February 27, 2022

From Scarcity to Abundance: Complementary Government and Private Initiatives to Manage the Allocation of N95 Masks in the U.S. During the COVID-19 Pandemic

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ABSTRACT

I examine how federal regulatory agencies, federal procurement agencies, N95 manufacturers, N95 distributors, and other public and private entities, responded to the challenge of allocating scarce N95 respirator supplies during the first 12 to 15 months of the COVID-19 pandemic. The pandemic led to a huge increase in the demand for N95s that were (initially) permitted to be used to treat COVID-19 patients consistent with pre-pandemic regulations. This created a large gap between supply and demand at pre-pandemic prices. N95 prices initially increased dramatically as the pandemic emerged in early 2020, while health care organizations scrambled to meet their needs. The relaxation of pre-pandemic FDA, OSHA, and CDC regulations played an important role in rapidly increasing the effective supplies of N95s early in the pandemic. Despite the initial increase in prices and the chaos associated with sourcing supplies, no government rationing or price controls were ever applied to private sector sales of N95 or N95-like masks. Federal contracting and distribution initiatives did have the effect of allocating a significant fraction of N95s manufactured in the U.S. to priority health care and emergency response organizations, as well as increasing domestic manufacturing capacity and supply, and maintaining pre-pandemic prices. However incumbent domestic N95 manufacturers and their authorized distributors continued to control a large fraction of the N95s produced. They voluntarily adopted policies to allocate most of these N95s to priority health care and emergency response organizations and away from their traditional industrial and retail customers, consistent with government policy goals. They also committed to increase domestic production by a factor of 400 to 500% by Winter 2020/2021 and to maintain pre-pandemic prices during the pandemic. They delivered on these commitments. The rationing and price maintenance policies led to the creation of multiple market segments with different prices in each segment. Counterfeit N95s proliferated to try to fill the needs of organizations which could not obtain a sufficient supply through the public and private priority allocation systems. The potential reasons explaining why legacy domestic manufacturers adopted these rationing and price maintenance policies and how they implemented them are discussed. Potential social costs of these policies are identified.

Keywords: COVID, N95, FFR, face masks, rationing, price controls, reputation, relational contracts

* Department of Economics, MIT and National Bureau of Economic Research. I have benefited from comments from Richard Schmalensee, John Deutch, Clifford Winston, Dennis Carlton, and Chad Bown. I want to thank the members of my family, my friends and colleagues who gave me the opportunity to purchase N95 and N95-like respirators for them in 2020 and 2021. This allowed me to learn first-hand about the market. I also want to thank distributors and my doctors and dentists for answering my questions about the procurement and use of masks in health care settings. Research support was provided by MIT. There are no conflicts.

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1. Introduction and Overview

This paper examines the structure, behavior and performance of the N95 respirator market in the U.S. before and during the COVID-19 pandemic (2020-early 2022). It focuses on the behavior and performance of government and private sector organizations in the allocation of scarce supplies of N95 respirators during the pandemic in the U.S. The paper is on the one hand a classical old style industrial organization study (no structural model), and on the other an economic history relying on diverse primary and secondary sources. The experience with the supply, demand, allocation, rationing, and pricing of N95s during the first two years of the pandemic provides instructive examples of how the public and private sectors can work in tandem with regulatory support rather than coercion to achieve widely accepted public health goals. Of particular interest is the adoption of voluntary private market segmentation, rationing and price maintenance policies during roughly the first year of the pandemic, led by the dominant U.S. manufacturer of N95s.

Why focus on N95 masks? When fitted properly, N95 respirators are the gold standard for (normally) inexpensive and easy to use respiratory protection from tiny particles and certain airborne pathogens. In ordinary times, roughly 90% of the N95s sold in the U.S. are used by industrial workers, emergency responders, and individuals, in order to provide respiratory protection from particles produced from activities like sanding, sawing, blasting, mining, oil drilling and refining, forest fires, cleaning the basement, etc. N95 respirators are also particularly effective for protection from airborne infectious disease situations where individuals are exposed for example, to influenza viruses and, as it is now realized, COVID-19. Under ordinary circumstances only N95 respirators with certain characteristics defined by federal regulators (surgical N95s), making up roughly 90% of sales, are used in a limited number of health care settings for this purpose. During epidemics and pandemics, when infected individuals, transmission rates and hospitalizations increase dramatically, the business as usual (BAU) demand for utilization of N95s by health care personnel (HCP) in hospitals and other health care venues, and emergency response personnel (ERP) in contact with potentially infected individuals, increases dramatically.

The first COVID case was confirmed in the U.S. on January 20, 2020, and the first fatality attributed to COVID on February 6, 2020. As the COVID-19 pandemic gained speed in the U.S. in early 2020, the demand for Personal Protection Equipment (PPE) for HCP and ERP, as well as the demand for medical

equipment like ventilators, skyrocketed. I estimate that the BAU demand for N95s certified by U.S. regulators for use at that time by HCP and ERP increased by between one and two orders of magnitude during the first year of the COVID-19 pandemic, assuming business as usual (BAU) N95 utilization patterns and no changes in federal N95 certification regulations. Large perceived shortages of N95s for HCP and ERP quickly attracted considerable government, industry, and media attention and widespread calls for action by policymakers to allocate scarce supplies to front line HCP and ERP dealing with COVID patients, to increase supplies of N95s quickly, to mitigate fraudulent business practices, and to keep prices from skyrocketing to balance supply and demand. As a result of complementary government and private sector actions, price increases in the domestic manufacturer to authorized distributor and federal government distribution channels were maintained at roughly pre-pandemic levels while very significant increases in the supply of N95s and N95-like respirators were realized. Prices in other segments with private price maintenance and fraud control policies were significantly higher than pre-pandemic levels during the first years of the pandemic, but lower than in the uncontrolled "open market." Prices in all market segments returned to pre-pandemic levels and rationing and price maintenance arrangements largely came to an end mid-2021. As the Omicron variant spread rapidly in late 2021 and early 2022, N95s and N95-like respirators were (finally) being recommended to be used by individuals for protection from infection in certain settings as well as by HCP and ERP.[1] These policies were not without some potential costs, especially in connection with changes in utilization protocols for HCP and ERP, for purchasers which had to turn to other non-priority distribution channels to meet their incremental N95 needs, who were not working for HCP/ERP organizations with any access at all to these priority distribution channels or market segments, or ended up with counterfeit or underperforming respirators

Government policy and industry behavior during the first year to 18 months of pandemic focused on (a) allocating the available supplies of N95s into the "right hands" --- front line health care and emergency response workers dealing with COVID patients, (b) expanding the effective supply of N95 and N95-like respirators for use by these workers, (c) reducing the demand for N95s by changing hospital utilization protocols to reduce demand below business as usual (BAU) levels, and (d) containing "excess prices," "price gouging" and various fraudulent sales practices, especially the sale of counterfeit N95 and N95-like respirators. These policies were pursued through what I believe to be an unusual complementary mix of (temporary) relaxations of pre-pandemic federal regulations governing the certification and use of N95 and N95-like masks, including imports of respirators that did not have to go through the standard U.S. government certification protocols, government contracting and allocation initiatives supported by

[1]Aaron Steckelberg and Bonnie Berkowitz, "Why most of us should be wearing N95 masks," *The Washington Post*, January 20, 2022.

Congressional appropriations of funds to support these initiatives, voluntary industry policies to support government policies to allocate available N95s to front line health care workers and emergency responders such as EMTs, to increase domestic N95 supplies by 400% to 500% by the end of 2020, and to maintain their pre-pandemic wholesale and end-customer prices during the course of the pandemic. While there has been a lot of criticism of various aspects of the federal government's response to the pandemic, the government and private sector policies governing the allocation, supply enhancement, and pricing appears to have worked pretty much as intended.

The behavior of the leading pre-pandemic domestic N95 manufacturers, led by the 3M Corporation (3M), by far the dominant pre-pandemic U.S. supplier of N95s with a market share of about 60 - 65%, is especially interesting. Early in the pandemic, 3M announced that it would work with the six leading medical supply companies and with the Federal Emergency Management Agency (FEMA) voluntarily to allocate the bulk of the N95s it produced to front line health care workers, to increase its domestic supply from 26 million respirators per month in January 2020 to over 95 million respirators/month by Winter 2020, to import N95 and N95-like respirators from its international manufacturing facilities, and to maintain its pre-pandemic wholesale prices and to urge its authorized distributors to maintain their pre-pandemic end-customer prices. The other major legacy domestic manufacturers adopted similar policies. By the winter of 2020-21 domestic supplies of N95 respirators had increased from about 500 million per year to about 2 billion per year and by January 2022 the Strategic National Stockpile had increased from about 15 million N95s in January 2020 to 750 million N95s, of which 400 million were distributed to the public free starting in January 2022. The supply of N95 and N95-like respirators to HCP and ERP grew much more quickly and substantially as a result of regulatory actions that relaxed restrictions on the use of "standard" N95s for respiratory protection by HCP and ERP, relaxing regulations restricting the use of expired N95s in these settings, allowing for decontaminated respirators to be used in these settings, and probably most importantly, allowing imported N95-like respirators meeting their country's certification criteria, but not existing U.S. certification criteria and procedures, to be used in HCP, ERP, and industrial settings in the U.S. These temporary deregulatory responses did result in some problems, as counterfeit or sub-performing N95 and N95-like respirators, primarily manufactured in China, flooded the market along with supplies of legitimate N95-like respirators. Market segmentation by the legacy domestic manufacturers led to different availabilities and end-customer prices in each segment until late Spring and early Summer 2021 for most N95 models.

While the legacy domestic manufacturers of N95s implemented their own form of rationing and voluntary price controls for N95s, the federal government never seriously considered or implemented formal price controls for N95s, though lawsuits by the Department of Justice (DOJ) permitted by the 1950 Defense Production Act (DPA) and by some state attorneys general did target a few distributors, brokers

and individuals for hoarding and resale of respirators at "above prevailing market prices." This litigation was typically wrapped in the rhetoric of "price gouging," but it usually focused on a variety of fraudulent sales practices such as offering counterfeit respirators, misrepresenting the performance of respirators, contracting to sell N95s to which the intermediary did not actually have access and associated failures to deliver on commitments, rather than on controlling prices generally.

In ordinary times the U.S. sales of government certified N95s is fairly small, on the order of perhaps $500 million of sales revenue per year. It is so small that separate statistics for N95 and related disposable respirators were not reported either in U.S. government statistics or, prior to the pandemic, in company annual reports, 10-K filings or press releases. Accordingly, the empirical analysis in this paper has required a lot of detective work relying on government studies and reports, corporate documents (primarily 3M), media reports, press releases, informed guesses, and data from private sources. I suppose that we can call this economic archeology.

The paper proceeds as follows: The first section discusses the attributes of the various types of face masks that are available for respiratory protection, their intended uses, and the regulatory framework governing certification and utilization. The focus is on the class of respirators generally referred to as N95 filtering face pieces (FFR), the subject of this paper. I then turn to a brief discussion of the manufacturing process for N95s and the materials that give them high levels of filtration. The following section discusses the pre-pandemic horizontal and vertical market structure of N95 manufacturing and distribution, followed by the discussion of the BAU demand for N95s and the changes in utilization protocols implemented to reduce demand during the first 18 months or so of the pandemic. The paper goes on to examine the "deregulatory" actions taken by federal authorities to rapidly increase the effective supplies of certified N95s and imports of N95-like respirators (arguably) meeting certification regulations in other countries similar to those in the U.S. that could be used by HCP and ERP, as well as federal government contracting actions designed to increase domestic manufacturing capacity and supplies over the first year of the pandemic. This section is followed by a discussion of the commitments of legacy domestic manufacturers to dramatically increase supplies, to allocate virtually all of the N95s they manufactured to front line HCP and ERP and away from their traditional industrial and retail distributors while maintaining prices at pre-pandemic levels. The penetration of counterfeit or underperforming FFRs and fraudulent sales practices in the "residual" market segments that fell outside the priority manufacturing/distribution chains is discussed next, followed by the documentation of the entry of roughly 25 new U.S. companies manufacturing and distributing legitimate certified N95s later in the pandemic. Finally, I examine and discuss the fragments of evidence examining whether or not the N95 rationing, market segmentation, and pricing commitments made by legacy domestic manufacturers and their authorized distributors are reflected in the actual pricing and allocation behavior. The paper concludes with a discussion of how the domestic manufactuers

implementing their rationing and price allocation policies, why they voluntarily adopted these policies, and their potential social costs.

2. Face Masks for Respiratory Protection: Overview and Regulatory Frameworks

There are three general types of disposable[2] face masks that are used for respiratory protection in the U.S.[3] These are:

(a) N95 disposable filtering facepiece respirators (FFR): FFRs are generally referred to as N95 respirators in the U.S. The "95" stands for the minimum standard of 95% filtration of particles of 0.3 microns in size or larger. The designation "N95s" is an umbrella term that covers similar respirators with slightly different filtration efficiencies, fluid and contaminant resistance, but made with very similar materials (e.g. N99 (99%), N100 (99.97%), R95 (95% with oil-based aerosol resistance), P95 (95%, liquid petroleum resistance).[4] I will use "N95" and "FFR" interchangeably to refer to this entire class of respirators in what follows. The term N95-like will refer to FFRs that have not gone through the standard U.S. regulatory approval process but (supposedly) have been approved in other countries using similar performance criteria.

For the purposes of this paper, the primary relevant difference between N95 categories is between "Standard" N95 respirators and "Surgical" N95 respirators: (i) Standard N95: At least 95% filtration of particles greater than 0.3 microns and other National Institute of Safety and Health (NIOSH) specified performance and testing criteria. Not resistant to oil. Double head bands. No ear loops. With and without exhalation valves; Not authorized for use in health care setting[5] (ii) Surgical N95: Meets NIOSH N95 criteria and well as Food and Drug Administration (FDA) specified fluid (synthetic blood) resistance

[2] "Disposable" refers to face masks that are used for a short period of time. In the case of N95 respirators, in the medical context pre-covid once per day for each patient or once for each encounter, and then thrown away. In the industrial context they are typically be used for longer periods, until they get too dirty, breathability deteriorates, or are damaged.

[3] Toner, et. al. (2021) has an excellent description of different types of masks and respirators and opportunities for innovation. It was issued after this section of the paper was written. In an earlier version of this paper I discussed reusable respirators which Toner et.al. (2021) seems to favor for future development and distribution efforts.

[4] https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsourceTypes.html accessed September 15, 2021.

[5] Standard N95 masks come with and without one-way exhalation valves. In the standard industrial setting, the purpose of these respirators is to protect the worker. An exhalation valve improves the breathability and associated comfort of the mask. (Toner et. al. (2021, page 10.) However, in the COVID pandemic setting, where HCP are expected to wear N95 respirators for protection from being infected themselves as well as protecting others from being infected if the wearer has been infected, the respirators with exhalation valves can allow virus-laden particles to be released into the air and infect other people. Accordingly, N95 respirators with exhalation valves have been strongly discouraged for use during the COVID-19 pandemic and some jurisdictions have banned respirators with exhalation valves. However, respirators with exhalation valves provide better respiratory protection both for the individual wearing one and others than no mask at all and there are ways to block the valves to reduce leakage, though manufacturers like 3M recommend against doing so.

criteria. Double headbands. No ear loops. No exhalation valves.[6] The primary difference between standard N95 respirators and surgical N95 respirators is that the surgical N95s meet fluid resistance criteria specified by the FDA and must be cleared as Class II medical devices for use in health care settings for surgical and related procedures where there is a risk of exposure to high pressure streams of blood and other bodily fluids.[7, 8] There are also a variety reusable powered and non-powered respirators that can provide equivalent (or better) protection than NIOSH approved N95 disposable respirators, though their use is limited due to wearability, maintenance, patient care and cost factors.[9, 10,11]

Under ordinary circumstances, the vast majority of N95s --- roughly 90%---produced and sold in the U.S. are "standard" N95s for use by individuals requiring respiratory protection in various industrial and emergency settings (e.g. grinding, sanding, mining, oil drilling and refining, chemical manufacturing, bad air pollution due to fires, 9/11 recovery operations, etc.), as prescribed by Occupational Safety and Health Administration (OSHA) regulations and guidelines. In pre-pandemic times they could not be used by HCP or ERP in patient care settings as they were not approved for these purposes by the FDA.[12]

Accordingly, in the U.S., N95s are subject to overlapping regulation by OSHA, the FDA, and NIOSH, a division of the Center for Disease Control (CDC) an agency within the Department of Health and Human Services (HHS). Both OSHA and the FDA rely heavily on the testing and certification done by NIOSH. NIOSH certification is required for both standard and surgical N95s. Surgical N95s authorized for use by health care personnel (HCP) are also subject to regulation by the FDA as class II medical

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[6] There are four basic disposable N95 respirator designs: molded or cup masks (e.g. 3M 8210, 3M 1860, Makrite 9500), flat fold masks (e.g. 3M 8520+ (imported from China), Honeywell DF300), and "fish front" masks (e.g. 3M 1870, 3M 9205, Korean KF94 respirators). Kimberley-Clark (Kimtech), Owens & Minor (Halyard, spun off from Kimberly-Clark in 2014 and acquired by O&M in 2018), Prestige America and a couple of other smaller manufacturers make NIOSH certified N95 respirators with a "duckbill" or "pouch" design. They are all designed to fit tightly on the face so that there is no leakage of particles. OSHA requires that all FFRs respirators must be fit-tested annually for each individual following CDC guidelines. Fit testing can be costly (Toner, et. al. 2021, page 10) All NIOSH certified FFRs must use two-head bands to help to tighten the fit rather than ear loops which are common in similar respirators certified in China (KN95), Korea (Korea 1st Class), the EU (FFP2), and other countries.

[7] (https://multimedia.3m.com/mws/media/1794572O/surgical-n95-vs-standard-n95-which-to-consider.pdf) accessed August 6, 2021.

[8] Surgical N95 respirators must apply a standard test method (ASTM F1862) for resistance to blood. Synthetic blood is shot horizontally at the mask at a distance of 30cm (12 inches) at three velocities corresponding to the range of human blood pressures. The CDC recommends that in times of shortage only healthcare professionals who are working in a sterile field or who may be exposed to high velocity splashes, sprays or splatters of blood or bodily fluids should wear these respirators. If surgical N95s are not available, a Level 3 surgical mask plus a face shield may be used in these situations.https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html. Accessed August 6, 2021.

[9] https://www.cdc.gov/niosh/npptl/pdfs/FY17_N95infographicWhatAreAPR-508.pdf undated. accessed August 15, 2021.

[10] https://www.cdc.gov/niosh/npptl/respirators/elastomeric/ accessed August 15, 2021.

[11] National Academies Press (2021) and Toner et. al. (2021, pages 17-19).

[12] Pre-pandemic, hospitals and other health care providers were permitted to use standard N95 respirators in non-patient care settings such as chemical, biological, radiological, mold removal, and maintenance hazard situations (NAS 2019, p. 40).

devices.[13] Other countries have very similar standards for FFRs and have roughly equivalent categories to those in the U.S. However, FFRs or "N95-like respirators" approved in other countries applying their own performance criteria cannot be used either by industrial workers to meet OSHA respiratory requirements or by HCP involved in patient care in the U.S. without also going through the NIOSH and FDA approval and clearance processes.

(b) disposable medical or surgical masks, generally referred to simply as surgical masks: These are the masks that pre-covid one typically saw used by most medical professionals in hospitals, at doctor and dentist offices, etc. They provide varying levels of respiratory protection and differ from FFRs in several ways. They are loose fitting around the sides of the face, may have different headband/ear loop standards which affect the tightness of fit, are subject to different and somewhat looser testing procedures than are NIOSH approved FFRs, and do not come in molded or cup versions to fit tightly to the user's face. Surgical masks are constructed from similar materials to N95s and under typical conditions are much less expensive.[14]

(c) low performance masks: These are face masks that have no regulatory filtration or other performance standards and provide physical barriers only. They include molded (cup) utility masks like those one might use mowing the lawn and foldable masks --- sometimes referred to as procedure masks --- that also have no performance standards and are physical barriers only. The flood of cloth masks that appeared during the pandemic also can be placed in this category.[15] As physical barriers these masks can provide some protection to others from infections and vice versa, but the filtration efficiency is typically much lower than for N95s and FDA regulated surgical masks.[16]

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[13] Class II medical devises are those that have a high risk to the patient and/or user. Most medical devices are considered to be class II devices.

[14] Disposable surgical masks fall into three categories which differ primarily in their protection from fluids and filtration of tiny airborne particles. In the U.S., surgical face masks are regulated by OSHA, NIOSH, and by the FDA as Class II medical devices and must meet one of three standards established by the American Society for Testing Materials (ASTM): ASTM Level 3 --- high fluid resistance and high filtration efficiency, ASTM Level 2 --- moderate fluid resistance and somewhat lower filtration efficiency, and ASTM level 1 --- low fluid resistance and still lower filtration efficiency. See Toner et. al. (2021, pages 4-5). Under ordinary circumstances, almost all face masks used in hospitals are surgical masks meeting one of the ASTM standards. There is some evidence that surgical face masks meeting ASTM standards have lower filtration efficiencies when subject to NIOSH rather than ASTM testing procedures and in other controlled experiments. See Toner et. al. (2021, pages 14-15) for a discussion of new standards for nonmedical public masks

[15] e.g. https://www.etsy.com/market/masks?utm_source=google&utm_medium=cpc&utm_term=etsy%20masks_e&utm_campaign=Search_US_Brand_GGL_ENG_Bath-Beauty_General_All&utm_ag=Face+Masks&utm_custom1=_k_CjwKCAjwmK6IBhBqEiwAocMc8rgotX50OZQUHuImvhcwF8zpwZMEgmNlQ8EhDnbVR-SnBONcT5m33BoCN4UQAvD_BwE_k_&utm_content=go_6518959182_127012058082_536666964896_kwd-463812258475_c_&utm_custom2=6518959182&gclid=CjwKCAjwmK6IBhBqEiwAocMc8rgotX50OZQUHuImvhcwF8zpwZMEgmNlQ8EhDnbVR-SnBONcT5m33BoCN4UQAvD_BwE) accessed August 15, 2021

[16] Elisabeth Mahase 2021, "Are Cloth Masks Still Effective," BMJ, February 15, 372, https://doi.org/10.1136/bmj.n432 https://www.bmj.com/content/372/bmj.n432 accessed August 6, 2021.

3. N95 Respirator Manufacturing

The materials used to manufacture N95s and their design is what makes them especially effective for a high level of respiratory protection. The various N95 mask varieties all use the same basic materials and have the same basic design. The composition of a typical N95 respirator is reproduced in Figure 1. It has three or four layers of fabric materials along with head bands, nose clips (typically), cushion material to improve comfort (sometimes), and exhalation valves (for valved respirators). An outer layer, an inner layer, a center layer between the outer and inner layer, and sometimes a layer to support the form of the mask or for comfort. The outer layer and the inner layer are typically comprised of some type of polyester textile material. They are primarily physical barriers or stabilize the form and construction of the respirator rather than being high efficiency filtering materials. The key material that makes the high filtration rates possible at relatively modest cost per mask is the middle layer --- the FFR filter. This material is a synthetic fabric called non-woven melt blown polypropylene. It is manufactured to create a dense web of fibers that can trap particles larger than 0.3 microns. It is manufactured using special resins and an extrusion process requiring specialized machinery (Edwards, Hutton 2007).[17] This material is manufactured globally, including in the U.S. The melt-blown non-woven polypropylene is then shipped to manufacturers and used in automated manufacturing machines that combine the multiple components to create the final disposable N95 FFR.[18] As part of this manufacturing process the polypropylene filtering level is given an electrostatic charge to help to trap tiny particles. This charge dissipates over time and is the source of the expiration dates specified by respirator manufacturers (e.g. 3 years, 5 years, etc., from date of manufacture). The modern non-woven melt-blown polypropylene FFR filtering layer was invented by Peter Tsai, a professor of materials science at the University of Tennessee, now retired. He received a U.S. patent in 1995.[19,20]

[INSERT FIGURE 1]

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[17] Ed Edwards, "What is Melt-blown Extrusion and How is it used in Making Masks," What is Melt-Blown Extrusion and How is it Used for Making Masks? https://www.thomasnet.com/articles/machinery-tools-supplies/what-is-melt-blown-extrusion/ Accessed August 6, 2021; Irwin M. Hutton, "Processes for Non-woven Filter Media," Handbook of Non-woven Filter Media, 2007. https://www.sciencedirect.com/book/9780080983011/handbook-of-nonwoven-filter-media Accessed via Elsevier Science Direct August 6, 2021..

[18]See McLantis Group, http://www.mclantisgroup.com/product-medical/N95_Mask_Production_Line.html . Accessed August 6, 2021.

[19] Sidney Page, "The Retired Inventor of N95 Masks is back at work, mostly for free, to fight covid-19," The Washington Post, July 7, 2020. https://www.washingtonpost.com/lifestyle/2020/07/07/peter-tsai-n95-mask-covid/ accessed August 6, 2021.

[20] Non-woven synthetic fabrics are used in many products in addition to making N95 respirators and ASTM certified surgical masks (Edwards).Wikipedia, "Nonwoven Frabric," https://en.wikipedia.org/wiki/Nonwoven_fabric ; Accessed August 6, 2021, The Association of the Nonwoven Fabric Industry is the industry's trade association. https://www.inda.org/ . Accessed August 7, 2021.

4. Pre-Pandemic Horizontal and Vertical Market Structure

(a) N95 Manufacturing market structure

The primary U.S. manufacturers of N95 respirators in the U.S. and their estimated U.S. production of FFRs as of January 2020, what I consider to be "pre-pandemic in the U.S. are listed in Table 1. Estimated total imports of NIOSH approved N95 respirators is also included in Table 1. The derivation of these estimates is contained in the Data Appendix.

[INSERT TABLE 1]

3M was by far the largest producer of FFRs in the U.S. as the pandemic first surged in the U.S. in early 2020, accounting for roughly 65% of domestic supplies and 60% of total supplies marketed in the U.S. counting NIOSH certified imported N95s. Most of the 3M models marketed in the U.S. pre-pandemic were manufactured in the U.S. with "globally sources materials." 3M also has the most extensive international manufacturing presence in the industry with N95 respirator manufacturing plants in China, Singapore, South Korea, Japan, Turkey, and a recently opened plant in Canada. In early 2022 3M indicated that it had distributed about 4.3 billion respirators globally during the pandemic, reflecting the enormous growth is its output over the previous two years.[21] It appears that 3M's pre-pandemic strategy was to manufacture respirators in different locations to serve local and regional markets and meet country-specific performance criteria. For example, prior to the pandemic, all but one model sold in the U.S. was manufactured in the U.S. 3M NIOSH certified and FDA cleared respirators manufactured in the U.S. were also exported to Canada and to Latin America pre-pandemic, a source of some controversy with the Trump Administration early in the pandemic. Honeywell (including respirators previously produced by Sperian and North which Honeywell previously acquired) manufactures respirators "around the world," "at multiple locations," including the U.S., UK, India, and UAE through a partnership. It is not completely clear whether or not Honeywell was still manufactured N95 respirators at all in the U.S. at the onset of the pandemic, though I have made an estimate based on related Honeywell information. We do know that in 2020 Honeywell opened production lines in Rhode Island and Arizona. It also opened lines in Germany, Scotland and India. Moldex is a relatively small private company with its core respiratory protection manufacturing facilities located in the U.S. and Europe. Louis M. Gerson is an even smaller company that has been

[21] https://s24.q4cdn.com/834031268/files/doc_events/2022_StrategicOutlook_Event/Presentations/Mike-Roman-Presentation.pdf Accessed February 18, 2022.

manufacturing N95 respirators in a facility in Massachusetts since 1985. It has manufacturing facilities outside the U.S., but it is unclear whether or not it manufactures N95 respirators there. O&M Halyard (part of Owens & Minor) manufactures its N95 Fluidshield respirators in the U.S. Alpha Pro Tech, which has NIOSH approval for one N95 respirator (an FDA cleared model) manufactures its N95 respirators only at a plant in New York City. Prestige America's N95 respirators are manufactured in the U.S. Kimberly-Clark, not included in Table 1, appears to have been manufacturing its Kimtech respirators in Mexico in January 2020, though it ultimately exported N95s to the U.S.

There are also many non-U.S. companies which have NIOSH certified N95 respirator models that can be sold in the U.S. to meet OSHA and (many fewer models) FDA regulations. These companies have their headquarters in China, Taiwan, UK, Japan, India, Germany, France, Switzerland, Canada, Mexico, and other countries. However, Chinese and Taiwanese companies have by far the largest presence on the NIOSH approved model list. Some companies use their NIOSH approved N95s for internal use at their facilities in the U.S. and do not sell them to third parties.

All of the legacy U.S. manufacturers listed in Table 1, except for 3M, also have a private label business. This means that they manufacture N95 respirators for which they have NIOSH approval under their own brand names and also manufacture these same respirators for third parties which affix their own brand names to the respirators.[22] Indeed, the vast majority of the NIOSH certified N95 models listed on the CDC web site are in fact private label models produced by "name brand" domestic and foreign manufacturers which also market the same N95s under their own brand names. For example, The Home Depot has NIOSH approvals for N95 respirators which it sells under the "HDX" store brand name. The respirators are manufactured by a Chinese company and by a Taiwanese company with N95 respirator manufacturing facilities in China. They are NIOSH certified. Cardinal Health, a large medical supply company, has NIOSH approvals for several N95 respirators which it sells under the Cardinal Health brand name. These respirators are actually manufactured by a Taiwanese company with factories in China and by another U.S. company. Among the non-U.S. private label companies making NIOSH approved respirators for U.S. branded distributors, as well as distributors in other countries, are Makrite (Taiwan with factories in China), San Huei United Company (Taiwan with factories in China), Shanghai Dasheng Health Products (China),[23] Jinfuyu Industrial Company (China and Vietnam), other Chinese manufacturers as well as companies in France, India, UK, Brazil, and Japan.[24]

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[22] The private label brands carry the manufacturer's NIOSH certification number so the actual manufacturer of a private label brand is easy to trace. Non-U.S. manufacturers also have large U.S. private label businesses.

[23] Certain Shangai Dasheng respirators were decertified by the FDA on August 21, 2021 due to poor quality control. https://www.fda.gov/medical-devices/medical-device-recalls/stop-using-certain-n95-respirators-manufactured-shanghai-dasheng-letter-health-care-providers. accessed September 15, 2021.

[24] For example, Makrite markets respirators under its own brand name and has received regulatory certification for various models of its respirators in the U.S., EU, Japan, South Korea, and Australia/NZ, in addition to its large

Prior to the pandemic, sales of surgical N95 respirators approved by NIOSH and cleared by the FDA for use by health care personnel accounted for about 50 million units annually (4 million surgical N95 respirators per month) at an MSRP for the top selling 3M surgical respirator of about $1.25/respirator. This sales number is consistent with anecdotal reports from hospitals[25] and manufacturers.[26]

Table 1 leads to a number of observations. This is a highly concentrated business that was and is dominated by the 3M Corporation. 3M, became the leader of the domestic industry response during the pandemic. For companies like 3M, Honeywell, Owens and Minor and Kimberly-Clark (not in Table 1), respirator sales are a very small fraction of their business. 3M alone had total revenues of about $32 billion in 2019 and N95 respirator production is a small part of its safety and industrial group where it sits for manufacturing and marketing purposes. Honeywell had sales of about $36 billion in 2019, of which about $6 billion was attributed to it Safety and Productivity division. Kimberly-Clark had about $18 billion of sales in 2019 of which about $3 billion was accounted for by its K-C professional group where respirator and surgical mask production sits (Kimtech). Owens & Minor had annual sales of over $9 billion in 2019 and sells a wide range of products to the health care sector.[27] In short, N95 respiratory sales pre-pandemic were very small product lines within these large multi-product firms. Aside from these four firms, U.S. manufacturing of N95 respirators was done by relatively small firms pre-covid. Both Moldex and Louis M. Gerson are relatively small private companies which manufacture a wide range of respiratory protection products of which N95 respirators are only one of their product lines. Dunn and Bradstreet estimates that Moldex has annual sales of just under $100 dollars[28] and Louis M. Gerson just under $35 million in 2020.[29] Both Moldex and Louis Gerson manufacture primarily standard N95s for industrial applications.

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private label business. http://www.makrite.com/wp-content/Downloads/2019-Makrite-Product-Catalogue.pdf accessed June 15, 2021.

[25] "Doug Bock Clark,"Inside the Chaotic Gray Market for N95 Masks," The New York Times, November 20, 2020, https://www.nytimes.com/2020/11/17/magazine/n95-masks-market-covid.html; Felice J. Freyer, "Amid a rising tide of COVID-19, hospitals stock up on respirator gear," The Boston Globe, October 18, 2020.

[26]Dee DePass, "3M's complicated road to enough N95 capacity took many hands," Star Tribune, April 25, 2020, quoting a 3M executive indicating that 15% of 3M's N95 respirator sales were made to health care customers. https://www.startribune.com/3m-s-complicated-road-to-enough-n95-capacity-took-many-hands/569929962/; Another report indicates that 90% of 3Ms masks were sold for industrial applications," Austen Hufford, "N95 Mask Makers Ramp Up Production to meet U.S. COVID-19 Demand," The Wall Street Journal, July 17, 2020. https://www.wsj.com/articles/n95-mask-makers-ramp-up-production-to-meet-u-s-covid-19-demand-11594987201 . Accessed July 15, 2021. Moldex-Metric, "Moldex Responds to the Coronavirus Epidemic with Increased Manufacturing," indicating that the " The vast majority of Moldex N95 respirator masks have traditionally been produced for use in industrial settings such as construction, oil & gas, defense, and mining applications," https://www.moldex.com/moldex-responds-to-coronavirus-pandemic-with-increased-manufacturing/

[27] https://investors.owens-minor.com/node/24706/html accessed September 1, 2021.

[28] https://www.dnb.com/business-directory/company-profiles.moldex-metric_inc.43f48d238eb6e1cc39ffb1fa3c966680.html accessed September 1, 2021.

[29] https://www.dnb.com/business-directory/company-profiles.louis_m_gerson_co_inc.e39dc13ec9c9eca6fa40da27b39cc6b4.html accessed September 1, 2021

(b) Distribution Chains

The manufacturers of N95 respirators listed in Table 1 typically do not deal directly with end-use customers but rather sell respirators through authorized distributors. For surgical N95 respirators, the most important distributors to major health care systems are six large medical supply companies like Cardinal Health, McKesson, Medline Industries, and Henry Schein (IFC 2020, p. 26). During the pandemic, 3M, and presumably the other U.S. manufacturers, relied heavily on these major medical supply distributors to implement their allocation, distribution, and pricing strategy which I will discuss further presently.[30] For the very largest health care systems ("key accounts"), there may be contracts directly with manufacturers. There are also many smaller national and local distributors of medical supplies and brokers serving small hospitals, physician offices, dental offices, convenience and drug stores, etc. Finally, there has been a growing number of specialized e-commerce medical supply and personal safety distributors both with and without brick and mortar stores, including third party sellers using e-commerce hosting platforms --- e.g. Amazon.

For standard N95 respirators used in industrial and emergency response settings, distribution is more decentralized with specialized personal safety protection distributors, home improvement distributors like The Home Depot, lumber yards, home and garden stores, big box stores like Walmart, Target, Lowes, etc. Amazon. Walmart, Google, etc. have offered standard N95 respirators for sale on their e-commerce platforms, both on their own behalf and through third party sellers hosted on their platforms.

Finally, the federal government maintains a Strategic National Stockpile[31] of critical antibiotics, vaccines, equipment and medical supplies, including both surgical and standard N95 respirators. It is designed to provide a buffer to serve demand quickly as manufactured supplies increase in response to a

[30] "3M Outlines Latest Actions on COVID-19 Response," March 31, 2020, https://news.3m.com/2020-03-31-3M-Outlines-Latest-Actions-on-COVID-19-Response accessed June 15, 2021.

[31] Early in the pandemic (April 2, 2020), the Trump administration changed the public description of the role of the Strategic National Stockpile on various government web sites to conform to its policy of turning more responsibilities for acquiring equipment and supplies to the states. After the initial chaos in the federal response in March and early April 2020, it appears that the federal government pretty much followed the Bush administration's plan. Michael Bender and Rebecca Baullaus, "How Trump Sowed Covid Supply Chaos. 'Try Getting It Yourselves," The Wall Street Journal, August 31, 2020, https://www.wsj.com/articles/how-trump-sowed-covid-supply-chaos-try-getting-it-yourselves-11598893051 accessed July 15, 2021; Paul Biasco, "All the things George W. Bush said we should do to prepare for a pandemic that Donald Trump ignored," Business Insider, May 31, 2020. https://www.washingtonpost.com/politics/2020/04/03/jared-kushner-stands-trump-proceeds-offer-very-trumpian-claim-about-stockpiles/ ; Aaron Blake, "The Trump administration just changed its description of the national stockpile to jibe with Jared Kushner's controversial claim," The Washington Post, April 3, 2020. https://www.washingtonpost.com/politics/2020/04/03/jared-kushner-stands-trump-proceeds-offer-very-trumpian-claim-about-stockpiles/ . See also https://thehill.com/homenews/administration/491037-trump-administration-changes-definition-of-national-stockpile-after and https://www.politico.com/news/2020/04/03/strategic-national-stockpile-description-altered-after-kushners-remarks-163181 . accessed August 29, 2020.

sudden increase in demand. The medical supplies in the stockpile are managed by Department of Health and Human Service (HHS), in cooperation with the Federal Emergency Management Agency (FEMA) and the CDC.[32] The inventory is stored in secret locations around the country.[33] Prior to the pandemic the stockpile has been used 13 times since it was established in 1999 to provide emergency medical and safety supplies during epidemics and other emergencies, such as for workers searching the rubble after the attacks on 9/11.[34] The Strategic National Stockpile had about 12-13 million N95s at the beginning of the pandemic and another 5 million that had expired.[35] (3M N95s typically have manufacturer specified shelf-lives of 3 or 5 years).[36] Most states have complementary strategic stockpiles as well. The pandemic plan prepared by the G.W. Bush administration suggested a stockpile of N95 respirators sufficient to supply 2-3 weeks of peak use during a pandemic. Apparently, this was determined to be 100 million N95 respirators, though determining optimal stockpile levels is extremely difficult (National Strategy for Pandemic Influenza 2006).[37] The target set by the Secretary of Health and Human Services in February 2020 was 300 million N95s in the stockpile. Obviously at that time, the federal stockpile was far short of either target.

5. Demand for N95s in Industrial, Personal Safety, and Health Care settings

(a) BAU demand by HCP and ERP

In what follows I refer to "BAU demand" for respirators for use by HCP and ERP to characterize the demand that would have emerged if pre-Covid N95 respirator utilization protocols had continued during the pandemic as assumed in models that forecast PPE demand during infectious virus epidemics and pandemics (Carias, et. al. 2015). As I will discuss presently, the actual utilization of N95s for much of this period was far below the BAU demand as hospitals and other health care providers adjusted their utilization

[32] https://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-Authorization-Toolkit/Strategic-National-Stockpile-Fact-Sheet/ . accessed August 29, 2021

[33] https://www.npr.org/sections/health-shots/2016/06/27/483069862/inside-a-secret-government-warehouse-prepped-for-health-catastrophes accessed August 29, 2021.

[34]Matthew Brown, "Fact Check: Did the Obama Administration deplete the federal stockpile of N95 Masks?" USA Today, April 3, 2020. https://www.usatoday.com/story/news/factcheck/2020/04/03/fact-check-did-obama-administration-deplete-n-95-mask-stockpile/5114319002/; HHS history of the strategic stockpile, August 13, 2021, https://www.phe.gov/about/sns/Pages/responses.aspx (accessed August 28, 2021).

[35] https://www.pressdemocrat.com/article/news/face-masks-in-the-national-stockpile-have-not-been-substantially-replenishe/

[36]During the H1N1 flu epidemic (2009-2010), 85 million N95s were drawn from the stockpile,[36] and FEMA again drew on the stockpile during Zika and Ebola outbreaks, hurricanes, floods and other emergencies. But apparently these respirators were never replaced prior to the COVID pandemic.

[37]"National Strategy for Pandemic Influenza: Implementation Plan, May, 2006. https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-implementation.pdf. accessed August 28, 2021.

protocols to reduce utilization in response to administrative supply constraints, much higher than normal prices for "open or residual market" purchases, and concerns about counterfeits.[38]

I will focus first on the demand for respiratory protection for HCP and ERC in proximity to infectious or potentially infectious COVID patients. Given the OSHA, CDC/NIOSH and FDA regulatory rules in place at the start of the pandemic, this is effectively the BAU demand for surgical N95 respirators. As noted earlier, this is the case because pre-covid, standard industrial N95 respirators, imported respirators that are not NIOSH approved and FDA cleared, expired and decontaminated respirators, were not permitted to be used for patient care; only surgical N95 respirators (NIOSH approved and FDA cleared) could be used by HCP and ERP in these circumstances. This regulatory distinction between standard N95 respirators and surgical N95 respirators has potentially significant implications for the dynamics of both demand and supply during the pandemic. The estimates in Table 1 show that prior to the pandemic, the U.S. produced and imported only about 4 million surgical N95 respirators per month or about 50 million surgical respirators per year based on existing CDC/NIOSH approval and FDA clearance requirements.

The BAU demand for surgical N95 respirators for use by HCP for respiratory protection against the COVID-19 during the pandemic was very hard to estimate for many reasons (Lum, et.al. 2020, Furman et. al 2021). Conceptually, it would depend primarily on hospital N95 utilization protocols, the number of individuals infected, the rate of hospitalizations, the length of hospitalizations, the length of the pandemic, the infection or transmission rate, utilization outside the hospital sector, for example, in doctor and dental offices, by EMTs, and of course, by individuals seeking personal respiratory protection. It should also depend on availability of preferred N95 respirators, their prices, and the availability of reasonably close substitutes. Actual observed utilization by HCP and ERP would be lower than BAU demand if health care providers changed N95 utilization protocols to reduce demand in response to the scarcity of supplies, their cost, and concerns about counterfeit or underperforming respirators from sources with which they were unfamiliar.

The timing of the hospitalization "surges" varied from one region of the U.S. to another, but I will use the national numbers here since supplies of N95s can be moved from one region to another as regional demand varies.[39] The first surge and associated increase in the BAU demand for N95 respirators started

[38] Consistent total COVID hospitalization data is not reported by the CDC until about July 15, 2020 and I want to look at variations COVID hospitalizations starting from the beginning of the pandemic in the U.S. early in 2020. Figure 5 is a chart of the variations in U.S. COVID hospitalizations over time based on the data reported by the CDC COVID-NET participating hospitals, covering about 10% of the U.S. population.[38] My interest here is the variations over time not the absolute magnitude of hospitalizations, so the CDC COVID-NET data are adequate for this purpose.

[39] https://covid.cdc.gov/covid-data-tracker/#hospitalizations; https://gis.cdc.gov/grasp/covidnet/covid19_5.html; https://www.nytimes.com/interactive/2021/us/covid-cases.html all accessed February 20, 2022. The first surge took place most heavily in Northeastern urban areas, the second surge in the South and West, the third and smaller fourth surge more widely dispersed geographical, the fifth delta variant surge emerged across the country but led to many

in early March 2020 and peaked in April 2020. The second surge in hospitalization of about equal size occurred in the summer of 2020. The third, and until then, largest surge in hospitalizations occurred during the fall/winter of 2020-21. A fourth much smaller surge in hospitalizations occurred in the Spring of 2021. The Delta variant surge began in summer of 2021, weighted heavily in Southern states before it moved North in the Fall. In early September 2021 total U.S. COVID hospitalizations reached another local peak. As this is written in February 2022, the Fall/Winter 2021/2022 Delta/Omicron surge resulted in peak COVID hospitalizations higher than the previous peaks in Winter 2020/21 and summer 2021, although hospital stays are apparently much shorter.[40]

Despite the difficulties, there are estimates of the BAU demand for N95 respirators during a hypothetical flu pandemic using models that take most of these demand-side factors into account. These are the models policymakers relied upon to estimate N95 demand to provide respirators to protect HCP and ERP at the beginning of the COVID-19 pandemic in the U.S. A 2015 paper that models the potential demand for N95 respirators during a hypothesized flu pandemic is especially well done and very transparent as the assumptions are laid out in considerable detail (Carias et. al. 2015).[41] Depending on the assumptions, the potential demand for N95 respirators varies between 1.5 and 7.3 billion over the course of the pandemic, lasting about a year. The COVID-19 pandemic has attributes that are closer to and likely exceed the upper bound in this study. In early 2020 the U.S. Department of Health and Human Services used a number of 3.5 billion N95 respirators "needed" by HCP and ERP during a serious pandemic.[42]

I will just use the 3.5 billion number to make an important point about the supply-demand balancing challenge that the system confronted as the pandemic quickly surged in the U.S. in March 2020. A BAU demand of 3.5 billion respirators per year is almost 70 times the pre-pandemic supply of surgical N95 respirators approved by NIOSH and cleared the FDA that could be used to patient care settings in the U.S. If we assume instead that all NIOSH approved standard N95 respirators were authorized to be used in health care settings through a relaxation of FDA regulations, as they eventually were (see below), the demand shock was still a factor of almost 10. This second calculation ignores the fact that roughly 90% of standard N95s would ordinarily be used in their intended industrial and personal safety applications, so diversion

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more hospitalizations in Southern and some Western states, and by December 31, 2021 the Omicron variant surge was spreading quickly across the entire country as hospitalizations continued to rise in early January 2022 as this paper is written.

[40] John Kamp and Melanie Evans,"COVID-19 Hospitalizations Reported in U.S. Hit New High," The Wall Street Journal, January 11, 2022. https://www.wsj.com/articles/covid-19-hospitalizations-reported-in-u-s-hit-new-high-11641924596?mod=djemalertNEWS accessed January 11, 2022.

[41] Utilization by police officers, firefighters, nursing home workers, and ERP are included, but not demand from the general public.

[42] Jeanne Whalen, "Changes in U.S. law will make millions more masks available to doctors and nurses, White House says," The Washington Post, March 20, 2020. https://www.washingtonpost.com/business/2020/03/19/change-us-law-will-make-millions-more-masks-available-doctors-nurses-white-house-says/

from industrial uses to HCP/ERP uses would have been necessary. The magnitude of this demand shock is consistent with more anecdotal evidence. 3M reports that the demand for surgical N95s it received from some hospitals was 40 times pre-covid normal.[43] Before the pandemic a group of Massachusetts hospitals reports using 1000 surgical N95 respirators per month but needed 1000 per day at the peak of the pandemic in New England in March, April, May, 2020 or an increase of a factor of 30.[44] Another hospital group reported a "burn rate" 10-15 times normal.[45] And, as discussed further below, this is after measures were taken to reduce N95 utilization, only reflects the increase in hospital utilization and ignores non-hospital medical and dental practices, nursing homes, EMTs, other emergency response, etc. demand. Whatever the precise numbers, this is a huge unanticipated sudden demand shock relative to pre-pandemic surgical N95 supplies and perhaps explains the almost hysterical concerns raised at the beginning of the pandemic about a huge N95 "shortage," (as well as expected "shortage" of other PPE – surgical masks, gloves, gowns, face shields, as well as hospital equipment, especially ventilators) and the sometimes frantic efforts to secure additional N95 supplies, such as the use of the New England Patriot's Boeing 767 to bring respirators from China to Boston in April 2020.[46]

(b) Changing N95 utilization protocols to reduce HCP/ERP demand

Under normal circumstances, HCP and ERP dealing with infectious patients would use a surgical N95 once when treating a patient and then throw it away --- so-called single-use. In the hypothetical potential flu pandemic demand study (Caris 2015) that I referred to earlier, the upper bound estimate was 16 respirator per patient-day for ICU patients and 8 per day for other infected patients. In response to the challenges of expanding the pre-pandemic supply of N95 respirators by one to two orders of magnitude, HCP were asked to use the same N95 for multiple patients, sometime for several days, and to clean and decontaminate respirators so that they could be reused. These changes in utilization protocols were guided by detailed CDC guidance identifying strategies for safely conserving and decontaminating respirators for reuse[47] and wider set of "Strategies for Optimizing the Supply of N95 Respirators."[48] The FDA also issued Emergency Use Authorizations (EUAs) regarding reuse and decontamination of N95 respirators in order to

[43] https://www.3m.com/3M/en_US/company-us/coronavirus/ accessed September 1, 2021.
[44] Felice J. Freyer, " Amid a rising tide of COVID-19 hospitals stock up on protective gear," The Boston Globe, October 18, 2020, https://www.bostonglobe.com/2020/10/18/metro/amid-rising-tide-covid-19-hospitals-stock-up-protective-gear/
[45] "Bonnie Berkowitz, "How far would a million N95 masks go? It's complicated and this is why," The Washington Post, May 19, 2020. https://www.washingtonpost.com/graphics/2020/health/virus-masks-ppe/
[46] Andrew Beaton, "A Million N95 Masks from China, on Board the New England Patriots' Plane," The Wall Street Journal, April 2, 2020. https://www.wsj.com/articles/a-million-n95-masks-are-coming-from-chinaon-board-the-new-england-patriots-plane-11585821600 . Accessed June 30, 2020.
[47]https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html accessed October 30, 2020.
[48] https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html accessed August 22, 2021.

extend the useful life of a respirator.[49] Finally, OSHA issued guidance regarding appropriate criteria and procedures for decontamination and reuse of respirators.[50] The reduction in BAU demand must have been quite significant initially since HCP and ERP could not use more surgical N95s than could be physically produced or imported at any particular point in time, a number much smaller than the BAU demand during the first several months of the pandemic.

(c) Demand for Surgical N95s by Individuals

Pre-pandemic there was very little demand for N95s individuals requiring respiratory protection other than what was required by OSHA, their employers for on-the-job respiratory protection, and individual home utilization for personal safety. Until summer 2021, the utilization of N95s by individuals to protect themselves and those they came in contact with from COVID-19 infection was also quite limited for several reasons: (a) for much of the period studied here, individuals were strongly discouraged from buying or using N95 or N95-like respirators so that the supplies could be directed to front line health care and emergency response personnel, (b) surgical N95s would not provide individuals with any discernable benefit over standard N95s and (c) it was extremely difficult for ordinary individuals and most non-medical businesses to obtain legitimate NIOSH approved and/or FDA cleared standard N95 and surgical N95 respirators through established distribution channels until roughly March 2021 even if they wanted them. As I will discuss, this is a consequence of the way domestic manufacturers, their authorized distributors and FEMA rationed and allocated N95 respirators until Spring/Summer 2021 as supplies increased and standard competitive market mechanisms took over the resource allocation process.

The utilization of N95 respirators by individuals for respiratory protection from the virus was strongly discouraged by the CDC and other policymakers involved with the U.S. response to COVID for until mid to late 2021. First, we were told that individuals did not need to wear masks of any kind and certainly shouldn't purchase N95 respirators which were needed by front line HCP.[51] Then we were told that face coverings of some kind would help to protect others from virus laden droplets an infected individual might produce, but the details of what kind of face covering were not specified. A bandana was deemed to be acceptable at first. Next, we were told that cloth masks with two or three layers would be better both to protect others and to protect ourselves because the virus spread through tiny airborne droplets called aerosols which required higher filtration for protection. Then after the vaccines became available, fully vaccinated people were told that they didn't need masks at all. Then we were told that due to the Delta variant everyone should wear masks indoors. Only as the Omicron surge emerged did federal public health

[49] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reissues-emergency-use-authorizations-revising-which-types accessed August 23, 2021.
[50] https://www.osha.gov/laws-regs/standardinterpretations/2020-04-24 accessed June 30, 2020.
[51] https://www.cnn.com/factsfirst/politics/factcheck_e58c20c6-8735-4022-a1f5-1580bc732c45. Accessed June 30, 2021.

officials begin to advise that "better masks" (N95 or N95-like respirators) would provide superior protection from infection gained a lot of traction.[52] The changing guidance to "wear good masks" when you must or chose to wear a mask voluntarily coincided with the increasing availability to the public of N95 and N95-like respirators at roughly pre-pandemic prices in mid and late 2021. The CDC did not officially change its guidance regarding N95s and imported Chinese KN95s until January 2022.[53, 54] While these policy changes were attributed to advances in "the science," my reading of the literature is that the importance of aerosols for transmission was recognized early in the pandemic and but for other considerations it was well-known that NIOSH certified N95s and legitimate N95-equivalent respirators provide superior respiratory protection.[55] This changing guidance regarding masks may have contributed to controversies about the need to wear them. A subject for a separate paper.

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[52] Scott Gottlieb, "Some Masks Will Protect You Better than Other: Surgical outperforms cloth and an N95 is far superior to a bandana," The Wall Street Journal, November 22, 2020. https://www.wsj.com/articles/some-masks-will-protect-you-better-than-others-11606081251 ; Scott Gottlieb, "Where is the Science Behind CDC's 6-Foot Social-Distance Decree, The Wall Street Journal, March 21, 2021. https://www.wsj.com/articles/wheres-the-science-behind-cdcs-6-foot-social-distance-decree-11616358952. Eliza Mackintosh, (CNN), "European countries mandate medical-grade masks over homemade class face coverings," January 22, 2021 (with a picture of Angela Merkel wearing a KN95) https://www.cnn.com/2021/01/22/europe/europe-covid-medical-masks-intl/index.html . "Martin Finucane, "With the Delta variant on the loose, some experts say people should wear better masks," The Boston Globe, August 12, 2021. https://www.bostonglobe.com/2021/08/12/nation/with-delta-variant-loose-some-experts-say-people-should-wear-better-masks/ ; Betsy Morris, "How to find the Best Children's Masks as the Delta Variant Surges," September 16, 2021. https://www.wsj.com/articles/finding-good-kids-mask-is-even-harder-this-fall-as-delta-variant-surges-11631683626?page=1 . Accessed September 16, 2021; Lena H. Sun and Rachel Roubein, "CDC weighs recommending better masks against omicron variant," *The Washington Post*, January 11, 2022. https://www.washingtonpost.com/health/2022/01/10/cdc-weighs-n95-kn95-masks-guidance-omicron/ accessed January 11, 2022.

[53] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html accessed January 24, 2022; Diti Kohli, "It's time to upgrade your mask, public health experts say," *The Boston Globe,* December 21, 2021. https://www.bostonglobe.com/2021/12/21/nation/its-time-upgrade-your-mask-public-health-experts-say/ . accessed December 27,2021.Emma Platoff and Taylor Dolven, "As experts advise better masks to protect against Omicron, government is starting to provide them," *The Boston Globe*, December 30, 2021. https://www.bostonglobe.com/2021/12/30/nation/experts-advise-better-masks-protect-against-omicron-government-is-starting-provide-them/ accessed December 31, 2021. Clare Ansberry and Nidhi Subbaraman, " Why Cloth Masks May Not be Enough as Omicron Spreads," *The Wall Street Journal*, January 2, 2022. https://www.wsj.com/articles/cloth-face-mask-omicron-11640984082?mod=djemHL_t . accessed January 2, 2022. Lena H. Sun and Rachel Roubein, "CDC weighs recommending better masks against omicron variant," *The Washington Post*, January 11, 2022. https://www.washingtonpost.com/health/2022/01/10/cdc-weighs-n95-kn95-masks-guidance-omicron/ accessed January 11, 2022. Aaron Steckelberg and Bonnie Berkowitz, "Why most of us should be wearing N95 masks," *The Washington Post*, January 20, 2022.

[54] John Kamp and Melanie Evans,"COVID-19 Hospitalizations Reported in U.S. Hit New High," The Wall Street Journal, January 11, 2022. https://www.wsj.com/articles/covid-19-hospitalizations-reported-in-u-s-hit-new-high-11641924596?mod=djemalertNEWS accessed January 11, 2022.

[55] Hitoshi Oshitani, "What Japan Got Right About Covid-19," The New York Times, January 24, 2022. https://www.nytimes.com/2022/01/24/opinion/japan-covid.html . accessed January 24, 2022.

(d) Demand for standard N95s in industrial settings and retail settings

As long as the regulatory distinction between surgical and standard N95s remained in place the demand for standard N95s should have reflected changes in economic activity. The economic contraction in the first half of 2020 and reduced employment in many sectors where standard N95s would have been in use (e.g. construction, welding, sandblasting, mining, oil and gas drilling) should have reduced temporarily the demand for standards N95s. However, as I will discuss in the next section, the FDA issued an Emergency Use Authorization (EUA) early in the pandemic which removed most restrictions on the use of standard NIOSH certified N95s by HCP and ERP. And the effective private and public rationing and allocation policies channeled almost all N95 and N95-like respirators to HCP and ERP, shifting from a 90/10 split between standard N95 and surgical N95 distribution to a 10/90 split in 2020. As a result, availability of standard NIOSH certified N95s for industrial and personal protection applications suddenly declined dramatically as allocations shifted almost completely to HCP and ERP. In response, OSHA issued guidance regarding conservation of N95s in industrial settings, including extended use, use of imperfect substitutes (surgical masks, face shields, goggles, partitions, engineering controls, etc. requirements.)[56] It urged employers to consider alternative to N95 masks.[57] However, as the economy picked up it is reported that some non-health care workers found it difficult to acquire traditional N95 respirators which they would ordinarily have relied upon to provide respiratory protection.[58]

6. Government Actions to Increase N95 and N95-like Supplies

An important lesson learned by manufacturers from other recent pandemics and epidemics such as the H1N1 epidemic in 2009 and the Ebola epidemic in 2014 --- is that expanding capacity to increase supplies of PPE, including surgical N95 respirators, by an enormous quantity quickly to meet BAU demand, is a major challenge (Patel et. al. 2017). Domestic producers cannot instantly increase supplies as they must acquire raw materials, equipment, and train labor in quantities far beyond what the supply chain was producing pre-pandemic. New entrants must not only source these materials and labor but must get the respirators they manufacture approved by NIOSH and, if surgical N95s, cleared by the FDA. Bottlenecks can emerge in the supply and distribution chains. This is why the government maintains N95s in the Strategic National Stockpile to help to meet surges in demand until suppliers can ramp up production. From

[56] https://www.osha.gov/laws-regs/standardinterpretations/2020-04-03 ; https://www.osha.gov/sites/default/files/respiratory-protection-covid19-long-term-care.pdf ; accessed July 15, 2021.

[57] John Huetter, "OSHA urges employers to consider alternatives to N95 masks," RDN, April 3, 2020. https://www.repairerdrivennews.com/2020/04/03/osha-urges-employers-to-consider-alternatives-to-n95-masks/ accessed June 15, 2021.

[58] Michaelle Bond, "As construction resumes, some workers are finding a shortage of recommended N95 masks," The Philadelphia Inquirer, May 17, 2020. https://www.inquirer.com/real-estate/coronavirus-construction-n95-masks-pennsylvania-20200517.html accessed July 15, 2021

N95 suppliers' perspective, the number of people who will be infected, hospitalization attributes, and the duration of the pandemic are very uncertain. Accordingly, another lesson learned by N95 manufacturers from earlier experience with expanding production in response to an epidemic or pandemic, is that when the pandemic or epidemic comes to an end the suppliers can be left with more materials and machinery than they need to meet reduced demand, making large investments in capacity potentially uneconomical and maintaining surge capacity without some external financial support very expensive (IFC 2020, p. 33). This is one rationale for longer term government contract support effectively to share costs with manufacturer who have expanded capacity if demand is less than anticipated.

Despite the early arguments about who was responsible for leading PPE supply procurement and the associated initial market chaos in February, March and April 2020,[59] the federal government played a key and very constructive role in expanding N95 supplies, working with the states, working with and supporting N95 manufacturers, major medical supply distributors and health care providers. The approach was consistent with the pandemic response plan produced during the George W. Bush administration (Homeland Security Council 2006). Federal regulatory authorities (FDA, HHS/CDC/NIOSH, OSHA) implemented a number of policies to relax regulations that had a significant positive effect on the effective supply of N95 or N95-like respirators that could be used in health care settings as alternatives or complements to the traditional NIOSH approved and FDA cleared surgical N95 respirators. OSHA and the FDA also relaxed some pre-pandemic utilization protocols. Their actions were supported by Congress which passed the COVID-19 Preparedness and Response Supplemental Appropriations Act (CPRSA) and The Families First COVID-19 Response Act (CARES) in March of 2020 which provided substantial financial support for government efforts to increase supplies of PPE, including N95 respirators, medical equipment like ventilators, and to develop vaccines.

The major [de]regulatory actions were:

(1) *Relaxation of FDA regulations permitting for the use of standard NIOSH approved N95s by HCP and ERP*. On March 2, 2020, the FDA issued an Emergency Use Authorization (EUA)[60] which temporarily permitted all NIOSH approved FFRs (N95, N99, etc.), both standard and surgical N95 respirators, to be used by HCP and ERP in health care settings where exposure to infected individuals was a risk. The EUA deemed these FFRs (temporarily) to be treated as FDA cleared Class II medical devices even though they did not necessarily meet the standard FDA regulatory requirements. Since the vast

[59] Michael Bender and Rebecca Ballhaus, "How Trump Sowed Covid Supply Chaos. Try Getting it Yourselves," The Wall Street Journal, August 31, 2020. https://www.wsj.com/articles/how-trump-sowed-covid-supply-chaos-try-getting-it-yourselves-11598893051 accessed June 15, 2021.

[60] The FDA's ability to use EUAs to supplement its existing regulations was made possible by the issuance of a determination that a public health emergency existed by the Secretary of HHS on January 31, 2020. It was renewed several times. https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx accessed August 31, 2021.

majority of FFRs produced in the U.S. at that time were not intended for or marketed for medical use and were not cleared as Class II medical devices by the FDA for use to protect workers against COVID-19 infection, this EUA greatly expanded the availability of FFRs for use by HCP and ERP at risk from COVID infections. 3M reported that it ultimately increased its shipments of standard plus surgical FFRs to eligible health care organizations and eligible emergency responders from 10-15% to 90% of its production.[61] Moldex reported that this EUA made it possible for it to reallocate its primary production of standards N95 respirators from industrial users to HCP and ERP. Of course, this policy reduced the availability of standard NIOSH approved FFRs for use in their intended industrial and emergency settings. In response, OSHA issued guidance regarding conservation of N95s in industrial settings, including extended use, use of imperfect substitutes (surgical masks, face shields, goggles, partitions, engineering controls, etc. requirements.)[62] It urged employers to consider alternative to N95 masks.[63] Moreover, the economic contraction in the first half of 2020 and reduced employment in many sectors where FFRs may have been in use (e.g. construction, welding, sandblasting, mining, oil and gas drilling) helped to reduce temporarily the demand for standards N95s. However, as the economy picked up, it was reported that some non-health care workers found it difficult to acquire traditional N95 respirators which they would ordinarily have relied upon to provide respiratory protection.[64]

(2) *Relaxation of regulations to permit utilization of expired NIOSH approved N95s.* Manufacturers of N95s often assign shelf-lives to their products, typically between 2 and 5 years. N95s "expire" when they are beyond the specified shelf-lives. It was thought that many organizations, including the Strategic National Stockpile, had expired FFRs in inventory and storage as a result of previous outbreaks that led to the acquisition of FFRs (Swine Flu 2009, SARS 2003) as well as for protection from environmental hazards, including air pollution from wildfires, and to meet OSHA worker protection standards. In March 2020, the FDA issued an EUA authorizing the use of "expired" NIOSH approved N95s which continued to meet NIOSH performance criteria. The March EUA also created a process for the CDC to test and certify for use "expired" respirators in health care settings, including expired respirators in the

[61] Jeanne Whalen, "Change in U.S. Law will make millions more masks available to doctors and nurses," The Washington Post, March 20, 2020. https://www.washingtonpost.com/business/2020/03/19/change-us-law-will-make-millions-more-masks-available-doctors-nurses-white-house-says/ accessed June 30, 2021.
[62] https://www.osha.gov/laws-regs/standardinterpretations/2020-04-03 ; https://www.osha.gov/sites/default/files/respiratory-protection-covid19-long-term-care.pdf ; accessed July 15, 2021.
[63] John Huetter, "OSHA urges employers to consider alternatives to N95 masks," RDN, April 3, 2020. https://www.repairerdrivennews.com/2020/04/03/osha-urges-employers-to-consider-alternatives-to-n95-masks/ accessed June 15, 2021.
[64] Michaelle Bond, "As construction resumes, some workers are finding a shortage of recommended N95 masks," The Philadelphia Inquirer, May 17, 2020. https://www.inquirer.com/real-estate/coronavirus-construction-n95-masks-pennsylvania-20200517.html accessed July 15, 2021

Strategic National Stockpile. Several models of expired N95 respirators received this approval.[65] Along with the previous EUA permitting the use of standard N95 respirators to support COVID response, this EUA also facilitated donations of these respirators to hospitals and other health care providers.[66] A study that made use of the inventories of N95 and N95-like respirators in Boston-area teaching hospitals in October 2020 found that while pre-pandemic the hospitals would hold 2 to 5 N95 respirator models in their inventories, in October 2020 there were 100 models of N95 and N95-like respirators in their inventories, primarily NIOSH approved N95s, including many models that were not previously cleared as surgical N95s (Plana, et. al. 2021, Table 1).

(3) *Authorized the use of properly decontaminated N95s.* The FDA authorized use of decontaminated NIOSH approved N95s and certain powered air purifying respirators. These expansions were incorporated in a revised EUA on March 28, 2020

(4) *Resolved liability uncertainties.* Congress clarified the availability of liability protections for sale and use of FFRs approved under this EUA and subsequent revisions to it. The Families First Coronavirus Response Act (CARES) signed into law on March 18, 2020, clarified and expanded the availability of certain liability protections through October 1, 2024. This was a response to concerns expressed by manufacturers, distributors, and users that these expanded N95 uses might be a target for future liability litigation.[67]

(5) *Relaxed regulations to allow use of imported "N95-like" respirators.* On March 24, 2020, the FDA issues an EUA permitting importation and use in medical settings of "equivalent" or "N95-like" non-NIOSH approved FFRs that were manufactured or sold in other countries and satisfied that country's (similar) regulatory requirements. However, this EUA did not cover non-NIOSH approved respirators manufactured in and supposedly meeting regulatory requirements in China. (Imports of NIOSH approved respirator models were treated as domestic NIOSH approved respirators, though this required clarification by the FDA.) However, it is unlikely that permitting imports of non-NIOSH approved FFRs from countries other than China, Taiwan, and Mexico had much of an effect on the supply of FFRs in the U.S. in 2020.

(6) *Further relaxed regulations to allow use of "N95-like" respirators manufactured in China*. On April 3, 2020, the FDA authorized importation and use in medical settings of non-NIOSH approved respirators from China that (supposedly) met Chinese KN95 regulatory requirements. There had been an enormous expansion in the production of FFRs and surgical masks in China in very early 2020 as the

[65] https://stacks.cdc.gov/view/cdc/86280; https://www.cdc.gov/niosh/npptl/respirators/testing/ExpiredN95results.html. accessed August 15, 2021.
[66] Rebecca Heilwell, "As millions of respirators keep surfacing, health care workers say they need more," VOX, April 3, 2020. https://www.vox.com/recode/2020/4/1/21196941/coronavirus-n95-mask-respirator-shortage-trump , accessed June 30, 2021.
[67] https://www.jdsupra.com/legalnews/cares-act-expands-liability-protections-69776/ accessed August 15, 2021.

pandemic surged to meet local Chinese demand. Indeed, for some months China restricted exports and increased imports of respirators, including from the U.S. (e.g. from 3M). By April 2020, new COVID cases in China were very low (based on the official Chinese data) and Chinese manufacturers began to export respirators in large quantities.

The data for U.S. imports of N95-like respirators and surgical masks during this time period demonstrate that the FDA's relaxation of restrictions on imports of Non-NIOSH certified N95-like respirators, especially imports from China, had a very substantial impact on respirator supplies available in the U.S. for use by HCP and ERP. The information comes from a data base compiled by the U.S. International Trade Commission (ITCb 2021). The ITC did not define a separate product code for N95 and N95-like respirators until July 2020. The previous code included respirators, as well as surgical masks, other masks, and related textile products. Table 2 displays the value of imports of respirators, surgical masks and other masks for this ITC product category for the period January 2020 through June 2020. Table 3 contains data for imports of NIOSH certified N95s and N95-like respirators, a narrower product category subsequently created by the ITC in response to the interest in N95s during the pandemic, for the July 2020 through December 2020 period. Table 4 contains the respirator import data for this new and narrower ITC product category for January to June 2021. It is evident that China accounts for the bulk of the imports of respirators and masks with Mexico[68] a distant second. Moreover, Chinese exports to the U.S. were flat through March 2020 and then expanded very significantly starting in April after the Chinese pandemic was brought under control in China and coincides with the April 2020 EUA (and subsequent revisions to it) authorizing imports of non-NIOSH approved Chinese respirators (KN95) for use by HCP and ERP.[69]

[INSERT TABLE 2]

[INSERT TABLE 3]

[INSERT TABLE 4]

Over 1.7 billion NIOSH approved N95 and N95-like respirators covered by the FDA EUA's governing the use of imported non-NIOSH/FDA approved respirators were imported into the U.S. between July and December 2020, about half of the 3.5 billion FFR "need" estimated earlier by HHS. Imports then declined dramatically after September 2020. In 2021, imports continued to come primarily from China and

[68] The imports from Mexico may be N95s manufactured by U.S. companies that previously moved some or all of their manufacturing to Mexico.

[69] Separate ITC data for ocean freight shipments (only) of respirators indicates that the increase in imported respirators from China via ocean freight began in May and June 2020 after the EUA was issued (ITCa 2020, page 94).

Mexico. As discussed further below, the decline in respirator imports reflects the fact that the supply-demand balance for N95s and N95-like respirators started to improve significantly by early 2021.

Unfortunately, based on NIOSH sampling and testing data many of the imported respirators were of poor quality and did not meet either NIOSH or Chinese KN95 performance criteria. On May 7, 2020 and again on June 6, 2020, the EUA authorizing imports of non-NIOSH approved FFRs manufactured in China was clarified and the respirators supplied by over 50 Chinese companies were removed from the EUA's approval list (Appendix A of the EUA) because they either did not meet the 95% filtering standard or were decontaminated rather than new respirators. The Boston Hospital FFR inventory data indicates that by October 2020 there were 25 models of Chinese KN95s in those inventories, many of which may not have been cleared by the FDA under the EUA for use by HCP requiring respiratory protection from infection.[70]

These FDA EUAs increased supplies of N95 and N95-like respirators primarily by relaxing regulatory restrictions that pre-pandemic had permitted only NIOSH approved and FDA cleared surgical N95 respirators in health care and emergency response settings to protect workers from the COVID-19 infection. These actions did not require rapid physical expansion of FFR production but instead expanded the definition of FFRs eligible for protecting HCP and ERP from infection from the COVID-19. In some sense these supply-increasing initiatives were both fast and "free."

(7) *Federal government contracting and financial support to increase domestic production of N95s and allocating them to HCP and ERP.*

During the early months of the pandemic there was also controversy about whether and how the President would invoke the Defense Production Act of 1950 (DPA) for critical PPE that were determined to be in short supply.[71] The DPA gives the President the authority to order the allocation of materials, services and facilities to support national defense needs. The DPA also gives the President the authority to contract for supplies and equipment, to make loans to support increased production, and to order the use of private or government owned facilities to install equipment needed to increase supplies. The law further gives the President the authority to restrict exports. Basically, the DPA allows the federal government to get at the front of the line for supplies and equipment, but the federal government still has to pay for the costs of the associated supplies and equipment. The administration of the DPA's authorities is provided by HHS and FEMA.[72] Section 4512 of the DPA also makes illegal "hoarding … for the purposes of resale at

[70] It's a little hard to know which of these donated KN95s were approved (Appendix A of the EUA), which were removed from Appendix A, and which never bothered registering with the FDA. This is because the identification information on the KN95s often carry a different company name from what appears on Appendix A. We do know that there were many counterfeit respirators and respirators that did not meet Chinese KN95 performance standards that entered the U.S. during this period.

[71] https://www.fema.gov/disaster/defense-production-act Accessed July 30, 2021

[72] https://www.fema.gov/disaster/defense-production-act accessed August 30, 2021.

prices in excess of the prevailing market price" (often referred to in press releases as "price gouging") of critical equipment, goods and services specified by the President. These provisions can lead to fines and/or imprisonment if an individual or organization is convicted.

The President first invoked the DPA for critical supplies and equipment needed to fight the pandemic on March 18, 2020 in response to the growth in COVID cases, in an effort to increase domestic supplies of ventilators, N95 respirators and other medical supplies, testing resources, treatments and vaccines needed to respond to the COVID-19 pandemic. One of the administration's first specific actions under the DPA was an order on April 2, 2020 targeting 3M, and ordering it to increase domestic supplies of respirators and to prioritize supplying N95s to American health care workers and first responders.[73] The order was accompanied by requests that 3M stop exports of N95 respirators and to start importing respirators from its manufacturing facilities in other countries.[74] This led to a conflict with 3M, the major N95 respirator producer in the U.S., which pre-covid routinely exported N95s to Canada and several Latin American countries. 3M also had recently exported respirators from the U.S. to China, in response to China's requests for N95 respirators earlier in the year to support its response to the COVID-19 epidemic there. This controversy was quickly resolved by an agreement with 3M that permitted continued exports to Canada and Latin American countries and allowed 3M to fill a 10 million respirator order from China.[75] 3M also agreed to import 166.5 million NIOSH approved N95 and KN95 respirators from its Asian production facilities over three months beginning in April 2020.[76] These N95s were delivered to FEMA for distribution to the states and then on to health care providers for use by HCP and ERP.[77] The number of respirators ultimately delivered pursuant to this agreement increased to 228 million over six months beginning in April 2020.[78] These imports were about equal to ten times 3M's monthly domestic N95 production pre-COVID, occurred at a time when domestic production was just starting to ramp up, and other imports mainly from China were just beginning to become available in large quantities.

The impact of the activation of the DPA alone would have been limited without appropriations by Congress since the purpose of using the DPA to increase N95 supplies were both to increase domestic

[73] https://trumpwhitehouse.archives.gov/presidential-actions/memorandum-order-defense-production-act-regarding-3m-company/ accessed July 30, 2021
[74] https://www.ehstoday.com/ppe/article/21128174/3m-will-import-166-million-respirators-from-china accessed August 30, 2021
[75] https://www.industryweek.com/operations/safety/article/21128168/3m-will-import-166-million-respirators-from-china-as-trump-tiff-terminates accessed August 30, 2021
[76] https://www.ehstoday.com/ppe/article/21128174/3m-will-import-166-million-respirators-from-china accessed August 30, 2021
[77] https://multimedia.3m.com/mws/media/1831871O/respirators-from-asia-imported-and-distributed-by-fema-technical-bulletin.pdf accessed June 30, 2021.
[78] 3M Corporation, "Respirators from Asia Imported and Distributed by FEMA," September 2021 (Revision 5), https://multimedia.3m.com/mws/media/1831871O/respirators-from-asia-imported-and-distributed-by-fema-technical-bulletin.pdf . Accessed December 1, 2021.

supplies as well as to reallocate supplies from other purchasers to HCP and ERP needing protection from infection by the COVID-19. The Coronavirus Preparedness and Response Supplemental Appropriations Act (March 6, 2020),[79] appropriated $8.3 billion in emergency funding for state and local governments to prepare for and respond to COVID. Among many other things, the subsequent CARES Act (March 27, 2020).[80]), provided $45.4 billion to support continuing efforts to respond to the pandemic, $100 billion to HHS to be allocated to hospitals and providers to support COVID response efforts, $16 billion to rebuild the Strategic National Stockpile, $14.4 billion to the Veterans Administration to support care for its patients, and about $5 billion to the Department of Defense to support the Defense Industrial Base and implementation of the Defense Production Act. Most of these funds could be used to purchase equipment and supplies and to otherwise support increases in production capacity of supplies critical to the COVID response effort. Indeed, during the first several months of the pandemic, the federal government became the largest purchaser of N95 respirators and other PPE in the world (IFC, 2020, p. 97). This facilitated the rapid expansion of domestic supplies of N95 respirators by about 500% by the end of 2020.

7. Market Segmentation, Rationing, and Pricing Policies Announced by Legacy Domestic Manufacturers

As soon as it was realized that COVID-19 might become a pandemic, 3M and other domestic N95 respirator suppliers all quickly committed to expand supplies in response to the dramatic increases in the demand for N95 respirators. 3M, Honeywell, Moldex and apparently other domestic manufacturers also committed not to raise their wholesale prices and urged their distributors to maintain prices at pre-pandemic levels as well. 3M began to ramp up global production of N95s in January 2020 as it became clear that infections in China and then Italy would seed a global pandemic. 3M first committed to increasing domestic production from 22 million/month in December 2019 to 50 million/month by June 2020[81] and then to more than 95 million/month by the winter of 2020.[82] 3M also opened a manufacturing facility in Canada, reducing the need to export N95s from the U.S. to Canada.[83] Moldex also announced that it was ramping up N95 production in January 2020, though it did not announce by how much.[84] It subsequently added production

[79] https://www.congress.gov/116/plaws/publ123/PLAW-116publ123.pdf. accessed June 15, 2021.
[80] https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf accessed June 15, 2021.
[81] 3M press release dated April 6, 2020. https://news.3m.com/3M-and-Trump-administration-announce-plan-to-import-166-5-million-additional-respirators-into-the-United-States-over-the-next-three-months accessed June 30, 2020.
[82] Austen Hufford,"N95 Mask Makers Ramp Up Production to meet U.S. COVID-19 Demand," The Wall Street Journal, July 17, 2020 (Table). https://www.wsj.com/articles/n95-mask-makers-ramp-up-production-to-meet-u-s-covid-19-demand-11594987201 accessed June 30, 2021.
[83] https://sciencecentre.3mcanada.ca/articles/first-batch-of-canadian-made-3m-n95-respirators-manufactured-and-delivered accessed June 30, 2021.
[84] https://www.moldex.com/moldex-responds-to-coronavirus-pandemic-with-increased-manufacturing/ accessed June 30, 2020.

lines in Tennessee and in California. In March 2020, Honeywell announced investments to increase production initially to 20 million respirators/month by adding production capacity at its facilities in Rhode Island and then Phoenix and to 40 million/month by the end of the year.[85] In December 2020, Honeywell delivered 225 million N95 respirators and surgical masks and the FT reported that it had expanded N95 production capacity to 1 billion respirators per year (ITC 2020, page 91).[86] O&M Halyard and Prestige Ameritech also announced increases in N95 production. Total domestic N95 production was estimated by FEMA to have risen to 180 million/month by Winter 2020-21 or about 2 billion N95 respirators per year, roughly five times pre-covid domestic production.[87]

U.S. government contracts helped to support the increases in domestic production.[88] The financial support took two primary forms. First, contracts to supply respirators to FEMA and other government agencies like the Veterans Administration (VA) and the Department of Defense (DOD). Second, contracts to increase production capacity. In April 2020, HHS signed contracts with 3M, Moldex, Honeywell, O&M Halyard, and Draeger (a German company, which planned to manufacture the respirators at a new plant in the U.S.)[89] for 600 million respirators to be delivered to the Strategic National Stockpile over the next 18 months (Congressional Research Service (2020), page 20).[90] In April 2020 FEMA signed a contract with Prestige America for 12 million N95 respirators. In May 2020, HHS signed a contract with Louis M. Gerson for over 7 million respirators.[91] As discussed further below, the contract prices were all below $1/respirator

[85] https://www.honeywell.com/us/en/news/2020/03/n95-mask-and-the-coronavirus-more-production-underway accessed May 15, 2020; https://www.honeywell.com/us/en/press/2020/03/honeywell-further-expands-n95-face-mask-production-by-adding-manufacturing-capabilities-in-phoenix accessed May 15, 2020. Honeywell 2020 Annual Report, page 11.

[86] U.S. International Trade Commission, December 2020, page 91; Andrew Edgcliffe-Johnson," Manufacturers warn U.S. must do more to maintain fragile PPE production," The Financial Times, April 13, 2021. https://www.ft.com/content/c04571c0-69d9-49a6-b1a0-40a6cfa892fe

[87] Austen Hufford,"N95 Mask Makers Ramp Up Production to meet U.S. COVID-19 Demand," The Wall Street Journal, July 17, 2020 (Table). https://www.wsj.com/articles/n95-mask-makers-ramp-up-production-to-meet-u-s-covid-19-demand-11594987201 accessed June 30, 2021; Statista, "Production volume of N95 masks in the United States in January 2020 and winter 2020," https://www.statista.com/ accessed August 15, 2020; John P. Powlowczyk, White House Coronavirus Supply Chain Task Force, https://www.hassan.senate.gov/imo/media/doc/SCTF%20Demand%20PPE%20Chart.pdf . accessed September 30, 2021.

[88] Some states also provided modest financial support to help to finance increases in production capacity. e.g. "Baker-Polito Administration Announces Grants to Boost Production of Personal Protective Equipment, Critical Supplies in Massachusetts to support COVID-19 Response," May 21, 2020. https://www.masslifesciences.com/baker-polito-administration-announces-grants-to-boost-production-of-personal-protective-equipment-critical-supplies-in-massachusetts-to-support-covid-19-response/ accessed September 1, 2021.

[89] Katelyn Polantz, CNN, "600 million facemask order won't help fight coronavirus epidemic at its peak," April 7, 2020. https://www.cbs58.com/news/600-million-facemask-order-wont-help-fight-coronavirus-epidemic-at-its-peak accessed June 30, 2021.b

[90] https://news.bloomberglaw.com/health-law-and-business/honeywell-draeger-among-manufacturers-in-line-to-produce-masks accessed August 15, 2021.

[91] https://projects.propublica.org/coronavirus-contracts/contracts/75A50120C00104 accessed accessed August 30, 2021.

consistent with these manufacturers' commitment not to raise wholesale prices. The Department of Defense (DOD), the Veterans Administration (VA) and other federal agencies signed additional contracts for respirators with O&M Halyard, 3M, Honeywell, Louis M. Gerson, Moldex and with Alpha Protech, and other smaller manufacturers.[92] Altogether, the ProPublica Coronavirus contract data base which I have relied upon (ProPublica 2021) reports over 160 federal agency contracts for N95 respirators directly with N95 manufacturers or with procurement and distribution intermediaries. The GAO found that by July 2020 federal agencies had committed $1.2 billion to purchase N95 respirators, equivalent to roughly 1.5 billion N95s,[93] of which roughly half eventually were added to the National Strategic Stockpile.

The HHS/FEMA contracts were designed to help to increase supplies of N95 respirators and not just to reallocate them from other distribution channels to FEMA for onward distribution to be used by front line HCP and ERP. The contracts were for delivery over 18 months and not for delivery as soon as possible. They were focused on providing financial security to N95 manufacturers increasing supplies. Perhaps more importantly, the contracts did not use the DPA to put the deliveries under these contracts at the front of the line, but rather specified that they were not to disrupt private sector distribution contracts (Congressional Research Service, (2020), page 20).

Federal agencies also signed contracts to provide financial support to N95 manufacturers specifically to increase production capacity that could be relied upon to manufacture more N95s if needed. Unfortunately, the publicly available information is limited. In October 2020 DOD, in coordination with HHS, signed a contract with 3M for $126 million to increase production capacity by 26 million N95s per month.[94] The GAO reports that through May 2021, DOD contracts with manufacturers to expand production capacity helped manufacturers expand capacity by 58 million respirators per month or about 700 million N95s per year.[95]

There was also concern that supplies of non-woven melt-blown polypropylene would become a significant constraint in the global supply chain for N95 respirators during most of 2020, especially affecting the availability and cost of these materials to potential entrants.[96] The demand for this filtering material increased dramatically reflecting the increase in the global demand for N95 and N95-like

[92] https://projects.propublica.org/coronavirus-contracts/vendors/louis-m-gerson-co-inc accessed August 15, 2021; https://projects.propublica.org/coronavirus-contracts/contracts/75A50120C00047 accessed August 30, 2021.
[93] United States Government Accountability Office (GAO), "COVID-19 Contracting, A Report Congressional Committees," . GAO-20-632, July 2020.
[94] https://www.defense.gov/Newsroom/Releases/Release/Article/2178152/dod-awards-126-million-contract-to-3m-increasing-production-of-n95-masks/ accessed August 30, 2021 This may be two contracts.
[95] United States Government Accountability Office (GAO), "Covid-19, Report to Congressional Committees,"GAO-21-551, July 2021, page 96.
[96] Martha Mendoza, et. al. , "Textile's scarcity leads to shortages of N95 masks," The Associated Press, September 11, 2020. https://www.dispatch.com/story/business/2020/09/13/shortage-still-plagues-n95-mask-material/42614143/ accessed August 21, 2021; International Finance Corporation, December 2020, page 33.

respirators. HHS and DOD invested a total of $16 million in Lydall, Inc. and Hollingsworth and Vos Co. to increase domestic production of this filtering fabric. Lydall reported that it had increased its domestic capacity to produce enough melt-blown polypropylene material for 140 million N95s per month, up from 21 million per month at the start of the pandemic.[97]

8. Counterfeit Respirators and Fraudulent Sales Practices

Counterfeit and sub-standard versions of products can adversely affect demand for and prices of legitimate products. This is why luxury brands like Chanel, Louis Vuitton, Prada, Fendi, Gucci and Dior work aggressively to stamp out forgeries.[98] However, in the case of N95 respirators it's not "just" about the money. Counterfeit and misrepresented respirators that do not meet expected performance criteria can adversely affect the health of those who rely on them for respiratory protection.[99] Moreover, HCP likely were more reluctant to use the imported respirators than to use the surgical N95 respirators and standard N95 respirators manufactured by familiar companies like 3M if they were concerned that the imports did not meet required performance standards.

Offers of sub-standard or counterfeit respirators by unauthorized distributors, brokers and other intermediaries to meet the residual demand by health care providers that could not be filled by the limited supplies available to priority health care organization via HHS/FEMA contracts or through the domestic manufacturers' authorized distribution channels immediately became a problem at the beginning on the pandemic. Hospitals and other health care providers were sometimes in various residual markets as they struggled to close the gap between supply and BAU demand for N95s beyond what was allocated to them by the manufacturers and distributors or by FEMA and supporting state agencies. There is no easy way for purchasers of N95s to distinguish legitimate from counterfeit respirators. The difference between the critical melt-blown non-woven propylene layer and an inferior synthetic material requires analysis and expertise that the typical purchaser did not have. This situation affected buyers of all types who had to turn

[97] Andrew Edgecliffe-Johnson," Manufacturers warn U.S. must do more to maintain fragile PPE production," The Financial Times, April 13, 2021. https://www.ft.com/content/c04571c0-69d9-49a6-b1a0-40a6cfa892fe accessed August 31, 2021; Shira Stein, "U.S. to continue needing 2.2 billion N95s per year post-pandemic," Bloomberg Law, January 12, 2021. https://news.bloomberglaw.com/health-law-and-business/u-s-to-continue-needing-2-2-billion-n95s-per-year-post-pandemic accessed July 15, 2021. https://projects.propublica.org/coronavirus-contracts/search?q=lydall accessed July 15, 2021.

[98] Don-Alvin Adegeest, "Global Counterfeiting Costs Luxury Brands Billions of Dollars," May 19, 2018. https://fashionunited.uk/news/fashion/global-counterfeiting-costs-luxury-brands-billions-of-dollars/2018051929734 accessed August 1, 2021.

[99] The Partnership for Safe Medicines, "Fake N95 Masks Threaten Our First Responders and Healthcare Workers," May 27, 2020. https://www.safemedicines.org/2020/05/covidscams-may-27-masks.html . Accessed July 16, 2020.

to smaller distributors and foreign manufacturers outside of the authorized distribution channels to fill their residual needs. Counterfeit respirators became a problem in many other countries as well.[100]

The CDC issued guidance to help buyers to distinguish real from counterfeit respirators. The guidance included examples of counterfeit respirators and "home brew" methods to distinguish legitimate and fake respirators. It has been updated continuously, most recently on January 2022, as fraudulent activity continues to be a problem.[101] Customs and Border Patrol (CBT) agents also seized millions of imported counterfeit masks at the border.[102] Attorney General William P. Barr created the COVID Hoarding and Price Gouging Task Force in late March 2020[103] and the Department of Justice also pursued cases of sales of defective and misbranded masks as well as the other types of fraud, hoarding and so-called price gouging pursuant to authority in the DPA (more on price gouging below).[104] Several state Attorney Generals brought similar cases under state law.[105]

Counterfeits were not good for business for manufacturers of legitimate N95 and N95-like respirators that met required performance standards. Respirator manufacturers posted warnings about counterfeit respirators. Chinese manufacturers of legitimate NIOSH approved N95 and legitimate EUA authorized KN95 respirators such as Makrite, BYD, and Powecom also posted warnings about counterfeit respirators and advised potential buyers to deal only with authorized distributors.[106] 3M used a "safeguard" system for some models that made it possible for purchasers to use code numbers on the boxes that the masks came in to verify authenticity in real time.[107] It also published lists of fake lot numbers for its two

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[100] e.g. Australia, https://www.safework.nsw.gov.au/safety-alerts/safety-alerts/supply-of-fake-face-masks accessed August 17, 2020; UK, "Use of face masks designated KN95 Safety Alert," accessed July 7, 2020 https://www.hse.gov.uk/safetybulletins/use-of-face-masks-designated-kn95.htm accessed August 19, 2020; and Canada, "Medical Device Respirator Recalls," June 23, 2020, https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73137a-eng.php accessed July 7, 2020. Note that a Powecom KN95 appears on the Canadian list, though there are legitimate Powecom KN95s as well as discussed below. The largest authorized distributor in the U.S. is bonafidemasks.com. https://bonafidemasks.com/largest-powecom-distributor-in-u-s- accessed August 31, 2021.

[101] https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html accessed September 3, 2021.

[102] e.g. Jonathan Williams, "Federal agents seize more than 11 million fake N95 masks," The Hill, February 17, 2021. https://thehill.com/policy/national-security/539322-federal-agents-seize-more-than-11-million-fake-n95-masks. https://www.cbp.gov/newsroom/local-media-release/over-65k-counterfeit-3m-masks-seized-chicago accessed February 20, 2021; https://www.cbp.gov/newsroom/local-media-release/108000-counterfeit-3m-surgical-masks-stopped-cincinnati-cbp . accessed June 30, 2021.

[103] https://www.justice.gov/file/1262776/download accessed June 17, 2020.

[104] e.g. The United States Attorney's Office, District of New Jersey, "Chinese Manufacturers Charged with Exporting Defective and Misbranded Masks Falsely Purporting to be KN95 Respirators," June 17, 2020. https://www.justice.gov/usao-nj/pr/chinese-manufacturer-charged-exporting-defective-and-misbranded-masks-falsely-purporting . accessed August 1, 2021.

[105] Julie Steinberg, "E-bay Hit with Suit Alleging Price Gouging During COVID-19," Bloomberg, May 5, 2020. https://news.bloomberglaw.com/class-action/ebay-hit-with-suit-alleging-price-gouging-during-covid-19 accessed August 1, 2021.

[106] http://www.makrite.com/scam-notice-14/ ; accessed September 3, 2021; https://en.byd.com/news/byd-warns-customers-about-counterfeit-ppe-posing-as-authentic-byd-products/ accessed September 3, 2021.

[107] https://www.3m.com/3M/en_US/worker-health-safety-us/3m-safeguard/ . accessed September 3, 2021.

most popular U.S. models (1860 and 8210).[108] Powecom used an anti-fake label that allowed the buyer to scan a QR code and check the authenticity of the package on the company's web site.[109]

As the largest and most important manufacturer of N95 respirators in the U.S. and with manufacturing facilities in several other countries as well, 3M had an interest in stamping out counterfeit versions of its respirators, associated fraudulent sales practices, including offers at very high prices that appeared to be inconsistent with 3M's commitment to maintain prices at pre-pandemic levels. In short, 3M had a large stake in the integrity of the N95 market. In cooperation with law enforcement, 3M launched the most aggressive program in the U.S. and globally to combat these types of frauds. It also maintained global fraud hotlines and based on personal experience they were quite responsive. Its antifraud activities as of July 14, 2021, are summarized in Table 5 which provides a sense for the magnitude of these fraudulent practices.

[INSERT TABLE 5]

9. Entry of Domestic Manufacturers

While the federal government focused on expanding domestic supplies from the legacy manufacturers there was also some expectation that excess demand for N95s would attract entrants into N95, especially since new entrants were under no obligation to adopt allocation and pricing commitments as did the incumbents. As of a survey I performed in September 2021, I identified twenty-three U.S. companies, including Ford and GM, that received NIOSH approval for one or more N95 respirator models for the first time in 2020 and 2021. Table 6 lists the entrants that I identified, the number of N95 models that had received NIOSH approvals by September 2021, and information on whether or not these companies were still in business in September 2021. Note that only two of the models manufactured by new entrants were FDA cleared surgical N95 respirators.[110]Thus, if and when the EUA permitting the use of NIOSH approved standard as well FDA cleared surgical N95 respirators for HCP and ERP respiratory protection is revoked, almost all of these models will only be available for industrial and personal uses; unless of course there is a permanent change in the pre-covid OSHA, CDC and FDA guidance and regulations, which would be a sensible thing to do.

For a new entrant, starting from scratch to NIOSH approval and arranging for distribution and sales can be fairly time consuming. The materials for the respirators must be acquired, the respirators

[108] https://multimedia.3m.com/mws/media/1934748O/3m-counterfeit-communication-letter.pdf updated July 14, 2021. accessed August 15, 2021.

[109] http://www.powecom.com/verification.html accessed July 1, 2021.

[110] After my September 15, 2021 survey five additional companies received their first NIOSH approvals for an N95 by the end of 2021. Two of these were surgical N95 models. AirBoss Defense (10/14/2021), AMD Medicom (10/19/2021—surgical), ivWatch (11/8/2021-- surgical), Phenotype Pharmaceutical (12/20/2021), Pure Environmental—Shatkin (12/10/2021). The home office of AMD Medicom is in Canada with manufacturing facilities in several countries, including the U.S.

manufactured, a sample of completed respirators submitted to NIOSH for testing, approval received based on test results, and distribution and sales arrangements made. NIOSH implemented a temporary Public Health Emergency (PHE) approval process which expedited the certification process, though if N95 manufacturers that relied on this approval process want to continue to offer their respirators to meet OSHA, NIOSH and FDA requirements after the HHS declared health emergency is over, they will have to go through the normal NIOSH and FDA approval processes.[111] Ten of the companies in Table 6 made use of this expedited process (all for standard N95s) and I have no way of knowing whether they will ultimately go through the full NIOSH process. Aside from Ford and GM, which manufactured respirators for internal use, suppliers' needs, and donations,[112] the other entrants were all relatively small companies without previous experience with N95 respirator manufacturing and sales. Seven of the entrants did not receive their first NIOSH certifications until 2021. By then the supply demand balance had improved considerably and prices in the "residual" open markets were falling. As far as I can tell, none of these manufacturers received direct federal contracts for N95 respirators. They had to rely instead on attracting orders from procurement and distribution intermediaries which themselves had contracts or hoped-for contracts with the federal, state, industrial, and other purchasers and at least in part on company web sites or e-commerce sites like Amazon to make direct sales, including to individuals.[113] Despite the distribution challenges that they faced most of the entrants were still offering N95s for sale as of mid-September 2021; one advertised that it had produced 90 million N95 respirators by June 1, 2021.[114] Two listed "sold out" on their company web sites without any indication that they planned to manufacture more respirators for sale. And five more U.S. firms received their first NIOSH approvals after my September 15, 2021 survey, suggesting that entry continued to be expected to be profitable.

[INSERT TABLE 6]

Given that there were fewer than 10 legacy domestic N95 manufacturers active pre-pandemic, and the number producing N95s in the U.S. had been declining prior to the pandemic, it seems to me that this is a surprisingly large number of entrants. Despite concerns expressed in some expert reports (IFC 2020),

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[111] In February 2021 NIOSH announced that it would not accept new PHE applications. https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2021-1032.html ; In July 2021, the CDC announced that the PHE process would be terminated after the declared public health emergency comes to an end. At that time those with PHE approvals would have to go through the regular NIOSH approval process to continue to be considered to be NIOSH approved N95 respirators. https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2021-1036.html . accessed September 10, 2021.

[112] https://corporate.ford.com/articles/products/ford-producing-respirators-and-masks-for-covid-19-protection.html; https://media.gm.com/media/us/en/gm/news.detail.html/content/Pages/news/us/en/2020/jul/0714-n95.html accessed August 15, 2021.

[113] ProPublic contract data base and company web sites

[114] https://acin95.com/after-making-90-million-masks-a-lakeland-manufacturer-isnt-stopping-after-making-90/ accessed September 15, 2021.

the supply of raw materials and manufacturing machinery does not appear to have been a significant barrier to entry. Securing large sales contracts and distribution through more than just a few e-commerce sites appear to have been more challenging than obtaining the necessary materials and equipment to manufacture the respirators. As discussed further below, by Spring 2021 several of the new entrants reported having difficulty making sales, especially large volume sales, at prices that covered their costs; some entrants indicated they there were facing financial difficulties by Spring and Summer 2021.

10. Supply Side Dynamics: Summary

1. Despite what appeared to be early chaos regarding procurement of N95s, other PPE, ventilators, etc., in the end, the primary government agencies generally made good decisions regarding supplies and allocations of N95 and N95-like respirators. The federal government and legacy private sector manufacturers and intermediaries worked well together in pursuing the stated public health goals about which there was, perhaps surprisingly, broad agreement. The overlapping jurisdictions of CDC, NIOSH, FDA and OSHA could have created time consuming bureaucratic hurdles but in fact they worked well together. The FDA, not known for decision making speed, issued EUAs fairly quickly that effectively "created" a large number of N95s for use by HCP and ERP almost overnight.

2. The FDA's decision to issue an EUA which allowed NIOSH certified standard N95s to be used in most health care settings, quickly increased to supply of NIOSH certified N95s available for respiratory protection against infection for HCP and ERP. Since the domestic manufacturers and their authorized distributors allocated most of these respirators to priority HCP/ERP organizations either via government contracts, especially contracts with HHS/FEMA, DOD and the VA, for distribution to priority organizations with HCP and ERP needs, or through arrangements with authorized medical supply companies, the fraction of N95s available for traditional industrial applications declined. The economic contraction and guidance provided by OSHA to reduce utilization of N95s in industrial applications, mitigated adverse effects of this reallocation. As domestic N95 supplies increased quickly during 2020 and 2021, the absolute number of N95s available through authorized dealers for traditional industrial uses increased from their initial very low levels.

3. An unknown number of N95s that were in private stockpiles, expired N95s, or N95s that may have leaked out the primary domestic HCP/ERP priority allocation and distribution chains were available to unauthorized distributors and brokers and on some new e-commerce sites at prices roughly six times the pre-pandemic MSRP. Some of these legacy N95 were also donated to HCP and ERP organizations.

4. The FDA's decision to issues an EUA authorizing the use of imported Non-NIOSH certified N95-like respirators (arguably) meeting similar filtration and other performance criteria to those applied in the U.S. by NIOSH, but established and supposedly enforced by other countries, especially KN95s from

China, led to a dramatic increase in respirator supplies available to HCP/ERP as well as in industrial applications based on OSHA guidance starting in April 2020. There was no formal or informal allocation or pricing policies for these imported respirators. They were sold through a mix of authorized dealers, brokers, existing and new e-commerce sites at prices substantially higher than they could fetch as the supply/demand balance improved during 2021. These price patterns are discussed in more detail below.

5. The federal government's longer term contractual commitments and financial support directed specifically to increasing production capacity provides stable incentives for manufacturers to invest in increasing production capacity, helped to increase supplies and investments in additional production capacity.

6. The penetration of counterfeit and underperforming respirators was quite significant. One source estimated that 60% of the KN95s imported into the U.S. from China were counterfeit or underperforming and many counterfeit KN95s remained on the market after the EUA authorizing their use in health care settings, and associated OSHA guidance for industrial settings, was revoked in June 30, 2021, just as public health experts began to promote "better masks" to the public, meaning N95, KN95, and KR94 (Korea) respirators.[115] These imported counterfeit respirators continue to be available in the open market. While the initial concerns focused on imported KN95s from China, counterfeit N95s became a problem for all domestic and foreign manufacturers selling legitimate masks, including 3M.

7. The diffusion of counterfeits may have been stimulated in part by the market segmentation discussed above. During 2020 at least, there remained significant excess BAU demand by health care organizations for NIOSH certified N95s beyond what was allocated to them by FEMA, state agencies and through the legacy manufacturer/authorized distributor pipelines. This excess BAU demand had to be filled with imported N95-like respirators, from private stockpiles, expired respirators and leakage from the manufacturer-FEMA-authorized distributor pipelines which allocated a large fraction of domestic NIOSH certified N95s to HCP and ERP. This excess demand created sales opportunities for suppliers of counterfeit respirators, especially targeting smaller purchasers, including individuals, which did not have established relationships with authorized distributors and relied on inexperience distributors, fly-by-night brokers, and e-commerce sites like e-bay without HCP/ERP rationing and fair pricing policies.

[115] Andrew Jacobs, "Counterfeit COVID Masks Are Still Sold Everywhere, Despite Misleading Claims," The New York Times, December 1, 2021, https://www.nytimes.com/2021/11/30/health/covid-masks-counterfeit-fake.html . Accessed December 15, 2021; Lena H. Sun and Rachel Roubein, "CDC weighs recommending better masks against omicron variant," *The Washington Post*, January 11, 2022. https://www.washingtonpost.com/health/2022/01/10/cdc-weighs-n95-kn95-masks-guidance-omicron/ accessed January 11, 2022.

11. N95 BAU Demand and Supply Come into Balance in Mid-2021

Despite the problems related to counterfeit respirators, mislabeled respirators, and other types of fraud which could have undermined the residual open market for legitimate respirators, by the late spring or early summer of 2021, the physical supply/demand balance for N95 and N95-like respirators was moving from severe scarcity to abundance or even overabundance by mid-2021. Hospitals initially took advantage of the increased availability of N95 and N95-like respirators to build or rebuild inventories which helped to sustain demand as did demand from traditional industrial sectors as the economy rebounded.[116] So too did the Strategic National Stockpile. Reflecting the transition from severe scarcity to abundance Honeywell closed the respirator manufacturing lines in Rhode Island and Arizona which it opened early in the pandemic, though it retained its N95 production at a plant in Houston that it opened earlier in 2021.[117] Some U.S. companies, especially new entrants came under financial pressure as the market softened and imports declined dramatically as demand and residual market prices declined toward pre-pandemic levels.[118] Between July 2020 and June of 2021 imports of N95 and N95-equivalent respirators declined by 95% (See Tables 3 and 4), with China and Mexico the primary remaining suppliers in June 2021.[119]

Reflecting the view that the supply of NIOSH certified N95s had increased sufficiently to end the supply "crisis," along with declining hospitalizations and associated demand, on June 30, 2021, the FDA revoked the EUAs for non-NIOSH approved FFRs as it concluded that the FFR supply emergency was

[116] Emily Kopp, ""Masks stack up in US warehouses as nurses reuse N95 respirators," March 1, 2021. Roll Call. https://www.rollcall.com/2021/03/01/covid-19-n95-respirator-masks/ accessed August 26, 2021; Andrew Edgecliffe-Johnson," Manufacturers warn U.S. must do more to maintain fragile PPE production," The Financial Times, April 13, 2021. https://www.ft.com/content/c04571c0-69d9-49a6-b1a0-40a6cfa892fe accessed August 31, 2021; Shira Stein, "U.S. to continue needing 2.2 billion N95s per year post-pandemic," Bloomberg Law, January 12, 2021. https://news.bloomberglaw.com/health-law-and-business/u-s-to-continue-needing-2-2-billion-n95s-per-year-post-pandemic accessed July 15, 2021. https://projects.propublica.org/coronavirus-contracts/search?q=lydall accessed July 15, 2021; Matt Kempner, "Georgian designs new approved N95 Masks, will anyone buy them?" The Atlanta Constitution, December 9, 2020. https://www.ajc.com/ajcjobs/georgian-devises-new-approved-n95-masks-now-will-anyone-buy-them/DIRHOBXDANGPNEYIO55Z7SDIXM/ . accessed September 15, 2021. This company is Thermpore with 12 employees. Production started in March 2021. It did not expect to sell directly to the public. There is no evidence that it has been successful in finding distributors. https://www.formnfit.com/ . accessed September 15, 2020.

[117] Thomas Black and Shira Stein," Honeywell Closes Two Mask Factories as Face-covering Demand Drops," Bloomberg, June 14, 2021. https://www.bloomberg.com/news/articles/2021-06-15/honeywell-shuts-two-mask-factories-as-face-covering-demand-drops accessed August 1, 2021; https://communityimpact.com/phoenix/chandler/government/2021/02/18/mayor-announces-honeywell-commitment-to-long-term-lease-in-west-chandler/ accessed August 30, 2021.

[118]Andrew Jacobs, "Can't Find an N95 Mask? This Company has 30 million it Can't Sell," The New York Times, February 10, 2021, https://www.nytimes.com/2021/02/10/health/covid-masks-china-united-states.html accessed February 11, 2021. This article indicates that there were nearly 22 new entrants registered. I found 23 in Table 9. They appear to have received little if any direct federal contract support. They made sales through procurement and distribution intermediaries and through online wholesale and retail sites like Google Shopping, Facebook Marketplace, Amazon

[119] 3M and Kimberly-Clark manufacture respirators in Mexico and 3M has a large manufacturing facility in Shanghai.

over. The EUAs that were revoked included the EUAs permitting imported non-NIOSH approved respirators from China to be used in health care settings.[120] NIOSH-approved imported N95s were not affected by this EUA nor were NIOSH-approved standard respirators which had not been FDA cleared as Class II medical devices. OSHA also revised its temporary emergency regulations to conform to the FDA's revocation of the EUA governing imports of non-NIOSH certified respirators. These non-NIOSH certified imported respirators could still be and are being sold to companies that did not need them to meet OSHA requirements and to individuals for personal respiratory protection. By Summer 2021 many models of KN95s were widely available in drug stores, big box stores, garden and home improvement stores, established e-commerce sites like Amazon, and the new e-commerce sites that entered during the pandemic. Many of the new domestic entrants use e-commerce sites to advertise and make sales, including via Amazon. The EUA covering decontamination systems was also revoked on June 30, 2021. In short, the federal government concluded that the "supply crisis" was over.

Hospitalizations began to increase once again in November 2021 as a result of the spread of the Delta and then the Omicron variants and reached a peak that exceeded the Winter 2020/2021 surge peak by early January 2022 and then began to decline in late January 2022. However, at least by early February 2022 as this paper is written, shortages of N95 respirators did not appear to have emerged again as a public policy issue, except perhaps for some surgical respirator models like the 3M 1860. . As discussed in the section on price behavior below, by this time, N95 and KN95 respirators were widely available to organizations and individuals at roughly pre-pandemic prices and public health experts finally began to promote their widescale use as the Omicron surge in infections and hospitalizations emerged and their use outside of HCP and ERP expanded.[121] This reflects the abundant supply of N95s and N95-like respirators stimulated by public and private initiatives during roughly the first year of the pandemic. By January 2022 the federal strategic stockpile had increased its inventory of N95 respirators to 750 million from about 15 million two years earlier and more than double the initial target proposed by HHS. The federal government began to distribute these respirators free to the public in late January 2022.[122]

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[120] https://www.fda.gov/news-events/press-announcements/fda-brief-fda-revokes-emergency-use-authorizations-certain-respirators-and-decontamination-systems

[121] Diti Kohli, "Its time to upgrade your mask, public health experts say," *The Boston Globe,* December 21, 2021. https://www.bostonglobe.com/2021/12/21/nation/its-time-upgrade-your-mask-public-health-experts-say/ . accessed December 27,2021.Emma Platoff and Taylor Dolven, "As experts advise better masks to protect against Omicron, government is starting to provide them," *The Boston Globe*, December 30, 2021. https://www.bostonglobe.com/2021/12/30/nation/experts-advise-better-masks-protect-against-omicron-government-is-starting-provide-them/ accessed December 31, 2021. Clare Ansberry and Nidhi Subbaraman, " Why Cloth Masks May Not be Enough as Omicron Spreads," *The Wall Street Journal*, January 2, 2022. https://www.wsj.com/articles/cloth-face-mask-omicron-11640984082?mod=djemHL_t . accessed January 2, 2022.

[122] Aaron Steckelberg and Bonnie Berkowitz, "Why most of us should be wearing N95 masks," *The Washington Post*, January 20, 2022.

12. Behavior of Prices in Practice: Fragments of Evidence

Did the behavior of prices reflect the allocation, market segmentation and price maintenance policies articulated by the legacy manufacturers and their authorized distributors of N95s? Did N95 prices reflect the changing supply/demand balance which gradually moved from severe scarcity to abundance in 2020 and 2021? While the data available for N95 prices before and during the evolution of the pandemic are fragmentary, the available data make it possible to match N95 prices for several market segments with the policies articulated by domestic manufacturers and the changing supply/demand balance. The price time series and cross-sectional price data show that they are consistent with the policies and actions taken by the federal government and by the legacy N95 manufacturers and their authorized distributors.

(a) Private Sector Rationing, Prices, and Distribution Chains

The federal government and private initiatives and associated rationing, allocation and pricing policies discussed in the previous sections suggest that there emerged at least seven sometimes overlapping distribution channels during various stages of the pandemic in 2020-2021. The importance of each distribution channel changes along with increases in the supply increased over time.

1. Legacy domestic manufacturers ==➔ HHS, FEMA, DOD ==➔ state agencies =➔ health care organizations

a. Priority allocation to HCP and ERP
b. Manufacturer and Federal government price maintenance

2. Legacy domestic manufacturers ==➔ Major health care suppliers ==➔ health care organizations

a. Priority allocation to HCP and ERP
b. Manufacturer and authorized distributor price Maintenance

3. Legitimate imported NIOSH N95 manufacturers ===➔ authorized distributors, other distributors==➔ Health care and other end-users

a. Some priority allocation to HCP and ERP
b. No announced manufacturer or distributor price maintenance

4. Legitimate imported N95-like manufacturers =➔ authorized distributors, brokers, and other =➔ Health care and other end-users

a. Limited priority allocation to HCP and ERP
b. No announced manufacturer or distributor price maintenance

5. Legacy N95s (private stockpiles, expired, leakage from other channels) ==➔ non-authorized dealers, e-commerce, donations ==➔ Various end-users

a. Limited priority allocation to HCP and ERP by major e-commerce sites
b. Some counterfeit/quality and some "fair pricing" rules

6. Counterfeit N95s/N95-like respirators ===➔ non-authorized distributors, e-commerce and brokers ==➔ various organizations and individuals

a. No priority allocation policies
b. No price maintenance

7. New domestic entrants ==➔ various distributors, brokers, e-commerce sites ==➔ Various end-users especially small organizations and individuals

a. No priority allocation policies
b. No manufacturer or distributor price maintenance

From a private market segmentation, rationing and pricing perspective, for simplicity these distribution channels fall into three groups during roughly the first year of the pandemic in the U.S.:

1. Priority rationing to HCP and ERP with manufacturer/distributor price maintenance (P_1)
2. Priority rationing to HCP and ERP with "fair pricing" rules (e.g. Amazon) (P_2)
3. No priority rationing to HCP and ERP and no pricing restraints (P_3)

$P_1 < P_2 < P_3$ (March 2020- March/June 2021)

Price convergence (March/June 2021 rhrough December 2021 when I stopped tracking prices)

In order to compare the time series and cross-sectional behavior of prices, it is useful to define a pre-pandemic benchmark against which to compare prices subject to manufacturer/ authorized distributor price maintenance policies (P_1), partially controlled prices by other distributors (P_2) and uncontrolled or "open market" prices (P3). I decided to use the pre-pandemic MSRP for six popular 3M NIOSH certified models as a benchmark to examine price behavior over time and across N95 and N95 models with different regulatory and utilization attributes. Three models are surgical N95s and three are standard N95s. I chose these models because 3M provided the pre-pandemic MSRPs for these models, they were widely used pre-pandemic, and they do not have exhalation valves. See Table 7.

[INSERT TABLE 7]

The average (unweighted) list price for these respirators is $1.20/ respirator. I was able to find three pre-pandemic (January 2020) offers on e-commerce sites for the 3M 1860 and three for the 3M 8210. The

average retail price for the 3M 1860 was $1.38 and for the 3M 8210 it was $1.00. These prices are very similar to 3M's MSRPs. Accordingly, a pre-pandemic retail price for the 3M 8210 and 1860 in the $1.00 to $1.25 range seems to me to be a good pre-pandemic benchmark price for examining the patterns of actual market prices over time and across distribution platforms during the pandemic. The MSRPs for the other U.S. manufacturers for similar respirators were on the order of 20% lower than 3M's on overage.

3M's respirator press releases stated that "These list prices represent suggested prices to end customers. 3M's prices to authorized distributors are lower than these list prices." And goes on to state that "An end customer's actual prices may be lower than these list prices, as negotiated between the end customer and its chosen distributor."[123] As previously noted, 3M also announced that it would not change its prices during the pandemic and that it would prioritize distribution to customers whose workers have critical needs for respiratory protection from the COVID-19.[124]

As described in the Data Appendix I can observe the prices that the federal government (e.g. HHS/ FEMA) paid for over 600 million N95 respirators pursuant to several large contracts made directly with manufacturers in April and May 2020 when supplies were particularly tight. See Table 8.[125]

[INSERT TABLE 8]

These large early contracts between N95 respirator manufacturers and the lead federal response agencies all came in at less than $1/respirator. The contracted delivery period was over the following 18 months, so the manufacturers had time to expand production to help to meet these and other orders. These prices are all well-below the pre-pandemic 3M benchmark price defined above. The prices in these contracts are effectively wholesale prices and the contracts are for large volumes so we should expect the prices would be below the pre-covid bench MSRPs if the manufacturers adhered to their commitments not

[123] Ibid.

[124] https://www.3m.com/3M/en_US/company-us/coronavirus/ ; https://news.3m.com/3M-CEO-on-COVID-19-response-We-have-a-unique-and-critical-responsibility; https://news.3m.com/2020-07-16-3M-Updates-Ongoing-Actions-to-Combat-COVID-related-Fraud. accessed June 30, 2020.

[125] There are many more contracts in the ProPublica data base but while they list the dollar value of the contracts they generally do not list the quantity of respirators purchased. Without the quantity information a price cannot be calculated. In most cases in Table 8. I had to match the contracts with corporate press releases and media reports to find the associated quantities.

to raise their wholesale prices during the pandemic.[126] These contracts and their associated prices fall in the first category discussed above. The monthly delivery requirements in these contracts alone were about 80% of pre-pandemic domestic N95 sales. By May 2021, the Strategic National Stockpile has distributed over $400 million N95s.[127]

The ProPublica data base lists many additional contracts made by other federal agencies, via contracts with a variety of distribution intermediaries, sometimes directly with manufacturers or the major medical supply intermediaries, but frequently with small distributors and brokers. Unfortunately, only the dollar cost of these contracts and not the quantity of respirators is typically listed. However, as discussed in the Data Appendix, I found information for several contracts entered into by the City of Atlanta and by a few federal agencies with small intermediaries or brokers rather than directly with manufacturers or major established medical supply companies. Table 9 displays this information. These contracts fall in the third category as prices here were not subject to any private or public sector administrative constraints, except for the competitive constraints of relying on competitive bidding processes . Most respirator purchasers did not deal directly with N95 manufacturers and the number of N95 or N95-like respirators they contracted to purchase was typically much smaller than the contracts represented in Table 8. Larger health care organizations typically already had relationships with one or more of the major medical supply companies. Unfortunately, the prices the major medical supply companies and other authorized distributors charged are not publicly available. I performed a very wide media, corporate press release, annual report, and Form 10-k search I could find no complaints or litigation claiming that the major medical supply companies had raised their prices significantly for 3M and other domestic legacy N95 manufacturers.

[INSERT TABLE 9]

The prices in these tables represent roughly the "residual" open market prices (P_2 or P_3) at this time for smaller organizations seeking N95s for HCP and ERP that relied on competitive procurement from brokers and smaller distributors rather than directly with legacy domestic manufacturers. Most of the intermediaries who were the suppliers under these contracts were small and inexperienced in the respirator acquisition business and did not manufacture respirators or any other PPE themselves. In these cases, the intermediaries were bidding to supply respirators that they typically didn't have in stock or under contract in the hope that they could go out into the market and buy them from manufacturers, established distributors with access to manufacturer supplies, private stockpiles and "leakage" from the priority allocation/price

[126] Roughly half of these respirators were to be used to rebuild the Strategic National Stockpile and the rest allocated to the states (free) for distribution to health care and emergency response organization with "front line" health care personnel.

[127] Toner et. al. (2021), page 11 which also cites anecdotal evidence that these distributions created fit-testing challenges.

maintenance chain. However, the established domestic manufacturers would not supply to inexperienced intermediaries during at least the first year of the pandemic and the established medical supply and other distributors which received allocations from domestic manufacturers had their hands full trying to satisfy the needs of their regular customers at this point in the pandemic. The prices in the Table 9 contracts are roughly 6 times the prices in the contracts in Table 8 made directly by the lead federal response agencies with domestic manufacturers and the pre-pandemic MSRPs for 3M N95s. These prices appear to represent the unregulated open market prices for N95s and N95-like respirators sold through competitive bidding to organizations with HCP and ERP needs in Spring 2020. However, delivery commitments have not yet been met in connection with any of the federal contracts, four were ultimately cancelled, and one led to a fraud conviction. It also appears that three of the City of Atlanta KN95 contracts provided for delivery of masks that failed NIOSH filtration tests, and the contracts between inexperienced intermediaries and the federal agencies were typically cancelled before delivery, with one contract leading to fraud litigation and conviction. Contracting for N95 and N95-like respirators with inexperienced intermediaries in the "open market" at this time was clearly perilous.

I turn next to an examination of the prices for two domestic NIOSH certified respirator models, one imported NIOSH certified model, and one Chinese KN95 subject to the EUA discussed earlier offered on Amazon's sites --- either offers by Amazon itself or by third-party storefronts. The patterns of prices of N95s and N95-like respirators on Amazon's platforms provide a particularly interesting illustration of the rationing, market segmentation, and multiple price categories during roughly the first year of the pandemic. Amazon is the second largest retailer in the U.S. (Walmart is first) and by far the largest e-commerce retailer in the U.S. (Walmart is a distant second.) It sells products on its own behalf as well as providing a platform and other sales and distribution services to third party sellers.

Before I discuss the Amazon price data, it is important to understand how Amazon managed its own sales of N95 respirators and those of third-party storefronts hosted on its sites. Beginning in February 2020 Amazon received complaints about fraudulent respirators being offered at extremely high prices by third parties sellers using its sites. In response, Amazon first established criteria for respirators listed on its sites, basically requiring compliance with NIOSH and FDA regulations including those specified in the EUAs as they rolled out.[128] In early March 2020, Amazon began to apply more restrictive anti-fraud criteria for third-party sellers, applied a non-transparent "fair pricing" policy, and removed many sellers from its platforms.[129] (Google and Facebook also ultimately restricted sales of N95s except to organizations with

https://sellercentral.amazon.com/gp/help/external/8DRWTHCU73PGDR5 accessed September 7, 2021.

[129]Nick Statt, "Amazon restricts sales of face masks and hand sanitizer due to coronavirus price gouging," The Verge, March 11, 2020. https://www.theverge.com/2020/3/11/21175719/amazon-restricts-sale-face-masks-hand-sanitizer-coronavirus-price-gouging accessed September 8, 2021.

priority HCP and ERP, although I could find no comparable information on these sites.)[130] Finally, on April 2, 2020 Amazon began to block all sales of N95 respirators except to verified health care organizations with eligible HCP and ERP.[131] Thus, Amazon reinforced most of the policies of 3M and other domestic manufacturers, restricting the sales of N95 respirators offered for sale on its sites to front line HCP and other priority purchasers, rejected allowing sales of counterfeit respirators. It did not enforce the "no price increase" policy adopted by the legacy domestic manufacturers, but it did adopt a "fair pricing" policy and rejected the posting of third-party offers at "excessive" prices, though the definition of excessive prices is not transparent.

Amazon implemented this strategy in the following way. If a customer logged on to an Amazon web site and searched for say "N95," or "respirator," she was sent immediately to a special web site. On that site the customer had to demonstrate that she was a health care provider seeking N95s to protect its "front line" HCP or ERP from infection from the COVID-19. Thus, individuals and on-health care organizations were precluded from purchasing N95s for their own use. Amazon began to slowly allow sales of N95 and KN95 respirators without the HCP/ERP buyer and "fair pricing" restrictions directly on its regular sites in early 2021, but it was not until the summer of 2021 that a large number of N95 and N95-like models were available to the public on Amazon sites at unconstrained prices.[132] For sales of respirators that Amazon was able to acquire and sell as an authorized distributor of N95s, rather than sales by third-party storefronts, it was no doubt under some pressure to follow the "no price" increase policy adopted by the domestic manufacturers.

Accordingly, Amazon's distribution and sales practices during 2020 and early 2021 fall into both the first (authorized distributor and price maintenance) and the second categories (rationing N95 respirators to HCP and ERP, fraud controls, and "soft" "fair pricing" restrictions applied to third party storefront distributors). Amazon's price data are especially useful because I have several consistent sets of prices observations for N95 and N95-like respirators sold on Amazon's platforms from January 2020, prior to the pandemic reached the U.S., through December 2021 when the N95 supply "crisis" had previously been deemed to be over. Specifically, as described in the Data Appendix, I have information from Keepa.com for prices posted on Amazon for two popular NIOSH certified 3M models, one a standard respirator (8210) and one a surgical N95 (1806s) starting in January 2020. They are among the first N95s to receive NIOSH

[130] Joshua Sargent, "Amazon, Facebook and Google N95 mask restrictions at odds with professional advice," SFGate, March 8, 2020. https://www.sfgate.com/shopping/article/amazon-facebook-google-n95-mask-restrictions-15994666.php accessed September 7, 2021.
[131] Annie Palmer," Amazon blocks sale of N95 masks to the public, begins offering supplies to hospitals," CNBC, April 2, 2020. https://www.cnbc.com/2020/04/02/amazon-blocks-sale-of-n95-masks-to-public-begins-supplying-hospitals.html accessed September 7, 2021.
[132] "Amazon Increasing N95 Mask Sales to the Public," Positively Osceola, March 7, 2021, https://www.positivelyosceola.com/amazon-increasing-n95-mask-sales-to-the-public/ accessed September 7, 2021.

certification (1995). The 3M 8210 is a very popular standard N95 respirator for industrial and emergency response worker protection. I view these models as representative of comparable NIOSH-approved respirators manufactured by the established domestic manufacturers. The other domestic manufacturers and some foreign manufacturers produced more or less comparable NIOSH certified standard N95 respirators as well. (As discussed earlier, the use of NIOSH approved standard respirators in most health care settings was first authorized by an FDA EUA at the end of March 2020.) The 3M 1860 was pre-pandemic and still is the "go to" surgical N95 respirator in Boston areas hospitals, and I assume many other hospitals as well and was in especially scarce supply for many months outside of 3M/FEMA priority allocation and distribution channels well into 2021. I also have data for an imported NIOSH certified N95 (Makrite 9500) and an imported KN95 (Powecom) authorized by the FDA EUA. The Powecom model was also sample testing by NIOSH and the results exceeded NIOSH N95 filtration criteria. Amazon applied its HCP/ERP allocation rules and "fair pricing" rules to these respirators as well during 2020 and early 2021, but Amazon was not an authorized distributor of these respirators.

To summarize, we have price data for a top-of-the-line surgical N95 (3M 1860), a popular 3M standard respirator authorized by an FDA EUA for use in HCP/ERP settings (3M 8210), an imported NIOSH certified and FDA cleared surgical N95 (Makrite 9500), and an imported Chinese KN95 authorized for use by HCP/ERP by an FDA EUA and having very good filtration testing results from NIOSH. The 3M 1860 and the 3M 8210 should have been allocated and priced using 3M's rationing procedures and pricing maintenance guidance. Since Amazon was not an authorized distributor of the 3M 1860 it should not have had any to sell during 2020 and the first few months (at least) of 2021. If third-party sellers had 1860s to sell on an Amazon Marketplace site they would have come from private stockpiles, expired respirators, or leakage from manufacturer/authorized distributor channel (or were counterfeits).[133] They would also have been subject to Amazon's policy of restricting purchases of all N95s to priority organization with HCP and ERP and a non-transparent fair pricing policy. The Powecom KN95 would have been subject to similar sales rules in 2020 and early 2021, though it had its own U.S. authorized distributors making wholesale and retail sales by mid-2020.

Table 10 displays a time series of Amazon prices for the 3M 8210 model (20/box) and Table 11 for the 3M 1860s (small size, 120/case) model. The tables display both the prices posted by third-party sellers using the Amazon platform prices for respirators sold directly by Amazon. Between April 2020 and until roughly March 2021, these prices are for sales to organizations with priority HCP/ERP since sales on

[133] Note both 3M models were counterfeited, so this was not just a problem with KN95s and other imported respirators. https://multimedia.3m.com/mws/media/1934748O/3m-counterfeit-communication-letter.pdf ; https://multimedia.3m.com/mws/media/1960842O/3m-8210-counterfeit-communication-letter.pdf . Accessed December 1, 2021.

the Amazon platforms were restricted in this way. They also reflect Amazon's non-transparent fair pricing criteria. See the Data Appendix for more information.

In January 2020, prior to the realization that the pandemic was coming to the U.S., the prices for the 8210 are less than $1/respirator, below the pre-pandemic MSRP, for both Amazon and third-party sellers using the Amazon Marketplace. The third-party offers and Amazon prices for the 3M 1860s are slightly below or slightly above the MSRP. Accordingly, the pre-pandemic benchmark prices developed in Table 7 are good estimates of the pre-pandemic unconstrained open market prices.

As infections and hospitalizations in the U.S. started to grow rapidly by late February 2020, the patterns of prices and availability of the 3M 8210s offered by third parties are quite different from Amazon's own prices. Third party prices jumped immediately and significantly by the end of February 2020 as the pandemic gained force and the demand for N95s by HCP and ERP grew rapidly. In late February and March 2020, third party prices rose into the $7.75-$15.00 range or an average of $10.45/mask (excluding a few higher extreme prices), roughly 7 to 10 times the MSRP. Amazon did not start to strictly limit sales only to health care organizations and emergency responders and apply "fair pricing" rules until early April 2020, so these prices may be considered to be the unrestrained open market prices at that time (category P_3). In April and May 2020 and again in July 2020 there were no third party or Amazon sales offers for 8210 models and the third party offers in June 2020 averaged over $7.00/respirator. The availability at prices for these respirators likely reflect both 3M's and Amazon's allocation and pricing policies. It is unlikely that either Amazon or third party sellers could obtain regular supplies of this respirator model during this phase of the pandemic since 3M channeled them primarily through authorized medical supply distributors and HHS/FEMA to HCP/ERP at this stage of the pandemic. These observations are also after Amazon's April 2 announcement that it would restrict sales to priority HCP and ERP organizations and its March announcement that it would reject third-party sales offers if they could not satisfy its authenticity requirements and offered the respirators at a "fair price."

Offers by third party sellers for the M 8210 became available regularly (to priority front line health care workers through the implementation of Amazon's allocation policies) rather than intermittently in August 2020 starting at prices of about $7.50/respirator. This is the price at which these N95s were sold by third party storefronts as constrained by Amazon's HCP/ERP allocation and fair pricing policies, or roughly 6 times the pre-pandemic MSRP (category P2). Third party prices began to fall in December 2020 and ultimately fell back to about the MSRP in March 2021. Prices have more or less stayed in this range through December 2021. Amazon itself appears to have begun to receive regulator supplies from 3M in March 2021 and the Amazon and third-party prices converged in March 2021 as well. Accordingly, from roughly late February 2020 until March 2021 we observe Amazon offering the 3M 8210 respirator intermittently to eligible health care providers at prices reflecting the MSRP, while third party "residual market" prices, also

allocated to eligible HCP and ERP organizations, were five to seven times higher until they converged with Amazon prices and the MSRP around March 2021. However, the third part seller prices are lower than they were before Amazon implemented its allocation and fair pricing rules. This nicely illustrates the rationing, market segmentation, and multiple-price system that emerged at that time as Amazon itself adhered to both 3M's allocation and pricing policies while third parties with access to respirators could sell then at "fair" market prices but only to legitimate HCP/ERP organizations as administered by Amazon's allocation and fair pricing rules.[134]

I also have data from Keepa.com (see Data Appendix) on the number of third-party suppliers who were offering this product on the Amazon sites. (An individual supplier may operate multiple Amazon storefronts.) Prior to January 2020 there were as many as 45 third-party storefronts offering to sell 3M 8210 respirators. The number of offers fell dramatically beginning in February 2020, usually to one and never more than four until August 2021. It appears that most third-party sellers who could find 3M 8210s to sell may have preferred to sell elsewhere so that they did not have to deal with Amazon's anti-fraud, fair pricing and allocation policies. (e.g. ebay was always available as an alternative site without these restrictions, though it was buyer beware in terms of counterfeits, expired, and used N95s.) The number of third-party offers began to rise in August 2021 and reached 23 by August 30, 2021. By the summer of 2021 it appears that Amazon had indeed removed all of its restrictions on sales of 3M 8210 respirators and was receiving a regular supply from 3M for its own sales.

[INSERT TABLE 10]

Turning now to the behavior of prices for the 3M 1860 surgical N95 respirators posted on an Amazon site. See Table 11. As already noted, after April 2020 these respirators were subject both to 3M's allocation, anti-fraud, and price maintenance guidelines as well as those implemented by Amazon. The pre-pandemic market for these respirators was composed almost entirely of a limited group of health care personnel who needed both the filtration and splash protection these respirators offered. The 1860 is one of only three surgical N95 models that was distributed by 3M in the U.S. pre-pandemic (aggregating regular and small sizes of the same model). During the pandemic, 3M allocated these respirators to HCP and ERP in most need with the government contracts discussed earlier (20%) and through six major medical supply companies (80%) from its U.S. factories and eventually from its foreign manufacturing facilities. The allocation period was likely longer for the 1860 than for the 8210 since hospitals have a long history using this surgical N95 1860 model and it could be used in patient settings where only surgical N95s continued

[134] The highest third-party price that I found in the Amazon price data was for a 3M 8511 model (valved) with a price of $39/respirator on March 5, 2020, before the third-party seller was booted from the site and subsequently sued by 3M for selling fake or misrepresented N95s at unreasonable prices.

to be permitted pursuant to EUAs. It was impossible for non-priority organizations and individuals to acquire legitimate 1860s through authorized distributors, though counterfeits, legacy stockpiled and expired respirators, and respirators that leaked out of the 3M allocation and authorized distribution system appeared on some e-commerce sites by mid-2020.

In January 2020 prior to the start of the pandemic in the U.S., Table 11 indicates that prices for these respirators offered by third parties and by Amazon were roughly the same and in line with the MSRP. Again, this reinforces my conclusion that the MSRP prices in Table 11 are good pre-pandemic benchmark market prices. Beginning in February 2020 Amazon no longer offered the 3M 1860s and prices for these respirators disappeared entirely from the Amazon postings. They disappeared from third-party offers on Amazon as well from February 2020 until mid-January 2021 since 3M allocated these respirators through other channels. This familiar surgical N95 model was simply unavailable except through allocations by 3M through its major authorized distributors and via allocations of contracted N95s by HHS/FEMA and perhaps other government agencies, or from private stockpiles, leakage from 3M's authorized distribution channel, or counterfeits. The first third party offer for an 1860 observed on the Amazon site was on January 20, 2021, at a price of $6.25/respirator. The sales were subject to Amazon's authenticity, priority allocation and fair pricing rules.

I also have four e-bay transaction prices for the 3M 1860 model for July 2020 which were not subject to the kinds of restrictions that Amazon placed on third-party sales and somehow escaped from 3M's authorized distribution channels. The average price was about $15/respirator, roughly 10 times the pre-pandemic MSRP. At least one of these offers was from an expired lot. This suggests that Amazon's non-transparent "fair pricing" policies was a binding constraint on the third-party sellers who continued to offer these respirators on Amazon's Marketplace rather than, say, ebay. Where did these 1860s come from given 3M's allocation policies and those of its authorized distributors? They likely came from private stockpiles, expired respirators, leakage from 3M's authorized distribution channels and counterfeits.

The prices for the 3M 1860 offered by third-party sellers on Amazon's sites stayed at roughly the January 2021 level until May 2021 when they began to fall to about $2.50/respirator in June 2021. This is roughly double the pre-pandemic MSRP and double the price for the 3M 8210 standard N95 respirator. The number of third-party offers has remained in the 1-3 storefront range since the 1860 became available through third-party sellers in late January 2021. As of December 31, 2021, Amazon was still not selling this model and the third-party seller price on an Amazon site was $2.15/respirator, remaining above the MSRP but much lower than earlier in the pandemic. (Let me note that I purchased two boxes (20 per box) of the 3M 1860 N95s at this price in February 2022. They appeared to be counterfeits based on 3M's published counterfeit lot number list, but 3M subsequently confirmed that they were legitimate.)

[INSERT TABLE 11]

What do these price patterns for these respirators sold on Amazon's sites reflect? The patterns of prices and availability observed are consistent with the legacy manufacturers' allocation and price maintenance policies and the rapidly increasing supplies of N95s for use by HCP and ERP. Most N95s manufactured by domestic manufacturers were not made available except to authorized distributors and allocated to organizations with HCP/ERP needs. Some N95s were initially available in an unconstrained market, though supplies were limited to N95s that came out of private stockpiles, expired masks, masks that leaked out of the legacy manufacturers' authorized distribution channels, and counterfeits. Before Amazon initiated its HCP/ERP allocation and fair pricing policies price rose quickly to 7 to 10 times the pre-pandemic MSRP. These high prices had little or no effect on N95 supplies though since they did not flow back to manufacturers whose supplies increased dramatically due to other government and private policies. Amazon's allocation and fair pricing policies followed the manufacturers' and government policy by steering the available N95s to organizations with priority HCP/ERP. The fair pricing rules also appear to have constrained prices below fully unconstrained prices but well above MSRP for roughly the first year of the pandemic, making it attractive for secondary suppliers to bring private inventories, expired respirators, and N95s that leaked out of the authorized supply chains to the market. Amazon itself adhered to 3M's pricing policies for its intermittent allocations of 8210 models and received no 1860s to sell on its own behalf.

The supply-demand balance gradually moved from severe scarcity to abundance during the first year of the pandemic and prices on Amazon sites fell as the pandemic proceeded and supplies increased, despite the repeated surges in hospitalizations. By Spring of 2021 the prices for the 8210 had returned to pre-pandemic levels. The supply/demand balance for the 3M 1860 surgical N95 respirators improved significantly by mid-May 2021. Prices for the 1860 continued to fall as 2021 proceeded, although by December 2021 prices were still about 50% about the pre-pandemic MSRP and the pre-pandemic prices observed on Amazon in January 2020. This probably reflects the continuing higher value of the 1860 for HCP/ERP treating certain infectious patients compared to the 8210 and other NIOSH certified standard N95s, as well as the difficulty third-party sellers faced to obtain these 3M 1860s for resale outside of 3Ms authorized distribution pipelines.

I turn next to additional data on prices posted on Amazon sites for two <u>imported</u> respirator models. The first is Makrite (model 9500 N95), a Taiwanese company with N95 manufacturing facilities in China. This respirator model is interesting because it was NIOSH-approved and FDA cleared as a <u>surgical</u> N95 respirator <u>prior</u> to the pandemic and also has a large private label business in the U.S. and other countries. Thus, it is technically equivalent to the 3M 1860, though I don't think it was nearly as popular in U.S.

hospitals pre-pandemic and from my perspective not as comfortable.[135] In my experience, authorized distributors tried initially to prioritize sales of the Makrite respirators, as well as other NIOSH approved N95 models, to HCP and ERP early in the pandemic, though by mid-2020 these NIOSH approved imported N95s began to become available more widely from non-major medical supply distributors and on some e-commerce sites. This Makrite model was also subject to Amazon's allocation, fraud and "fair pricing" rules when offered by third parties at least until around March 2021. Makrite did not make pre-pandemic price maintenance commitments as far as I can tell, so it sold these respirators at open market prices, subject only to any restrictions applied by distributors. The respirators offered on the Amazon platform did have to adhere to Amazon's HCP/ERP allocation and fair pricing rules up until roughly Spring 2021. This Makrite model was also frequently counterfeited and Makrite warned customers to beware and urged them to buy only from authorized distributors.[136]

The longest Amazon price series that I could find for this Makrite model starts in August 2020 and it is only for third-party sellers as Amazon did not sell this product on its own behalf during this time period, probably because it is a surgical N95 designed and certified for certain hospital uses prior to the pandemic. I have no MSRP or pre-pandemic price for this model. See Table 12. In August 2020, the Makrite N95 respirator was being sold to qualified health care providers and first responders on Amazon for $6.25/respirator. As noted above, the technically comparable 3M 1860 was completely unavailable on Amazon until early 2021. However, the prices for the Makrite respirator were about $1 less than the price of the 3M 8210 at this time, even though the 3M 8210 is not a surgical N95 respirator. The price for the Makrite model model fell slowly as time passed until the price reached $1.25/respirator on September 1, 2021 and remained roughly at that level until the end of 2021. The 3M 1860 first became available again from third party sellers on Amazon on January 20, 2021 at a price of $6.25/respirator. By this time the price of the Makrite 9500 had fallen to $4.50/respirator, $2.00 less. From a regulatory perspective (NIOSH/FDA), the 3M 1860 and the Makrite 9500 may appear to be close substitutes but based on their relative prices and availability in the Amazon marketplace they are not perfect substitutes. The standard 3M 8210 N95, also sold at a premium to the Makrite 9500 in early 2021 when that 3M model was still largely unavailable except through the authorized distributor chain. Thus, it appears that buyers preferred familiar domestic respirator models over more or less equivalent imported models, probably influenced in part by the warnings about counterfeits.[137]

[135] It is not found on the list of models in inventory in Boston area hospitals in October 2020 (Plana et. al. Table 1).
[136] http://www.makrite.com/scam-notice-14/ accessed September 15, 2021.
[137] The 3M respirators were also counterfeited, despite the fact that the 8210 could be verified though 3M's safeguard system, 3M published lists of counterfeit lots of the 1860 on its web site, and it pursued counterfeiters aggressively.

Finally, I turn to price data for the Powecom KN95, a Chinese respirator that has been widely distributed in the U.S. Powecom[138] began selling its products through authorized distributors in the U.S. by May of 2020, after the EUA authorized the use of qualified imported respirators in HCP/ERP settings. Legitimate Powecom KN95s were tested several times by NIOSH's laboratory through its sample testing program for non-NIOSH approved imported respirators. The Powecom KN95 had excellent filtration metrics, uniformly in excess of 95%.[139] So, it was a good product. However, the Powecom respirator was also frequently counterfeited. Powecom began to use an "anti-fake tag" on the respirator packages in May 2020. This tag contains a QR code that links back to the Powecom web site for authenticity verification.[140] I do not believe that the Powecom KN95 respirator was widely used in hospitals for protecting HCP or ERP in direct contact with COVID patients, though this Powecom respirator model does appear in the Boston area teaching hospital inventory (Plana. et. al. 2021, Table 1).

I have Amazon platform price data for the Powecom KN95 offered by third party sellers starting in July 2020 for sales to organizations with priority HCP/ERP pursuant to Amazon's allocation, anti-fraud, and fair pricing rules and starting in October 2020 prices for Amazon sales on its own behalf (with some missing months). See Table 13. The Powecom KN95 respirators have lower third-party Amazon storefront prices than the NIOSH approved N95s on any particular date and the prices decline from about $4.00/respirator in August 2020 to about $1/respirator on September 1, 2021 and remaining at this level until the end of 2021. The Amazon sales prices follow a similar pattern to what we have already observed for the other respirator models examined here. It is somewhat surprising that by August 2021 the non-NIOSH certified Powecom KN95 has about the same price as the NIOSH approved 3M 8210 N95. They both satisfy the NIOSH 95% filtration criterion, the 3M 8210 is a popular and well-established model whose authenticity can also be verified by using 3M's Safeguard system, and neither is a surgical N95. Moreover, on July 1, 2021 the blanket EUAs clearing imports of non-NIOSH approved respirators meeting regulatory criteria in other countries, including China, were revoked and these N95-like respirators (including the Powecom KN95s) were no longer cleared by the FDA for HCP and ERP use. OSHA made comparable adjustments to its guidance. This shifted the utilization for these imported respirators entirely to non-HCP, ERP, and OSHA regulated settings. The FDA EUA authorizing the use of standard NIOSH approved N95s (domestic or imported) in health care settings continued to be in effect.

It is likely that the Powecom and 3M 8210 respirators were purchased by different types of buyers. The Powecom KN95s by individuals and companies without HCP, ERP or OSHA respiratory protection

[138] The official corporate name is Guangzhou Powecom Labor Supplies Company, LTD. http://powecom.com/ accessed September 1, 2021.
[139] Many imported Chine respirators demonstrated poor performance through this testing program.
[140] http://www.powecom.com/verification.html accessed September 15, 2021.

requirement, using them as "better masks" to meet indoor or outdoor masking preferences or requirements. The buyers of the 3M 8210s are companies and individuals who need OSHA compliant work-related respiratory protection which can only by satisfied with a NIOSH approved N95.[141] In this case, the prices likely reflect the demand by two different consumer groups. (Or perhaps 3M overproduced the 8210s by mid-2021.) Table 14 compares the prices in January 2021 and July 2021. By January 2021 NIOSH certified N95 supplies from domestic manufacturers had increased substantially while non-NIOSH approved N95-like respirators were still authorized by the April 2020 EUAs. By mid-summer 2021, the prices for the surgical N95s had converged to a price about twice the prices of the standard NIOSH/EUA respirators. This likely reflects the higher value of the surgical N95s in HCP and ERP settings and continued scarcity of the 3M 1860 model. Accordingly, during most of 2020 and early 2021 there is a clear hierarchy of prices. The established NIOSH approved 3M 1860 surgical respirators carried the highest price, the Makrite NIOSH approved Makrite 9500 surgical respirator a lower price, the 3M NIOSH certified 3M 8210 standard respirator a little lower price, and the Powecom KN95 the lowest price.

Regarding the new entrants listed in Table 9, as of mid-September 2021 when I performed the survey of these entrants, the unweighted sales price for the new entrants was $2.35, varying between $0.50 and $4.00 per respirator, though prices were falling during the month. At that time, a box of NIOSH approved 3M 8210 respirators (cup style) could be purchased for just under $1.00 per respirator on Amazon and a NIOSH approved 3M 9502+ respirator, with a flat-fold design similar to the design of most of the entrant respirators, for $1.25 per respirator on Amazon. A case (120 units) of the superior 3M 1860s surgical N95 respirators was available on Amazon for about $2.50/respirator. It appears that several of the new entrants set prices that were not competitive with the equivalent established brand models.

[INSERT TABLE 12]

[INSERT TABLE 13]

[INSERT TABLE 14]

(b) Private Sector Market Segmentation, Rationing and Pricing: Summary

1. The prices that were charged for respirators that were sold through the legacy manufacturer to HCP/ERP channel were roughly equivalent to pre-pandemic wholesale and retail prices during the periods of severe scarcity, roughly the first year of the pandemic. The clearest evidence comes from the federal government contracts with the legacy manufacturers which we consummated at wholesale prices below pre-pandemic benchmark MSRP. There are no data available on sales by the legacy domestic

[141]I personally find the Powecom KN95 to be more comfortable than the 3M 8210. Unlike the 3M 1860 which is available in two sizes, the 3M 8210 is available in one size only.

manufacturers to the major medical supply companies or the prices charged by these distributors to priority HCP/ERP organizations. However, I found not a single complaint reported in the media or any "price gouging" litigation that suggests that the legacy domestic manufacturers and their authorized distributors charged unusually high prices for N95 that were transacted to HCP and ERP organizations through the major medical supply distributors or any other authorized distributors during 2020 and 2021.

2. Legitimate imported and counterfeit respirators, sometimes labeled as standard NIOSH certified models manufactured by brands like 3M or Moldex or Makrite (Taiwan), traded through inexperienced and fraudulent intermediaries rather than manufacturer authorized distributors, carried higher prices, sometimes much higher prices than either the MSRP or the Amazon-constrained "fair prices. These intermediaries were the major target of efforts by manufacturers, domestic and foreign, and by the U.S. Department of Justice and state attorney generals, to use litigation to penalize these intermediaries with fines, prison, and agreements to cease sales activities. Allocation and market segmentation policies by many established intermediaries forced these sales into a gray market, sometimes referred to as the "wild west,"[142] which HCP and ERP organization, including some state and some federal agencies, turned to as their allocations of N95s through the established distribution channels were too little to fully satisfy their needs.

3. The relative prices and the availability of different types of respirators suggests that NIOSH certified and FDA cleared N95s were more highly valued than standard NIOSH certified respirators or non-NIOSH certified imported respirators authorized by an EUA until July 1, 2021.

4. The time series pattern of respirator prices follow the changes in the supply/demand balance during 2020 and 2021. Prior to the pandemic becoming a concern in the U.S., prices for the most popular 3M models reflected their pre-pandemic MSRP. As concerns about the pandemic grew by mid-February 2020 "open market" prices increased dramatically until actions by legacy manufacturers and authorized distributors, initiated allocation and pricing policies to manage to whom N95s were sold and their prices. As both domestic and imported N95 and N95-like supplies increased dramatically by the end of 2020, the respirators offered in the "residual markets" fell until they reached pre-pandemic levels by Spring/Summer 2021 and remained there until the end of 2021. Prices had not yet increased for most models by early 2022, but counterfeit N95 and KN95s continue to be sold widely in the U.S.[143]

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[142] Doug Block Clark, *"Inside the Chaotic Gray Market for N95 Masks," The New York Times,* November 17, 2020, updated May 29, 2021, https://www.nytimes.com/2020/11/17/magazine/n95-masks-market-covid.html . last accessed December 1, 2021.

[143] Andrew Jacobs, "Counterfeit COVID Masks Are Still Sold Everywhere, Despite Misleading Claims," The New York Times, December 1, 2021, https://www.nytimes.com/2021/11/30/health/covid-masks-counterfeit-fake.html . Accessed December 15, 2021; Lena H. Sun and Rachel Roubein, "CDC weighs recommending better masks against omicron variant," *The Washington Post*, January 11, 2022. https://www.washingtonpost.com/health/2022/01/10/cdc-weighs-n95-kn95-masks-guidance-omicron/ accessed January 11, 2022.

5. Despite the market segmentation, rationing, and price constraints, applied by legacy domestic manufacturers, and the favored treatment of the legacy domestic manufacturers by federal government contractors, there was substantial entry of new domestic manufacturers. They typically did not get big federal contracts and have relied heavily on e-commerce sites, including their own web sites, and independent wholesale brokers to make sales. The growing consensus in late 2021 that individuals should be using "better masks" has expanded the market for these entrants to make sales. By Fall 2021 they were heavily represented on Amazon, Google Shopping, Walmart, and other e-commerce sites.

13. Conclusions

The stated policy goals of the U.S. response to perceived shortages of N95 respirators at the beginning of the COVID-19 pandemic focused on (a) allocating the available supplies of N95s into the "right hands" --- front line health care and emergency response workers dealing with COVID patients, (b) expanding the supply of N95s for use by these workers, (c) reducing the demand for N95s by changing hospital utilization protocols from business as usual (BAU), and (d) containing "excess prices," "price gouging" and fraudulent sales practices. While several federal government regulatory agencies took a number of important "deregulatory" actions quickly to increase the effective supply of N95 and N95-like respirators that could be used by HCP and ERP treating COVID-19 patients, the success in realizing these policy goals depended heavily on the apparently voluntary actions by the legacy domestic manufacturers.

These actions supporting these policy goals included: (a) the allocation of most of the available N95s supplies to priority HCP and ERP organizations, (b) the withdrawal of supplies of N95s from their traditional industrial customers and suppliers (e.g. Home Depot) of their traditional retail customers, (c) maintaining prices charged to these priority HCP and ERP organizations at pre-pandemic levels indirectly through major medical supply distributors and through several federal contracting agencies which either needed the respirators for their own use (e.g. the VA and DOD) or in the case of FEMA, contracted for supplies and allocated them to state agencies which then redistributed them to priority HCP and ERP organizations in these states, and (d) rapidly increased domestic manufacturing output of N95s by about 500% compared to the pre-pandemic production. In short, the legacy domestic manufacturers adopted rationing and price maintenance policy to support government policy goals.

The private sector actions resulted in market segmentation, rationing, and price maintenance policies that led to multiple prices being charged for similar N95s and N95-like respirators in each market segment until the supply of N95 respirators caught up with BAU demand by Spring or early summer of 2021, a little over a year after the U.S. recognized and began to address the pandemic. During most of 2020 and early 2021 there were three types of market segments and three levels of prices. Prices for N95s manufactured by the legacy manufacturers and sold through direct contracts with federal agencies or

through their authorized medical supply distributors were maintained at pre-pandemic levels. Until Spring or early summer 2021 these supplies could not satisfy all HCP/ERP demand, as well as all traditional industrial and individual demand. Buyers seeking to increasing purchases beyond what they were allocated in the priority distribution channels had to turn to other market segments to fill this residual demand. The FFRs available in these market segments came from N95s released from existing private inventories, expired N95s, and N95s that leaked out of the manufacturers' primary distribution chain, as well as imported NIOSH certified and EUA cleared imported respirators. The prices in these market segments were much higher than pre-pandemic prices or the prices charged through the priority distribution channels during most of 2020 and early 2021 and the prices depended on exactly how they were distributed. Some distribution platforms like Amazon voluntarily applied their own priority allocation, anti-fraud, and (non-transparent) "fair pricing" rules, to these supply segments, though the prices were much higher than the prices charged by domestic manufacturers through their authorized priority distribution chains. Authorized distributors of <u>imported</u> NIOSH certified respirators frequently fell into this segment as well, applying "fair pricing rules" and trying to mitigate sales of counterfeit version of their N95s. Small often inexperience brokers, some e-commerce platforms, and other intermediaries who were not manufacturer authorized distributors and did not apply any quality or price constraints represented a third market segment, often referred to as the "wild west."[144] Prices in this market segment were higher still, but the proliferation of fraudulent sales practices, broken contracts and counterfeit N95 and N95-like respirators became an important feature of this segment as well.

Why did the domestic N95 manufacturers voluntarily pursue these rationing, market segmentation and price maintenance strategies? How did they enforce these rationing, market segmentation, and price maintenance strategies? What were the potential inefficiencies in their allocation strategy compared to plausible alternatives? The most relevant paper that that I found in the literature initially was Olmstead and Rhode (1985) which examines private sector rationing during the West Coast gasoline shortages in 1920. They find that "… despite the outward indications of government intervention – priority users, two-tier pricing, ration cards, and quality deterioration – there were no government price controls or rationing programs. Western gasoline marketers voluntarily suppressed price advances and, instead, created and administered a complex allocation scheme." (Olmstead and Rhode, 1985, page 1044). The paper goes on to "… argue that regional isolation, industry concentration, and vertical integration of the larger firms made rationing possible." (Olmstead and Rhode, 1985, page 1044). The paper's explanation of why the oil suppliers adopted these practices was fear of government regulation.

[144] Doug Block Clark, *"Inside the Chaotic Gray Market for N95 Masks," The New York Times,* November 17, 2020, updated May 29, 2021, last accessed December 1, 2021.

Dennis Carlton (1991, page 232) has correctly observed that private rationing and price restraint like what I find in the market(s) for N95s are foreign to the thinking of most economists. That is, price controls, rationing and shortages are expected to be the result of government actions to intervene in unregulated markets and lead to well-known Economics 101 inefficiencies. Olmstead and Rhode (1985) make a similar observation about the standard economist view of price controls and rationing of gasoline in the 1970s. Of course, the standard view of price controls, rationing and shortages is often correct (e.g. government price controls of the field price of natural gas and oil during the 1970s and 1980s and the resulting shortages, complex and inefficient rationing mechanism such as the entitlements program for oil and government mandated priority allocation rules for natural gas). Olmstead and Rhode (1985) provides a compelling counter example. Carlton (1991) develops a more general theory that shows that "[I]t is natural and optimal for long term relationships to emerge between buyers and sellers and for sellers to use and for sellers to use their knowledge about buyers to ration goods when demand is high." (Carlton 1991, page 232) To oversimplify, Carlton's theory turns on the fact that adjusting prices to balance supply and demand can be costly to the firm and that there may be differences in the stochastic demands that are revealed by different types of customers and their correlation with the total demand faced by a firm. Non-price rationing by a supplier may be profit maximizing and efficient when there is a relatively high correlation between a customer's demand and the total demand faced by the firm (Carlton (1991), page 254). When demand is high, regular customers (high correlation) are more likely to be served while other customers are rationed. Carlton (1991) provides several empirical examples from the industrial organization literature. Carlton's paper led me to think more about this and I realize that this type of private rationing occurs more frequently than one might think based on the standard economic view of the causes on non-price rationing reflecting the assumption that all markets are properly characterized as auction markets with perfect information.

However, all things considered I believe that Olmstead and Rhode's (1985) analysis and conclusions regarding the 1920 Western gasoline shortages is much more closely related to the rationing and price restraints initiated by 3M and the other legacy domestic N95 manufacturers discussed here. First, the rationing and price restraints in the N95 market were temporary responses to a national public health crisis and not a permanent attribute of this market. Pre-pandemic sales and pricing practices returned as supply caught up with demand. Second, the health care and emergency response organizations that were the beneficiaries of the rationing and price maintenance policies were not the primary regular customers of the domestic N95 manufacturers. Under ordinary circumstances only a small fraction of the N95s were sold to these health care organizations. Indeed, in the case of 3M, responsibility for N95 manufacturing and distribution was located in its industrial and safety group not in its health care group. In response to the national public health emergency, the domestic manufacturers shifted most of their sales from industrial

customers and authorized retail distributers to organizations serving front line HCP and ERP. Of course, 3M's health care group likely did have close relationships with the major medical supply distributors which could be relied upon by the industrial and safety group. Third, the marketing departments of these manufacturers did not have any special knowledge of the demand for N95s by these HCP and ERP organizations. This is why they relied on the major medical supply distribution companies as authorized distributors and federal government emergency response organizations, primarily FEMA, to distribute the N95s allocated to priority health care customers. Finally, the dramatic and rapid increase in manufacturing capacity and output does not appear to be a feature of either Carlton's theory or Olmstead and Rhode's 1920 oil example.

Accordingly, I will be guided here primarily by the conclusions in Olmstead and Rhode (1985), though Carlton's (1991) paper is quite stimulating and provides a very useful perspective on the organization and behavior of private firms in diverse real-world markets. When economists advocate "leave to the market," it is important to recognize that market and firm attributes are more complicated than they are typically characterized in elementary economics textbooks. Not only do we observe private rationing and price restraints, but we observe long-term contracts of various durations, other forms of relational contracting in many markets, as well as vertical integration (Joskow 1987, Williamson 1985, MacNeill 1978). Indeed, classical spot auction markets are likely to be more the exception than the rule.

The allocation and pricing policies adopted by 3M and its authorized distributors, the other legacy domestic manufacturers, as well as distribution platforms like Amazon, raise a number of questions. First, how did 3M and other manufacturers manage what was effectively a system that relied on government contracts and six major medical supply distributors to ration and allocate supplies to the HCP and ERP user segment and maintain pre-pandemic prices? If the major medical supply distributors could acquire the respirators directly from manufacturers for less than $1/respirator, why didn't they turn around and resell them at much higher market prices during 2020 and early 2021 ? Separating high price from low price markets is a challenge. But for at least a year market segmentation and price maintenance policies were largely maintained. While some domestically manufactured N95 respirators did find their way into the residual markets with limited fair pricing rules or without any price or allocation restrictions, they were few and far between March 2020 and Spring/Summer 2021. Second, why did the domestic manufacturers adopt these policies rather than adopting an auction market allocation model which would have supported much higher prices and output restrictions rather than large increases in supply during this time period?

I believe that there are several reasons why this private rationing and price maintenance strategy could be sustained for over a year. First, as was the case3 in the1920 Western gasoline market analyzed by Olmstead and Rhode (1985), the domestic N95 business was highly concentrated, with 3M accounting for 60-65% of domestic supplies pre-pandemic and a small set of much smaller domestic N95 manufacturers.

It is quite clear that 3M was the leader of this program. I believe that 3M's leadership was a very important facilitator of this strategy.

Second, 3M's health care group had an established distribution network for health care products prior to the pandemic. This conclusion may seem surprising since N95 respirators were not even manufactured and distributed by 3M's health care group prior to the pandemic and the bulk of its sales of N95s pre-pandemic where standard respirators that were used in non-health care, primarily industrial and personal safety respiratory protection applications. However, 3M sold many other products to health care organizations through its health care group and the associated distribution relationships could be shared across the company. 3M and other domestic manufacturers urged their distributors to follow their lead and maintain pre-pandemic end-user prices. 3M also drop-shipped respirators directly to end-users, working with its distributors, FEMA, state and local governments to support this allocation system.[145] It was hard for the respirators to get lost in the 3M distribution system or "fall off the truck." What is surprising to me is how little leakage there appears to have been since the gap between the prices maintained in the priority distribution channels and the other market segments was huge. This kind of disciplined distribution network is similar to vertical integration, another factor identified by Olmstead and Rhode (1985) as facilitating the rationing and price maintenance practices.

3M and other major manufacturers did take the position that they could not force independent authorized distributors to adopt their restricted allocation and pricing policies, as they could if they were vertically integrated into distribution. N95 respirator distribution is a small part of the business of the six major medical supply companies which had long established relationships with hospitals and health care providers to arrange for them to purchase a wide range of medical supplies and equipment. Smaller distributors which also restricted sales to high priority users no doubt valued their relationships with the manufacturers as well. There was also the threat of dealer terminations if the intermediaries engaged in practices that damaged the reputation of upstream manufacturers. Honeywell made the following recommendations to its authorized distributor network:

- " Our expectation that, at a minimum, all of our partners will comply with all applicable laws prohibiting price gouging and apply appropriate diligence to the greatest extent possible to understand how our products are being purchased so that they are placed quickly and cost-effectively in the hands of those most in need – including first responders and medical professionals.

- While we do not control the prices that third parties set, we expect our partners to fairly price PPE used in the COVID-19 response effort.

[145] https://multimedia.3m.com/mws/media/1792056O/3m-product-availability-update-re-2019-novel-coronavirus-end-customer.pdf March 25, 2020. accessed June 30, 2020 https://news.3m.com/2020-03-31-3M-Outlines-Latest-Actions-on-COVID-19-Response March 31, 2020. accessed June 30, 2020.

- If we find that one of our partners is not upholding the letter or spirit of these principles, we reserve the right not to fulfill that partners orders and terminate our relationship with that party."[146]

Third, the U.S. market was in a sense "isolated" as a result of pre-pandemic regulatory rules requiring NIOSH certification and FDA clearance for N95s to be used for infectious disease protection in health care settings. This is another factor identified by Olmstead and Rhode (1985). Prior to the EUAs issued in March and April 2020, FFRs meeting similar regulatory criteria in other countries could not be used for these purposes in the U.S. However, these EUA's largely removed restrictions on imports of FFRs that (supposedly) met similar performance criteria required for certification in other countries. However, there is price evidence that suggests that purchasers had some preference for NIOSH certified and FDA cleared respirators, especially compared to KN95s imported from China.

Why did 3M and other domestic manufacturers adopt these allocation and pricing policies? Why didn't they maximize short run profits and sell to the highest bidders at prices many times the pre-pandemic levels? Why did they expand manufacturing capacity and supplies so quickly and dramatically? Maybe they were just being good corporate citizens who wanted to help the government to pursue its goals or did not want to be publicly accused of price gouging during a pandemic. However, at least for the major companies, I believe that their policies reflect a larger set of long run relational contracting considerations as well. 3M is a big company with global sales of $32 billion and a profit of $7 billion in 2019. It sells many products to governments, companies, hospitals, and retail distributors (e.g. Scotch tape, Post-its) around the world. N95 respirator sales were a very small part of its business prior to the pandemic and the BAU demand has and will continue to decline as the pandemic-related demand declines as the pandemic recedes and lesson learned about utilization reduce BAU demand permanently. Honeywell and Kimberly-Clark are also large global companies with many irons in the fire and a much smaller N95 business. Moldex and Louis M. Gerson are much smaller private companies, but they also depend on sales of other respiratory protection products to governments and businesses. I don't think that it made much sense from an overall long-term business perspective for the legacy domestic manufacturers to try to make a big short-term profit by restricting supplies and dramatically increasing prices. It may just be bad business to be perceived to be exploiting loyal customers and engaging in otherwise legal behavior contrary to government policies during an emergency like the COVID-19 pandemic. Large price increases as a response to sudden increases in demand can be perceived as being unfair an effect firm behavior (e.g. Kahneman, et. al. 1986). Why risk the company's reputation and be the target rather than the plaintiff in price-gouging suits for a relatively

[146] Honeywell International 2020 Annual Report, page 11. https://www.annualreports.com/Company/honeywell-international-inc accessed August 15, 2021.

small short-term gain? I think that these companies were playing a longer term profit maximizing game as well as burnishing their reputations as good corporate citizens.

Second, as Olmstead and Rhode conclude regarding the behavior of the oil companies in the West in 1920, it is possible that the domestic manufacturers feared government regulation of supply, its allocation, and the introduction of government price controls; in this case they may have preferred supporting government policies voluntarily. For example, the Defense Production Act (DPA) could have been used to force domestic manufacturers both to increase production and require that all sales be made through contracts with government agencies like FEMA for onward distribution to priority health care and emergency response organization. Moreover, as discussed above, the federal government's first effort to apply the Defense Production Act (DPA) was targeted directly at 3M's export policies. This quickly led to a settlement consistent with the public health goals articulated by the government. However, I found no other evidence of federal government efforts to regulate the allocation or prices charged by domestic manufacturers aside from the contractual arrangements discussed above. The Department of Justice did use the DPA to initiate several lawsuits to attack fraudulent sales practices and "price gouging." However, I found none of this litigation targeted at either domestic manufacturers or their authorized distributors. Indeed, 3M itself had a much more aggressive anti-fraud activity than did either the Department of Justice or state attorney generals under state anti-fraud and price gouging statutes. The targets of this litigation were typically inexperience intermediaries that frequently tried to sell respirators that they did not have at relatively high prices. In addition, it is likely that the distribution relationships that the domestic manufacturers relied upon were much more effective in getting N95s to the right places than could FEMA and other government agencies if they tried to use the DPA to acquire and then distribute all of the N95s manufactured themselves.

Third, it has been suggested to me, that perhaps the policies adopted by the manufacturers and their distributors were strategies to deter entry into the N95 market. The N95 demand shock was expected to be temporary and attracting a lot of entry could increase competition post-pandemic. The story here would be that the dominant firm led a domestic industry strategy to keep prices low and increase supplies to deter the entry that would have occurred if they had pursued a short run profit maximizing strategy. Then at the end of the pandemic they could recoup their lost short-run profits somehow or reduce post-pandemic competition and realize higher prices than otherwise. However, I have seen no evidence that this was the strategy of any of the incumbent domestic manufacturers. And if entry deterrence was an important part of their strategy, it was not particularly successful since about 25 domestic companies entered the N95 business in 2020 and 2021. Moreover, respirator prices have returned to and been sustained at pre-pandemic levels or below at least through December 2021. Accordingly, the standard predatory pricing "recoupment" story has not played out (Joskow and Klevorick 1979).

Let me conclude with some brief observations about the potential social costs of the federal government policy goals and the complementary policies implemented by domestic manufacturers and their authorized distributors. The government and private sector allocation and rationing policies could only have imperfectly allocated N95s to their highest valued uses given imperfect information about the relevant values and likely differences between public policy goals and the unobservable valuations by actual and potential purchasers, primarily organizations on behalf of individuals rather than individuals themselves. There seems to have been general agreement among policymakers, domestic manufacturers and distributors, and the public, that the scarce supplies of N95s should have been allocated first to be used by front-line health care workers dealing with COVID patients. However, which health care organizations received the allocations depended on decisions made by manufacturers and their distributors, FEMA, and state emergency preparedness and public health organizations. Established distribution relationships probably made it easier for large health care organization with supply procurement organizations to get allocations while small health care organizations and organizations which had not previously purchased N95s struggled to get allocations they would have been willing to pay for. Perhaps some organizations got too many N95s and others got too few, given the goals of the priority allocation policy. Maybe health care organizations would have made utilization patterns stricter in response to higher prices --- FEMA's distributions carried a price of zero. However, since the priority allocation mechanism controlled limited supplies N95s this generally left a residual demand for N95s by health care providers which sought incremental supplies from other less regulated or unregulated market segments.[147] As a result, the marginal prices were substantially higher than the priority prices during the period that the priority allocation policy was in effect. And there may have been individuals or non-health care organizations such as traditional industrial and personal safety N95 users, that placed a higher value on obtaining the best respiratory protection but were not on the priority allocation lists and were frozen out of the market. For much of 2020 it was extremely difficult for individuals and organizations with such preferences to purchase legitimate N95s at any price. In short, it is likely that these administrative allocation policies sometimes got N95s into the wrong hands and adversely affected N95 utilization conservation. I have heard some complaints along these lines from smaller health care organizations and especially from organizations that were not in the market pre-pandemic --- like my dentist.

However, the relevant question is not whether there were imperfections in these administrative allocation mechanisms, there almost certainly were. The question is would allocations through an auction

[147]Consider the experience of Baystate Health, a hospital system in Massachusetts, described in Doug Block Clark, *"Inside the Chaotic Gray Market for N95 Masks," The New York Times,* November 17, 2020, updated May 29, 2021, https://www.nytimes.com/2020/11/17/magazine/n95-masks-market-covid.html . last accessed December 1, 2021.

based spot market, or I suppose some other alternative, would have done better in getting respirators into the hands of the highest value users? There are several reasons to believe that the answer is not so simple. There are externality and incentive alignment issues that would have to be considered. Specifically, if health care workers become infected they can pass the virus on to other individuals including other workers, patients, friends and their families (Chen, Chevalier and Long 2021). Moreover, N95 respirator procurement and utilization protocols are determined by hospitals and other health care providers not by the HCP, ERP, patients, or others, who are at risk, and the financial implications for health care providers purchasing more N95s was clearly an important factor in their purchasing decisions and their changes in utilization protocols --- in addition to HCP and ERP safety. The information provided to individuals about the value of N95 respirators (or any masks for that matter) by the U.S. government has been confused and changed over time, making rational decisions by individuals difficult. Whether these changing recommendations for individuals were a conscious effort to suppress demand or reflected the changing scientific consensus or a combination of both is hard to know. However, the impact was to steer individuals away from buying or using the N95 respirators until the late roughly early summer of 2021 as the pandemic appeared to be disappearing, though this turned out not to be the case. Moreover, the voluntary decision by the manufacturers and distributors to focus on long term rather than short term profits, reputational constraints, and relational contracting considerations are properly considered to be a "free market" response. Finally, the markets outside of the legacy domestic manufacturer distribution channels that gradually emerged had their own problems --- counterfeit and misrepresented FFRs and fraudulent sales practices.

On balance it seems to me that the complementary actions of government agencies to remove various regulatory restrictions on standard N95s, expired N95, imports, etc., combined with private sector rationing and price maintenance policies were quite successful in achieving widely accepted public policy goals in a relatively short period of time.

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TABLES AND FIGURE

Figure 1

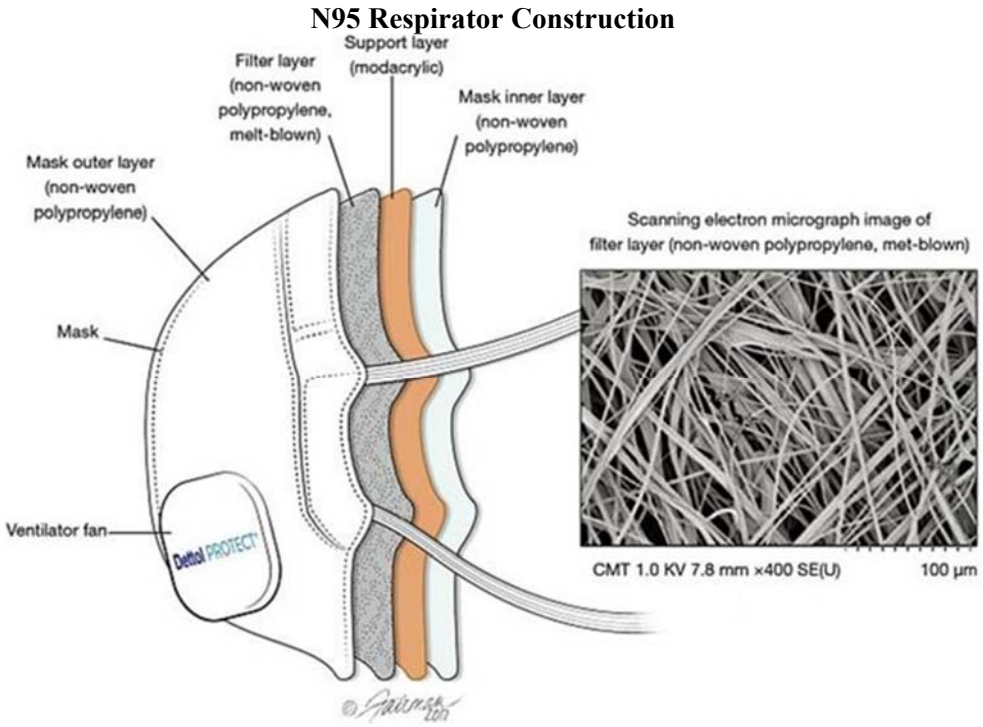

Image credited to Steve Zhou et. al. 2018.

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Table 1

Estimates of domestic manufacturing of NIOSH approved N95 respirators in January 2020

Companies		
3M Corporation	26 million	
Honeywell International	2 million	
Moldex-Metric	6 million	
Alpha Pro Tech	0.5 million	
Prestige America	2 million	
(Louis M. Gerson, O&M Halyard, Kimberly Clark, other)	3 million	
TOTAL Domestic	~ 40 million	
Imports of NIOSH approved FFRs	~ 4 million	
Total NIOSH approved:	~ 44 million	
Surgical N95 respirators: (NIOSH + FDA)	~ 4 million	(included in the 44 million above)

Sources: See Data Appendix

Table 2
Value of Imports of Respirators, Surgical Masks, and other Masks (ITC HTS Number 6307.90.9889)
January – June 2020

Month	Value of Imports
January	$253,000,000
February	$217,000,000
March	$241,000,000
April	$1,903,000,000
May	$3,712,000,000
June	$2,714,000,000

Country Shares (2020)	January	February	March	April	May	June
China	71.0%	66.9%	64.73%	92.4%	92.0%	92.4%
Mexico	8.7	11.8	12.7	2.3	1.8	2.2
Germany	0.45	0.34	0.54	0.1	0.03	0.04
UK	0.15	0.67	0.72	0.04	0.04	0.06
France	0.28	0.30	0.31	0.03	0.02	0.03
Canada	2.9	3.47	3.49	0.54	0.33	0.32
Taiwan	2.88	1.70	1.60	0.27	0.12	0.22
Singapore	0.08	0.07	0.35	0.20	0.12	0.07
105 other countries	13.5	14.79	15.57	4.12	5.54	4.12

Source: See Data Appendix

Table 3
Imports of N95 Respirators July 2020-December 2020
ITC/HTS Code Number 6307.90.9845
(Number of Respirators)

Month 2020	Number of Respirators
July	523,000,000
August	469,000,000
September	555,000,000
October	107,000,000
November	67,000,000
December	104,000,000

Country Shares 2020 (%)	
China	91.25%
Mexico	7.50
53 Others	1.25

Table 4
Imports of Respirators January 2021-June 2021
ITC/HTS Code Number 6307.90.9845
(Number of Respirators)

Month 2021	
January 2021	67,000,000
February	118,000,000
March	76,000,000
April	64,000,000
May	41,000,000
June	26,000,000

Country Shares 2021 (%)	
China	60.56%
Mexico	34.30
22 others	5.50

Source: See Data Appendix

Table 5

3M's Global Anti-fraud Actions (as of January 11, 2022)

# counterfeit respirators seized:	55,570,000+	(in cooperation with law enforcement)
False and deceptive social media posts removed:	27,800+	
Fraudulent e-commerce offerings Removed:	30,500+	
Lawsuits filed:	41	
Cease and desist letters issued:	220+	
Cases with damages awarded	23	
Temporary restraining orders	21	
Deceptive internet addresses removed:	400+	
Global reports to 3M fraud Hotline:	16,800+	

https://www.3m.com/3M/en_US/worker-health-safety-us/covid19/covid-fraud/
accessed January 31, 2022

Table 6
Domestic Entrants with their First NIOSH Approved Respirators in 2020 or 2021
(survey as of September 15, 2021)

Company	N95 Models	Surgical Models	Entry Date	Sales Activity (9/15/2021)
A&Z Pharmaceutical	1	0	4/6/2021	None observed
Advanced Concept Innov.	1	1	4/30/2021	e-commerce stores
Advoque	1	0	1/15/2021	None observed
Aegle PPE	3	0	4/21/2021	Company web site and Amazon
Aidway Personal Care	2	0	10/23/2020	Company web site and Amazon
ALG Health	13	1	10/30/2020	Company web site and Amazon
AMSAFE	1	0	9/25/2020	None observed
BNX Converting	5	0	3/3/2021	Amazon and Accumed
DemeTech	4	0	10/7/2020	Company web site and Amazon
Ford	1	0	6/18/2020	Internal allocations
Indiana Face Mask	1	0	12/1/2020	Company web site and Amazon
General Motors	3	0	5/22/2020	Internal/donations
Lighthouse Worldwide (Hope 2020)	1	0	11/23/2020	Company web site (sold out)
Merilogy	1	0	2/19/2021	Company web site and Amazon
Outdoor Research	2	0	9/23/2020	Company web site and Amazon
Pacific PPE	3	0	12/20/2020	Amazon
Pandmedic	1	0	9/22/2020	Company web site and Amazon
Protective Health Gear	1	0	8/25/2020	Company web site and Amazon
Shawmut Corp	1	0	2/24/2021	Company web site and e-commerce
Thermopore	5	0	9/4/2020	None observed
United States Mask	1	0	10/27/2020	Company web site (sold out)
ViruDefense	1	0	6/22/2020	Wholesale and Amazon
Wellspan Health	2	0	6/12/2020	e-commerce

Sources: See Data Appendix

Table 7[1]
Benchmark Pre-pandemic prices: 3M Pre-pandemic Manufacturer Suggested Retail Prices for Six Models of Unvalved N95 Respirators
($/respirator)

Model	Type	List Price
1804	surgical	$ 0.68
1860	surgical	$ 1.27
1870+	surgical	$ 1.78
8210	standard	$ 1.02-1.31
8200	standard	$ 0.63-0.80
9210+	standard	$ 1.40-1.78

Source: See Data Appendix

Table 8
Large Federal Contracts for N95 Respirators

Manufacturer	Quantity	price/respirator ($)	Month
3M	190,000,000	$0.91	April 2020
Honeywell	190,000,000	$0.78	April 2020
O&M Halyard	130,000,000	$0.48	April 2020
Moldex	38,000,000	$0.75	April 2020
Draeger[2]	50,000,000	$0.62	April 2020
Prestige Ameritech	12,000,000	$0.79	April 2020
Louis M. Gerson	7,067,220	$0.94	May 2020

Sources: See Data Appendix

[1] https://multimedia.3m.com/mws/media/1862179O/get-the-facts-n95-respirator-pricing.pdf accessed June 30, 2020.
[2] Draeger is a German company with a large U.S. subsidiary. It has about 15 standard respirator models that are NIOSH approved. It committed to manufacturing these respirators in the U.S.

Table 9
Respirator Purchase Orders and Contracts with Non-Authorized Distributor Intermediaries

a. City of Atlanta

Type	Number	$/respirator	Month
N95	14,000	$5.57	April 2020
N95	30,000	$6.30	April 2020
KN95	30,000	$6.75	April 2020
KN95	10,000	$6.75	April 2020
KN95	19,390	$6.50	April 2020
KN95	6,000	$6.30	April 2020
N95	4,380	$5.57	May 2020

Note: Three of the KN95 models appear to have subsequently failed the NIOSH filtration tests.[3]

b. Other federal Agency Contracts (e.g. VA, DOD) with small intermediaries

Type	Number	$/respirator	Month	Status
N95	785,000	$7.00	April 2020	Cancelled
N95	6,000,000	$5.90	April 2020	Cancelled
N95	2,000,000	$7.25	April 2020	Not yet completed
N95	10,000,000	$5.50	May 2020	Cancelled
N95	1,000,000	$3.90	May 2020	Not yet completed
N95	6,500,000	$5.85	April 2020	Cancelled. Fraud conviction

Sources: See Data Appendix

[3] https://www.cdc.gov/niosh/npptl/respirators/testing/results/MTT-2020-84.1_International_ShenzhenHangsenStar_TestReport_Redacted-508.pdf https://www.cdc.gov/niosh/npptl/respirators/testing/results/MTT-2020-137.4_International_ShenzhenCrawford_XO-01-or-XO-03_TestReport_Redacted-508.pdf . accessed June 15, 2021.

Table 10

Amazon Prices 3M 8210/8210+

		MSRP	pre-covid	$1.02-$1.31	
Month	Day			$/Respirator	
			3rd party		Amazon
January	1	2020	$ 0.81		$ 0.83
January	15		$ 0.65		$ 0.79
February	2		$ 4.60		$ 0.86
February	29		$ 15.00		N/A
March	5		$ 9.00		N/A
March	10		$ 10.00		N/A
March	14		$ 7.75		N/A
April			N/A		N/A
May			N/A		N/A
June	8		$ 7.58		N/A
June	21		$ 6.75		N/A
July			N/A		N/A
August	19		$ 7.25		$ 1.23
September	1		$ 7.75		N/A
September	15		$ 7.95		N/A
October	3		$ 7.00		$ 1.83
October	16		$ 7.25		$ 1.83
November	3		$ 7.25		N/A
November	17		$ 6.80		$ 1.23
December	5		$ 3.80		$ 1.22
December	14		$ 5.75		$ 1.15
January	1	2021	$ 4.45		N/A
January	14		$ 4.10		N/A
February	6		$ 2.65		$ 1.21
February	15		$ 2.25		N/A
March	5		$ 1.23		$ 1.08
March	14		$ 1.08		$ 1.08
April	1		$ 1.21		$ 1.21
April	14		$ 1.21		$ 1.21
May	5		$ 1.23		$ 1.21
May	14		$ 1.08		$ 1.21
June	3		$ 1.15		$ 1.16
June	16		$ 1.00		$ 1.01
July	4		$ 1.05		$ 1.21
July	13		$ 1.10		$ 1.21
July	31		$ 1.21		$ 1.21
August	1		$ 1.21		$ 1.21
August	15		$ 1.15		$ 1.00
August	29		$ 0.88		$ 1.00
September	30		$ 0.71		$ 0.89
October	30		$ 0.85		$ 0.89
November	30		$ 0.86		$ 0.89
December	31		$ 0.89		$ 0.89

Source: See Data Appendix

TABLE 11

Amazon Prices 3M 1860s (120 unit case)

MSRP $1.27 $/respirator pre-covid

Month	Day		3rd party	Amazon
January	2	2020	$ 0.96	$ 1.41
January	15		$ 1.35	$ 1.41
February			N/A	N/A
March			N/A	N/A
April			N/A	N/A
May			N/A	N/A
June			N/A	N/A
July			N/A	N/A
August			N/A	N/A
September			N/A	N/A
October			N/A	N/A
November			N/A	N/A
December			N/A	N/A
January	1	2021	N/A	N/A
January	20		$ 6.25	N/A
February	1		$ 6.25	N/A
February	16		$ 5.58	N/A
March	2		$ 6.24	N/A
March	16		$ 3.63	N/A
April	2		$ 6.24	N/A
April	16		$ 6.24	N/A
May	2		$ 5.00	N/A
May	15		$ 3.30	N/A
June	2		$ 2.50	N/A
June	16		$ 2.50	N/A
July	1		$ 2.50	N/A
July	15		$ 2.50	N/A
August	1		$ 2.50	N/A
August	15		$ 2.00	N/A
September	1		$ 2.71	N/A
September	3		$ 3.53	N/A
September	5		$ 2.91	N/A
September	30		$ 2.50	N/A
October	30		$ 2.39	N/A
November	29		$ 2.16	N/A
December	30		$ 2.15	N/A

Source: See Data Appendix

Table 12

Amazon Prices Makrite 9500 (small)

$/respirator (20 units)

Month	Date	Year	3rd-party	Amazon	
August	20	2020	$ 6.35	N/A	First price available
September	1		$ 6.35	N/A	
September	15		$ 6.20	N/A	
October	1		$ 5.35	N/A	
October	15		$ 5.30	N/A	
November	1		$ 5.32	N/A	
November	15		$ 4.00	N/A	
December	1		$ 5.00	N/A	
December	15		$ 5.00	N/A	
January	1	2021	$ 5.00	N/A	
January	15		$ 4.50	N/A	
February	15		$ 3.50	N/A	
March	1		$ 3.50	N/A	
March	15		$ 3.50	N/A	
April	1		$ 2.50	N/A	
April	15		$ 2.50	N/A	
May	1		$ 2.50	N/A	
May	15		$ 2.45	N/A	
June	1		$ 2.30	N/A	
June	15		$ 2.30	N/A	
July	1		$ 2.20	N/A	
July	15		$ 2.20	N/A	
August	2		$ 2.00	N/A	
August	15		$ 1.45	N/A	
September	1		$ 1.25	N/A	
October	30		$ 1.29	N/A	
November	30		$ 1.25	N/A	
December	30		$ 1.21	N/A	

Source: See Data Appendix

Table 13

Amazon Prices Powecom KN95 (10-pack)

Month	Date	Year	3rd party	Amazon
July	12	2020	$ 3.00	N/A
August	1		$ 4.00	N/A
August	15		$ 4.00	N/A
September	1		$ 2.62	N/A
September	15		$ 2.63	N/A
October	1		$ 2.63	N/A
October	15		$ 2.03	$ 2.03
November	1		N/A	$ 2.54
November	15		$ 1.98	$ 1.98
December	1		$ 2.50	N/A
December	15		$ 2.00	N/A
January	1	2021	$ 2.05	$ 1.72
January	15		$ 1.45	$ 1.50
February	1		$ 1.26	$ 1.29
February	15		$ 1.50	N/A
March	1		$ 1.10	$ 1.30
March	17		$ 1.40	$ 1.40
April	1		$ 1.26	$ 1.40
April	15		$ 1.20	$ 1.20
May	1		$ 1.40	$ 1.40
May	15		$ 1.40	$ 1.40
June	1		$ 1.40	$ 1.40
June	15		$ 1.40	$ 1.40
July	1		$ 1.26	$ 1.26
July	15		$ 1.33	$ 1.33
August	1		$ 1.29	$ 1.29
August	15		$ 1.08	$ 1.33
September	1		$ 0.81	$ 1.26
October	1		$ 1.02	$ 1.15
October	30		$ 0.45	N/A
November	30		$ 0.45	N/A
December	31		$ 1.20	N/A

Source: See Data Appendix

Table 14
Prices for Four Respirator Models

	January 2021	July 2021
3M 1860 (domestic surgical N95 – NIOSH/FDA)	$6.25	$2.50
Makrite 9500 (imported surgical N95 – NIOSH/FDA)	$4.75	$2.30
3M 8210 (domestic standard N95 --- NIOSH)	$4.45	$1.20
Powecom KN95 (imported KN95 – EUA)	$1.75	$1.30

Source: See Data Appendix

February 27, 2022

DATA APPENDIX

In ordinary times the U.S. disposable N95 (FFR) manufacturing and sales business is quite small, on the order of about $500 million of sales per year. It is so small that separate statistics for N95 and related disposable FFRs were not reported either in government statistics or, prior to the pandemic, in company reports or press releases. There are even fewer pre-pandemic data on the mix of surgical N95 respirators used by health care personnel and standard N95 masks used in various industrial, emergency response, and personal respiratory protection (e.g. air pollution caused by wild fires). Accordingly, the empirical analysis in this paper has required a lot of detective work relying on government studies and reports, corporate documents (primarily 3M) media reports, press releases, and informed guesses.

Table 1

Table 1 displays estimates of pre-pandemic domestic production and imports of NIOSH approved N95 respirators. 3M's production of N95s is by far the best documented in its press releases and media coverage during all of 2020. I estimate that 3M produced 26 million N95s in January 2020 which I consider to be pre-pandemic (3M produced 22 million in December 2019).[1] There is also agreement that at the beginning of the pandemic that domestic companies produced about 40 million NIOSH approved N95s in January 2020 and imported about 4 million NIOSH-approved N95s from other countries. The specific production of N95s by other manufacturers in January 2020 is much less transparent. Honeywell's annual report states that it increased domestic production during the year by a factor of 20, so the estimate is 2 million for January 2020.[2] An article in the Wall Street Journal on April 2, 2020 estimates Moldex-Metric to be producing 8 million N95s per month at that time. This is after Moldex-Metric began to increase production so I pulled that number back to 6 million for January 2020.[3] The same article indicates that Prestige America was producing 2 million respirators per month at that time. Prestige America previously offered to increase its production to about 7 million/month by reactivating idle production lines in return for government contracts. This offer was rejected. I used the 2 million figure in Table 1. Alpha Pro Tech's 2019 SEC Form 10K reports about $20 million of revenue in the companies Disposable Protective Apparel segment of which 15% or $3 million was attributed to sales of "masks."[4] However, Alpha Pro Tech makes both N95 surgical respirators and surgical masks. If we simply assume that all of the masks reported by Alpha Protect are N95 respirators and they sell for $0.75/respirator then that gives us 4 million respirators per year or less than 0.5 million per month pre-pandemic.[5] As far as I can tell Kimberly-Clark, not included in Table 1, manufactured N95s in Mexico at that time.[6] I could not find any January 2020 production data

[1] Austen Hufford, "N95 Face Mask Makers Ramp Up Production to Meet U.S. Covid-19 Demand, The Wall Street Journal, July 17, 2920, click on the figure to get monthly numbers. https://www.wsj.com/articles/n95-mask-makers-ramp-up-production-to-meet-u-s-covid-19-demand-11594987201 accessed July 15, 2021; Congressional Research Service (2020, Appendix C). These numbers are consistent with 3M press releases and other media reports.

[2] Honeywell International Annual Report, page 11. https://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_HON_2020.pdf . Accessed September 1, 2021.

[3] Austen Hufford, "3M CEO on N95 Masks: 'Demand Exceeds Our Production Capacity,' April 2, 2020, The Wall Street Journal, https://www.wsj.com/articles/3m-ceo-on-n95-masks-demand-exceeds-our-production-capacity-11585842928 accessed July 15, 2020.

[4] Alpha Pro Tech is registered as a Delaware Corporation but its executive offices are in Canada. It's respirator manufacturing takes place in Utah.

[5] Alpha Pro Tech 2019 SEC Form 10-K, page 30. https://last10k.com/sec-filings/apt/0001437749-20-004678.htm accessed June 30, 2020.

[6] Kimberly-Clark is based in Texas but its N95 respirators apparently were made in Mexico at this time. It spun off Halyard in 2014 and Halyard was subsequently sold to Owens and Minor in 2018.

for Gerson or O&M Halyard, though both manufacturers were active since they entered into contracts with HHS in April 2020 for delivery over 18 months. See Table 8. Indeed O&M Halyard's contract was for over 7 million N95s per month over 18 months, so its production capacity was likely substantial in January 2020. Gerson is a much smaller private company and entered into a much small contract with HHS. A 3M executive estimated that 15% of its production pre-pandemic was surgical N95s and another report indicates 10% surgical N95 respirators.[7] Much of the rest of the manufacturers were more focused on industrial personal protection, so I used 10% for surgical N95s.

Table 2

Calculated from (ITCb, 2021) web data base ITC/HTS product code 6307.90.9889. This product category includes N95 respirators, other respirators, other disposable face masks, other face masks and a residual category. The table report the customs value of the imports. Starting in March 2020 the 7.5% tariff on these items was no longer applied.

Table 3
Starting in July 2020, product code 6307.90.9889 was divided into 5 less aggregated product lines. This table is for the new product code 6307.90.9845 which is for N95 respirators (ITCb, 2021). The table lists the number of N95 respirators imported each month.

Table 4
Same source as Table 3 but for January 2021 through June 2021.

Table 5
https://www.3m.com/3M/en_US/worker-health-safety-us/covid19/covid-fraud/
accessed January 31, 2022

Table 6
This table is constructed from two CDC data bases for NIOSH approved respirators, media, and internet searches. I first searched the CDC's list of approved N95 respirators for respirators that that were not listed for the established domestic brands (e.g. 3M), established import brands (e.g. Makrite), and private label NIOSH approved respirators manufactured by one of the established domestic or foreign import brands. https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/n95list1.html (last accessed October 4, 2021). This yielded a set of NIOSH approval codes TC-84A-xxxx. I then used a second CDC data base to check each NIOSH approval code for these models and manufacturers to identify whether the manufacturer was domestic or foreign and the date of the NIOSH approval. https://wwwn.cdc.gov/NIOSH-CEL/ (last accessed October 4, 2021). This produced a set of domestic manufacturers whose first NIOSH approval for any N95 model was in 2020 or 2021. I used the internet to search for a web site for each of these manufacturers to determined whether and how their N95s were being marketed. Finally, in September 2021 I searched for each manufacturer on Amazon to determine if its respirators were being offered there.

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[7] "Doug Bock Clark,"Inside the Chaotic Gray Market for N95 Masks," The New York Times, November 20, 2020, https://www.nytimes.com/2020/11/17/magazine/n95-masks-market-covid.html; Felice J. Freyer, "Amid a rising tide of COVID-19, hospitals stock up on respirator gear," The Boston Globe, October 18, 2020.
[7]Dee DePass, "3M's complicated road to enough N95 capacity took many hands," Star Tribune, April 25, 2020, quoting a 3M executive indicating that 15% of 3M's N95 respirator sales were made to health care customers. https://www.startribune.com/3m-s-complicated-road-to-enough-n95-capacity-took-many-hands/569929962/; Another report indicates that 90% of 3Ms masks were sold for industrial applications," Austen Hufford, "N95 Mask Makers Ramp Up Production to meet U.S. COVID-19 Demand," The Wall Street Journal, July 17, 2020. 2020. https://www.wsj.com/articles/n95-mask-makers-ramp-up-production-to-meet-u-s-covid-19-demand-11594987201 accessed July 15, 2020.

Table 7
3M has circulated its MSRP information widely in an effort to provide information to purchasers about "normal" pricing as well as to encourage 3M's authorized distributors to maintain pre-pandemic prices. https://multimedia.3m.com/mws/media/1862179O/get-the-facts-n95-respirator-pricing.pdf accessed June 30, 2020.

Table 8
This information comes from media reports, press releases and a data base of federal Covid-19 related contracts compiled by Pro-publica. All accessed September 1, 2021

https://news.bloomberglaw.com/health-law-and-business/honeywell-draeger-among-manufacturers-in-line-to-produce-masks

https://projects.propublica.org/coronavirus-contracts/contracts/75A50120C00027

https://projects.propublica.org/coronavirus-contracts/contracts/75A50120C00029

https://projects.propublica.org/coronavirus-contracts/contracts/75A50120C00030

https://projects.propublica.org/coronavirus-contracts/contracts/75A50120C00028

https://www.salon.com/2020/04/18/trump-admin-awards-n95-contract-far-above-normal-price-to-bankrupt-company-with-no-employees-report/

https://projects.propublica.org/coronavirus-contracts/contracts/70FB7020P00000018
(Prestige America)

https://projects.propublica.org/coronavirus-contracts/contracts/75A50120C00104 (Louis M. Gerson)

Table 9
a. City of Atlanta Contracts
I stumbled across these contracts on the internet while searching for more information about federal government contracts which had enough information to calculate a price/respirator. The information on filtration efficiency for the KN95s comes from NIOSH testing data. All accessed September 10, 2021.

https://www.atlantaga.gov/government/departments/procurement/emergency-procurements/emergency-procurement-contracts

https://www.atlantaga.gov/home/showpublisheddocument/46253/637248261279100000

https://www.atlantaga.gov/home/showpublisheddocument/48001/637347339948600000

https://www.atlantaga.gov/home/showpublisheddocument/46576/637274883984900000

https://www.atlantaga.gov/home/showpublisheddocument/46249/637248257861170000

https://www.atlantaga.gov/home/showpublisheddocument/46247/637248257263130000

https://www.atlantaga.gov/home/showpublisheddocument/46574/637274881978330000

https://www.atlantaga.gov/home/showpublisheddocument/46251/637248260095570000

https://www.cdc.gov/niosh/npptl/respirators/testing/results/MTT-2020-84.1_International_ShenzhenHangsenStar_TestReport_Redacted-508.pdf

https://www.cdc.gov/niosh/npptl/respirators/testing/results/MTT-2020-137.4_International_ShenzhenCrawford_XO-01-or-XO-03_TestReport_Redacted-508.pdf

b. Other Federal Agency Contracts with Intermediaries
The ProPublica contracts data base includes over 160 contracts for N95 respirators with both manufacturers and intermediaries. Unfortunately, in most cases the contract data reported have the total dollar value of the contract but not the quantity of respirators contracted. The information here is primarily from media reports and litigation reports. All accessed September 15, 2021.

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwjX_cTY19HyAhVjnuAKHVIPAYAQFnoECAsQAw&url=https%3A%2F%2Fwww.wsj.com%2Farticles%2Fu-s-pays-high-prices-for-masks-from-unproven-vendors-in-coronavirus-fight-11587218400&usg=AOvVaw1-QEZk4WJ29eFA5-EJNNGH

https://www.justice.gov/usao-edva/pr/former-ceo-sentenced-defrauding-multiple-federal-agencies

https://www.wsj.com/articles/fema-cancels-55-5-million-mask-contract-with-panthera-11589330231

https://projects.propublica.org/coronavirus-contracts/contracts/15BFA020PVNP10766

Table 10
The Amazon prices come from Keepa 2021. "Amazon Price Tracker," https://keepa.com.
Keepa provides prices offered by Amazon and prices offered by third party storefronts hosted on one of the Amazon cites. I looked for the longest prices series in each case. I pulled prices for the first and fifteenth day of the month or if, unavailable, prices within a two of days of those dates. Otherwise, the entry is N/A. The paid version of Keepa 2021 also has information on the number of third-parties making offers to sell. Tables 10-13, all last accessed February 1, 2022.
3M 8210: https://keepa.com/#!product/1-B008MCUZZS

Table 11
3M 1860s: https://keepa.com/#!product/1-B01AWCDZ3O

Table 12
Makrite 9500 small: https://keepa.com/#!product/1-B08CY6KHY1

Table 13
Powecom KN95 (10-pack): https://keepa.com/#!product/1-B08M132NQV

Table 14
Calculated from data in Tables 10-13 which come from keepa.com.