COVID-19 and Collateral Profits

(03/09/2021)

It is happening. Healthcare workers and people at risk are getting the COVID-19 vaccination. A family member came to me, who received a document entitled "Fact Sheet for Recipients and Caregivers - Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older". The Fact Sheet is very detailed as to what the disease is and how the vaccine works. Addressed by the materials are people who may question receiving the vaccine, such as those with allergies and pregnant women. The Fact Sheet provides information concerning ingredients and how the vaccine is given. A list of risks is provided, not including death or any effect on one's DNA. Side effects are discussed, as well as other choices besides the vaccine. "Currently, there is no approved alternative vaccine available for prevention of COVID-19."

Other information is given, including the "Countermeasures Injury Compensation Program."

> **WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**
> The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

Therefore, Pfizer makes it clear that a person may have a claim, albeit they suggest that it is only through the Compensation Program. The Fact Sheet also discusses Emergency Use Authorization (EUA) and makes it clear that the COVID-19 vaccine "has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives."

Finally, in this particular instance, there is a separate COVID Vaccine Intake Consent Form on a document utilized by "CVS Pharmacy".

Aside from screening questions and immunization screening questions, there is a provision under "Consent for Services" that provides, in its entirety, as follows:

> **CONSENT FOR SERVICES.** I have been provided with the Vaccine Information Sheet(s) or patient fact sheet corresponding to the vaccine(s) that I am receiving. I have read the information provided about the vaccine I am to receive. I have had the chance to ask questions that were answered

> to my satisfaction. **I understand the benefits and risks of vaccination and I voluntarily assume full responsibility for any reactions that may result.** I request that the vaccine be given to me or to the person named above for whom I am authorized to make this request. State of Georgia only: I verify a case history was taken by the pharmacist and I was asked whether I have had an physical examination within the past year. No condition for which the vaccine is contraindicated was identified. (Emphasis added).

The Consent for Services may be understood as only applying to allergic responses to the vaccine, but the language is ambiguous, especially that which states that the recipient has agreed to "voluntarily assume full responsibility for any reactions that may result."

Supposing, for example, that Pfizer has provided misinformation to the FDA or failed to warn of a known risk of the product. No doubt, defendants, including the seller, would claim voluntary assumption of the risk and preemption; the only remedy being the vaccine Compensation Program.

The Fact Sheet that is distributed to vaccine recipients is a requirement of the Emergency Use Authorization Act that permits the use of these vaccines. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii) & (e)(2)(A). The statute does not require a signed written informed consent form from each recipient, however.

Section 564 of the Emergency Use Authorization Act, 21 U.S.C. §360bbb-3 et seq., as amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, provides authority for the FDA to allow use of drugs, biological products and medical devices that have not gone through the usual rigorous statutory approval process, during a public health emergency declared by Secretary of the Department of Health and Human Services. The product must meet certain statutory criteria to receive Emergency Use Authorization**:** the "agent" [virus, chemical, biological product, etc.] involved can cause a serious or life-threatening disease or condition; the product "may be effective" in diagnosing, treating, or preventing such disease or condition; the known and potential benefits of the product, drug, vaccine outweigh the known and potential risks; and there is no adequate, approved, and available alternative. 21 U.S.C. § 360bbb-3(c). The statement in the Fact Sheet that "there is no approved alternative vaccine available" is a reference to this section of the statute, meaning that there is no vaccine that has gone through the FDA's regular approval process.

The doctrine of preemption provides that where state and federal law directly conflict, federal law preempts or "trumps" the state law. Preemption is disfavored, however, and complete preemption only exists in limited circumstances. A federal law must demonstrate that it was the intent of Congress to replace the state-law claim with a federal law claim, and the federal law must create a civil enforcement mechanism that vindicates the same interest as the state cause of action. In the context of the current pandemic, the Public Readiness and Protection Act ("PREP Act"), 42 U.S. C.§247d et. seq., empowers the Secretary of the Department of Health and Human Services to deem an event a "public health emergency" and then take action to utilize funds established by the

Treasury to manage the emergency. 42 U.S.C. § 247d(a), including to "facilitate and accelerate, as applicable, advanced research and development of security countermeasures . . . qualified countermeasures . . . or qualified pandemic or epidemic products . . . that are applicable to the public health emergency or potential public health emergency . . .". 42 U.S.C. § 247d(b)(2)(C). The PREP Act creates immunity for all claims causally connected to the administration or use of “covered countermeasures,” which are certain drugs, biological products, or devices. Exceptions to immunity exist for claims of willful misconduct but suit must be brought in the United States District Court for the District of Columbia. All other claims for injuries "directly caused by the administration or use of a covered countermeasure" must be pursued through the Covered Countermeasure Process Fund.

The COVID-19 Declaration under the PREP Act, 85 Fed. Reg. 15,198 (Mar. 10, 2020), specifically defines covered countermeasures as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19 . . . or any device used in the administration of any such product, and all components and constituent materials of any such product."

Currently, courts have found that state negligence claims based upon *failures* to provide COVID protective measures are not preempted. However, in December of 2020 the COVID -19 Declaration specified that under certain circumstances, such as when vaccine or other protective measures are in short supply, the failure to administer or supply such measures, particularly when prioritization is done in accordance with a public health authority’s directive, may fall within the PREP Act and its liability protections. 85 Fed. Reg. 70190 (Dec. 9, 2020). It is clear that the scope of the immunity applicable under the PREP Act and the question of preemption will undoubtedly be litigated for years to come.

Clifford A. Rieders, Esquire
Rieders, Travis, Humphrey,
Waters & Dohrmann
161 West Third Street
Williamsport, PA 17701
(570) 323-8711 (telephone)
(570) 323-4192 (facsimile)

Cliff Rieders is a Board-Certified Trial Advocate in Williamsport, is Past President of the Pennsylvania Trial Lawyers Association and a past member of the Pennsylvania Patient Safety Authority. None of the opinions expressed necessarily represent the views of these organizations.