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Subject:

Date: January 10, 2022 at 12:20 PM

To:



From FDA Presentation - VRBPAC-10.22.20-Meeting-Presentation-COVID19-CBER-Monitoring-Vaccine (See Page 16 Pfizer Adverse Events).pdf

FDA Safety Surveillance of COVID-19 Vaccines: <u>DRAFT</u> Working list of possible adverse event outcomes ***Subject to change***

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease

- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

Regards,

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"There is no greater tyranny than that which is perpetrated under the shield of the law and in the name of justice."