

EXHIBIT 22

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA**

Alexandria Division

BLUE FLAME MEDICAL LLC,

Plaintiff,

v.

CHAIN BRIDGE BANK, N.A.,

JOHN J. BROUGH, and

DAVID M. EVINGER,

Defendants.

Civil Action No. 1:20-cv-00658

EXPERT REPORT OF MARK FAULKNER

February 12, 2021

TABLE OF CONTENTS

I.	QUALIFICATIONS	1
II.	ALLEGATIONS AND ASSIGNMENT	3
III.	SUMMARY OF OPINIONS	4
IV.	BACKGROUND	6
	A. The Relevant Parties	6
	1. Blue Flame	6
	2. The State of California	7
	B. California Orders 100 Million N95 Masks From Blue Flame	8
V.	OVERVIEW OF THE MARKET FOR N95 MASKS	10
	A. Types of Masks	10
	B. Distribution and Supply of N95 Masks	12
VI.	CHANGES IN THE DEMAND FOR, SUPPLY OF, AND PROCUREMENT OF N95 MASKS FOLLOWING THE OUTBREAK OF THE COVID-19 PANDEMIC.....	16
	A. Demand for N95 Masks Increased Substantially	16
	B. Supply of N95 Masks Was Insufficient to Meet Demand	17
	1. U.S. Production and Exports	17
	2. International Production and Export Restrictions	17
	C. Procuring N95 Masks at the Outset of the Pandemic was Difficult	20
	1. Mass General Brigham's Procurement from Domestic Suppliers	21
	2. Mass General Brigham's Efforts to Procure from International Suppliers.....	23
VII.	BLUE FLAME COULD NOT HAVE FULFILLED CALIFORNIA'S ORDER OF 100 MILLION N95 MASKS, OR PROVIDED ANY SIGNIFICANT QUANTITY OF N95 MASKS WITHIN 60 DAYS, LET ALONE WITHIN 30 DAYS.....	25
	A. There Was Insufficient Supply of N95 Masks to Fulfill California's Order	26
	1. Blue Flame's Agreement to Supply California With 100 Million N95 Masks Would Have Required Blue Flame To Secure More N95 Masks Than Were Available From China	26
	2. The Manufacturers of N95 Mask Models California Ordered Did Not Have Sufficient Production Capacities or Inventories to Fulfill California's Order.....	29

3.	Domestic Production Had Supply Constraints and Access Was Limited By Pre-Existing Supply Contracts and Claims By the U.S. Government	31
B.	Blue Flame's Supply Partners Were Unable to Provide Blue Flame 100 Million N95 Masks	33
1.	Great Health	34
2.	Suuchi.....	38
C.	Blue Flame's Inability To Fulfill Other Orders For N95 Masks Confirms That It Could Not Have Supplied California With Any Significant Quantity of N95 Masks.....	39
D.	Blue Flame Was An Inexperienced and Unsophisticated Participant In The PPE Market That Failed to Comply With Standard Industry Practice	41
1.	Blue Flame's Failures To Follow Industry Standard Procurement Practices Undermine Its Credibility as a Supplier of PPE	42
2.	Blue Flame's Lack of Experience And Longstanding Buying Relationships Also Undermine Its Credibility as a Supplier of PPE	51

I. QUALIFICATIONS

1. I am currently the Senior Director of Strategic Supply Chain Management and Sourcing at Mass General Brigham, an integrated academic health care system of community and specialty hospitals, a health insurance plan, physician networks, community health centers, home care, and long-term care facilities. I have over 35 years of experience within the medical supply procurement industry, including product and strategic sourcing, group purchasing, contracting, inventory and operations management, capital, physician relations, analytics, and healthcare management. During this time, I developed extensive relationships within the supplier community.

2. I have served in my current role for approximately thirteen years, where I am responsible for the procurement of all products and supplies (both medical and non-medical) used throughout the Mass General Brigham health care system, comprising over \$3 billion of purchases each year. This includes contracting with suppliers of N95 masks, surgical masks, isolation and surgical gowns, nitrile gloves, goggles, and face shields and other face coverings, among other types of personal protective equipment (“PPE”).¹ I have the ultimate responsibility to ensure that staff and patients have all of the required clinically acceptable equipment to effectively and safely provide and receive care, which includes ensuring we have up to six months of available supplies on hand at all times. I am engaged in all phases of the procurement process, including identifying and negotiating with potential suppliers, verifying product samples, vendor bidding, negotiating and finalizing contracts, and inventory management. I direct a team of over 50 employees that have the responsibilities of identifying potential suppliers who can provide medical products to meet specific needs, including, for example, our required quality standards for PPE items, including those for N95 masks.

3. I have longstanding relationships with suppliers, distributors, and manufacturers in the United States and abroad. Mass General Brigham currently utilizes and contracts with over 3,000 different vendors during each year, and during the COVID-19 pandemic I have used these relationships to source scarce products, including N95 masks and other PPE items. During the COVID-19 pandemic I have sought out additional suppliers and have communicated with more than 50 new domestic and international suppliers in order to fulfill Mass General Brigham’s supply chain needs for PPE items. These new suppliers have gone through an industry-standard vetting

¹ I discuss N95 and other masks in Section V.A below.

and validation process, which has been done, in part, by leaning on longstanding and trusted connections that I have built up over the years who have relationships with both domestic and international manufacturers. In particular, I have overseen the procurement of over \$200 million of PPE items since the beginning of the pandemic, including N95 masks.

4. I am a member of multiple supply procurement industry organizations through which I regularly discuss procurement experiences, attend supply chain-related conferences, and learn about PPE suppliers. This includes membership in Vizient, a health care group purchasing organization with approximately 3,500 member organizations, with whom I have been involved for approximately 25 years, as well as having a membership in their large integrated service network ("LISN") of professional colleagues that includes the largest 25 purchasing organizations within Vizient, with whom I have been involved for the last 15 years. I was a founding member of the LISN's Executive Steering Committee, which leads discussions on important issues in the medical supply market, best practices in sourcing and procurement, supplier and vendor performance, and leading practice strategies to improve the supply chain; I twice served as the committee's chairperson. This network consists of many of the largest healthcare providers in the country, including Kaiser Permanente, Mayo Clinic, and Cleveland Clinic, among others. I also am a member of a supply chain committee for Gartner, a research and advisory company, for whom I have consulted on panels and reviewed best practices in PPE procurement, as well as a Provider Partner member of Strategic Marketplace Initiative, a non-profit organization focused on improving the healthcare supply chain and marketplace. Further, multiple times in the last year I have participated as a presenting panel member to students at Harvard Medical School to discuss the PPE supply chain, including issues related to procurement challenges during the COVID-19 pandemic.

5. Between 1993 and 2001, I worked in the supply chain department of Newton-Wellesley Hospital (which became part of Partners HealthCare System after Newton-Wellesley Hospital was acquired in 1999). I initially held the role of Departmental Buyer where I assisted in identifying and negotiating with potential suppliers, soliciting bids, and creating purchase orders. I later held a management position in which I oversaw all of the hospital's supply chain purchasing and contracting needs for both medical and non-medical products. Between 2001 and 2007, I served as Corporate Manager at Partners HealthCare System (which was a predecessor to Mass General Brigham), where I continued to oversee critical PPE sourcing and contracting projects.

During this time I worked directly with executive PPE suppliers and manufacturers and formed important relationships that have been instrumental to Mass General Brigham's ability to procure its needed products in a timely manner.

6. I received a Masters of Management in HealthCare from Cambridge College in 2009. My curriculum vitae is attached hereto as **Appendix A**. I have not provided any other expert testimony in the last four years.

II. ALLEGATIONS AND ASSIGNMENT

7. I have been retained by Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP, counsel for Defendants Chain Bridge Bank, N.A. ("Chain Bridge"), John J. Brough, and David M. Evinger (collectively, "Defendants"), as well as by Wilmer Cutler Pickering Hale and Dorr LLP, counsel for JPMorgan Chase Bank, N.A. ("JPMorgan"), in connection with the lawsuit *Blue Flame Medical LLC v. Chain Bridge Bank, N.A., John J. Brough, and David M. Evinger*.

8. Plaintiff Blue Flame Medical LLC ("Blue Flame")² brings claims related to a wire transfer of \$456.89 million. I understand this wire transfer was sent on March 26, 2020 by the State of California ("California"), through its bank JPMorgan, to Chain Bridge, where Blue Flame had a bank account.³ This wire transfer was California's initial deposit to purchase 100 million N95 masks from Blue Flame for \$609.16 million.⁴ The wire transfer was subsequently recalled and the funds were returned.⁵ Blue Flame alleges, among other claims, that the return of the wire transfer "caused Blue Flame to lose all profits it expected to receive from the transaction [with California] as well as substantial future business opportunities with California and other governmental entities."⁶

² Blue Flame Medical LLC is affiliated with Blue Flame Strategies LLC, which had entered into referral fee agreements with Velox Medical, Inc., and Healthcom Pacific Inc., which is affiliated with Great Health Companion Group Ltd., among other companies. See, Referral Fee Agreement between Velox Medical, Inc. and Blue Flame Strategies LLC, dated March 13, 2020, BFM000000675 - 681; Referral Fee Agreement between Healthcom Pacific Inc. and Blue Flame Strategies LLC, dated March 13, 2020, BFM000000668 - 674; First Amendment and Addendum to Referral Fee Agreement between Healthcom Pacific Inc. and Blue Flame Strategies LLC, dated March 25, 2020, BFM000116345 - 346.

³ Complaint, *Blue Flame Medical LLC v. Chain Bridge Bank, N.A., John J. Brough, and David M. Evinger*, Civil Action No. 20 Civ 658, In the United States District Court for the Eastern District of Virginia Alexandria Division, filed June 12, 2020 ("Complaint"), ¶¶ 1-3 and 61.

⁴ Complaint, ¶¶ 25, 61.

⁵ Fedwire Funds Processor Message, March 26, 2020, CBB00002780; Complaint, ¶ 70.

⁶ Complaint, ¶ 80.

9. I have been asked by counsel for Chain Bridge and JPMorgan to apply my experience and knowledge of PPE procurement, including N95 mask procurement, to the circumstances at issue in this matter. Specifically, counsel has asked me to:

- a. Describe the N95 marketplace, including how demand for, supply of, and procurement of N95 masks were affected by the COVID-19 pandemic in the first half of 2020; and
- b. Assess whether Blue Flame could have fulfilled California's order of 100 million N95 masks.

10. All opinions expressed in this report are my own. In preparing this report, I relied upon my experience and knowledge of PPE procurement and sourcing; data and documents produced in discovery; deposition testimony; and publicly-available data and documents. A list of the materials that I considered in preparing my report is attached hereto as **Appendix B**.

11. Employees of Analysis Group, Inc., an economics, finance, and strategy consulting firm, working under my direction and supervision, assisted me with this assignment. I am being compensated at a rate of \$750 per hour for my independent review and analysis provided in this case. This compensation is not contingent on the nature of my findings or the outcome of this litigation.

III. SUMMARY OF OPINIONS

12. Based on my work to date, as well as my education and experience, I conclude the following:

- a. N95 respirator masks are a critical piece of protective equipment for healthcare providers. Not all respirators meet U.S. quality standards for N95 masks, and different makes, models, and sizes of N95 masks are not interchangeable. Purchasers of N95 masks have specific requirements for which N95 masks will meet their needs;
- b. The COVID-19 pandemic caused demand for N95 masks to skyrocket. By February 2020, market conditions were chaotic, and demand far exceeded the supply available anywhere in the world. In sourcing N95 masks during March and April 2020, I faced the most difficult sourcing environment of my career;

- c. Blue Flame could not have fulfilled California's order of 100 million N95 masks within 60 days, much less within the 30 days pledged by Blue Flame. Nor could Blue Flame have supplied California with 63 million N95 masks within 30 days. Indeed, it is highly unlikely that Blue Flame could have provided California with any significant quantity of N95 masks within 60 days. This is due to multiple factors:
 - i. There was insufficient global supply of N95 masks due to production constraints, export restrictions, and increased demand from buyers worldwide;
 - ii. Supplies of the particular models of N95 masks that Blue Flame had agreed to supply to California were even more limited and constrained;
 - iii. Blue Flame's failure to fulfill N95 mask orders from other customers during the same time period confirms that Blue Flame could not have fulfilled California's order either; and
 - iv. Although Blue Flame claims that it would have fulfilled California's order, notwithstanding all of these obstacles, this claim is not credible in light of Blue Flame's lack of experience and sophistication in the PPE procurement industry and Blue Flame's repeated failures to comply with standard industry practice for PPE procurement.

13. My opinions, and the bases for my opinions, are presented in this report and the exhibits and appendices attached hereto. I hold all of my opinions as provided in this report to a reasonable degree of professional certainty. My work on this matter is ongoing, and I reserve the right to supplement or amend my report should new information become available. I am prepared to testify at trial on the topics discussed in this report and to provide any additional relevant background; I also anticipate using certain demonstrative exhibits at trial to illustrate and support the concepts described in this report.

14. The remainder of this report is organized as follows. Section IV discusses the background of the relevant parties and California's order of 100 million N95 masks from Blue Flame in March 2020. Section V provides an overview of the market for N95 masks, including the types of masks available and their distribution processes prior to the COVID-19 pandemic.

Section VI discusses changes in the N95 market in early 2020 that made it challenging to procure N95 masks, as well as my personal experience procuring N95 masks at that time. Section VII sets out my opinion that Blue Flame could not have fulfilled California's order of 100 million (or 63 million) N95 masks within 60 days, much less within the 30 days pledged by Blue Flame.

IV. BACKGROUND

A. The Relevant Parties

1. Blue Flame

15. Blue Flame was founded on March 23, 2020 by Michael Gula and John Thomas.⁷ According to their testimony, neither Mike Gula nor John Thomas had any experience procuring medical supplies, knowledge of the PPE supply chain, or any experience with the logistics of importation, customs, or shipping of goods from overseas prior to March 2020.⁸ The company nevertheless described itself as “the largest global network of COVID-19 medical suppliers providing healthcare logistics and hard to find certified medical supplies” that are “delivered with industry-leading efficiency.”⁹ Blue Flame claimed it could procure a variety of PPE items, including various types of N95 masks, and told prospective customers that it is “able to deliver our goods between 7-12 days after the initial order is placed.”¹⁰

16. On March 24, 2020, Blue Flame entered into a Product Reseller Agreement with Great Health Companion Group Ltd. (“Great Health”), whereby Great Health agreed to purchase and assist in procuring PPE on behalf of Blue Flame.¹¹ According to Blue Flame, Great Health is

⁷ Blue Flame Medical Presentation, BFM000002416 - 430 at 417 - 418; State of Delaware Limited Liability Company Certificate of Formation for Blue Flame Medical LLC, March 23, 2020, CBB00002569 - 571. Mr. Gula and Mr. Thomas, are political consultants. Mr. Gula is a co-founder of the Gula Graham Group, a political fundraising firm, and Prime Advocacy, a “fly-in and logistics firm” for advocates to schedule meetings with legislators. Mr. Thomas is the founder and President of Thomas Partners Strategies, a “media, strategy and crisis communications firm,” is an “on air [t]elevision pundit and commentator,” as well as a “radio personality.” Blue Flame Medical Presentation, BFM000002416 - 430 at 419 - 420; Complaint, ¶ 22; “About Us,” Prime Advocacy, available at: <http://www.primeadvocacy.com/about-us>.

⁸ See, e.g., Deposition of John Thomas, January 11, 2021, at pp. 19-21; Deposition of Mike Gula, January 12, 2021, at pp. 25-28.

⁹ Blue Flame Medical Presentation, BFM000002416 - 430 at 417.

¹⁰ Blue Flame Medical Presentation, April 2020, BFM000021079 - 093 at 093; Email from Michael Gula to Julio Cabral, April 1, 2020, BFM000021076; Product Catalog, April 1, 2020, BFM000021094.

¹¹ Product Reseller Agreement between Blue Flame and Great Health, dated March 24, 2020, BFM000170163 - 174.

a subsidiary of a majority owned and controlled Chinese State-Owned Enterprise (“SOE”), and contracts with “leading SOE PPE manufacturers in China.”¹² On March 25, 2020, Blue Flame signed a similar Product Reseller Agreement with Suuchi Inc. (“Suuchi”).¹³ Suuchi is a supply chain, operations, and sales company that claims to have re-purposed part of its supply chain capacity to produce and source PPE for local, state, and federal health organizations.¹⁴ Blue Flame did not have supplier or purchase agreements with any companies other than Great Health and Suuchi at the time of California’s N95 mask order from Blue Flame.¹⁵

2. The State of California

17. In early 2020, officials from state government offices in California were actively working to provide healthcare and frontline workers with the PPE and supplies needed to support California’s response to the COVID-19 pandemic. By mid-March 2020, state officials had petitioned the United States Congress and President Trump for emergency funding to procure PPE, and had requested shipments of over 20 million N95 masks from the Strategic National Stockpile.¹⁶ As part of these efforts, representatives from multiple government offices, including the Department of General Services, the Governor’s Office of Emergency Services, and the Office of the Controller, also worked to purchase large quantities of PPE from non-governmental sources. In particular, California looked to buy “about 100 million each” of N95 masks, surgical masks, face shields, gowns, and coveralls for hospitals, emergency medical service providers, and other

¹² Blue Flame Medical Presentation, BFM000002416 - 430 at 422.

¹³ Product Reseller Agreement between Blue Flame and Suuchi, dated March 25, 2020, BFM000170152 - 162.

¹⁴ “About Us,” Suuchi, available at: <https://www.suuchi.com/about-suuchi-inc/>; “Suuchi, Personal Protective Equipment Catalog,” available at: <https://www.suuchi.com/wp-content/uploads/2020/06/Suuchi-Inc.-PPE-Catalog-V.1.4-5.19-May-2020-Compressed.pdf>, at p. 2.

¹⁵ See, e.g., Email from Ethan Bearman to Marc Serrio (Blue Flame), March 31, 2020, BFM000170149 - 151 at 149.

¹⁶ “Governor Newsom Takes Action to Strengthen California’s Health Care Delivery System to Respond to COVID-19,” Office of Governor Gavin Newsom, March 21, 2020, available at: <https://www.gov.ca.gov/2020/03/21/governor-newsom-takes-action-to-strengthen-californias-health-care-delivery-system-to-respond-to-covid-19/>; “Governor Newsom Requests Federal Assistance to Support California’s Efforts to Prepare for COVID-19 Surge,” Office of Governor Gavin Newsom, March 19, 2020, available at: <https://www.gov.ca.gov/2020/03/19/governor-newsom-requests-federal-assistance-to-support-californias-efforts-to-prepare-for-covid-19-surge/>; “Governor Newsom Requests Presidential Major Disaster Declaration for State’s COVID-19 Response Efforts,” Office of Governor Gavin Newsom, March 22, 2020, available at: <https://www.gov.ca.gov/2020/03/22/governor-newsom-requests-presidential-major-disaster-declaration-for-states-covid-19-response-efforts/>.

medical first responders throughout California.¹⁷ California's demand for N95 masks consisted specifically of NIOSH-approved N95 masks.¹⁸ I discuss NIOSH-approved N95 masks below in Section V.A.

B. California Orders 100 Million N95 Masks From Blue Flame

18. By March 20, 2020, Blue Flame had begun communicating with California to discuss the procurement and delivery of PPE, including N95 masks.¹⁹ On March 23, 2020, Blue Flame and California discussed PPE supplies, and California informed Blue Flame it was interested in buying "about 100 million" N95 masks that "[m]ust have NIOSH Certification."²⁰ On March 24, 2020, California asked Blue Flame via text, "[w]hat volume of the DTC 3B, DT[C] 3X, L-288, and SEKURA-321 model [N95] masks can you ship immediately?"²¹ Blue Flame replied saying that it "can deliver 63,000,000[] [N95] masks within 30 days for sure," and that timing on delivery for the remaining 37 million N95 masks would be determined after speaking with its manufacturers.²² After Blue Flame confirmed that it understood that California could "only accept the approve[d] N95 masks (specifically the model numbers I texted you)," California informed Blue Flame that it would like to execute a purchase order.²³

19. On March 25, 2020, California ordered 100 million N95 masks from Blue Flame at \$4.76 per unit, for a total purchase price of \$609.16 million (inclusive of \$37.96 million in sales

¹⁷ Emails from Abby Browning (Office of Private Sector / NGO Coordination at California Governor's Office of Emergency Services) to Mike Gula *et al.*, March 23, 2020, CAL-OES-00000020 - 026 at 022 - 024; Emails between Michael Wong (California Department of General Services) and John Thomas, March 23-24, 2020, CAL-OES-00000027 - 034; Emails between John Thomas and Bill Simonson (California Department of General Services), March 20, 2020, CAL-DGS-00000195 - 263 at 204 - 217; Texts between Betty Yee (State Controller) and John Thomas, March 20, 2020, BFM000074882.

¹⁸ Emails from Abby Browning to Mike Gula *et al.*, March 23, 2020, CAL-OES-00000020 - 026 at 023; Emails from Bill Simonson to John Thomas, March 20, 2020, CAL-DGS-00000195 - 263 at 207.

¹⁹ Emails between John Thomas and Bill Simonson, March 20, 2020, CAL-DGS-00000195 - 263 at 204 - 217.

²⁰ Emails from Abby Browning to Mike Gula *et al.*, March 23, 2020, CAL-OES-00000020 - 026 at 022 - 025.

²¹ Texts between John Thomas and Michael Wong, March 24, 2020, CAL-DGS-00000292 - 311 at 300. Although California's text message listed N95 mask model "DTX 3X" instead of "DTC 3X," I understand this was a typographical error. See, Texts between Suuchi Ramesh and Ethan Bearman, March 26, 2020, BFM000077942 - 956 at 953.

²² Email from John Thomas to Michael Wong, March 24, 2020, CAL-DGS-00000195 - 263 at 223. See, also, Texts between John Thomas and Michael Wong, March 24, 2020, CAL-DGS-00000292 - 311 at 301 - 302.

²³ Emails between John Thomas and Michael Wong, March 24, 2020, CAL-DGS-00000195 - 263 at 219 - 222.

tax and \$95.20 million in shipping costs).²⁴ The order invoice specified that the “N95 Mask Models” would include the same four NIOSH-approved N95 mask models that the parties discussed on the previous day, including: DTC 3B and DTC 3X, which are manufactured by Shanghai Dasheng Health Products Manufacture Company, Ltd. (“Shanghai Dasheng”); L-288, which is manufactured by Guangzhou Harley Commodity Company, Ltd. (“Guangzhou Harley”); and SEKURA-321, which is manufactured by Makrite Industries, Inc. (“Makrite”).²⁵ All three of these producers manufacture N95 masks in China.²⁶ On the same day, Blue Flame told representatives from California that after “talking to [their] main manufacturer ... the delivery dates are early. We’ll then ramp up quickly to essentially have planes landing every day to meet our deadline for California,” and sent California a delivery schedule showing that all 100 million N95 masks would be delivered by April 24, 2020 (*i.e.*, 30 days from March 25, 2020).²⁷ I therefore understand that Blue Flame pledged to fill California’s order within 30 days.²⁸

²⁴ Invoice from Blue Flame to California, dated March 25, 2020, BFM000066431; Purchasing Authority Purchase Order, from the California Department of General Services to Blue Flame Medical LLC, March 25, 2020, BFM000095501. Blue Flame testified that its estimated gross profit from the order would be \$143.12 million, and that Blue Flame Strategies (Blue Flame’s affiliate) would potentially receive an additional \$47.6 million through its referral fee agreement with Great Health. Plaintiff’s Responses to Defendants’ First Set of Interrogatories to Blue Flame Medical LLC, *Blue Flame Medical LLC v. Chain Bridge Bank, N.A., John J. Brough, and David M. Evinger*, Civil Action No. 20 Civ 658, In the United States District Court for the Eastern District of Virginia Alexandria Division, filed October 13, 2020, (“Plaintiff’s Responses to Defendants’ First Set of Interrogatories to Blue Flame Medical LLC, October 13, 2020”), at Schedule A; Deposition of Ethan Bearman, January 21, 2021, at pp. 289-296.

²⁵ “NIOSH-Approved N95 Particulate Filtering Facepiece Respirators: Manufacturers Listed Alphabetically - S,” Centers for Disease Control and Prevention, updated December 30, 2020, available at: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1sect3.html; “NIOSH-Approved N95 Particulate Filtering Facepiece Respirators: Manufacturers Listed Alphabetically - M,” Centers for Disease Control and Prevention, updated December 14, 2020, available at: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1sect2-m.html; “NIOSH-Approved N95 Particulate Filtering Facepiece Respirators: Manufacturers Listed Alphabetically - G,” Centers for Disease Control and Prevention, updated September 8, 2020, available at: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1-g.html.

²⁶ “Makrite Special Announcement!,” Makrite, March 25, 2020, available at: <http://www.makrite.com/makritespecialannouncement/>; “DaSheng Introduce,” Shanghai Dasheng, available at: <http://www.dashengmask.com/About-US/id/174.html>; “No Borders, Inc., Subsidiary MediDent Supplies Announces Becoming a Factory Authorized Distributor of Guangzhou based Harley Commodity’s L-288 and L-188 NIOSH N95 Respirators,” Globe Newswire, January 5, 2021, available at: <https://www.globenewswire.com/news-release/2021/01/05/2153773/0/en/No-Borders-Inc-Subsidiary-MediDent-Supplies-Announces-Becoming-a-Factory-Authorized-Distributor-of-Guangzhou-based-Harley-Commodity-s-L-288-and-L-188-NIOSH-N95-Respirators.html>.

²⁷ Texts from John Thomas to Daniel Kim (California Department of General Services) and Michael Wong, March 25, 2020, BFM000129957 - 960 at 959 - 960; Deposition of John Thomas, January 11, 2021, at p. 220.

²⁸ Blue Flame states that the schedule it sent California was a “rough delivery schedule” and that the “deadline to deliver [was] as fast as possible.” Deposition of John Thomas, January 11, 2021, at pp. 220-221. However, Blue

20. On March 26, 2020, California initiated a 75 percent down payment in the form of a wire transfer of \$456.89 million, through its bank JPMorgan, to Chain Bridge for the benefit of Blue Flame.²⁹ On the same day, Blue Flame ordered 100 million N95 masks from Great Health. The Order Confirmation specified that Great Health would fulfill the order “within 40 days from the time payment is received and cleared.”³⁰ I understand that later that day, Chain Bridge returned the wire transfer to JPMorgan.³¹

21. On April 8, 2020, Blue Flame informed California that it was still “confident that [it] can provide [California] 100 million N95 masks,” but that because “the market for PPE is very volatile and everyone is trying to lock up supply,” California would now need to pay \$4.99 per N95 mask, and it would now take Blue Flame “60-90 days to deliver all 100 million masks.”³² I have not seen any evidence that California agreed to Blue Flame’s new terms.³³

V. OVERVIEW OF THE MARKET FOR N95 MASKS

A. Types of Masks

22. One of the most important types of PPE items for healthcare and frontline workers during the COVID-19 pandemic are masks that cover the nose and mouth. There are many types of masks, but N95 masks provide the most protection to both the wearer and those nearby, and are

Flame also states that “the terms agreed between Blue Flame and California [were] memorialized in a March 25, 2020 invoice and in communications between the parties.” See, Letter from Howard Waltzman (Mayer Brown) to Hon. Frank Pallone, Jr. and Hon. Diana DeGette (United States Congress), Re: Response to Committee Request, dated June 22, 2020, Exhibit A to “Memorandum in Support of Defendants’ Motion to Dismiss,” *Blue Flame Medical LLC v. Chain Bridge Bank, N.A., John J. Brough, and David M. Evinger*, Civil Action No. 20 Civ 658, In the United States District Court for the Eastern District of Virginia Alexandria Division, filed July 20, 2020 (“Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette”), at p. 4. Further, Michael Wong, the State of California contract administrator who worked with Blue Flame on this transaction, testified that he understood Blue Flame to have “guarantee[d]” that Blue Flame could deliver 63 million N95 masks within 30 days of California’s order. Deposition of Michael Wong, January 19, 2021, at pp. 71-72.

²⁹ Complaint, ¶¶ 25, 61.

³⁰ Order Confirmation from Great Health to Blue Flame, March 26, 2020, BFM000013610 - 611.

³¹ Complaint, ¶¶ 68-70; Defendants’ Responses to Plaintiff’s First Set of Interrogatories, *Blue Flame Medical LLC v. Chain Bridge Bank, N.A., John J. Brough, and David M. Evinger*, Civil Action No. 20 Civ 658, In the United States District Court for the Eastern District of Virginia Alexandria Division, filed October 28, 2020, (“Defendants’ Responses to Plaintiff’s First Set of Interrogatories, October 28, 2020”), at pp. 2-5.

³² Email from John Thomas to Michael Wong, April 8, 2020, CAL-DGS-00000195 - 263 at 242.

³³ See, e.g., Emails between John Thomas and Michael Wong, April 10-21, 2020, CAL-DGS-00000195 - 263 at 244 - 254.

generally considered the “gold standard” of masks for most settings.³⁴ N95 masks (also referred to as “N95 respirators”) are protective devices certified by the National Institute for Occupational Safety and Health (“NIOSH”), a research agency that is part of the Centers for Disease Control and Prevention (“CDC”), which studies worker safety and health, and tests masks to verify that they meet certain quality standards.³⁵ Specifically, N95 masks have at least 95 percent efficiency, meaning that they filter at least 95 percent of airborne particles.^{36,37} N95 masks are designed to seal around the nose and mouth, and users typically perform a fit test to identify which model and size best fits their face. A particular person may require a different size mask from one manufacturer versus another (*e.g.*, someone may wear a “small” size mask made by 3M Company but a “regular” size mask made by Louis M. Gerson Co.). Thus, one particular make, model, and size of N95 mask is therefore not interchangeable with another.

23. There are also other types of masks that are not tested and approved by NIOSH, and therefore are not N95 masks, but do purport to have approximately 95 percent efficiency. For example, the European Union’s Conformité Européen tests and certifies CE-type (also known as FFP-type) masks, while the Government of China tests and certifies KN-type masks, including KN95 masks.³⁸ However the performance standards of CE-type and KN-type masks differ from those of N95 masks (*e.g.*, the maximum withstood inhale/exhale pressure), and therefore such

³⁴ See, *e.g.*, Cheney, Christopher, “Coronavirus: There are Viable Alternatives to New N95 Masks, Research Shows,” HealthLeaders Media, August 21, 2020, available at: <https://www.healthleadersmedia.com/clinical-care/coronavirus-there-are-viable-alternatives-new-n95-masks-research-shows>; Duque, Theresa, “This Anti-COVID Mask Design Breaks the Mold,” Berkeley Lab, December 9, 2020, available at: <https://newscenter.lbl.gov/2020/12/09/anti-covid-mask-breaks-mold/>.

³⁵ “About NIOSH,” Centers for Disease Control and Prevention, available at: <https://www.cdc.gov/niosh/about/default.html>; “Surgical N95 vs. Standard N95 - Which to Consider?,” 3M Company, June 2020, available at: <https://multimedia.3m.com/mws/media/1794572O/surgical-n95-vs-standard-n95-which-to-consider.pdf> (“Surgical N95 vs. Standard N95 - Which to Consider?,” 3M Company”).

³⁶ “NIOSH-Approved N95 Particulate Filtering Facepiece Respirators,” Centers for Disease Control and Prevention, available at: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/n95list1.html.

³⁷ The “N” in N95 stands for “Non-Oil,” meaning that N95 masks are not resistant to oil-based particulates. Other mask ratings include “R” (resistant to oil for up to eight hours) and “P” (oil proof). See, “N95 Masks Explained,” Honeywell, available at: <https://www.honeywell.com/us/en/news/2020/03/n95-masks-explained>.

³⁸ D’Alessandro, Maryann M., *et al.*, “Understanding the Use of Imported Non-NIOSH-Approved Respirators,” Centers for Disease Control and Prevention, April 23, 2020, available at: <https://blogs.cdc.gov/niosh-science-blog/2020/04/23/imported-respirators/>. See, also, “Overview of CE marked respirator masks,” Makrite North America, available at: <https://www.makritenorthamerica.com/disposable-respirators/ce-masks/>.

masks may not meet NIOSH's quality standards.³⁹ In response to the shortage of N95 masks that has resulted from the COVID-19 pandemic, which I discuss further in Section VI.B below, on March 24, 2020, the FDA began authorizing the emergency use of certain non-NIOSH approved masks when N95 masks are unavailable.⁴⁰ However, the CDC warned in May 2020 that "an unprecedented number of products on the market do not perform as advertised," and a NIOSH review of documents from Chinese-based manufacturers "has found a significant amount of falsified documentation" regarding masks' performance.⁴¹ There is recent evidence that certain KN95 masks do not achieve their purported efficiency when subjected to laboratory testing.⁴²

B. Distribution and Supply of N95 Masks

24. Large purchasers of N95 masks typically procure directly from manufacturers or third-party suppliers (*e.g.*, wholesalers and distributors). In my experience, manufacturers and suppliers arrange the shipping and delivery logistics associated with large orders prior to order execution, or at the very least have processes in place prior to order execution to quickly finalize such logistics after order execution. These logistics can include, among other things, transportation from the manufacturer to the purchaser, or if product is being supplied from abroad, transportation from the manufacturer to the port or airstrip, contracts with a cargo company, storage locations (if applicable), preparations for clearing customs, *etc.* Individual buyers of small quantities (*i.e.*, up to a few hundred units) can also purchase N95 masks directly from retail stores.

³⁹ "Comparison of FFP2, KN95, and N95 Filtering Facepiece Respirator Classes," 3M Company, November 2020, available at: <https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf>.

⁴⁰ D'Alessandro, Maryann M., *et al.*, "Understanding the Use of Imported Non-NIOSH-Approved Respirators," Centers for Disease Control and Prevention, April 23, 2020, available at: <https://blogs.cdc.gov/niosh-science-blog/2020/04/23/imported-respirators/>.

⁴¹ "Factors to Consider When Planning to Purchase Respirators from Another Country," Centers for Disease Control and Prevention, updated May 15, 2020, available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/international-respirator-purchase.html>.

⁴² ECRI, a nonprofit organization that conducts independent medical device testing, found that 60 to 70 percent of imported, non-NIOSH-approved masks that were purported to provide the same level of protection as N95 masks, including KN95 masks, did not meet N95 masks' filtration requirements. "Use of Imported N95-Style Masks, without NIOSH Certification or Independent Lab Validation, May Put Healthcare Workers and Patients at Risk during the COVID-19 Pandemic," Medical Device Hazard Report, ECRI, September 22, 2020, available at: <https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-N95-Mask-Testing-Alert.pdf>, at pp. 1, 3. See, also, Sickbert-Bennett, Emily E., *et al.*, "Filtration Efficiency of Hospital Face Mask Alternatives Available for Use During the COVID-19 Pandemic," *JAMA Internal Medicine*, Vol. 180(12) (2020): 1607-1612.

25. Prior to the COVID-19 pandemic, users in the United States consumed an estimated 445 million N95 masks each year, less than 10 percent of which were for medical uses.⁴³ This consumption was fulfilled by both domestic production and imports from abroad.⁴⁴ By the end of 2019 or early-January 2020, U.S. manufacturers were producing approximately 30-45 million N95 masks each month.⁴⁵ 3M Company, the largest of these manufacturers,⁴⁶ produced approximately 22 million N95 masks in the United States per month in 2019,⁴⁷ while other manufacturers, including Honeywell, Halyard Health, Moldex-Metric Inc., Louis M. Gerson Co., Prestige Ameritech Ltd., and Alpha Pro Tech Ltd., each produced smaller quantities.⁴⁸ Some of this domestic production was exported.⁴⁹ It is estimated that as much as 70 percent of N95 masks used

⁴³ “COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges,” United States International Trade Commission, Publication No. 5145, Investigation No. 332-580,” December 2020, available at: <https://www.usitc.gov/publications/332/pub5145.pdf> (“USITC, December 2020”), at p. 89.

⁴⁴ The United States also has a reserve of N95 masks in the Strategic National Stockpile (“SNS”), which can be used during public health emergencies. According to the Department of Health and Human Services, the SNS only held approximately 12 million N95 masks in early March 2020. State agencies also did not maintain significant stockpiles of N95 masks prior to the COVID-19 pandemic. See, “Strategic National Stockpile,” Public Health Emergency, available at: <https://www.phe.gov/about/sns/Pages/default.aspx>. See, also, Lovelace Jr., Berkeley, “HHS clarifies US has about 1% of face masks needed for ‘full-blown’ coronavirus pandemic,” CNBC, March 4, 2020, available at: <https://www.cnbc.com/2020/03/04/hhs-clarifies-us-has-about-1percent-of-face-masks-needed-for-full-blown-pandemic.html>; Freedman, David H., “How 3M Blew Its Reputation on the N95 Mask,” Marker, August 19, 2020, available at: <https://marker.medium.com/how-3m-gambled-its-reputation-on-the-n95-mask-e266a2fd8933>.

⁴⁵ USITC, December 2020, at p. 90; Hufford, Austen, “N95 Face Mask Makers Ramp Up Production to Meet U.S. Covid-19 Demand,” The Wall Street Journal, July 17, 2020, available at: <https://www.wsj.com/articles/n95-mask-makers-ramp-up-production-to-meet-u-s-covid-19-demand-11594987201> (“Hufford, Austen, July 17, 2020”).

⁴⁶ Contrera, Jessica, “The N95 shortage America can’t seem to fix,” The Washington Post, September 21, 2020, available at: <https://www.washingtonpost.com/graphics/2020/local/news/n-95-shortage-covid/> (“Contrera, Jessica, September 21, 2020”). See, also, Hufford, Austen, July 17, 2020.

⁴⁷ Clark, Doug Bock, “Inside the Chaotic, Cutthroat Gray Market for N95 Masks,” The New York Times, November 17, 2020, available at: <https://www.nytimes.com/2020/11/17/magazine/n95-masks-market-covid.html>.

⁴⁸ Hufford, Austen, “3M CEO on N95 Masks: ‘Demand Exceeds Our Production Capacity,’” The Wall Street Journal, April 2, 2020 available at: <https://www.wsj.com/articles/3m-ceo-on-n95-masks-demand-exceeds-our-production-capacity-11585842928> (“Hufford, Austen, April 2, 2020”).

⁴⁹ See, e.g., Bown, Chad P., “COVID-19: Trump’s curbs on exports of medical gear put Americans and others at risk,” Peterson Institute for International Economics, April 9, 2020, available at: <https://www.piie.com/blogs/trade-and-investment-policy-watch/covid-19-trumps-curbs-exports-medical-gear-put-americans-and>.

in the United States are imported.⁵⁰ In 2019, the United States imported \$3.2 billion of N95, surgical, and other types of medical masks, 72 percent of which came from China.⁵¹

26. Prior to the COVID-19 pandemic, the N95 market was relatively stable and efficient. That is, demand was fairly constant and suppliers were able to procure new product just as they were delivering existing product to their customers.⁵² High barriers to entry also limited expansions in production capacity. One barrier to increasing production capacity is that there is a limited supply of the principal raw material needed to produce N95 masks (namely, melt-blown fabric in the form of nonwoven polypropylene or polymer fibers).⁵³ This limited supply exists for at least three reasons. First, its production requires specialized machines that are expensive and are only manufactured by five or six companies worldwide.⁵⁴ One German manufacturer stated in March 2020 that it takes five or six months to produce a single new melt-blown fabric machine line, while the President of the Association of the Nonwoven Fabrics Industry said in April 2020 that delivery of a melt-blown fabric machine normally takes nine to twelve months.⁵⁵ The President of Prestige Ameritech estimates that it would cost \$15 million and take one year for the N95 manufacturer to start producing its own melt-blown fabric.⁵⁶ Second, the production of melt-blown

⁵⁰ McKenna, Maryn, “Amid Coronavirus Fears, a Mask Shortage Could Spread Globally,” *Wired*, February 4, 2020, available at: <https://www.wired.com/story/amid-coronavirus-fears-a-mask-shortage-could-spread-globally/>.

⁵¹ Bown, Chad P., “COVID-19: Trump’s curbs on exports of medical gear put Americans and others at risk,” Peterson Institute for International Economics, April 9, 2020, available at: <https://www.piie.com/blogs/trade-and-investment-policy-watch/covid-19-trumps-curbs-exports-medical-gear-put-americans-and>.

⁵² Clark, Doug Bock, “Inside the Chaotic, Cutthroat Gray Market for N95 Masks,” *The New York Times*, November 17, 2020, available at: <https://www.nytimes.com/2020/11/17/magazine/n95-masks-market-covid.html>; Report Summary, “N95 Mask Market Size, Share & Trends Analysis Report By Product (With Exhalation Valve, Without Exhalation Valve), By Distribution Channel (Online, Offline), By End Use, By Region, And Segment Forecasts, 2020 - 2027,” Grand View Research, November 2020, available at: <https://www.grandviewresearch.com/industry-analysis/n95-mask-market>.

⁵³ Park, Cyn-Young, *et al.*, “Global Shortage of Personal Protective Equipment amid COVID-19: Supply Chains, Bottlenecks, and Policy Implications,” Asian Development Bank, April 2020, available at: <https://www.adb.org/publications/shortage-ppe-covid-19-supply-chains-bottlenecks-policy>, at p. 3.

⁵⁴ Kates, Graham, “N95 mask shortage comes down to this key material: ‘The supply chain has gotten nuts,’” *CBS News*, April 9, 2020, available at: <https://www.cbsnews.com/news/n95-mask-shortage-melt-blown-filters/>.

⁵⁵ Kates, Graham, “N95 mask shortage comes down to this key material: ‘The supply chain has gotten nuts,’” *CBS News*, April 9, 2020, available at: <https://www.cbsnews.com/news/n95-mask-shortage-melt-blown-filters/>; Feng, Emily and Amy Cheng, “COVID-19 Has Caused A Shortage Of Face Masks. But They’re Surprisingly Hard To Make,” *National Public Radio*, March 16, 2020, available at: <https://www.npr.org/sections/goatsandsoda/2020/03/16/814929294/covid-19-has-caused-a-shortage-of-face-masks-but-theyre-surprisingly-hard-to-mak> (“Feng, Emily and Amy Cheng, March 16, 2020”).

⁵⁶ Mendoza, Martha, *et al.*, “Scarcity of key material squeezes medical mask manufacturing,” *The Detroit News* via Associated Press, September 10, 2020, available at:

fabrics is customized to the intended end-use. Less than 1 percent of the U.S.'s melt-blown fabric was produced for use in N95 masks prior to the COVID-19 pandemic,⁵⁷ thus limiting N95 manufacturers' ability to purchase more melt-blown fabric. Third, melt-blown fabric is generally sold under long-term contracts, thus restricting short-term access to existing production.⁵⁸ Therefore, even if N95 manufacturers were to have the factory space, machinery, labor supply, *etc.* to increase N95 production, they still would be constrained by difficulties in procuring the necessary raw materials.

27. In addition to the limited supply of the necessary raw materials, another barrier to increasing production capacity is the significant risk of investing in new factory space and machinery given that N95 mask production has historically been a low-margin business and without large increases in demand.^{59,60} Even months into the COVID-19 pandemic, when demand had clearly increased, many firms remained hesitant to invest in increased capacity because there was uncertainty over how long the heightened demand would last.⁶¹ Finally, there are time and monetary costs associated with applying for NIOSH approval. According to the Vice President of Technical Services at Moldex-Metric Inc., the application process from submittal to approval generally takes around three months.⁶² This regulatory process would delay any new manufacturer's ability to sell N95 masks.

<https://www.detroitnews.com/story/life/wellness/2020/09/10/coronavirus-outbreak-mask-shortages/3460060001/> ("Mendoza, Martha, *et al.*, September 10, 2020").

⁵⁷ USITC, December 2020, at p. 92.

⁵⁸ USITC, December 2020, at p. 92.

⁵⁹ Sun, Lena H. and Rachel Siegel, "As demand spikes for medical equipment, this Texas manufacturer is caught in coronavirus's supply chain panic," *The Washington Post*, February 15, 2020, available at: <https://www.washingtonpost.com/business/2020/02/15/coronavirus-mask-shortage-texas-manufacturing/>; Contrera, Jessica, September 21, 2020.

⁶⁰ Although sales prices for N95 masks have increased in 2020, which I discuss in Section VI below, prices of inputs into the production of N95 masks (*e.g.*, melt-blown fabric) have also increased substantially. Feng, Emily and Amy Cheng, March 16, 2020.

⁶¹ Mendoza, Martha, *et al.*, September 10, 2020.

⁶² Birkner, Jeffrey S. "Detailing the process for NIOSH respirator approval," *Safety+Health Magazine*, March 1, 2006, available at: <https://www.safetyandhealthmagazine.com/articles/detailing-the-process-for-niosh-respirator-approval-2#comments-container>.

VI. CHANGES IN THE DEMAND FOR, SUPPLY OF, AND PROCUREMENT OF N95 MASKS FOLLOWING THE OUTBREAK OF THE COVID-19 PANDEMIC

A. Demand for N95 Masks Increased Substantially

28. Following the outbreak of the COVID-19 pandemic, there was an enormous increase in the demand for N95 masks. Hospitals and healthcare organizations increased purchases of N95 masks by 400 percent, 585 percent, and up to 1,700 percent relative to their pre-pandemic levels in January, February, and March 2020, respectively.⁶³ An official from the U.S. Department of Health and Human Services said in early March 2020 that “[i]f [the pandemic] were to be a severe event, [the U.S.] would need 3.5 billion N95 respirator masks” over a year — nearly an eight-fold increase over pre-pandemic levels.⁶⁴ Industry sources have even indicated that demand has become “essentially limitless” given the need to safeguard healthcare workers and first responders.⁶⁵ Not only had demand from traditional buyers such as hospitals, industrial and construction companies, and other healthcare organizations soared, but also new buyers had started purchasing N95 masks, such as state and local governments and governmental entities (*e.g.*, police and fire departments), nursing homes, schools, private medical practices, other non-health-related businesses, and even individual households. Similar demand patterns were occurring in countries across the world. In February 2020, the Director-General of the World Health Organization said that global demand for masks and other PPE items had increased by “up to 100-fold.”⁶⁶

⁶³ USITC, December 2020, at pp. 89-90.

⁶⁴ Lovelace Jr., Berkeley, “HHS clarifies US has about 1% of face masks needed for ‘full-blown’ coronavirus pandemic,” CNBC, March 4, 2020, available at: <https://www.cnbc.com/2020/03/04/hhs-clarifies-us-has-about-1percent-of-face-masks-needed-for-full-blown-pandemic.html>; Hufford, Austen, July 17, 2020. A 2015 study estimated that total United States demand for N95 masks in a hypothetical influenza pandemic would be 1.7 billion in a base case “high attack rate/low severity scenario,” 3.5 billion in a base case “low attack rate/high severity scenario,” and as much as 7.3 billion in a “maximum demand scenario.” Carias, Cristina, *et al.*, “Potential Demand for Respirators and Surgical Masks During a Hypothetical Influenza Pandemic in the United States,” *Clinical Infectious Diseases*, Vol. 60 (Suppl 1) (2015), S42-S51, at pp. S42, S47.

⁶⁵ USITC, December 2020, at p. 87.

⁶⁶ Nebhay, Stephanie, “Demand for masks soars 100-fold, disrupting coronavirus fight: WHO,” Reuters, February 7, 2020, available at: <https://www.reuters.com/article/us-china-health-who-masks/demand-for-masks-soars-100-fold-disrupting-coronavirus-fight-who-idUSKBN20121J>.

B. Supply of N95 Masks Was Insufficient to Meet Demand

1. U.S. Production and Exports

29. Domestic production of N95 masks increased in 2020, but these increases were unable to satisfy U.S. (or worldwide) demand. Domestic production increased from 42-45 million N95 masks in January 2020 to approximately 50 million in March 2020, and by June 2020, production capacity from four of the largest domestic manufacturers was expected to be 80 million units per month.^{67,68} These quantities were fewer than the amount that consumers were demanding at the time. U.S. manufacturers also continued to export N95 masks during the first half of 2020. In fact, U.S. exports of protective masks (including both N95 and surgical masks) reached a record high in March 2020.⁶⁹

2. International Production and Export Restrictions

30. Changes in U.S. access to international production of N95 masks throughout 2020 likewise were insufficient to satisfy the enormous increase in demand. For example, 3M Company doubled its global N95 mask production over a two month period in early-2020, and by the end of 2020 had increased production capacity above 2019 levels by three-fold.⁷⁰ Production in China

⁶⁷ U.S. manufacturers committed to further production increases, but such increases were not expected to be online until later in 2020. Hufford, Austen, April 2, 2020; Hufford, Austen, July 17, 2020; Mendoza, Martha, *et al.*, September 10, 2020.

⁶⁸ In addition to traditional N95 mask manufacturers (*e.g.*, 3M Company, Honeywell, Moldex-Metric Inc., *etc.*), other non-PPE companies, such as automakers and clothing companies, converted production lines and began producing N95 masks. However, most of these new entrants did not begin producing any certified N95 masks until the summer of 2020, and they confronted many production obstacles, including shortages of key supplies and equipment that limited production capacities. Mendoza, Martha, *et al.*, September 10, 2020; “GM Receives N95 Certification Under New NIOSH Public Health Emergency Process,” General Motors, July 14, 2020, available at: <https://media.gm.com/media/us/en/gm/news.detail.html/content/Pages/news/us/en/2020/jul/0714-n95.html>; Hufford, Austen, “New Manufacturers Jump Into Mask Making as Coronavirus Spreads,” *The Wall Street Journal*, March 21, 2020, available at: <https://www.wsj.com/articles/new-manufacturers-jump-into-mask-making-as-coronavirus-spreads-11584792003>.

⁶⁹ Exports of N95 masks were partially restricted in early-April 2020, but domestic manufacturers continued to have limited exports. Soergel, Andrew, “Trump Administration Partially Lifts Protective Face Mask Export Ban,” *US News*, April 7, 2020, available at: <https://www.usnews.com/news/economy/articles/2020-04-07/trump-administration-partially-lifts-protective-face-mask-export-ban>; Zhang, Dian, *et al.*, “U.S. companies kept shipping masks overseas even as hospitals ran out and despite warnings,” *USA Today*, May 8, 2020, available at: <https://www.usatoday.com/story/news/investigations/2020/05/08/u-s-companies-kept-shipping-masks-overseas-despite-warnings/3090505001/>.

⁷⁰ “A year of helping fight COVID-19,” 3M Company, January 22, 2021, available at: <https://news.3m.com/English/3m-stories/3m-details/2021/-A-year-of-helping-fight-COVID-19/default.aspx>.

increased from approximately 20 million N95 masks in February 2020 to a monthly rate of approximately 50 million by early March 2020, and then to over 150 million by the end of April 2020.⁷¹ However, increases in international production did not at that time result in increased U.S. imports available to domestic purchasers. Between March and April 2020, approximately 65 countries issued bans or restrictions on the export of protective masks and other PPE items, including China, Taiwan, South Korea, France, Germany, India, and Russia,⁷² among others. These restrictions led to reduced and delayed shipments of N95 masks to the United States. For example, the number of shipping containers arriving at U.S. ports containing N95 masks in the thirty days ending March 15, 2020 was 55 percent lower than in the same period in 2019.⁷³

31. As the largest producer of face masks in the world,⁷⁴ China's export restrictions had a particularly significant effect on overall N95 mask supply. On March 31, 2020, Chinese authorities announced that certain PPE items, including N95 masks, would need certifications from China's National Medical Products Administration, and then on April 10, 2020, they announced that medical masks must pass new inspections prior to export.⁷⁵ These restrictions are said to have

⁷¹ China's February 2020 production was significantly lower than its pre-pandemic production due to factory closures from holidays and lockdowns. "Mask production in China resumes 60 pct capacity: ministry," Xinhua, February 2, 2020, available at: http://www.xinhuanet.com/english/2020-02/02/c_138750201.htm; "China's daily mask output exceeds 110 million units," Xinhua, March 2, 2020, available at: http://www.xinhuanet.com/english/2020-03/02/c_138835152.htm; "Fighting Covid-19: China in Action," The State Council Information Office of the People's Republic of China, June 2020, available at: <http://www.scio.gov.cn/zfbps/32832/Document/1681809/1681809.htm>; Wu, Huai-liang, *et al.*, "Facemask shortage and the novel coronavirus disease (COVID-19) outbreak: Reflections on public health measures," *EClinicalMedicine*, Vol. 21 (April 2020): 1-7, at pp. 2, 4; "Coronavirus: Does China have enough face masks to meet its needs?," BBC News, February 6, 2020, available at: <https://www.bbc.com/news/world-asia-china-51363132>.

⁷² "COVID-19 Temporary Trade Measures," International Trade Centre Market Access Map, updated January 29, 2021, available at: <https://www.macmap.org/covid19>; Bradsher, Keith, and Liz Alderman, "The World Needs Masks. China Makes Them, but Has Been Hoarding Them.," *The New York Times*, March 13, 2020, available at: <https://www.nytimes.com/2020/03/13/business/masks-china-coronavirus.html> ("Bradsher, Keith, and Liz Alderman, March 13, 2020").

⁷³ Mendoza, Martha and Juliet Linderman, "Imports of medical supplies plummet as demand in US soars," *Associated Press*, March 20, 2020, available at: <https://apnews.com/article/6d9382c1e8ee36f9ed1a4dfe7815ceb1>.

⁷⁴ Bradsher, Keith, and Liz Alderman, March 13, 2020.

⁷⁵ Certain of China's export restrictions related to new certifications were eased on April 26, 2020. Zhang, Laney, "China: New Medical Supplies Export-Control Measures Issued," *Global Legal Monitor*, May 13, 2020, available at: <https://www.loc.gov/law/foreign-news/article/china-new-medical-supplies-export-control-measures-issued/>; O'Keeffe, Kate, *et al.*, "China's Export Restrictions Strand Medical Goods U.S. Needs to Fight Coronavirus, State Department Says," *The Wall Street Journal*, April 16, 2020, available at: <https://www.wsj.com/articles/chinas-export-restrictions-strand-medical-goods-u-s-needs-to-fight-coronavirus-state-department-says-11587031203> ("O'Keeffe, Kate, *et al.*, April 16, 2020"). Blue Flame was aware as early as March 22, 2020 that there may have

“created bottlenecks at a time of urgent need” and “left American companies’ U.S.-bound face masks ... stranded.”⁷⁶ Some Chinese manufacturers characterized the restrictions as “effectively bann[ing] them selling their products abroad.”⁷⁷ These restrictions also led to delays in the shipments of N95 masks that were able to be exported. Logistics companies and PPE distributors noted in April 2020 how “companies are preparing to wait an extra one to three weeks for supplies ... because of China’s newly implemented export restrictions, and limited space to fly items out of China.”⁷⁸ 3M Company and Owens & Minor each reported having “large quantities of masks sitting in Chinese warehouses waiting on approval” for export.⁷⁹

32. At the same time, there are reports that the Chinese government was also claiming manufacturers’ N95 production.⁸⁰ For example, masks produced in 3M Company’s facility in Shanghai, China were being diverted to local authorities.⁸¹ Great Health wrote on March 24, 2020 that certain “private enterprise[s]” were being “summoned by the [People’s Republic of China] gov[ernment] not allowing them to export to [the] US market,”⁸² and on April 29, 2020 that “the Chinese government has directly intervened in the operations of manufacture and export of N95 masks, making it extremely difficult, if not impossible, for us to fulfill [Blue Flame’s] [o]rder

been restrictions on exportation of Chinese manufactured N95 masks based on a notice Makrite issued stating that “there is no extra stock available for export.” Email from Martha Medina to Mike Gula, March 22, 2020, BFM000110675 - 678 at 676.

⁷⁶ O’Keeffe, Kate, *et al.*, April 16, 2020.

⁷⁷ Wu, Wendy, “Coronavirus: China loosens controls on medical exports after suppliers complain they were ‘banned’,” South China Morning Post, April 26, 2020, available at: <https://www.scmp.com/news/china/politics/article/3081632/coronavirus-china-loosens-controls-medical-exports-after>.

⁷⁸ Sandler, Rachel, “‘It’s Chaos’: Medical Supply Shipments From China Are Being Delayed Because Of Export Restrictions, Limited Cargo Space,” Forbes, April 17, 2020, available at: <https://www.forbes.com/sites/rachelsandler/2020/04/17/its-chaos-medical-supply-shipments-from-china-are-being-delayed-because-of-export-restrictions-limited-cargo-space/> (“Sandler, Rachel, April 17, 2020”).

⁷⁹ Sandler, Rachel, April 17, 2020. Lockdowns within China that were issued in an effort to reduce the spread of COVID-19 also increased the challenges in sourcing PPE items from China. These lockdowns “shutter[ed] factories and disrupted ports.” “Medical supply shortage in U.S. traced back to factory shutdown in China as it dealt with coronavirus,” The Oregonian via Associated Press, March 20, 2020, available at: <https://www.oregonlive.com/coronavirus/2020/03/medical-supply-imports-to-us-plummet-as-demand-soars-amid-coronavirus-pandemic.html>.

⁸⁰ Bradsher, Keith, and Liz Alderman, March 13, 2020.

⁸¹ O’Keeffe, Kate, *et al.*, April 16, 2020.

⁸² Email from Henry Huang to John Thomas, March 24, 2020, BFM000012004 - 005.

without causing undue delay.”⁸³ I personally spoke to distributors during March and April 2020 who themselves had trouble importing masks from China into the U.S. This is consistent with Blue Flame’s experience in April 2020 of having the Chinese government divert product that John Thomas testified Blue Flame expected to import into the U.S.⁸⁴ In total, according to China’s own public estimate, China exported only approximately 74 million N95 masks to the U.S. in the 46 days between March 1 and April 15, 2020.⁸⁵ As such, despite the enormous increase in demand, the available supply of internationally produced N95 masks at the time of California’s order was not meaningfully larger than such supply pre-pandemic.

33. In response to these circumstances, the U.S. Department of Health and Human Services issued an official notice on March 25, 2020 — the same day Blue Flame issued California an invoice for its 100 million N95 mask order — whereby N95 masks were declared to be “in short supply (scarce materials) or the supply of which would be threatened by hoarding (threatened materials).”⁸⁶ Limited supply of N95 masks continued throughout 2020. Even in September, 3M Company noted that “the demand is more than we, and the entire industry, can supply for the foreseeable future.”⁸⁷

C. Procuring N95 Masks at the Outset of the Pandemic was Difficult

34. By February 2020 the market for PPE was chaotic. Long-term buyers such as health care facilities were demanding larger quantities; new buyers such as municipalities, schools, small businesses, and individual households were entering the market; suppliers were running out of available product because their inventories and supply networks were not prepared for the increased demand; prices were changing (primarily increasing) on a daily basis; buyers were only able to procure a fraction of their desired quantities; and orders were taking longer to fulfill, and

⁸³ Letter from Great Health to Blue Flame, April 29, 2020, BFM000076873 - 874 at 873.

⁸⁴ Deposition of John Thomas, January 11, 2021, pp. 258-259.

⁸⁵ Brunnstrom, David “U.S. appeals to China to revise export rules on coronavirus medical gear,” Reuters, April 16, 2020, available at: <https://www.reuters.com/article/us-health-coronavirus-usa-china/u-s-appeals-to-china-to-revise-export-rules-on-coronavirus-medical-gear-idUSKBN21Z07G>.

⁸⁶ “Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures Under Executive Order 13910 and Section 102 of the Defense Production Act of 1950,” United States Department of Health and Human Services, March 25, 2020, available at: <https://www.hhs.gov/sites/default/files/hhs-dfa-notice-of-scarce-materials-for-hoarding-prevention.pdf>.

⁸⁷ Contrera, Jessica, September 21, 2020.

at times were not fulfilled at all. These conditions continued into March and April 2020. Blue Flame has even stated that at this time it faced “‘Wild West’ conditions” in “a broken marketplace.”⁸⁸ As an illustration, below I discuss how changes to the market for N95 masks affected Mass General Brigham’s procurement experience in the early- to mid-2020.

35. As is typical in this industry, I had frequent discussions with peers and professional colleagues who worked in the purchasing, distributing, and manufacturing of N95 masks during March and April 2020. Based upon these discussions, I know that Mass General Brigham’s experience was consistent with what other hospitals and organizations who procure PPE items experienced at the time. During these discussions we shared information on potential suppliers and strategies to navigate the challenges in the market. I also regularly spoke with executives at major PPE distributors, including McKesson Corporation, Cardinal Health, Owens & Minor, and Medline Industries, to understand and learn from their experiences procuring product from both domestic and international manufacturers. All of the fellow buyers I spoke with faced supply and pricing challenges that made it difficult for them to procure sufficient quantities of PPE items in a timely manner.

1. Mass General Brigham’s Procurement from Domestic Suppliers

36. Prior to the COVID-19 pandemic, Mass General Brigham purchased approximately 50,000 N95 masks each month. Approximately 40,000 to 45,000 of these were through a supply contract with 3M Company, while 4,000 to 5,000 were through a pricing agreement with Halyard Health.⁸⁹ We also periodically purchased N95 masks from two to three other suppliers each year. Prior to the COVID-19 pandemic, the average cost of an N95 mask was approximately \$0.50-\$0.75 per unit.

37. After the start of the COVID-19 pandemic, Mass General Brigham needed to purchase significantly greater quantities of PPE, and in particular, N95 masks. By April 2020, Mass General Brigham was using between 160,000 and 200,000 N95 masks per month — as much as four times our typical monthly quantity before the pandemic — although we would have used

⁸⁸ Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at p. 2.

⁸⁹ Supply contracts are generally used for large, regular purchases. They establish pre-determined prices for each item (*e.g.*, specific models of N95 masks) over the term of the contract (typically two or three years), and can sometimes pre-commit Mass General Brigham to purchasing specific product quantities. Pricing agreements are generally used for small, infrequent purchases. They also establish pre-determined purchase prices, but are less formal than contracts and do not include quantity commitments.

even more had we been able to procure larger quantities. Mass General Brigham determined in February 2020 that our typical domestic suppliers were no longer able to fulfill our PPE needs due to heightened demand for, and limited supply of, such products. My job is to make sure that the workers and patients I serve have the protective supplies they need to stay safe. My team and I spent hours every day for the next two months trying to identify additional reputable PPE suppliers, and I personally spoke with and met with dozens of companies to fulfill our needs. At one point in March 2020, certain Mass General Brigham facilities were down to as little as one week's worth of supply of critical PPE items. These purchasing conditions were, without a doubt, the most challenging I have faced in my career.

38. Procurement of N95 masks was the most challenging out of all PPE items at this time.⁹⁰ Despite Mass General Brigham having an existing supply contract for N95 masks with 3M Company, Mass General Brigham was put "on allocation" with this supplier. This meant that Mass General Brigham would only be provided a portion of its needs because 3M Company did not have enough product to meet all of its existing contractual commitments because: (i) demand for N95 masks had increased dramatically from all of its customers, and (ii) the U.S. federal government was claiming large quantities of 3M Company's production through its use of the Defense Production Act (see Section VII.A.3 for additional discussion). At least one other manufacturer (Halyard Health) told me that it was limited in its ability to sell to the public due to federal government orders. Nonetheless, our prior purchasing history and existing contractual relationship with 3M Company assisted in Mass General Brigham being able to procure between 75,000 and 100,000 N95 masks per month from the company, or only about half of what we would have expected given our prior supply contract, at a time when our demand had increased at least four-fold.

39. Mass General Brigham supplemented its purchases from 3M Company with purchases from other domestic suppliers. We were able to secure an order of 80,000 N95 masks per month for nearly five months from Louis M. Gerson Co. and between 12,000 and 15,000 N95 masks per month from Halyard Health. We had prior purchasing relationships with both of these companies. We attempted to purchase from Honeywell, including making a 10 percent deposit on an order of 750,000 N95 masks. However, after three months of waiting, we eventually cancelled

⁹⁰ Procurement of isolation gowns was equally challenging at this time.

our order without receiving any product. We also made multiple unsuccessful attempts to buy from third-party suppliers who claimed to have 3M-brand N95 masks. We made wire transfers to three different domestic suppliers, two of which we had previously purchased from, but none of them were able to deliver on the orders and we eventually requested refunds.

40. Mass General Brigham initially aimed to procure as many as 3 million N95 masks. However, we were unable to procure that amount between March and April 2020. Further, none of the above-mentioned suppliers was able to individually fulfill Mass General Brigham's N95 mask needs, although we were ultimately able to piece together adequate supply of N95 masks by purchasing various quantities from multiple suppliers. That said, Mass General Brigham wanted to purchase only medical-grade N95 masks in order to provide the highest level of protection to our workers and patients.⁹¹ Because we could not identify additional reputable suppliers who could fulfill such needs, we were forced to instead order mostly industrial-grade N95 masks as a temporary substitute. We also risked running out of critical PPE supplies, and had no viable alternative but to at times pay dramatically higher prices as dictated by sellers. By March and April 2020, Mass General Brigham was at times paying between \$2 and \$5 per N95 mask.⁹²

2. Mass General Brigham's Efforts to Procure from International Suppliers

41. As part of our N95 mask procurement efforts, I also worked with sourcing agents that had relationships with foreign manufacturers and suppliers, including those in China. During this time, I received dozens of emails each week from newly formed companies who claimed to be able to source NIOSH-approved N95 masks from abroad. Although we identified potential Chinese suppliers, we learned that some may not have been trustworthy (this too was an issue with certain domestic companies). Also, there were companies that were increasing the price of PPE

⁹¹ Medical-grade N95 masks (also referred to as "surgical respirators") are those that, in addition to meeting NIOSH's standards for filtration efficiency, also meet the American Society of Testing and Materials' ("ASTM") standards for filtration efficiency, fluid resistance, and breathability (*i.e.*, differential pressure), as determined by the Food and Drug Administration ("FDA") based on the FDA's review of the manufacturer's testing data. Non-medical-grade N95 masks are commonly referred to as industrial-grade N95 masks. "Surgical N95 vs. Standard N95 - Which to Consider?," 3M Company; Rengasamy, Samy, *et al.*, "Filtration Performance of FDA-Cleared Surgical Masks," *Journal of the International Society for Respiratory Protection*, Vol. 26(3) (2009): 54-70; "Personal Protective Equipment: Questions and Answers," Centers for Disease Control and Prevention, available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>.

⁹² Some manufacturers continued to honor prices that were contracted with Mass General Brigham from prior to the COVID-19 pandemic, while others increased their prices more than 100 percent.

products by over 1,000 percent, others that would guarantee delivery even though there were Chinese export and travel restrictions in place at the time, as well as some that falsely claimed their warehouses were full of product waiting to be shipped. None of the foreign suppliers I dealt with were willing to provide product samples or other information that would allow us to authenticate the products' quality.

42. In one instance, Mass General Brigham received samples of one type of a supposed N95 mask that was procured from a Chinese supplier. We sent the product for laboratory testing, which determined that the sample did not meet the specifications required for that type of N95 mask. In fact, these samples came in a box that had a Makrite-brand label on the outside (which is one of the manufacturers that produces one of the products listed on Blue Flame's invoice to California), but upon inspection and testing, the product inside was not a Makrite-brand N95 mask. In another instance, Mass General Brigham sent a wire transfer in April 2020 for \$6 million to a Chinese supplier to purchase approximately 1 million N95 masks, but after two months we had not received any masks, we were continuously provided excuses for why they had not arrived, and therefore, we eventually cancelled the transaction.

43. Mass General Brigham's experience with international suppliers was consistent with what other U.S. buyers experienced at this time. Difficulties in verifying suppliers' claims regarding available inventory and product authenticity resulted in many buyers being victims of N95 mask scams. I am aware of cases where my healthcare industry peers lost deposits to Chinese suppliers who claimed they could deliver N95 masks, and other cases where a delivery of supposed 3M-brand N95 masks was made, but the delivered boxes were empty.

44. Such cases have prompted U.S. federal law enforcement agencies, regulatory bodies, and N95 manufacturers to issue public warnings related to fraudulent activity and the sale of counterfeit N95 masks throughout the first half of 2020. Exhibit 1 provides a selection of these warnings. For example, the Financial Crimes Enforcement Network stated on March 16, 2020 that it has been "monitoring public reports and [Bank Secrecy Act] reports of potential illicit behavior connected to COVID-19" including "emerging trends" related to product scams and "fraudulent marketing of COVID-19-related supplies, such as certain facemasks," and the Federal Bureau of Investigation ("FBI") warned on March 27, 2020 of "increased potential for fraudulent activity dealing with the purchase of COVID-19-related medical equipment" and urged buyers to "exercise due diligence and appropriate caution when dealing with any vendors with whom they have never

worked ... and when relying on unidentified third-party brokers in the supply chain.”⁹³ These experiences and warnings demonstrate the product, timing, and deposit risks associated with PPE procurement at this time, and in particular with sourcing from international suppliers (see Section VII.D.1 for further discussion of these risks).

VII. BLUE FLAME COULD NOT HAVE FULFILLED CALIFORNIA’S ORDER OF 100 MILLION N95 MASKS, OR PROVIDED ANY SIGNIFICANT QUANTITY OF N95 MASKS WITHIN 60 DAYS, LET ALONE WITHIN 30 DAYS

45. Based on my personal experience and knowledge of the PPE procurement process and N95 market, and the materials I have reviewed in this case, Blue Flame could not have fulfilled California’s order within 60 days, much less within the 30 days pledged by Blue Flame. Even with decades of experience in this market, with long-established supplier purchasing relationships and a team of more than 50 dedicated procurement professionals, I could not have obtained 100 million N95 masks within 60 days in the spring of 2020. I am neither aware of any such verified quantity in inventory at the time nor any other entity throughout my professional network who could have procured such quantity at the time. Nor was it possible for Blue Flame to procure 63 million N95 masks within a 30-day period, which Michael Wong, the State of California’s contract administrator who worked with Blue Flame on this transaction, understood Blue Flame to have guaranteed.⁹⁴

46. As I discuss below, there was not sufficient supply available from any source to fulfill California’s order for 100 million (or 63 million) N95 masks. Access to international production was restricted and the manufacturers associated with the N95 mask models California ordered did not have sufficient production capacities. Domestic production was also limited. Blue Flame’s two asserted supply partners provided no evidence that they could source 100 million N95 masks within 60 days, as shown in Blue Flame’s contemporaneous communications with those

⁹³ “The Financial Crimes Enforcement Network (FinCEN) Encourages Financial Institutions to Communicate Concerns Related to the Coronavirus Disease 2019 (COVID-19) and to Remain Alert to Related Illicit Financial Activity,” Financial Crimes Enforcement Network, March 16, 2020, available at: <https://www.fincen.gov/news-releases/financial-crimes-enforcement-network-fincen-encourages-financial-institutions>; “FBI Warns Health Care Professionals of Increased Potential for Fraudulent Sales of COVID-19-Related Medical Equipment,” Federal Bureau of Investigation, March 27, 2020, available at: <https://www.fbi.gov/news/pressrel/press-releases/fbi-warns-health-care-professionals-of-increased-potential-for-fraudulent-sales-of-covid-19-related-medical-equipment>.

⁹⁴ Deposition of Michael Wong, January 19, 2021, at pp. 71-72.

supply partners and by Blue Flame's inability to fulfill other orders for N95 masks during the same time period. Furthermore, although Blue Flame claims that it could have fulfilled California's order,⁹⁵ this claim is not credible in light of Blue Flame's lack of experience and sophistication in the PPE procurement industry and its repeated departures from industry standard practice regarding California's order.

A. There Was Insufficient Supply of N95 Masks to Fulfill California's Order

1. Blue Flame's Agreement to Supply California With 100 Million N95 Masks Would Have Required Blue Flame To Secure More N95 Masks Than Were Available From China

47. As discussed in Section IV.B, the invoice Blue Flame issued California specified four models of N95 masks produced by manufacturers who produce in China, including two produced by Shanghai Dasheng, one by Guangzhou Harley, and one produced by Makrite. Blue Flame could not have procured 100 million (or 63 million) N95 masks produced by these manufacturers within 60 days in the spring of 2020, much less within the 30 days pledged by Blue Flame.

48. Indeed, China *as a whole*, which is the U.S.'s primary source of imported N95 and other protective masks,⁹⁶ exported only approximately 74 million N95 masks to the United States in the 46 days between March 1 and April 15, 2020 — a daily average of approximately 1.6 million.⁹⁷ As discussed in Section VI.B.2, the limited exports of N95 masks resulted from government policies that substantially disrupted the market for N95 masks, significantly reduced the quantity of product that was available for export, and led to delays in N95 mask shipments. This included approximately 65 countries (including China) issuing bans or restrictions on the

⁹⁵ See, e.g., Deposition of John Thomas, January 11, 2021, at pp. 176-178.

⁹⁶ Bown, Chad P., "COVID-19: Trump's curbs on exports of medical gear put Americans and others at risk," Peterson Institute for International Economics, April 9, 2020, available at: <https://www.piie.com/blogs/trade-and-investment-policy-watch/covid-19-trumps-curbs-exports-medical-gear-put-americans-and>.

⁹⁷ Brunnstrom, David "U.S. appeals to China to revise export rules on coronavirus medical gear," Reuters, April 16, 2020, available at: <https://www.reuters.com/article/us-health-coronavirus-usa-china/u-s-appeals-to-china-to-revise-export-rules-on-coronavirus-medical-gear-idUSKBN21Z07G>.

export of protective masks and other PPE items between March and April 2020,⁹⁸ as well as the Chinese government claiming manufacturers' N95 mask production.⁹⁹

49. Blue Flame has admitted to facing these obstacles in its attempt to fulfill California's order with international production. For example, John Thomas testified that "the Chinese government ended up stealing [Blue Flame's] inventory after it came off the line."¹⁰⁰ Blue Flame told the United States Congress in June 2020 that "impediments to deliveries" included Chinese authorities disrupting "shipping schedules by seizing products and imposing new export restrictions and inspection requirements," including the seizure from Great Health of "more than 1.6 million N95 masks awaiting delivery to the United States."¹⁰¹ Mike Gula also stated that he had "been lied to up and down in China on when we were getting everything and product that was supposed to have shipped and wasn't."¹⁰² These statements are consistent with the difficulties many buyers experienced at the time, including my experience attempting to procure N95 masks from international suppliers (as discussed in Section VI.C.2 above).

50. To fulfill California's order for 100 million N95 masks within the 30-day schedule pledged by Blue Flame, Blue Flame would have been required to supply an average of approximately 3.3 million N95 masks per day. That daily figure (3.3 million) is more than twice the daily average amount of all N95 masks that were actually exported from China to the United States during this period (1.6 million).¹⁰³ Based on my experience seeking to procure N95 masks

⁹⁸ "COVID-19 Temporary Trade Measures," International Trade Centre Market Access Map, updated January 29, 2021, available at: <https://www.macmap.org/covid19>.

⁹⁹ Bradsher, Keith, and Liz Alderman, March 13, 2020.

¹⁰⁰ Deposition of John Thomas, January 11, 2021, at pp. 258-259. Mike Gula also wrote in May 2020 that Blue Flame's "masks and PPE were seized in China." Text from Mike Gula to Michael Jensen (Velox Medical), May 1, 2020, VLX-007876 - 907 at 903; Deposition of Mike Gula, January 12, 2021, at pp. 87-88.

¹⁰¹ Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at pp. 1-2.

¹⁰² Text from Mike Gula to Michael Jensen, May 1, 2020, VLX-007876 - 907 at 903.

¹⁰³ It is reasonable to compare Blue Flame's required average daily supply need to the March 1 and April 15, 2020 figure regarding China's N95 mask exports to the U.S. since that 46 day period overlaps with 21 days out of Blue Flame's pledged 30-day schedule (*i.e.*, March 26 through April 24, 2020) and even as late as April 29, 2020 Great Health believed that the Chinese government's actions had made "it extremely difficult, if not impossible, [] to fulfill [Blue Flame's] [o]rder without causing undue delay." Letter from Great Health to Blue Flame, April 29, 2020, BFM000076873 - 874 at 873. Moreover, even if Blue Flame was only expected to supply 63 million N95 masks within 30 days (rather than 100 million units), that too would have been virtually impossible since that would have required Blue Flame to supply N95 masks at a daily average rate of 2.1 million units, which also would have exceeded the daily rate of all U.S. N95 mask imports from China at this time.

during this period, it was virtually impossible that Blue Flame (or any other private purchaser of PPE) could have procured anything approaching this quantity of N95 masks. As discussed above in Section VI.B, demand for N95 masks outpaced supply by a wide margin during this period. The inability of other purchasers to acquire their desired quantities of N95 masks from China during the spring of 2020, including Mass General Brigham and other major PPE distributors (*e.g.*, McKesson Corporation, Cardinal Health, Owens & Minor, and Medline Industries), provides further evidence that there were not sufficient Chinese N95 mask exports at this time to fulfill California's order.

51. In addition, Blue Flame faced competition for any available N95 mask exports from all other buyers in the United States and elsewhere. The available N95 masks that were being exported from China were sought after by governments, healthcare organizations, and countless other entities across the globe. This competition to procure product, combined with limited supply, led to suppliers demanding exorbitant prices for N95 masks.¹⁰⁴ Buyers that did not have pre-existing contracts with suppliers from prior to the COVID-19 pandemic (and even those that did but whose contracts were no longer being honored) were paying between \$4 and \$9 per N95 mask. However, California agreed to pay Blue Flame only \$4.76 per N95 mask (or \$5.71 per mask including shipping), which was at the low end of the market price range at the time. Mark Ghilarducci, Director of the California Governor's Office of Emergency Services, testified that this \$4.76 price was "was one of the lowest [California] had seen to date compared to purchases that had [previously] been made at \$8.50 and \$5.50 and \$5.00."¹⁰⁵ Thus, even if there had been international N95 mask production available that Blue Flame or its supply partners could potentially have procured, in my experience, manufacturers and suppliers would not have sold this product to Blue Flame or its supply partners for a price that was significantly below what many other prospective buyers were willing to pay at the time.

52. Moreover, even if Blue Flame or its supply partners somehow were able to procure this product, each shipment would have taken weeks (if not longer), to be delivered to California.

¹⁰⁴ See, *e.g.*, Healy, Beth and Christine Willmsen, "I Have A Guy In China": Inside The Pandemic Market For Medical Masks," New England Public Media, June 11, 2020, available at: <https://www.nepm.org/post/i-have-guy-china-inside-pandemic-market-medical-masks#stream/0>.

¹⁰⁵ Audio Recording of the Hearing of the Assembly Accountability and Administrative Review Committee, California State Assembly Media Archives, May 11, 2020, available at: <https://www.assembly.ca.gov/media/assembly-accountability-administrative-review-committee-20200511/audio>, at 01:02:34 - 01:02:50.

One medical equipment supplier said in mid-April 2020 that “[o]rders that would normally take two or three days to leave China are now taking an extra 10 to 15 days,” and even “fast-tracking a ship to Los Angeles from China takes at least 18 to 20 days.”¹⁰⁶ Mike Gula also told a prospective customer on April 14, 2020 that “if you are talking with someone who says they can get something out of [C]hina in under 13 days run away.”¹⁰⁷ All other procurement challenges notwithstanding, the time needed to export and ship product from China alone significantly reduced the likelihood that Blue Flame could have fulfilled California’s order in 30 or 60 days.

2. The Manufacturers of N95 Mask Models California Ordered Did Not Have Sufficient Production Capacities or Inventories to Fulfill California’s Order

53. My conclusion that Blue Flame could not have fulfilled California’s order for 100 million (or 63 million) N95 masks within 30 or 60 days is reinforced by considering the available production capacities of the particular manufacturers of the N95 models that Blue Flame agreed to supply. One of these manufacturers, Shanghai Dasheng, produced N95 masks at a rate of approximately 2.4 million per month in early-February 2020, and by mid-May 2020 its production had risen to a rate of only approximately 15 million per month.¹⁰⁸ Even if Blue Flame could have procured 100 percent of Shanghai Dasheng’s N95 mask production, which is implausible for the reasons discussed above in Section VII.A.1 (*e.g.*, Chinese export restrictions, competition from other buyers), Blue Flame would have needed to procure Shanghai Dasheng’s production over the course of several months, if not longer, to fulfill California’s order.¹⁰⁹ Further, according to the CDC, Shanghai Dasheng produces approximately 30 different models of N95 masks,¹¹⁰ and thus

¹⁰⁶ Sandler, Rachel, April 17, 2020.

¹⁰⁷ Email from Mike Gula to Zach Hargett (South Carolina Biotechnology Industry Organization), April 14, 2020, BFM000045714 - 721 at 714.

¹⁰⁸ Hongpei, Zhang, “Mask production full speed ahead,” *Global Times*, February 3, 2020, available at: <https://www.globaltimes.cn/content/1178390.shtml>; “Chinese mask producer denies having exported N95 masks with ear loops to US,” *Xinhua*, May 14, 2020, available at: http://www.china.org.cn/business/2020-05/14/content_76042423.htm.

¹⁰⁹ Shanghai Dasheng’s mask exports to the United States accounted for only 5 percent of the company’s exports in mid-2020. See, “Chinese mask producer denies having exported N95 masks with ear loops to US,” *Xinhua*, May 14, 2020, available at: http://www.china.org.cn/business/2020-05/14/content_76042423.htm.

¹¹⁰ “NIOSH-Approved N95 Particulate Filtering Facepiece Respirators: Manufacturers Listed Alphabetically - S,” Centers for Disease Control and Prevention, updated December 30, 2020, available at: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1sect3.html.

the two models of N95 masks listed on California's order invoice make up only a portion of Shanghai Dasheng's monthly production.

54. Makrite, another of the manufacturers associated with California's order, publicly announced in February 2020 that it did not have N95 mask inventory or production capacity available for sale. On February 6, 2020, Makrite issued a notice stating that its facilities "have been fully commissioned by the Chinese Government. We are banned from exporting and doing business domestically. ... [W]e will not be taking additional inquiries or purchase orders until the epidemic is over."¹¹¹ Then on March 22, 2020, Blue Flame received a notice Makrite had issued stating that the "Government of China had made a contract with Makrite to fully fulfill the demand from the local hospitals. Therefore, there is no extra stock available for export. Hereby, we would like to clarify that any claim to export Makrite N95 or CE certified masks at this time is a fraud."¹¹² These notices suggest that there was limited or no available production and inventory of Makrite N95 masks accessible for sale in the spring of 2020. Further, Makrite produces over 50 different models of N95 masks,¹¹³ and thus the one specific model of Makrite N95 mask that was designated on California's order invoice would have comprised only a fraction of whatever production and inventory may have been accessible to buyers. It is not credible that Blue Flame or its supply partners would have been able to rely on Makrite production or inventory to fulfill California's order.

55. Guangzhou Harley, the third manufacturer of the N95 masks designated in California's order, also does not appear to have had sufficient production capacity to fulfill California's order. According to an independent auditing company that conducted an onsite inspection at Guangzhou Harley's manufacturing facility, Guangzhou Harley's production capacity for all face masks (*i.e.*, N95 masks plus all other types of masks) was only 15.1 million

¹¹¹ "Makrite Official Notice," Makrite, February 6, 2020, available at: <http://www.makrite.com/notice/>.

¹¹² Email from Martha Medina to Mike Gula, March 22, 2020, BFM000110675 - 678 at 676. I understand that Great Health nonetheless claimed that it was legally exporting Makrite products based on its status as a state-owned enterprise and existing contracts with Makrite. However, Great Health's claim is undermined by its inability to fulfill any other Makrite-brand N95 mask orders for Blue Flame for which it received payment during April 2020. See, Section VII.B.1 and footnotes 142-143.

¹¹³ "NIOSH-Approved N95 Particulate Filtering Facepiece Respirators: Manufacturers Listed Alphabetically - M," Centers for Disease Control and Prevention, updated December 14, 2020, available at: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1sect2-m.html.

units per month in mid-May 2020.¹¹⁴ Since Guangzhou Harley also produces many other types of face masks besides N95 masks, this figure can be viewed as an upper bound on the company's N95 production capacity at the time. Guangzhou Harley's monthly N95 mask production capacity was likely significantly smaller than this figure since producers can typically manufacture far more non-N95 masks (*e.g.*, surgical masks) than they can N95 masks.¹¹⁵ Blue Flame would thus have needed to procure *all* of Guangzhou Harley's production over the course of several months, if not longer, to fulfill California's order. It is implausible that Blue Flame could have done so.

3. Domestic Production Had Supply Constraints and Access Was Limited By Pre-Existing Supply Contracts and Claims By the U.S. Government

56. As noted above, California's order required that Blue Flame supply 100 million N95 masks, consisting of four specified models from manufacturers that all produced in China. Even assuming that California would have accepted N95 mask models other than the four models specified on Blue Flame's invoice to California, U.S. production was too small to fulfill California's order within 60 days. It was not possible for one private buyer (such as Blue Flame or any other supplier with whom it may have partnered) to procure 100 million (or even 63 million) N95 masks from U.S. manufacturers in the spring of 2020. As I discuss in Section VI.B.1, monthly U.S. production of N95 masks was only 50 million in March 2020. Blue Flame would therefore have needed to procure nearly *every* unit of *every* U.S.-made N95 mask over a two month period to fulfill California's order of 100 million N95 masks (assuming fulfillment could be achieved with models beyond the four specified by California).¹¹⁶ Procuring every U.S.-made N95 mask at this time would have been virtually impossible for several reasons.

57. First, Blue Flame faced intense competition from hospitals, healthcare organizations, state and local governments and governmental entities, nursing homes, and other PPE suppliers, among others. Many of these buyers had pre-existing contracts with manufacturers,

¹¹⁴ TÜV Rheinland, a third-party verification agency, conducted an onsite inspection of Guangzhou Harley's manufacturing facility on May 18, 2020 to verify production capacity figures (among other aspects of the company's facility). Supplier Assessment Report: Guangzhou Harley Commodity Company, Ltd., TÜV Rheinland, May 18, 2020, available at: https://harleymask.en.alibaba.com/company_profile/capability_assessment.html#preview-report-1, at pp. 2, 9-10.

¹¹⁵ See, *e.g.*, Bradsher, Keith, and Liz Alderman, March 13, 2020. U.S. imports of non-N95 masks were also significantly larger than N95 mask imports in 2020. USITC, December 2020, at p. 95.

¹¹⁶ Alternatively, to supply California with 63 million N95 masks from U.S. production, it would have required that Blue Flame procure every U.S.-made N95 mask for approximately five weeks. This too was virtually impossible for the reasons I outline in this section.

including Mass General Brigham, which would have given them priority over Blue Flame. By April 2020, Mass General Brigham was unable to procure more than 200,000 N95 masks per month, and this was even with its team of over 50 procurement professionals working under my direction, including having pre-existing contracts and buying relationships with several domestic manufacturers.

58. Second, Blue Flame did not have pre-existing purchasing relationships with U.S. manufacturers, which were critically important for being able to procure PPE items at a time when demand was outpacing available supply (as I discuss in Section VII.D below).

59. Third, the United States federal government was claiming domestic manufacturers' production. In particular, the federal government invoked the Defense Production Act in March 2020, which allowed it to "place priority ratings on medical supply contracts so that [federal] agencies' orders would get preference over others."¹¹⁷ Between March 26 and April 28, 2020, five U.S. manufacturers were awarded nine different "Priority Rated" contracts for N95 masks totaling \$561.5 million.¹¹⁸ These contracts meant that a sizeable portion of U.S. manufacturers' production was not available for sale to private companies such as Blue Flame. In fact, according to the U.S. Government Accountability Office, "[a]s of September 1, 2020, the federal response had provided approximately 92.4 million N95 respirators ... to state, tribal, and territorial entities."¹¹⁹ Thus over a period of at least six months, federal agencies (including the Department of Health and Human Services, the Department of Defense, and the Federal Emergency Management Agency) delivered fewer N95 masks combined than Blue Flame claimed it could deliver within 30 days.

60. I understand that Blue Flame also knew in March 2020 that there was an insufficient supply of N95 masks within the U.S. to fulfill California's order. Mike Gula wrote on March 23, 2020 that "if [A]merica had more than 5,000 [N]95 masks in country the president wouldn't be bragging about handing out 5,000 yesterday. [H]e would be bragging (rightfully so) [about]

¹¹⁷ "Defense Production Act," United States Government Accountability Office, GAO-21-108, November 2020, available at: <https://www.gao.gov/assets/720/710806.pdf>, at p. 1.

¹¹⁸ These manufacturers included 3M Company, Draeger Inc., Halyard Health, Honeywell, and Moldex-Metric Inc. "Defense Production Act," United States Government Accountability Office, GAO-21-108, November 2020, available at: <https://www.gao.gov/assets/720/710806.pdf>, at p. 33.

¹¹⁹ "Federal Efforts Could Be Strengthened by Timely and Concerted Actions," United States Government Accountability Office, GAO-20-701, September 2020, available at: <https://www.gao.gov/assets/710/709934.pdf>, at pp. 191-192.

500,000 if we had those,”¹²⁰ on March 24, 2020 that “[A]merica does not have the supplies on shore,”¹²¹ and on March 25, 2020, he told a prospective customer that “[t]he FASTEST I can get you 2 million N95 masks is 8-9 days. [A]nyone who says sooner is lying to you. There are NO masks in country. [P]eriod.”¹²² In a discussion that was forwarded to John Thomas on March 22, 2020, Velox Medical wrote: “There is no on-hand supply left in the USA. There are no 3M [N95] masks anywhere.”¹²³

61. Barriers to quickly increasing domestic production capacity of N95 masks also limited Blue Flame’s ability to source product domestically. As discussed in Section V.B, in the spring of 2020 there was limited supply of raw materials, the raw materials that were available had become expensive, there remained significant risks to investing in new capacity given that N95 mask production has historically been a low-margin business, and there were time and monetary costs associated with applying for NIOSH approval that delayed any new manufacturer from immediately being able to commercialize N95 masks. For these reasons, it would have been virtually impossible for Blue Flame to rely on domestic production as the source for procuring 100 million N95 masks in March and April 2020, let alone 63 million.

B. Blue Flame’s Supply Partners Were Unable to Provide Blue Flame 100 Million N95 Masks

62. Even though there was limited supply of N95 masks in the spring of 2020, I understand that Blue Flame attempted to leverage the asserted relationships that its supply partners, Great Health and Suuchi, had with manufacturers in order to fulfill California’s order. In particular, Blue Flame has stated that it “would have been able to fulfill the State of California’s order for 100 million N95 masks ... because it had reached agreements with Great Health Companion and Suuchi, Inc. to supply the entirety of California’s order for 100 million N95 masks at the time Blue

¹²⁰ Email from Mike Gula to Genevieve Hillis (Direct Supply), March 23, 2020, BFM000011436 - 445 at 436.

¹²¹ Email from Mike Gula to Chad Jones (Velox Medical), March 24, 2020, BFM000012004 - 005 at 004.

¹²² Email from Mike Gula to Caroline Delleney (Mercury LLC), March 25, 2020, BFM000012837 - 838 at 837.

¹²³ Email from Kate Arnold (Velox Medical) to Brian Merrick (State of Massachusetts), March 22, 2020, BFM000066087 - 088 at 087 - 088 (emphasis in original). Velox Medical had a referral fee agreement with Blue Flame Strategies (Blue Flame’s Affiliate). Referral Fee Agreement between Velox Medical, Inc. and Blue Flame Strategies LLC, dated March 13, 2020, BFM000000675 - 681.

Flame Medical contracted with the State of California on March 25, 2020.”¹²⁴ That statement is implausible because, as discussed in Section VII.A above, it would have been virtually impossible for any entity to procure the quantities of N95 masks necessary to fulfill California’s order. Moreover, I have seen no evidence that these suppliers were able to leverage any relationships with manufacturers to secure sufficient quantities of NIOSH-approved N95 masks within Blue Flame’s pledged 30-day delivery time frame, or even within a longer 60-day time frame.¹²⁵

1. Great Health

63. Blue Flame considered Great Health to be its “primary supplier.”¹²⁶ I have seen no evidence that Great Health was able to leverage any relationships with manufacturers to secure sufficient quantities of N95 masks. Instead, Great Health struggled to secure shipments, faced competition from other buyers, and did not appear to be a high priority customer in March and April 2020. This is consistent with my own experience in procuring PPE items from manufacturers with whom Mass General Brigham did not have pre-existing supply contracts or pricing agreements.

64. Great Health informed Blue Flame on several occasions that it could not procure 100 million (or 63 million) N95 masks in 30 days.¹²⁷ For example, on March 19, 2020, Henry Huang of Great Health told John Thomas and Mike Gula that he was “working on securing 50 [million]-100 [million] N95/[KN]95s masks [multiple] brands over [a] 3-4 month period for you guys.”¹²⁸ On March 24, 2020, Henry Huang told Mike Gula that he could not confirm his ability

¹²⁴ Plaintiff’s Responses to Defendants’ First Set of Interrogatories to Blue Flame Medical LLC, October 13, 2020, at p. 25.

¹²⁵ Blue Flame also claims to have spoken with a few other potential PPE suppliers and manufacturers, including Jason Lee of First Alta, Joseph Choi of Two Point Zero, Glymate Corp., and NeVap Inc. However, Blue Flame could not identify any U.S.-based manufacturers with whom it had written supply agreements and admits that it never purchased significant quantities of N95 masks from any international manufacturer. I have not seen any evidence that these entities could supply Blue Flame with sufficient quantities of N95 masks in the amount of time needed to fulfill California’s order. Emails between John Thomas and Jason Lee, March 19, 2020, BFM000008866 - 868; Deposition of John Thomas, January 11, 2021, at pp. 52, 109-110, 122-123, 144, 161-162; Email from John Thomas to Mike Gula and Jennilee Brown, March 10, 2020, BFM000004058 - 060 at 058 - 059; Deposition of Ethan Bearman, January 21, 2021, at pp. 132-133.

¹²⁶ Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at p. 2.

¹²⁷ Even Great Health’s March 26, 2020 order confirmation to Blue Flame specified that Great Health would only fulfill the order “within 40 days from the time payment is received and cleared.” Order Confirmation from Great Health to Blue Flame, March 26, 2020, BFM000013610 - 611.

¹²⁸ Email from Henry Huang to Michael Jensen *et al.*, March 19, 2020, BFM000008038 - 039 at 038.

to fulfill orders without a deposit payment, and that if Great Health were unable “to get a spot” with N95 manufacturers, “[p]lan b is we just have to scavage [sic] for what we can as we go. ... But no where near the volumes of [N]95s we talked about. ... [A f]ew million per month a[t] best from diff[erent] brands collectively.”¹²⁹ These statements make clear that any estimate of Great Health’s capacity to supply N95 masks prior to it actually having possession of those N95 masks was inherently unreliable.

65. Later in the day on March 24, 2020, Henry Huang said, “[o]ur manufactuers [sic] for [N]95s [are] waiting for the order for the gov[ernment] to allocate all to [E]urope first in the coming days. Only preexisting contracts will be fulfilled,” and when asked if Great Health could secure supplies if an order came within 12 hours, Henry Huang responded “it[’]s [R]ussian roulette [sic] now.”¹³⁰ On the same day, Blue Flame told California that Great Health could deliver 27-32 million units “within 30 days.”¹³¹ Then, on April 7, 2020, Henry Huang told Mike Gula:¹³²

There are only a set of number of [N]95 masks throughout the country being produced every day, most of which are existing long term contracts dating back to February. [U]nderstanding that there is infinite demand but limited supply, we must balance the customers[’] expectations and allotments wisely. ... [O]rders for 10-50 [million] [N]95 [masks] would be impossible to fulfill given the number of people that all want it. I do not wish for [B]lue [F]lame to commit to something it will have a hard time delivering on.

66. These statements make clear that Great Health was unable to fulfill California’s order.¹³³ At the same time, they are inconsistent with John Thomas’ testimony that “Great Health Companion can procure essentially as much PPE as they want,”¹³⁴ as well as Blue Flame’s representation to California on March 25, 2020 that Great Health was going to supply “the full order from [its] shop alone.”¹³⁵ Instead, Great Health’s admissions regarding its difficulties in

¹²⁹ Texts between Mike Gula and Henry Huang, March 24, 2020, BFM000011979 - 982 at 979.

¹³⁰ Texts between Mike Gula and Henry Huang, March 24, 2020, BFM000011979 - 982 at 981.

¹³¹ This included 2 million units that would be arrive “on day 7” and 25-30 million units delivered “within 30 days.” Emails between John Thomas and Michael Wong, March 24, 2020, CAL-DGS-00000195 - 263 at 222 - 223.

¹³² Email from Henry Huang to Mike Gula, April 7, 2020, BFM000032772 - 773 at 772.

¹³³ Great Health’s statements also make clear that it was unable to supply Blue Flame with 63 million N95 masks within 30 days.

¹³⁴ Deposition of John Thomas, January 11, 2021, at p. 155.

¹³⁵ Texts from John Thomas to Daniel Kim and Michael Wong, March 25, 2020, BFM000129957 - 960 at 959.

sourcing N95 masks from manufacturers indicate that Great Health did not have sufficient inventory on hand or the necessary agreements or buying relationships with N95 mask manufacturers to fulfill California's order. Great Health's concerns and difficulties securing inventory were consistent with my own experience procuring PPE from international sources at this time. Even Blue Flame later stated that it "recogniz[ed] that Great Health would not have the capacity to fulfill California's mask order on its own,"¹³⁶ and discussed on March 25, 2020 how Great Health's "latest numbers broken down by model number for what Calif[ornia] needs ... are still short."¹³⁷ On March 26, the day of California's wire transfer, Ethan Bearman, Blue Flame's Chief Legal Officer, even stated that he was "very concerned from Henry [Huang]'s [purchase order] that he doesn't have access to the masks we need."¹³⁸

67. Great Health's internal documents also demonstrate that it did not have the capacity to fulfill California's order within Blue Flame's pledged 30-day delivery time frame, or even within a longer 60-day time frame. Around March 25, 2020, Great Health distributed a "Products Catalogue" listing PPE and other medical items (*e.g.*, masks, gloves, disinfectant, COVID-19 test kits, *etc.*) to which Great Health allegedly had access.¹³⁹ Mike Gula even referred to this catalogue as "a spreadsheet of what our manufacturer can produce."¹⁴⁰ The catalogue listed an "[a]llocatable [i]nventory" of 720,000 N95 masks and a "[m]onthly [c]apacity" of just 11.5 million units for all brands, but an "[a]llocatable [i]nventory" of only 470,000 N95 masks and a "[m]onthly [c]apacity" of only 3.5 million units associated with Shanghai Dasheng, Guangzhou Harley, and Makrite (*i.e.*, the manufacturers associated with the N95 mask models listed on California's order invoice).¹⁴¹ Had I received such a catalogue, I would have expected the monthly capacity figures to represent

¹³⁶ Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at pp. 3-4.

¹³⁷ Email from John Thomas to Mike Gula, March 25, 2020, BFM000012804 - 805 at 804.

¹³⁸ Signal message from Ethan Bearman to Mike Gula and John Thomas, March 25, 2020, BFM000202805 - 869 at 859; Deposition of Ethan Bearman, January 21, 2021, at pp. 41-42.

¹³⁹ Great Health Products Catalogue, BFM000012839; Email from Mike Gula to Caroline Delleney, March 25, 2020, BFM000012837 - 838 at 837.

¹⁴⁰ Email from Mike Gula to Caroline Delleney, March 25, 2020, BFM000012837 - 838 at 837. John Thomas nonetheless testified that the catalogue "was more of a guide for what brands of masks and product types Great Health Companion could procure at that moment" than an indication of precise capacities. Deposition of John Thomas, January 11, 2021, at pp. 155-156. This testimony is inconsistent with Mike Gula's characterization of the catalogue and my experience seeing such catalogues throughout my career.

¹⁴¹ Although Great Health's product catalogue lists N95 masks produced by Shanghai Dasheng, Guangzhou Harley, and Makrite, it does not specify particular models of N95 masks. Great Health Products Catalogue, BFM000012839.

the maximum quantity of N95 masks that Great Health would receive from manufacturers each month, and the allocatable inventory to differ from Great Health's monthly capacity due to preexisting customer orders at the time the catalogue was produced. In other words, allocatable inventory would represent product not already claimed by prior customer orders, and would thus change on a daily basis as new customer orders came in. This catalog appears to have indicated that Great Health could only supply 720,000 N95 masks of any make or model (or 470,000 N95 masks from the three relevant manufacturers) at the time. Particularly when demand is at a high point, as it was in the spring of 2020, PPE suppliers would have no reason to understate their supply capacities. Thus, I understand the monthly capacity figures listed on this catalogue to represent the total amount of N95 masks that Great Health believed it could procure at that time. These figures thus demonstrate that at the time of California's order, Great Health did not believe it had the capability to supply Blue Flame with 100 million N95 masks in less than eight months, let alone in 30 or 60 days (or the capability to supply Blue Flame with 63 million masks in less than five and a half months).

68. My conclusion that Great Health could not have supplied Blue Flame with 100 million (or 63 million) N95 masks to fulfill California's order is also consistent with Great Health's inability to fulfill other orders for N95 masks that Blue Flame placed during the same time period. In particular, Blue Flame paid Great Health approximately \$6.7 million in April 2020 for orders that included more than 1.7 million N95 masks, but Great Health did not provide Blue Flame with any N95 masks in that month.¹⁴² Instead, Great Health issued Blue Flame a refund for these N95 mask orders because of its inability to fulfill such orders at the time, explaining that "the Chinese government has recently implemented a number of regulatory measures designed to restrict export of N95 masks from China" and "the Chinese government has directly intervened in the operations of manufacture and export of N95 masks, making it extremely difficult, if not impossible, for us to fulfill [orders] without causing undue delay."¹⁴³ These statements — together with Great Health's inability to fulfill Blue Flame's N95 mask orders — undermine any suggestion that Great

¹⁴² This payment was made in multiple instalments between April 3 and April 16 for orders primarily of N95 masks, but also included orders of nitrile gloves and face shields (which Great Health did fulfill). Emails between Joy Xu (Great Health), Henry Huang, and Marc Serrio, April 7-9, 2020, BFM000046589 - 593 at 590 - 593; Payment from Blue Flame Medical to Wingar Industrial Inc. on Behalf of Great Health, April 17, 2020, BFM000048393 - 396; Order Confirmation from Great Health to Blue Flame, April 7, 2020, BFM000120324 - 327; Letter from Great Health to Blue Flame, April 29, 2020, BFM000076873 - 874 at 873.

¹⁴³ Letter from Great Health to Blue Flame, April 29, 2020, BFM000076873 - 874 at 873.

Health was exempt from or otherwise could circumvent the disruptions and regulatory restrictions that affected the N95 mask market in the spring of 2020.

2. Suuchi

69. Suuchi's communications with Blue Flame demonstrate that Suuchi claimed to be able to procure only a relatively small portion of the 100 million (or 63 million) N95 masks that Blue Flame had agreed to supply to California. For example, on March 23, 2020, Suuchi informed Blue Flame that the monthly capacity for N95 masks from one of its sources was 6 million units and that it would take "5-15 days for 1st shipment."¹⁴⁴ On March 24, 2020, Suuchi told Blue Flame "We will try our best for 5 [million N95 masks] in 14 days."¹⁴⁵ Then on March 25, 2020, Suuchi and Blue Flame entered into a purchase order for 6 million N95 masks, which listed the same four N95 mask models that were listed on Blue Flame's invoice to California.¹⁴⁶ This is the only order that Blue Flame placed with Suuchi,¹⁴⁷ and I have not seen any additional evidence that Suuchi ever claimed any ability to provide Blue Flame with more than these 6 million N95 masks within 60 days of California's order.

70. Suuchi's attempts to fulfill Blue Flame's order of 6 million N95 masks also did not appear to be focused on procuring the four models of N95 masks listed on California's order invoice. On March 26, 2020, Suuchi informed Blue Flame that it planned to "assign[] to 3 [to] 4 factories, 1.5 [million]-2 [million] units each," and that one of the factories would be Shaoxing Yikui Textile Co., Ltd. ("Shaoxing Yikui Textile").¹⁴⁸ Not only does Shaoxing Yikui Textile not produce any of the four N95 mask models listed on California's order invoice, but it also is not even certified by NIOSH to produce *any* N95 masks.¹⁴⁹ NIOSH's certification process does not allow for one company (such as Shaoxing Yikui Textile) to manufacture an N95 mask produced

¹⁴⁴ Email from Suuchi Ramesh to Ethan Bearman *et al.*, March 23, 2020, BFM000012279 - 285 at 283.

¹⁴⁵ Suuchi indicates that it may be able to procure larger quantities in the future, but does not provide specifics on those future prospects. Texts between Suuchi Ramesh and Ethan Bearman, March 24, 2020, BFM000077942 - 956 at 946.

¹⁴⁶ Purchase Order from Blue Flame to Suuchi, March 25, 2020, BFM000116424 - 425.

¹⁴⁷ Deposition of Ethan Bearman, January 21, 2021, at pp. 260-261.

¹⁴⁸ Email from Suuchi Ramesh to Ethan Bearman *et al.*, March 26, 2020, BFM000116521 - 522 at 521.

¹⁴⁹ "NIOSH-Approved N95 Particulate Filtering Facepiece Respirators: Manufacturers Listed Alphabetically - S," Centers for Disease Control and Prevention, updated December 30, 2020, available at: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1sect3.html.

by another company (such as Shanghai Dasheng, Guangzhou Harley, or Makrite).¹⁵⁰ Further, the day after Blue Flame issued Suuchi a purchase order for N95 masks, Suuchi told Blue Flame regarding the four relevant N95 mask model numbers that “it’s tough for me to give you exact info until my team gets to officially place [purchase orders].”¹⁵¹ These facts cast doubt upon Suuchi’s understanding of the N95 mask supply chain and undermine the possibility that Blue Flame could have relied on Suuchi to fulfill California’s order.

71. Furthermore, Suuchi’s communications with Blue Flame refer to Suuchi having placed “draft” purchase orders with manufacturers in connection with the 6 million N95 masks that Blue Flame ordered from Suuchi.¹⁵² In my opinion, a supplier’s placing of a “draft” purchase order with a manufacturer would offer no assurance that the supplier would in fact receive product from that manufacturer. This is particularly true given the large quantity of N95 masks that Suuchi had agreed to supply to Blue Flame. To the extent that Suuchi only had “draft” purchase orders, it is highly implausible that Suuchi could have secured 6 million N95 masks in light of the market conditions in the spring of 2020.

C. Blue Flame’s Inability To Fulfill Other Orders For N95 Masks Confirms That It Could Not Have Supplied California With Any Significant Quantity of N95 Masks

72. Blue Flame’s acknowledged failure to fulfill other, much smaller, orders for N95 masks that Blue Flame received around the same time as the California order provides additional confirmation that Blue Flame could not have supplied California with any significant quantity of N95 masks within the schedule pledged by Blue Flame. Blue Flame told the United States Congress that, as of June 22, 2020, it had “delivered more than 100,000 N95/KN95 masks ... to customers in the United States.”¹⁵³ That is, during the nearly three months after California’s order, Blue Flame succeeded in delivering only approximately 0.1 percent of the quantity of N95 masks needed to fulfill California’s order. I understand that Blue Flame received N95 mask orders from

¹⁵⁰ Letter from Heinz Ahlers, “Meaning of NIOSH Approval,” Centers for Disease Control and Prevention, United States Department of Health and Human Services, March 17, 2006, available at: <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/pdfs/ltr031706-508.pdf>.

¹⁵¹ Texts between Suuchi Ramesh and Ethan Bearman, March 26, 2020, BFM000077942 - 956 at 952.

¹⁵² Email from Suuchi Ramesh to Mike Gula *et al.*, March 26, 2020, BFM000013830.

¹⁵³ Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at p. 2.

at least 13 other federal, state, or local governments or governmental entities between March 30 and April 9, 2020, yet fulfilled barely any of these customers' orders. A list of these orders is shown in Exhibit 2. For example, the State of Tennessee paid Blue Flame a total of \$2.59 million between April 4 and April 15, 2020 as partial payment for an order of 500,000 N95 masks and 500,000 disposable gowns. However, Blue Flame informed Tennessee that it was unable to fulfill the State's order "because of significant global market shifts in pricing."¹⁵⁴ As another example, the State of Alabama paid Blue Flame a total of \$1.80 million on April 7 and 8, 2020 as partial payment for two orders comprising 700,000 N95 masks (among other PPE items) with an estimated schedule of "12-14 days." However, Blue Flame states that it "was unable to procure the ordered goods at the prices and within the schedule Alabama required."¹⁵⁵ Blue Flame was also unable to fulfill much smaller orders, including orders from the Marion County Sheriff's Office for only 400 N95 masks and from the Oklahoma State Bureau of Investigation for 400 N95 masks and 1,000 surgical masks, despite receiving payments from both customers upfront.¹⁵⁶ Notably, Blue Flame received at least a partial payment from all 13 of these customers, yet it was still unable to fulfill their orders in the spring or summer of 2020.¹⁵⁷

73. The 13 orders listed in Exhibit 2 combined were for 2.82 million N95 masks, or only 2.82 percent of the 100 million N95 masks California had ordered. In my experience, if Blue Flame was unable to procure 2.82 million N95 masks between March 30 (the first order date among the 13 orders listed in Exhibit 2) and May 15, 2020 (the last date on which Blue Flame refunded these customers' orders), it is implausible that it would have been able to procure 100 million (or 63 million) N95 masks to fulfill California's order during the approximate same time period. Indeed, Blue Flame's inability to supply more than 100,000 N95 or KN95 masks during this period suggests that Blue Flame had no ability to procure *any* significant quantities of N95 masks to fulfill California's order, let alone any quantity that would come close to the enormous quantity that California had ordered.

¹⁵⁴ Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at p. 5.

¹⁵⁵ Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at p. 5.

¹⁵⁶ Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at p. 7.

¹⁵⁷ Blue Flame eventually agreed to supply Maryland with N95 masks in late-2020 after settling a dispute related to its order. Settlement Agreement between Blue Flame Medical, LLC and the Maryland Department of General Services, in connection with the Maryland Department of General Services Purchase Order #HOOP0601445, October 9, 2020.

74. Blue Flame has stated that its “inability to fill other N95 mask orders in April and May 2020 involved different circumstances” from those involving California’s order because “many of those [other] orders involved quantities of N95 masks and other PPE that were too small to secure inventory from PPE suppliers given the intense competition within the marketplace.”¹⁵⁸ In my experience, however, Blue Flame’s claim is inconsistent with the reality of the N95 mask market in the spring of 2020. Given that manufacturers and suppliers were struggling to service existing orders and pre-existing contracts, all else equal (*e.g.*, purchase price and order date), it is my opinion that it would have been *more likely* for Blue Flame to be able to fulfill smaller orders than a large order such as California’s. This is because (i) manufacturers would not want to turn away long-time customers in favor of entirely new customers, (ii) with small orders, manufacturers could simultaneously serve multiple customers relatively quickly, and (iii) very large orders would require additional logistics planning over multiple days’ operations. Additionally, higher-priced orders would also be given priority since manufacturers could earn greater profits relative to lower-priced orders. During my regular conversations with PPE distributors, I was specifically told by multiple distributors that import N95 masks that, following the outbreak of the COVID-19 pandemic, manufacturers began prioritizing orders with higher prices and smaller quantities. Some of the 13 orders listed in Exhibit 2 appear to be for purchase prices higher than what California agreed to pay (*e.g.*, the Marion County Sheriff’s Office paid \$7.21 per N95 mask¹⁵⁹), in which case these orders would have been more likely to be fulfilled by Blue Flame. Thus, Blue Flame’s inability to fulfill its other orders for N95 masks confirms that it would not have been able to fulfill California’s order either.

D. Blue Flame Was An Inexperienced and Unsophisticated Participant In The PPE Market That Failed to Comply With Standard Industry Practice

75. I understand that, notwithstanding all of the obstacles discussed above that made it virtually impossible for Blue Flame to fulfill California’s order of 100 million N95 masks, Blue Flame has nonetheless expressed confidence that it would have been able to fulfill the order. For

¹⁵⁸ Plaintiff’s Responses to Defendants’ First Set of Interrogatories to Blue Flame Medical LLC, October 13, 2020, at p. 26.

¹⁵⁹ This price represents the per unit value of the full order, which may include sales taxes and shipping or other fees. If these taxes and fees are included, this \$7.21 per unit price is comparable to \$6.09 per unit from California’s order. Letter from Howard Waltzman to Hon. Frank Pallone, Jr. and Hon. Diana DeGette, at p. 7.

example, Mike Gula testified that he felt “very confident that Blue Flame has an incredible reach of suppliers to help procure any amount of PPE” and that “Blue Flame always dealt with very reliable suppliers,”¹⁶⁰ while John Thomas testified that he “had every confidence and belief that Henry [Huang, of Great Health,] as well as our other suppliers could have fulfilled the California order.”¹⁶¹ Blue Flame has also stated that, “[w]hile certain of the N95 masks purchased by the State of California were scheduled to be shipped in April 2020,” after Chinese government officials “began delaying and, in some cases, seizing, shipments of PPE,” Blue Flame nonetheless believes those N95 masks “would have been delivered and that any potential delays caused by intervention by the Chinese government would have resulted in further discussions with California officials.”¹⁶²

76. Blue Flame’s expressions of confidence and belief in its ability to fulfill California’s order are unfounded for all of the reasons discussed above: (i) there was insufficient global supply of N95 masks, (ii) Blue Flame’s supply partners could not procure sufficient quantities of N95 masks, and (iii) Blue Flame could not fulfill at least 13 other orders for N95 masks for which it was paid. In addition, Blue Flame was an inexperienced and unsophisticated participant in the market for PPE, as evidenced by its repeated failures to follow industry standard practice for PPE procurement. Blue Flame’s statements about its alleged ability to fulfill California’s order are not credible.

1. Blue Flame’s Failures To Follow Industry Standard Procurement Practices Undermine Its Credibility as a Supplier of PPE

77. The overall goal of procurement is to ensure that an end-use buyer (such as California) has a reliable supply of the materials it needs to operate. The successful procurement of PPE items, including N95 masks, requires the implementation of many industry standard practices, steps, and processes. The purpose of these industry standard practices, which guide how and when these steps and processes should be performed, is to minimize various risks and ensure that a transaction will go forward as planned.¹⁶³ Such risks include the possibility the product is

¹⁶⁰ Deposition of Mike Gula, January 12, 2021, at pp. 39, 66.

¹⁶¹ Deposition of John Thomas, January 11, 2021, at pp. 176-177.

¹⁶² Plaintiff’s Responses to Defendants’ First Set of Interrogatories to Blue Flame Medical LLC, October 13, 2020, at p. 26.

¹⁶³ See, e.g., Khan, Syed Abdul Rehman and Zhang Yu, *Strategic Supply Chain Management*, AG: Springer International Publishing (2019), at pp. 191-206.

not going to be of the stated quality or certification level (*i.e.*, product risk), risk that if money is transferred, such as to an international entity, it may be impossible to secure a refund if there is a problem with the order (*i.e.*, deposit risk), and risk that the product will not arrive in the time frame as promised (*i.e.*, timing risk). While procurement operations may vary depending on the size of purchase, type of goods being procured, or the specific needs of the end-use buyer, there are nonetheless common practices that would be expected to be part of any large PPE order. In the following discussion, I outline typical industry standard steps and processes up through the point of purchase order execution for an order such as California's order for N95 masks. I conclude that, in spite of the importance of following these procurement steps and processes, Blue Flame did not follow industry standard procurement practices regarding California's order.

78. The first step in the procurement process is to determine the exact products needed, such as makes, models, sizes, or other applicable specifications, as well as the required quantities and the time period(s) in which these quantities are required. This step is important since it is costly to go through the procurement process and later realize that the products being ordered are incorrect or not needed. In my experience at Mass General Brigham, this step begins by working with internal clinicians to determine the health system's product needs. An intermediate supplier must also do this by discussing and confirming exact product specifications with the end-use buyer.

79. However, Blue Flame did not appear to perform this first step as evidenced by the fact that it issued California an invoice that: (i) had an error in its product description, and (ii) was missing information on the purchase quantities for each specific item.¹⁶⁴ Specifically, its invoice to California listed N95 mask model "DTX 3X" (instead of DTC 3X), which is not an N95 mask model and which Blue Flame admits was in error.¹⁶⁵ This suggests that Blue Flame did not have a proper billing system in place with an item master, which is a core component of any well-established and sophisticated supply chain operations company and allows the vendor to accurately and efficiently review product details and procure ordered products.¹⁶⁶ Ethan Bearman stated that

¹⁶⁴ Invoice from Blue Flame to California, dated March 25, 2020, BFM000066431.

¹⁶⁵ Invoice from Blue Flame to California, dated March 25, 2020, BFM000066431; Texts between Suuchi Ramesh and Ethan Bearman, March 26, 2020, BFM000077942 - 956 at 953.

¹⁶⁶ "The Gold Standard for Item Master Management: Good data is where great supply chain begins," Vizient, 2018, available at: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/p2p_imms_what_best_in_class_vfinal.pdf, at p. 2.

as of March 25, 2020, Blue Flame was not “setup with an [Enterprise Resource Planning] system like NetSuite [o]r Oracle, SAP, etc.”¹⁶⁷ Further, the missing information on the purchase quantities for each specific item indicates that Blue Flame did not fully discuss with California its client’s procurement needs. Instead, Blue Flame discussed needing “to figure out how to write the invoice with flexibility” since it was “still short” of having the N95 masks needed to fulfill the order on March 25, 2020.¹⁶⁸ Even the orders Blue Flame had with Great Health and Suuchi suffered from a lack of detailed information, as they too omitted any mention of specific quantities that Blue Flame was seeking for each model of N95 mask.¹⁶⁹ In my experience, these invoice and purchase order errors lack the level of professionalism I would expect from a reputable and experienced supplier.

80. The second step in the PPE procurement process is to identify suppliers, manufacturers, or other vendors that have the capability to supply the desired products, in the desired quantities, in the needed time frame. Crucially, this includes verifying that each potential supplier, manufacturer, or other vendor actually has in its possession the desired products in the desired quantities, or has a confirmed method for procuring them in the needed time frame. For example, if working with a potential supplier, this could include observing that that supplier has an executed purchase order in hand from a manufacturer *along with* certification from that manufacturer that it is in the process of providing product to the supplier, or, if working directly with a manufacturer, receiving confirmation from that manufacturer that it has the capacity to produce the desired quantity in the needed time frame. This is one of the most important steps since using a reliable and reputable supplier, manufacturer, or vendor that has a history of successfully fulfilling orders reduces product, deposit, and timing risks for the buyer. This second step can also involve vetting potential suppliers by evaluating their reputation in the industry; reviewing prior customer reviews; and discussing their connections, pre-existing contracts, and purchase histories with upstream sourcing companies and manufacturers. Depending on the needs

¹⁶⁷ Signal message from Ethan Bearman to Mike Gula and John Thomas, March 25, 2020, BFM000202805 - 869 at 846. An enterprise resource planning system is used to help manage business operations such as accounting, procurement, supply chain operations, and risk management. Deposition of Ethan Bearman, January 21, 2021, at pp. 21-22.

¹⁶⁸ Email from John Thomas to Mike Gula *et al.*, March 25, 2020, BFM000066389 - 390 at 389.

¹⁶⁹ Order Confirmation from Great Health to Blue Flame, March 26, 2020, BFM000013610 - 611; Purchase Order from Blue Flame to Suuchi, March 25, 2020, BFM000116424 - 425.

of the end-use buyer, such as the urgency with which the buyer needs supplies, it can be common for procuring entities to also have alternative suppliers readily available in case the chosen supplier is unable to fulfill the order. This practice of “multi-sourcing” reduces vulnerabilities associated with the performance of one individual supplier, can allow procuring entities to more easily navigate periods of volatile demand, and can give them access to more information about the state of the market.

81. At Mass General Brigham, this second step involves first contacting trusted suppliers with whom we have previous business relationships. Use of longstanding suppliers is critical because the Mass General Brigham health system cannot afford to run out of necessary supplies if an order is delayed or falls through unfulfilled. We also sometimes rely on long-term supply contracts and pricing agreements to procure needed PPE items. If our longstanding suppliers are unable to fulfill our procurement needs, or we are in need of a product that we do not already have a supply contract to procure, then we work to identify and vet alternative suppliers.

82. However, as I discuss in detail in Section VII.B above, based on the materials I have seen, neither of Blue Flame’s stated supply partners (*i.e.*, Great Health and Suuchi) could demonstrate that they were capable of supplying sufficient quantities of N95 masks in the amount of time needed to fulfill California’s order. Neither of these entities showed Blue Flame product “proof of availability” as evidence that they had the capability to fulfill California’s order. In the days leading up to California’s order, Great Health discussed its procurement efforts as “[R]ussian roulette [*sic*]” and that it was “working on securing” product.¹⁷⁰ This second step also involves vetting potential suppliers. However, Blue Flame appears to have been willing to buy product from any potential supplier, without asking probing questions to verify their reliability, and without receiving confirmation of supply capabilities. For example, just hours after being introduced to one potential supplier, John Thomas told that supplier that Blue Flame “will literally buy anything you can get. Masks or otherwise.”¹⁷¹ Actions such as these appear to have been done without the knowledge of California and without ensuring that this supplier’s alleged product met the required specifications for California’s order.

¹⁷⁰ Texts between Mike Gula and Henry Huang, March 24, 2020, BFM000011979 - 982 at 981; Email from Henry Huang to Michael Jensen *et al.*, March 19, 2020, BFM000008038 - 039 at 038.

¹⁷¹ Email from John Thomas to Jason Lee, March 19, 2020, BFM000008593 - 594 at 593; Email from William Lee to Jason Lee *et al.*, March 19, 2020, BFM000110581 - 582 at 581.

83. In addition, the documents I reviewed that discuss Blue Flame's stated supply partners' efforts to supply Blue Flame with N95 masks generally do not distinguish between different makes, models, or sizes of N95 masks. However, California only agreed to accept four specific models of N95 masks. As I discuss in Section V.A, different models of N95 masks are not interchangeable with one another. Therefore, while Blue Flame discussed with its supply partners their capabilities of procuring N95 masks *in general*, which, as I discuss above did not comprise 100 million (or 63 million) N95 masks within 30 days, Blue Flame failed to appropriately focus these discussions on specifically the procurement of 100 million units *of the four required* N95 mask models.

84. The third step in the procurement process is to authenticate the products that the supplier claims to be able to provide. This is a critical step in the PPE procurement process to minimize product risk, since poor quality products that do not fulfill their intended need can put users at risk (*e.g.*, hospital staff, patients, and first responders in the case of N95 masks). If a supplier could not provide the necessary information to authenticate the products, this would be a significant "red flag" and we would stop the transaction. If procuring N95 masks through an intermediary supplier (rather than directly from a manufacturer), it is customary to authenticate product in the following ways:

- a. Requesting information on the masks' model numbers, NIOSH testing and certification numbers (*i.e.*, "TC-approval" numbers), and lot numbers (which can be used to confirm dates of manufacturing) to corroborate against information directly from the manufacturer;
- b. Ordering samples and sending them to an independent laboratory for testing, or alternatively asking the supplier to provide documentation detailing the manufacturer's results from its own independent laboratory testing; and
- c. If obtaining samples is not possible, receiving photos of the masks, the boxes in which they are stored, and the masks' stockpile to ensure available quantity.¹⁷²

¹⁷² Mass General Brigham primarily began requesting photos in 2020 after the start of the COVID-19 pandemic.

Even if procuring directly from a manufacturer, it is still customary to ask for samples of new products to ensure the ultimate users of the product (*e.g.*, hospital staff or first responders) would be comfortable using it.

85. Although Blue Flame testified that it would ask its potential suppliers for certifications of NIOSH approval and third-party inspection reports,¹⁷³ I have seen no evidence that Blue Flame actually conducted a thorough authentication process for any of its proposed suppliers' inventories. Blue Flame sent California Great Health's "Products Catalogue" listing PPE and other medical items (*e.g.*, masks, gloves, disinfectant, COVID-19 test kits, *etc.*) to which Great Health allegedly had access. The catalogue even appeared to identify one brand of N95 mask as the "BEST," yet Blue Flame did not appear to validate the authenticity of any of these items or claims prior to sharing the catalogue with California.¹⁷⁴ Additionally, as of March 27, 2020, two days after accepting California's order, Blue Flame appears to have been unable to supply prospective customers with N95 mask samples when requested.¹⁷⁵

86. The fourth step is for the seller to negotiate and agree to specific purchasing terms with the buyer.¹⁷⁶ These terms should include, but are not limited to: the specific items (*e.g.*, makes, models, sizes, *etc.*) and quantities of each item; each item's purchase price; payment methods (*e.g.*, credit card, wire transfer, letter of credit, *etc.*) and terms; shipping method, its associated cost and schedule for payment, and which party is responsible for arranging shipping; expected delivery date or delivery schedule; cancellation, refund, and return policies; and, if applicable, which party is responsible for handling customs and international trade requirements. This step reduces risks for both parties. For example, the seller can ensure how and when it will be paid, while the buyer can ensure when it will receive its ordered product and what recourse it has if the correct product is not delivered on time. Not only is it industry standard practice for these terms to be determined

¹⁷³ Deposition of John Thomas, January 11, 2021, at pp. 28-29.

¹⁷⁴ Great Health Products Catalogue, BFM000012839; Email from John Thomas to Michael Wong, March 24, 2020, BFM000012554 - 560 at 554, 560.

¹⁷⁵ Mike Gula said: "I don't have samples. I wish I did." Further, one of Blue Flame's referral partners, who Mike Gula characterized as "working it HARD and getting us into places," said to Mike Gula that it is "[c]razy" for a potential customer to request N95 mask samples prior to ordering, and even suggested that he could fulfill the potential customer's request by "try[ing] to buy one off of Amazon." Emails between Mike Gula and Brian Chatwin, March 27, 2020, BFM000117054; Email from Mike Gula to Jennilee Brown, March 24, 2020, BFM000012775; Plaintiff's Responses to Defendants' First Set of Interrogatories to Blue Flame Medical LLC, October 13, 2020, at p. 16.

¹⁷⁶ If multiple potential suppliers are identified based on the first three steps, part of this process may include requesting bids from each of these suppliers.

prior to the execution of a purchase order, but many of these order components will also typically be arranged, or at least be in progress, prior to finalizing an order. This is because many of the above order components can take days or longer to arrange, and if the parties agree on a near-term delivery schedule, there may not be enough time to start arranging them after the purchase order is executed and still deliver the goods on time. Such order components that can often require pre-arranging include logistics for shipping and delivery (*e.g.*, transportation from the manufacturer to the foreign port or airstrip, a contract with an international cargo company, transportation from the domestic port or airstrip to end-use buyer's delivery location), storage (*e.g.*, in ports or airstrips, if applicable), and export and import (*e.g.*, customs declarations, if applicable).

87. However, Blue Flame did not agree to many of these terms with California or finalize shipping-related logistics prior to finalizing the order. In particular, the delivery schedule Blue Flame provided California, which indicated Blue Flame would complete the order by April 24, 2020 (*i.e.*, within 30 days), appears to have been put together on an ad hoc basis without any regard for actual timing of product availability or expected shipping and travel times.¹⁷⁷ Blue Flame prepared three different versions of this schedule in a two hour period on March 25, 2020, which differed in expected delivery quantities by tens of millions of units, and eventually shared with California a version that Blue Flame described as being “[a]nother version of the spreadsheet for [California].”¹⁷⁸ In my experience, even with the chaotic nature of the N95 market at this time, it would not have been credible for a supplier to make such dramatic changes to a delivery schedule in such a short period of time. It calls into question the integrity of Blue Flame's procurement process, and suggests that Blue Flame did not actually know when it would be able to acquire the product that it claimed it could supply to California.

88. Additionally, I have not seen any evidence that shipping-related logistics, including international trade and customers-related documentation, were coordinated by Blue Flame, nor by

¹⁷⁷ Ethan Bearman testifies that he cannot recall Great Health ever providing Blue Flame with a delivery schedule on which to base Blue Flame's schedule, and if Great Health had provided such a schedule, it would not have been necessary for Blue Flame to create its own. He says that in beginning to prepare the schedule, “I don't believe there was a basis [for the initial draft]. I believe I was just starting to plug in numbers for our discussion to fill it out.” Deposition of Ethan Bearman, January 21, 2021, at pp. 191, 216-217.

¹⁷⁸ Email from Ethan Bearman to Mike Gula *et al.*, March 25, 2020, BFM000013560 - 561; Email from Ethan Bearman to Mike Gula *et al.*, March 25, 2020, BFM000013558 - 559; Email from Ethan Bearman to John Thomas, March 25, 2020, BFM000116497 - 498; Texts from John Thomas to Daniel Kim and Michael Wong, March 25, 2020, BFM000129957 - 960 at 960.

any entity on its behalf, at the time of California's order. For example, Ethan Bearman wrote on March 25, 2020 that he decided on a 20 percent shipping fee "because of the unknown nature" of the shipping terms at that time,¹⁷⁹ John Thomas testified that shipping for California's order "was a little open-ended" at the time of its order,¹⁸⁰ and Michael Wong similarly testified that at the time of the order it was not yet determined whether Blue Flame or California would handle the shipping.¹⁸¹ Contrary to John Thomas' testimony that "Suuchi was going to be handling shipping from her end on her masks," Suuchi asked Blue Flame on March 26, 2020 "if California can pick up from India."¹⁸² Blue Flame's March 25, 2020 purchase order to Suuchi also lists a blank "ship to" address for the State of California.¹⁸³

89. Two additional terms related to Blue Flame's order with California depart from industry standard practice. First, Blue Flame required a 75 percent upfront payment on the cost of shipping.¹⁸⁴ However, during normal market conditions, shipping is typically not a cost that is pre-paid, and even during the outset of the COVID-19 pandemic, I am not aware of a supplier that charged more than 50 percent of the shipping cost upfront. Requiring a 75 percent upfront payment on the cost of shipping is even more unusual given that fact that Blue Flame and California had not agreed on shipping arrangements at the time of the order and that it was discussed that California might handle the shipping on its own. Second, Blue Flame informed California that it would have a 48-hour window upon receipt of the N95 masks to inspect the product and reject delivery if it was not satisfied.¹⁸⁵ However, 100 million N95 masks is such an enormous amount of physical product that it would not be reasonable to believe California could have inspected the

¹⁷⁹ Signal message from Ethan Bearman to Mike Gula and John Thomas, March 25, 2020, BFM000202805 - 869 at 826.

¹⁸⁰ Deposition of John Thomas, January 11, 2021, at p. 194.

¹⁸¹ Deposition of Michael Wong, January 19, 2021, at pp. 92, 103, and 107-108.

¹⁸² Deposition of John Thomas, January 11, 2021, at p. 194; Email from Suuchi Ramesh to Ethan Bearman, March 26, 2020, BFM000116525 - 527 at 525.

¹⁸³ Purchase Order from Blue Flame to Suuchi, March 25, 2020, BFM000116424 - 425.

¹⁸⁴ Deposition of Michael Wong, January 19, 2021, at pp. 81-82.

¹⁸⁵ Deposition of Michael Wong, January 19, 2021, at pp. 29-30.

delivered product within 48 hours.¹⁸⁶ Blue Flame's offer of a 48-hour inspection window thus further demonstrates its inexperience and lack of understanding of the PPE procurement process.

90. The fifth step is for the involved parties to review draft purchase orders and invoices to ensure they accurately represent the agreed-upon terms from step four, and once satisfied, execute the order by signing any relevant documentation.¹⁸⁷ For particularly large orders, special attention is paid to ensure accuracy of all aspects of the order documentation. Prior to the COVID-19 pandemic, this entire process (*i.e.*, steps one through five) could take up to three months, plus an additional two to four weeks for an executed purchase order to be fulfilled by our suppliers if product was being sourced domestically, or four to eight weeks if being sourced internationally.

91. Although Blue Flame pledged to fulfill California's order by April 24, 2020, the purchase order California prepared lists April 3, 2020 as the "required delivery date."¹⁸⁸ Mike Gula testified that he did not inform California of this inconsistency and is unaware whether anyone else at Blue Flame did either.¹⁸⁹ Not only does the invoice that Blue Flame sent California not list any expected delivery date, but it also fails to list any of the other terms to which the parties should have agreed prior to finalizing the order.¹⁹⁰

92. Even though there can be circumstances in which it is difficult to adhere to industry standard practice, such as during early 2020 at the outbreak of the COVID-19 pandemic, parties should strive to adhere to these practices as closely as possible in order to minimize risks as much as possible. Given the chaotic nature of the N95 mask market at that time (as discussed in Section VI.C above), both buyers and sellers needed to more quickly complete the procurement process, and therefore some components of these steps were not carried out in full. In March and April 2020, even though Mass General Brigham did not have time to, for example, obtain N95 mask samples and send them to an independent laboratory for testing (for products obtained from new-

¹⁸⁶ Consistent with industry standard practice, when Mass General Brigham receives N95 mask shipments we check for potential damage (*e.g.*, holes or tears in the packaging, water damage, evidence of mold, *etc.*) and create an inventory of lot numbers and expiration dates printed on the outside of the boxes. Additionally, we open a sample of boxes to closely examine the contents. One large truckload of product might require a few hours to review, and 100 million N95 (or even 63 million) masks would likely comprise a few hundred truckloads.

¹⁸⁷ Draft invoices are typically prepared at this stage if the buyer is making an upfront payment.

¹⁸⁸ Purchasing Authority Purchase Order from the California Department of General Services to Blue Flame Medical LLC, March 25, 2020, BFM000095501.

¹⁸⁹ Deposition of Mike Gula, January 12, 2021, at pp. 129-130.

¹⁹⁰ Invoice from Blue Flame to California, dated March 25, 2020, BFM000066431.

to-us suppliers), it nonetheless continued to do its best to authenticate products by instead asking suppliers for data on models, NIOSH testing and certification, and lot numbers (*i.e.*, “TC-approval” numbers). We refused to do business with companies that could not provide such information.

93. In sum, even in view of the chaotic conditions that prevailed in the spring of 2020 upon the outbreak of the COVID-19 pandemic, there are multiple actions Blue Flame took (or did not take) regarding California’s order that, in my experience, are outside of industry standard practice and were serious “red flags.” These include, but are not limited to: (i) sending California an invoice with a product description error, missing information regarding purchase quantities, no details related to shipping logistics, and inconsistencies with California’s purchase order; (ii) not limiting its discussion with potential suppliers to the four required models of N95 masks or ensuring that those suppliers were procuring the required models in the needed quantities; (iii) not confirming product “proof of availability” or its potential suppliers’ claimed capabilities of supplying sufficient quantities of N95 masks in the needed time frame; (iv) not authenticating product through independent testing or a review of N95 mask production-specific data; (v) developing a shipping and delivery schedule on an ad hoc basis that was independent from the actual timing of product availability; and (vi) failing to arrange shipping-related logistics. If I were to become aware of any of these issues while engaging with a potential supplier, I would immediately stop the transaction and only continue if they could adequately be resolved.

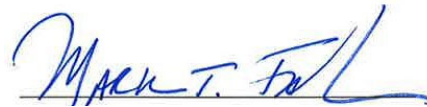
2. Blue Flame’s Lack of Experience And Longstanding Buying Relationships Also Undermine Its Credibility as a Supplier of PPE

94. Longstanding buying relationships with manufacturers and suppliers were critically important to procuring PPE items in early-2020, particularly for N95 masks. In my experience, these pre-existing buying relationships facilitated and expedited communications, increased buyers’ priority in suppliers’ customer queues, and aided in Mass General Brigham being able to procure the volume of N95 masks it did. For example, Louis M. Gerson Co., a local Massachusetts-based firm, was able to increase our N95 mask allocation by marginally increasing their N95 mask production based, in part, on our prior ties. Mass General Brigham purchases over \$200 million worth of medical supplies each year from Owens & Minor, the parent company of Halyard Health, which assisted in us being able to increase our N95 mask procurement quantities with Halyard Health in early 2020. I also believe our lack of purchase history with Honeywell was a factor in

Mass General Brigham being of lower order priority and ultimately never receiving a delivery from that company. Similarly, Emerson Hospital, a neighbor to Mass General Brigham with whom I have close contacts in their Supply Chain Contracting department, was unable to procure, and did not even get a response, from 3M Company during this time due to their limited prior purchasing relationship.

95. However, I have not seen any evidence indicating that Blue Flame had pre-existing relationships with N95 manufacturers or suppliers as a buyer prior to March 2020. John Thomas testified that as of March 2020 he did not “have any contracts or pricing agreements with any manufacturers of N95 masks,”¹⁹¹ and Mike Gula testified that prior to early-2020, he did not have “any experience in the field of medical supplies” nor “any specialized training or certifications relating to supply chain management.”¹⁹² Blue Flame’s founders also did not have any experience importing N95 masks or any other PPE items at the time of California’s order.¹⁹³ 100 million N95 masks is an enormous amount of physical product that would fill perhaps a dozen airplane cargo holds, more than 130 shipping containers, or constitute 200 tractor-trailer loads,¹⁹⁴ thus requiring a multitude of logistical steps that take time and experience to arrange (as I discuss in Section VII.D.1 above). Yet, Blue Flame was not even founded until just two days prior to sending California an invoice for its N95 mask order. It is my opinion that a new buyer such as Blue Flame, whose founders had no prior experience in purchasing or transporting N95 masks, would not have been able to directly make significant inroads with manufacturers to procure and deliver the volume of PPE that they sought to purchase at a time when manufacturers were inundated with order requests and unable to honor all of their pre-existing contracts.

Submitted on February 12, 2021



Mark Faulkner

¹⁹¹ Deposition of John Thomas, January 11, 2021, at pp. 20.

¹⁹² Deposition of Mike Gula, January 12, 2021, at p. 25.

¹⁹³ Deposition of John Thomas, January 11, 2021, at p. 19; Deposition of Mike Gula, January 12, 2021, at pp. 26-28.

¹⁹⁴ See, e.g., Email from Jason Lee to Michael Jensen, March 20, 2020, BFM000008866 - 868 at 866.

Exhibit 1**Select News Releases and Warnings Related to Fraudulent Activity and the Sale of Counterfeit N95 Masks During the COVID-19 Pandemic**

Date	Entity	Description
[A] February 10, 2020	NIOSH	NIOSH issued its first warning of 2020 related to non-NIOSH-approved Chinese manufacturers purporting to sell N95 masks.
[A] March 12, 2020	NIOSH	NIOSH posted an example of a mask manufacturer selling counterfeit Moldex-Metric Inc. N95 masks to assist the public in identifying counterfeit products.
[B] March 16, 2020	Financial Crimes Enforcement Network ("FinCEN")	FinCEN "advise[d] financial institutions to remain alert about malicious or fraudulent transactions" and said it was monitoring reports of "potential illicit behavior connected to COVID-19." It noted emerging trends including "Product Scams" in which "[t]he [FTC] and [FDA] have issued public statements and warning letters to companies selling unapproved or misbranded products that make false health claims pertaining to COVID-19. Additionally, FinCEN has received reports regarding fraudulent marketing of COVID-19-related supplies, such as certain facemasks."
[C] March 18, 2020	U.S. Attorney's Office for the Eastern District of Virginia	The U.S. Attorney's Office for the Eastern District of Virginia warned of "supply scams" that "claim[] to sell medical supplies currently in high demand, such as surgical masks," and urged the public to "be wary of any business ... requesting payments ... by wire transfer" and to avoid "send[ing] money through any of these channels."
[D] March 20, 2020	European Anti-Fraud Office ("OLAF")	OLAF announced an inquiry into the "imports of fake products used in the fight against the COVID-19 infection." OLAF warned of fraudulent actors looking "to take advantage of ... [the] need, sometimes desperate, for these products." It noted that counterfeit masks were being sold at three times the standard price and smuggled into Europe.
[E] March 27, 2020	FBI	The FBI warned of "increased potential for fraudulent activity dealing with the purchase of COVID-19-related medical equipment" in which "scammers may promise equipment they do not have access to." It also urged the general public to "[be] alert to counterfeit products like sanitizing products and personal protective equipment (PPE), including N95 respirator masks, goggles, full-face shields, protective gowns, and gloves." The FBI asked the medical community to "exercise due diligence and appropriate caution when dealing with any vendors with whom they have never worked and/or of which they've never heard, and when relying on unidentified third-party brokers in the supply chain."
[F] March 31, 2020	3M Company	3M Company introduced a new hotline for people to report fraudulent activity and publicized price lists for many of its most commonly sold N95 masks to help combat sales of counterfeit masks and price gouging.
[G] April 1, 2020	U.S. Attorney's Office for the District of Kansas; Kansas Attorney General	The U.S. Attorney's Office for the District of Kansas and the Kansas Attorney General announced a partnership to investigate COVID-19-related scams, including "people offering for sale respiratory masks they were not going to deliver."
[H] April 1, 2020	Makrite	Makrite issued a warning about unauthorized companies claiming to be its official distributors. Makrite continued to post notices of fraud and counterfeit PPE items throughout 2020 and 2021.
[I] April 7, 2020	Agence France Presse	News outlet Agence France Presse warned of a scam in Germany where distributors purchased masks from Asian suppliers that did not exist.
[J] April 8, 2020	U.S. Senate	A group of U.S. Senators alerted President Trump to reports of sales of "counterfeit or fraudulent personal protective equipment."
[A] April 17, 2020	NIOSH	NIOSH provided examples of counterfeit N95 masks and instances of misrepresentation of NIOSH approval. NIOSH also provided guidance for users on how to identify counterfeit N95 masks. The number of notices NIOSH posted to mention instances of counterfeit N95 masks and misrepresentations of NIOSH approval increased substantially between 2019 and 2020.

Exhibit 1**Select News Releases and Warnings Related to Fraudulent Activity and the Sale of Counterfeit N95 Masks During the COVID-19 Pandemic**

Date	Entity	Description
[K] April 22, 2020	3M Company	3M Company warned that “the outbreak has led to reports of counterfeiting and price gouging connected with [3M Company] products.” It noted that scams included suppliers fraudulently claiming to have access to large supplies of N95 masks and consumers purchasing 3M Company N95 masks but receiving counterfeit product.
[L] May 1, 2020	3M Company	3M Company filed five legal actions to “combat fraud and counterfeiting.” The lawsuits involved defendants offering government officials “to sell N95 respirators—in one case claiming to have up to five billion respirators—at inflated prices, all while falsely affiliating themselves with 3M.”
[M] May 7, 2020	FDA	The FDA provided an update on its efforts to combat scams and exploitative actions taken by companies and individuals during the COVID-19 pandemic. The FDA had uncovered “hundreds of [unproven and potentially dangerous] products including fraudulent drugs, testing kits and personal protective equipment (PPE) sold online with unproven claims.” The FDA monitored “the online ecosystem for fraudulent products peddled by bad actors seeking to profit from [the] global pandemic.”
[N] May 13, 2020	OLAF	OLAF provided an update regarding its March 2020 inquiry, in which it “identified over 340 companies acting as intermediaries or traders of counterfeit or substandard products linked to the COVID-19 pandemic.”
[O] May 18, 2020	FinCEN	The FinCEN warned of “red flags” regarding COVID-19-related “non-delivery scams,” and detailed a \$317 million fraudulent transaction for face masks that was flagged by a Virginia financial institution and investigated by the U.S. Secret Service.
[P] May 22, 2020	U.S. Department of Justice (“DOJ”), Office of the Inspector General	The DOJ Office of the Inspector General warned about the “emerging fraud risks related to the COVID-19 pandemic,” stating that there had been instances in which certain federal offices “may have been provided substandard or mislabeled personal protective equipment (PPE), including N-95 and KN-95 face mask respirators.”
[Q] June 5, 2020	U.S. Attorney’s Office for the District of New Jersey	The U.S. Attorney’s Office for the District of New Jersey stated that it had filed a suit against a Chinese PPE manufacturer for “producing and exporting to the United States in the midst of the COVID-19 pandemic nearly half a million misbranded and defective masks that falsely purported to be N95 respirators.”

Exhibit 1**Select News Releases and Warnings Related to Fraudulent Activity and the Sale of Counterfeit N95 Masks During the COVID-19 Pandemic****Sources:**

- [A] “Counterfeit Respirators / Misrepresentation of NIOSH-Approval,” Centers for Disease Control and Prevention, updated January 5, 2021, available at: <https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html>.
- [B] “The Financial Crimes Enforcement Network (FinCEN) Encourages Financial Institutions to Communicate Concerns Related to the Coronavirus Disease 2019 (COVID-19) and to Remain Alert to Related Illicit Financial Activity,” Financial Crimes Enforcement Network, March 16, 2020, available at: <https://www.fincen.gov/news/news-releases/financial-crimes-enforcement-network-fincen-encourages-financial-institutions>.
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Exhibit 2**Summary of Unfulfilled Purchase Orders for N95 Masks Received by Blue Flame¹***As of June 22, 2020*

	Customer	Order Dates	Number of N95 Masks Ordered	Other PPE Products Ordered	Amount Paid to Blue Flame	Refund Issuance Dates
1.	Idaho State Police	March 30, 2020	800 ²	200 surgical masks	\$5,643	April 23, 2020
2.	Melbourne Airport Police Department	March 30, 2020	400	36 16.9-ounce bottles of hand sanitizer	\$3,008	May 15, 2020
3.	Maryland Department of State Police	March 30, 2020; March 31, 2020	400 ²	24 16.9-ounce bottles of hand sanitizer; 40 surgical masks; 100 nonwoven gowns; 30 digital thermometers	\$7,145	May 5, 2020; May 6, 2020
4.	Florida Department of Law Enforcement	March 31, 2020	400	600 face shields; 504 16.9-ounce bottles of hand sanitizer; 1,000 disposable caps; 1,000 disposable shoe covers	\$11,913	April 23, 2020
5.	Maryland	April 1, 2020	1,550,000	110 ventilators	\$6,271,000	N/A ³
6.	Santa Rosa County Sheriff's Office	April 1, 2020	400	1,000 shoe covers; 1,000 coveralls	\$5,006	May 15, 2020
7.	Oklahoma State Bureau of Investigations	April 2, 2020	400	1,000 surgical masks	\$4,812	April 19, 2020
8.	Riverside University Health System	April 3, 2020	64,000	100,000 disposable caps; 100,000 shoe covers	\$495,974	April 30, 2020
9.	Northern Arizona University	April 3, 2020	800 ²	288 2-ounce bottles of hand sanitizer; 1,000 surgical masks	\$8,424	May 8, 2020
10.	Marion County Sheriff's Office	April 3, 2020	400	N/A	\$2,885	May 8, 2020
11.	Tennessee	April 6, 2020	500,000	500,000 disposable gowns	\$2,590,122	April 22, 2020; May 7, 2020
12.	Alabama	April 6, 2020; April 8, 2020	700,000	200,000 gowns; 50,000 nitrile gloves	\$1,800,000	April 30, 2020
13.	North Carolina Department of Safety	April 7, 2020; April 9, 2020	800	192 2-ounce bottles of hand sanitizer	\$6,405	May 11, 2020
Total			2,818,800		\$11,212,338	

Exhibit 2**Summary of Unfulfilled Purchase Orders for N95 Masks Received by Blue Flame¹***As of June 22, 2020*

Notes:

1. Includes all purchase orders from “federal, state, or local governments or governmental entities for medical supplies or equipment,” other than the at-issue order from California, received by Blue Flame as of June 22, 2020.
2. Includes “foldable” N95 masks.
3. Maryland and Blue Flame settled a dispute associated with this purchase order in October 2020, whereby Blue Flame would keep the \$6.27 million down payment it received in April 2020 and agreed to fulfill Maryland’s order of N95 masks, while Maryland would pay no additional amounts.

Sources:

- [A] Letter from Howard Waltzman (Mayer Brown) to Hon. Frank Pallone, Jr. and Hon. Diana DeGette (United States Congress), Re: Response to Committee Request, dated June 22, 2020, Exhibit A to “Memorandum in Support of Defendants’ Motion to Dismiss,” *Blue Flame Medical LLC v. Chain Bridge Bank, N.A., John J. Brough, and David M. Evinger*, Civil Action No. 20 Civ 658, In the United States District Court for the Eastern District of Virginia Alexandria Division, filed July 20, 2020, at pp. 4-9.
- [B] Settlement Agreement between Blue Flame Medical, LLC and the Maryland Department of General Services, in connection with the Maryland Department of General Services Purchase Order #HOOP0601445, October 9, 2020.