IT'S A (VITAL) SIGN: HOW POST-COVIDIEN INTERAGENCY COLLABORATION CAN PREVENT FUTURE MEDICAL DEVICE SHORTAGES

CAROLINE M. TRABUCCO*

* J.D. Candidate, American University Washington College of Law (2022); B.A., Political Science, University of Mary Washington (2018). I would like to thank my family and friends for their unwavering support throughout this process, especially my Uncle Jack, whose guidance has never steered me wrong. This Comment would not have taken shape without the mentorship of Professor Andrew F. Popper, who instilled in me the confidence to pursue this topic. Thank you to the entire *Administrative Law Review* staff, especially Kirsten Bickelman and Andrea Belanger, for graciously fielding my many texts and emails and cheering me on along the way. Special thanks to Eric and Francis for seeing me through long nights and weekends with patience and love.

INTRODUCTION

"I feel like I'm trying to ventilate bricks instead of lungs," remarked one intensive care unit physician who has been treating COVID-19 patients for the last several months.[1] The change in lung texture encountered by practitioners handling severe COVID-19 cases is caused by a potentially lethal presentation of acute respiratory distress syndrome (ARDS),[2] in which "breathing becomes impossible without a ventilator."[3] Ventilators are not curative,[4] but they are essential in some cases: they keep the body alive while it fights infection.[5]

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1. Kathryn Dreger, Opinion, *What You Should Know Before You Need a Ventilator*, N.Y. TIMES (Apr. 4, 2020), https://www.nytimes.com/2020/04/04/opinion/coronavirus-ventilators.html.

2. *See ARDS*, MAYO CLINIC (June 13, 2020), https://www.mayoclinic.org/diseases-conditions/ards/symptoms-causes/syc-20355576 (listing COVID-19 as a primary underlying cause of acute respiratory distress syndrome (ARDS), as it creates fluid accumulation in the lungs and can fatally disrupt function).

3. *See* Dreger, *supra* note 1 (explaining that a ventilator buys a patient time by using positive pressure to force open fluid-obstructed lungs and facilitate oxygen delivery to vital organs).

4. *See* Jon Hamilton, *Ventilators Are No Panacea for Critically Ill COVID-19 Patients*, NPR (Apr. 2, 2020, 3:43 PM), https://www.npr.org/sections/health-shots/2020/04/02/826105278/ventilators-are-no-panacea-for-critically-ill-covid-19-patients (recognizing that while taxing, ventilators are a necessity for COVID-19 patients because high levels of lung inflammation require high pressure oxygen flow and prolonged treatment).

5. *See* Carrie MacMillan, *Ventilators and COVID-19: What You Need to Know*, YALE MED. (June 2, 2020), https://www.yalemedicine.org/stories/ventilators-covid-19/ (identifying COVID-19's ability to critically impair lung function); *see also* Jon Hamilton, *New Evidence Suggests COVID-19 Patients on Ventilators Usually Survive*, NPR (May 15, 2020, 1:45 PM), https://www.npr.org/sections/health-shots/2020/05/15/856768020/new-evidence-suggests-covid-19-patients-on-ventilators-usually-survive.

In the United States, the reported death toll from COVID-19 has surpassed 513,122, overwhelming the healthcare system.[6] Not only do hospitals lack an adequate reserve of ventilators, but often they have not been able to purchase extra machines, either.[7] Healthcare providers and state and local governments cannot prepare an adequate medical surge[8] response when life-saving equipment simply does not exist.[9] Thus, medical practitioners across the country currently face a choice: get creative or get selective.[10]

The U.S. Food and Drug Administration (FDA) endorses innovative solutions,[11] often devised by nurses tinkering with old machine parts.[12] While adapting simple machines is preferable to using a pseudo-ethical algorithm to

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6. *COVID Data Tracker: United States COVID-19 Cases and Deaths by State*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (Mar. 2, 2021, 12:56 PM); *see also* Michael Rothfeld et al., *13 Deaths in a Day: An 'Apocalyptic' Coronavirus Surge at an N.Y.C. Hospital*, N.Y. TIMES, https://www.nytimes.com/2020/03/25/nyregion/nyc-coronavirus-hospitals.html (Apr. 14, 2020) (profiling a New York City hospital that kept the bodies of COVID-19 victims in a refrigerated truck).

7. *See* Sarah Kliff et al., *There Aren't Enough Ventilators to Cope with the Coronavirus*, N.Y. TIMES, https://www.nytimes.com/2020/03/18/business/coronavirus-ventilator-shortage.html (Mar. 26, 2020) (noting how manufacturers cannot meet increased demands, even in light of "wartime-mobilization tactics").

8. *What Is Medical Surge?*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.phe.gov/Preparedness/planning/mscc/handbook/chapter1/Pages/whatismedicalsurge.aspx (Feb. 14, 2012) (defining medical surge as "the ability to provide adequate medical evaluation and care during events that exceed the limits of the normal medical infrastructure").

9. *See generally* Kliff et al., *supra* note 7 (discussing several issues in the global supply chain for manufacturing of ventilators that contribute to shortages).

10. *See* Andrew Jacobs, *Fears of Ventilator Shortage Unleash a Wave of Innovations*, N.Y. TIMES (Apr. 17, 2020), https://www.nytimes.com/2020/04/17/health/ventilators-coronavirus.html (detailing instances of pulmonologists adapting donated continuous positive airway pressure machines for use as makeshift ventilators, or repurposing hooded hair salon dryers as personal negative pressure chambers); *see also* Martin Kaste & Rebecca Hersher, *Ventilator Shortages Loom as States Ponder Rules for Rationing*, NPR (Apr. 3, 2020, 5:00 AM), https://www.npr.org/sections/health-shots/2020/04/03/826082727/ventilator-shortages-loom-as-states-ponder-rules-for-rationing (documenting New York's cautionary ventilator rationing measures as projected cases quickly outpaced the quantity of available machines).

11. *See* U.S. FOOD & DRUG ADMIN., ENFORCEMENT POLICY FOR VENTILATORS AND ACCESSORIES AND OTHER RESPIRATORY DEVICES DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY 6–12 (2020), https://www.fda.gov/media/136318/download (providing guidance on the expansion of available respiration devices and validating modifications made to breathing circuit devices).

12. *See* Jacobs, *supra* note 10 (discussing how nurses created makeshift ventilated helmets to help COVID-19 patients avoid intubation).

ration available ventilators,[13] it is a risky endeavor. Provisional devices—like those that siphon air into multiple tubes to service two patients at once[14]—and emergency triage techniques,[15] are suboptimal fixes employed against a life-threatening ventilator shortage.

In 2006, the U.S. Department of Health and Human Services (HHS) created the Biomedical Advanced Research and Development Authority (BARDA), a division to oversee emergency medical countermeasures in response to a series of highly pathogenic respiratory diseases.[16] BARDA immediately began work on an initiative to develop and produce a fleet of portable, inexpensive ventilators for the Strategic National Stockpile (SNS).[17] Existing ventilators were cumbersome, technically complex, and expensive to manufacture[18]—poor characteristics for a device intended to combat a public health crisis.

In 2009, the federal government awarded a contract for the initiative—named Project Aura—to Newport Medical Instruments (Newport), a small California company.[19] As Newport was hitting its stride,[20] a much larger medical device manufacturer, Covidien, acquired Newport for $108 million in May 2012.[21] Despite receiving additional funding, Covidien officials were ultimately dissatisfied with projected profits on the Newport prototype and indicated their intent to terminate the contract, to which the federal

13. *See* Douglas B. White & Bernard Lo, *A Framework for Rationing Ventilators and Critical Care Beds During the COVID-19 Pandemic*, JAMA (Mar. 27, 2020), https://jamanetwork.com/journals/jama/fullarticle/2763953 (utilizing an impartial algorithm to assign a priority score to patients in need of ventilators based on their predicted health outcome).

14. *See* Alexander Gelfand, *Why It's So Hard to Solve the Ventilator Shortage*, GLOB. HEALTH NOW (Apr. 6, 2020), https://www.globalhealthnow.org/2020-04/why-its-so-hard-solve-ventilator-shortage (asserting that shared and repurposed devices pose great risk to ARDS patients because they may underinflate the lungs and cause protracted physiological damage).

15. *See* Nathaniel Marchetti, *Acute Respiratory Distress Syndrome (ARDS)*, CHEST FOUND., https://foundation.chestnet.org/lung-health-a-z/acute-respiratory-distress-syndrome-ards/# (Nov. 2, 2020) (indicating that maneuvering ARDS patients into a chest-down position can reduce pressure on the lungs but requires several medical staff members to accomplish).

16. Nicholas Kulish et al., *The U.S. Tried to Build a New Fleet of Ventilators. The Mission Failed.*, N.Y. TIMES, https://www.nytimes.com/2020/03/29/business/coronavirus-us-ventilator-shortage.html (Apr. 20, 2020).

17. *Id.*

18. *See id.* (noting that the new model would be produced at a 70% price reduction).

19. *Id.*

20. *See id.* (chronicling Newport's progress from presentation of prototypes to federal officials in 2011 to an anticipated filing date for market approval of the device by September 2013).

21. *Covidien Grabs Newport Medical Instruments for $108 Million*, MASSDEVICE (Mar. 22, 2012), https://www.massdevice.com/covidien-grabs-newport-medical-instruments-108-million/.

government acquiesced.[22] In 2014, the federal government awarded a new contract to the Dutch company Philips,[23] but beginning the process anew set researchers back nearly a decade.[24]

The regulatory authority tasked with protecting consumers from anticompetitive behavior failed to intervene, but the consequences of this failure did not materialize until recently.[25] The Federal Trade Commission (FTC) granted antitrust approval to Covidien's acquisition of Newport without second request.[26] A second request is a discovery procedure that enables the FTC to investigate the anticompetitive implications of mergers and acquisitions, and requires the parties involved to produce extensive documentation related to their business structures.[27] Renewed interest in the decision to forego this step provoked such public controversy that FTC Commissioner Kelly Slaughter called for a retrospective review of the acquisition.[28]

The likelihood of another pandemic to follow COVID-19 is too great to ignore.[29] The United States has failed to adequately contain COVID-19, as

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22. Kulish et al., *supra* note 16.

23. Press Release, Philips, Philips Respironics to Assist US Government in Development of Ventilation Solutions for Disaster Preparedness (Oct. 1, 2014), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2014/20141001-Philips-Ventilation-Solutions-for-Disaster-Preparedness.html.

24. *See* Kulish et al., *supra* note 16 (noting that the U.S. Food and Drug Administration (FDA) did not grant market approval to the Philips model until July 2019, postponing delivery to the Strategic National Stockpile (SNS) until summer 2020).

25. *See* Matt Stoller, *The Danger of No Antitrust Enforcement: How a Merger Led to the US Ventilator Shortage*, PROMARKET (Apr. 2, 2020), https://promarket.org/2020/04/02/the-danger-of-no-antitrust-enforcement-how-a-merger-led-to-the-us-ventilator-shortage/ (highlighting the conclusion of David Cicilline, Chair of the Congressional Antitrust Committee, that the Newport deal was anticompetitive).

26. Letter from House Comm. on the Judiciary to Joseph Simons, Chairman, Fed. Trade Comm'n (Apr. 10, 2020), https://judiciary.house.gov/uploadedfiles/2020-04-10_letter_to_ftc_on_covidien_acquisition.pdf.

27. *Merger Review*, U.S. FED. TRADE COMM'N, https://www.ftc.gov/news-events/media-resources/mergers-and-competition/merger-review (last visited Mar. 2, 2021).

28. David McLaughlin, *Ventilator Maker's 2012 Merger Spurs Query from FTC Official*, BLOOMBERG, https://www.bloomberg.com/news/articles/2020-03-30/covidien-ventilator-merger-needs-new-look-ftc-official-says (Mar. 30, 2020, 8:27 PM).

29. *See* Karin Brulliard, *The Next Pandemic Is Already Coming, Unless Humans Change How We Interact with Wildlife, Scientists Say*, WASH. POST (Apr. 3, 2020, 4:37 PM), https://www.washingtonpost.com/science/2020/04/03/coronavirus-wildlife-environment/ (identifying human behavior patterns in agriculture, deforestation, and urbanization as a cause of cross-contamination with diseased animal vectors).

the virus continues to exhaust metropolitan hospitals into 2021,[30] and rural hospitals face a unique predicament: no intensivists on staff trained to operate highly complex ventilation machinery, forcing them to transfer critical care patients to regional medical centers already pushing the bounds of capacity.[31] Therefore, an improved federally coordinated response is necessary to protect against future public health emergencies.[32] Since corporate transactions dictate the availability and quantity of countermeasures,[33] the FTC must collaborate with HHS researchers and practitioners responsible for developing and deploying those countermeasures—including life-sustaining devices. To avoid another devastating shortage, the FTC must review its decision to grant antitrust approval to Covidien, commit to collaboration over review of health industry mergers with the Office of the Assistant Secretary for Preparedness and Response (ASPR), and revise its merger guidelines.

This Comment discusses the implications of the FTC's mishandling of the Newport acquisition in the context of the COVID-19 pandemic. Part I establishes HHS jurisdiction over integrating the federal response to public health crises, including the authority to compel participation from any appropriate federal agency. Part II discusses the antitrust laws and potential anticompetitive effects of the acquisition, asserting that the FTC should consider the potentially harmful effects of health industry transactions regardless of market share. Part III explains the relevant uniqueness of the health industry and argues for greater interagency collaboration between the FTC and the ASPR on review of mergers that impact the development of countermeasures and medical devices. Part IV calls for the FTC to take

30. *See* Luke Money et al., *Short on Equipment, Ambulances and Oxygen, L.A. County Hospitals Face Darkest Month*, L.A. TIMES, https://www.latimes.com/california/story/2021-01-05/short-on-equipment-ambulances-los-angeles-medical-systems-hit-dire-crisis-point (Jan. 5, 2021, 6:42 AM) (revealing that California hospitals, like Harbor-UCLA Medical Center, are close to depleting their ventilator supply, and the Los Angeles County Emergency Medical Services Agency also issued a directive in early January 2021 instructing ambulance crews to supply oxygen only to the most critical patients).

31. *See* Andrew Jacobs, *Now the U.S. Has Lots of Ventilators, but Too Few Specialists to Operate Them*, N.Y. TIMES (Nov. 22, 2020), https://www.nytimes.com/2020/11/22/health/Covid-ventilators-stockpile.html (detailing the predicament for rural patients who can neither be transferred to city hospitals due to capacity strains nor receive care from intensivists as calls to relocate continue to go unanswered).

32. *Cf. Tracking the Coronavirus at U.S. Colleges and Universities*, N.Y. TIMES, https://www.nytimes.com/interactive/2020/us/covid-college-cases-tracker.html (Dec. 11, 2020) (reporting an increase in COVID-19 outbreaks at universities since the start of the fall 2020 semester).

33. *See generally* MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 224 (2017), http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0.

retrospective and preventative measures to ensure future mergers will not cause device shortages or jeopardize the mobilization of countermeasures during a public health emergency.

I. TRIAGING THE INDUSTRY: HHS JURISDICTION OVER MERGERS IN MEDICINE

Industry consolidation trends in the healthcare market are a rapidly evolving problem that warrants HHS oversight.[34] The HHS's Office of the ASPR operates chiefly to prepare for modern health–security threats by coordinating response capabilities within the private and public sectors.[35] Without express authorization to mobilize resources from industry and other federal agencies, the ASPR cannot effectively anticipate and combat health security threats.[36] However, the authority to mobilize resources is inconsequential if the resources are inaccessible or nonexistent—the ASPR could not deploy the Project Aura model ventilator because the FTC did not intervene to ensure the integrity of Newport's contract with the federal government.[37]

A. Biomedical Advanced Research and Development Authority

Established in the wake of a slew of major viral outbreaks,[38] the Biomedical Advanced Research and Development Authority (BARDA) takes point within the HHS on the development and acquisition of countermeasures against manufactured or naturally occurring threats to public health.[39] To secure

34. *See Regulations and Laws that May Apply During a Pandemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/flu/pandemic-resources/planning-preparedness/regulations-laws-during-pandemic.htm (Nov. 3, 2016).

35. *Saving Lives and Protecting Americans from 21st Century Health Security Threats*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.phe.gov/about/aspr/Pages/default.aspx (Feb. 4, 2021).

36. *See* OFF. OF THE ASSISTANT SEC'Y FOR PREPAREDNESS & RESPONSE, U.S. DEP'T OF HEALTH & HUM. SERVS., STRATEGIC PLAN FOR 2020–2023 10–12 (2020), https://www.phe.gov/about/aspr/Documents/2020-ASPR-Strategic-Plan-508.pdf (detailing how vital interconnectedness is to the federal response to health crises).

37. *See* Tim Wu, Opinion, *A Corporate Merger Cost America Ventilators*, N.Y. TIMES (Apr. 12, 2020), https://www.nytimes.com/2020/04/12/opinion/ventilators-coronavirus.html (reporting that a former Federal Trade Commission (FTC) official considered it a success to "steer[]" the merger through review without second request, which went on to bridle a "prescient" federal program).

38. *See* Kulish et al., *supra* note 16 (noting how Project Aura was immediately mobilized after the SARS outbreak and developed concurrently with the MERS, bird flu, and swine flu outbreaks).

39. *See Innovation*, U.S. DEP' OF HEALTH & HUM. SERVS., https://www.medicalcountermeasures.gov/barda/advancing-innovation/ (last visited Mar. 2, 2021) (conveying Biomedical

countermeasures for response and recovery, BARDA supports product development and coordinates the acquisition of approvable countermeasure products for the SNS.[40] Product development is supported by the Chemical, Biological, Radiological, and Nuclear Threat Programs division (CBRN), which fortifies the "valley of death" funding gap existing between the early stages of product development and acquisition upon FDA approval.[41] BARDA organization efforts are a critical function of Project BioShield,[42] and since its enactment, BARDA has awarded numerous contracts for "late-stage development and acquisition of CBRN medical countermeasures."[43]

In June 2020, the Department of Defense (DoD) and BARDA entered into a $143 million agreement with SiO2 Materials Science, a privately-owned company in Alabama that produces "state-of-the-art" packaging for pharmaceuticals and vaccines.[44] The agreement will accelerate production of SiO2's patented packaging technology for COVID-19 vaccines and therapeutics, and relies on the desirable characteristics of SiO2's material, given how common it is for innovations in drug development to be limited by unstable packaging variables.[45] BARDA occupies a niche in the development of critical medical equipment and technology.[46] The extensive coordination required to facilitate agreements with companies like SiO2 and

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Advanced Research and Development Authority (BARDA) assessment and promotion capabilities used to quickly develop and deliver innovative countermeasures).

40. *See generally Chemical, Biological, Radiological, and Nuclear (CBRN) Threat Programs*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.medicalcountermeasures.gov/barda/cbrn/ (last visited Mar. 2, 2021).

41. *See id.* (explaining how BARDA uses Project BioShield funding to support product acquisition programs for vaccines, therapeutics, antivirals, antimicrobials, diagnostics, and multi-use countermeasures for health threats like community-acquired pneumonia).

42. *See generally* FRANK GOTTRON, CONG. RSCH. SERV., RS21507, PROJECT BIOSHIELD: PURPOSES AND AUTHORITIES (2009), https://fas.org/sgp/crs/terror/RS21507.pdf.

43. *See Stockpile Building*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.medicalcountermeasures.gov/barda/stockpile-building/ (last visited Mar. 2, 2021) (highlighting how a long-term funding source facilitates easier agency and industry partner collaboration).

44. *SiO2 Materials Science Receives $143 Million Contract from U.S. Government to Accelerate Capacity Scale-Up of Advanced Primary Packaging Platform for COVID-19 Vaccines and Therapeutics*, BUS. WIRE (June 8, 2020, 8:00 AM), https://www.businesswire.com/news/home/20200608005120/en/SiO2-Materials-Science-Receives-143-Million-Contract.

45. *See id.* (explaining how SiO2 vials are chemically stable, "eliminat[ing] these variables").

46. *See This Tiny Federal Agency Was Built to Respond to a Crisis Like Coronavirus. Now That It's Here, Is BARDA Ready?*, GA. BIO (Apr. 6, 2020), https://gabio.org/this-tiny-federal-agency-was-built-to-respond-to-a-crisis-like-coronavirus-now-that-its-here-is-barda-ready/ (analyzing how quickly BARDA develops contracts and how it takes on projects that the private industry will not bother with).

Newport—which was selected for its small size and specialty portfolio[47]—is directly undermined when the FTC permits large corporate firms to acquire assets from smaller rivals without deferring to HHS officials to determine the significance and impact of those agreements.[48]

B. Public Health Emergency Medical Countermeasures Enterprise

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is responsible for "coordinat[ing] [f]ederal efforts" to strengthen the CBRN and Emerging Infectious Diseases (EID) divisions.[49] PHEMCE works primarily with three internal agency partners: the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the FDA.[50] Interagency cooperation and initiative fulfillment is directed and counseled by the Enterprise Senior Counsel (ESC), which focuses on strategy and resource prioritization.[51] The ESC forum is comprised of senior leadership from each internal agency partner, as well as comparable senior level representatives from each interagency partner.[52] For instance, the Defense Advanced Research Projects Agency (DARPA) within the DoD has developed several programs for rapid detection of exposure and infection of COVID-19 in coordination with HHS.[53] Notably, the FTC does not contribute in any capacity to PHEMCE efforts.[54]

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47. Kulish et al., *supra* note 16.

48. Wu, *supra* note 37.

49. *Public Health Emergency Medical Countermeasures Enterprise*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx (Dec. 30, 2020).

50. *Id.*

51. *PHEMCE Governance*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.phe.gov/Preparedness/mcm/phemce/Pages/governance.aspx (Feb. 3, 2017); *see also* OFF. OF THE ASSISTANT SEC'Y FOR PREPAREDNESS & RESPONSE, U.S. DEP'T OF HEALTH & HUM. SERVS, THE PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE REVIEW 13, 16, 18 (2010), https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf (indicating that the Enterprise Senior Counsel was established in response to the 2010 U.S. Department of Health and Human Services (HHS) Secretary's Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Review, which called for PHEMCE partners to contribute technical and regulatory assistance in addition to financial aid).

52. *See Public Health Emergency Medical Countermeasures Enterprise*, *supra* note 49 (listing the U.S. Department of Defense, U.S. Department of Veterans Affairs, U.S. Department of Homeland Security, and the U.S. Department of Agriculture as the acting PHEMCE interagency partners).

53. *COVID-19*, DEF. ADVANCED RSCH. PROJECTS AGENCY, https://www.darpa.mil/work-with-us/covid-19 (Dec. 7, 2020).

54. *See supra* note 52 and accompanying text.

C. Public Health Service Act

The Secretary of HHS (Secretary) is legally authorized to compel the FTC to participate in this collective effort.[55] The Public Health Service Act (PHSA) grants the Secretary authority to assert operational control over emergency public health assets and to coordinate an interagency response during crises.[56] The Secretary has an obligation to coordinate policy on federal public health and medical preparedness before, during, and following public health emergencies, and must implement strategic initiatives to fund and procure medical countermeasures to satisfy this obligation.[57] While the text of the PHSA only explicitly designates nine agencies as members of the PHEMCE, the Secretary can determine that it would be appropriate to coordinate services with any other federal agency.[58]

D. Pandemic All-Hazards Preparedness Act

The Pandemic All-Hazards Preparedness Act (PAHPA) further defines HHS authority to coordinate the federal public health response by authorizing the Assistant Secretary for Preparedness and Response (Assistant Secretary) to compel interagency collaboration over promotion and financial support of rapid, innovative development of cost-effective countermeasures.[59] The PAHPA authorizes the reach of coordination to federal agencies, relevant industries, and academia.[60] By virtue of the antitrust exemption in these Acts, the Secretary may also consult with persons engaged in the development of qualified pandemic or epidemic

55. *See* Public Health Service Act, 42 U.S.C. § 247d(a) (providing the foundation of HHS's legal authority to respond to public health emergencies).

56. *See id.* § 300hh(b) (establishing HHS's "operational" authority over "the head of any other relevant federal agency" during a coordinated emergency response, with the exception of members of the armed forces).

57. *See id.* § 300hh-10(b)(4)(D) (stating the Secretary's obligation to "[p]rovide integrated policy coordination" consistent with the National Response Plan); *see also* 6 U.S.C. § 314(a)(9) (detailing the four-pronged approach of "mitigation," "preparedness," "response," and "recovery" for HHS to take in leading a "risk-based, comprehensive emergency management system" for public health crises as part of the National Response Plan); 42 U.S.C. § 300hh–1.

58. *See* 42 U.S.C. § 300hh-10a(b)(10).

59. Pandemic All-Hazards Preparedness Act of 2006, Pub. L. No. 109-417, § 401, 120 Stat. 2831, 2867–68, 2872 (codified as amended in scattered sections of 42 U.S.C.); *see also* 42 U.S.C. § 300hh–10(a), (b)(1)–(3) (identifying the Assistant Secretary's authority to coordinate integration and ensure federal preparedness and response to public health emergencies).

60. 42 U.S.C. § 247d–7e(c)(2)(A).

products for countermeasure development purposes.[61] Ventilators are a vital part of the response to a pandemic characterized by severe respiratory ailment.[62] It is highly likely that both the PHSA and the PAHPA would have authorized HHS to compel the FTC to flag the Newport acquisition for extensive review, given the implications of the Project Aura contract.[63]

II. MULTI-SYSTEM (ORGAN) FAILURE: THE CONSEQUENCES OF MERGER AND ACQUISITION TRENDS IN MEDICAL TECHNOLOGY

A. The Antitrust Laws

The Sherman Antitrust Act of 1890 (Sherman Act) prohibits restraints on trade deemed to be unreasonable, as defined in *United States v. Patterson*.[64] Overlapping directly with the Sherman Act in terms of substantive prohibitions, only the FTC may invoke the Federal Trade Commission Act of 1914 (FTC Act).[65] The FTC Act bans methods of competition that exceed the scope of the Sherman Act.[66] It also prescribes rules to the FTC establishing agency requirements designed to prevent unfair or deceptive anticompetitive acts.[67] Established in the same year as the FTC Act, the

61. *See* 42 U.S.C. § 247d-6a(a)(1)(A); *see also* 42 U.S.C. § 247d-6b(c)(1)(B) (a qualified pandemic product may be a drug, biological product, or device identified as a security countermeasure that the HHS Secretary "determines to be a priority . . . to diagnose, mitigate, prevent or treat harm" caused by a "material threat" to health).

62. Dreger, *supra* note 1.

63. *See* Carl W. Hittinger & Brady Cummins, *Competitor Collaborations—Necessity, Enforcement and Defenses During Pandemic*, LEGAL INTELLIGENCER (Apr. 24, 2020, 11:05 AM), https://www.law.com/thelegalintelligencer/2020/04/24/competitor-collaborations-necessity-enforcement-and-defenses-during-pandemic/ (identifying the minimal administrative hurdles of invoking the Pandemic All-Hazards Preparedness Act to afford "antitrust immunity" to consultation on countermeasure efforts).

64. *See* Sherman Antitrust Act, 15 U.S.C. §§ 1–7; United States v. Patterson, 205 F. 292, 300–02 (S.D. Ohio 1913) (upholding an indictment against officers of the cash register trust, as its violent methods of maintaining control could be considered monopolizing); *see also* William Letwin, *The First Decade of the Sherman Act: Judicial Interpretation*, 68 YALE L.J. 900, 906–09 (1959) (explaining how *Patterson* and other early antitrust decisions established doctrine for interpreting the Sherman Act, which dictates that only unreasonable restraints on trade are illegal).

65. *The Antitrust Laws*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws (last visited Jan. 28, 2021).

66. *Id.*

67. *See* 15 U.S.C. § 1; *see also Anticompetitive Practices*, FED. TRADE COMM'N, https://www.ftc.gov/enforcement/anticompetitive-practices (last visited Mar. 2, 2021) (identifying single firm conduct—the attempt of "a firm with market power" to "maintain or acquire a dominant position by excluding competitors"—as an unlawful practice).

Clayton Antitrust Act of 1914 (Clayton Act) further defines prohibited practices not explicitly addressed by the Sherman Act.[68] Notably, the Clayton Act prohibits the acquisition of stock where the effect may be to substantially lessen competition.[69]

The Hart–Scott–Rodino Antitrust Improvements Act of 1976 (HSR) amended the Clayton Act to require firms planning particularly large mergers or acquisitions to give the federal government advance notice.[70] Congress established the HSR Premerger Notification Program to allow the FTC and the U.S. Department of Justice (DOJ) Antitrust Division to determine which acquisitions are likely to be anticompetitive and effectively challenge them.[71] The HSR determines required waiting periods for large mergers, but filing parties may request "early termination" before the end of the applicable period, which is granted if the FTC and the DOJ decide against antitrust enforcement action upon completion of their review.[72] Antitrust challenges are most effective in the premerger review stage.[73] At $108 million, Covidien's acquisition of Newport was well above the premerger notification threshold for 2012 and, thus, merited thorough review by the FTC.[74]

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68. *The Antitrust Laws*, *supra* note 65.

69. *See* 15 U.S.C. § 18 (prohibiting corporations from wholly or partially owning the stock of a subsidiary corporation if the effect of such a formation significantly impedes competition).

70. *See* Hart–Scott–Rodino Antitrust Improvements Act of 1976 (HSR), Pub. L. No. 94-435, § 201, 90 Stat. 1383, 1390 (requiring firms to submit notice to both FTC and the U.S. Department of Justice (DOJ)); *see also* Premerger Notification Off., *HSR Threshold Adjustments and Reportability for 2020*, FED. TRADE COMM'N (Jan. 31, 2020, 2:34 PM), https://www.ftc.gov/news-events/blogs/competition-matters/2020/01/hsr-threshold-adjustments-reportability-2020 (indicating that the HSR creates a statutory minimum dollar threshold for premerger notification that is adjusted yearly based on change in gross national product—in 2020 the threshold was $94 million).

71. *See* PREMERGER NOTIFICATION OFF., FED. TRADE COMM'N, WHAT IS THE PREMERGER NOTIFICATION PROGRAM?: AN OVERVIEW 1 (rev. 2009), https://www.ftc.gov/sites/default/files/attachments/premerger-introductory-guides/guide1.pdf (explaining that antitrust challenges are most effective at this stage because it is often impossible to fully restore competition after an anticompetitive acquisition, and it incurs great cost for the public).

72. *About Early Termination Notices*, FED. TRADE COMM'N https://www.ftc.gov/enforcement/premerger-notification-program/early-termination-notices/about-early-termination-notices (last visited Mar. 2, 2021).

73. PREMERGER NOTIFICATION OFF., *supra* note 71.

74. *See* Robert Fleming, Jr., *FTC Announces Increased 2012 HSR Thresholds*, HODGSON RUSS LLP (Jan. 27, 2012), https://www.hodgsonruss.com/newsroom-publications-FTCAnnouncesIncreasedHSRThresholds.html (indicating that the HSR filing notification threshold for 2012 was $68.2 million).

B. Killer Acquisition?

"Killer acquisition" is a term coined for market maneuvers, most often by incumbent firms, that terminate innovation and preempt future competition.[75] Most often, the target firm's project is still in the development stage, making it costly and uncertain to be profitable.[76] Additionally, the incumbent firm usually has little to no incentive to complete the project if it substitutes for an existing product in its portfolio.[77] When Covidien acquired Newport, the Aura model was still in the prototype phase and was functionally similar to an existing ventilator in Covidien's portfolio.[78] The common motive behind this type of acquisition is known to FTC officials: Kevin Arquit, the former head of the FTC Bureau of Competition, remarked that "elimination of a maverick rival" is a strong reason for an antitrust challenge.[79]

C. The Pulmonary Embolism: Consequences of the Antitrust Safety Zone

The real killer may be the market itself. When a blood clot forms in a vein deep within the body, it can travel to the lungs and become lodged in one of the pulmonary arteries, blocking blood flow to the lung tissue.[80] Similarly, merger trends in the hospital industry have led to metropolitan behemoths that divert resources away from more rural communities.[81] A Clinton-era set of policy statements on antitrust enforcement in healthcare set forth an "antitrust safety zone" in which hospital mergers will not be challenged by antitrust law.[82]

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75. Colleen Cunningham et al., *Killer Acquisitions*, J. POL. ECON. (forthcoming) (manuscript at 1), https://dx.doi.org/10.2139/ssrn.3241707.

76. *Id.* (manuscript at 2).

77. *See id.* (manuscript at 3) (noting that pharmaceutical projects are 23.4% less likely to finish development when subject to an acquisition by an incumbent firm with an overlapping portfolio, compared to nonoverlapping incumbent acquirer portfolios).

78. Kulish et al., *supra* note 16.

79. Ben Remaly, *Ventilator Merger Scrutinised as Potential "Killer Acquisition"*, GLOB. COMPETITION REV. (Mar. 31, 2020), https://globalcompetitionreview.com/ventilator-merger-scrutinised-potential-killer-acquisition. *But see id.* (noting Arquit's assertion that it is unlikely that FTC officials knew of any explicitly nefarious intent at the time of the Newport acquisition).

80. *Pulmonary Embolism*, MAYO CLINIC (June 13, 2020), https://www.mayoclinic.org/diseases-conditions/pulmonary-embolism/symptoms-causes/syc-20354647.

81. *See* Brian Alexander, *America's Rural Hospitals Are Dangerously Fragile*, ATLANTIC (Jan. 9, 2018), https://www.theatlantic.com/business/archive/2018/01/rural-hospitals/549050/ (reporting how consolidation harms rural hospitals' already fragile financial margins).

82. *See* U.S. DEP'T OF JUST. & FED. TRADE COMM'N, STATEMENT OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE 8–9 (1996), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf (stipulating that a merger between two general acute care hospitals will

The guidance asserts that this type of merger is unlikely to substantially reduce competition because "in some cases" a hospital of this nature will be the only one in the relevant market.[83]

This safety zone initiated a consolidation trend that has greatly contributed to the loss of rural hospitals.[84] This loss is particularly concerning amid a pandemic, when the unprecedented patient influx compounds the bed shortage crisis.[85] The financial sector's influence over the health sector has exacerbated the problem, as hospitals face pressure to reduce costs and raise profits by acquiring rivals and shifting to an outpatient care model.[86] The passage of the Patient Protection and Affordable Care Act (ACA)[87] in 2010 revealed the urgency of the crisis and encouraged market behavior that simply made it worse.[88] For example, when formerly uninsured patients were newly able to seek medical care,[89] several large insurers formed Accountable Care Organizations,[90] giving them a greater market share and more leverage to reduce patient care options.[91]

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not be challenged if one has an average of fewer than 100 licensed beds and an average daily inpatient census of fewer than forty patients over the last three years).

83. *Id.* at 9.

84. *See* Andrea Flynn & Ron Knox, *We're Short on Hospital Beds Because Washington Let Too Many Hospitals Merge*, WASH. POST https://www.washingtonpost.com/outlook/2020/04/08/were-short-hospital-beds-because-washington-let-too-many-hospitals-merge/ (Apr. 8, 2020, 6:00 AM) (noting a 15% decline in rural hospitals since the mid-1970s).

85. *See id.*

86. *Id.*

87. Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010).

88. *See* James C. Robinson & Leonard D. Schaeffer, *More Evidence of the Association Between Hospital Market Concentration and Higher Prices and Profits*, NAT'L INST. FOR HEALTH CARE MGMT. (Nov. 2011), https://nihcm.org/assets/articles/nihcm-ev-robinson-final.pdf.

89. *See* Dennis Thompson, *U.S. Hospital Beds Were Already Maxed Out Before Coronavirus Pandemic*, U.S. NEWS & WORLD REP. (Mar. 26, 2020, 9:00 AM), https://www.usnews.com/news/health-news/articles/2020-03-26/us-hospital-beds-were-already-maxed-out-before-coronavirus-pandemic (explaining that capacity constraints existed prior to COVID-19, with New York averaging 23% availability for hospital beds on any given day before the outbreak).

90. *See* Jenny Gold, *Accountable Care Organizations, Explained*, KAISER HEALTH NEWS (Sept. 14, 2015), https://khn.org/news/aco-accountable-care-organization-faq/ (explaining that Accountable Care Organizations, or networks of physicians and hospitals that share responsibility for patient care, may accelerate the merger trend by acting as a tool for hospitals looking to become integrated systems).

91. *See* Joel T. Dodge, *Health Care Market Concentration Trends in the United States: Evidence and Policy Responses*, COMMONWEALTH FUND (Sept. 6, 2017), https://www.commonwealthfund.org/publications/journal-article/2017/sep/health-care-market-concentration-trends-united-states (noting that presently, 90% of major U.S. cities are served by a highly concentrated healthcare industry due to concentrated practice organizations).

D. The Pulmonary Infarction: Medical Device Manufacturers Follow the Leader

Left unchecked, a pulmonary embolism may impede the flow of oxygenated blood to the lung tissue and cause necrosis.[92] Healthcare consumers are experiencing the complications of an undiagnosed clot right now: medical device firms are mirroring the consolidation trend. As hospitals increase in size and offer a broader range of specialized care services, manufacturers seek to present themselves as "one-stop shops" with a wide array of products.[93] Covidien is not an exception to this trend. From 2008 to 2014, the firm purchased seventeen other manufacturing corporations and pitched itself as a diverse device distributor for hospitals.[94] In 2014, shortly before its acquisition by Medtronic, Covidien acquired assets from the firm PMT Partners and was later accused of violating the Administrative Procedure Act[95] when it abandoned pending patents and decided to destroy, rather than return, molds for products it shelved.[96] This trend is alarming, and the FTC's approach to merger review of medical devices is insufficient. Rather than consider the necessary specialty of a market producing life-saving equipment, the FTC often treats these products in the same way as common leisure commodities.[97]

Despite this, the FTC has exercised regulatory authority over mergers similar to the Newport acquisition before, citing realized or anticipated anticompetitive effects.[98] In a complaint issued in 2009 against Inverness Medical Innovations, Inc. (Inverness), the FTC charged that Inverness, a manufacturer of consumer pregnancy tests, engaged in unfair competition when it acquired but did not use a water-soluble dye technology conceived by a competing producer.[99] The FTC ordered Inverness to divest its assets in this technology.[100] Production also stalled on the Aura ventilator model after Covidien acquired Newport—the federal government agreed to

92. *See* Alec Emerling & Jeffrey Cook, *Pulmonary Infarction*, STATPEARLS PUBL'G, https://www.ncbi.nlm.nih.gov/books/NBK537189/ (Aug. 23, 2020) (stating that a pulmonary infarction is a complication of a primary disease state, most commonly evolving from a pulmonary embolism).

93. *See* Kulish et al., *supra* note 16.

94. *See* Stoller, *supra* note 25 (highlighting that after the Newport acquisition, Covidien issued a press release stating its intention to strengthen its "ventilation platform" for the global market).

95. Administrative Procedure Act, 5 U.S.C. §§ 551–559, 561–570a, 701–706.

96. *See* PMT Partners, LLC v. Covidien AG, No. 2:13CV377DAK, 2014 WL 700510, at *2 (D. Utah Feb. 24, 2014).

97. *See* Wu, *supra* note 37 (explaining that the scope of antitrust review is too narrow to account for concerns regarding life-saving products like ventilators).

98. *Infra* notes 99–104 and accompanying text.

99. Inverness Med. Innovations, Inc., 147 F.T.C. 1, 5–6 (2009) (Complaint), https://www.ftc.gov/system/files/documents/commission_decision_volumes/volume-147/vol147complete.pdf.

100. *Id.* at 24 (Decision and Order).

terminate the contract while Covidien systematically reassigned technicians and abandoned the prototype.[101] When Covidien acquired Newport, the firm already produced ventilators.[102] More specifically, Covidien produced portable ventilators: Covidien commercialized the Puritan Bennett™ 560 (PB 560) model in 2010[103]—the year portable ventilators were released on the market.[104]

It is conceivable that Covidien's anticompetitive behavior was intentional. The more urgent concern, however, is the harm the Newport acquisition caused.[105] In 1997, the FTC challenged a proposed merger transaction between the two largest firms in the country that rent movable medical equipment to hospitals.[106] The FTC recognized the inability of any new entrant to compete against the merged firms quickly enough to offer this service to hospitals, which is most commonly sought during periods of peak need.[107] A month after the FTC brought its challenge, the firms abandoned the transaction.[108] Several years later, when the dominant firm in the left ventricular assist device (LVAD) market attempted to acquire its only direct competitor, the FTC filed a complaint alleging the acquisition would deny LVAD patients life-saving benefits of competition, and the firms terminated the merger agreement.[109] The complaint noted

101. *See* Kulish et al., *supra* note 16 (making note of the president of Newport's sustained enthusiasm for the project up until the transaction, despite Covidien executives' claims that Project Aura was "winding down" by the time of the acquisition).

102. *See id.*

103. Jean Thilmany, *Medtronic Opens Its PB560 Ventilator Files to Makers*, AM. SOC'Y MECH. ENG'RS (Apr. 27, 2020), https://www.asme.org/topics-resources/content/medtronic-opens-its-pb560-ventilator-files-to-makers.

104. *Portable Ventilator*, WORLD HEALTH ORG. [WHO]. https://www.who.int/medical_devices/innovation/compendium_med_dev2011_11.pdf?ua=1 (last visited Mar. 2, 2021).

105. *See* Kliff et al., *supra* note 7.

106. Complaint at 3–4, FTC v. MEDIQ Inc., No. 97-1916 (D.D.C. Aug. 22, 1997).

107. *Id.* at 4, 6; *see also* Elizabeth Svoboda, *Invention Awards: An Inexpensive, Portable Ventilator*, POPULAR SCI. (May 28, 2010), https://www.popsci.com/diy/article/2010-05/invention-awards-breathing-easy/ (noting that it is impractical for hospitals to stockpile ventilators to use during emergencies due to the high cost); Jeffrey S. Baird & Kelly T. Custer, *Renting Equipment to Hospitals During the COVID-19 Crisis*, HOMECARE MAG. (Mar. 30, 2020), https://www.homecaremag.com/renting-equipment-hospitals-during-covid-19-crisis (acknowledging the increased demand for respiratory equipment rentals during COVID-19).

108. *See* Press Release, Fed. Trade Comm'n, Mediq Informs FTC that It Will Abandon Merger with UHS in Face of Challenge (Sept. 22, 1997), https://www.ftc.gov/news-events/press-releases/1997/09/mediq-informs-ftc-it-will-abandon-merger-uhs-face-challenge (publicizing that Mediq Incorporated informed the FTC that it abandoned the acquisition due to the challenge).

109. *See* Thoratec Corp., No. 9339, at 2 (July 28, 2009) (Administrative Complaint), https://www.ftc.gov/sites/default/files/documents/cases/2009/07/090730thorateadmincc

how competition and innovation intensify when a rival device is granted FDA approval.[110]

COVID-19 patients who succumbed to the virus while in untended respiratory distress were denied life-sustaining treatment by the FTC's nonintervention.[111] The Aura ventilator was slated for FDA approval in September 2013,[112] and could have been effectively deployed to combat COVID-19. Providers must look elsewhere, however, and given that the overdue Philips Trilogy Evo model is more expensive per unit than anticipated,[113] providers instead have the option to clear several administrative hurdles to potentially receive a ration of ventilators from Covidien's pre-Newport portfolio, which are stockpiled by the federal government in limited numbers.[114] Providers can also acquire Covidien ventilators privately: Covidien's PB 560 is not FDA-approved,[115] yet is sanctioned for use under an Emergency Use Authorization (EUA).[116] Despite this lack of approval, but in accordance with the EUA, Medtronic, the company that acquired Covidien in 2015,[117] made public in late March 2020 the design specifications for the

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mpt.pdf (noting that competition forced technical innovation and that continued competition would lower prices and enhance features, increasing the availability and quality of the devices).

110. *Id.*

111. Rothfeld et al., *supra* note 6.

112. Kulish et al., *supra* note 16.

113. *See* Patricia Callahan & Sebastian Rotella, *The White House Paid Up to $500 Million Too Much for These Ventilators, Congressional Investigators Say*, PROPUBLICA (Aug. 7, 2020, 3:40 PM), https://www.propublica.org/article/the-white-house-paid-up-to-500-million-too-much-for-these-ventilators-congressional-investigators-say.

114. *See* AMANDA KOBOKOVICH, JOHN HOPKINS BLOOMBERG SCH. OF PUB. HEALTH, VENTILATOR STOCKPILING AND AVAILABILITY IN THE U.S. 1 (2020), https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/200214-VentilatorAvailability-factsheet.pdf (announcing that the LP10 model, a Puritan Bennett design since acquired by Covidien, is one of three ventilator models available in the meager 12,000-unit stockpile).

115. *Puritan Bennett™ 560 Ventilator*, MEDTRONIC, https://www.medtronic.com/covidien/en-us/support/products/mechanical-ventilation/puritan-bennett-560-ventilator.html (last visited Mar. 3, 2021).

116. *Ventilators and Ventilator Accessories EUAs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas#appendixb (Jan. 12, 2021); *see also Emergency Use Authorizations*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization (Jan. 27, 2021) (explaining that § 564 of the Food, Drug, and Cosmetic Act allows the FDA Commissioner to approve unapproved medical products or methods of use for medical products to prevent harm where no "adequate, approved, and available" alternatives exist).

117. Press Release, Medtronic, Medtronic to Acquire Covidien for $42.9 Billion in Cash and Stock (June 15, 2014), https://newsroom.medtronic.com/node/29996/pdf.

PB 560, hoping to curate a global response in ventilator production to combat COVID-19.[118]

Perhaps altruistic, yet this gesture is inadequate for several reasons. By March 30, 2020, the date Medtronic announced it would share the PB 560 design, there were 122,653 total confirmed cases of COVID-19 in the United States.[119] Additionally, adapting the engineering files requires prospective manufacturers to overcome several logistical hurdles, like acquiring the model's specialized valves, which are made only by the Swiss company Norgren.[120] Even if these hurdles are overcome, the result will not be of maker quality.[121] In addition to the delay—which is compounded by the fact that the Philips Trilogy Evo model was not readily available at the beginning of the pandemic[122]—and the logistical hurdles, the FDA recalled[123] the alternative offered by one of the only other ventilator manufacturers with as much market power[124] as Medtronic and Philips. Medtronic is currently under investigation by the federal government after receiving a civil subpoena from the DOJ requesting information specific to the Newport deal.[125]

The FTC must recognize that in the context of healthcare mergers, even transactions that are not clear-cut antitrust violations may cause irreparable harm. Covidien did not occupy a monopolistic share of the market when it

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118. Press Release, Medtronic, Medtronic Shares Ventilation Design Specifications to Accelerate Efforts to Increase Global Ventilator Production (Mar. 30, 2020), https://newsroom.medtronic.com/node/31306/pdf.

119. WHO, *Novel Coronavirus (2019-nCoV) Situation Report-70* (Mar. 30, 2020), https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200330-sitrep-70-covid-19.pdf?sfvrsn=7e0fe3f8_4.

120. Thilmany, *supra* note 103.

121. *See id.* (explaining that the design files are complicated, outdated, and incomplete).

122. Kulish et al., *supra* note 16; *see also* Callahan & Rotella, *supra* note 113 (documenting how the Trump Administration failed to accelerate shipment of the model by granting three extensions on the contract).

123. *See ResMed Recalls Stellar 100 and 150 Non-Invasive and Invasive Ventilators Due to Sound Alarm Failure*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/medical-device-recalls/resmed-recalls-stellar-100-and-150-non-invasive-and-invasive-ventilators-due-sound-alarm-failure (Feb. 19, 2020) (noting that affected ResMed ventilators, which can experience sound alarm failure among other defects, have already led to one death).

124. *See Ventilators Market*, MARKETS & MARKETS, https://www.marketsandmarkets.com/Market-Reports/ventilators-market-11018337.html (last visited Mar. 2, 2021) (listing Philips Healthcare, ResMed, and Medtronic as the three most prominent players in the ventilator market).

125. *See* Brent Kendall, *Justice Department Opens Ventilator Antitrust Probe Focused on Medtronic*, WALL ST. J., https://www.wsj.com/articles/justice-department-opens-ventilator-antitrust-probe-focused-on-medtronic-11601497943 (Sept. 30, 2020, 7:28 PM) (indicating that Medtronic is cooperating with the DOJ's antitrust probe of its pre-2012 acquisitions).

acquired Newport like MEDIQ Incorporated did when it attempted to acquire Universal Hospital Services, Inc.,[126] but it successfully terminated a federal contract that would have fortified the U.S. COVID-19 response.[127] Depriving consumers of a vital good during a pandemic is harmful regardless of the market share occupied by the acquiring firm that ceased development of the good. Healthcare workers have to piece together suboptimal solutions,[128] and for critically ill patients it may not be enough.[129] The FTC has exercised its regulatory authority against threats to healthcare consumer welfare before, so why did it fail to stop Covidien?

III. RAPID RESPONSE TEAM: THE NEED FOR INTERAGENCY COLLABORATION

A. Page the Specialist: Healthcare as a Unique Industry

As an industry, healthcare is at odds with the free market.[130] While no market allocates resources with perfect efficiency, healthcare deviates considerably because it is a compound of several interdependent markets.[131] Healthcare is also not a consumable good; it derives from the demand for health and thus is not marketable or exchangeable, making it extremely difficult for the market itself to determine resource allocation.[132] Additionally, the development of medical device technology is unique. Given its crucial function, market innovation in this industry requires immense cross-disciplinary communication and collaboration for effective use in clinical practice.[133]

Disrupting this collaborative effort may have dire consequences: the first attempt to equip the SNS with ventilators required a panel of officials to authorize

126. Complaint at 4, FTC v. MEDIQ Inc., No. 97-1916 (D.D.C. Aug. 22, 1997).

127. Kulish et al., *supra* note 16.

128. *See* Jacobs, *supra* note 10.

129. *See* Katie Thomas, *Coronavirus Attacks the Lungs. A Federal Agency Just Halted Funding for New Lung Treatments*, N.Y. TIMES, https://www.nytimes.com/2020/06/19/health/coronavirus-lung-treatment-funding.html (June 24, 2020) (reporting BARDA's announcement that it would no longer use federal funding on lung repair therapies, and instead would shift its strategy towards vaccine development in response to the Trump Administration's goals).

130. *See* Ari Mwachofi & Assaf F. Al-Assaf, *Health Care Market Deviations from the Ideal Market*, 11 SULTAN QABOOS UNIV. MED. J. 328, 328–30 (2011).

131. *See id.* at 329 (identifying education, labor, and pharmaceutical as just a few of the markets that comprise the healthcare industry).

132. *See id*. at 331–32 (identifying consumer inability to make independent judgments about their welfare as another factor making healthcare nonconsumable).

133. INST. OF MED., SOURCES OF MEDICAL TECHNOLOGY: UNIVERSITIES AND INDUSTRY 4 (Nathan Rosenberg et al. eds., 5th ed. 1995) (noting that medical innovation is dependent on interdisciplinary research).

a federal contract to develop equipment and combat an impending pandemic, and the result was still fatally delayed.[134] Admittedly, COVID-19 has delayed review of more than $145 billion in pending mergers and acquisitions, including a $26.6 billion deal between Caesar's Entertainment Corp. and Eldorado Resorts, Inc.[135] Delayed review in the entertainment industry has consequences, certainly,[136] but those consequences do not include loss of life. Disrupting collaboration in the health industry, by contrast, can be catastrophic.[137]

B. Doctor Knows Best: Relying on HHS Expertise

Anticipating another SARS-like outbreak, HHS officials understood the significance of Project Aura and its implications for availability of care during a health crisis.[138] The HHS established a new operating division to specialize in medical emergency preparedness.[139] The federal budget accounted for what experts believed to be a crucial vulnerability within the medical system.[140] In this particular instance, however, all of that preparation proved to be fruitless as no deference was shown to HHS expertise in the review of an acquisition with the potential to seriously harm the project.[141] The total lack of coordination between the FTC and the HHS has proven fatal for many virus patients.[142] Deferring to agency expertise in matters of industry specialty is essential.[143] If the FTC had

134. Kulish et al., *supra* note 16.

135. Grace Maral Burnett & Eleanor Tyler, *Pandemic Delays Antitrust Review of $130B in M&A Deals*, BLOOMBERG L. (Apr. 10, 2020, 6:51 AM), https://news.bloomberglaw.com/bloomberg-law-analysis/analysis-pandemic-delays-antitrust-review-of-130b-in-m-a-deals.

136. *See* Scott Deveau & Christopher Palmeri, *As Caesars Deal Lingers, Buyer Faces $2.3 Million a Day in Fees*, BLOOMBERG (Mar. 25, 2020, 6:11 PM), https://www.bloomberg.com/news/articles/2020-03-25/as-caesars-deal-lingers-buyer-faces-2-3-million-a-day-in-fees (noting that since the nine-month deadline on the transaction has passed, Eldorado must pay Caesars a ticking fee of ten cents a share per month).

137. *See* Thomas, *supra* note 129 (noting how the reallocation of federal funds toward vaccine research "blindsided" researchers and will create a ceiling for treating the critically ill).

138. Kulish et al., *supra* note 16.

139. *Id.*

140. *Id.*

141. *See id.* (highlighting the perilous implications of outsourcing crucial public health projects to private companies, as profit maximization is often at odds with conscientious and deliberate preparation for future crises).

142. *See id.* (noting how the FTC's cursory internal review of the Newport acquisition prevented in-depth analysis of potentially negative implications).

143. *See* Gonzales v. Oregon, 546 U.S. 243, 269–70 (2006) (holding that Congress did not intend to define the standards of medical practice when it passed the Controlled Substances Act, and thus Oregon's 1994 Physician Assisted Suicide law did not violate its provisions).

relied on HHS expertise, healthcare providers would not have had to play the dual role of doctor and engineer.[144]

The FTC has incorporated industry-specific concerns in its approach to merger review in other industries before, even within healthcare regarding hospitals and pharmaceuticals.[145] For instance, in a joint statement issued by the DOJ and the FTC concerning preservation of competition in the defense industry, the agencies emphasized particular aspects of the industry crucial to merger review, like the importance of investment in research and development as well as the need for surge capacity.[146] These are aspects clearly shared by the medical device industry. Since FTC has the capacity to cater to specific industries, why not medical devices?

C. Second Opinion: Mechanisms for Interagency Collaboration

Coordinating efforts and responses to goals, initiatives, or crises is difficult to achieve because all agencies "seek to preserve their autonomy and independence."[147] While collaboration is not a natural behavior for agencies, they can be incentivized to participate for political gain, by legal mandate, or for their own problem-solving interests.[148] Through whatever mechanism it is achieved, interagency collaboration is necessary to address problems with interrelated causes and reduce policy fragmentation.[149]

There are various means through which to achieve interagency integration.[150] A relatively simple way to establish a working relationship

144. *See* Jacobs, *supra* note 10.

145. *See generally* HEALTH CARE DIVISION, FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS 108–12 (2020), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_health_care_final_updated_07272020.pdf (outlining various ways the FTC has made accommodations for otherwise impermissible antitrust activity within the healthcare industry to allow for safety zones).

146. Press Release, Fed. Trade Comm'n, FTC, DOJ Issue Joint Statement on Preserving Competition in the Defense Industry (Apr. 12, 2016), https://www.ftc.gov/news-events/press-releases/2016/04/ftc-doj-issue-joint-statement-preserving-competition-defense.

147. Rodrigo Serrano, What Makes Inter-Agency Coordination Work?: Insights from the Literature and Two Case Studies 2 (Aug. 2003) (unpublished manuscript), https://publications.iadb.org/publications/english/document/What-Makes-Inter-Agency-Coordination-Work-Insights-from-the-Literature-and-Two-Case-Studies.pdf.

148. *See id.* at 8 (indicating that empirical data suggests that solving a pressing problem is the most effective incentive for coordination).

149. *See generally id.*

150. *See* FREDERICK M. KAISER, CONG. RSCH. SERV., R41803, INTERAGENCY COLLABORATIVE ARRANGEMENTS AND ACTIVITIES: TYPES, RATIONALES, CONSIDERATIONS 2 (2011), https://fas.org/sgp/crs/misc/R41803.pdf (stating that the Government Accountability Office defines interagency integration as "any joint activity by two or more organizations that is

between agencies is to facilitate an agreement for formal collaboration. Collaboration relies on discretionary participation among agency members who have parity in the participation agreement.[151] A common example of interagency collaboration is a Memorandum of Understanding (MOU), which details the specific responsibilities of each agency.[152] In this arrangement, neither department has direct control over the other; the functionality of the MOU relies on each department meeting its commitment in good faith.[153]

D. Patient History: Examples of Existing FTC Interagency Agreements

1. Food and Drug Administration

The FTC and the FDA maintain a MOU for the purpose of preserving truth in advertising on food, drug, cosmetic, and device labels.[154] It states that each agency will commit to "joint planning of coordinated programs, exchange of information and evidence to the extent permitted by law . . . and the careful selection of the procedure of either agency (or simultaneously by both) promising greatest benefits to the public."[155] Additionally, the FTC and the FDA announced plans in early 2020 to jointly combat anticompetitive behavior in the biosimilars marketplace.[156] In a joint statement with the FDA, FTC Chair Joseph Simons emphasized the FTC's commitment to enforcing antitrust laws in healthcare markets.[157]

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intended to produce more public value than could be produced when the organizations act alone") (quoting U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-15, RESULTS-ORIENTED GOVERNMENT PRACTICES THAT CAN HELP ENHANCE AND SUSTAIN COLLABORATION AMONG FEDERAL AGENCIES 6 (2005), https://www.gao.gov/assets/250/248219.pdf).

151. *Id.* at 3.

152. *Id.* at 7.

153. *Id.*

154. Memorandum of Understanding Between the Fed. Trade Comm'n and the Food & Drug Admin. Concerning Exchange of Information (May 14, 1971) [hereinafter FTC–FDA Memorandum of Understanding], https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003.

155. *Id.*

156. *See* Stanton Mehr, *The FDA/FTC Workshop: Beginning to Address Misleading Biosimilar Information*, BIOSIMILARS REV. & REP. (Mar. 10, 2020), https://biosimilarsrr.com/2020/03/10/the-fda-ftc-workshop-beginning-to-address-misleading-biosimilar-information/ (explaining the urgent need for FTC enforcement action against reference biologic manufacturers who routinely levy outright false statements to undermine the safety and effectiveness of biosimilars).

157. *Cf.* Joe Simons, Chairman, Fed. Trade Comm'n, Remarks on Fostering Biologic Competition 5 (Mar. 9, 2020), https://www.ftc.gov/system/files/documents/public_statements/1568645/simons_-_biosimilars_workshop_opening_remarks_3-9-20.pdf (stating that

2. U.S. Department of Justice & U.S. Department of Agriculture

The FTC maintains a MOU jointly with the DOJ and the U.S. Department of Agriculture (USDA) in which the agencies agree that it is in the interest of the public to cooperate in monitoring competitive conditions in the agricultural marketplace.[158] This commitment to cooperative monitoring requires the agencies to agree to share information and provide each other with legal, economic, and technical assistance.[159] Enacted in 1999, this MOU was agreed upon after years of informal collaboration between the agencies, proven to substantially benefit enforcement actions for the purpose of protecting consumer interests.[160] Similar to the structure of the healthcare market, the food and agricultural sector can be characterized as a "series of successively linked markets," within which competition is essential to maintaining food security.[161] Access to life-sustaining medical equipment, like food security, is an unquestionably vital facet of emergent health crisis preparedness preserved by competition.

IV. RECOMMENDATIONS

To preserve consumer welfare, reduce harm in the medical device market, and prevent firm transactions from interfering with countermeasure development, the FTC must achieve three things: a comprehensive retrospective review of the Newport acquisition, a Memorandum of Understanding with ASPR within HHS, and a revision of the current Horizontal Merger Guidelines. Combined, these objectives will give the FTC a clear picture of the significance of the market's contribution to the severity of the COVID-19 pandemic and allow the agencies to collaborate in preventing future market contributions to health crises.

A. Retrospective Review

The FTC must conduct an extensive review of Covidien's acquisition of Newport. Though harm is most effectively mitigated in the pre-merger

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biologics are essential to the treatment of many illnesses, and practices in the market are delaying their availability).

158. Memorandum of Understanding Between the Antitrust Div., Dep't of Just. And the Fed. Trade Comm'n and the Dep't of Agric. Relative to Cooperation with Respect to Monitoring Competitive Conditions in the Agricultural Marketplace (Sept. 16, 1999), https://www.ftc.gov/system/files/documents/cooperation_agreements/ftcdojdoa-mou.pdf.

159. *Id.*

160. *Id.*

161. Food & Agric. Org. [FAO], *The State of Agricultural Commodity Markets 2015–16: Competition and Food Security*, at 3, I5225E/1/12.15 (2016), https://www.fao.org/3/a-i5225e.pdf.

review phase,[162] in this case, the damage is already done.[163] Determining precisely what was missed during the cursory review of this merger in 2012 will allow the FTC to identify the cause of harm and provide a basis for future challenges.[164] A comprehensive review can achieve several things: improved predictive tools based on retrospective findings, informed judicial review of prospective transactions, and accurate determination as to whether premerger remedies are effective or if post-merger enforcement should be considered.[165] The FTC should approach retrospective review of the Newport acquisition in two phases. First, the FTC should issue a Section 6(b) order to compel information not previously obtained from Covidien to assess Covidien's business structure and intentions. Second, the FTC should conduct a retrospective merger analysis to determine any realized anticompetitive effects or harm.

1. Section 6(b)

Section 6(b) of the FTC Act is an investigative tool that authorizes the FTC to compel firms to furnish reports or answers to interrogatories as a part of a special or general order.[166] The FTC's authority under 6(b) allows the agency to conduct studies not constrained by a specific law enforcement purpose.[167] Recently, the FTC sent special orders to five dominant tech firms requiring each to submit extensive documentation on previously unreported acquisitions between 2010 and 2019.[168] The orders concern acquisitions that were not subject to HSR reporting requirements,[169] and come at a time when

162. PREMERGER NOTIFICATION OFF., *supra* note 71.

163. *See* Kaste & Hersher, *supra* note 10 (detailing one state's preparation to use ethical rationing guidelines to deny care to patients deemed unlikely to survive).

164. Kulish et al., *supra* note 16; *see also* Wu, *supra* note 37 (noting that a former FTC lawyer who advised Covidien on the transaction boasted of his ability to help the firm clear antitrust review).

165. Karen Hoffman Lent & Kenneth Schwartz, *A Caution for Retrospective Merger Reviews*, N.Y. L.J. (May 13, 2019, 12:45 PM), https://www.law.com/newyorklawjournal/2019/05/13/a-caution-for-retrospective-merger-reviews/.

166. *See* 15 U.S.C. § 46(b) (noting that the reach on an inquiry extends to a firm's "organization, business, conduct, practices, management, and relation to other corporations, partnerships, and individuals").

167. *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, FED. TRADE COMM'N, https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority (Oct. 2019).

168. Lesli C. Esposito, *FTC Issues 6(b) Orders to Tech Companies – Healthcare Companies Could Be Next*, DLA PIPER (Feb. 14, 2020), https://www.dlapiper.com/en/us/insights/publications/2020/02/ftc-issues-6b-orders-to-tech-companies/.

169. *Id.*

economists are questioning the strength of merger control regimes that allow dominant incumbents to pick off nascent firms.[170]

The Newport acquisition surpassed the HSR reportability threshold yet received antitrust approval without second request.[171] While not a nascent firm, Newport developed an innovative ventilator model that Covidien halted production on, preempting future competition. For these reasons, the FTC must issue Section 6(b) orders against former Covidien executives.[172] Specifically, the FTC should compel Covidien to respond to a report detailing inquiries into what Covidien knew about the significance of Project Aura, when Covidien stopped production on its own ventilator model and for what purpose, and how greatly the Newport acquisition affected Covidien's market share. The information gathered in response to this formal request will serve as the basis for further FTC studies or, if appropriate, revised industry guidance.

2. Retrospective Merger Analysis

The highly publicized harm associated with the Newport acquisition makes it the worthy subject of a comprehensive retrospective study.[173] Just as firms like Covidien, and subsequently Medtronic, adapted in response to a rash of hospital consolidations,[174] the FTC should respond to its 2002 study—the Hospital Merger Retrospectives Project (HMRP)—with a series of merger retrospectives on medical device firms.[175] The HMRP was intended to influence prior assumptions about transactional consequences and the nature of competitive forces in healthcare, and to justify enforcement against consummated mergers found to be anticompetitive.[176]

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170. Organisation for Economic Co-operation and Development [OECD], *Start-Ups, Killer Acquisitions and Merger Control*, at 5, OECD Doc. JT03462563 (June 11, 2020), https://one.oecd.org/document/DAF/COMP/WD(2020)30/en/pdf.

171. *See* Kulish et al., *supra* note 16.

172. *But cf.* Press Release, Medtronic, *supra* note 117 (announcing Medtronic's acquisition of Covidien in 2015).

173. *See* Kulish et al., *supra* note 16 (describing how the acquisition of Newport did not result in the production of new ventilators).

174. *Id.*

175. *See generally* Joseph Farrell et al., *Economics at the FTC: Retrospective Merger Analysis with a Focus on Hospitals*, 35 REV. INDUS. ORG. 370, 375–76 (2009) (describing the Hospital Merger Retrospectives Project's purpose).

176. *See generally* Deborah Haas-Wilson & Christopher Garmon, *Hospital Mergers and Competitive Effects: Two Retrospective Analyses*, 18 INT. J. ECON. BUS. 17, 17, 18 (2011) (indicating that the FTC issued an administrative complaint under § 7 of the Clayton Act against a hospital consolidation found to be anticompetitive because it allowed the merged entities to raise prices through an exercise of market power).

The Newport acquisition is an appropriate candidate for study,[177] and can serve as the first of the series. Merger retrospectives seek to determine *ex post* how consolidation impacts market equilibrium.[178] The most damning indicator of post-consummation anticompetitive effect is cost: empirical data from the HMRP revealed that merged hospitals' market power encourages price increases for a considerable percentage of firms.[179] This is due in part to an increased reliance on fewer, more dominant firms—for hospitals, this means a singular option in a given geographic area—that controls the availability of medical technology.[180] Reliant on Philips to provide for the SNS which should have been stocked nearly a decade ago with Aura ventilators, the Trump administration overpaid by as much as $500 million for ventilators that were functionally identical to cheaper models.[181]

The FTC should commence a study on the medical device firms reacting to this consolidation trend, having studied the effects and associated harm of consolidation trends in the hospital industry. A retrospective on hospitals likely entails identifying a geographic location that has not undergone consolidation as a control to measure against changes in location value, cost, quality of care, and innovation post-merger.[182] There is no equivalent geographic control group for device firms with a national consumer base, so the FTC must choose effects to measure. The most obvious is price, but the FTC must also measure non-price effects—including product quality, variety, and innovation—of the Newport acquisition to understand fully the harm caused by termination of Project Aura.[183] Establishing evidence of anticompetitive harm legitimizes

177. *See generally* Melissa Quintana, Note, *Measuring Hospital Post-Merger Effects: Developing a Standard for Antitrust Analysis*, 21 N.Y.U. J. LEGIS. & PUB. POL'Y 957, 972 (2019) (noting that candidates for retrospective study arise when enforcement agencies lose merger challenges in court or when the agencies do not challenge a transaction for reasons other than perceived anticompetitive effect).

178. *See* Farrell et al., *supra* note 175, at 371 (positing that a successful *ex post* study, or retrospective, will study the impact of the merger in every relevant market it impacts).

179. Quintana, *supra* note 177, at 969–70.

180. *See generally* Doni Bloomfield, *Lax Antitrust Enforcement Has Made America's Medical Supply Shortages So Much Worse*, SLATE (Apr. 6, 2020, 5:09 PM), https://slate.com/news-and-politics/2020/04/coronavirus-crisis-equipment-medicine-supply-chain.html (explaining that streamlined efficiency can actually incentivize dominant firms to cease manufacturing life-saving drugs or equipment: after generic drug maker Teva acquired its rival, it stopped making dexmedetomidine, a drug used to manage patients on ventilators, just months before the COVID-19 pandemic).

181. Callahan & Rotella, *supra* note 113.

182. Quintana, *supra* note 177, at 972.

183. *See generally* Organisation for Economic Co-operation and Development [OECD], *Roundtable on Impact Evaluation of Merger Decisions*, at 3–4, OECD Doc. JT03304247 (June 20,

FTC enforcement decisions against similar proposed mergers in the medical device industry moving forward, and will serve as a basis for broader, policy-based changes in antitrust review methodology.

B. Memorandum of Understanding

The COVID-19 pandemic is a constant reminder of how essential medical technology is to our survival;[184] yet, federal agency oversight on the development and deployment of this technology is lacking. The FTC lauds its own efforts on antitrust enforcement in the healthcare industry, citing premerger successes against proposed hospital mergers and litigious victories against pharmaceutical settlements.[185] In neither past nor proposed future efforts, however, does the FTC commit to specialized enforcement efforts against medical device firms.[186]

This is a glaring oversight: it does not matter how innovative or highly functional a hospital is if it is not fully equipped, and drugs used to support lung function in ventilator patients are a useless medical advancement if ventilators are in short supply.[187] And ventilators that are in supply are of little use if they cannot combat severe respiratory distress or hold up without frequent maintenance.[188] The FTC will not fulfill its responsibility to set healthcare policy until its approach to antitrust review and enforcement in the healthcare industry is uniformly rigorous.[189]

2011) [hereinafter *Roundtable on Impact Evaluation of Merger Decisions*] (indicating that while it is difficult to study non-price effects, they are vital to consumer welfare and thus should play an important role in the decisionmaking of a competition agency).

184. *See* MacMillan, *supra* note 5 (emphasizing the critical life-sustaining capabilities of ventilators in the context of COVID-19).

185. *See* Christine S. Wilson, Comm'r, Fed. Trade Comm'n, Keynote Remarks at the Council for Affordable Health Coverage 5 (Jan. 16, 2020), https://www.ftc.gov/system/files/documents/public_statements/1562909/csw_remarks_-_cahc_0.pdf.

186. *See id.* at 11–12 (summarizing the FTC's intention to build upon long-standing efforts related to hospitals and pharmaceuticals, and pay greater attention to the biosimilar marketplace).

187. *See* Daniela Mokra et al., *Corticosteroids in Acute Lung Injury: The Dilemma Continues*, INT'L J. MOLECULAR SCIS., Oct. 2019, at 1, 10, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6801694/pdf/ijms-20-04765.pdf (noting that patients requiring steroidal support are likely already receiving lung-protective ventilation treatment and the most common benefit of a steroid is to lessen the time a patient requires ventilation support).

188. *See* Jacobs, *supra* note 31 (reporting that despite recent production efforts, newly manufactured machines may not be sophisticated enough for use on COVID-19 patients in severe respiratory distress and were not "built to be stockpiled" due to their maintenance needs).

189. *See Antitrust Enforcement in the Medical Device Sector – Ten Areas of Focus in 2015*, SIDLEY (Feb. 18, 2015), https://www.sidley.com/en/insights/newsupdates/2015/02/medical-device-antitrust-update (asserting that while enforcement agencies have maintained a historical

The FTC must account for research and development efforts undertaken by HHS in its review of proposed mergers and acquisitions between medical device firms. If the FTC accounts for federal investments in research and development of countermeasure projects, it will be aware of the project's expected benefit and purpose and be able to anticipate whether acquiring firms will stall or halt development.[190] Increased interagency collaboration between the FTC and HHS can mitigate typical merger harms[191] in the medical device and broader health industries by establishing a niche antitrust focus on the overlooked medical device industry.

Curating this focus will require a joint agency effort. The FTC and the ASPR should sign a MOU to clarify cooperative procedures and more effectively utilize collective resources. Specifically, this common line of action—a commitment to effective healthcare delivery—will require constant communication between the two agencies on developments in medical device technology. The FTC should alert the ASPR to proposed mergers implicating these developments and consult with the Agency to determine any potential non-price effect harm.[192] Naturally, the ASPR's expertise will most directly benefit review of mergers that implicate BARDA-sponsored projects. However, the MOU should specify the ASPR as the primary interagency collaborator on mergers involving any medical device to bridge the oversight gap.[193]

The Secretary can compel FTC involvement in PHEMCE efforts,[194] but an established agreement between the agencies will address antitrust concerns before they are amplified by a public health emergency. In addition

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commitment to antitrust review in the pharmaceutical sector, it was not until recently that the medical device sector began receiving the same attention).

190. *See* Press Release, Fed. Trade Comm'n, FTC's Bureau of Competition Launches Task Force to Monitor Technology Markets (Feb. 26, 2019), https://www.ftc.gov/news-events/press-releases/2019/02/ftcs-bureau-competition-launches-task-force-monitor-technology (announcing the FTC's formation of a taskforce for monitoring potential anticompetitive conduct in the U.S. technology market, which will adopt a highly coordinated approach to review prospective mergers).

191. *See* Justus Haucap & Joel Stiebale, *Research: Innovation Suffers When Drug Companies Merge*, HARV. BUS. REV. (Aug. 3, 2016), https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge (observing that reduced innovation and spending on research and development is typical post-merger behavior for firms, but there is a troubling trend in the pharmaceutical industry where acquiring firms and competitors simultaneously reduce innovation).

192. *See* OECD, *supra* note 170, at 12, 27, 43 (identifying non-cost effect harms as relating to innovation, risk, and consumer welfare).

193. *See* Wilson, *supra* note 185, at 2 (indicating FTC commitment to antitrust scrutiny of hospital and pharmaceutical mergers, but making no mention of device firm mergers).

194. *See* 42 U.S.C. § 300hh(b) (giving the Secretary the authority to compel heads of other agencies to coordinate resources and services in a joint health emergency response).

to general authority over research on disease prevention, the Assistant Secretary has the authority to coordinate with interagency partners to maintain a current assessment of threats that could result in a public health emergency.[195] The Assistant Secretary is also responsible for identifying all anticipated countermeasure needs.[196] The FTC is responsible for merger and acquisition review and must intervene to prevent unfair anticompetitive acts or practices.[197] ASPR jurisdiction is invoked where mergers involving countermeasures are proposed or where a merger in the health industry may pose a threat to public health.[198] Accordingly, via an appointed liaison, the FTC should alert ASPR to mergers of concern for collaborative review.

Countermeasure development is time-sensitive and research, cost, and cross-discipline intensive.[199] Presently, BARDA intends to use Project BioShield funding to award a contract to secure countermeasures for treatment of neutropenia.[200] Treatment for neutropenia, an abnormally low count of a type of white blood cell, may involve stem cell transplantation.[201] Instruments for cell transplantation are still relatively crude, and development of superior devices will require an innovative multidisciplinary approach.[202] Once a contract for neutropenia is awarded, collaboration between the FTC and ASPR will allow the agencies to jointly monitor its development and prevent implication of relevant countermeasure devices in anticompetitive merger activity.[203]

A MOU between the FTC and the FDA established in 1971 yielded joint commitment to innovation and competition in the pharmaceutical industry over several decades. MOU 225-71-8003 delineates a shared objective of maximum consumer protection, achieved by liaison officers "currently

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195. *Id.* § 300hh–10(b)(4)(I).

196. *Id.* § 300hh–10(b)(7)(D).

197. *See* 15 U.S.C. § 45(a)(2) (authorizing the FTC to prevent persons, partnerships, and corporations from using unfair methods of competition and deceptive practices).

198. *See* 6 U.S.C. § 314(a)(9)(A)–(D) (outlining the FTC's emergency management system).

199. *See generally* Wu, *supra* note 37 (providing examples of several mergers to show that countermeasure development is a slow, costly, and complicated process).

200. *Stockpile Building*, *supra* note 43.

201. Mario López & Margarita Martín, *Medical Management of the Acute Radiation Syndrome*, 16 REPS. PRAC. ONCOLOGY RADIOTHERAPY 138, 144 (2011).

202. *See Development and Preclinical Testing of New Devices for Cell Transplantation to the Brain*, CAL. INST. FOR REGENERATIVE MED., https://www.cirm.ca.gov/our-progress/awards/development-and-preclinical-testing-new-devices-cell-transplantation-brain (last visited Mar. 2, 2021) (indicating the reason for the inadequacy of current instruments is a lack of coordination between stem cell scientists, device manufacturers, and neurosurgeons).

203. *See* Asher Schechter, *Mergers Are Bad for Innovation*, PROMARKET (Sept. 29, 2017), https://promarket.org/2017/09/29/mergers-bad-innovation/ (stating that decreased innovation post-merger is the norm).

informing each other of proposed proceedings and of internal developments in areas of joint concern."[204] Some of the most recent examples of competition preservation and harm reduction include close cooperation on the creation of biosimilar marketplace competition,[205] as well as the issuance of warning letters to corporations against fraudulent promotion of scientifically unsupported COVID-19 treatments.[206] Facilitating a formal collaboration agreement with a MOU will allow the FTC and ASPR to similarly preserve competition among medical device firms, promoting innovation and saving lives.

C. Amending the Horizontal Merger Guidelines

The FTC should revise the Horizontal Merger Guidelines (Guidelines) to account for risk. As they are written, the Guidelines compel the FTC and the DOJ Antitrust Division to prohibit mergers that consolidate market power.[207] The Guidelines specify that "merger[s] enhance[] market power if [they are] likely to encourage one or more firms to raise price, reduce output, diminish innovation, or otherwise harm customers as a result of diminished competitive constraints or incentives."[208] Increased market power, particularly in the context of diminished innovation, poses inherent risk which must be accounted for in merger review. Risk can be defined as "the expected value of harm to third parties resulting from a supply or demand shock to a particular firm."[209]

COVID-19 continues to be a demand shock on the market for respiratory support devices and personal protective equipment[210] due to diminished

204. FTC–FDA Memorandum of Understanding, *supra* note 154.

205. *See* Allison Inserro, *FDA, FTC Pledge Close Cooperation to Create Biosimilar Competition*, CTR. FOR BIOSIMILARS (Feb. 4, 2020), https://www.centerforbiosimilars.com/news/fda-ftc-pledge-close-cooperation-to-create-biosimilar-competition (noting the FDA's commitment to advertisement and promotion of biosimilars and the FTC's commitment to antitrust review of patent settlement agreements).

206. *See* Press Release, Fed. Trade Comm'n, FTC, FDA Send Warning Letters to Seven Companies about Unsupported Claims that Products Can Treat or Prevent Coronavirus (Mar. 9, 2020), https://www.ftc.gov/news-events/press-releases/2020/03/ftc-fda-send-warning-letters-seven-companies-about-unsupported (indicating the FTC's regulatory enforcement support for the FDA's view that the sale and promotion of fraudulent treatments are a public health threat).

207. U.S. DEP'T OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES 1–2 (2010), https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.

208. *Id.*

209. Doni Bloomfield, Competition and Risk 14 (July 3, 2020) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3566661.

210. *See* Christine Smith, *Understanding Supply and Demand Shocks amid Coronavirus*, FED. RSRV. BANK ST. LOUIS (Mar. 25, 2020), https://www.stlouisfed.org/open-vault/2020/march/supply-demand-shocks-coronavirus (explaining that a demand shock is a type of unexpected economic shock that increases aggregate demand for certain goods).

innovation after the Newport acquisition. After Covidien terminated Project Aura, it took several years for the government to align with Philips,[211] and dependence on a new firm resulted in delivery delays and increased costs.[212] In the Newport acquisition, third party hospitals were unable to provide their COVID-19 patients with standard respiratory care as a result of the ventilator shortage.[213] A quantity reduction impacting the availability of a given product may contribute to direct or systemic risk, quantifiably harming consumers in the same way as traditionally-measured anticompetitive effects.[214] When evaluating proposed mergers between medical device firms for direct or systemic risk, the FTC can consider whether a proposal's increased efficiencies—reducing diversity in innovation and manufacture of medical devices—will increase systemic risk to consumer health in the event of a demand shock on devices, like ventilators.[215]

Updating the Guidelines is feasible and will greatly improve the review process.[216] The FTC will need to work collaboratively with the DOJ on revisions and release a draft for public comment.[217] Since the first release in 1968, the Guidelines have been updated five times, most recently in 2010. Each update makes use of modern economic tools, theories, and considerations. Factoring in direct and systemic risk will require the FTC to confront the feasibility of harm mergers pose to the development of countermeasures and medical devices more broadly. It will also protect consumers absent grounds for a merger challenge, because risk analysis can eliminate harm without an antitrust challenge through conduct agreements or divestiture.[218] The FTC could have granted antitrust approval to

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211. Kulish et al., *supra* note 16.

212. Callahan & Rotella, *supra* note 113.

213. *See* Jacobs, *supra* note 10 (detailing the use of less sophisticated and less powerful machines to sustain others in order to free up critical care ventilators for COVID-19 patients).

214. Bloomfield, *supra* note 209, at 27–28.

215. *See id.* at 71–72 (proposing language for amended Guidelines to incorporate risk consideration in review of hospital mergers).

216. *See* Neal Mollen & Aaron Ver, *Agencies Can Revise, or Abandon, Prior Regulatory Interpretations Without Notice-and-Comment Rulemaking, Says Supreme Court*, PAUL HASTINGS 1 (Mar. 11, 2015), https://www.paulhastings.com/publications-items/details/?id=ddcfe369-2334-6428-811c-ff00004cbded (commenting on the Supreme Court decision that the Administrative Procedure Act allows an agency to revise the interpretation of its own rules without engaging in notice-and-comment).

217. *See* Press Release, Fed. Trade Comm'n, FTC and DOJ Announce Draft Vertical Merger Guidelines for Public Comment (Jan. 10, 2020), https://www.ftc.gov/news-events/press-releases/2020/01/ftc-doj-announce-draft-vertical-merger-guidelines-public-comment (publicizing this as the process observed in development of the 2020 Vertical Merger Guidelines).

218. *See* Bloomfield, *supra* note 209, at 68 (noting that while agencies are not always effective compliance monitors, conduct agreements are preferable to ignoring risk issues).

Covidien in 2012 contingent on an agreement not to discontinue Project Aura, especially considering its conception in response to a highly pathogenic respiratory disease, its development concurrently with such diseases, and its intent to combat future pandemics.[219] Certainly, an acquiring firm with an overlapping product portfolio should be assessed for risk of harm.

CONCLUSION

The antitrust oversight gap in the health industry is not benign and will remain a problem once COVID-19 is under control.[220] The likelihood of another pandemic makes it clear that now is the time for the FTC to act.[221] The FTC must recognize that medical devices are as essential a component of the distinct healthcare market as hospitals and pharmaceuticals.[222] When devices are in short supply, physicians are forced to perform a risk assessment to determine which patients are more likely to survive.[223] By consulting with HHS experts and instead incorporating risk assessment into merger analysis,[224] the FTC can spare healthcare workers these agonizing choices. The pandemic exposed the problem but stopping at countermeasure oversight is not enough. If the FTC does not implement a plan for comprehensive medical device review,[225] the lung tissue will succumb to necrosis.

219. Kulish et al., *supra* note 16.

220. *Supra* notes 97–129 and accompanying text.

221. Brulliard, *supra* note 29.

222. *See* Mwachofi & Al-Assaf, *supra* note 130, at 329–30 (assessing the multifaceted mechanism of healthcare delivery to conclude that health is not a consumable good and must be reviewed independent of other, dissimilar markets).

223. *See* Kaste & Hersher, *supra* note 10 (reporting that physicians must exercise their discretion to allocate devices based on factors such as life expectancy and physical disabilities).

224. *See* Bloomfield, *supra* note 209, at 16, 27 (noting increased market power and consumer reliance on merged firms as indicators of direct or systemic risk).

225. *See OECDs*, *supra* note 183, at 3 (asserting that comprehensive review will include analysis of non-price effects).