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ICAN | LEGAL UPDATE

ICAN FILED A FORMAL PETITION WITH THE FDA TO DEMAND VALID ENDPOINTS FOR DETERMINING WHETHER A COVID-19 VACCINE IS EFFECTIVE

On November 6, 2020, ICAN filed a Citizen Petition and a Petition for a Stay of Action demanding that the FDA require valid endpoints for determining efficacy in the COVID-19 vaccine trials currently being run by Pfizer, Moderna, AstraZeneca, and Johnson & Johnson. ICAN's demands include that the vaccine be shown to prevent serious cases of COVID-19 (not just mild cases) and that it can stop transmission of COVID-19.

As explained in our previous legal updates, ICAN's legal team has been hammering away at the safety requirements for the clinical trials of COVID-19 vaccines, including demanding they be placebo-controlled, long-term, and have other safeguards. Many of those demands were subsequently met and we are not done fighting on that front. But there is now another battle we are fighting.

ICAN's legal team, led by Aaron Siri, has now also focused its efforts on the basis the

FDA will rely upon to determine whether any of the COVID-19 vaccine frontrunners are effective. Many Americans have been led to believe that the vaccines currently in trials are the answer to all pandemic-related problems. Many believe this is because a vaccine, when available, will prevent individuals from having a serious case of COVID-19 and will stop people from spreading it to others. However, the clinical trials for Pfizer, Moderna, AstraZeneca, and Johnson & Johnson's products are **not designed** to determine either of these!

Instead, each of the four trials' primary goals for determining whether the vaccine is effective merely requires determination of whether it can reduce symptoms of mild cases of COVID-19. The trials will also not demonstrate whether or not a vaccine recipient can still transmit COVID-19 to others. This means that, under the current rules, a COVID-19 vaccine can be licensed without demonstrating it can prevent severe COVID-19, hospitalization, or deaths, nor stop the spread of COVID-19.

Also concerning is that "cases" of COVID-19 for trial purposes are being demonstrated by positive PCR tests. The scientific literature has shown that such PCR tests can be highly unreliable, frequently giving false positives. Consistent with this literature, we demanded that only positive PCR results meeting certain criteria be relied upon. ICAN also demanded that all participants be tested before and after vaccination for T-cell immunity to SARS-CoV-2, which is not currently part of the protocols. If a person has pre-existing immunity to SARS-CoV-2 (either from being exposed to COVID-19 or otherwise) their presence in the study could affect the result by showing fewer people getting sick than would actually occur in the "wild."

These alarming deficiencies in the studies were what led ICAN to direct its attorneys to file a petition demanding that all four Phase III COVID-19 vaccine trials amend their efficacy endpoints. ICAN demanded, among other things, that the trials test and determine (1) whether these vaccines will prevent severe cases of COVID-19; and (2) whether they will stop the spread of the virus. ICAN further demanded improvements in the PCR testing protocol and T-cell testing pre-and-post vaccination.

Recognizing the critical importance that these changes be made in a timely manner, on November 11, 2020, ICAN's attorneys filed a Petition for a Stay of Action with the FDA which asks that the agency stay, or pause, any action related to the trials until the requested actions in the efficacy petition are implemented.

ICAN's attorneys separately sent a letter to Dr. Peter Marks, the Director of the Center for Biologics Evaluation and Research at the FDA, bringing these very concerns to his attention. You can read that letter here. Dr. Marks has referred to himself as "the FDA point person on COVID-19 vaccines" and has assured Americans that the FDA "will make sure they're safe and effective." ICAN will closely review any response from Dr. Marks given his promise that he and the FDA "uphold globally respected standards for product quality, safety, and efficacy" and his statement that he would resign if "something that was unsafe or ineffective [] was being put through."

There are numerous other legal and non-legal efforts ICAN is engaged in with regard to COVID-19 vaccines that are not yet ready to be discussed here but will be featured in future updates.

If you would like to provide the FDA a comment regarding the efficacy petition we have filed regarding COVID-19 vaccines, you can do so here.

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