

United States Senate

WASHINGTON, DC 20510

July 2, 2020

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Peter T. Gaynor
Administrator
Federal Emergency Management Agency
500 C Street S.W.
Washington, D.C. 20472

Dear Secretary Azar and Administrator Gaynor,

We write today to express our serious concerns about the safety and efficacy of hundreds of thousands of COVID-19 testing supplies recently provided to the states, including Michigan, by the federal government. Since the start of the COVID-19 crisis, the State of Michigan has successfully conducted over 1.1 million tests for the virus. This has been made possible, in part, due to the assistance of the federal government in obtaining the supplies necessary for accurate and reliable testing. Continuing to expand testing and ensuring that it is widely available across the State, and that the results are reliable, is the only way that we can obtain the information needed to protect our citizens and continue to safely lift quarantine restrictions.

However, earlier this month the State received notification from the Federal Emergency Management Agency (FEMA) and the Department of Health and Human Services (HHS) instructing the State to sequester more than 322,000 tubes of transport media it had received that were manufactured by Fillakit. The tubes used are not the appropriate size for use in existing laboratory equipment. Recent reporting by ProPublica has revealed that these tubes are in fact repurposed soda bottle preforms that have not been manufactured or packaged in sterile conditions, with a packaging process described as unmasked employees gathering “miniature soda bottles with snow shovels and dump(ing) them into plastic bins before squirting saline into them, all in the open air.” Even if the tubes themselves were not unsuitable for testing purposes, the contamination risks inherent in such careless handling would cause serious concerns about the reliability of any tests conducted using these materials.¹

Furthermore, many of these tubes were delivered pre-packaged with equally unsuitable viral transport media, the liquid used to preserve a test specimen from the time of collection to the time it is received at the laboratory to be processed. Some of these media even have a propensity for emitting cyanide as a by-product when placed in testing equipment. Sterile vials fit for purpose of the right size and high quality transport media are necessary in order to process

¹ *The Trump Administration Paid Millions for Test Tubes — and Got Unusable Mini Soda Bottles*, ProPublica (June 18, 2020).

COVID-19 tests. Without an adequate supply of transport media, the State will not be able to continue to expand the testing regime that has been essential to our effort to halt the spread of the virus.

There have been concerns with Fillakit's ability to deliver the required supplies since the contract was first awarded by FEMA in early May. According to reporting by NPR, Fillakit was incorporated on May 1, 2020, a week before it was awarded a no-bid contract by FEMA worth more than \$10 million. Not only was a contract for urgently needed medical supplies awarded to a company with no demonstrated ability to fulfill its terms, but the company itself was reportedly headed by Paul Wexler. In 2013, Mr. Wexler was fined \$2.7 million for running a telemarketing scam targeting individuals in financial distress and charging them hundreds of dollars based on misrepresentations that they could obtain credit card interest rates as low as zero percent. Despite these concerns, FEMA awarded Fillakit the no-bid contract for testing supplies with only boilerplate assurances that the company could deliver.²

In order for the State of Michigan to continue to protect its citizens from the COVID-19 virus and safely lift quarantine restrictions, the State must be able to conduct widespread, reliable tests. The sudden and unexpected shortfall of hundreds of thousands of vials of transport media runs the risk of compromising the State's ability to effectively detect and prevent the further spread of COVID-19. Given the immediate and urgent need for transport media in vials suitable for COVID-19 testing, and in order to ensure taxpayer dollars are spent wisely and similar problems do not occur in the future, we ask that you respond to the following questions:

- 1) Which states have received testing supplies purchased by FEMA and HHS that have subsequently been determined to be unsuitable, including those provided by Fillakit? Please provide a summary of the nature and quantity of the unsuitable supplies received by each state.
- 2) What steps are FEMA and HHS taking to ensure that any states, including Michigan, that have received COVID-19 testing supplies will receive the supplies needed to continue testing at adequate levels? When can states expect to receive those supplies?
- 3) What is the estimated number of COVID-19 tests in the United States that have been administered with supplies purchased from Fillakit?
- 4) What is the estimated number of COVID-19 tests that states have been unable to perform due to lack of supplies since FEMA and HHS issued guidance against using Fillakit supplies on June 20, 2020?
- 5) Please provide us with copies of any contracts between FEMA or HHS and Fillakit.
- 6) Please provide us with copies of any contractor assurance statements provided to FEMA or HHS by Fillakit.

² *Feds Spend Billions On COVID-19 Contracts, Often Without Fully Competitive Bidding*, NPR (June 9, 2020).

- 7) What steps were taken by FEMA or HHS during the contracting process to verify the accuracy of any representations or assurances made by Fillakit?
- 8) Is it the position of FEMA or HHS that Fillakit is in breach of contract? If so, what steps are being taken to hold it liable? If not, why not?
- 9) What controls do FEMA or HHS have in place to ensure that other entities that have been awarded contracts to provide COVID-19 testing supplies are in fact providing supplies fit for COVID-19 testing purposes?

The ability of states to widely administer reliable COVID-19 tests is the keystone of our national efforts to contain and reverse the spread of this virus and move past quarantine conditions. For states to have confidence in their ability to prevent the further spread of the virus, they must have confidence in their ability to test for the virus. For these reasons, it is essential that you ensure that any states that have received unsuitable testing supplies immediately receive replacements and that such incidents do not occur again. To that end, please provide us with answers to our questions no later than July 16, 2020.

Sincerely,



Debbie Stabenow
United States Senator



Gary C. Peters
United States Senator