August 20, 2020

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Dr. Peake:

We represent the leadership of faculty organizations at two Virginia universities: George Mason University and Virginia Commonwealth University. As outlined below, we have serious concerns regarding testing for COVID-19 on our campuses, specifically with the qualifications of the companies and health professionals involved, and the appropriateness of the tests being used. **We respectfully request that you and your office investigate this matter immediately to ensure the health and safety of our students, staff, and faculty members.**

First, we are concerned that the companies involved may not have sufficient experience for such an important task. Each of our universities (as well as William & Mary) has a contract with Kallaco, a software company that says it coordinates tests conducted at three laboratories: Opteo Laboratory in New Orleans; Wisconsin Diagnostic Laboratories in Milwaukee; and VCU Health Laboratory in Richmond. From our research, Kallaco was originally registered in Louisiana in April of this year, with a name change in July. It seems odd to us that this young IT company, which has been awarded sole source state contracts with a potential value of over $4 million, has been entrusted with the critical COVID-19 testing for up to 28,500 students at our universities.

Second, we are concerned about some odd information we found regarding the health professionals involved. Our universities have not been forthcoming with detailed information, so we have had to collect information from test kits shared by cooperative students. For example, at GMU, student COVID-19 tests are being sent to Opteo Laboratories in New Orleans. (Why not VCU Health Laboratory here in Virginia, instead of sending samples across the country?) On the PCR Test Requisition form we were able to see, the ordering physician is Michael J Bauer, M.D. in Castle Rock, Colorado; according to Google, his address is a UPS Store mailbox. Likewise, the lab director listed on the form for Opteo Laboratories in New Orleans, Hannis Thompson, M.D., seems to live and work in Centennial, Colorado. A doctor with a UPS Store

address? A lab director who lives and works several states away from the lab? These defy logic and are very troubling.

Lastly, we have become concerned that, at least at one university, the student test kits may not have an Emergency Use Authorization (EUA) from the US Food and Drug Administration for the home collection of specimens. In late July and August, Kallaco LLC sent Mason residential students a home test kit that required a throat swab to be mailed to Opteo Laboratory for testing. Our review of the FDA website revealed that only 19 molecular diagnostic tests have been granted EUAs for home sample collection, *and none of these approved home tests use throat swabs.* Instead, the approved home tests ask patients to collect saliva in a cup or use nasal swabs. So what test did GMU students receive? And did it receive an EUA for home use? All attempts to answer these questions (e.g., numerous phone calls and emails to Opteo, Kallaco, and university officials) have yet to produce any clarity or reassurance.

According to Opteo Lab's website, the lab offers two types of processes for analyzing patient covid samples including the "ThermoFisher Quant Studio 12K Flex Real Time PCR System for the SARS-CoV-2 assay" and a "Next Generation Sequencing" system. We believe that GMU students may have been sent the "TaqPath COVID-19 Combo Kit" developed and sold by ThermoFisher. As confirmed by an FDA email, the TaqPath COVID-19 Combo Kit is the only ThermoFisher test that has been given an Emergency Use Authorization by the FDA. But, importantly, this ThermoFisher test was *not* approved for home sample collection, according to the FDA.

There are other red flags as well. For example, many students have complained that their test results were "rejected" by Kallaco with little explanation as to what that means. One GMU student received a test kit that included a tube labeled "For research use only. Not for use in diagnostic procedures." And just this past Monday, the FDA announced that the ThermoFisher test is at risk of inaccuracies. All of this information raises questions about the validity of the entire testing operation at our institutions.

We understand that we are in the midst of an unprecedented crisis, and that some decisions may have been made in haste. Mistakes made in haste would be more understandable if our universities had been legally required to reopen their campuses, but this is not the case. All experts we are familiar with insist that reliable testing is absolutely necessary to prevent viral spread during this pandemic, and so the scant information provided to our communities about the nature and quality of the testing done on our campuses is deeply concerning. We are committed to protecting the health and wellbeing of our communities, both on- and off-campus, and so wish

to understand these situations regarding COVID-19 testing to the best of our ability. We greatly appreciate you looking into these matters at the earliest possible time and look forward to hearing from you.

With highest regards,

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