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SUBCOMMITTEE ON
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April 8, 2020

Christi A. Grimm
Principal Deputy Inspector General
HHS Office of the Inspector General
330 Independence Ave SW
Washington, DC 20201

Dear Ms. Grimm,

We write to you today with questions regarding the integrity of this country’s medical supply chain. As the country grapples with the health and economic effects of the COVID-19 global pandemic, we are concerned that potentially fraudulent medical supply companies are taking advantage of American medical workers — workers whose lives depend on personal protective equipment (PPE) largely regulated by various departments under the purview of the Department of Health and Human Services.

Two weeks ago, a medical supply firm named Blue Flame Medical LLC was established in Delaware. According to their website, Blue Flame now claims to be “the largest global network of COVID-19 medical suppliers providing healthcare logistics and hard to find medical supplies to beat the outbreak.”¹ However, the origins of Blue Flame are not in the medical supply field, nor are they in adjacent fields that could easily convert to aggregation and distribution of medical supplies. Media reports indicate the CEO of Blue Flame, Mike Gula, and his business partner, John Thomas have little to no experience in supply chain dynamics or the medical field.² Despite their new entry to the field, they claim that their personal connections are already enabling Blue Flame to fulfill “100-million mask orders.”³ No information is readily available as to the price at which these masks are being sold or to whom. Additionally, their website fails to provide any information regarding who they are procuring these masks from and if their supplies have received approval by the National Institute for Occupational Safety and Health (NIOSH), the Food and Drug Administration (FDA), or the Occupational and Safety and Health Administration (OSHA).

We use this as an example of the ease in which it appears to have taken a new corporation to position itself so quickly as a vital source of masks for frontline providers. As such, we write to request

¹ Blueflame Medical, Homepage. Retrieved at: <https://blueflamemedical.health/>

² Republican fundraiser looks to cash in on coronavirus, POLITICO, Retrieved at: <https://www.politico.com/news/2020/03/27/republican-fundraiser-company-coronavirus-152184>

³ Blueflame Medical, Homepage. Retrieved at: <https://blueflamemedical.health/>

information about the safeguards in place to ensure that the U.S. and state governments are contracting with legitimate medical resource suppliers and getting quality equipment.

1. At this time, we have no clear understanding of what BlueFlame is selling; however, if they are procuring and selling N95 respirators, these masks should be “tested for fluid resistance, filtration efficiency (particulate filtration efficiency and bacterial filtration efficiency), flammability and biocompatibility.”⁴ How will HHS ensure that all masks being sold in the U.S. are being procured from manufacturers who meet the regulatory requirements set forth by HHS?

We are also concerned that the presence of BlueFlame in the PPE market is potentially creating a costly and burdensome middleman from which states and localities must now purchase supplies.

With new suppliers entering the supply chain, we want to ensure products they are procuring are sold at reasonable rates. Typical masks used in healthcare settings cost between 30 and 50 cents per piece.^{5,6} 3M, which is one of the largest N95 surgical mask producers in the United States, has received reports of price gouging. The company has stated that, while it has not changed its prices, it cannot control the prices dealers or retailers charge.⁷

1. Is HHS concerned about the price gouging of medical products during the COVID-19 pandemic?
2. What is the Secretary doing to ensure that companies are not entering the supply chain simply to purchase masks from companies like 3M and sell them to desperate state, local, and hospital officials for exorbitant prices?
3. What steps can the Secretary take proactively to prevent medical supply companies from taking advantage of those in desperate need of masks and other protective equipment during the COVID-19 pandemic?
4. The FDA and CDC have made clear that N95 respirators are not for use by the general public.⁸ What measures have been taken to prohibit suppliers from selling masks to non-healthcare workers who are willing and able to pay large sums of money for these products despite the recommendations from the Administration?

⁴ FDA N95 Respirators and Surgical Masks (Face Masks). Retrieved at: <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>

⁵ In Desperation, New York State Pays Up to 15 Times the Normal Prices for Medical Equipment, Pro Publica, Retrieved at: <https://www.propublica.org/article/in-desperation-new-york-state-pays-up-to-15-times-the-normal-price-for-medical-equipment>

⁶ Nearly One-Fifth of Providers Dealing with Higher Medical Mask Prices, Health Leaders Media, Retrieved at: <https://www.healthleadersmedia.com/finance/nearly-one-fifth-providers-dealing-higher-medical-mask-prices>

⁷ For New York, 58-Cent Medical Masks Now Priced at \$7.50 Each, Bloomberg News, Retrieved at: <https://www.bloomberg.com/news/articles/2020-03-24/for-new-york-58-cent-medical-masks-now-priced-at-7-50-each>

⁸ N95 Respirators and Surgical Masks (Face Masks), FDA, Retrieved at: <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks#s1>

Due to the life or death nature of the nationwide PPE shortage, we are concerned Blue Flame is indicative of a potentially growing trend. As such, we ask that you respond to the following questions by April 13, 2020.

Thank you for your attention to these issues. The safety of our frontline workers is of the utmost importance during this dangerous and unprecedented time. We look forward to your response.

Sincerely,

A handwritten signature in blue ink that reads "Katie Porter". The signature is written in a cursive, flowing style.

Katie Porter
MEMBER OF CONGRESS