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**SAFETY MEETS EFFICIENCY: THE MEDICAL DEVICE
DRONE'S ROLE IN BRINGING ABOUT A WORKABLE
REGULATORY FRAMEWORK FOR
COMMERCIAL DRONES**

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INTRODUCTION

DRONES, UNMANNED AERIAL VEHICLES (UAVs), and Unmanned Aerial Systems (UASs) are relatively new innovations. Their uses have ranged from recreational toys to lethal weapons on the battlefield. As drones' popularity has grown among hobbyists and government agencies, another group has begun to show interest in the economic benefits they could bring: private companies. Domino's Pizza's drone-delivered pizza¹ and Amazon Prime's Air Delivery² have sparked the public's interest and subsequent debates regarding the correct way to regulate the burgeoning industry. The current regulations make it impossible for commercial drone operations, and specifically the drone delivery business, to thrive; but too little regulation could lead to more accidents and less consistency around which companies will be able to build a business model. Consequently, there is a need to identify a specific use for drones in which the efficiencies gained trump the safety considerations that lead to overly burdensome regulations. The transport of medicine, blood, and medical devices is an ideal testing ground by which companies are provided incentives to improve drone

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¹ David Wells, *Domino's Delivers World's First Ever Pizza by Drone*, CNBC (Nov. 16, 2016), <https://www.cnbc.com/2016/11/16/dominos-has-delivered-the-worlds-first-ever-pizza-by-drone-to-a-new-zealand-couple.html> [<http://perma.cc/FX4U-JD6V>].

² Georgia Wells & Lauren Stevens, *Amazon Conducts First Commercial Drone Delivery*, WALL ST. J. (Dec. 14, 2016), <https://www.wsj.com/articles/amazon-conducts-first-commercial-drone-delivery-1481725956> [<http://perma.cc/TZK4-UJCG>].



technology while also saving lives. Current regulations do not allow a for-profit company to deliver these life-saving instruments. However, creating a carve-out for drones to deliver these items would allow patients to get them quicker and provide companies a financial incentive to expand on current drone technology. By using the medical industry and medical device drones (MDDs) as a testing ground, the United States could provide a better healthcare system for its citizens while also encouraging growth in drone technology that would eventually lead to more comprehensive drone delivery systems.

This article analyzes the federal regulations regarding the use of commercial drones and argues for a modification of current regulations through initiatives aimed at promoting drone use in the medical field. Part I is a discussion of the current legal landscape of commercial drones and a cost-benefit analysis of expanding commercial drone activity, especially in the drone delivery field. Part II proposes that a carve-out for MDDs would allow private investment in the technology and enable the United States to keep pace with the rest of the world in regard to autonomous drone technology. Part III analyzes the different federal regulatory agencies and their respective regulations that an MDD would have to comply with if the medical industry were allowed more freedom than its commercial drone counterparts are under current law. Finally, Part IV explains how expounding on current executive initiatives could facilitate the implementation of MDDs by pairing private companies with legislators to create collaboration in compliance expertise.

I. PART I

A. CURRENT STATE OF LAWS REGULATING DRONE USE

In 1958, the Federal Aviation Administration (FAA) was created to promote the “safe and efficient use of national airspace”—a goal still pursued today.³ By 1981, the FAA realized the need for regulations on model aircraft and issued guidelines by which hobbyists could safely fly their aircraft.⁴ More recently, with the rise of public drone use, came memoranda from the

³ See *A Brief History of the FAA*, FED. AVIATION ADMIN., https://www.faa.gov/about/history/brief_history/#origins (last modified Jan. 4, 2017) [<http://perma.cc/7SPY-BFXL>].

⁴ See *Advisory Circular*, FED. AVIATION ADMIN. (June 9, 1981), https://www.faa.gov/documentLibrary/media/Advisory_Circular/91-57.pdf [<http://perma.cc/E2GG-2NTT>].

FAA in 2005 and 2007 further defining the rules for hobbyists and excluding the use of drones for business purposes from the permitted uses the regulations provided.⁵ Under these rules, a private company wanting to use drones for profit needed a public entity as a sponsor and had to request a Certificate of Waiver or Authorization (COA) to operate commercially.⁶ This process was slow and exceedingly burdensome, so many private companies, such as Amazon and Google, began lobbying for legislative change.⁷

In 2012, the Department of Transportation (DOT), after prodding by Congress, further amended commercial drone legislation by enacting the Federal Aviation Administration Modernization and Reform Act of 2012 (FAAMRA).⁸ Of specific importance was Section 333, which allowed private companies to request a waiver for their commercial drone operations from the Secretary of Transportation without the need for public sponsorship.⁹ This improved the existing regulations but still favored safe use of national airspace at the expense of efficiency.¹⁰

The most important law governing drones today is the FAA's Small UAS Rule (Part 107), which went into effect on August 29, 2016.¹¹ As opposed to drone regulations for hobbyists, Part 107 is a solid first attempt at regulating drone commerce, and it rightfully places emphasis on safety over expansion of the drone industry. By setting up a regulatory framework, Part 107 creates an avenue, albeit a limited one, for the private sector to begin expanding commercial drone operations.¹²

⁵ See Michael Berry & Nabihah Syed, *The FAA's Slow Move to Regulate Domestic Drones*, WASH. POST (Sept. 24, 2014), https://www.washingtonpost.com/news/volokh-conspiracy/wp/2014/09/24/the-faas-slow-move-to-regulate-domestic-drones/?utm_term=.442c5ecdc783 [<https://perma.cc/BYP7-FNFB>].

⁶ Abby Speicher, *Drone Laws: The History of Drone Regulations and Laws*, DART-DRONES (Nov. 9, 2016), <https://www.dartdrones.com/blog/drone-laws/> [<https://perma.cc/GLY7-PKFQ>].

⁷ See *id.*

⁸ FAA Modernization and Reform Act of 2012, Pub. L. No. 112-95, 126 Stat. 11 (2012) (amending 49 U.S.C. § 40101), <https://www.gpo.gov/fdsys/pkg/CRPT-112hrpt381/pdf/CRPT-112hrpt381.pdf> [<https://perma.cc/JY6X-T7MR>].

⁹ Section 333, FED. AVIATION ADMIN., https://www.faa.gov/uas/beyond_the_basics/section_333/ (last modified Feb. 10, 2017) [<https://perma.cc/D8K2-5TFU>].

¹⁰ See Speicher, *supra* note 6.

¹¹ See 14 C.F.R. § 107.1 (2018).

¹² See *id.*

Subpart B of Part 107 provides guidelines for legal drone use.¹³ Currently, private businesses may only work with drones weighing less than fifty-five pounds, including all attached systems, payloads, and cargo.¹⁴ Subpart B institutes a rule that the drone cannot be flown beyond the visual line of sight (BVLOS) of the remote pilot in command (RPIC) or a visual observer who has effective communication with the drone operator.¹⁵ The person in visual line of sight must be able to determine the location, attitude, altitude, and direction of flight of the drone at all times during flight.¹⁶ It requires an RPIC who must be able to command the aircraft, thereby restricting autonomous drones.¹⁷ Additionally, the rule restricts swarms by requiring that the remote pilot only operate one drone without obtaining a waiver.¹⁸ The drones may not be operated from a moving vehicle,¹⁹ nor can they be operated over a non-participating person or moving vehicle.²⁰ An operator wanting to fly after sunset, in contravention of current restrictions, must request a waiver.²¹ Finally, unless the operator has been granted a waiver, the drones cannot be operated in airspace designated Class B, C, or D, or in certain sections of Class E airspace.²² This means that drone operators cannot fly in key airport traffic areas (Class B), moderate airport traffic areas (Class C), near any airport with a functioning tower (Class D), or in any Class E airspace designated for an airport.²³ However, any airspace not otherwise classified as Class A-E airspace is called Class G airspace, and no prior approval is required to fly a drone within its boundaries.²⁴ Part 107 further restricts drones from flying at speeds of more than 100 miles per hour, at altitudes above 400 feet, or within 500 feet vertically or 2,000 feet horizontally of a cloud.²⁵

¹³ *See id.* §§ 107.11–.51.

¹⁴ *Id.* § 107.3.

¹⁵ *Id.* §§ 107.31, 107.33.

¹⁶ *Id.* § 107.31.

¹⁷ *See id.* § 107.19.

¹⁸ *See id.* § 107.35.

¹⁹ *Id.* § 107.25.

²⁰ *Id.* § 107.39.

²¹ *See id.* § 107.41.

²² *Id.*

²³ FED. AVIATION ADMIN., *Airspace, PILOT'S HANDBOOK OF AERONAUTICAL KNOWLEDGE 15-2 to -3* (2016), https://www.faa.gov/regulations_policies/handbooks_manuals/aviation/phak/media/17_phak_ch15.pdf [https://perma.cc/7NDP-6WH3].

²⁴ *Id.*

²⁵ *See* 14 C.F.R. §§ 107.205, 107.51 (2018).

However, Subpart C of Part 107, as a replacement for Section 333 of FAAMRA, provides that certain restrictions in Subpart B are subject to waiver.²⁶ The restrictions subject to waiver include: (1) operation from a moving vehicle or aircraft (except in carriage of the property of another or operations for compensation or hire);²⁷ (2) daylight operation;²⁸ (3) visual line of sight aircraft operation (except in carriage of the property of another or operations for compensation or hire);²⁹ (4) visual observer;³⁰ (5) operation of multiple small unmanned aircraft systems;³¹ (6) yielding the right of way;³² (7) operation over people;³³ (8) operation in certain airspace;³⁴ and (9) operating limitations for small unmanned aircraft.³⁵ A waiver authorizing deviation is permissible if it can be proven that operation can be conducted safely.³⁶ These Part 107 waivers for commercial operations replaced the prior process of obtaining a “Section 333 exemption,” which had been used in the past.³⁷

While the overwhelming majority of Part 107 waivers granted allow the drones to be flown after daylight hours (with special lighting equipment),³⁸ the biggest aid to the expansion of the delivery drone service would be to grant BVLOS waivers to allow drones to fly past the operator’s line of sight. Under Part 107 as it stands, a BVLOS waiver cannot be granted to commercial operators for any purpose.³⁹

²⁶ *See id.* § 107.3.

²⁷ *Id.* §§ 107.205, 107.25.

²⁸ *Id.* §§ 107.205, 107.29.

²⁹ *Id.* §§ 107.205, 107.31.

³⁰ *Id.* §§ 107.205, 107.33.

³¹ *Id.* §§ 107.205, 107.35.

³² *Id.* §§ 107.205, 107.37(a).

³³ *Id.* §§ 107.205, 107.39.

³⁴ *Id.* §§ 107.205, 107.41.

³⁵ *Id.* §§ 107.205, 107.51.

³⁶ *Id.* § 107.205.

³⁷ *See* Adam Uzialko, *10 Cool Commercial Drone Uses Coming to a Sky Near You*, BUS. NEWS DAILY (Sept. 18, 2017), <https://www.businessnewsdaily.com/9276-commercial-drones-business-uses.html> [<https://perma.cc/7KSJ-SM5X>].

³⁸ *See Part 107 Waivers Granted*, FED. AVIATION ADMIN., https://www.faa.gov/uas/request_waiver/waivers_granted/ (last modified Feb. 1, 2018) [<https://perma.cc/G2B7-VHV5>]; Tariq Rashid, *How to Apply for a Part 107 Waiver*, SKYWARD, <https://skyward.io/how-to-apply-for-a-part-107-waiver-from-the-faa-the-right-way/> [<https://perma.cc/ER9Z-HZEN>].

³⁹ 14 C.F.R. §§ 107.205, 107.31 (2018).

B. BENEFITS OF COMMERCIAL DRONES

An integration of drones into the private sector, as with any entrepreneurial endeavor, will come with inherent risks. In this case, the risk is that an automated drone network will compromise the privacy and safety of the public. Therefore, projects should not be greenlighted nor regulations loosened without assurance that the future benefits of a commercial drone delivery network will outweigh the costs.⁴⁰

The potential for economic benefits of delivery by unmanned drones is recognized by regulatory agencies and private companies alike. When the FAA passed Part 107, they expected the new rule alone would result in a “net social benefit ranging from about \$733 million in the low case to about \$9.0 billion in the high case over five years.”⁴¹ The Association for Unmanned Vehicles International (AUVSI) reports that with loosened regulation and improved technology, the impact of commercial drones could be \$82 billion and a 100,000 job boost to the U.S. economy by 2025.⁴² There is public support for this new technology as nearly 300,000 drone owners registered their UAVs in the first thirty days after the FAA opened its online registration system in January of 2016.⁴³

Commercial drones could have a variety of uses: (1) aerial photography for journalism and film; (2) gathering information and supplying essentials for disaster management; (3) search and rescue operations using thermal sensor drones; (4) geographic mapping of inaccessible terrain and locations; (5) building safety inspections; (6) precision crop monitoring; (7) law enforcement and border control surveillance; (8) storm tracking; (9) forecasting hurricanes and tornadoes; and more.⁴⁴

⁴⁰ See Wayne Hicks, *Maryland State Drone Law Puts Residents at Risk of Privacy Intrusions from Drone Surveillance by Law Enforcement Agencies*, 47 U. BALT. L. FORUM 130, 142 (2017).

⁴¹ OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, RIN 2120-AJ60 at 560, https://www.faa.gov/uas/media/RIN_2120-AJ60_Clean_Signed.pdf [<https://perma.cc/9H8M-2C23>].

⁴² Darryl Jenkins & Bijan Vasigh, *The Economic Impact of Unmanned Aircraft Systems Integration in the United States*, AUVSI (Mar. 2013), <http://www.auvsi.org/our-impact/economic-report> [<https://perma.cc/W5HT-Q3LP>].

⁴³ See Press Release—FAA Registered Nearly 300,000 Unmanned Aircraft Owners, Fed. Aviation Admin. (Jan. 22, 2016), https://www.faa.gov/news/press_releases/news_story.cfm?newsId=19914 [<https://perma.cc/2684-C3EL>].

⁴⁴ See Divya Joshi, *Exploring the Latest Drone Technology for Commercial, Industrial and Military Drone Uses*, BUS. INSIDER (July 13, 2017), <http://www.businessinsider.com/drone-technology-uses-2017-7> [<https://perma.cc/2ZYP-JRYV>].

While current regulations have allowed for modest expansion of drone use in the areas of photography, real estate, utilities, and construction, a significant amount of future benefit could be realized by permitting use of drone technology by commercial delivery services.⁴⁵

Package delivery is one of the most immediate and practical future extensions of drone technology. Companies like Amazon, UPS, NASA, and hundreds of start-ups around the globe are beginning to experiment with drones as a means of delivery.⁴⁶ While Amazon Prime currently costs consumers around \$8 per delivery (or free with a subscription), a company called ARK Invest has projected that delivery by partially autonomous drone swarms could cost Amazon \$0.88 for each delivery, and, by charging \$1 per delivery, the company could realize a 50% return on its drone infrastructure while offering deliveries in thirty minutes.⁴⁷

The Walker Sands Future of Retail 2016 Study surveyed over 1,400 consumers across the United States and found that 79% said they were “very likely” or “somewhat likely” to request drone delivery if their package could be delivered in under an hour.⁴⁸ Further, 73% of respondents claimed they would pay up to \$10 for drone delivery.⁴⁹ This study shows that there is a public demand for quick deliveries by drone—a demand a quarter of those surveyed believed would be allayed in two years’ time.⁵⁰ However, drone deliveries have not become mainstream due to burdensome restrictions placed on the industry. A loosened regulatory system would greatly increase convenience for the modern consumer, but it would not come without a corresponding decrease in public safety.⁵¹ To justify allowing swarms of autono-

⁴⁵ *See id.*

⁴⁶ *See* Christina Mercer, *Best Uses of Drones: How 25 Companies Are Using Drones*, TECH WORLD (Jan. 10, 2018), <https://www.techworld.com/picture-gallery/apps-wearables/best-uses-of-drones-in-business-3605145/> [https://perma.cc/ELL9-48KZ].

⁴⁷ Dan Wang, *The Economics of Drone Delivery*, FLEXPOR, <https://www.flexport.com/blog/drone-delivery-economics/> [https://perma.cc/N87F-JFEC].

⁴⁸ Eric McCollum, *Drone Delivery Is About to Revolutionize the Supply Chain Industry*, RED STAG (Jan. 4, 2017), <https://redstagfulfillment.com/drone-delivery-is-about-to-revolutionize-the-supply-chain-industry/> [https://perma.cc/JSM9-2DP2].

⁴⁹ *Id.*

⁵⁰ *See id.*

⁵¹ *See id.*; Alan Levin, *Surge in Drone Safety Reports Prompts ‘Emergency’ Action at FAA*, BLOOMBERG TECH. (Oct. 13, 2017), <https://www.bloomberg.com/news/arti->

mous drones to fly overhead, regulators may need more than increased convenience.⁵²

Additionally, a robust drone industry will have positive effects on the environment. The most obvious environmental benefit stems from the use of drones as a substitute for delivery trucks.⁵³ A University of Washington study found that, when used effectively, drones emit less carbon dioxide into the environment than their delivery counterparts.⁵⁴ The study found that drones provide the most benefits over trucks with light packages over shorter distances.⁵⁵ This benefit surely will be maximized as Amazon has reported that 86% of its packages weigh less than five pounds.⁵⁶ Further, with 70% of Americans living within five miles of a Walmart, the majority of the trips do not need to be long, increasing the benefits of drones over delivery trucks.⁵⁷

Along with reduced carbon dioxide emissions, environmental advocates tout the drone's potential ability to improve the environment in other ways.⁵⁸ The many environmentally beneficial uses of drones include inspecting infrastructure on solar farms to increase their efficiency, using attachments to map industrial emissions, stopping poachers in Africa, and conserving water by identifying leaks in underground water pipes.⁵⁹ Additionally, the agriculture industry is excited for the drone's potential in the field of "precision agriculture."⁶⁰ By allowing farmers to assess the health of their crops from above, drones help the farmers to use their land as efficiently as possible. This efficiency translates to the reduction of environmentally damaging pesticides.⁶¹ According to a study by Timiryazev State Agrarian University in

cles/2017-10-13/surge-in-drone-safety-reports-prompts-emergency-action-at-faa [https://perma.cc/42CF-22WH].

⁵² See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 10.

⁵³ See Jennifer Langston, *Drone vs. Truck Deliveries: Which Create Less Carbon Pollution?*, UW NEWS (May 30, 2017), <http://www.washington.edu/news/2017/05/30/drone-vs-truck-deliveries-which-create-less-carbon-pollution/> [https://perma.cc/S5YM-AJ29].

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ See Wang, *supra* note 47.

⁵⁷ See Wang, *supra* note 47.

⁵⁸ See Malek Murison, *5 Ways Drones Are Saving the Environment*, DRONELIFE (Mar. 19, 2017), <https://dronelife.com/2017/03/19/drones-saving-planet-environment/> [https://perma.cc/76WA-5KLLK].

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

Moscow, when drones were used to map the land, farmers were able to optimize their nitrogen application, leading to a 20% decrease in the amount of nitrogen put into the environment.⁶²

Finally, drones that deliver medicine, blood, and medical devices would provide society with expedited delivery of time sensitive and life-saving products.⁶³ Companies such as Zipline are already testing this technology in rural African countries such as Rwanda and Tanzania.⁶⁴ Zipline, in partnership with the Rwandan government, is providing 20% of the country's blood supply, and delivery times are a fraction of that of deliveries by conventional means.⁶⁵ Zipline, and other companies such as Matternet, are attempting to bring these efficiencies to the United States, but the current regulatory framework will not allow these businesses to operate.⁶⁶ By allowing medical drone delivery companies more freedom to operate in the United States, regulators would of course be trading away a small amount of public safety. But in return, they would get not only convenience but also an improved healthcare system as well.⁶⁷

C. CHALLENGES FOR COMMERCIAL DRONES

The current state of regulations in the United States presents the most immediate roadblock in the path of a thriving commercial drone delivery industry. The Small UAS Rule, Part 107, restricts drones from flying after daylight hours or over people.⁶⁸ This creates problems as nighttime would provide a better

⁶² *Id.*

⁶³ See Kyree Leary, *Matternet Is Expanding Drone Delivery to Hospitals in Switzerland*, FUTURISM (Sept. 27, 2017), <https://futurism.com/matternet-is-expanding-drone-delivery-to-hospitals-in-switzerland/> [https://perma.cc/R372-T8Y6].

⁶⁴ See Esther Landhuis, *Tanzania Gears Up to Become a Nation of Medical Drones*, NAT'L PUB. RADIO (Aug. 24, 2017), <https://www.npr.org/sections/goatsandsoda/2017/08/24/545589328/tanzania-gears-up-to-become-a-nation-of-medical-drones> [https://perma.cc/TT8P-R2XA].

⁶⁵ Alice L. George, *Using Drones to Build the Ambulance Fleet of the Future*, TECH CRUNCH (Dec. 25, 2017), <https://techcrunch.com/2017/12/25/using-drones-to-build-the-ambulance-fleet-of-the-future/> [https://perma.cc/R5PD-QZJF].

⁶⁶ See *Fact Sheet: New Commitments to Accelerate the Safe Integration of Unmanned Aerial Systems*, THE WHITE HOUSE (Aug. 2, 2016), <https://obamawhitehouse.archives.gov/the-press-office/2016/08/02/fact-sheet-new-commitments-accelerate-safe-integration-unmanned-aircraft> [https://perma.cc/KR8X-K2ZQ]; Leary, *supra* note 63.

⁶⁷ See Manohari Balasingam, *Drones in Medicine: The Rise of the Machines*, INT'L J. OF CLINICAL PRAC. 2 (Jul. 10, 2017), <http://onlinelibrary.wiley.com/doi/10.1111/ijcp.12989/pdf> [https://perma.cc/NJR6-TXAG].

⁶⁸ 14 C.F.R. §§ 107.29, 107.39 (2016).

opportunity for the drones to fly without people below. Part 107 also limits an RPIC to flying one drone at a time and requires that the pilot be in constant control of the drone, or at least be able to take control at any point.⁶⁹ This reduces the possibility of profits for drone companies by necessitating the payment of numerous drone pilots instead of allowing for multiple autonomous drones to be overseen by a single operator.⁷⁰ While these restrictions can be waived by a showing of safety, the restriction on visual line of sight operations (VLOS) may not be waived by commercial operators.⁷¹ Thus, current law does not allow for operation of a commercial drone delivery service because the technology needed to make the endeavor profitable is outlawed by the federal government.⁷²

Further, President Trump's recent Executive Order requiring that two federal regulations be rescinded for every new one enacted has slowed any possible change in these regulations.⁷³ While the private drone companies want looser regulations, they still need a regulatory framework to guide their development without fear of government intervention.⁷⁴ The executive order will invariably delay any necessary regulatory changes.⁷⁵ As a result, lobbying legislatures to drastically alter their existing framework becomes a further lengthened and expensive process, keeping American companies from competing in the global drone market.⁷⁶

To argue for a relaxation of the rules, those lobbying Congress for change must first understand why the current regula-

⁶⁹ *Id.* §§ 107.19, 107.35.

⁷⁰ See Wang, *supra* note 47.

⁷¹ 14 C.F.R. § 107.1 (2018); *Drones in the Sky: An Analysis of FAA's Milestone Rules for Commercial Operations*, PILLSBURY'S UNMANNED AIRCRAFT SYS. L. TEAM (June 23, 2017), <https://www.uaslawblog.com/2016/06/23/drones-sky-analysis-faas-milestone-rules-commercial-operations/> [<https://perma.cc/V8EA-TRD7>].

⁷² See Wang, *supra* note 47.

⁷³ See Exec. Order No. 13,771, 82 Fed. Reg. 42,751 (2017), <https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/> [<https://perma.cc/KQA4-M3RG>]; April Glaser, *Trump's Freeze on New Regulation Means That We Won't Get Drone Delivery Anytime Soon*, RECODE (Feb. 19, 2017), <https://www.recode.net/2017/2/9/14462390/trump-freeze-regulation-faa-drone-delivery> [<https://perma.cc/3MMD-EVZL>].

⁷⁴ See Glaser, *supra* note 73.

⁷⁵ See Glaser, *supra* note 73.

⁷⁶ See Valerie Nolan, *Drone Use in the US vs. Internationally: What You Need to Know*, CREWS CONTROL (May 25, 2016), <http://crewscontrol.com/blog-central/blog-centraldrone-use-us-vs-internationally-need-know/> [<https://perma.cc/T68Z-GDLY>].

tions are so cumbersome. Public safety has been a paramount concern of the FAA since its founding in 1958.⁷⁷ Sixty years later, this is still a driving cause of the burdensome regulations surrounding both private and commercial drone operations.⁷⁸ And these concerns are shown to have merit as the number of “safety incidents” continues to rise rapidly as drone use becomes more and more common.⁷⁹ The writers of Part 107’s restrictions on drone use feared that the current drone technology subjects drones to the possibility of mid-air collisions and loss of control by the operator.⁸⁰ Within the last six months, a civilian drone struck and damaged a Black Hawk helicopter in New York, and another hit an airplane landing at the Quebec City airport.⁸¹ To ensure the safety of the public, the FAA enacted regulations requiring constant control by a licensed operator and restricting when and where operators could use drones.⁸² Drone technology must advance to a point where the possibility of collisions or lack of control are minimized in order to allow regulators to feel comfortable relaxing these restrictions.

More recently, the FAA has become more vocal about concerns that rampant drone use could infringe on privacy rights, but they have not addressed that concern in their legislation.⁸³ Although the Obama administration understood the drone’s effect in the realm of privacy in 2015,⁸⁴ in 2016, Part 107 did not contain any provisions relating to privacy.⁸⁵ Because drone usage is growing, the amount of data that can be gathered by these low-flying cameras is both enormous and vulnerable to hacking

⁷⁷ See *A Brief History of the FAA*, *supra* note 3.

⁷⁸ See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 15.

⁷⁹ See Levin, *supra* note 51.

⁸⁰ See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 16–17.

⁸¹ David Shepardson, *Trump Administration Program to Test Expanded Drone Use*, REUTERS (Oct. 25, 2017), <https://www.reuters.com/article/us-usa-trump-drones/trump-administration-program-to-test-expanded-drone-use-idUSKBN1CU2EA> [<https://perma.cc/A5EE-WQB2>].

⁸² See 14 C.F.R. § 107 (2018).

⁸³ See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 16-526.

⁸⁴ See Memorandum on Promoting Economic Competitiveness While Safeguarding Privacy, Civil Rights, and Civil Liberties in Domestic Use of Unmanned Aircraft Systems, 2015 DAILY COMP. PRESS. DOC. 1 (Feb. 15, 2015), <https://www.gpo.gov/fdsys/pkg/DCPD-201500103/pdf/DCPD-201500103.pdf> [<https://perma.cc/N9DL-U64E>].

⁸⁵ 14 C.F.R. § 107 (2018).

and misappropriation.⁸⁶ As technology progresses, legislative and judicial governance lags significantly behind.⁸⁷ The Supreme Court has only recently ruled in 2001 that using infrared technology to watch someone can violate the Fourth Amendment's protections of privacy, even though modern infrared technology has existed since the late 1960s.⁸⁸ The drone regulators are succumbing to the same lag by not including any privacy provisions in their most recent regulations.

II. PART II

A. THE CASE FOR MDDs AS A TESTING GROUND FOR COMMERCIAL DRONE TECHNOLOGY

With the implementation of the UAS Integration Pilot Program (IPP), the Trump Administration wishes to “accelerate the safe integration” of drone technology in order to reap any benefits this technology may provide.⁸⁹ However, any efficiency gains proposed by future legislation will most likely come at the expense of public safety.⁹⁰ Therefore, in order for the commercial drone industry to grow, regulators should focus on loosening regulations in sectors where the efficiency gains are tied to less significant reductions in safety. One such sector of the commercial drone delivery field is the delivery of medical devices and supplies by MDDs.⁹¹ Loosening regulations within this sector would incentivize private companies to improve drone technology, leading to efficiency gains while also providing patients with

⁸⁶ April Glaser, *The U.S. Government Showed Just How Easy it is to Hack Drones Made by Parrot, DBPower and Cheerson*, RECODE (Jan. 4, 2017), <https://www.recode.net/2017/1/4/14062654/drones-hacking-security-ftc-parrot-dbpower-cheerson> [<https://perma.cc/JYV5-9S4A>].

⁸⁷ See Vivek Wadhwa, *Laws and Ethics Can't Keep Pace with Technology*, MIT TECH. REV. (Apr. 15, 2014), <https://www.technologyreview.com/s/526401/laws-and-ethics-cant-keep-pace-with-technology/> [<https://perma.cc/MW57-ESG9>].

⁸⁸ See generally *Kyllo v. United States*, 533 U.S. 27, 28 (2001); *Dr. Michael Tompsett Designed and Built the First Digital Camera*, UNIV. OF CAMBRIDGE (Mar. 8, 2012), <http://www.eng.cam.ac.uk/news/alumni-feature-dr-michael-tompsett-designed-and-built-first-digital-camera> [<https://perma.cc/CN7T-MD83>].

⁸⁹ See *News & Updates*, FED. AVIATION ADMIN. (Oct. 25, 2017), <https://www.faa.gov/news/updates/?newsId=89007> [<https://perma.cc/DQ7Q-CJJC>].

⁹⁰ See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 31.

⁹¹ See Jacquelin Howard, *How Drones Could Be 'Lifesaving' in an Emergency*, CNN (Oct. 9, 2017), <https://www.cnn.com/2017/10/09/health/ambulance-drone-teching-care-of-your-health/index.html> [<https://perma.cc/YKV8-J3B8>].

life-saving and perishable blood and plasma, in addition to other medical devices.⁹²

Currently, U.S. companies have to perform their tests overseas where the drone laws are less stringent.⁹³ One company out of Silicon Valley, Zipline, has already partnered with the Rwandan government to deliver medical supplies to rural hospitals with great success.⁹⁴ Hospitals around the world fight a battle between waste and access: storing donor blood in rural locations means greater access but also more waste as blood spoils quickly; however, storing the blood in a centralized location will increase its longevity but limit access to it.⁹⁵ Using autonomous drone technology, Zipline now delivers 20% of Rwanda's national blood supply in a fraction of the time it would take to deliver via traditional routes.⁹⁶ Zipline has not only been successful in saving lives but also has turned a profit, leading it to announce its expansion into neighboring Tanzania.⁹⁷

The efficiency increases and consequent health benefits coming from MDDs do not have to be limited to rural countries without modern infrastructure. Another U.S.-based company, Matternet, is expanding its drone delivery system to hospitals in Switzerland.⁹⁸ Even in America, there are approximately 1,300 Critical Access Hospitals that could save time and money by delivering supplies via drone rather than a helicopter.⁹⁹ The CEO of Zipline has stated that with twenty distribution centers, MDDs could cover 70%–80% of the U.S. population—a feat he claims could be attained in six to eight months, given an amenable regulatory scheme.¹⁰⁰

By creating a carve-out for MDDs, regulators would allow both hospitals and patients to benefit from existing drone technol-

⁹² *See id.*

⁹³ *See* George, *supra* note 65.

⁹⁴ *See* Karen McVeigh, "Uber for Blood": How Rwandan Delivery Robots Are Saving Lives, *GUARDIAN* (Jan. 2, 2018), <https://www.theguardian.com/global-development/2018/jan/02/rwanda-scheme-saving-blood-drone> [<https://perma.cc/S8LG-CT2A>].

⁹⁵ *See id.*

⁹⁶ George, *supra* note 65.

⁹⁷ George, *supra* note 65.

⁹⁸ Leary, *supra* note 63.

⁹⁹ Critical Access Hospitals (CAHs) are defined as being in a rural area at least thirty-five miles from any other hospital or CAH. *See HCF Information*, SYNnex CORP., <https://www.synnexcorp.com/us/govsol/hcf-information/> [<https://perma.cc/PM8V-29JY>].

¹⁰⁰ *See* George, *supra* note 65.

ogy.¹⁰¹ This would also incentivize entrepreneurs in America to invest in research and development to advance drone technology with the hope that MDD companies will buy it.¹⁰² This testing ground would initially come at the expense of safety as there would inevitably be accidents,¹⁰³ but it would undoubtedly save lives in the process.¹⁰⁴

Technology developed in the MDD sector, like software for autonomous flight and control of multiple drones, could then later be adopted by drone delivery companies such as Amazon to expand the range of products delivered to people's doorsteps.¹⁰⁵ After MDD technology has advanced to a point where drone crashes and malfunctions are a distant worry, regulators may then feel comfortable expanding the MDD carve-out to include all commercial drone uses (given safe operation and use of the technology).¹⁰⁶

Given a workable regulatory framework in Rwanda, Zipline has already created a system in which hospitals are able to order blood via an app on a doctor's phone and have it delivered in less than twenty minutes.¹⁰⁷ The blood is loaded by hand onto a fix-winged drone, which then takes off from the distribution center and flies a predetermined route to its destination.¹⁰⁸ The drone then drops the blood (which parachutes to the ground), flies back to the distribution center, and lands.¹⁰⁹ After the blood is loaded onto the drone, every step of the delivery process is done without pilot control.¹¹⁰ An improvement in technology is needed before it is adequately safe for more populated areas, but with the financial incentive the U.S. drone market

¹⁰¹ See Balasingam, *supra* note 67.

¹⁰² See Anjali Jain, *A VC Perspective: Drone Technology Changing the Face of Robotics Revolution*, ENTREPRENEUR INDIA (Dec. 4, 2017), <https://www.entrepreneur.com/article/305757> [<https://perma.cc/LR8Y-3KPX>].

¹⁰³ See Shepardson, *supra* note 81.

¹⁰⁴ See McVeigh, *supra* note 94.

¹⁰⁵ See Ed Oswald, *Here's Everything You Need to Know About Amazon's Drone Delivery Project, Prime Air*, DIGITAL TRENDS 4 (May 3, 2017), <https://www.digitaltrends.com/cool-tech/amazon-prime-air-delivery-drones-history-progress/> [<https://perma.cc/D72H-3Y2F>].

¹⁰⁶ See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 28 (noting that "new technologies could come into existence after this rule is issued that could alleviate some of the risk concerns underlying the provisions of this rulemaking").

¹⁰⁷ See McVeigh, *supra* note 94.

¹⁰⁸ McVeigh, *supra* note 94.

¹⁰⁹ McVeigh, *supra* note 94.

¹¹⁰ McVeigh, *supra* note 94.

promises, the investment in research and development of advanced drone technology will be substantial.

The transition from MDD to other forms of drone package delivery would be a smooth one. Currently, relatively small drones are needed to deliver medical supplies like blood and plasma to hospitals.¹¹¹ Because 86% of Amazon packages weigh less than five pounds¹¹² and 70% of Americans live within five miles of a Walmart, the majority of the trips do not need to be long, reducing the possibility of a “safety incident.”¹¹³

III. PART III

A. STEPS TO MAKE THIS HAPPEN

Because MDDs will often carry biologics such as blood or tissue samples, they will be thoroughly regulated by the litany of agencies currently governing medical courier companies,¹¹⁴ including: (1) the International Civil Aviation Administration (ICAA); (2) International Air Transport Association (IATA); (3) DOT, Center for Disease Control (CDC); (4) Transportation Security Administration (TSA); (5) Food and Drug Administration (FDA); (6) Occupational Safety and Health Administration (OSHA); and (7) the FAA.¹¹⁵ However, because courier companies are already well-versed in navigating these regulations to transport biologics, this comment only focuses on the regulatory agencies that would burden the MDDs more extensively than other existing medical courier companies: the FAA and the FDA.

B. WHAT CAN THE FAA DO?

Because the MDD industry can lead the way to a comprehensive commercial drone delivery system, the question becomes what changes need to be made in order to reach that goal. First, the existing regulatory framework needs to be relaxed to allow more private companies to begin testing drone technology in the United States.¹¹⁶ Under the current framework, some restrictions pose no barrier to the commercial drone industry, some

¹¹¹ McVeigh, *supra* note 94.

¹¹² Wang, *supra* note 47.

¹¹³ See Wang, *supra* note 47.

¹¹⁴ See *Courier Instructions*, MAYO CLINIC, <https://www.mayomedicallaboratories.com/specimen/courier/index.html> [<https://perma.cc/JM7N-3X8S>].

¹¹⁵ *Id.*

¹¹⁶ See Nolan, *supra* note 76.

can be waived by a showing of safety, and some are written to be especially prohibitive of the drone delivery industry.

The drone delivery system can operate under some current size and speed restrictions listed in Part 107—under fifty-five pounds and 100 miles per hour.¹¹⁷ The current rules regarding the medical condition of the pilot, conditions for safe operation, registration, hazardous operation, carriage of hazardous materials, and preflight inspection place no additional burden on commercial companies that wish to deliver customers' property.¹¹⁸ In fact, scholarly articles contend that these regulations are redundant since civil and criminal penalties already exist to protect society from drone misuse.¹¹⁹ A hazardously-operated or negligently-inspected delivery drone that caused damage would already be subject to the same penalties as any other product (along with being a public relations nightmare).¹²⁰

The next set of restrictions are waivable for commercial companies if they can prove that their operations will be conducted safely.¹²¹ These restrictions prevent (1) nighttime operation;¹²² (2) operation without a visual observer;¹²³ (3) operation of multiple small unmanned aircraft systems;¹²⁴ (4) operation near possible aircraft flight paths;¹²⁵ (5) operation over people;¹²⁶ and (6) operation in certain airspace.¹²⁷ Restrictions also include operating limitations for small unmanned aircraft.¹²⁸ While these waivers theoretically provide leeway for the commercial drone companies to operate, the vast majority of waivers to date have been to allow for nighttime operation given special lighting, with few exceptions.¹²⁹ The small number of waivers granted for commercial operations shows that the FAA wants to

¹¹⁷ See 14 C.F.R. § 107.51 (2018).

¹¹⁸ See *id.* §§ 107.17, 107.15, 107.13, 107.23, 107.36, 107.49.

¹¹⁹ See Jason Snead, *How the FAA is Killing Drone Innovation*, FOUND. FOR ECON. EDU. (Nov. 25, 2016), <https://fee.org/articles/how-the-faa-is-killing-drone-innovation/#0> [<https://perma.cc/SCU9-CLP2>].

¹²⁰ See *id.*

¹²¹ See 14 C.F.R. § 107.200 (2018).

¹²² *Id.* §§ 107.205, 107.29.

¹²³ *Id.* §§ 107.205, 107.33.

¹²⁴ *Id.* §§ 107.205, 107.35.

¹²⁵ *Id.* §§ 107.205, 107.37(a).

¹²⁶ *Id.* §§ 107.205, 107.39.

¹²⁷ *Id.* §§ 107.205, 107.41.

¹²⁸ *Id.* §§ 107.205, 107.51.

¹²⁹ See *Part 107 Waivers Granted*, *supra* note 38.

“limit[] carriage of property by small UAS” instead of allowing the industry to expand.¹³⁰

Lastly, the restrictions mandating that drones fly within the visual line of sight of the operator and not be operated from a moving vehicle are expressly not waivable by commercial drone companies.¹³¹ These restrictions not only serve to “mitigate[] . . . safety concerns” but also prevent a finding that the commercial operations are “air transportation.”¹³² Air transportation is entitled to “economic authority to ensure adequate protection of consumers’ interests,” which would tilt the scales toward innovation and away from safety.¹³³ Together these tiers of rules impose harsher and harsher restrictions on the drone delivery companies and evince the FAA’s reluctance to loosen regulations until “technology develops in the future.”¹³⁴

However, this traps the drone delivery companies in a “catch-22”: regulations will not be loosened until technology develops, but technology will not develop until regulations are loosened.¹³⁵ Therefore, a carve-out must be created so at least a small section of the market is allowed to test new technology that may allow the regulations to be relaxed in the future. By keeping the existing framework for all commercial companies, including industry giants Amazon and Google, the FAA will be able to retain its emphasis on safety. However, allowing MDD companies to expand operations will provide a narrow avenue for technological growth in the U.S. drone industry while saving lives in the process.¹³⁶

The FAA should start by allowing for an expedited waiver process for MDD companies and the hospitals they work with. After a showing of significant safety, the FAA should allow for nighttime deliveries, operation over people, operation in certain airspace (closer to airports), operation of multiple drones by a single operator, and operation beyond visual line of sight. With

¹³⁰ OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 49.

¹³¹ 14 C.F.R. §§ 107.205, 107.25, 107.31 (2018).

¹³² OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 50.

¹³³ See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 50.

¹³⁴ See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 49.

¹³⁵ See OPERATION AND CERTIFICATION OF SMALL UNMANNED AIRCRAFT SYSTEMS, *supra* note 41, at 49; Snead, *supra* note 119.

¹³⁶ See McVeigh, *supra* note 94.

these restrictions lifted (upon a showing of safe operation), companies like Zipline and Matternet will no longer have to move operations abroad and can instead focus on improving drone technology and saving lives in the United States.¹³⁷

C. FAA INTERACTIONS WITH STATE LAW

The FAA must then choose the level of state law preemption they will assert. As drone use has skyrocketed, state legislatures have begun crafting their own legislation in response.¹³⁸ The Supreme Court has ruled that field preemption applies to aviation issues, meaning that the FAA has broad authority over state legislatures when dealing with flight specifications and requirements.¹³⁹ However, the Tenth Amendment protects the sovereignty of the states and has led courts, such as the Ninth Circuit, to refuse to support the idea that Congress intended for the FAA to exclude all state law remedies.¹⁴⁰ That court analyzed the FAA's preemption authority by "looking to the pervasiveness of federal regulations in the specific area covered by the tort claim or state law at issue."¹⁴¹ Because the FAA has chosen to be silent on the issues of MDDs and other types of commercial drone delivery, there is room for state legislatures to craft distinct sets of laws to regulate drone use.

Due to the limits on their preemption powers, the FAA can choose to enact limited provisions, allowing the states to individually craft drone laws, or it can enact broad legislation, preempting state laws.¹⁴² The FAA currently intends to enact broad legislation to promote consistency in the laws of navigable airspaces.¹⁴³ Its theory is that fractionalized control over airspace will lead to a "patchwork quilt" of differing restrictions that will

¹³⁷ See Leary, *supra* note 63; McVeigh, *supra* note 94.

¹³⁸ *Current Unmanned Aircraft State Law Landscape*, NAT'L CONF. OF STATE LEGIS. (Feb. 1, 2018), <http://www.ncsl.org/research/transportation/current-unmanned-aircraft-state-law-landscape.aspx> [<https://perma.cc/9ZUT-2PXY>].

¹³⁹ See *State and Local Regulation of Unmanned Aircraft Systems Fact Sheet*, FED. AVIATION ADMIN. (Dec. 17, 2015), https://www.faa.gov/uas/resources/uas_regulations_policy/media/uas_fact_sheet_final.pdf [<https://perma.cc/5FPN-7NQM>].

¹⁴⁰ See U.S. CONST. amend. X; *Martin ex rel. Heckman v. Midwest Exp. Holdings, Inc.*, 555 F.3d 806, 809 (9th Cir. 2009).

¹⁴¹ *Heckman*, 555 F.3d at 809.

¹⁴² *Id.*

¹⁴³ *State and Local Regulation of Unmanned Aircraft Systems Fact Sheet*, *supra* note 139.

stop the FAA from ensuring a safe and efficient airspace.¹⁴⁴ In a media publication, the FAA even cites judicial precedent espousing a single enforcement body for the regulation of UAVs in the national airspace to protect the public from inconsistent state and local restrictions.¹⁴⁵ However, with new technology comes difficulty in crafting a workable legislative framework that promotes both safety and efficiency. Because drones and their related regulations are so new—the most recent attempt at comprehensive federal legislation was passed fewer than two years ago—little data has been collected about the effects the regulations have on the various aspects of drone use.¹⁴⁶ As drone technology develops, regulations must adapt when they allow for unsafe operations or stifle innovation to too great an extent.¹⁴⁷

A limited federal framework combined with state regulatory discretion to provide nuance to laws as the need arises would provide a quicker route to drone regulations that promote safety yet are amenable to private businesses.¹⁴⁸ Allowing states to begin crafting laws to govern the use of airspace by MDDs will begin the process of trial and error by which the best system for regulating MDDs (and perhaps eventually package delivery drones) will emerge.

Further, allowing each state to choose its level of restriction or freedom will provide all states with their desired level of efficiency or safety. Law enforcement's use of drones has already prompted arguments for state regulation of drones.¹⁴⁹ An article from the *Harvard Law Journal on Legislation* proposes a framework in which states that place greater emphasis on law enforcement interests may enact a loose set of regulations, while those states which place a greater emphasis on privacy can place stricter restrictions on drone surveillance by law enforcement of-

¹⁴⁴ See *State and Local Regulation of Unmanned Aircraft Systems Fact Sheet*, *supra* note 139.

¹⁴⁵ See *State and Local Regulation of Unmanned Aircraft Systems Fact Sheet*, *supra* note 139; *Montalvo v. Spirit Airlines*, 508 F.3d 464 (9th Cir. 2007); *French v. Pan Am Express, Inc.*, 869 F.2d 1 (1st Cir. 1989); *Arizona v. United States*, 132 S. Ct. 2492, 2502 (2012); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 386–87 (1992).

¹⁴⁶ See 14 C.F.R. § 107 (2016).

¹⁴⁷ See Guy R. Bissonnette, *Eyes in the Skies: Regulating Drones*, 64 R.I. BAR J. 9, 32 (Nov./Dec. 2015).

¹⁴⁸ See Michael L. Smith, *Regulating Law Enforcement's Use of Drones: The Need for State Legislation*, 52 HARV. J. ON LEGIS. 423, 448 (2015).

¹⁴⁹ See *id.*

ficers.¹⁵⁰ This provides an apt analogy for the use of MDDs: those states that wish for faster delivery of medical devices can enact a loose set of regulations, while those that focus on privacy can place stricter restrictions on MDDs.¹⁵¹

An article published by the Brookings Institute proposes a legislative framework it calls “federal superintendence.”¹⁵² While the article deals with drone privacy laws, because the FAA did not include language in its 2016 legislation concerning privacy or medical device restrictions, the two concerns are equally open to new regulatory frameworks.¹⁵³ The article calls for a strict yet nonintrusive framework to be regulated by the FAA for the most serious of offenses.¹⁵⁴ This results in a system where the worst violations are punished by the federal government, yet each state gets to determine its own level of punishment for lesser violations—a system that dictates the level of risk private companies are willing to take.¹⁵⁵

The case for state regulation has even pervaded broader discussions of federalism in the Supreme Court.¹⁵⁶ In a case concerning the confluence of state and federal law, Justice Brandeis wrote in his dissent that a benefit of state legislation is that each state may “serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”¹⁵⁷ State legislation of MDDs will have a similar effect: allowing states to find the most effective means of regulation while insulating other states from bad ideas.¹⁵⁸

D. COMPLICATIONS REGARDING FDA REGULATION

Whether MDDs will fall under the purview of the FDA further complicates the issue. One of the FDA’s goals is to “protect[] the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical

¹⁵⁰ *Id.*

¹⁵¹ *See id.*

¹⁵² Wells C. Bennett, *Civilian Drones, Privacy, and the Federal-State Balance*, BROOKINGS INST. 1, 3 (Sept. 2014).

¹⁵³ *See id.*

¹⁵⁴ *See id.*

¹⁵⁵ *See id.*

¹⁵⁶ *See* *Gonzales v. Raich*, 545 U.S. 1, 42 (2005) (O’Connor, J., dissenting) (quoting *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)).

¹⁵⁷ *Liebmann*, 285 U.S. at 311 (Brandeis, J., dissenting).

¹⁵⁸ *See* Bennett, *supra* note 152.

devices.”¹⁵⁹ The Federal Food Drug & Cosmetic Act (FDCA) gives the FDA, an agency of the Department of Health and Human Services, the authority to govern any “medical devices” to be put in circulation in U.S. markets.¹⁶⁰ The FDA has been given the authority to regulate medical devices used in the hospital setting *and* home-use medical devices.¹⁶¹ The question then becomes: is a drone that carries a medical device, blood, or plasma from a hospital to a home or a blood sample from a home to a hospital, a “medical device” as defined in the FDCA?

The FDA defines a medical device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”¹⁶² Previous articles have pointed out that an MDD itself is a machine intended for the mitigation, treatment, or prevention of a disease and thus subject to regulation by the FDA as a medical device.¹⁶³ Alternatively, an MDD is so intertwined with the lifesaving device or drug it is delivering that it is also possible to consider it a component or accessory of a device combatting a disease. Accordingly, it is likely that MDDs will be treated as medical devices, placing them under the authority of the FDA.¹⁶⁴

The next step is to determine into which category of medical device classifications an MDD would fall. There are currently three classes of medical devices under the FDCA.¹⁶⁵ Class I medical devices have the lowest level of risk and are therefore subject to the lowest level of regulation.¹⁶⁶ Examples of Class I

¹⁵⁹ See *About the FDA: What We Do*, FOOD AND DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/> [https://perma.cc/J7RD-4NEG] (last updated Dec. 29, 2017).

¹⁶⁰ See 21 C.F.R. § 806.1(a) (2018).

¹⁶¹ See *Home Use Devices*, FOOD AND DRUG ADMIN., <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/default.htm> (last updated Nov. 3, 2017) [https://perma.cc/3E36-R8KE].

¹⁶² *Medical Device Overview*, FOOD AND DRUG ADMIN., <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm510630.htm> (last updated Dec. 1, 2017) [https://perma.cc/2M3T-RWZT].

¹⁶³ See, e.g., An Thien Tran, *A Trifold Regulatory Convergence: Medical-Device Drones Under the FAA, FDA, and State Regimes*, 68 ADMIN. L. REV. 701, 710 (2016).

¹⁶⁴ See *id.*

¹⁶⁵ See 21 C.F.R. § 860.3 (2018).

¹⁶⁶ See *id.*

medical devices include Band-Aids and sunglasses.¹⁶⁷ Class II devices, such as motorized wheelchairs, syringes, and surgical masks, come with a higher level of risk and consequently a higher level of regulation.¹⁶⁸ And finally, Class III devices are the most complex and carry the most risk and regulation.¹⁶⁹ These devices, which include heart valves and implantable neuromuscular stimulators, must be used in “supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.”¹⁷⁰

MDDs will have to be classified through a de novo process because there is not a device substantially similar to the MDD already in existence.¹⁷¹ Due to the complexity of MDDs and the software on which they operate, it is likely that they will be classified as Class III devices subject to the highest level of scrutiny.¹⁷² Like all other Class III devices, MDDs “present[] a potential unreasonable risk of illness or injury” if they are misused or incorrectly designed.¹⁷³ They are also already being used to “support and sustain human life” in Rwanda by delivering blood to rural areas which otherwise would not have access.¹⁷⁴ Therefore, an MDD would have to go through a Premarket Approval (PMA) process “to provide reasonable assurance of the safety and effectiveness of the device” before it enters the medical device market.¹⁷⁵

All Class III medical devices must obtain pre-market approval under Section 515 of the FDCA.¹⁷⁶ The PMA process is in place to determine whether there is “sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).”¹⁷⁷ To get approval, the application must submit enough evidence to show that the “possible benefits to health

¹⁶⁷ William M. Sutton, *Classification Overview: FDA Small Business Regulatory Education for Industry*, FOOD AND DRUG ADMIN. (Sept. 29, 2017), <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM466473.pdf> [<https://perma.cc/3LMM-767E>].

¹⁶⁸ *See id.*; 21 C.F.R. § 860.3 (2018).

¹⁶⁹ *See* 21 C.F.R. § 860.3 (2018).

¹⁷⁰ *Id.*; 21 U.S.C. § 360c(a)(1)(C)(ii) (2018); Sutton, *supra* note 167.

¹⁷¹ 21 C.F.R. § 880.6910 (2018) (a powered stretcher for transporting patients most resembles the MDD and is classified as Class II).

¹⁷² *See* Tran, *supra* note 163.

¹⁷³ *See* 21 C.F.R. § 860.3(c)(3) (2018).

¹⁷⁴ *See id.*; George, *supra* note 65.

¹⁷⁵ *See* 21 C.F.R. § 860.3(c)(3) (2018); 21 U.S.C. § 360c(a)(1)(C)(i) (2018).

¹⁷⁶ *See* 21 U.S.C. § 360(e) (2018).

¹⁷⁷ *Medical Devices: Premarket Approval (PMA)*, FOOD AND DRUG ADMIN., <https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyour>

from the intended use of a device outweigh the possible risks [and] that the device will significantly help a large portion of the target population.”¹⁷⁸ As discussed previously, the potential benefits of MDDs in addition to the technology’s future application to other sectors of the drone industry clearly show that those standards are met.

E. HOW THE FDA CAN SPEED UP THE PROCESS

Requiring every advancement in MDD technology to pass PMA scrutiny would further slow the already-burdened drone industry. Aside from assuring the safety of the products, a second goal of the FDA is “advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable.”¹⁷⁹ This idea has led to the development of procedures such as the submission of “510(k)s” for substantially equivalent products.¹⁸⁰ In this way, the approval process is expedited for a device that is substantially similar to an already-approved device.¹⁸¹ By performing a thorough vetting of an initial model of an MDD, the FDA could accelerate the regulatory procedures for future innovations and allow companies to provide this potentially life-saving technology faster and more effectively.¹⁸² However, only moderate-risk devices that are substantially similar to an existing device meet the criteria for the 510(k) “fast-track” route.¹⁸³ Therefore, MDDs would have to be classified as moderate risk in order to qualify for expedited clearance.¹⁸⁴ This seems unlikely as containers for the collection of blood are already classified as a Class II device, and a drone which stores and transports blood is likely to be considered more risky, putting it in Class III.¹⁸⁵

Another alternative to the rigorous PMA process has recently been announced by Scott Gotlieb, the U.S. Food and Drug Com-

device/premarket submissions/premarket approval pma/ (last updated Feb. 1, 2018) [<https://perma.cc/N7VG-DA22>].

¹⁷⁸ *Step 3: Pathway to Approval*, FOOD AND DRUG ADMIN., <https://www.fda.gov/ForPatients/Approvals/Devices/ucm405381.htm> (last updated Jan. 4, 2018) [<https://perma.cc/M9Q2-VEK5>].

¹⁷⁹ See *About the FAA: What We Do*, *supra* note 159.

¹⁸⁰ See *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

¹⁸¹ *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

¹⁸² See *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

¹⁸³ See *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

¹⁸⁴ *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

¹⁸⁵ See 21 C.F.R. § 864.9100 (2018).



missioner.¹⁸⁶ The “Pre-Cert for Software Pilot Program” is designed to facilitate innovation of the digital healthcare market.¹⁸⁷ As part of the broader Digital Health Innovation Action Plan developed by the FDA, the Pre-Cert Program focuses on digital products that have potential effects that could be “revolutionary” to the medical field but are currently being reviewed by the FDA’s traditional approach, which is “not well suited to these products.”¹⁸⁸ Instead, pre-certified companies can now submit less information to the FDA than is currently typically required, and in some cases, the companies do not have to offer any premarket submission at all.¹⁸⁹ This would mark a dramatic shift from premarket data collection to postmarket data collection, which would allow companies to bring their products to market quicker while also requiring them to report their findings to the FDA to ensure safety.¹⁹⁰ However, this postmarket data collection is only available to companies marketing low-risk digital health devices.¹⁹¹

The requirements for participation in this program also serve to limit the Pre-Cert Program’s scope: (1) the company must be in the process of developing a software product that is classified as a medical device; (2) the company must have a track record in developing, testing, and maintaining software products; and (3) the company must agree to collect and provide to the FDA real-world data about its track record, meet periodically with the FDA, be available for on-site visits by the FDA, and provide information about its quality management system.¹⁹² Commissioner Gottlieb has designed this initial criteria to be “inclusive and flexible” in order to promote “dynamic entrepreneurship and competition and help continue to drive product innovation.”¹⁹³

MDDs are a great candidate for inclusion in the Pre-Cert Program because they will rely heavily on software to navigate the airspace and bring potentially life-saving devices to people when

¹⁸⁶ See generally Scott Gottlieb, *FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare*, FOOD AND DRUG ADMIN. (July 27, 2017), <https://blogs.fda.gov/fdavoices/index.php/2017/07/fda-announces-new-steps-to-empower-consumers-and-advance-digital-healthcare/> [https://perma.cc/WY5R-RSBT].

¹⁸⁷ See *id.*

¹⁸⁸ See *id.*

¹⁸⁹ *Id.*

¹⁹⁰ See *id.*

¹⁹¹ *Id.*

¹⁹² See *id.*

¹⁹³ *Id.*

traditional delivery methods would be less effective.¹⁹⁴ Gottlieb praises the digital health industry for bringing “benefits to patients’ lives and to our healthcare system by facilitating prevention, treatment, and diagnosis[,] and by helping consumers manage chronic conditions outside of traditional healthcare settings.”¹⁹⁵ MDDs are able to further these goals by bringing needed blood, plasma, anti-venom, or other necessary medical devices to those outside of the traditional healthcare setting.¹⁹⁶ Working within the existing Pre-Cert framework or creating a new framework specifically for the regulation of MDDs would fall perfectly in line with the FDA’s goals of efficiently and safely advancing digital health innovation.¹⁹⁷

As it currently stands, any company offering time sensitive deliveries via MDD would most likely have to pass PMA scrutiny for the product itself and any improvements to the product implemented in the future. The process of developing drone technology coupled with collecting safety data to submit to the FDA with no assurance that the product will pass scrutiny will do much to deny the public access to MDDs. With little tweaking, the Pre-Cert platform could allow all facets of an MDD, from the rotor to the software it runs on, to be approved quicker and thus aid in improving drone technology at a faster pace.¹⁹⁸ A classification of MDDs as modest-risk devices or a postmarket approach to data collection would clear the way for companies that hope to provide the benefits of MDDs to the public.¹⁹⁹ By classifying them as modest risk, once a substantially similar MDD enters the market, all subsequent variations of MDDs would be able to take advantage of the 510(k) fast-track route already in place.²⁰⁰ Alternatively, classifying MDDs as a high-risk device yet allowing the technology to follow Pre-Cert procedures would allow consumers access to potentially life-saving devices while allowing the FDA to monitor the safety and progress of the technology in a postmarket setting.²⁰¹

¹⁹⁴ *See id.*

¹⁹⁵ *Id.*

¹⁹⁶ *See* Nick Lavars, *Drone Delivers Anti-Venom for Amazonian Snakebites*, NEW ATLAS (Feb. 21, 2017) <https://newatlas.com/drone-anti-venom-amazon-snake/48029/> [<https://perma.cc/Y5LF-XEGW>].

¹⁹⁷ *See id.*

¹⁹⁸ *See* Gottlieb, *supra* note 186.

¹⁹⁹ *See* Sutton, *supra* note 167.

²⁰⁰ *See* *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

²⁰¹ *See* Gottlieb, *supra* note 186.

Allowing a subsection of the drone market to profit from research and development of MDD technology will invariably improve the technology across all aspects of the drone landscape, from photography to package delivery.

IV. PART IV

A. HOW SHOULD STATES, THE FAA, AND THE FDA INTERACT TO ALLOW THE MDD INDUSTRY TO FLOURISH?

With three levels of unique regulatory compliance—state, FAA, and FDA—MDD manufacturers will have an arduous and lengthy road to bring their product to market.²⁰² This will delay, if not fully prevent, public enjoyment of the benefits of quick medical delivery, and will also stymie the development of technology that could provide for faster and more environmentally-friendly package delivery. Therefore, the three regulatory bodies must create a system in which the public can benefit from MDDs while also being protected from their misuse or negligent construction.²⁰³

Dividing the regulations into two stages, premarket and postmarket, would allow drone companies to compartmentalize their operations and more effectively traverse the regulatory landscape. In the premarket stage, the FAA should use its expertise in regulating national airspace to ensure that MDDs would follow basic requirements such as height, weight, and speed. Current commercial trucking regulations are an example of federal regulations that could be applied to drones. The Federal Motor Carrier Safety Administration (FCMSA) regulates testing for prospective drivers, testing for drugs or alcohol, carriage of hazardous materials, vehicle requirements and vehicle identification, and the amount of consecutive hours that can be driven.²⁰⁴ By copying this framework, the FAA could ensure that a baseline of regulations would be followed, and all MDD companies could look to the same regulatory agency for direction before they placed their product in the market.²⁰⁵

²⁰² See *State and Local Regulation of Unmanned Aircraft Systems Fact Sheet*, *supra* note 139; Snead, *supra* note 119; *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

²⁰³ See Alden Abbot, *Penalizing Innovation: The FAA's Regulation of Drones*, HERITAGE FOUND. (Mar. 22, 2016), <https://www.heritage.org/economic-and-property-rights/commentary/penalizing-innovation-the-faas-regulation-drones> [https://perma.cc/2L8X-ZN9M].

²⁰⁴ See 49 C.F.R. §§ 382.301, 382.205, 385.415, 395.3, 390.3, 390.21 (2018).

²⁰⁵ See *id.*

Ideally, the FDA would also play a premarket role. Because the MDD would be so intertwined with the medical field, FDA involvement would be helpful to make sure the MDDs remain in compliance with standards of the medical industry. However, this review process cannot be as onerous as the current PMA system.²⁰⁶ This is why the Pre-Cert model initiated by Commissioner Gottlieb would be crucial in ensuring that MDD companies are not over-burdened by a triumvirate of regulatory agencies.²⁰⁷

Then, once a drone company is able to comply with baseline regulations restricting operations in the national airspace and ensuring safe delivery of biologics and other devices, the states should be allowed to have postmarket regulatory control over the nuances of drone regulation.²⁰⁸ While some states may support the existing FAA regulations keeping drones out of the skies, others may wish to allow more relaxed regulations. By permitting states to choose the level of regulation, those that wish to keep the BVLOS and operation over people restrictions may do so while others are able to withhold those restrictions and allow MDDs to operate more freely.²⁰⁹ Take, for example, New Mexico, North Dakota, and Oklahoma.²¹⁰ New Mexico has a history of interaction with the FAA, as evidenced by its four Air Force bases, its Air Force research laboratories, and its 3,000 square mile White Sands Missile Range.²¹¹ North Dakota has invested \$35 million in the drone industry and was the first state to offer an undergraduate degree in UAS.²¹² And Dr. Stephen McKeever, Oklahoma's Secretary of Science and Technology, has recently stated that "Oklahoma made a strategic decision to promote itself as a drone state," given the drone's ability to contribute to the state's energy, agriculture, and aerospace industries.²¹³ These three states are not only hungry for improved drone technology but also sparsely populated, making

²⁰⁶ See *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

²⁰⁷ See Gottlieb, *supra* note 186.

²⁰⁸ See Tran, *supra* note 163 at 726.

²⁰⁹ See 14 C.F.R. §§ 107.31, 107.39 (2018).

²¹⁰ See generally Miriam McNabb, *The Top 3 Drone Friendly States May Surprise You*, DRONELIFE (May 13, 2016), <https://dronelife.com/2016/05/13/top-drone-friendly-states/> [<https://perma.cc/BX58-UNRU>].

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.*



them safer choices for MDD testing.²¹⁴ Allowing for relaxed FAA regulations for MDDs would mean that states such as these could serve as testing grounds for drone technology, while others could impose restrictions similar to those currently promulgated by the FAA for all commercial drones.²¹⁵

B. USING THE INTEGRATION PILOT PROGRAM AS A FRAMEWORK FOR TESTING

One major problem with forcing drone companies to comply with three agencies, each imposing restrictions, is that the companies do not have the expertise needed to effectively comply with all three sets of regulations. A drone company may have expertise in complying with FAA regulations but have no experience dealing with FDA or state regulatory schemes (because they may not exist yet). A solution is to build on the UAS IPP enacted by President Trump in October.²¹⁶

The IPP intends to allow local governments to team up with private-sector partners to form a regulatory proposal, which they will then submit to the DOT.²¹⁷ These proposals can allow for low altitude flights by drones without the VLOS and other current requirements in designated “innovation zones.”²¹⁸ The DOT and FAA will then select a “minimum of five partnerships” that will begin testing their proposals and the consequent outcomes.²¹⁹ This will allow the federal government to collect data and identify issues that need to be addressed in future federal regulation.²²⁰

²¹⁴ See *Population Density (Most Recent) by State*, STATEMASTER, http://www.statemaster.com/graph/peo_pop_den-people-population-density [<https://perma.cc/3KES-TCA2>].

²¹⁵ See Smith, *supra* note 148, at 448.

²¹⁶ See *News & Updates*, *supra* note 89.

²¹⁷ *News & Updates*, *supra* note 89.

²¹⁸ See *News & Updates*, *supra* note 89.; *UAS Integration Pilot Program White House Fact Sheet*, DEPT. OF TRANSP., <https://www.transportation.gov/briefing-room/uas-integration-pilot-program-white-house-fact-sheet> [<https://perma.cc/G72U-PUKE>].

²¹⁹ See *News & Updates*, *supra* note 89.

²²⁰ See Miriam McNabb, *Trump's New Drone Integration Pilot Program: What It Is—and Is Not*, DRONELIFE (Oct. 25, 2017), <https://dronelife.com/2017/10/25/trumps-new-drone-integration-pilot-program-not/> [<https://perma.cc/42GZ-YMPL>].

While this initiative has received support from a drone industry previously cut off from testing new technology,²²¹ testing technology and sharing insights does not have to be limited to a select number of applicants over the course of three years.²²² The initiative should go further by partnering drone companies, hospitals, and state legislatures.

Each of the partners would have specific insights into compliance with the different levels of regulations: drone companies have already been working with the FAA, hospitals have FDA compliance experience, and state legislatures are able to determine the level of restrictions demanded by their constituents and advise on how to adhere to their enacted regulations. This would allow drone companies to get through the premarket vetting process more quickly, meaning they could introduce their products to the market sooner and begin collecting data concerning effective drone use.²²³ Beyond providing healthcare expediency to surrounding communities, these proposed teams would be charged with creating a comprehensive legislative scheme to supplant the authority of local governments and alleviate some of the FAA's concerns about the formation of a "patchwork quilt" of legislation.²²⁴ Although allowing states more freedom to regulate the postmarket industry goes further than IPP, it also narrows the scope to restrict this regulation to a single industry, mitigating fears of an unworkable sporadic framework.

Additionally, this interaction between drone companies, medical professionals, and state legislatures is a safe way to expand on IPP in areas that have been criticized. Three major critiques of IPP are (1) the lengthy gap between the application and the start of the proposed program leaves too much time for public policy and sentiment to change and thus disrupt the program; (2) private companies must participate at their own expense to offset the costs of the program; and (3) having a finite selection process limits the momentum the regulation can create in the

²²¹ See *Exploring the FAA's New UAS Integration Pilot Program*, VIGILANT AEROSPACE (Nov. 18, 2017), <https://vigilantaerospace.com/exploring-faas-new-uas-integration-pilot-program/> [<https://perma.cc/6DRD-HEC2>].

²²² *Presidential Memorandum for the Secretary of Transportation*, DEPT. OF TRANSP., <https://www.transportation.gov/briefing-room/presidential-memorandum-secretary-transportation> (last updated Oct. 31, 2017) [<https://perma.cc/D3KH-TR9P>].

²²³ See *Medical Devices: Premarket Approval (PMA)*, *supra* note 177.

²²⁴ See *State and Local Regulation of Unmanned Aircraft Systems Fact Sheet*, *supra* note 139.

drone community.²²⁵ Limiting the scope of the proposed initiative to the medical field would reduce the risk of capricious attitudes affecting the program because better access to healthcare is more universally needed than other drone uses, such as fast package delivery. Encouraging the three sectors to work together allows them to enact a safe and usable regulatory framework in areas that demand a pathway for commercial drone operations.²²⁶ The proposed initiative would not hear proposals for regulatory changes; it would only find willing participants to pair together to draft workable legislation and effective devices.

Next, drone companies under the IPP framework are forced to bear the cost of the program while hoping that the FAA will someday change its existing laws.²²⁷ Under a regulatory triumvirate, companies have a direct incentive to work towards the goal of an MDD system because their suggestions can be immediately implemented by the state legislature they are working with.²²⁸ Moreover, hospitals and state governments are both incentivized to bear some of the costs because they want to provide better healthcare to citizens living in the states that decide to participate in this program.

Finally, this three-part program would not have a date by which a selection application is closed, thereby allowing momentum to build within the MDD industry. Ideally, as other hospitals, companies, and states see the benefits of the MDD industry, they would be able to form more teams, enabling them to more successfully navigate the regulatory landscape. This would allow for a more natural progression of the technology as success would lead to more momentum, and failure would lead to a scale back in operations.²²⁹

The IPP was a solid step forward in “accelerat[ing] the safe integration of UAS into the national airspace and to realiz[ing] the benefits of unmanned technology in our economy,” but more can be done—and more can be done safely.²³⁰ Instituting an initiative specifically aimed at the MDD industry would allow

²²⁵ See *Exploring the FAA’s New UAS Integration Pilot Program*, *supra* note 221.

²²⁶ See Tran, *supra* note 163, at 726.

²²⁷ See *Exploring the FAA’s New UAS Integration Pilot Program*, *supra* note 221.

²²⁸ See *Drones Reporting for Work*, GOLDMAN SACHS, <http://www.goldmansachs.com/our-thinking/technology-driving-innovation/drones/> [https://perma.cc/336E-RBZF].

²²⁹ See Thomas McGarity, *The Expanded Debate over the Future of the Regulatory State*, 63 U. CHI. L. REV. 1463, 1492 (1996).

²³⁰ See *News & Updates*, *supra* note 89.

the United States to keep pace with other countries that it has fallen significantly behind and help develop the technology for later use in package delivery, while at the same time providing improved healthcare to U.S. citizens.²³¹

V. CONCLUSION

The goal of ordering an Amazon package that arrives at your doorstep in under thirty minutes is not achievable under current regulations.²³² Jeff Bezos, the CEO of Amazon, understood years ago that an autonomous drone navigating solely by software “looks like science fiction.”²³³ A leap from an unachievable goal to implementation of technology once thought of as science fiction does not occur overnight. However, the leap also cannot occur without important and well-regulated small steps that address safety concerns while still promoting innovation. By giving drone operators more flexibility in the medical sphere, an initial small step could be taken in the direction of science fiction while paying dues to safety in the form of better healthcare. MDDs regulated by states whose citizens are willing to allow hospitals and private companies to partner in the pursuit of science fiction should not be thwarted by an overemphasis on protecting the population from risks inherent in innovation.

²³¹ See Nolan, *supra* note 76.

²³² Wang, *supra* note 47.

²³³ Charlie Rose, *Amazon's Jeff Bezos Looks to the Future*, CBS (Dec. 1, 2013), <https://www.cbsnews.com/news/amazons-jeff-bezos-looks-to-the-future/> [<https://perma.cc/BQ6J-SGYI>].