COMMENT

A TRIFOLD REGULATORY CONVERGENCE: MEDICAL-DEVICE DRONES UNDER THE FAA, FDA, AND STATE REGIMES

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TABLE OF CONTENTS

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INTRODUCTION

BB-8 is a white astromech droid with orange and silver accents.[1] The fictitious BB-8 has a coy, childish personality, winning over the hearts of many *Star Wars* fans.[2] Magnetic attraction around his edges keeps the head and body in close proximity, while weak repulsion prevents the head from directly contacting the body, minimizing friction so that BB-8 slides smoothly across planetary surfaces.[3] With its spherical build and high-tech ingenuity, BB-8 assists with piloting an X-wing Starfighter.[4] In our galaxy, with the advent of drones occupying civilian airspace, we may not be too far from having an armada of BB-8s rolling through local neighborhoods on a mid-summer afternoon, transforming our world into a *Star Wars*-esque universe.

Once only dreamed up by our most imaginative science fiction writers, drones today have new capabilities that facilitate their uses in the civilian world. In the military, the United States typically uses drones for airstrikes.[5] For instance, the military has used drones in combat operations in Afghanistan[6] and Libya,[7] and to launch targeted killings in Somalia[8] and

1. *See* STAR WARS: EPISODE VII – THE FORCE AWAKENS (Lucasfilm Ltd. & Bad Robot Productions 2015) [hereinafter STAR WARS]); *see also* STAR WARS DATABANK, http://www.starwars.com/databank/bb-8 (last visited Nov. 28, 2016) (describing BB-8 as an astromech droid and illustrating the look of BB-8).

2. STAR WARS, *supra* note 1. For an example of BB-8 fandom, see @BB8awakens, BB-8 Fan Club, https://twitter.com/bb8awakens, which posts fan art and commentary exclusively related to BB-8.

3. *Id.; see also* Nitish Kulkarni, *How BB-8 Works*, TECHCRUNCH (Dec. 22, 2016), https://techcrunch.com/2015/12/22/how-bb-8-works/(explaining the mechanics of BB-8).

4. *See* STAR WARS, *supra* note 1; *see also* DATABANK, *supra* note 1 (explaining that BB-8 keeps an X-wing working properly).

5. *See* Byron Tau, *Obama Administration to Open Drone Books, Disclose Numbers Killed in U.S. Strikes*, WALL ST. J. (Mar. 7, 2016, 4:57 PM), http://www.wsj.com/articles/obama-administration-to-open-drone-books-disclose-numbers-killed-in-u-s-strikes-1457387859 (announcing the Obama administration's intent to release the number of casualties from U.S. counterterrorism strikes overseas made by drones).

6. *See, e.g.*, Christopher Drew, *Drones Are Playing a Growing Role in Afghanistan*, N.Y. TIMES (Feb. 19, 2010), http://www.nytimes.com/2010/02/20/world/asia/20drones.html?_r=0.

7. *See, e.g.*, Martha Raddatz & Kirit Radia, *Pentagon Confirms First Predator Drone Strike in Libya*, ABC NEWS (Apr. 23, 2011), http://abcnews.go.com/International/pentagon-confirms-predator-drone-strike-libya/story?id=13442570.

8. *See, e.g.*, Mark Mazzetti & Eric Schmitt, *U.S. Expands its Drone War into Somalia*, N.Y.

Yemen.[9] The military and intelligence institutions view drone capabilities as invaluable and have plans for long-term investments to sharpen drone vision and precision by employing more powerful cameras and more accurate and sizeable missiles.[10] Like the military agencies, the federal government envisions that drones will prevail in civilian airspace because their capabilities have proven to be consistent, practical, and fruitful.[11] However, drone use in civilian airspace is not quite the zero-sum game it is made out to be in the military context.

While drones are becoming increasingly visible in civilian airspace, they are not an everyday feature of our lives in the same way that manned aircrafts, such as airplanes, are.[12] However, drones have the potential to be invaluable resources in our lives with respect to delivering medical products and devices. Even today, drones are beginning to save lives around the world with their delivering capabilities. For example, a robotics company in Silicon Valley is working with the Rwandan government to effectively employ drones that deliver medical supplies to those in hard-to-reach locations.[13] The central purpose of this collaboration is to reduce the time it takes to deliver medicine to one of Eastern Africa's poorest nations,

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TIMES (July 2, 2011), http://www.nytimes.com/2011/07/02/world/africa/02somalia.html (discussing the expansion of the American military campaign to combat Al Qaeda's franchise in Somalia based on new evidence that insurgents in the two countries are becoming closer and plotting attacks against the United States).

9. *See* Afsheen John Radsan & Richard Murphy, *Measure Twice, Shoot Once, Higher Care for CIA-Targeted Killing*, 11 U. ILL. L. REV. 1201, 1202–03 (2011) (noting that the Obama administration has ordered a U.S. citizen residing in Yemen to be added to the hit-list); *see also* Siobhan Gorman & Adam Entous, *CIA Plans Yemen Drone Strikes*, WALL ST. J. (June 14, 2011), http://online.wsj.com/article/SB10001424052702303848104576384051572679110.html (disclosing the CIA's secret program to eliminate Al Qaeda members in Yemen).

10. *See Drones: What Are They and How Do They Work?*, BBC NEWS (Jan. 31, 2012), http://www.bbc.com/news/world-south-asia-10713898 (revealing that the United States Army planned to develop new drones equipped with higher pixelated cameras to monitor ground activity and utilize other sensor-equipped drones in Afghanistan).

11. *See infra* Section II.A.1.

12. *See* Aili McConnon, *Drones Pique the Interest of Entrepreneurs*, N.Y. TIMES (May 25, 2016), http://www.nytimes.com/2016/05/26/business/smallbusiness/drones-pique-the-interest-of-entrepreneurs.html?_r=0 ("[D]rones have gone from being a contentious military tool for airstrikes to a far more mundane magnet for aerial hobbyists.").

13. *See* Rohini Nambiar, *How Rwanda Is Using Drones to Save Millions of Lives*, CNBC (May 27, 2016, 12:26 AM), http://www.cnbc.com/2016/05/27/; *see also* Laura Bassett, *Contraception Drones Are the Future of Women's Health in Rural Africa*, HUFFINGTON POST (Jan. 27, 2016, 8:29 AM), http://www.huffingtonpost.com/entry/birth-control-drones-africa_us_56a8a3b4e4b0947efb65fc11 (reporting on the success of the Dr. One pilot program delivering "birth control, condoms, and other medical supplies to rural areas of Ghana" by drones).

where healthcare resources are not readily available.[14]

While the prospects for the establishment of a systematic drone delivery program are bleak, drone deliveries specifically related to health products and services are not far in the future.[15] Although the timeline for drones making uninterrupted deliveries is uncertain, scholars debate whether it is more appropriate for the state or for the federal government to regulate these flying bots, as they not only attempt to deliver retail goods, but also medical supplies, to our front doors.[16] In other written works, scholars advocate for a singular regulatory system strongly in favor of either the state governments, the federal government, or a hybrid system where federal decisions weigh more heavily than state decisions, or vice versa, when it comes to shuttling and operating drones in private, civilian airspace.[17] With respect to medical devices, academic writing shows that the federal government frequently preempts state tort law when issues arise from medical devices, leaving very little room for legal maneuverability for states.[18]

This Comment posits that drones capable of delivering medical products and devices are considered medical devices themselves, and that they are

14. *See* Nambiar, *supra* note 13.

15. Logan Campbell, the CEO of Aerotas, averred that drone delivery "is definitely getting left out in the cold with these rules," and noted that " All of the long-distance stuff will clearly still have to wait." *See* Ben Popper, *New FAA Rules Mean US Companies Can Fly Drones Without a Pilot's License*, VERGE (June 21, 2016, 10:11 AM), http://www.theverge.com/2016/6/21/11978308/new-faa-rules-mean-us-companies-can-fly-drones-without-a-pilots.

16. *See, e.g.*, Margot E. Kaminski, *Drone Federalism: Civilian Drones and the Things They Carry*, 4 CALIF. L. REV. CIR. 57, 58–59 (2013).

17. *See* Henry H. Perritt, Jr. & Albert J. Plawinski, *One Centimeter Over My Back Yard: Where Does Federal Preemption of State Drone Regulation Start?*, 17 N.C.J.L. & TECH. 307, 384 (2015) (explaining that a cooperative federal–state regime is the bedrock regulatory mechanism in fields like air pollution, occupational safety, and health regulation); Michael Smith, *Regulating Law Enforcement's Use of Drones: The Need for State Legislation*, 52 HARV. J. ON LEGIS. 423, 424 (2015) (arguing that state legislatures, not courts, should regulate government drone use); Timothy T. Takahashi, *The Rise of Drones – The Need For Comprehensive Federal Regulation*, 8 ALB. GOV'T L. REV. 63, 93–95 (2015) (finding that it is within Congress's purview to grant the FAA broad authority to regulate interstate commerce); Kaminski, *supra* note 16 (arguing that a state-centered approach is necessary to regulate the complex drone-related privacy issues).

18. *See generally* Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After* Medtronic, 64 TENN. L. REV. 691, 747 (1997) (noting that federal preemption language in consumer protection laws displaced "inconsistent state-law directives."). *But see* Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2119 (2000) (concluding that it is necessary to retain tort liability for medical devices, and not only rely on federal regulatory compliance, because "a key aspect of the risk posed by devices—their design—is not subject to FDA regulation.").

also subject to aviation regulations. This classification would call for state legislatures and federal agencies—namely, the FAA and FDA—to formulate a stronger, unique regulatory triumvirate. Ultimately, this Comment argues that a stronger or more equal regulatory scheme is required for medical-device drones (MDDs), which are not yet entirely covered by federal law.

Part II bifurcates the traditional regulatory authority of both the federal government and the states as it pertains to aerial vehicles and medical devices. Part III begins by exploring the broad preemptive influence that the federal government reserves in aviation and medical devices based on judicial omnipresence and legislative chronicles. It then unfolds the precedent that states have interpreted in order to offset the preemptive force that the federal government traditionally relies on in aviation conductivity and medical-device distribution to demonstrate a greater need for MDD regulation. Part III builds upon Part II by qualitatively distinguishing the advent of Amazon.com, Inc.'s (Amazon's) drones and its' delivery services from those of MDDs, and justifying this distinction by discussing overlapping regulatory oversight and divergent legal authority. Part III ultimately recommends a modest multi-phased arrangement among the FAA, FDA, and the states that is cooperative and politically healthy to standardize MDDs in the national airspace. This Comment concludes by examining the strengths and pitfalls of both the federal and state regulatory schemes and recognizes that the roles of the FAA, FDA, and states can be dissected into three phases—pre-market, on-market, and post-market—in order to effectively regulate MDDs.

I. BACKGROUND

Profound breakthroughs in medicine have given rise to sophisticated medical devices that "hold the promise of improving the health and longevity of the American people."[19] These developments happened in part because Congress empowered the FDA to effectively regulate medical devices, pushing research and development to the forefront of the health industry to reduce the risk of using unsafe medical devices.[20]

To begin, it is important to set a geographical stage where these devices can roam. In the most impoverished corners of our country, there is a dearth of supermarkets, and food banks are teeming with canned foods that

19. S. REP. NO. 94-33, at 2 (1975), *as reprinted in* 1976 U.S.C.C.A.N. 1070, 1071 (Leg. Hist).

20. *See id.*

lack the healthy qualities of fresh food.[21] Consequently, if the residents of these neighborhoods subsist on subpar nutrition, it is likely that access to competent health care and services is also lacking.[22] Not only is the inability to access healthcare concerning in the United States, it is also a problem in the world's most populous countries, which have scant access to physicians and medical care.[23] As a result, viable solutions have come in creative forms, such as attempting to bring emergency medical care to patients through telemedicine.[24] However, MDDs offer a more expedient solution to inaccessible health remedies and institutions. They have the ability to deliver medicine without incurring the time and expense, from lengthy commutes, that comes with obtaining medical devices and products at physical health facilities.[25] But bearing the responsibility of transporting such life-sustaining medical products and devices will require a firmer regulatory system reinforced by the FAA, FDA, and states.

First and foremost, to understand why it is relevant to have a federal–state hybrid of regulations for MDDs, it is important to discern what both the state and federal governments have been known to traditionally regulate. The following subsections will examine how state and federal governments administer laws and regulations as they pertain to aerial drones and medical devices.

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21. *See* Cathlynn Groh, *The Poor Often Lack Access to Healthy Food*, WALL ST. J. (May 17, 2016, 4:57 PM), http://www.wsj.com/articles/the-poor-often-lack-access-to-healthy-food-1463518641.

22. *See* OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. HEALTH & HUMAN SERV., FIN. CONDITION AND HEALTHCARE BURDENS OF PEOPLE IN DEEP POVERTY (2015), https://aspe.hhs.gov/basic-report/financial-condition-and-health-care-burdens-people-deep-poverty; *see also* John Patton Jr., *Poor Health: Poverty and Scarce Resources in U.S. Cities, Part One*, PITTSBURGH POST-GAZETTE, http://newsinteractive.post-gazette.com/longform/stories/poorhealth/1/, (last visited Sept. 30, 2016) ("Hospitals and family doctors, the mainstays of health care, are pulling out of poor city neighborhoods, where the sickest populations live.").

23. *See* Marilyn Chase & Amir Efrati, *Lack of AIDS Doctors in Poor Countries Stalls Treatment*, WALL ST. J. (July 13, 2004, 12:01 AM), http://www.wsj.com/articles/SB108967121527261716; *see also* Thomas F. Martin II, *The Stark Inaccessibility of Medical Care in Rural Indiana: Judicial and Legislative Solutions*, 11 IND. HEALTH L. REV. 831, 832 (2014) (proferring a "comparative analysis of rural and urban locales" to highlight a lack of hospitals and healthcare professionals in the State of Indiana).

24. *See, e.g.*, Avery Schumacher, *Telehealth: Current Barriers, Potential Progress*, 76 OHIO ST. L.J. 409, 418–19 (2015) (arguing that telehealth benefits can transcend distance barriers, allowing physicians to use video conferences to engage in real-time examinations).

25. *See, e.g.*, *Medical Drones Poised to Take Off*, MAYO CLINIC, (Jan. 8, 2015), http://www.mayoclinic.org/medical-professionals/clinical-updates/trauma/medical-drones-poised-to-take-off ("Instead of courier services or the highway patrol transporting blood to a hospital that needs it, a UAV [unmanned aerial vehicle] could deliver the blood in advance, taking off as soon as the EMS call comes in.").

A. A Traditional Schematic of Federal Regulation

1. The Past and Current Authority of the FAA on Aerial Vehicles

In 2012, Congress mandated that the Department of Transportation (DOT) develop a comprehensive plan to safely integrate unmanned aircraft systems (UAS) into the national airspace system through the Federal Aviation Administration Modernization and Reform Act of 2012 (FAAMRA).[26] For the purposes of this article, the convention of "drones" is used interchangeably with "UAS." Since 2012, the DOT has charged the Secretary with the responsibility of assessing the potential for unmanned aircrafts to fly safely in our national airspace system under § 333 of FAAMRA.[27] This section created UAS test site programs to embolden further research and tests of drones in real world grids,[28] developed the Pathfinder Program (via the FAA) to spur research and innovation to enable advanced UAS operations,[29] and issued a notice of proposed rulemaking (NPRM) through the FAA.[30] The FAA is a modal organization within the DOT that is responsible for ensuring the safety and integrity of the national airspace system.[31] Its NPRM published on February 23, 2015 focused on the regulation of small, unmanned aircraft systems and invited public comments on how to improve this newly-minted industry.[32]

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26. *See generally* FAA Modernization and Reform Act of 2012, Pub. L. No. 112-95, 126 Stat. 11 (2012) (amending 49 U.S.C. § 40101).

27. *See* 49 U.S.C. § 40101(a)–(c) (2012) (authorizing the Secretary of Transportation to determine whether an unmanned aircraft may operate safely in the national airspace by assessing the aircraft's size, weight, speed, operational capability, proximity to airports and populated areas, and operation within the visual line of site).

28. *See* Operation and Certification of Small Unmanned Aircraft Systems, 80 Fed. Reg. 9544, 9551 (proposed Feb. 23, 2015) (to be codified at 14 C.F.R. pts. 21, 43, 45, 47, 61, 91, 101, 107, and 183) (disclosing that these tests sites were selected and assessed based on geographic and climatic diversity. The FAA sought comments on how to improve these test sites to encourage innovation and safe development).

29. *See* Michael Huerta, Unmanned Aircraft Sys. Adm'r, FAA, Speech at the Ass'n for Unmanned Vehicle Sys. Int'l (AUVSI) Pathfinder Program Announcement Press Conference, (May 6, 2015), http://www.faa.gov/news/speeches/news_story.cfm?newsId=18754&omniRss=speechesAoc&cid=104_Speeches (revealing the FAA's intention to launch the Pathfinder Program by partnering with CNN, PrecisionHawk, and BNSF Railroad to exhaust substantial resources to perform research that can determine how to safely expand Unmanned Aircraft Systems (UAS) operations nationally).

30. *See* Operation and Certification of Small Unmanned Aircraft Systems, 80 Fed. Reg. at 9544.

31. *See A Brief History of the FAA*, FAA (Feb. 19, 2015), http://www.faa.gov/about/history/brief_history/#birth.

32. *See* Operation and Certification of Small Unmanned Aircraft Systems, 80 Fed. Reg. at 9583. Note that the FAA issued the final rules earlier this year, amending its regulations

An "aircraft" is defined as "any contrivance invented, used, or designed to navigate, or fly in, the air."[33] An *unmanned* aircraft adds another component to the core definition; it is "operated without the possibility of direct human intervention from within or on the aircraft."[34] Because drones are aircrafts, they are subject to FAA regulation[35] and statutory requirements.[36] In addition to the basic operational limitations—weight must not exceed fifty-five pounds, airspeed cannot exceed 100 miles per hour, maximum flight altitude cannot exceed 500 feet above ground level, operation in Class G airspace without air traffic control is permissible, flight in Class A airspace is prohibited, air traffic control permission is required to enter Class B, C, D, and E airspace, flight can only occur during daylight hours, etc.[37]—the NPRM proposed more complex limitations that require careful consideration and modification if drones are to participate in commercial operations at their utmost capacities.[38]

Even with these limitations, drones are still far from flawless. Reports have evidenced that "unsafe UAS operations, the lack of awareness of operators regarding what must be done to operate UAS safely in the [national airspace system], and the lack of identification of UAS and their operators pose significant challenges in ensuring accountability" and responsibility.[39] The FAA noted that "[t]he risk of unsafe operations [may]

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to permit the safe operation of unmanned aircrafts in the national airspace. *See generally* Operation and Certification of Small Unmanned Aircraft Systems, Final Rule, 81 Fed. Reg. 42,064–42,214 (June 28, 2016) (codified at 14 C.F.R. pts. 21, 43, 61, 91, 101, 107, 119, 133, and 183).

33. 49 U.S.C. § 40102(a)(6) (2012).

34. FAA Modernization and Reform Act of 2012, Pub. L. No. 112-95, 126 Stat. 11 § 331(8); *see also* Administrator v. Pirker, NTSB Order No. EA-5730, at 12 (Nov. 17, 2014) (declaring that the statutory definition of an aircraft is unambiguous and "includes any aircraft, manned or unmanned, large or small").

35. Aircraft Registration Rule, 14 C.F.R. § 47.1 (2016) (outlining its applicability).

36. *See* 49 U.S.C. § 44101(a) (2012). "Historically, the FAA, through the exercise of its discretion, has not enforced the statutory requirements for aircraft registration in 49 U.S.C. 44101 for model aircraft." Clarification of the Applicability of Aircraft Registration Requirements for Unmanned Aircraft Systems (UAS) and Request for Information Regarding Electronic Registration for UAS, 80 Fed. Reg. 63,912, 63,914 (Oct. 22, 2015) (to be codified at 14 C.F.R. Chapter I).

37. *See* Operation and Certification of Small Unmanned Aircraft Systems, 80 Fed. Reg. at 9551. However, under the final rules, the maximum altitude is limited to 400 feet above ground level. *See* Operation and Certification of Small Unmanned Aircraft Systems, Final Rule, 81 Fed. Reg. at 42,066.

38. For example, a drone must remain within the visual line-of-sight of the operator and close enough for the operator to see it. *See* Operation and Certification of Small Unmanned Aircraft Systems, 80 Fed. Reg. at 9546; *see also* Operation and Certification of Small Unmanned Aircraft Systems, Final Rule, 81 Fed. Reg. at 42,066.

39. *See* Clarification of the Applicability of Aircraft Registration Requirements for

only increase as more UAS enter" the national airspace system.[40]

2. The Past and Current Authority of the FDA on Medical Devices

For purposes of this Comment, it is necessary to narrowly focus on the category of home health and consumer devices that the FDA regulates.[41] In addition to its mission to protect the public health from subpar "human and veterinary drugs, vaccines, and other biological products," the FDA zeroes in on how people can use medical devices safely and effectively.[42] Of the many products under its purview, it also regulates devices that consumers can use without professional medical assistance,[43] such as blood glucose monitoring devices[44] or home-use tests.[45] The Home Health Care Committee, subsumed within the FDA, ensures the safety and effectiveness of these home-use devices by addressing the issues that arise and recommending further action for safe use in the future.[46]

The Federal Food Drug & Cosmetic Act (FDCA) is the legal authority that permits the FDA to regulate this subset of medical devices.[47] Under the FDCA, the FDA is required to regulate medical devices that pose substantial risks to the collective public health, while only promoting devices that are considerably beneficial.[48] Specifically, with respect to

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Unmanned Aircraft Systems (UAS) and Request for Information Regarding Electronic Registration for UAS, 80 Fed. Reg. at 63,914.

40. *Id.* at 63,913. For example, a drone during flight may lose positive control, meaning that an operator cannot use the control interface to operate the drone because the control link between an aircraft and control station disconnected. *See* Operation and Certification of Small Unmanned Aircraft Systems, 80 Fed. Reg. at 9549; *see also* Operation and Certification of Small Unmanned Aircraft Systems, Final Rule, 81 Fed. Reg. at 42,068.

41. *FDA Fundamentals*, FDA, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm (last updated Dec. 3, 2015) (noting that the FDA is an agency within the U.S. Department of Health and Human Services).

42. *Id.*

43. *See Home Health and Consumer Devices*, FDA, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/default.htm (last updated July 8, 2015).

44. This device quantitatively measures the amount of sugar (glucose) in an individual's blood and is typically used by people with diabetes. *See Blood Glucose Monitoring Devices*, FDA, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/GlucoseTestingDevices/default.htm (last updated Jan. 26, 2015).

45. While these tests should not replace periodic visits to a physician, they are cost-effective and confidential tests that allow an individual to test for certain diseases or conditions at home even when no symptoms are visible. *See Home Use Tests*, FDA, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/default.htm (last updated June 5, 2014).

46. *See Home Health and Consumer Devices*, *supra* note 43.

47. *See* 21 C.F.R. § 806.1(a) (2016).

48. *See generally Overview of FDA Modernization Act of 1997, Medical Device Provisions*, FDA,

medical devices, the FDA regulates the requirements of labeling, medical-device reporting, registration, premarket approval, tracking, post-market surveillance, and medical-device classification procedures.[49]

While the FDA oversees the use and integrity of medical devices, the legal inquiry that should be addressed is whether drones can be classified as medical devices. This Comment is premised on the principle notion that drones should be classified as medical devices under the FDA's medical-device classification procedures.[50] The regulations generally prescribe the criteria and procedures to determine the class of regulatory control that is appropriate for medical devices, triggering §§ 513, 514(b), 515(b), and 520(l) of the FDCA.[51] To date, there are three categories of classes of regulatory control: Class I, Class II, and Class III. Class I devices are those that can reasonably assure the safety and effectiveness of a device, are not life-supporting, and do not present a high risk of illness or injury because general controls are sufficiently in place.[52] Class II devices, like contraceptives, are those that are or will be subject to special controls.[53] These devices are unable to reasonably assure their safety and effectiveness solely through general controls and need special controls to provide that assurance.[54] Finally, Class III medical devices are the highest-risk devices, subject to the most regulatory control and must be FDA-approved before hitting the market.[55]

B. A Traditional Schematic of State Regulation

1. Aerial Drones

With respect to aerial drones, the Supreme Court has addressed situations in which the police attempted to investigate marijuana-growing operations based on information received from tipsters. In *California v.*

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http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094526.htm (last updated Aug. 5, 2015).

49. *See* 21 C.F.R. §§ 801, 803, 807, 814, 821, 822, 860 (2016).

50. *See infra* Section II(B)(1)(b).

51. *See* 21 C.F.R. § 860.1(a)–(b) (2016).

52. *See* 21 C.F.R. § 860.3(c)(1). General controls are prohibitions against adulteration and misbranding, while adhering to good manufacturing practices. *See id.*

53. *See* 21 C.F.R. § 860.3(c)(2) ("including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents," and recommendations); *see also, e.g.*, *What Does It Mean for FDA to "Classify" a Medical Device?*, FDA, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm (last updated Dec. 28, 2015).

54. *See* 21 CFR § 860.3(c)(2).

55. *Id.* § 860.3(c)(3).

Ciraolo,[56] a challenge to the Fourth Amendment was considered by the Court.[57] The county police responded to an anonymous tip that the respondent was growing marijuana in his backyard.[58] Because the police were unable to examine the contents of the respondent's backyard from ground level, they conducted aerial surveillance in order to readily identify the illegal substance.[59] The Supreme Court reasoned that anyone who can fly in public navigable airspace and peer down into the backyard could be at a favorable vantage point to see the marijuana, thus nullifying the reasonableness of the respondent's expectation of privacy.[60] In a similar case, the Court dealt with a police officer's observation of a respondent's greenhouse from a helicopter.[61] The outcome of that case readily aligned with *Ciraolo* because the respondent did not have a reasonable expectation that his greenhouse was immune from government inspection in public navigable airspace.[62] Although there is scholarship that delves into the constitutional hurdles that government drone use poses, those issues related to the Fourth Amendment are beyond the scope of this Comment and will not be discussed in detail.[63] The focus here is to define a legally substantive and cooperative relationship between state and federal regulation that paves the way for a safe and efficient airspace for MDDs.

Moving beyond precedent, some states have enacted or proposed laws that regulate the multifaceted use of drones with respect to regulating government drone use. For instance, Alaska has broad warrant exception laws, where law enforcement agencies may use drones to gather evidence during a criminal investigation as long as such activity is "in accordance with a judicially recognized exception to the warrant requirement."[64] In contrast with Alaska's law, Florida enforces warrant restrictions with

56. 476 U.S. 207, 211 (1986) (affirming that "The touchstone of Fourth Amendment analysis is whether a person has a 'constitutionally protected reasonable expectation of privacy.'" (quoting Katz v. United States, 389 U.S. 347, 360 (1967)(Harlan, J., concurring)).

57. *Id.*

58. *See id.* at 209.

59. *See id.*

60. *See id.* at 213–14.

61. Florida v. Riley, 488 U.S. 445, 448 (1989).

62. *Id.* at 450.

63. *See, e.g.*, Matthew R. Koerner, Note, *Drones and the Fourth Amendment: Redefining Expectations of Privacy*, 64 DUKE L.J. 1129 (2015) (arguing that courts should expand on the subjective-expectation-of-privacy requirement while applying the reasonable-expectation-of-privacy test when reconciling issues of drone domestic surveillance); Taly Matiteyahu, Note, *Drone Regulations and Fourth Amendment Rights: The Interaction of State Drone Statutes and the Reasonable Expectation of Privacy*, 48 COLUM. J.L. & SOC. PROBS. 265 (2015) (examining the relationship between state statutes that govern drones and Fourth Amendment jurisprudence).

64. *See* ALASKA STAT. § 18.65.902(1)(B) (2015).

explicit statutory exceptions. In Florida, a law enforcement agency is prohibited from gathering evidence with a drone; and a person, state agency, or political subdivision cannot use a drone that carries an imaging device to record privately-owned real property or occupants of the property intending to surveil without consent.[65] However, the prohibition does not apply under certain exceptions, such as challenging a high risk of terrorist attack, obtaining an initial search warrant, or preventing "imminent danger to life or serious damage to property," among others.[66] Similarly, North Carolina placed a moratorium on drone use for surveilling or photographing an individual without proper consent, unless the drone activity falls within a law enforcement exception, similar to those in Florida.[67] While these states comprehensively address government drone usage, each varies with regard to restrictions.

2. Medical-Device Distribution

Many medical-device companies focus their resources on compliance with the FDA's requirements.[68] However, as specifically related to device distribution, state agencies handle a compelling portion of medical-device regulations. These laws vary in degree among the states with respect to the types of devices, activities and entities that are subject to regulation, licensure requirements, requirements related to facilities, processes and quality, and methods of how each state interprets and enforces these laws.[69]

For instance, Massachusetts created policies designed to ascertain whether medical-device manufacturers and distributors need to obtain controlled substances registration, as long as their purpose is not inconsistent with the public interest.[70] Those who are registered to manufacture and distribute controlled substances must keep records and inventories in accordance with the requirements set forth in the Federal Comprehensive Drug Prevention and Control Act of 1970, the FDCA, and

65. *See* FLA. STAT. § 934.50(3)(a)–(b) (2016).

66. *Id.* § 934.50(4)(a)–(c).

67. *See generally* Current Operations and Capital Improvements Appropriations Act of 2014, ch. 15A, sec. 34.30(a), § 15A-300.1, 2013 N.C. Sess. Laws 227–28.

68. For example, Johnson & Johnson created healthcare compliance guidelines premised on applicable law and FDA codes. *See, e.g.*, *The Right Course: Everyday Health Care Compliance, an Introductory Guide for Our Employees*, JOHNSON & JOHNSON INT'L (2009), https://www.jnj.com/sites/default/files/pdf/the-right-course.pdf.

69. *See* Michele L. Buenafe, *State Regulation of Medical Device Distribution: Managing a Complex Regulatory Scheme*, FOOD & DRUG LAW INST. 21–22 (2015), https://www.morganlewis.com/~/media/files/publication/outside%20publication/article/state-regulation-of-medical-device-distribution-update.ashx?la=en.

70. *See* Controlled Substances Act, MASS. GEN. LAWS ch. 94C, § 12(a) (2016).

the board of registration's pharmaceutical regulations for retail drug businesses.[71] Massachusetts also holds pharmacists accountable for filing written or oral prescriptions for controlled substances as it relates to packaging, where the department of public health distributes written and electronic forms to pharmacies and educational pamphlets to consumers.[72] Additionally, Massachusetts established criminal penalties for violating its state distribution laws with respect to five classes of controlled substances.[73] It defines a controlled substance as "a drug, substance, controlled substance analogue or immediate precursor in any schedule or class referred to in this chapter."[74] Under this law, a medical device with a pharmaceutical prescription is classified as a controlled substance notwithstanding its characterization as a medical device.[75]

All in all, very few states have a regulatory framework for medical devices because the FDA and medical-device experts are aware of the FDA's ubiquitous oversight in this field.[76] However, Bradley Merrill Thompson, a device attorney with Epstein, Becker & Green in Washington, D.C., explains that the FDA has sought to reduce its regulatory oversight, rather than to expand it, and advocates for continuous improvement of FDA regulation (rather than hardline reform) by reviewing agency performance data, marketplace trends, and scientific trends.[77] Consequently, the states are appropriate governing bodies that can supplement and assess this data from the FDA, requiring a cooperative effort by the federal government and state legislatures to regulate not only medical devices, but also MDDs as medical devices.

71. *See id.* § 15.

72. *See id.* § 21.

73. *See id.* § 31 (listing the various chemical designations for Classes A, B, C, D, and E).

74. *See id.* § 1.

75. *See Medical Device Manufacturer and Distributor Registration*, MASS. EXEC. OFF. OF HEALTH & HUMAN SERVS., (last visited Oct. 21, 2016), http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/mcsr/forms/manufacturers-distributors/medical-device-manufacturer-registration.html.

76. Scott Gottlieb, former FDA deputy commissioner, explains that the FDA is putting up more hurdles in order to apply a more uniform approach to regulating medical devices, treating low-risk devices similar to high-risk devices. *See* Thomas M. Burton, *Do the FDA's Regulations Governing Medical Devices Need to Be Overhauled?*, WALL ST. J. (Mar. 23, 2015), http://www.wsj.com/articles/do-the-fdas-regulations-of-medical-devices-need-to-be-overhauled-1427079649.

77. *See id.*

II. ARGUMENT

A. A Weakened Federal Preemption Doctrine

In the past, the Court has endorsed the idea that the FAA has broad authority over the guidelines and enterprise of aviation safety and efficiency. The Supreme Court noted that the interdependence of safety and efficiency "requires a uniform and exclusive system of federal regulation if the congressional objectives underlying the Federal Aviation Act are to be fulfilled."[78] In other words, there exists a sentiment that the FAA regulations and federal law preempt the category of state laws that deal with aviation norms.

Federal preemption is the displacement of state law by federal law, and Congress's power to preempt state law is derived from the Supremacy Clause of Article VI of the Constitution.[79] It provides that the Constitution and federal laws of the United States "shall be the supreme Law of the Land," binding upon every state.[80] Therefore, preemption issues arising between state and federal law are resolved by determining congressional intent, which "'is the ultimate touchstone' of preemption analysis."[81]

Both express preemption and implied preemption comprise the preemption taxonomy. The easiest preemption doctrine to identify is express preemption. Congress can include an express preemption clause in a federal statute if it has the authority to regulate a particular subject and, consequently, preempt state laws.[82] Under this analysis, whether a state law falls within a federal statute's express preemption clause is a question for a court to determine, applying the mechanics of statutory interpretation.[83] On the other hand, a federal statute may have a savings clause, allowing states to regulate certain activities that are concurrently regulated under

78. City of Burbank v. Lockheed Air Terminal Inc., 411 U.S. 624, 638–39 (1973); *see also* Nw. Airlines, Inc. v. Minnesota, 322 U.S. 292, 303 (1944) (Jackson, J., concurring) ("Federal control is intensive and exclusive. Planes do not wander about in the sky like vagrant clouds. They move only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under an intricate system of federal commands.").

79. *See* U.S. CONST. art. VI, cl. 2.

80. *Id.*

81. *See* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992) (quoting Malone v. White Motor Corp., 435 U.S. 497, 504 (1978)).

82. *See, e.g.*, Bruesewitz v. Wyeth LLC, 562 U.S. 223, 230–43 (2011) (conducting an analysis of Congress's intent and concluding that all tort law design-defect claims against vaccine manufacturers were expressly preempted by the National Childhood Vaccine Injury Act); *see also* Note, *A Framework for Preemption Analysis*, 88 YALE L. J. 363, 363–65 (1978) (providing an overview of express preemption).

83. *See* David S. Rubenstein, *Delegating Supremacy?*, 65 VAND. L. REV. 1125, 1137 (2012).

federal law.[84]

Absent an express preemption clause in a federal statute, or if a state law falls outside the defining language of an express preemption clause, federal preemption may still be implied. Implied preemption is split into two groups: conflict preemption and field preemption.[85] The first, conflict preemption, can arise in two ways: when a state law frustrates or impedes the execution of Congress's purpose and objectives, or when it is pragmatically impossible to comply with both federal and state law.[86] The second, field preemption, occurs when Congress defines a field or industry through such pervasive legislation that a court may presume that Congress intended to occupy the entire field, thus ostracizing the states.[87]

The Supreme Court has held that field preemption applies to aviation issues.[88] In addition to the Court recognizing that the FAA has broad authority over flight specifications and requirements, other lower federal courts have followed the Supreme Court's precedent. The Third Circuit held in *Abdullah v. American Airlines, Inc.*[89] that federal law preempts air safety standards and still preserves state damage remedies.[90] In *Abdullah*, turbulence during a storm caused serious injuries to the plaintiffs on an American Airlines flight.[91] The plaintiffs filed a lawsuit against American Airlines, alleging negligence for "failing to take reasonable precautions to avoid turbulent conditions."[92] The court noted that, "Congress's purpose in enacting the FAA was 'to promote safety in aviation and thereby protect the lives of persons who travel on board aircraft.'"[93] Moreover, in the guise of statutory authority, even federal law acknowledges the FAA's prominence in regulating air safety: "The Administrator of the Federal Aviation Administration shall develop plans and policy for the use of the navigable airspace and assign by regulation or order the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace."[94]

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84. *See A Framework for Preemption Analysis*, *supra* note 82, at 365–66 (providing a brief overview of express savings clauses).

85. *See* Rubenstein, *supra* note 83, at 1137–38.

86. *See id.* at 1138 (noting that these doctrines are known as the obstacle and impossibility preemption).

87. *See id.* at 1137–38.

88. *See* City of Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624, 638–39 (1973).

89. 181 F.3d 363, 364–65 (3d Cir. 1999).

90. *See id.*

91. *Id.* at 365.

92. *Id.*

93. *Id.* at 368 (quoting *In re* Mexico City Aircrash of Oct. 31, 1979, 708 F.2d 400, 406 (9th Cir. 1983)).

94. 49 U.S.C. § 40103(b)(1) (2012); *accord* Kohr v. Allegheny Airlines, Inc., 504 F.2d 400, 404 (7th Cir. 1974) (noting that the purpose of the Federal Aviation Act is to "create

With respect to medical devices, Congress enacted the Medical Device Amendments of 1976 (MDA) allowing the FDA to promulgate regulations, which provided a federal review of medical devices, depending on the type of device at issue.[95] Class III devices that underwent the premarket approval process were extensively regulated, where they can enter the market only if the FDA determines that design, labeling, and manufacturing specifications are reasonably safe and effective.[96]

Cases have considered whether a preemption clause in the MDA bars common law claims challenging the safety and effectiveness of a medical device.[97] For instance, in *Riegal v. Medtronic, Inc.*,[98] petitioners, husband and wife, brought a suit after a catheter—a Class III medical device—ruptured in the husband's coronary artery during heart surgery.[99] Petitioners alleged that the device's design, label, and manufacturing violated New York common law,[100] but lost their claim when the Court concluded that MDA's preemption clause bars common law claims that challenge the safety and effectiveness of medical devices that receive FDA premarket approval.[101] The Court reasoned that on its face the text of the MDA does not suggest that preempted state requirements must apply solely to the relevant medical device and not to all products generally.[102]

However, Congress intended for the MDA "to provide for the safety and effectiveness of medical device[s] intended for human use."[103] Additionally, a former chief counsel of the FDA explained that both "FDA product approval and state tort liability" are typically operated independently of

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one unified system of flight rules . . . for the safe and efficient use of the country's airspace.").

95. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified at 21 U.S.C. § 301).

96. *See* 21 C.F.R. § 860.3(c)(3) (2016).

97. This clause prohibits states from promulgating a device requirement, "(1) which is different from, or in addition to, any requirement applicable under [federal law] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [federal law]." 21 U.S.C. § 360k(a) (2012).

98. 552 U.S. 312, 320–21 (2008).

99. *Id.*

100. *See id.* at 320.

101. *See id.* at 320–30.

102. *See id.* at 328. *But see* Longs v. Wyeth, 621 F. Supp. 2d 504, 509 (N.D. Ohio 2009) (holding that the plaintiffs failed to demonstrate that pre-FDA approval claims were preempted).

103. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (preamble) (codified at 21 U.S.C. § 301); *see also* 121 CONG. REC. 10,688 (1975) (statement of Sen. Kennedy) (emphasizing that medical-device legislation is written to give deference to a consumer because it is the consumer's health and life that are on the line when medical devices malfunction).

each other, providing multiple layers of consumer protection.[104] FDA regulations of a medical device "cannot anticipate and protect against all safety risks to individual consumers" because even the most fleshed out regulation of a medical device may still not identify all possible issues over time.[105] Therefore, a significant layer of consumer protection would deteriorate if all device-failure claims were preempted.[106]

Furthermore, one of the most deep-seated concerns about federal preemption rests with the Tenth Amendment. Because the Constitution creates a system of dual governance, dividing power between the federal government and the states, the Tenth Amendment provides that states retain all governmental power, unless that power is explicitly reserved to the federal government.[107] This system of dual governance allows a state to regulate in its proper field of authority, maintaining a degree of sovereignty independent of the national government.[108] Courts have historically been known to keep federal power in check by applying a presumption against preemption and requiring a clear statement of congressional intent to preempt state law.[109]

With respect to aviation, the states have precedent on their sides. In *Martin ex rel. Heckman v. Midwest Express Holdings, Inc.*,[110] the Ninth Circuit refused to infer that Congress intended for the FAA to prevail over and exclude state law remedies, thereby limiting the Act's preemptive scope.[111] It held that state law is preempted by the FAA only if a particular area covered by a plaintiff's tort claim was the subject of "pervasive" federal regulations.[112] As it pertains to MDDs, federal aviation regulations are

104. *See* Margaret J. Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 11 (1997).

105. *Id.*

106. *See id.*

107. *See* U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.").

108. *See* Fry v. United States, 421 U.S. 542, 547 n.7 (1975) ("The [Tenth] Amendment expressly declares the constitutional policy that Congress may not exercise power in a fashion that impairs the States' integrity or their ability to function effectively in a federal system.").

109. *See, e.g.*, Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (propounding that courts should start with the assumption that state historic police powers are not preempted by federal law, unless there was a "clear and manifest purpose of Congress"); *see also* William N. Eskridge, Jr., *Public Values in Statutory Interpretation*, 137 U. PA. L. REV. 1007, 1023–25 (1989) (advocating that the courts use the presumption against preemption to protect local values from "inadvertent federal interference").

110. 555 F.3d 806, 808 (9th Cir. 2009).

111. *Id.*

112. *Id.* at 811.

silent on medical-device and drone delivery issues. This starkly contrasts with the comprehensive regulations on only unmanned aircraft operational limitations. Thus, it is the responsibility of the FDA to regulate only the medical-device attribute of these MDDs. If this approach is insufficient, precedent still limits the FDA's preemptive authority over state laws with regard to medical devices.

In *Medtronic, Inc. v. Lohr*,[113] the Court addressed the issue of whether the MDA's preemption provision superseded state law tort claims related to a defective pacemaker approved through the 510(k) premarket notification process, and held that at least some state law claims were not preempted.[114] The Court executed a preemption analysis of the MDA's general regulations governing labeling and manufacturing of almost all medical devices, and found that Congress did not intend for general federal regulations to preempt *all* medical-device claims.[115] The Second Circuit has held that FDA regulation of the component parts of an unclassified medical device does not preempt state tort claims relating to the unclassified device.[116] The Ninth Circuit held that where the product in question is not a medical device listed by the FDA, claims relating to it are not preempted by the MDA.[117]

It conclusively follows that the lack of, or limited, preemptive authority in both the FAA and FDA leaves room for the states to draft their own regulations and laws that can deal with specific activities of MDDs. Given the FAA and FDA's preemptive limits and the states' regulatory potential, this Comment recommends that there be a stronger, collaborative regulatory scheme among the three to promote MDD flight in the national airspace to deliver medical products.

B. A Hybridized Case for Medical-Device Drones

Basically stated, drones can deliver; medical devices can diagnose or treat.[118] Yet when drones harness and deliver medical products and devices, this elegant technological service may raise many concerns on state and federal levels because it is perceived as science fiction. While there is

113. 518 U.S. 470, 487 (1996).

114. *See id.*

115. *See id.* at 497–502. However, the Court was careful to note that it was not impossible for a "general" federal regulation to preempt a state claim. *See id.*

116. *See* Lamontagne v. E.I. Du Pont de Nemours & Co., 834 F. Supp. 576, 583 (D. Conn. 1993), *aff'd on other grounds*, 41 F.3d 846 (2d Cir. 1994).

117. *See* Anguiano v. E.I. Du Pont de Nemours & Co., 44 F.3d 806, 810 n.4 (9th Cir. 1995).

118. *See* Nambiar, *supra* note 13; Bassett, *supra* note 13.

already some degree of overlap between state and federal regulation of aerial drones and medical devices, drones that deliver medical products will require a hybrid of state and federal regulation to meet the safety and efficiency benchmarks under the FAA and FDA's missions.[119]

1. A Qualitative Distinction from Amazon Drones

a. Amazon Drones and the FAA

Amazon is a retail giant that is pushing for more innovation, expediency, and profit in its delivery services through the employment of drones.[120] It is etching a blueprint in the national airspace to ensure that it can effectively provide retail commerce in the shortest amount of time possible to consumers.[121] Consequently, Amazon views these automated drones as inherently having incredible business potential where Amazon would have more control over the general shopping experience and contain shipping costs to minimal rates.[122] However, a major obstacle that Amazon faces in order to transform this new service into a commercial reality is whether regulators, physical retailers, and deliverers will cooperate.[123] As of today, Amazon has not been able to effectively challenge parcel-delivery giants, such as UPS.[124] However, the FAA anticipates seven million drones to take flight by 2020.[125] Whether Amazon's new proposal will be included in the FAA's estimate is still unclear, but hope still exists for the state-of-the-art MDD delivery service. On March 19, 2015, the FAA "issued an 'experimental airworthiness certificate' to an Amazon Logistics, Inc." drone that Amazon will use for research and product development.[126] The certificate requires that all flight experiments must be conducted at no

119. *Compare* federal regulations discussed *supra* Part I.A, *with* state regulations discussed *supra* Part I.B.

120. *See* Jack Nicas, *Amazon Lays Out Plans for Drones to Navigate Skies*, WALL ST. J. (July 28, 2015, 2:08 PM), http://www.wsj.com/articles/amazon-lays-out-plan-for-drones-to-navigate-skies-1438106902.

121. *See id.*; Greg Bensinger, *Amazon's Next Delivery Drone: You*, WALL ST. J. (June 16, 2015, 11:00 AM), http://www.wsj.com/articles/amazon-seeks-help-with-deliveries-1434466857?cb=logged0.6146322535350919 ("In its ceaseless quest to speed delivery, Amazon.com Inc. wants to turn the U.S. into a nation of couriers.").

122. *See* Bensinger, *supra* note 121.

123. *See id.*

124. *See id.*

125. *See Should You Be Allowed to Prevent Drones From Flying Over Your Property?*, WALL ST. J. (May 22, 2016, 10:03 PM), http://www.wsj.com/articles/should-you-be-allowed-to-prevent-drones-from-flying-over-your-property-1463968981.

126. *See Amazon Gets Experimental Airworthiness Certificate*, FAA, https://www.faa.gov/news/updates/?newsId=82225 (last updated Mar. 19, 2015).

higher than 400 feet during daylight hours, and the drone must remain within the sight of a certified private pilot.[127] For accountability purposes, Amazon is also required to submit monthly reports to the FAA, including "the number of flights conducted, pilot duty time per flight, unusual hardware or software malfunctions, any deviations from air traffic controllers' instructions," and unintended loss of communication links.[128] While Amazon's delivery drones would courier retail goods, an MDD would be subject to more strict regulatory provisions because it would not only be subject to the guidelines for flight safety and efficiency set forth under FAA regulations, but also to the regulatory strictures of the FDA as a medical device.

b. The Medical-Device Drone: The FAA and FDA

Although an MDD delivering medical products to our doormats is related to home health and consumer devices, it does not appear to be the type of device that would be less risky than blood glucose monitoring devices, or home use tests, which are classified as Class II devices.[129] Based on the FAA's assessment of the drones in the current regulatory environment, discussed above in Section I.A.1, it is highly likely that drones manufactured for the purpose of delivering medical products will fall into the FDA's Class III category as a high-risk medical device that would be subject to stringent regulatory oversight.

Under the FDA regulations, all devices are subject to baseline general controls under the FDCA.[130] If viable for the commercial pharmaceutical market, an MDD is likely to be subject to Class III premarket approval under statutory authority. A Class III device is one that does not satisfy the requirements for Class I or Class II because, generally, there is insufficient information regarding general controls and special controls,[131] "to provide reasonable assurance of the safety and effectiveness of the device."[132] Per the regulations, determining a device's "safety and effectiveness" for classification purposes requires consideration of factors such as who is

127. *See id.*

128. *See id.*

129. *See supra* Section I.A.2; *see also, e.g.*, *Product Classification*, FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NBW (blood glucose monitoring devices); *Product Classification*, FDA, http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm (pregnancy tests).

130. For a brief discussion on general controls, see supra notes 52–56 and accompanying text.

131. *See id.* (discussing special controls).

132. *See* 21 U.S.C. § 360c(a)(1)(C)(i) (2012).

intended to use the device, the conditions of use suggested in labeling the device, and the benefits of using the device against the risk of injury or illness from its use.[133]

A device's "intended use" is determined by examining the objective intent of the legal authority responsible for labeling the device[134] (in this case, the FDA); that intent may be expressive, or shown through the circumstances surrounding the distribution of the article.[135] MDDs, as noted throughout this Comment, would be intended to maintain the virtue of health product availability and accessibility by delivering medical products and treatments to consumers.[136] That purpose is similar to the mission of the telemedicine field.[137] However, MDD technology is aimed at not only geographic accommodation, but handling high volume deliveries in the least amount of time.[138] MDDs have the ability to bring prescription bottles or insulin pens directly into the hands of a patient. In this way, they can simultaneously maximize the utility of delivery services and medical product distribution. Presuming that the FDA drafts conditions related to the caveats of utilizing MDDs, the FDA can employ the public comment formality and create labels that appropriately reflect its policies with regard to MDD operations, which can be visibly displayed on MDDs.

The benefits of receiving medical products from MDDs are clear. MDDs have the potential to lead the health market in transporting medical supplies to inaccessible locations.[139] Similar to the time-saving features that Amazon hopes to highlight in its drone delivery services, MDDs can reduce the time and expenses incurred by traveling to sites to retrieve medications and supplies. The cost-effective work—demonstrated internationally by drones delivering emergency medical supplies—can be useful in the United States, and may be modified to meet state needs.[140] While the risks of basic drone operation regulation lingers in the bakground, the comprehensive benefits of MDDs can transform the aviation and medical-device markets and be reliable medical-product transporters, depending on the quantity of

133. *See* 21 C.F.R. § 860.7(b)(1)–(4) (2016).

134. *See id.* § 801.4.

135. *See id.*

136. *See* Nambiar, *supra* note 13; Bassett, *supra* note 13.

137. *See, e.g.*, *Telemedicine Benefits*, AM. TELEMEDICINE ASS'N, http://www.americantelemed.org/main/about/about-telemedicine/telemedicine-benefits (offering the fundamental benefits of telemedicine where patients in distant locations can have improved access to healthcare services, the cost of healthcare is reduced, the quality is as good as face-to-face consultations, and a higher demand for telemedicine exists).

138. *See supra* note 14 and accompanying text.

139. *See* Nambiar, *supra* note 13.

140. *See supra* notes 12–14 and accompanying text.

consumers they are able to satisfactorily serve. Therefore, an MDD's intended use, conditions of use, benefits, and reliability all weigh in favor of MDDs operating under FDA authority safely and effectively.

Additionally, a Class III medical device must be intended to be used in "supporting or sustaining human life."[141] The regulations define "life-supporting or life-sustaining devices" to be those that restore important bodily functions that are essential to sustaining life.[142] MDDs may well be essential to the continuation of human life, especially to those who reside in isolated geographic locations. Accessibility is a key factor for all people in need of health care; distressingly, the World Health Organization and World Bank estimated essential health services are inaccessible for at least 400 million people worldwide.[143] MDDs can fill this void and combat inaccessibility, giving those who are disadvantaged a means to rudimentary health services and products. MDDs contribute to the continuation of important bodily functions because they transport medical necessities to those who need treatment the most.

Given that MDDs fall squarely within the conditions set forth by the FDA, they would likely be considered Class III medical devices and be subject to FDA regulations. Furthermore, it is possible that a Class III MDD, under the FDCA, could distribute Class II devices through its advanced capabilities, making it a stronger candidate for regulation by both the federal government and states.

2. A Regulatory Convergence Among the FAA, FDA, and the States

Currently, states have a largely untested framework for regulating MDDs.[144] However, it is in the best interests of the MDD industry to incrementally change this framework, rather than attempt to rearrange it entirely. Some believe that states already have the requisite protections for privacy rights as they relate to private drone usage in civilian airspace, in an amalgamation of the myriad of preexisting common law doctrines and statutes.[145] As MDDs, or drones in general, become more commonplace

141. *See* 21 U.S.C. § 360c(a)(1)(C)(ii) (2012).

142. *See* 21 C.F.R. § 860.3(e) (2016).

143. *See* Rick Gladstone, *400 Million Lack Basic Health Services, Report Finds*, N.Y. TIMES (June 12, 2015), http://www.nytimes.com/2015/06/13/world/americas/400-million-lack-basic-health-services-report-finds.html.

144. *See* ALASKA STAT. § 18.65.902(1)(B) (2015); FLA. STAT. § 934.50(3)(a)–(b) (2016).

145. *See* Wells C. Bennett, *Civilian Drones, Privacy, and the Federal–State Balance*, BROOKINGS INST. 1, 3 (Sept. 2014), http://www.brookings.edu/~/media/Research/Files/Reports/2014/09/civilian-drones-privacy/civilian_drones_privacy_bennett_NEW.pdf?la=en (examining three categories of state privacy laws: (1) "longstanding statutory and common-law protections against non-governmental intrusions"; (2) privacy offenses under state law

they will become more relevant, requiring a greater necessity for nuanced laws and stricter regulation on the state level. However, a concern may be how permissive or restrictive courts will be in cases alleging safety and privacy issues involving MDDs.[146] Beyond the uncertainty of judicial restriction, some scholars argue for state legislative regulation because it allows for more precise and readily-amendable laws.[147] On the other hand, though state laws are more malleable, the variance in laws between the states could create complications while attempting to successfully hybridize an authority for MDDs.[148] However, as discussed above, states can prescribe standards to lessen the risk that MDDs could give rise to medical malpractice liabilities and share the same potential benefits as telehealth technology.[149]

For example, states can require patients to seek in-person health care if MDDs are inadequate to diagnose or treat a patient.[150] States are in a favorable position to understand and assess the shortcomings of the local health systems in their respective regions, while the FAA has ample federal resources at its disposal to offset the states' geographical modesty.[151] Because airspace connectivity is important to the FAA, information sharing needs to be ascertainable at both the state and federal level in order to eradicate the risk of miscommunication.[152] Allowing both the state and

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that cover social privacy norms; and (3) civil and criminal laws that block uninvited aerial surveillance from privately owned, unmanned aircrafts).

146. *Compare* Montalvo v. Spirit Airlines, 508 F.3d 464, 471 (9th Cir. 2007) (ruling that federal law occupies the entire field of aviation safety in carrying out Congress' intent to preempt all state law with respect to aviation law), *with* Aircraft Owners & Pilots Ass'n v. FAA, 600 F.2d 965, 967 (D.C. Cir. 1979) ("The FAA is not empowered to prohibit or limit proposed construction it deems dangerous to air navigation.").

147. *See* Michael L. Smith, *Regulating Law Enforcement's Use of Drones: The Need for State Legislation*, 52 HARV. J. ON LEGIS. 423, 450 (2015) (conceding that the judicial alternative to regulating drones is broad and unpredictable).

148. *See* Bennett, *supra* note 145, at 13.

149. However, the shortcomings of telemedicine can potentially be the same for medical-device drones (MDDs). For instance, diagnostic possibility can still be stifled in the absence of an in-person examination. *See* Bradley J. Kaspar, Note, *Legislating for a New Age in Medicine: Defining the Telemedicine Standard of Care to Improve Healthcare in Iowa*, 99 IOWA L. REV. 839, 859 (2014) (noting that a physician loses all five senses when in-person examinations are eliminated in the telemedicine context).

150. *See id.* at 859–60 (noting that state legislatures have the power to limit risks by limiting the types of medications that physicians prescribe and allow to be delivered).

151. *See* Marin, *supra* note 23, at 867.

152. *See id.* For instance, state interest groups like the National Governors' Association and the National Association of Attorneys General can transmit state interests to congressional members because the organizations are in a favorable position to be heard in legislative decisionmaking, regularly testifying before Congress. *See* Nina A. Mendelson, *Chevron and Preemption*, 102 MICH. L. REV. 737, 762 (2004). Lobbyists can also raise these

federal governments to learn from other states' attempts to solve their local problems is a "value that accrues nationally."[153]

The Ninth Circuit found that the Tenth Amendment allows the federal government to have concurrent, regulatory power under both its taxing power[154] and the Commerce Clause.[155] Courts have interpreted this to mean that Congress can regulate channels of interstate commerce, instrumentalities of interstate commerce, and economic activities that have a substantial effect on interstate commerce.[156] The power given to the FAA is most appropriate in this realm. With the draft of the FAA's rules in its adolescence, the potential delivery capabilities of commercial drones is subject to regulation through the conduits of interstate commerce, as are retail delivery services.[157]

Recently, the DOT announced the formation of a UAS registration task force to explore and develop recommendations to streamline the registration process for UAS.[158] The FDA should follow the DOT's example and create a task force that is specifically driven to explore and develop recommendations to streamline MDD labeling, medical-device reporting, registration, premarket approval, tracking, post-market

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issues by directly contacting officials or "talk[ing] shop with them in informal settings." *Id.* at 762–63.

153. *See* Mendelson, *supra* note 152, at 767.

154. *See* United States v. Rosenberg, 515 F.2d 190, 198 (9th Cir. 1975).

155. *Id.*; *see also* U.S. CONST. art. I, § 8, cl. 3 (authorizing Congress "[t]o regulate Commerce with foreign Nations, and among the several States . . . .").

156. *See, e.g.*, Gonzales v. Raich, 545 U.S. 1, 16–17 (2005); *see generally* Perez v. United States, 402 U.S. 146 (1971).

157. *See* Fulfillment Servs., Inc. v. United Parcel Servs., Inc., 528 F.3d 614, 617 (9th Cir. 2008) (recognizing that UPS is a motor carrier that transports goods interstate and is governed by provisions in the Motor Carrier Act).

158. Clarification of the Applicability of Aircraft Registration Requirements for Unmanned Aircraft Systems (UAS) and Request for Information Regarding Electronic Registration for UAS, 80 Fed. Reg. 63,912, 63,912 (Oct. 22, 2015) (to be codified at 14 C.F.R. Chapter I); *see also* Registration and Marking Requirements for Small Unmanned Aircraft, 80 Fed. Reg. 79,225 (Dec. 21, 2015) (to be codified at 14 C.F.R. pt. 11) (notifying the "public that the Office of Management and Budget's (OMB's) approval of the information collection requirement" in the "FAA's . . . Registration and Marking Requirements for Small Unmanned Aircraft," published five days prior to this interim final rule); Registration and Marking Requirements for Small Unmanned Aircraft, 80 Fed. Reg. 78,594 (Dec. 16, 2015) (to be codified at 14 C.F.R. pts. 1, 45, 47, 48, 91, & 375) (simplifying registration by providing an alternative and streamlined web-based process in order to comply with the statutory requirement that all aircrafts register before taking flight); *Huerta Announces UAS Registration Task Force Members*, FAA (Oct. 29, 2015), https://www.faa.gov/news/updates/?newsId=84125 (announcing membership of the Unmanned Aircraft Systems Registration Task Force to represent stakeholder viewpoints, interests, and knowledge of the Task Force's objectives and scope).

surveillance, and medical-device classification procedures. As two autonomous agencies, the FAA and FDA are inherently different in "leadership structure, political independence, institutional capacity, resources, and reputation."[159] They also have "independent stature, responsibilities, and allegiances, and . . . their own policy agendas that they seek to advance on the political branches."[160] Thus, working together, the combined expertise of these two agencies can help overcome broad aviation and medical-device issues of MDD regulation on the federal level to supplement state regulation.

Skeptics may contend that the idea of a federal–state cooperation has too many layers of review and regulation, which can essentially slow down the approval process of MDDs and cause the drone and medical-device industries to develop sluggishly.[161] It may also be argued that this triangular review and regulatory approach is inefficient for an MDD industry, viewing this as a backward step for the state legislatures and federal regulators. In fact, the Court has stated that the FDA's application review process for medical devices averages about 1,200 hours.[162] Consider MDD registration requirements, for example, where an MDD would have to comply with both the FAA's commercial drone registration requirements[163] and the FDA's medical-device registration requirements.[164] An overlap in regulations may burden MDD industries where an extensive grocery list of registration requirements can create confusion and disorderly regulation among the FAA, FDA, and state legislatures.[165]

Although there is administrative merit to the arguments, opponents could materialize with respect to federal–state regulation of MDDs, the

159. *See* Gillian Metzger, Essay, *Agencies, Polarizations, and the States*, 115 COLUM. L. REV. 1739, 1743 (2015).

160. *Id.*; *see generally* Brigham Daniels, *Agency as Principal*, 48 GA. L. REV. 335 (2014); Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245 (2001).

161. Agency review is notoriously slow-going. *Cf.* Lisa Rein, *The Official Reference to Small Raisins as 'Midgets' Is Almost Gone. It's Taken the USDA More Than Two Years.*, WASH. POST (Sept. 3, 2015), https://www.washingtonpost.com/news/federal-eye/wp/2015/09/03/the-official-reference-to-small-raisins-as-midgets-is-almost-gone-its-taken-the-usda-more-than-two-years/ (noting that the Department of Agriculture took "51 months and counting to change one word . . . raisins officially remain on the books as 'midgets'").

162. Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996).

163. *See supra* Section I.A.1.

164. MDDs would have to submit to a pre-market submission where the FDA determines whether a device is substantially similar to a predicate device. *See* 21 U.S.C. § 360c(2)(C)(II) (2012).

165. *Cf.* Charles Murray, *Regulation Run Amok—And How to Fight Back*, WALL ST. J. (May 11, 2015, 10:08 AM), http://www.wsj.com/articles/regulation-run-amokand-how-to-fight-back-1431099256 ("The broadest problem created by intricately wrought regulatory mazes is that . . . they lose sight of the overall goal and thereby make matters worse.").

inaccessibility of health support and services weighs in favor of a practical solution in order to protect the public health. Roles of the FAA, FDA, and states can be parsed into three phases: pre-market, on-market, and post-market. The FAA would be the most appropriate for the pre-market phase where it would ensure that an MDD complies with its operational drone requirements. The FDA's role would tailgate near the latter half of the pre-market phase because it resolves packaging and labeling of MDDs to ensure that they are safe and optimally performing. However, the FDA's role seems more applicable during the on-market phase where, under the FDA's regulations, it could spearhead the advertising and sale of MDDs, as MDDs match up to medical-device standards. Finally, states could take over the post-market phase by monitoring the clinical performances of MDDs in their jurisdictions because it is critically important that MDD use is continually assessed. The pre-market review process may not be able to predict all of the possible failures of MDDs. Therefore, the post-market surveillance would fall to the states to collect and synthesize vast data and report issues to the FAA and FDA. Moreover, this information can be shared at the federal level to other states.

Conclusively, MDDs are a pragmatic solution to address the wide gap in health care. The expertise of both the FAA and FDA is enough to combat the broad concerns associated with MDDs as drones and medical devices. States are in an excellent position to study the intricacies of such devices and report their findings to the federal government to supplement its blanket regulations. Lastly, sustaining a safe and efficient airspace while transporting life-saving medical products is a high-stakes game: MDDs need a firm regulatory scheme guided by state legislatures, the FAA, and the FDA in the pre-, on-, and post-market phases.

CONCLUSION

Drone delivery services are still in beta testing, but this should not thwart efforts to imagine their superior potential, test their limits, and apply their successes. The pairing of drone delivery services with the medical product distribution industry is peculiar, but drones are highly capable of navigating through civilian airspace and delivering these medical products to our homes. With this innovative utility, drones should be subject to vast regulation among the FAA, FDA, and the states. Ultimately, the FAA, FDA, and states can learn from each other's mistakes and progress to build a cohesive regulatory system, draft national policy that enumerates the roles of each stakeholder, and create a prosperous new industry as MDDs gradually develop their new delivery roles.