



July 30, 2020

The Honorable Elizabeth Warren
United States Senate
309 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Warren,

Thank you for your letter of June 15, 2020, regarding Operation Warp Speed (OWS) and the procurement by which Dr. Moncef Slaoui has been brought on to serve as a consultant under contract to support the Department of Health and Human Services for OWS. HHS Secretary Azar asked me to respond on his behalf.

OWS is striving to deliver 300 million doses of a safe, effective vaccine for COVID-19 to combat the devastating impact of this deadly pandemic on the health of the American people in record time. OWS is a partnership among components of the HHS, including the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), the Centers for Disease Control and Prevention (CDC), and the Department of Defense (DoD). OWS engages with private industry and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. OWS coordinates existing HHS-wide efforts, including the NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership, NIH's Rapid Acceleration of Diagnostics (RADx) initiative, and work by BARDA.

The OWS team is aligning protocols for the demonstration of vaccine safety and efficacy, which should allow the trials to proceed more quickly. Under OWS, the federal government, as opposed to traditional public-private partnerships in which pharmaceutical companies decide on their own protocols, will oversee the protocols for the trials. Rather than eliminating steps from traditional development timelines, steps will proceed simultaneously, such as starting manufacturing of the vaccine well before a given vaccine proves safe and effective. This is a monumental undertaking.

Federal government officials are leading and managing OWS. HHS Secretary Alex Azar and Defense Secretary Mark Esper oversee OWS. General Gustavo Perna has been confirmed unanimously by the U.S. Senate to serve as the OWS chief operating officer. General Perna is responsible for all decisions made in execution of OWS. Additionally, highly qualified HHS career scientists are leading each countermeasure area. Likewise, the Department of the Defense (DoD) has identified subject matter experts to lead DoD support for diagnostics, therapeutics, vaccines, production and distribution, and security assistance. Finally, any COVID-19 vaccine must be independently approved by federal regulators at FDA.

Time is of the essence in this race for a vaccine. We have already lost over 130,000 Americans to this sinister virus. The race for a vaccine will not succeed without an enormous collaborative effort between the federal government, state and local governments, and the industrial and scientific sectors. Dr. Moncef Slaoui is the bridge between science, industry and government officials, and has the experience of actually “engineering-up” vaccines from small laboratory batches to large commercial production which is essential if Americans are to be safe. His willingness to lend his expertise to this life-saving effort is to be commended.

Enclosed is an explanation of Dr. Slaoui’s government contract from the HHS Office of the General Counsel. I trust you will find this information responsive to your inquiry. Should you have additional questions, please do not hesitate to contact me.

Sincerely,



Sarah Arbes
Assistant Secretary for Legislation

Enclosure

Information on Dr. Moncef Slaoui's Government Contract from the HHS Office of the General Counsel (OGC)

HHS procured Dr. Slaoui's expertise via a government contract in order to support Operation Warp Speed (OWS) federal leaders as a scientific and medical advisor. Dr. Slaoui is working under a contract awarded to Advance Decision Vectors, LLC, a federal contractor that is a participant in the Small Business Administration's 8(a) Business Development program. The terms of the contract provide that the contractor and its employees shall not perform inherently governmental functions. The contract also contains specific language to address potential conflicts of interest, and to ensure that Dr. Slaoui will not be in a position to gain financially from his participation as a consultant. Finally, it also includes terms relating to protecting sensitive information.

Dr. Slaoui is not a federal employee. HHS has not appointed him to federal service. He is working as a very high-level contract consultant supporting the federal battle against this deadly disease. Dr. Slaoui is sharing his expertise in the research, development, manufacture and global distribution of vaccines and therapeutics on an industrial scale. The level of expertise held by Dr. Slaoui is rare. He is an elite scientist with a comprehensive understanding of vaccine and therapeutic research development manufacture, production and distribution. His support via contract is critical to mission success for the federal employees who are leading OWS.

As a contractor, Dr. Slaoui will not make decisions with respect to licensing products, awarding grants, or federal contracts. He will not make decisions that are reserved to federal officials. Rather, the terms of the contract indicate that Dr. Slaoui will provide expert advice regarding development and mass production of new COVID-19 vaccine candidates, therapeutics, and diagnostics.

As a contractor, he is not subject to the same ethics laws and regulations that apply to federal decision-makers. Rather, as is the case with the approximately 3.7 million federal contractors¹ that serve as a force multiplier for the federal workforce, he is subject to the ethics provisions contained in the Federal Acquisition Regulations as incorporated in his employer's contract. Further, the contract through which Dr. Slaoui is serving contains robust supplemental contract provisions addressing personal financial conflicts of interest for contractors working on OWS. Although well above-and-beyond anything required by law, to assuage concerns about the integrity of the OWS process, the terms of the contract mandate that Dr. Slaoui provide a list of entities on which he served as a member of the board of directors. He was required to resign from any board where any of those companies is involved in developing or manufacturing vaccines, therapeutic and diagnostic products to combat COVID-19 under Operation Warp Speed. Dr. Slaoui agreed to resign from each of those boards, and he confirmed that he had done so. He further agreed not to assume membership on any additional boards so long as he serves as an employee under the OWS support contract.

¹ The federal government has relied on a mix of federal, contractors and grant recipient employees since the inception of the nation in 1776. The exact number of federal support contractors was estimated to be 3.7 million in 2015. See, <https://www.volckeralliance.org/true-size-government>.

Regarding the two affiliations you asked about, he was not required to resign from the SutroVax (now Vaxcyte) board as it has no vaccine that would compete in the COVID-19 space. Likewise, he did not resign from the Galvani Bioelectronics Board as this company makes miniaturized, implantable medical devices and is not involved in COVID-19.

As noted in your inquiry, Dr. Slaoui is a partner in Medicxi, a venture capital firm. Based on publicly available information and information provided by Dr. Slaoui, Medicxi has four active funds. One of those funds is financing a company, ViceBio, which although involved in a technology platform that could be used in a potential COVID-19 vaccine, the license to ViceBio in this technology platform expressly excludes pandemic vaccines; thus, the company cannot compete or participate in vaccine development under OWS. Otherwise, Dr. Slaoui has further indicated that the Medicxi funds are not in companies involved in the COVID-19 area. As already noted above, Dr. Slaoui was serving as a board member of Moderna but agreed to resign from this board when he began working under contract for HHS on OWS.

Additionally, Dr. Slaoui has agreed to donate any increase in the value of his remaining vested equity holdings in pharmaceutical (or other companies) that are involved in vaccines, therapeutics and diagnostic products developed to combat COVID-19, and subject to OWS, to the National Institutes of Health, based on a formula. Any increase in value will be calculated when he completes his service as a contractor.² Moreover, to reduce any optics concerns, he decided to donate to cancer research all incremental value accrued from his Moderna shares between the evening of Thursday, May 14, prior to the announcement of his position on Operation Warp Speed and the time of sale.

Dr. Slaoui and his financial advisor confirmed with career attorneys in the HHS OGC Ethics Division that Dr. Slaoui does not have any additional stock holdings in any other companies involved in vaccines, therapeutics and diagnostic products developed to combat COVID-19. He further agreed not to purchase any additional securities in the pharmaceutical sector, including securities related to vaccines, therapeutics and diagnostic products developed to combat COVID-19, during his tenure under the contract, other than ordinary stock dividends or dividends or options received as a result of service on the board of an entity.

² Any increase in value of those securities that is attributable to the government's efforts to combat COVID-19 will be measured based on a formula provided in the contract that uses a pharmaceutical index fund as a measuring tool.