15 years long term follow up in studies. This was acknowledged by Moderna in their 2Q 2020 filing.
- **Will FDA collect other long term data on autoimmune disease, cancer and other disorders** as contemplated in their Gene Therapy Guidance document?
- **VAERS system is clearly broken,** with underreporting and discrepancies as to what should be and what is reported. Cannot attribute causality.
- **Safety signal detection using disproportionality analysis (PRR) is known to be inadequate.**
- Using superior CDC published methods, normalizing for people vaccinated, wChildren's Health Defense **estimates 176x reports of VAERS deaths associated with C19 vaccines compared with flu vaccines.** 35x the number for H1N1 (where stimulated reporting is speculated)
- Using CDC published methods we estimate under-reporting of VAERS deaths to be 5-15x. for a total of 30,000-90,000 deaths, mostly non-C19. Underreporting for life-threatening events may be 24-64x.
- IN ADDITION – (Israel MOH, combined with Dagan study), **we have estimated between 35-86,000 EXCESS USA deaths due to Covid in those vaccinated (>=1 dose).**

- **Total range of deaths that may be associated with C19 vaccines – 65,000-176,000.** (can't assign causality)
- Note **total C19 deaths in USA since start of vaccination – about 300,000**.
- These alarming safety signals, related to death, along with a host of cardiac, neurological, and thromboembolic events warrant to adoption of the term: **Post Covid Vaccine Syndrome** – pCoVS
    - A syndrome occurring after injection of antigen-inducing, gene therapy vaccines to SARS-Cov-2 virus. The syndrome is currently understood to manifest variously as cardiac, vascular, hematological, musculoskeletal, intestinal, respiratory or neurologic symptoms of unknown long-term significance, in addition to effects on gestation. Manifestations of the syndrome may be mediated by the spike protein antigen induced by the delivered nucleic acids, the nucleic acids themselves, or vaccine adjuvants. As more data become available, subsets and longer-term consequences of pCoVS may become apparent, requiring revision of this definition. Sub-categories may be designated by suffix for example:
        - -C Cardiac
        - -N Neurologoc
        - -H Hematologic
        - -V Vascular
- **Regarding the Pediatric Indication Requirements** applied to the BioNTech license, Postmarketing requirements include multiple "deferred" studies
    - Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.
    - Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.
    - Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.
- **Regarding general postmarketing requirements**
    - AS noted above, the FDA acknowledges that "We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis. Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks."
    - The following studies are therefore required
        - Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.
        - Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine," to evaluate the

occurrence of myocarditis and pericarditis following administration of COMIRNATY.
        - Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.
        - Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).
        - Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.
        - Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.
        - Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.
        - Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."
        - Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."
- Regarding pregnancy postmarketing requirements
    - Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry."